JMIR mHealth and uHealth

Impact Factor (2024): 5.4
Volume 8 (2020), Issue 2 ISSN 2291-5222 Editor in Chief: Lorraine Buis, PhD, MSI

Contents

Original Papers

Reviews

Original Paper

Improving Calcium Knowledge and Intake in Young Adults Via Social Media and Text Messages: Randomized Controlled Trial

Anika Rouf[1], MND; Monica Nour[1], PhD; Margaret Allman-Farinelli[1], PhD, FDAA

The University of Sydney, School of Life and Environmental Sciences, Camperdown, Australia

Corresponding Author:
Anika Rouf, MND
The University of Sydney
School of Life and Environmental Sciences
Level 4 East, Charles Perkins Centre
Camperdown, 2006
Australia
Phone: 61 86274704
Fax: 61 86271605
Email: arou9270@uni.sydney.edu.au

Abstract

Background: Calcium is an important nutrient for the attainment of peak bone mass during adolescence and young adulthood. However, these life phases are characterized as hard to reach for health promotion. Social media platforms offer a promising channel as they are relatively low cost but used ubiquitously by youth.

Objective: The aim of the CAlcium Nutrition-Dietary Opportunities (CAN-DO) study was to conduct a randomized controlled trial to test the effectiveness of Facebook alone or with text messaging as channels to deliver a theory-based program to encourage optimal calcium intake.

Methods: The intervention was a 3-arm parallel trial. Young adults aged 18 to 25 years were recruited through university and social media for a 6-week trial. Participants were randomized to 1 of the 3 arms (ie, Facebook posts, Facebook posts plus text messages, and control group that received an electronic leaflet containing information on calcium intake). The primary outcome was change in intake of milk and other calcium-rich foods, and secondary outcomes were knowledge, self-efficacy, motivation, and habit formation concerning calcium-rich foods. Changes were assessed before and after the intervention, and the differences in change between groups were compared using multivariate regression models with multiple imputations for missing data.

Results: A total of 211 participants (64/211, 30.3% males) participated (mean age 21.4 years, SD 2.1) in this study. At the end of the program, no increase in milk intake (odds ratio [OR] 1.51, 95% CI 0.61-3.75 Facebook; OR 1.77, 95% CI 0.74-4.24 Facebook plus text messages; P=.41) nor calcium-rich food was detected (P=.57). There was a significant improvement in knowledge in the Facebook plus text messages group (P<.001), but habit formation improved less than that in the other 2 groups (P=.01). Our results showed a moderate level of engagement with intervention content and positive qualitative feedback from participants.

Conclusions: The CAN-DO study delivered via Facebook (with the additional support of text messages) was found to improve knowledge and was acceptable among young adults. However, further research is needed to better understand social media engagement and how to optimize the program for participants to be sufficiently motivated to increase their intake of calcium-rich foods.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12620000097943; http://www.anzctr.org.au/ACTRN12620000097943.aspx

(JMIR Mhealth Uhealth 2020;8(2):e16499) doi:10.2196/16499

KEYWORDS

calcium; social media; young adults; randomized controlled trial; telemedicine

Introduction

Background

As adolescents and young adults become increasingly independent, it is not uncommon for lifestyle behaviors to be adversely affected [1]. This may include decreased physical activity, increased rates of smoking and alcohol consumption, weight gain, and decreases in home-prepared meals [2-5]. Previous studies have shown that young adults are difficult to reach with traditional health promotion strategies [6,7], but it is important to support young adults through this transition to establish healthy dietary patterns for their own future health [3,8,9] and to potentially serve as role models to their children [10,11].

Among the consequences of poor-quality diets is a low intake of calcium, which remains a global concern [12] and among Australian young adults [13]. A secondary analysis from the most recent Australian National Nutrition Survey from 2011 to 2012 shows that 69% of males and 83% of females aged 19 to 25 years failed to meet the estimated average requirements for young adults [14]. An adequate intake of calcium in adolescence and young adulthood is important for the attainment of peak bone mass and prevention of osteoporosis in later life [15,16].

Our previous formative research has delved into the barriers and enablers to achieving adequate calcium intake for this population and revealed a gap in knowledge with respect to what amount of calcium-rich food constitutes a serve and the daily number of serves recommended [17]. Their level of motivation to improve calcium intake was low because a lack of knowledge meant more calcium seemed unnecessary, and financial factors influenced the opportunity to consume calcium-rich foods, wherein milk was seen as low cost, but sources such as nuts and fish were seen as high cost [17]. When asked about an appropriate medium to deliver an intervention program, the focus group participants preferred to learn from social media platforms, and Facebook was ranked as the preferred platform [17].

Young adults are ubiquitous users of social media [18]. Almost 90% of young adults (aged 18-29 years) access social media platforms at least once per day [19], so it has the potential for wide reach in an intervention. To date, the small evidence base for the effectiveness of nutrition-related interventions using a commercial social media platform, such as Facebook, is inconsistent and warrants further investigation [20-22]. Our previous meta-analysis of the effectiveness of interventions to increase calcium intake demonstrated a small effect size [23] but indicates that research into an intervention to improve calcium intake of Australian young adults is warranted.

Objective

A previous Facebook intervention for weight loss in young adults found that the use of social media combined with text messages was effective for weight loss but not Facebook alone [20]. Previous electronic health interventions conducted in young adults found a high level of acceptability and engagement with text messages and effective dietary changes [24-26]. Therefore, the aim of this study was to determine the effectiveness of an educational and motivational program to improve calcium intake in young adults and whether the addition of text messages enhanced behavior change when compared with the Facebook arm alone.

Methods

Trial Design

This was a 3-arm parallel trial with a 1:1:1 allocation ratio. The 3 groups were Facebook intervention (Facebook), Facebook intervention plus text messages (Facebook plus text), and electronic leaflet (e-leaflet) containing information on calcium intake (control). The sample size was determined using G*Power (Version 3.1.9.4, Universität Kiel), a statistical power analysis software [27]. To detect a mean difference of 125 mg calcium intake with P=.05 and 90% power, assuming a standard deviation of 259 mg, a sample size of 45 was required per arm and increased to 75 to allow for 40% dropout.

Participants

Young adults (males and females) aged 18 to 25 years were selected as this is the period where peak bone mass development is reached [28,29]. Inclusion criteria included owning a smartphone and a Facebook account. Exclusion criterion was having completed a nutrition course or currently undertaking a nutrition course on the basis of their high existing level of nutrition knowledge. In addition, any participants with a food allergy, known lactose intolerance, or currently taking calcium supplements (but not multivitamins) or eating disorders were excluded.

All materials and methods of the intervention were approved by the Human Research Ethics Committee at the University of Sydney, Australia. The ethics approval number is 2018/597. Each participant was reimbursed with an Aus $10 voucher after completing the final questionnaire. This offer did not impact the voluntary nature of consent as it was provided after the intervention finished rather than at the time of consent. The reporting of outcomes was guided by the Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth checklist [30]. As neither the primary outcome nor the secondary outcomes were clinical measurements, the study was not entered into a clinical trials registry.

Randomization and Concealment

A randomized sequence generation was used to allocate the participants. The randomization was performed by 2 independent researchers who were not study investigators.

Recruitment

Recruitment strategies included social media (posts to friends and paid advertising on Facebook), posting on University website (*volunteer for research study*), flyers (on campus noticeboards), volunteers on a research database (previous volunteers who took part in nutrition research and agreed for contact in the future), and active face-to-face recruitment. For each of the abovementioned recruitment methods, the potential participant was made aware that participation was voluntary.

Interested participants accessed the screening questionnaire for eligibility before joining the study.

CAlcium Nutrition-Dietary Opportunities Program

A theory-informed step-wise approach was used to develop the CAlcium Nutrition-Dietary Opportunities (CAN-DO) program using the Behavior Change Wheel system [31]. This framework posits that an individual requires capability (C), opportunity (O), and motivation (M) to perform a certain behavior (B) and includes a series of 9 intervention functions that can be mapped to the COM-B components [31,32].

The aim was to build relevant knowledge (capability) and influence beliefs and attitudes to generate intentions for individuals to change behaviors (reflective motivation). The details of the intervention functions and relevant behavior change techniques are presented in Table 1. In brief, the behavior change techniques included goal setting (behavior), self-monitoring of behavior, social support (unspecified), instruction on how to perform a behavior, information about health consequences, behavior substitution, habit formation, credible source, and restructuring the physical environment.

The content of the intervention was developed in 2 parts. A range of instructional videos was created to build skills in cooking calcium-rich, low-cost, and mostly plant-based meals. These were tested in focus groups for acceptability and refined based on the feedback (unpublished findings). The next step was to design text messages and Facebook posts tailored to the preferences of young adults as indicated in prior formative research [33]. The intervention content was focused on educating on calcium-containing food sources and recommended serves, tips for including more calcium, and recipe videos that provided instructions on how to incorporate calcium in main meals and snacks. Text messages were kept short (<160 characters) and designed to complement the Facebook posts. Text messages and Facebook posts also reminded participants about setting goals and tracking progress for habit formation and created social support via posts and 2-way text messaging. An infographic was created to inform participants of the recommendations and set as a cover photo on the Facebook page (Figure 1). The e-leaflet that was provided to participants in the control group is shown in Multimedia Appendix 1.

Table 1. Details of behavior change techniques with an example.

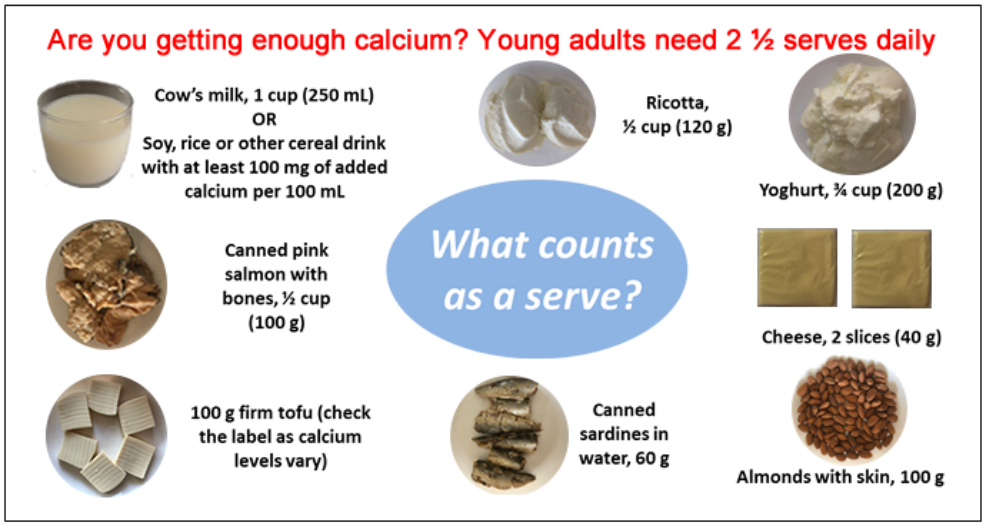
Intervention function	BCT[a,b] code	Name of BCT	An example of a Facebook post	An example of a text message
Enablement	1.1	Goal setting (behavior)	Males and females aged between 18 to 30 years should aim to consume about 1000 mg or 2.5 serves of dairy and/or alternatives per day. How much are you having? Check out this infographic which shows examples of what counts as a serve and set yourself a goal to have one more serve per day.	Hi [insert name], it's Anika from the CAN-DO[c] program. It's time to set your goals and start tracking! Have you downloaded your app and set a goal? Please reply to this message by typing YES or NO.
Enablement	2.3	Self-monitoring of behavior	Calcium intake is low in the Australian population; 44% of males and 71% of females aged 18 to 30 years don't get enough. Monitoring your progress can be useful when trying to establish new habits. You can use the app "Productive" (for iPhones) and "Loop Habit Tracker" (for Android) to track your intake.	Hi [insert name], are you still using the app to track your goals? Please reply to this message by typing YES or NO.
Enablement	3.1	Social support (unspecified)	Have you tried tofu? It is a great alternative to eggs and can be scrambled together with leftover veggies for breakfast. PS: Do you have any breakfast ideas you'd like us to share? Let us know what recipes you have tried in the comments below:)	Hi [insert name], it's Anika from the CAN-DO program. Did you check out the Facebook post yesterday? Give us a thumbs up if you like it.
Training	4.1	Instruction on how to perform a behavior	Not only is fish great for heart health, but some varieties are a good source of calcium. You can opt for canned options such as salmon or sardines that will save you time and money. Check out this salmon cannelloni recipe for a delicious way to cook with canned fish.	Hi [insert name], Have you tried any of the recipes from the cooking videos we've shared so far? Please reply to this message by typing YES or NO.
Education	5.1	Information about health consequences	It is important to get your calcium everyday as it can lower your risk of chronic diseases. Here's a photo of a veggie platter I created recently. I used the Tzatziki recipe shared on Monday as a side dip to boost the flavor. Make sure you give this a go and share your veggie platter with us :)	Hi [insert name], Did you know that calcium is important for your bone strength? To up the calcium, why not try anchovies and vegetables on your pizza.
Enablement	8.2	Behavior substitution	Is takeaway your go-to for work lunch? Try cooking larger amounts at dinner and taking the leftovers the next day for a healthier alternative. These delicious stuffed capsicums contain ricotta and parmesan and taste even better the next day. You can even use canned salmon to bump up the calcium content.	Hi [insert name], Do you get afternoon munchies? Why not swap those chips with some wholegrain crackers and cheese? Cheese is a great source of calcium and protein, and will help you beat the 3 pm slump.
Training	8.3	Habit formation	Research has shown that eating breakfast improves your cognitive function and memory. If you are not a breakfast eater, it's time to change and look after yourself! Here's an overnight chia pudding recipe for you to try.	Hi [insert name], How much calcium are you having now? Even if you've only increased a little, WELL DONE! You're on your way to healthier habits.
Persuasion	9.1	Credible source	Did you know that low fat dairy products have just as much as calcium as regular varieties? The Australian Dietary Guidelines advise that more than 50% of intake from dairy foods should be reduced-fat varieties. Check out this infographic!	Hi [insert name], Research shows that having calcium at breakfast increases your chance of meeting your requirement. Did you have your breakfast today? Reply YES or NO.
Environmental restructuring	12.1	Restructuring the physical environment	Need some meal prep inspiration? Here is a Mac and Cheese recipe you could try at home. Having pre-prepared meals in your fridge will help you avoid the temptation of take-away and keep you on track with healthy eating. TIP: to save time, you can use multiple containers to store so it is ready to grab and go for the next day!	Hi [insert name], Some canned varieties of fish with bones like salmon and sardines are a great source of calcium. Stock your pantry with canned fish for a quick calcium-rich sandwich filler.

[a]BCT: behavior change technique.

[b]BCTs were derived from Behavior Change Technique Taxonomy (version 1).

[c]CAN-DO: CAlcium Nutrition-Dietary Opportunities.

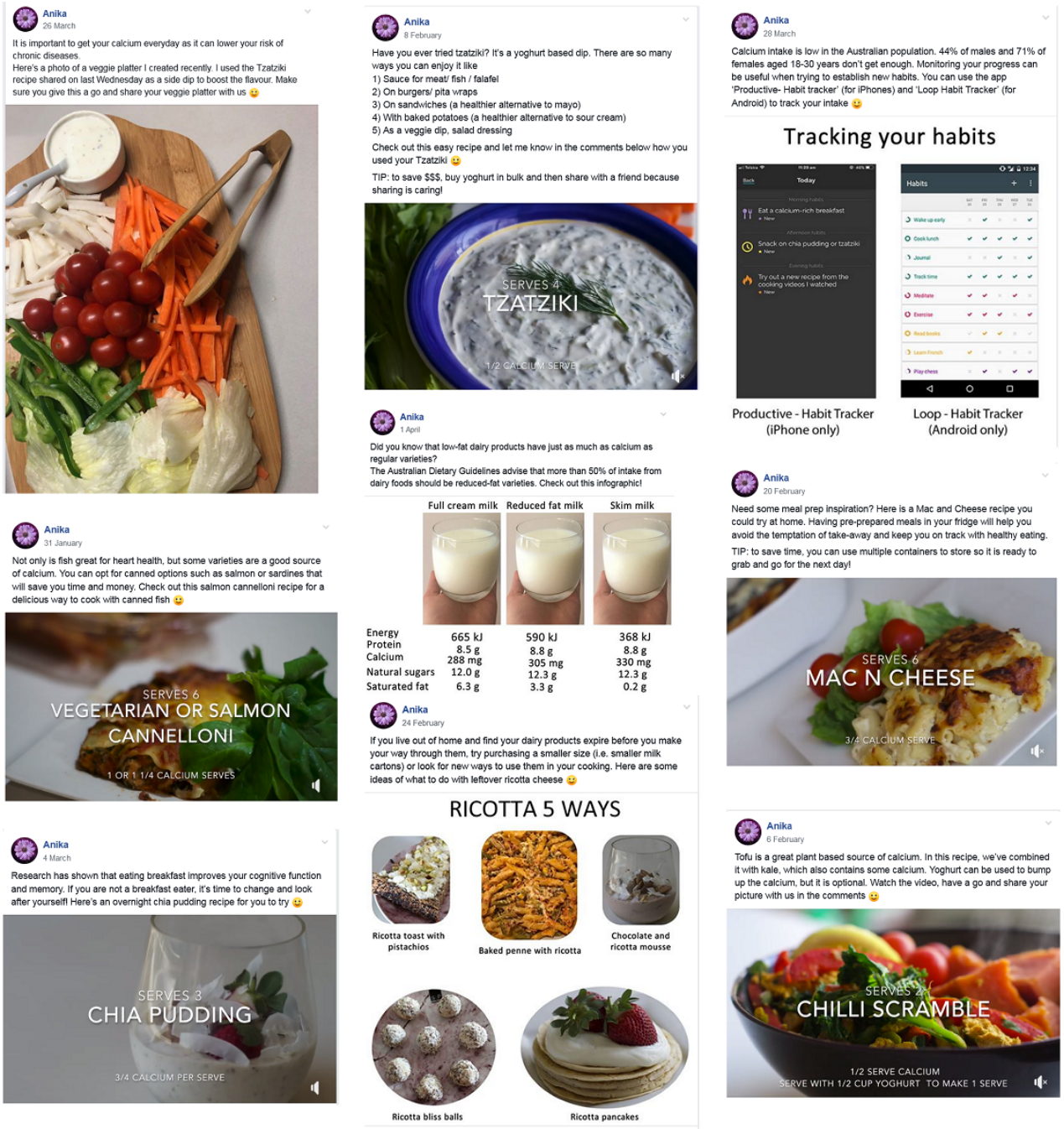
Figure 1. Infographic to inform participants of the recommendations.



Procedures

Interested participants completed a screening questionnaire hosted on Research Electronic Data Capture (REDCap) [34], where they could find out more about the study by reading the participant information statement and check their eligibility. Participants who were not eligible to participate were provided with the Australian Dietary Guidelines as a resource. Eligible participants completed the consent form and proceeded to the baseline questionnaire. After completing the baseline questionnaire, each participant was randomized to Facebook, Facebook plus text, or control group and received an email with their group allocation. Participants in the Facebook and Facebook plus text groups were invited to join a closed Facebook group, where a post was made every alternate day by the researcher (AR). The site had a pinned Facebook post used to ensure that all participants were provided with background information, which included links to educational resources and an overview of the intervention. Screenshots of the posts are shown in Figure 2. The 2 Facebook groups were kept separate to avoid potential contamination between groups. In addition, participants in Facebook plus text group were sent text messages every alternate day to the post. Participants in both intervention groups were encouraged to set goals using apps available on iPhone (Productive—Habit Tracker) and Android platforms (Loop—Habit Tracker) and self-monitor their progress. The participants in the control group were emailed once with an e-leaflet on calcium and did not receive any continued support on social media. This minimal intervention was to maintain their interest in completing the study.

Figure 2. Screenshots displaying Facebook posts that included photos, videos and the tracking apps for goal-setting and self-monitoring.



Measurement of Outcomes

Demographic information was collected from all participants, which included age, gender, educational level, postcode (for categorizing socioeconomic status), occupation, and income through a Web-based platform REDCap [34]. The postcode was used to categorize the socioeconomic status of participants using Socio-Economic Indexes For Areas (SEIFA) [35]. All outcomes were assessed at 2 time points, which were at baseline before commencing the study (T0) and at the end of intervention (T1) via a Web-based questionnaire on REDCap.

The primary outcome (calcium intake) was estimated using a validated calcium-specific food frequency questionnaire that asks about intake over the past week [36]. Milk was measured in cups, ranging from half a cup to more than 4 cups, and the other calcium-rich foods (30 foods and beverages included) were measured by weekly frequency of intake only. The secondary outcomes measured the impact of the intervention on determinants of calcium intake, which included knowledge of calcium recommendations and serve sizes, self-efficacy, motivation for consuming calcium-rich foods, and habit formation. Knowledge was assessed by a participant's ability to identify sources of calcium (maximum of 8), a correct serve of calcium (maximum of 8), and stating the calcium requirements for their age group (maximum of 2) using a researcher-designed questionnaire as no validated questionnaire could be found. The questions are included in Multimedia Appendix 2. A 5-item Likert scale questionnaire previously validated for other dietary behaviors was adapted to measure self-efficacy for improving calcium-rich food consumption. The

maximum score possible was 25; a higher score indicated stronger self-efficacy [37]. Autonomous and controlled motivation for consumption of calcium was measured using a 4-point scale. The questions were adapted from the Self-Regulation Questionnaire [38,39], where a higher score indicated greater motivation (score out of 16). Habit formation for calcium intake was measured using the validated 4-item 7-point scale Self-Report Behavioral Automaticity Index [40]. A greater score indicated a higher automaticity to perform a certain behavior.

Engagement and Process Evaluation

Engagement with the platform was measured quantitatively and qualitatively as research indicates the need to do both [41]. Quantitative measures were obtained from recording Facebook analytics. After all participants had completed the intervention, the number of participants who had seen, liked, and commented on the Facebook posts was recorded. For the Facebook plus text group, the number of replies to text messages was counted for each participant, and the content was analyzed using qualitative methods (see Qualitative Analyses below).

Feedback regarding the acceptability of the program was collected via open-response questions regarding ease of use, usefulness of program, likelihood of recommendation to others, and overall enjoyment using Likert scales (5 being highest). The other optional questions were related to intervention experience and uptake of content as well as frequency and reason for engagement. The last question provided participants with an opportunity for free text comments.

Statistical Analysis

To account for all participants, an intention-to-treat analysis with multiple imputations for missing values was used. This meant that all participants who were randomized at the start of the trial were retained for analyses. Owing to the large amount of missing data, 10 imputed datasets were created based on gender, SEIFA (socioeconomic index), cooking frequency per week, and baseline intake of primary (milk and calcium intake) and secondary (knowledge, self-efficacy, motivation, and habit) outcomes using Stata version 13.1 (StataCorp LP).

The primary outcome of change in milk intake, which was categorical in number of cups, was compared between 3 groups using a logistic regression model adjusted for gender, SEIFA, cooking frequency, baseline calcium (nonmilk), baseline knowledge, baseline self-efficacy, baseline motivation, and baseline habit. The quantitative values for change in calcium intake from other dietary sources were compared using linear regression as were the variables for the secondary outcomes of knowledge score, self-efficacy for change score, and motivation and habit score, adjusted for gender, SEIFA, cooking frequency, baseline calcium intake, baseline knowledge, self-efficacy, motivation, and habit. An analysis using completers-only data was conducted and is available in the Multimedia Appendices 3-5. The distribution of missing outcome data at both time points was investigated using counts and percentages across all sociodemographic variables. Furthermore, separate general estimating equation (GEE) models for binary data were used to investigate any relationships between sociodemographic variables and missingness in each outcome, adjusted for other sociodemographic variables. An independent samples *t* test was used to assess differences in number of views, likes, and comments for Facebook posts between the 2 groups receiving the intervention (SPSS for Windows 22.0 software IBM Corp, released 2013). A *P* value of less than .05 was considered statistically significant for all tests.

Qualitative Analyses

The feedback from the final questionnaire was transcribed and analyzed using an inductive approach where common themes were grouped together. The NVivo 12 Plus (2018, version 12.2.0; QSR International Pty Ltd) software was used for thematic analyses.

Results

Participant Characteristics

A total of 270 participants attempted the screener questionnaire. Of 270 participants, 59 were ineligible for the study or failed to continue to the baseline questionnaire. A total of 211 young adults were randomized into 3 groups. The flow of participants through the trial is shown in Figure 3. The characteristics and demographics of participants at baseline are presented in Table 2. The mean age was 21.4 years (SD 2.1), and the sample comprised 30.3% (64/211) males.

The majority of participants (139/211, 65.9%) were enrolled in tertiary education. Nearly one-third (65/211, 30.8%) of the participants were in health care for their field of work or study. Almost two-thirds (134/211, 63.5%) of the participants were earning less than Aus $500 per week. Nearly half (94/211, 44.5%) of the sample reported themselves as being the main purchaser of household groceries. The most commonly reported cooking frequency was less than twice weekly for 37.4% (79/211) of the young adults.

Figure 3. Participant flow diagram in the CAlcium Nutrition-Dietary Opportunities study.

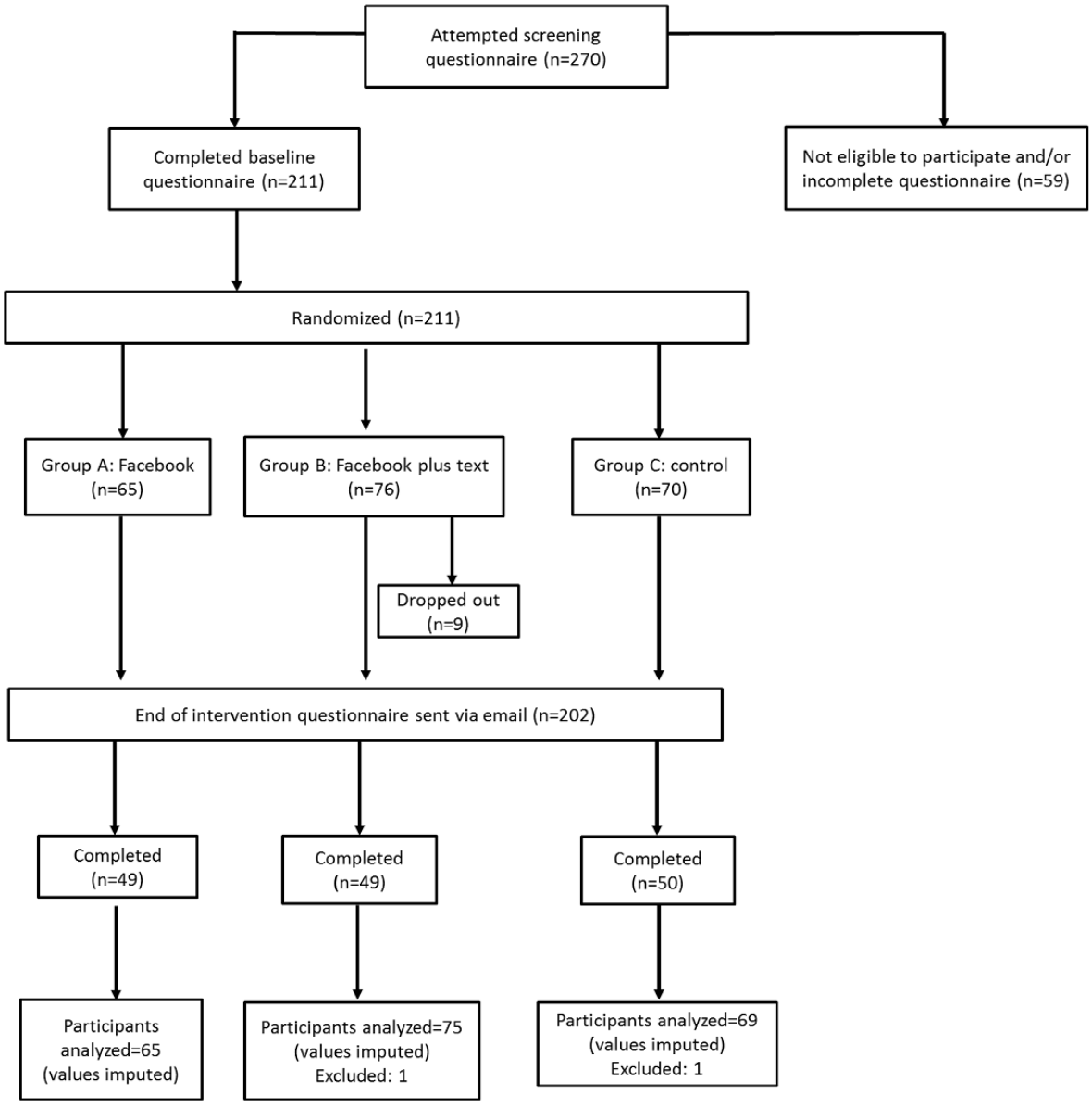


Table 2. Demographics of participants from the CAlcium Nutrition-Dietary Opportunities study.

Baseline characteristics	Facebook (n=65)	Facebook plus text (n=76)	Control (n=70)
Age (years), mean (SD)	21.3 (2.2)	21.6 (2.0)	21.4 (2.1)
Gender (n)			
Male	22	24	18
Female	43	52	52
Occupation (n)			
Student	38	53	48
Full-time work	15	14	15
Part-time or casual work	10	5	6
Unemployed	2	4	1
Field of work or study (n)			
Health care	22	20	23
Management or finance	5	7	0
Other[a]	38	49	47
Highest level of education (n)			
≤Year 12	35	34	37
Certificate or diploma	14	14	13
Bachelor or postgraduate degree	16	27	20
Prefer not to say	0	1	0
Socio-Economic Indexes For Areas (n)			
Quintiles 1 and 2	20	25	27
Quintile 3	15	29	19
Quintiles 4 and 5	30	21	23
Income per week[b] (n)			
Nil or negative income	8	19	12
Aus $1-Aus $499 per week (Aus $1-Aus $25,999 per year)	28	32	35
Aus $500-Aus $999 per week (Aus $26,000-Aus $51,999 per year)	18	15	13
More than Aus $500 per week	11	10	10
Purchaser of main household groceries (n)			
Myself	36	51	7
Others (partner, parents, and housemate/s)	29	25	63
Cooking frequency per week (n)			
Less than twice a week	23	29	27
3-4 times per week	24	24	26
5 or more times per week	18	23	17
Rating of own cooking skills (0-100), mean (SD)	63.0 (22.4)	59.4 (21.6)	57.6 (22.2)

[a]Some options from the other field of study or work include education, office support and management, food service industry, information technology, and building or construction.

[b]Includes wages/salaries, government benefits, allowances, and other income, excluding tax, superannuation contributions, or any other automatic deductions.

Attrition

Overall, 9 participants formally withdrew from the study. All participants were from the same arm (Facebook plus text) and opted out by sending a text—an option not available to other participants who could only opt out passively. The dropout time ranged from day 1 to day 29. Only 2 participants provided reasons (ie, lack of interest or time). In total, 148 (148/211, 70.1%) participants completed the final questionnaire but not necessarily every question.

Outcomes

Results from 209 participants (data from 2 participants could not be imputed because of incorrect postcodes) are reported in the following sections. Results using completers-only data are included in Multimedia Appendices 3-5. The percentage of data that were missing was approximately 35% for milk intake, knowledge, self-efficacy, motivation, and habit, but 75% for calcium-rich foods. This percentage was similar across all sociodemographic variables. The GEE indicated that females had lower adjusted odds ratio (OR) than males of have missing data, adjusted for all other sociodemographic variables. No other sociodemographic variables were associated with missing outcome values.

Primary Outcomes

Participants in the Facebook group were 1.51 times more likely to move to a higher milk category compared with those in the control group (Table 3). Similarly, those in the Facebook plus text group were 1.77 times more likely to move to a higher milk intake category. However, this was not significant (*P*=.41). There was no difference in the change in calcium intake from other foods between groups over the 6 weeks (*P*=.57; Table 4). The analysis on completers-only data demonstrated a significant increase in milk intake in the Facebook plus text messages group compared with the control group (OR 4.99, 95% CI 1.63-15.28).

Table 3. Change in category of the amount of milk intake from baseline to the end of the intervention for all participants (n=209, using imputed dataset); overall *P*=.41.

Groups	Baseline milk intake (%)			Participants who moved to a higher milk intake category (%)	Percentage increase (95% CI)	Odds ratio of participants moving to a higher milk intake category (95% CI)[a]	*P* value
	<125 mL	125-249 mL	>250 mL				
Facebook (n=65)	38.0	36.2	25.9	35.8	22.1-49.6	1.51 (0.61-3.75)	.37[b]
Facebook plus text (n=75)	27.7	40.0	32.3	41.2	29.0-53.4	1.77 (0.74-4.24)	.20[b]
Control (n=69)	37.1	30.3	32.2	28.1	15.8-40.4	Reference	Reference

[a]Covariates appearing in the logistic regression model have been adjusted for gender, Socio-Economic Indexes For Areas, cooking frequency, baseline calcium (except milk) intake, baseline knowledge, baseline habit, baseline motivation, and baseline self-efficacy. The logistic regression model was not adjusted for baseline milk consumption because everyone in the lower category having to stay the same or increase or everyone in the higher category having to stay the same or decrease. This resulted in a zero-cell count for these baseline categories in the respective outcome (0=same or decrease and 1=increase).

[b]*P* value is comparison with control as a reference.

Table 4. Change in calcium intake per day in mg (excluding milk) from baseline to the end of the intervention using logistic regression for all participants (n=209, using imputed dataset); *P*=.57.

Groups	Mean baseline intake (SE)	Mean change[a] (SE)
Facebook (n=65)	234.3 (25.0)	7.1 (39.1)
Facebook plus text (n=75)	271.9 (33.5)	65.5 (48.4)
Control (n=69)	226.4 (26.8)	43.0 (30.7)

[a]Covariates appearing in the linear regression model have been adjusted for gender, Socio-Economic Indexes For Areas, cooking frequency, baseline milk intake, baseline calcium intake, baseline knowledge, baseline habit, baseline motivation, and baseline self-efficacy.

Secondary Outcomes

Changes in secondary outcomes are reported in Table 5. The answers to the knowledge questions were combined together as an overall knowledge score. The change in knowledge was significant between the groups (*P*<.001). Those in the Facebook plus text intervention arm had a greater improvement in mean score compared with those in the Facebook and control groups. No significant difference between groups was observed for motivation (*P*=.79) or self-efficacy (*P*=.31). For habit formation, a significant group effect was observed (*P*=.01), with Facebook plus text group having the least increase in score. The improvement in knowledge in the Facebook plus text messages group was also found with completers-only analysis (*P*=.04). The effect on habit formation was not shown in the completers-only analysis.

Table 5. Change in secondary outcomes from baseline to the end of the intervention for all participants (n=209, using imputed dataset).

Outcome	Facebook		Facebook plus text		Control		*P* value[a]
	Mean baseline value (SE)	Mean change (95% CI)	Mean baseline value (SE)	Mean change (95% CI)	Mean baseline value (SE)	Mean change (95% CI)	
Habit formation score (out of 28)	15.7 (0.7)	3.5 (1.6 to 5.3)	16.4 (0.8)	0.5 (0.93 to 2.0)	15.3 (0.8)	3.4 (1.7 to 5.2)	.01
Overall knowledge score (out of 18)	6.7 (0.3)	1.6 (0.6 to 2.5)	6.3 (0.3)	2.9 (2.0 to 3.8)	6.6 (0.3)	0.2 (−0.7 to 1.1)	<.001
Motivation score (out of 16)	10.4 (0.4)	1.0 (0.3 to 1.7)	10.4 (0.3)	1.0 (0.3 to 1.8)	10.5 (0.3)	1.1 (0.4 to 1.9)	.79
Self-efficacy (out of 25)	19.4 (0.6)	1.2 (−0.1 to 2.4)	19.5 (0.5)	0.5 (−0.8 to 1.8)	17.8 (0.6)	1.0 (−0.4 to 2.4)	.31

[a]Covariates appearing in the linear regression model have been adjusted for gender, Socio-Economic Indexes For Areas, cooking frequency, baseline milk intake, baseline calcium intake, baseline knowledge, baseline habit, baseline motivation, and baseline self-efficacy.

Engagement

Facebook Posts and Text Messages

Table 6 shows the engagement with Facebook posts. More participants in the Facebook plus text intervention than those in the Facebook intervention viewed the posts and liked them (*P*<.001 for both). In the Facebook group, 3 participants made comments on posts, whereas 4 participants in the Facebook plus text group commented on posts.

For the Facebook plus text group, the mean number of replies from participants was 3.8 out of a maximum 21 (range 1-18). Of 75 participants, 12 made no reply texts (1 participant gave a wrong phone number, and texts could not be delivered). The highest number of replies was to the yes/no response as to whether they had set a goal on the app (n=22).

Table 6. Engagement with the program on Facebook.

Engagement recorded on Facebook per post	Facebook, mean (SD)	Facebook plus text, mean (SD)	*P* value[a]
Seen by	19.9 (3.6)	26.9 (5.0)	<.001
Likes	1.1 (1.4)	3.6 (2.4)	<.001
Comments	0.1 (0.5)	0.2 (0.9)	.41

[a]Conducted using an independent samples *t* test.

Process Evaluation

The majority of participants (n=133) completed the process evaluation questions, and Table 7 shows that there were no differences between intervention groups as to ease of use, their liking, likelihood of recommending it to others, or usefulness of the program. Participant responses in relation to message reading and interactions are included in Multimedia Appendix 6.

The thematic analysis with representative quotes is tabulated in Multimedia Appendix 7. The themes were grouped into ease of use, raised awareness, increased intake, feedback on recipes, reasons for reading/posting, and suggestions for improvement. Any comments that did not fit into these 5 groups were labeled as *general feedback*. There was a divergence of opinion on the ease of use, with some participants suggesting it was easy to follow, and others had more difficulty understanding and wanted more feedback. Successful participants shared their accomplishments in achieving their goals. The feedback on the recipes was overall positive, but some participants admitted they never prepared any of them. The majority of respondents chose not to share posts with reasons being they were uncertain they could add anything extra to the conversation or they did not feel comfortable with sharing. Some of the suggestions for improvement under general feedback included using an alternate platform that allows for active chat between members, sending text messages more frequently to check up on their progress, completing surveys weekly to track progress, and organizing meetings in person. Most participants viewed the notifications as a gentle and helpful reminder, whereas some found it intrusive.

Table 7. Process evaluation of the CAlcium Nutrition-Dietary Opportunities study on intervention experience.

Questions asked[a]	Facebook (n=45), rating (mean [SD])	Facebook plus text (n=44), rating (mean [SD])	Control (n=44), rating (mean [SD])
How easy was it to follow the program?	3.80 (0.89)	3.73 (1.25)	4.0 (0.96)
How much did you like the program?	3.54 (0.89)	3.57 (1.15)	3.82 (0.92)
How likely are you to recommend it to others?	3.41 (1.03)	3.50 (1.25)	3.80 (1.02)
How useful was the program to you?	3.35 (0.98)	3.57 (1.11)	3.57 (1.10)

[a]Participants were asked to rate on a scale of 1 to 5 (5 being highest).

Discussion

Principal Findings

This study showed that a 6-week intervention to increase calcium intakes tailored to young adults delivered using a social media platform and text messages was successful in improving knowledge about calcium-rich foods. However, this did not result in a significant increase in calcium-rich food and beverage intakes. The Facebook intervention delivered alone failed to show knowledge improvement, but engagement with the social media was significantly less than that in the intervention arm receiving text messages and might explain the disparate finding. Other reasons for the difference might be that the additions of texts appear to provide a more personalized program, and the need to reply to some messages engenders accountability and perception of monitoring by the staff delivering the intervention.

The findings of a successful outcome from the combined intervention arm concur with the earlier findings of a weight loss program delivered to overweight and obese college-aged students. Over 8 weeks, topics (1 per week) about weight loss were posted on Facebook, and the other intervention arm additionally received text messages with personalized feedback each week [20]. Although our text messages were generic, the participants' names were included, and they were written in the Generation Y tone for which young adults had previously expressed a preference [33]. The texts provided additional prompts to set goals and self-monitor their own behavior with some further education and persuasion. These 2 behavior change techniques have been demonstrated to result in behavior change [42].

Few dietary changes occur as a result of education alone, but it was indicated as a necessary antecedent to behavior change in this demographic based on our previous focus group findings. Although the Facebook plus text group improved knowledge, the overall score remained quite low, with the mean score only reaching 50% correct answers. Another barrier to improving calcium intakes seemed to stem from lack of motivation, with all groups scoring similarly at baseline (10 out of 16), with uniform small improvement at the end of the intervention. In future programs, more planning around the inclusion of other techniques to improve reflective motivation may be needed. Coercion, persuasion, and incentivization could be possible solutions [31]. Social media platforms readily offer the capacity for monitoring of an individual's behavior by others, and social comparison could be applied to intake of calcium-rich foods in this case. The vacillation might be that members are uncomfortable with sharing information with others as seen here in the replies to the process evaluation. The lack of posts made by group members is also indicative that such an approach may not work to positively influence motivation. Further research to understand what would allow participants to be relaxed with sharing dietary information in a nutrition intervention is desirable. With regard to incentivization and rewards, an earlier qualitative study with young adults for the co-design of an intervention to improve vegetable intakes reported that self-rewards were unlikely to motivate them as it required too much self-organization, so social or material rewards may be a better choice [21].

The validity of the food frequency instrument to measure changes in the primary outcome of calcium from milk and other foods in this population must also be questioned. Any self-report tool is always subject to participant bias [43]. In addition, this tool may not possess sufficient precision to detect small changes in intakes, as milk intakes are categorized in cups from half a serve of dairy to 4 or more serves of dairy. The calcium-specific food frequency questionnaire was selected rather than other tools as the burden of completion was low, but it does serve to rank individuals rather than assess absolute intake, and hence, the OR of increasing category of intake was used here.

Improvements in calcium intake were not achieved, but the retention and engagement in the social media intervention were substantial for an electronically delivered intervention [44]. Overall, 70% of the sample was retained, and more than half of the participants viewed the posts. Previous studies report large attrition and declining engagement in social media interventions for improving health behaviors [45]. A strength of the CAN-DO study was the formative research conducted to inform program design and materials [33]. The components were generally well received, and the recipe videos commended.

Among the limitations of this study was the overrepresentation of females comprising 70%, but this is not uncommon in nutrition studies even when males are equally targeted. In addition, in the case of calcium, it is females who are more likely to have inadequate intakes, so the population participating was appropriate. Some participants who did not do their own grocery shopping and cooked infrequently may have lessened the opportunity to alter their meals and snacks. The length of the program may have been too short to see the changes in knowledge translate into changes in consumption of calcium-containing foods, and intakes were only measured at 2 time points. An intervention delivered to university students that included a face-to-face session followed by text messages for 10 weeks did show increases in calcium intake [46]. In the future, a longer intervention might be appropriate. Finally, to

include the largest number of participants, multiple imputation was used. This increases the variance in the estimate and a more conservative interpretation of results than completers-only analysis.

Conclusions

The CAN-DO study was found to be feasible to deliver in our selected target population. Our qualitative results from the process evaluation mostly indicate that participants enjoyed the program. However, the quantitative result shows that 1 (change in knowledge) out of 5 outcomes improved in the Facebook plus text messages group only. The CAN-DO study has provided valuable insights into the process of disseminating a social media intervention for young adults, and a number of changes to program design are indicated to improve motivation. The lack of interaction between the members of the groups requires research to discover how to facilitate members to post and provide social support. This is important as it appears that the social interaction between the interventionist and participants via the text messages results in better outcomes.

Acknowledgments

AR, MN, and MAF contributed to the conception and design of the study. AR conducted the research, analyzed the data, and drafted the manuscript. MAF contributed to interpretation of the results and editing of the manuscript. All authors have read and approved the final version of the manuscript. AR was supported by the Australian Postgraduate Award Scholarship from the Commonwealth Government of Australia. The authors would like to thank Nematullah Hayba and Alyse Davis for randomizing the participants; Dr Leah Shepherd for her guidance on the statistical analysis plan and assistance with code writing on Stata; Dr Stephanie Partridge for providing guidance on multiple imputation, and the Sydney Informatics Hub, a Core Research Facility of the University of Sydney, for their assistance with statistical analysis (Jim Matthews and Christopher Howden) and survey design on REDCap (Olya Ryjenko). This research did not receive funding from any agencies.

Conflicts of Interest

MAF receives funding from the National Health and Medical Research Council, New South Wales (NSW) Health, Australian Research Council, and Cancer Council NSW.

This randomized study was only retrospectively registered. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because the risk of bias appears low. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
E-leaflet provided to participants in Group C.
[PNG File , 2807 KB - mhealth_v8i2e16499_app1.png]

Multimedia Appendix 2
Questionnaire used to measure change in knowledge at baseline and end of intervention.
[DOCX File , 636 KB - mhealth_v8i2e16499_app2.docx]

Multimedia Appendix 3
Change in the amount of milk intake from baseline to end of intervention (completers only).
[DOCX File , 15 KB - mhealth_v8i2e16499_app3.docx]

Multimedia Appendix 4
Change in calcium intake per day in mg (excluding milk) from baseline to end of intervention (completers only).
[DOCX File , 14 KB - mhealth_v8i2e16499_app4.docx]

Multimedia Appendix 5
Change in secondary outcomes from baseline to end of intervention (completers only).
[DOCX File , 15 KB - mhealth_v8i2e16499_app5.docx]

Multimedia Appendix 6
Process evaluation of the CAN-DO study on frequency of reading posts, messages and interaction.
[DOCX File , 14 KB - mhealth_v8i2e16499_app6.docx]

Multimedia Appendix 7

Quotations illustrating feedback from participants provided through text message replies and qualitative process evaluation (n=106).
[DOCX File , 18 KB - mhealth_v8i2e16499_app7.docx]

Multimedia Appendix 8
CONSORT‐EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2890 KB - mhealth_v8i2e16499_app8.pdf]

References

1. Lenz B. The transition from adolescence to young adulthood: a theoretical perspective. J Sch Nurs 2001 Dec;17(6):300-306. [doi: 10.1177/10598405010170060401] [Medline: 11804406]
2. Butler SM, Black DR, Blue CL, Gretebeck RJ. Change in diet, physical activity, and body weight in female college freshman. Am J Health Behav 2004;28(1):24-32. [doi: 10.5993/ajhb.28.1.3] [Medline: 14977156]
3. Nelson MC, Story M, Larson NI, Neumark-Sztainer D, Lytle LA. Emerging adulthood and college-aged youth: an overlooked age for weight-related behavior change. Obesity (Silver Spring) 2008 Oct;16(10):2205-2211 [FREE Full text] [doi: 10.1038/oby.2008.365] [Medline: 18719665]
4. Vadeboncoeur C, Townsend N, Foster C. A meta-analysis of weight gain in first year university students: is freshman 15 a myth? BMC Obes 2015;2:22 [FREE Full text] [doi: 10.1186/s40608-015-0051-7] [Medline: 26217537]
5. Australian Bureau of Statistics. 2014. Soft Drink, Burgers and Chips - the Diet of Our Youth URL: https://tinyurl.com/yxywg7tx [accessed 2019-09-25]
6. Poobalan AS, Aucott LS, Clarke A, Smith WC. Diet behaviour among young people in transition to adulthood (18-25 year olds): a mixed method study. Health Psychol Behav Med 2014 Jan 1;2(1):909-928 [FREE Full text] [doi: 10.1080/21642850.2014.931232] [Medline: 25750826]
7. Howarth CC, Street C. New Policy Institute. 2000. Young Adults' Access to Services URL: https://www.npi.org.uk/files/9113/7545/0719/Sidelined.pdf [accessed 2019-11-27]
8. Arnett JJ. Emerging adulthood. A theory of development from the late teens through the twenties. Am Psychol 2000 May;55(5):469-480. [doi: 10.1037//0003-066x.55.5.469] [Medline: 10842426]
9. Dunn JE, Liu K, Greenland P, Hilner JE, Jacobs DR. Seven-year tracking of dietary factors in young adults: the CARDIA study. Am J Prev Med 2000 Jan;18(1):38-45. [doi: 10.1016/s0749-3797(99)00114-2] [Medline: 10808981]
10. Loth KA, MacLehose RF, Larson N, Berge JM, Neumark-Sztainer D. Food availability, modeling and restriction: How are these different aspects of the family eating environment related to adolescent dietary intake? Appetite 2016 Jan 1;96:80-86 [FREE Full text] [doi: 10.1016/j.appet.2015.08.026] [Medline: 26327222]
11. Larsen JK, Hermans RC, Sleddens EF, Engels RC, Fisher JO, Kremers SP. How parental dietary behavior and food parenting practices affect children's dietary behavior. Interacting sources of influence? Appetite 2015 Jun;89:246-257. [doi: 10.1016/j.appet.2015.02.012] [Medline: 25681294]
12. Balk EM, Adam GP, Langberg VN, Earley A, Clark P, Ebeling PR, International Osteoporosis Foundation Calcium Steering Committee. Global dietary calcium intake among adults: a systematic review. Osteoporos Int 2017 Dec;28(12):3315-3324 [FREE Full text] [doi: 10.1007/s00198-017-4230-x] [Medline: 29026938]
13. Australian Bureau of Statistics. 2015. Australian Health Survey: Usual Nutrient Intakes, 2011-12 URL: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/4364.0.55.008~2011-12~Main%20Features~Calcium~401 [accessed 2019-03-21]
14. Rouf AS, Sui Z, Rangan A, Grech A, Allman-Farinelli M. Low calcium intakes among Australian adolescents and young adults are associated with higher consumption of discretionary foods and beverages. Nutrition 2018 Nov;55-56:146-153. [doi: 10.1016/j.nut.2018.04.005] [Medline: 30005331]
15. Matkovic V. Calcium and peak bone mass. J Intern Med 1992 Feb;231(2):151-160. [doi: 10.1111/j.1365-2796.1992.tb00518.x] [Medline: 1541939]
16. Cashman KD. Diet, nutrition, and bone health. J Nutr 2007 Nov;137(11 Suppl):2507S-2512S. [doi: 10.1093/jn/137.11.2507S] [Medline: 17951494]
17. Rouf A, Clayton S, Allman-Farinelli M. The barriers and enablers to achieving adequate calcium intake in young adults: a qualitative study using focus groups. J Hum Nutr Diet 2019 Aug;32(4):443-454. [doi: 10.1111/jhn.12653] [Medline: 30941809]
18. Greenwood S, Perrin A, Duggan M. Pew Research Center. 2016 Nov 11. Social Media Update 2016 URL: https://www.pewresearch.org/internet/2016/11/11/social-media-update-2016/ [accessed 2019-04-30]
19. Sensis. multi-screen site. 2017 Jun 22. Sensis Social Media Report 2017: Chapter 1 – Australians and Social Media URL: https://irp-cdn.multiscreensite.com/535ef142/files/uploaded/Sensis-Social-Media-Report-2017.pdf [accessed 2018-08-22]
20. Napolitano MA, Hayes S, Bennett GG, Ives AK, Foster GD. Using Facebook and text messaging to deliver a weight loss program to college students. Obesity (Silver Spring) 2013 Jan;21(1):25-31 [FREE Full text] [doi: 10.1002/oby.20232] [Medline: 23505165]

21. Nour M, Chen J, Allman-Farinelli M. Young adults' engagement with a self-monitoring app for vegetable intake and the impact of social media and gamification: feasibility study. JMIR Form Res 2019 May 10;3(2):e13324 [FREE Full text] [doi: 10.2196/13324] [Medline: 31094322]
22. NSW Food Authority. Evaluation of Kilojoule Menu Labelling URL: http://www.foodauthority.nsw.gov.au/_Documents/scienceandtechnical/fastchoices_evaluation_report.pdf [accessed 2019-10-02]
23. Rouf AS, Grech A, Allman-Farinelli M. Assessing the efficacy and external validity of interventions promoting calcium or dairy intake in young adults: A systematic review with meta-analysis. Crit Rev Food Sci Nutr 2018;58(15):2600-2616. [doi: 10.1080/10408398.2017.1336508] [Medline: 28661721]
24. Partridge SR, McGeechan K, Hebden L, Balestracci K, Wong AT, Denney-Wilson E, et al. Effectiveness of a mHealth Lifestyle Program With Telephone Support (TXT2BFiT) to Prevent Unhealthy Weight Gain in Young Adults: Randomized Controlled Trial. JMIR Mhealth Uhealth 2015 Jun 15;3(2):e66 [FREE Full text] [doi: 10.2196/mhealth.4530] [Medline: 26076688]
25. Allman-Farinelli M, Partridge SR, McGeechan K, Balestracci K, Hebden L, Wong A, et al. A Mobile Health Lifestyle Program for Prevention of Weight Gain in Young Adults (TXT2BFiT): Nine-Month Outcomes of a Randomized Controlled Trial. JMIR Mhealth Uhealth 2016 Jun 22;4(2):e78 [FREE Full text] [doi: 10.2196/mhealth.5768] [Medline: 27335237]
26. Partridge SR, Allman-Farinelli M, McGeechan K, Balestracci K, Wong AT, Hebden L, et al. Process evaluation of TXT2BFiT: a multi-component mHealth randomised controlled trial to prevent weight gain in young adults. Int J Behav Nutr Phys Act 2016 Jan 19;13:7 [FREE Full text] [doi: 10.1186/s12966-016-0329-2] [Medline: 26785637]
27. Erdfelder E, Faul F, Buchner A. GPOWER: a general power analysis program. Behav Res Methods Instrum Comput 1996;28(1):1-11. [doi: 10.3758/bf03203630]
28. National Institute of Health. National Institute of Health Osteoporosis and Related Bone Diseases National Resource Center. 2018. Osteoporosis: Peak Bone Mass in Women URL: https://www.bones.nih.gov/health-info/bone/osteoporosis/bone-mass [accessed 2019-10-01]
29. Lu J, Shin Y, Yen M, Sun SS. Peak bone mass and patterns of change in total bone mineral density and bone mineral contents from childhood into young adulthood. J Clin Densitom 2016;19(2):180-191 [FREE Full text] [doi: 10.1016/j.jocd.2014.08.001] [Medline: 25440183]
30. Eysenbach G. CONSORT-EHEALTH: implementation of a checklist for authors and editors to improve reporting of web-based and mobile randomized controlled trials. Stud Health Technol Inform 2013;192:657-661. [Medline: 23920638]
31. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide To Designing Interventions. United Kingdom: Silverback Publishing; 2014.
32. Michie S, West R, Campbell R, Brown J, Gainforth H. ABC of Behaviour Change Theories. London: Silverback Publishing; 2014.
33. Rouf A, Allman-Farinelli M. Messaging for interventions aiming to improve calcium intake in young adults-a mixed methods study. Nutrients 2018 Nov 5;10(11):pii: E1673 [FREE Full text] [doi: 10.3390/nu10111673] [Medline: 30400574]
34. Project REDCap. 2018. URL: https://projectredcap.org/ [accessed 2019-02-08]
35. Australian Bureau of Statistics. 2018. 2033.0.55.001 - Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2016 URL: https://www.abs.gov.au/ausstats/abs@.nsf/mf/2033.0.55.001 [accessed 2019-06-12]
36. Pasco JA, Sanders KM, Henry MJ, Nicholson GC, Seeman E, Kotowicz MA. Calcium intakes among Australian women: Geelong Osteoporosis Study. Aust N Z J Med 2000 Feb;30(1):21-27. [doi: 10.1111/j.1445-5994.2000.tb01049.x] [Medline: 10800873]
37. Ma J, Betts NM, Horacek T, Georgiou C, White A, Nitzke S. The importance of decisional balance and self-efficacy in relation to stages of change for fruit and vegetable intakes by young adults. Am J Health Promot 2002;16(3):157-166. [doi: 10.4278/0890-1171-16.3.157] [Medline: 11802261]
38. Coa K, Patrick H. Baseline motivation type as a predictor of dropout in a healthy eating text messaging program. JMIR Mhealth Uhealth 2016 Sep 29;4(3):e114 [FREE Full text] [doi: 10.2196/mhealth.5992] [Medline: 27688034]
39. Levesque CS, Williams GC, Elliot D, Pickering MA, Bodenhamer B, Finley PJ. Validating the theoretical structure of the Treatment Self-Regulation Questionnaire (TSRQ) across three different health behaviors. Health Educ Res 2007 Oct;22(5):691-702. [doi: 10.1093/her/cyl148] [Medline: 17138613]
40. Gardner B, Abraham C, Lally P, de Bruijn G. Towards parsimony in habit measurement: testing the convergent and predictive validity of an automaticity subscale of the Self-Report Habit Index. Int J Behav Nutr Phys Act 2012 Aug 30;9:102 [FREE Full text] [doi: 10.1186/1479-5868-9-102] [Medline: 22935297]
41. Merchant G, Weibel N, Patrick K, Fowler JH, Norman GJ, Gupta A, et al. Click 'like' to change your behavior: a mixed methods study of college students' exposure to and engagement with Facebook content designed for weight loss. J Med Internet Res 2014 Jun 24;16(6):e158 [FREE Full text] [doi: 10.2196/jmir.3267] [Medline: 24964294]
42. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. Health Psychol 2009 Nov;28(6):690-701. [doi: 10.1037/a0016136] [Medline: 19916637]
43. Althubaiti A. Information bias in health research: definition, pitfalls, and adjustment methods. J Multidiscip Healthc 2016;9:211-217 [FREE Full text] [doi: 10.2147/JMDH.S104807] [Medline: 27217764]

44. Klassen KM, Douglass CH, Brennan L, Truby H, Lim MS. Social media use for nutrition outcomes in young adults: a mixed-methods systematic review. Int J Behav Nutr Phys Act 2018 Jul 24;15(1):70 [FREE Full text] [doi: 10.1186/s12966-018-0696-y] [Medline: 30041699]
45. Chau MM, Burgermaster M, Mamykina L. The use of social media in nutrition interventions for adolescents and young adults-A systematic review. Int J Med Inform 2018 Dec;120:77-91. [doi: 10.1016/j.ijmedinf.2018.10.001] [Medline: 30409348]
46. Shahril MR, Dali WP, Lua PL. A 10-week multimodal nutrition education intervention improves dietary intake among university students: cluster randomised controlled trial. J Nutr Metab 2013;2013:658642 [FREE Full text] [doi: 10.1155/2013/658642] [Medline: 24069535]

Abbreviations

CAN-DO: CAlcium Nutrition-Dietary Opportunities
e-leaflet: electronic leaflet
GEE: general estimating equation
NSW: New South Wales
OR: odds ratio
REDCap: Research Electronic Data Capture
SEIFA: Socio-Economic Indexes For Areas

Edited by G Eysenbach; submitted 04.10.19; peer-reviewed by G Shakerinejad, PH Lin, J Bray; comments to author 28.10.19; revised version received 04.11.19; accepted 13.11.19; published 11.02.20.

Please cite as:
Rouf A, Nour M, Allman-Farinelli M
Improving Calcium Knowledge and Intake in Young Adults Via Social Media and Text Messages: Randomized Controlled Trial
JMIR Mhealth Uhealth 2020;8(2):e16499
URL: https://mhealth.jmir.org/2020/2/e16499
doi:10.2196/16499
PMID:32044755

Review

Social, Organizational, and Technological Factors Impacting Clinicians' Adoption of Mobile Health Tools: Systematic Literature Review

Christine Jacob[1,2], BSc, MSc; Antonio Sanchez-Vazquez[3], PhD; Chris Ivory[3], PhD

[1]Anglia Ruskin University, Cambridge, United Kingdom

[2]University of Applied Sciences Northwestern Switzerland, Brugg, Switzerland

[3]Innovation and Management Practice Research Centre, Anglia Ruskin University, Cambridge, United Kingdom

Corresponding Author:
Christine Jacob, BSc, MSc
Anglia Ruskin University
Cambridge Campus
East Rd
Cambridge, CB1 1PT
United Kingdom
Phone: 44 798769376
Email: christine.k.jacob@gmail.com

Abstract

Background: There is a growing body of evidence highlighting the potential of mobile health (mHealth) in reducing health care costs, enhancing access, and improving the quality of patient care. However, user acceptance and adoption are key prerequisites to harness this potential; hence, a deeper understanding of the factors impacting this adoption is crucial for its success.

Objective: The aim of this review was to systematically explore relevant published literature to synthesize the current understanding of the factors impacting clinicians' adoption of mHealth tools, not only from a technological perspective but also from social and organizational perspectives.

Methods: A structured search was carried out of MEDLINE, PubMed, the Cochrane Library, and the SAGE database for studies published between January 2008 and July 2018 in the English language, yielding 4993 results, of which 171 met the inclusion criteria. The Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines and the Cochrane handbook were followed to ensure a systematic process.

Results: The technological factors impacting clinicians' adoption of mHealth tools were categorized into eight key themes: usefulness, ease of use, design, compatibility, technical issues, content, personalization, and convenience, which were in turn divided into 14 subthemes altogether. Social and organizational factors were much more prevalent and were categorized into eight key themes: workflow related, patient related, policy and regulations, culture or attitude or social influence, monetary factors, evidence base, awareness, and user engagement. These were divided into 41 subthemes, highlighting the importance of considering these factors when addressing potential barriers to mHealth adoption and how to overcome them.

Conclusions: The study results can help inform mHealth providers and policymakers regarding the key factors impacting mHealth adoption, guiding them into making educated decisions to foster this adoption and harness the potential benefits.

(JMIR Mhealth Uhealth 2020;8(2):e15935) doi:10.2196/15935

KEYWORDS

telemedicine; smartphone; cell or mobile phone; electronic health record; workflow; workload; workplace; public health practice; technology; perception; health education; mHealth; mobile health; telehealth; eHealth

Introduction

Mobile health (mHealth) is one of the key areas of medical technology innovation that hold promise for reduction of cost, enhancement of health care access, and improvement in the quality of patient care [1-5]. It is also helping to shift the focus of health care to a more patient-centric model that goes beyond treating disease to a more predictive and preventative approach [6,7].

Although the body of evidence that proves the potential value of mHealth is growing, there are still cases where users, mostly clinicians, resist its adoption [8]. For example, scholars in the area of mHealth adoption, such as Gagnon et al [9], found in a previous systematic review that, in reality, many studies reported that health care professionals perceive factors such as mHealth cost more as a barrier than a facilitator. Furthermore, Brewster et al [10] reported in their systematic review on the same topic that clinicians perceive some negative impacts of mHealth on elements such as their credibility and autonomy, affecting staff acceptance of such tools. This should not be overlooked, given that previous research shows that clinicians' adoption is one of the most influential factors regarding the success of mHealth tools [11-15]; hence, the need and value of better understanding the factors impacting clinicians' adoption in this context.

The World Health Organization's global observatory of electronic health (eHealth) considers mHealth a subcategory of eHealth and defines it as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, Personal Digital Assistants (PDAs), and other wireless devices." Telemedicine is, in turn, a subcategory of mHealth and defined as "the communication or consultation between health professionals about patients using voice, text, data, imaging, or video functions of a mobile device. But it can be applied to other situations; the management of chronic diseases of patients living at home is one example." [16].

According to the diffusion of innovations theory [17], technology adoption studies should look into not only users' acceptance or rejection of specific innovations but also to what extent innovation is incorporated into a suitable context. Straub [18] examined the most prevalent technology adoption theories—Rogers's innovation adoption and diffusion theories, the Concerns-Based Adoption Model, the Technology Acceptance Model (TAM), and the unified theory of acceptance and use of technology (UTAUT)—and concluded that the process of user adoption of new technologies is complex, fundamentally social, and progressive. This complexity results from the users' unique views of technology that impact their decision to adopt or reject new technology, highlighting the importance of considering social and organizational factors to enable the successful adoption of new technological tools.

We were guided in our thinking about technology adoption by the field of social studies of technology; we view technology, roles, and practices and organizational structures as interacting parts of a mutually constituting ensemble of elements [19-22]. It follows that it is not simply a matter of *factors* affecting the decision to adopt a technology or not but also of the use of technologies enabling and triggering new forms of organizing and new work practices [23,24]. A *mutually constituting* sensibility alerts the researcher to the fact that the adoption of technology can be part of a deliberate change process and can result in new practices and different uses and interpretations of the technology itself. We are mindful of how such things as organizational culture and existing roles and practices are implicated not just in the decision to adopt but how the decision to adopt can lead to experimentation with new practices and organizational forms. The scope of our literature review engages in more depth with these broader concerns and interests than previous reviews.

A systematic review of relevant literature was carried out to provide an accurate and up to date account of factors that impact clinicians' adoption of mHealth tools both from a technology and a social and organizational perspective. This work complements a larger ongoing research project and supplements its initial findings, which have already been published [25].

In light of Leonardi's *Methodological Guidelines for the Study of Materiality and Affordances* [22], the authors analyzed the included studies following three key steps: (1) identifying utility and limitations of the studied solutions, (2) recognizing the real constraints upon opportunities faced by clinicians when using them, and (3) understanding the workflow advantages and disadvantages related to them, as reported in the included articles.

Findings from this review should benefit mHealth providers and policymakers by presenting them with an up to date and comprehensive review of key factors impacting clinicians' adoption of mHealth tools, as reported in the academic literature. This can inform and guide them in the development of a strategy for promoting the adoption of these tools and enable them to realize their potential benefits.

Methods

Overview

The methods for this review were drawn from the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines [26]and the Cochrane Handbook [27], both of which provide guidance toward a rigorous and reliable literature review methodology. The review methods were defined in advance and the protocol was published in the PROSPERO (International Prospective Register of Systematic Reviews) and is available on their website [28]. The analysis did not necessitate any major divergence from the initial protocol.

The key question that guided this review was the following: "According to the literature, what are the social, organizational and technological factors impacting clinicians' adoption of mHealth tools?"

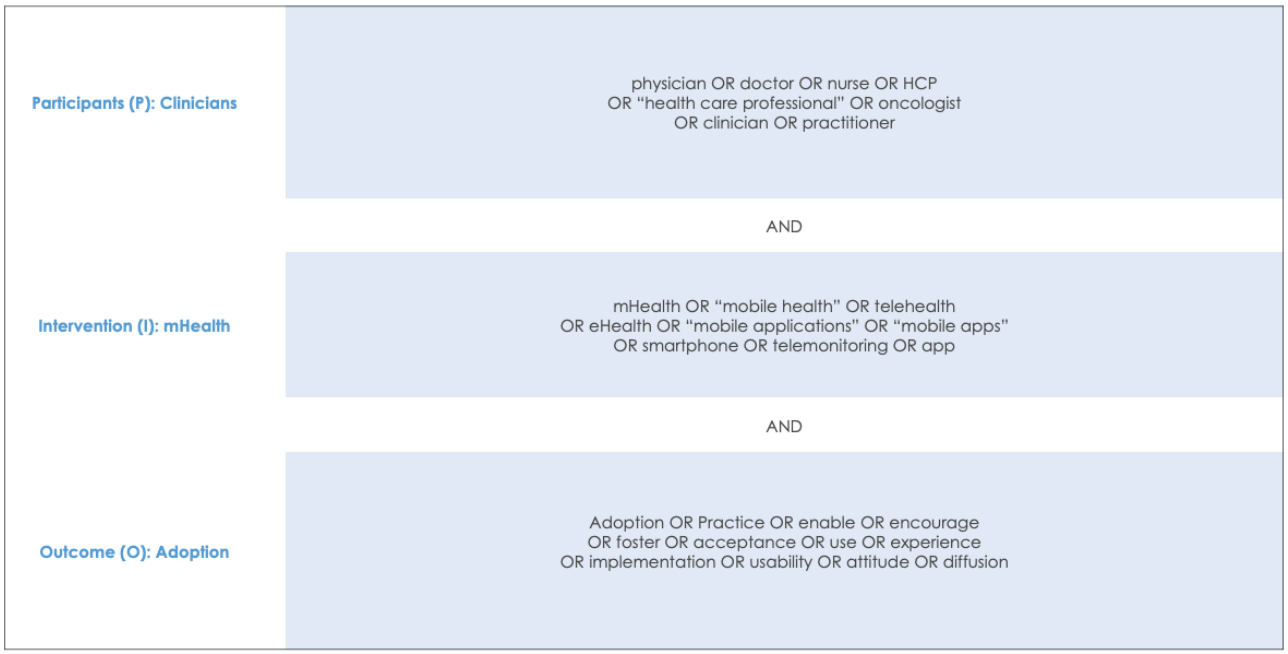
Search Strategy

A search of MEDLINE, PubMed, the Cochrane Library, and the SAGE database in August and September 2018 identified the relevant studies. The scope was narrowed to studies published in the English language between January 2008 and August 2018. Only original, peer-reviewed, and published papers were included. Other forms, such as editorials, unsystematic reviews, interviews, comments, unstructured observations, and position papers, were excluded.

It was decided not to include articles on the basis of on hand searches of reference lists for causes summarized in the Cochrane Handbook: "positive studies are more likely to be cited" and "retrieving literature by scanning reference lists may thus produce a biased sample of studies" [27].

The search string shown in Figure 1 was developed according to the participants, intervention, comparators, and outcome (PICO) framework [29]. There were no limitations on the kinds of conditions qualified for inclusion, and both qualitative and quantitative studies were included. Comparators were not applicable to this study. Participants (Clinicians) included studies focusing on clinicians and health care professionals. For the review, the Merriam-Webster dictionary's definition of the word *clinician* was used: "a person qualified in the clinical practice of medicine, psychiatry, or psychology as distinguished from one specializing in laboratory or research techniques or in theory" [30]. Interventions (mHealth) included studies involving smart device use, such as mHealth apps or telehealth. Outcomes (Adoption) included studies addressing the factors impacting mHealth technology adoption or use.

Figure 1. The search string according to the participants, intervention, comparator, and outcome (PICO) framework. mHealth: mobile health.



Study Selection

Independent researchers, CJ and ASV, were involved in the screening, eligibility, and inclusion phases, and any divergences were agreed in discussion between the 2. In the cases where they could not reach an agreement, a third reviewer, CI, discussed it with them and took the final decision. The research team used the open-source app Rayyan QCRI (Qatar Computing Research Institute) to facilitate collaborative screening by the team [31]. Screening lasted from August 2018 to February 2019. A screenshot of the app is included in Multimedia Appendix 1.

The inclusion and exclusion criteria, detailed in Textbox 1, were also developed according to the PICO framework. Studies were excluded if they did not involve the use of mHealth or smart devices; focused solely on, for example, patients, caregivers or technology providers, not including clinicians; were not peer-reviewed; were editorials, interviews, comments, unstructured observations, or position papers; did not address the factors impacting adoption; or if the full text was not available, freely available, or available in English.

After completing the screening, and resolving any conflicting views between the researchers, the selected full texts were assessed for eligibility by CJ and AV, independently. Any disagreements were resolved by discussing with CI.

Subsequently, the risk of bias was assessed using the Critical Appraisal Skills Program tool [32]. The checklist is included in Multimedia Appendix 2, and an Excel sheet with the appraisal of the included studies can be accessed in Multimedia Appendix 3. On the basis of the appraisal, 38 out of the 171 studies did not report a clear participant recruitment strategy, 40 papers did not give enough details on their data collection techniques, 76 did not clarify how they addressed potential ethical considerations, and 25 were not clear enough about their data analysis strategy and whether it was sufficiently rigorous. Articles were not excluded on the basis of technical quality to enable the researchers to capture both theoretical and empirical contributions from the published studies.

Textbox 1. Inclusion and exclusion criteria according to the participants, intervention, comparator, and outcome (PICO) framework.

Population (P)

- Include: Focused on health care professionals (eg, physicians and nurses).
- Exclude: Focused only on patients, caregivers, or technology providers.

Intervention (I)

- Include: Focused on solutions involving a smart device (eg, mHealth apps and telehealth).
- Exclude: Using other technologies (eg, virtual reality and machine learning).

Comparators (C)

- Does not apply.

Outcome (O)

- Include: Addresses factors impacting clinicians' adoption, acceptance, use, experience, implementation, usability, or attitude of using mHealth for health care service delivery, regardless of the condition.
- Exclude: Focused only on mHealth success or development in general.

Publication type

- Include: Original, peer-reviewed, and published paper.
- Exclude: Editorials, interviews, comments, unstructured observations, and position papers, or similar publications.

Data Collection and Synthesis

The variety of measures and outcomes that were identified in the included articles were not homogenous enough to enable a quantitative synthesis of the data. Therefore, a narrative synthesis was used and structured around the organizational and technological factors impacting clinicians' adoption of mHealth solutions. QSR NVivo, a computer-assisted qualitative data analysis software, was used to assist in this task.

Data coding began with an initial data extraction grid that included themes based on previous research and technology acceptance frameworks; more themes were added as they emerged during the review process. Braun and Clarke's thematic analysis [33] was used to identify and extract themes that addressed the review's research question. The phases of the thematic analysis are explained in detail in Multimedia Appendix 4.

The research themes were also guided by Leonardi's *Methodological Guidelines for the Study of Materiality and Affordances* [22]; hence, they were split into two key groups, on the one hand, the technological factors, and on the other the social and organizational factors. There was an additional category for implications for social and organizational practices. This process lasted from February to July 2019.

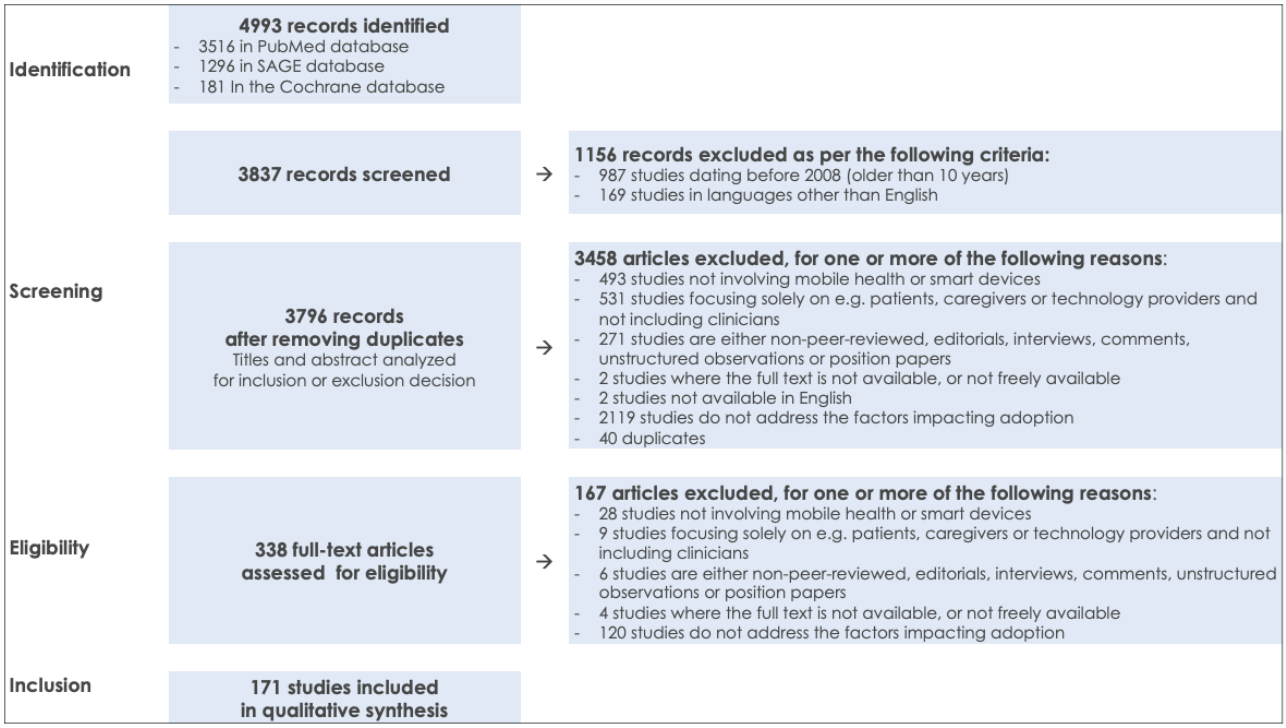
Results

Overview

As shown in the study selection flow diagram, visualized in Figure 2, the search string yielded a total of 4993 studies, out of which 3516 from PubMed, 1296 from SAGE, and 181 from the Cochrane database. From these, 1156 studies were excluded after limiting the scope to studies published in English and published after January 2008, leaving 3837 studies for screening. Screening of the titles and abstracts excluded another 3458 articles because 493 of them did not involve mHealth or smart devices, 531 focused solely on nonclinician populations such as patients, caregivers, or technology providers, 271 were editorials, interviews, comments, unstructured observations, position, or non–peer-reviewed papers, 2 were not available as full text, 2 were not available in English, 2119 did not address factors impacting adoption, and 40 were duplicates.

In the eligibility phase, 338 articles were included for full-text assessment. In total 167 articles were excluded for the following reasons: 28 for not involving mHealth or smart devices; 9 for focusing solely on nonclinician populations such as patients, caregivers, or technology providers; 6 for being either, editorials, interviews, comments, unstructured observations, position, or non–peer-reviewed papers; 4 because the full text was not available; and 120 for not addressing the factors impacting adoption. This resulted in the inclusion of 171 studies in the qualitative synthesis.

Figure 2. Study selection flow diagram on the basis of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines.



Characteristics of Included Studies

The sample characteristics of the included articles are detailed in Table 1. Overall, 62 studies focused on clinicians, 41 on physicians, 21 on nurses, and 46 included clinicians and other populations such as patients or caregivers. From a specialization perspective, some were more represented than others in the included studies; 17 studies focused on primary and acute care, 12 on chronic obstructive pulmonary disease, or congestive heart failure, or cardiovascular disease, 10 on diabetes, 9 on general and family practices, 8 on psychology and mental health, whereas the other specialties were represented four times or less in the included studies.

The majority of the publications did not mention the use of a theoretical framework. Among those that used one, the TAM was the most common (n=19), followed by the theory of diffusion of innovation (n=11), and the UTAUT (n=6). Other models were used once or twice, as detailed in Table 1. From a geographical perspective, 38 studies were conducted in the United States, 22 in the United Kingdom, 15 in Australia, 9 in Canada, 7 in Germany, 7 in Spain, whereas other geographies were covered in 4 studies or less.

Finally, 31 studies were identified as pilot projects. Such studies can be particularly relevant to mHealth providers when rolling out a new tool, as they provide insights into the potential *teething problems* that they can avoid to have better chances for success.

Table 1. Characteristics of included studies.

Study characteristic	References
Study Design	
Qualitative (n=64)	[1,2,4,34-94]
Quantitative (n=58)	[3,95-150]
Mixed methods (n=32)	[151-181]
Systematic review (n=11)	[5,9,10,182-189]
Others (n=5)	[8,190-193]
Sample size	
Less than 10 (n=8)	[67,71,76,85,88,93,171]
10-20 (n=41)	[1,2,4,10,34,37,39,40,42,46,49,50,54,56,57,61,63-66,68,72,75,79,80,82,86,89-92,141,150,154,157,163,180,181,183,193,194]
21-40 (n=30)	[9,35,36,41,44,45,47,51,53,55,60,62,69,70,73,74,77,78,81,95,101,110,131,135,155,165,166,172,176,195]
41-60 (n=11)	[3,48,52,58,59,84,119,153,156,175,192]
61-80 (n=8)	[38,87,114,115,137,174,191,196]
81-100 (n=5)	[97,132,146,160,179]
More than 100 (n=61)	[8,43,83,96,98-100,102-109,111-113,116-118,120-130,133,134,136,138-140,142-145,147-149,151,152,158,159,161,162,164,167-170,173,177,190]
Sample composition	
Clinicians (n=62)	[9,35,36,40,45,47,53,55,56,60-62,64,66,67,69,70,73-75,79,81,82,85,86,90,91,93,97,98,101,104,106,107,110,112,119,120,126,130,131,137-139,141,145,147,148,154,159,164,168,171,179,180,186,189,191,193,194]
Clinicians plus others (eg, patients) (n=46)	[2,4,5,8,34,38,41,43,48,51,52,58,59,68,78,83,84,87,92,94,103,115,117,151-153,155-158,160,162,163,166,167,169,174,176-178,182-184,187,192,195]
Physicians (n=41)	[1,3,37,39,46,49,50,54,77,89,95,99,100,102,105,108,113,114,116,118,121-123,125,127-129,132-134,136,140,143,144,149,150,161,165,170,175,190]
Nurses (n=21)	[10,42,44,63,71,72,76,88,96,109,111,124,135,142,146,172,173,181,185,188,196]
Specialty or condition	
Primary or acute care (n=17)	[1,42,43,48,59,68,72,94,103,130,132,139,169,183,184,187,192]
Chronic obstructive pulmonary disease, congestive heart failure, and cardiovascular disease (n=12)	[10,41,52,71,78,80,83,97,104,108,119,164]
Diabetes (n=10)	[38,51,75,88,92,115,125,147,160,162]
General and family practice (n=9)	[39,49,89,102,117,121,128,134,144]
Psychology and mental health (n=8)	[2,73,81,90,112,153,166,194]
Dermatology (n=4)	[1,54,126,152]
Substance use recovery (n=4)	[61,67,158,167]
Residential aged care, home health nursing (n=4)	[146,156,171,182]
Pediatric, maternal (n=4)	[57,74,141,168]
Neurology, stroke (n=4)	[69,123,150,176]
Intensive care unit (n=4)	[109,111,186,188]
Asthma (n=3)	[70,77,84]
Oncology (n=3)	[53,155,180]
Sexual health, HIV (n=3)	[138,163,177]
Others (n=13)	Ambulatory care [149], cognitive behavioral therapy [120], emergency [159], genetics [91], geriatrics [40,60], hypertension [5], nephrology [87], obesity and irritable bowel syndrome [36], otolaryngology [100], radiology [131], speech-language pathology [50], tuberculosis [58]

Study characteristic	References
Location	
The United States (n=38)	[1,2,36,45,53,54,57,60,61,67,68,75,77,88,93,99,102,109-112,120,121,123,127,137,138,141,159,166-169,173,194-196]
The United Kingdom (n=22)	[10,41,43,48,49,55,62,70,71,79,80,83,94,115,124,154,163,165,174,176,179,180]
Australia (n=15)	[39,42,50,51,69,73,81,91,92,103,153,156,161,164,171]
Canada (n=9)	[3,52,76,78,87,146,155,178,192]
Germany (n=7)	[100,108,117,134,135,149,150]
Spain (n=7)	[59,97,122,126,132,139,143]
Norway (n=4)	[85,86,89,90]
South Korea (n=4)	[8,107,114,129]
Sweden (n=4)	[46,72,82,175]
Austria (n=3)	[98,160,191]
Iran (n=3)	[131,147,170]
The Netherlands (n=3)	[84,142,152]
Taiwan (n=3)	[35,113,116]
Others (n=39)	Argentina [44], Australia–United Kingdom [65], Austria–Sweden [140], Bangladesh [56], Belgium [162], Brazil [37], Congo [193], Ethiopia [105], Europe [66,119], France [40,128], Ghana [74], Iraq [95], Israel–Portugal [34], Italy [158], Japan [125], Japan–Sweden [104], Jordan–Syria [151], Lebanon [190], Malaysia [145], Nepal [4], the Netherlands–Spain–United Kingdom [38], New Zealand [63,172], Nigeria [106], North America–Europe [130], Poland [96], Portugal [157], Russia [58], Senegal [118], South–North America [148], Spain–Colombia–Bolivia [133], Sri Lanka [47], Switzerland [181], Syria [101], Turkey [136,144], the United States–South Africa–Thailand–Peru [177]
Theoretical framework	
TAM[a] was the most used theoretical framework (n=19)	[90,97,102,111,126,127,129,132-136,139,146,149,168,170,173,196]
The theory of diffusion of innovation (n=11)	[47,52,73,115,120,127,133,134,138,175,196]
UTAUT[b] (n=6)	[38,98,106,107,142,181]
Others (n=23)	Affordability, practicability, effectiveness, acceptability, safety or side effects, and equity criteria [39]; Consolidated Framework for Implementation Research [61,86,166]; design science research methodology [157]; Giddens's concepts from structuration theory and consequence of modernity [79]; organizational readiness for change model [168]; organizational theory of implementation effectiveness [169]; reach, effectiveness, adoption, implementation, and maintenance framework [167]; sociotechnical theory [94,192]; stakeholder empowered adoption model [174]; the technology-organization-environment framework [95]; technological frames [46]; the dual-factor model [116]; the normalization process theory [65]; theory of change [176]; theory of planned behavior [113,132]; theory of reasoned action [132,133]; theory of technology readiness [133]; Updated DeLone and McLean Information System Success Model [125]
Pilot projects	
Studies identified as pilot projects (n=31)	[43,48,53,66,68,74,78,87-89,94,95,98,112,114,126,137,139,158,162-167,171,174,176,181,192,193]

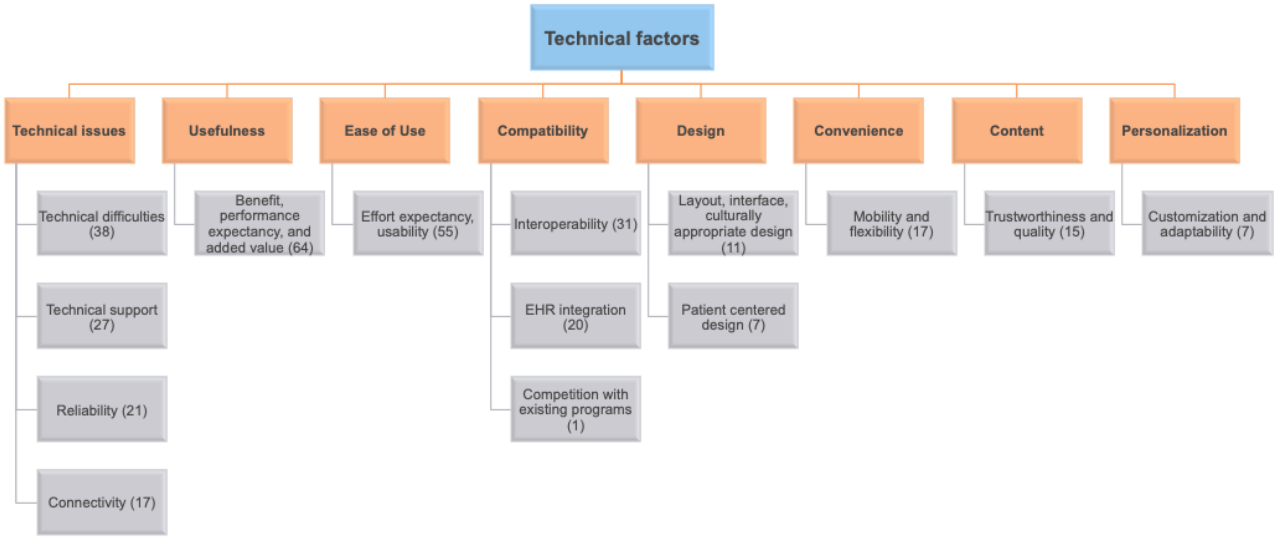
[a]TAM: Technology Acceptance Model.

[b]UTAUT: unified theory of acceptance and use of technology.

Technological Factors

The technological factors impacting clinicians' adoption of mHealth were categorized into 8 key themes: usefulness, ease of use, design, compatibility, technical issues, content, personalization, and convenience. These were, in turn, subdivided into a total of 14 subthemes. Figure 3 gives an overview of these technological factor themes and subthemes and their respective occurrence.

Figure 3. Overview of technological factors and their occurrence. EHR: electronic health record.



Technical issues were the most prominent factors, often related to matters such as connectivity (n=17), reliability (n=21), technical support (n=27), and technical difficulties in general (n=38). Features determining usefulness, such as expected benefits, performance expectancy, and added value, were also among the most prominent technological factors in the selected studies (n=64). Ease of use, determined by features such as effort expectancy and usability, was also quite central (n=55). Furthermore, several studies raised some concerns related to compatibility, such as interoperability issues (n=31), electronic health record (EHR) integration (n=20), and competition with existing programs (n=1).

Some design-related factors were also cited, such as layout, interface, culturally appropriate design (n=11), and the importance of patient-centered design (n=11). The tools' convenience, determined by its level of mobility and flexibility, also played a role (n=17), in addition to the trustworthiness and quality of the content (n=15), and personalization possibilities through customization and adaptability (n=7). Table 2 details the technological factors impacting adoption, their occurrence, and the respective studies where they were identified.

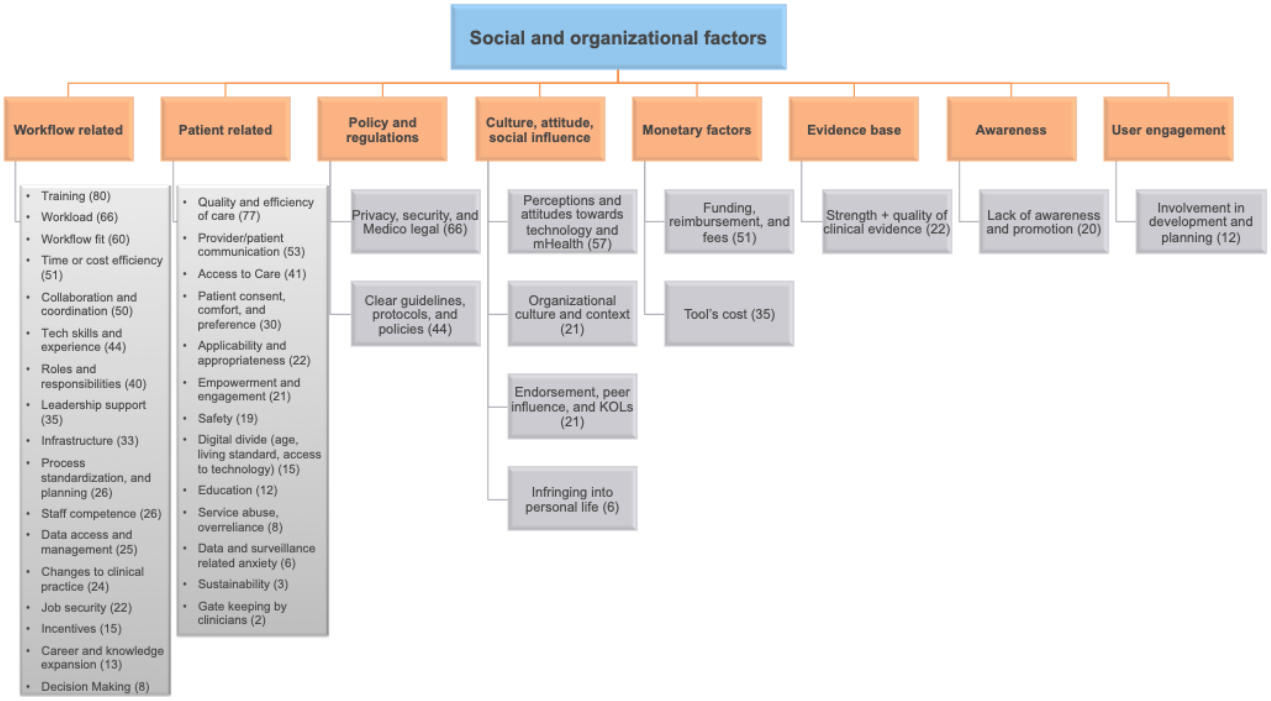
Table 2. Technological factors and their occurrence, with references.

Factor and subthemes	References
Technical issues	
Technical difficulties (n=38)	[2,9,37,41-44,51,54-56,61,74,75,82,83,86,90-92,101,109,115,128,150,156,162,163,165,172,177,181,182,186,188,189,194,197]
Technical support (n=27)	[2,9,10,44,49,51,57,63,68,71,72,79,80,90,92,95,97,98,126,136,139,144,153,154,174,185,189]
Reliability (n=21)	[9,10,35,36,44,49,50,55,69,79,91,92,96,108,117,140,152,153,163,177,182]
Connectivity (n=17)	[37,38,44,50,51,55,68,74,91,95,124,130,153,164,172,181,182]
Usefulness	
Benefit, performance expectancy, and added value (n=64)	[5,9,34,35,38,39,45,47,50,55,60,61,63,64,67,69,78,84-86,89,90,95,98,105-108,111,112,114-117,122,125-127,129,132,134-136,139,141-147,149,150,153,156,158,163,168,170,172,173,179,188,189]
Ease of use	
Effort expectancy and usability (n=55)	[4,5,9,10,38,42,44,52,59-61,69,70,72,73,78,81,84,86-89,92,105,106,110-112,116,120,122,126,129,132,136,141,144,146,149,155,156,158,166,168,170-173,179,181-183,185,189,192]
Compatibility	
Interoperability (n=31)	[2,9,10,34-36,41,53,54,59,61,66,70,72-74,80,87,95,127,128,134,139,156,165,169,172,174,184,186,196]
Electronic health record integration (n=20)	[9,38,48,72,78,84,85,87,129,143,151,162,167,172,174,175,182,188]
Competition with existing programs (n=1)	[169]
Design	
Layout, interface, and culturally appropriate design (n=11)	[9,38,41,60,73,78,83,155,171,182]
Patient-centered design (n=7)	[39,77,78,159,162,166,182]
Convenience	[5,61,68,73,75,78,82,89,91,116,124,131,136,161,162,165,173]
Mobility and flexibility (n=17)	
Content	[9,38,48,59,66,73,81,114,117,124,144,154,165,175,192]
Trustworthiness and quality (n=15)	
Personalization	[38,70,72,84,124,181,192]
Customization and adaptability (n=7)	

Social and Organizational Factors

The social and organizational factors impacting clinicians' adoption of mHealth were manifestly more numerous than the technical factors. These factors were also categorized into 8 key themes: workflow related, patient related, policy and regulations, culture or attitude or social influence, monetary factors, evidence base, awareness, and user engagement. Key themes were, in turn, divided into a total of 41 subthemes, as shown in Figure 4, which provides an overview of the social and organizational factors and their respective occurrence.

Figure 4. Overview of social and organizational factors and their occurrence. mHealth: mobile health; KOL: key opinion leader.



Workflow-related factors were the most prominent organizational factor in the included articles, with 17 subthemes. Training (n=80) was the most central workflow-related theme, followed by workload (n=66), workflow fit (n=60), time and cost efficiencies (n=51), collaboration and coordination (n=50), technical skills and experience (n=44), the impact on roles and responsibilities (n=40), the extent of leadership support (n=35), organizational or local infrastructure (n=33), process standardization and planning (n=26), staff competence (n=26), data access and management (n=25), changes to clinical practice (n=24), job security (n=22), incentives (n=15), impact on career and knowledge expansion (n=13), and decision making (n=8). Table 3 details the subthemes of the workflow-related factors impacting adoption, their occurrence, and the respective studies where they were identified.

Table 3. Workflow-related factors and their occurrence, with references.

Factor	Subthemes	References
Training (n=80)	Clinicians' training to enable an efficient use and management of the tools	[2,4,9,10,37,42-44,49,50,52-56,59,61,62,65,68,70-74,77,79-81,83,85,89,90,92-94,96,97,103,104,111,112,120,122,126,128,129,136,139,142,143,149-154,156,158,162,165,166,168-173,176,179,182,183,185-189,191,194]
Workload (n=66)	Availability and allocation of resources	[2-5,9,10,34-37,39,41,45,46,48,49,51,53,55,59,61,62,70-74,77-81,83-86,89,90,92,102,104,115,119,122,123,131,152,158-160,162,164,169,172,174,178,181-183,185,186,188-190,192,195]
Workflow fit (n=60)	Improvements versus disruptions of the workflow and organization of work	[1,8-10,36,39,40,46,48,53,57,59,61,67,70,72-74,78,80,81,83-89,94,104,107,109,114,120,122,129,135-137,141,147,150,155,156,159,161,163,166,169,171,172,178,180-182,185,188,193]
Time or cost-efficiency (n=51)	Impact on efficiency and competitiveness	[1,5,9,38,39,43,44,47,49,52-54,57,59-61,64,74,77,78,86,87,91,94,107-110,114,115,119,132,137,140,150,152,156,157,159,161,162,165,168,173,174,177,179,181,188,190,195]
Collaboration and coordination (n=50)	Coordination of health services and collaboration between health care professionals	[1,2,8-10,39,40,42,46,50,52,55-57,59,61,68,69,71,84,85,87,88,92,93,100,102,109,111,127,137,141,150,152,153,155,156,159,161,162,168,172,176,182,185,186,188,194]
Technical skills, and experience (n=44)	Clinicians' tech-savviness, and previous experience with technology or mHealth[a]	[9,37,44,49,55,59-61,67,72,73,81,83,96,100-102,112,121,122,127,129,133,134,136,138,142,143,145,146,149,153,155,157,158,161,168-170,179,184,188,191,196]
Roles and responsibilities (n=40)	Expansion, reassignment, or possible changes to clinical roles and responsibilities	[2,10,39,40,48,56,59-62,65,67,68,70-72,74,77-80,82,83,85,86,88-90,94,103,104,152,157,164,167,169,176,182,189]
Leadership support (n=35)	Senior management and organizational support	[5,9,34,35,40,42,59,61,71-73,86,95,103,105,106,111,127,131,132,134,138,145,156,157,164,166,170,174,181,182,188,192,195,196]
Infrastructure (n=33)	Availability and accessibility of the needed foundation	[2-4,9,35,47,51,54,69,70,77,82,83,87,91,93,95,116,124,126,127,130,151,153,154,157,163,169,172,179,181,187,193]
Process standardization and planning (n=26)	Governance and control, streamlined procedures, and processes	[5,8,9,39,40,44-46,61,65,67,73,80,82-84,86,88,103,149,155,160,164,167-169,180,182,185,189]
Staff competence (n=26)	Expertise in the required skills	[2,4,9,36,37,39,51,58,59,69,73,80,84,91,92,105,108,109,137,154-157,164,176,185]
Data access and management (n=25)	Accessing, analyzing, and interpreting generated data	[36,38,51,53,60,62,66,72-75,77,78,100,108,115,120,150,157,167,169,176,177,182,183]
Changes to clinical practice (n=24)	New paradigms of care and treatment	[10,35,37,40,46,48,49,59,64,65,72,79,80,92,94,123,130,139,162,182,185,186,189,192]
Job security (n=22)	Autonomy, loss of control, threat to own career, and professional identity	[9,10,55,62,72,79,80,108,113,116,118,124,130,140,141,151,159,176,182,185,188]
Incentives (n=15)	Different means to incentivize clinicians	[4,54,59,87,88,106,122,129,141,157,164,168,175,191]
Career and knowledge expansion (n=13)	Impact on professional development and expertise	[62,72-74,86,124,131,137,161,162,169,188,189]
Decision making (n=8)	The process of decision making in a fragmented health care system	[4,8,34,43,71,72,74,97,102,160,191]

[a]mHealth: mobile health.

Patient-related factors arose quite often in the included articles and were split into 13 subthemes. The most prevalent patient-related subtheme was the quality and efficiency of patient care, for example, treatment outcomes, clinical delivery, patient monitoring, and treatment compliance (n=77), followed by the quality and ease of communications between patients and the care team (n=53), enhancing patients' access to care and reaching the underserved (n=41), then patients' comfort with technology, personal preferences, and the ease of getting an informed consent from the patients (n=30). Applicability and appropriateness, meaning the suitability of patients on the basis of their needs and characteristics, also occurred quite often (n=24), seeing mHealth as an opportunity to empower and reassure patients and increase their engagement in managing their condition, which was also a key factor (n=21).

In addition to patient safety (n=19), factors included patient age, living standard, and access to technology (n=15), better patient education and awareness (n=12), patient overdependence on practitioner support (n=8), and patients' worries and anxiety related to the understanding and interpretation of data, or the feeling of being observed (n=6). The least common subthemes were those reflecting concerns regarding patients' long-term commitment and use (n=3) and protective or paternalistic

attitudes of the care team (n=2). Table 4 details the subthemes of the patient-related factors impacting adoption, their occurrence, and the respective studies where they were identified.

Table 4. Patient-related factors and their occurrence, with references.

Factor	Subthemes	References
Training (n=80)	Clinicians' training to enable an efficient use and management of the tools	[2,4,9,10,37,42-44,49,50,52-56,59,61,62,65,68,70-74,77,79-81,83,85,89,90,92-94,96,97,103,104,111,112,120,122,126,128,129,136,139,142,143,149-154,156,158,162,165,166,168-173,176,179,182,183,185-189,191,194]
Workload (n=66)	Availability and allocation of resources	[2-5,9,10,34-37,39,41,45,46,48,49,51,53,55,59,61,62,70-74,77-81,83-86,89,90,92,102,104,115,119,122,123,131,152,158-160,162,164,169,172,174,178,181-183,185,186,188-190,192,195]
Workflow fit (n=60)	Improvements versus disruptions of the workflow and organization of work	[1,8-10,36,39,40,46,48,53,57,59,61,67,70,72-74,78,80,81,83-89,94,104,107,109,114,120,122,129,135-137,141,147,150,155,156,159,161,163,166,169,171,172,178,180-182,185,188,193]
Time or cost-efficiency (n=51)	Impact on efficiency and competitiveness	[1,5,9,38,39,43,44,47,49,52-54,57,59-61,64,74,77,78,86,87,91,94,107-110,114,115,119,132,137,140,150,152,156,157,159,161,162,165,168,173,174,177,179,181,188,190,195]
Collaboration and coordination (n=50)	Coordination of health services and collaboration between health care professionals	[1,2,8-10,39,40,42,46,50,52,55-57,59,61,68,69,71,84,85,87,88,92,93,100,102,109,111,127,137,141,150,152,153,155,156,159,161,162,168,172,176,182,185,186,188,194]
Technical skills, and experience (n=44)	Clinicians' tech-savviness, and previous experience with technology or mHealth[a]	[9,37,44,49,55,59-61,67,72,73,81,83,96,100-102,112,121,122,127,129,133,134,136,138,142,143,145,146,149,153,155,157,158,161,168-170,179,184,188,191,196]
Roles and responsibilities (n=40)	Expansion, reassignment, or possible changes to clinical roles and responsibilities	[2,10,39,40,48,56,59-62,65,67,68,70-72,74,77-80,82,83,85,86,88-90,94,103,104,152,157,164,167,169,176,182,189]
Leadership support (n=35)	Senior management and organizational support	[5,9,34,35,40,42,59,61,71-73,86,95,103,105,106,111,127,131,132,134,138,145,156,157,164,166,170,174,181,182,188,192,195,196]
Infrastructure (n=33)	Availability and accessibility of the needed foundation	[2-4,9,35,47,51,54,69,70,77,82,83,87,91,93,95,116,124,126,127,130,151,153,154,157,163,169,172,179,181,187,193]
Process standardization and planning (n=26)	Governance and control, streamlined procedures, and processes	[5,8,9,39,40,44-46,61,65,67,73,80,82-84,86,88,103,149,155,160,164,167-169,180,182,185,189]
Staff competence (n=26)	Expertise in the required skills	[2,4,9,36,37,39,51,58,59,69,73,80,84,91,92,105,108,109,137,154-157,164,176,185]
Data access and management (n=25)	Accessing, analyzing, and interpreting generated data	[36,38,51,53,60,62,66,72-75,77,78,100,108,115,120,150,157,167,169,176,177,182,183]
Changes to clinical practice (n=24)	New paradigms of care and treatment	[10,35,37,40,46,48,49,59,64,65,72,79,80,92,94,123,130,139,162,182,185,186,189,192]
Job security (n=22)	Autonomy, loss of control, threat to own career, and professional identity	[9,10,55,62,72,79,80,108,113,116,118,124,130,140,141,151,159,176,182,185,188]
Incentives (n=15)	Different means to incentivize clinicians	[4,54,59,87,88,106,122,129,141,157,164,168,175,191]
Career and knowledge expansion (n=13)	Impact on professional development and expertise	[62,72-74,86,124,131,137,161,162,169,188,189]
Decision making (n=8)	The process of decision making in a fragmented health care system	[4,8,34,43,71,72,74,97,102,160,191]

Other social and organizational factors included policy and regulations related to privacy or security or medico-legal issues (n=66) and the need for clearer guidelines or protocols or policies (n=44). Cultural and social factors also prevailed quite often and were mostly linked to perceptions and attitudes toward technology and mHealth (n=57), organizational culture and context (n=21), and endorsement or peer influence (n=21).

Monetary factors, such as funding or reimbursement or fees (n=51) and the tools' cost (n=35), were also central, followed by the strength and quality of clinical evidence (n=22), lack of awareness and promotion (n=20), and user involvement in development and planning (n=12). Table 5 details the other social and organizational factors impacting adoption, their subthemes, occurrence, and the respective studies where they were identified.

Table 5. Other social and organizational factors and their occurrence, with references.

Factor and subthemes	References
Policy and regulations	
Privacy, security, and medico-legal issues (n=66)	[2,3,9,10,37-39,44,47,49,52,53,58-61,65,67,73,77,84,90,95,98,100,102,108,110,114,117,123,125,127,128,130-132,137,138,140,142-144,149,152,156,158,160-163,167,172,174,176-178,182-185,189-193]
Clear guidelines, protocols, and policies (n=44)	[1,4,5,9,10,34,35,37,42,43,47,51,61,63,64,67,73,76,92,95,102,104,121-124,130,141,143,145,151,155-157,159,161,162,168,175,176,178,179,190,193]
Culture, attitude, and social influence	
Perceptions and attitudes toward technology and mHealth[a] (n=57)	[5,9,10,34,35,37,50,55,58-61,63,64,67,69,83,85,95,97,100,104,107-109,111,113,116-118,124,125,127,130,132-134,136,138,143,146,147,153,155,157,166,168,173,174,178,185,186,188,190,191,193,195]
Organizational culture and context (n=21)	[37,42,45,63,76,86,95,101,113,124,130,145,148,151,161,165,168,170,176,179,193]
Endorsement, peer influence, and key opinion leaders (n=21)	[2,9,38,51,61,67,99,105,113,125,128,132,142,146,161,163,170,175,181,196]
Infringing into personal life (n=6)	[47,65,77,161,188,190]
Monetary factors	
Funding, reimbursement, and fees (n=51)	[2-5,8,9,35,36,39,51,54,56,60,61,64,67,68,70,71,74,77,84,86,91,92,100-102,119,122,123,128-131,141,143,151,152,156,159,160,162,164,167,168,182,184,186,191,195]
Tool's cost (n=35)	[1,2,5,9,34,38,39,41,51,53,55,60,61,63,64,67,73,78,84,91,95,110,114,123,130-132,142,144,147,156,159,177,182,191]
Evidence base	
Strength and quality of clinical evidence (n=22)	[5,43,55,60,67,69,70,73,84,85,89,108,109,115,155,159,160,162,169,175,186,188]
Awareness	
Lack of awareness and promotion (n=20)	[2,9,38,43,55,56,61,73,89,120,131,138,149-151,156,168,175,180,182]
User engagement	
Involvement in development and planning (n=12)	[10,38,52,61,68,72,86,135,169,172,182,183]

[a]mHealth: mobile health.

Discussion

The main findings of this review emphasize the principal factors impacting clinicians' adoption of mHealth tools. Factors' prevalence sheds light on the clear importance of social and organizational factors that go beyond the technical features, highlighting the importance of taking them into account during the development and deployment of these tools.

Technological Factors

Technical difficulties were the most cited technical barriers identified in the included articles. Studies reported technical difficulties and limitations in general, besides other issues, such as failing to update the system or testing and installation issues [2,10,51], system errors [74,163], poor output quality (eg, poor images or video quality) [37,82,91,189], login issues [42,86,150,172], and missing functionalities [181]. It was reported that such issues sometimes impacted the recruitment of eligible participants [163], created a feeling of frustration among users [44,75,162], or made the staff more reluctant to promote the tool, as it might not work properly [43], and resulted in interruption of care [75,90,109,188].

Technical support availability and cooperation from the information technology (IT) department can also impact clinicians' intention to use mHealth tools. Support is, moreover, expected to be available whenever a clinical shift is active such as during the night, weekends, and holidays [44]. The lack of technical support can create difficulties for the adoption, as clinical staff do not want to be expected to do the technical installation and troubleshooting themselves [10]. Some concerns were raised regarding outsourced offshore technical support models that were deemed impersonal and *script-driven* and not very useful [51]. Furthermore, IT departments in hospitals may not be fully prepared for supporting staff's mobile phones when these are used to access mHealth tools [63]. Although some studies reported staff's satisfaction with the technical support offered to them, there were still some concerns about delayed delivery of the service because of lack of technical support staff [71,72,79,90].

System reliability can also cause challenges that affect clinicians' intentions to use mHealth. System failures and malfunctions raised concern for staff [35,140,177], and clinicians who are skeptical about the reliability of the service might refrain from using it altogether [55,108]. Users want to be sure that it will work in every emergency even when patients are using them on their own [69,79]. Similarly, poor signal connectivity linked to speed and quality of the connection can cause major usability issues making the use of such tools almost

impossible [37,44,50,95,181], hence diminishing the usefulness of the tool [74] and resulting in frustration and reluctance to use the service [124,153]. An offline functionality whenever possible could help overcome such issue [38], although some clinicians did not perceive slow connections as a significant barrier [68,130]. In some cases, clinical staff developed some work-around routines to overcome connectivity issues by printing the needed patient information, resulting in additional data security and privacy issues [172].

Many of the included studies indicated that usefulness and perceived usefulness have a direct impact on the adoption and intention to use. Clinicians are more likely to use a tool when they understand its benefits [34,78,86], when they find it useful for their daily work [85,89,127,134,146,150,179], and in emergencies [47,188]; they would refrain from using it if they are skeptical about the value it brings to their clinical practice [35,60,69,84,108,115,141,153,156,158], sometimes because of their lack of awareness of studies demonstrating effectiveness [90]. Some studies noted that the positive perception of usefulness usually increases for clinicians that use such tools more frequently [143].

Studies also linked perceived usefulness in many cases to ease of use and effort expectancy. mHealth tools should be very user-friendly and intuitive so that every clinician can use them easily, including those not comfortable with technology [4,70,73,166,189]; otherwise, they might be considered a waste of time [72,156]. Although complex and unintuitive user interfaces are considered a clear barrier [141,155], it was also noted that usability alone is not enough for user acceptance [181]. This was sometimes explained by the specific context that clinicians operate in [168], so ease of use could be perceived as less important in underprivileged contexts where clinicians lack resources and are grateful for any tool that would help facilitate their professional duties [105].

The tools' technical compatibility also plays a role in its acceptance. Clinicians have a positive attitude toward tools that integrate well with the other systems that they are using on a daily basis [127,196]. Interoperability issues can raise clear concerns when mHealth tools cannot be integrated into the hospital or clinic's current systems [87,128]. Similarly, the lack of electronic medical records (EMRs) or EHR integration can cause similar issues [9,183]. This can create limitations in data integration and exchange [34,36,156,174] and therefore create duplication of effort and increase workload [70,72,80]. Some clinicians also raised the reliability of self-reported data and the importance of validating it in comparison to the data in the patient's EMR to make informed decisions [175]. Conversely, a tool that integrates well with current systems would be highly appreciated as it would ensure that patient data is always up to date and would alleviate clinicians' workload [38,129].

Layout, interface, and culturally appropriate and patient-centered design came up as important influencing factors in several studies. The choice of design and color should be well informed; for example, bright colors should be avoided as they may cause seizures in people suffering from epilepsy [38]. Cluttered and unorganized displays impact adoption negatively [83,155,171]. Users should also be able to adapt design elements, such as font size, according to their own preference [38]. Customization and personalization should also go beyond design elements to include the type of information displayed according to the context and the needs of the individual users [124,181]. Furthermore, clinicians are keen to see tools that can be customized to each patients' clinical condition [70,84]. Concerns were raised regarding the gap that sometimes exists between the tools' designers and users, hence the desire for the tools to be adaptable to the user needs, not the other way around [72].

The convenience and mobility of tools accessed via mobile phones were mostly seen as facilitators. They also have a positive impact on perceived usefulness and ease of use [116] and can increase clinicians' ability to offer care in a timely manner [5,78]. The portability of mHealth tools enabling clinicians to access information and achieve tasks anytime and anywhere was highly valued [73,131,136,161,162]. Conversely, it was also reported that some users perceived the small size of the mobile screen as an inconvenience that could hinder adoption [165].

Social and Organizational Factors: Workflow Related

Workflow-related factors were the most prominent in the studied articles, with 17 subthemes. Training came up in 80 articles, showing the central role it plays in making or breaking the success of mHealth tools. Several studies identified the impact that appropriate training programs could play in increasing clinicians' intention to use such tools [9,97,139,149,179].

Factors such as nonexistent, inadequate or insufficient training [4,10,42,72,80,151], lack of time to learn how to use the new tools [81,89,128,183], resources required to ensure the sustainability of training programs [73,156], and training programs that focus solely on the technical side without addressing the workflow changes associated with mHealth use [44,83,94,104,189,194] were among the most important training-related barriers. The significance of training is because of clinicians' need to develop new skills to be able to benefit from mHealth tools and embed them properly in their work practice [65,70,77,92,122,154]. Proper training also helps achieve the highest potential of such tools, given that research shows that clinicians sometimes do not benefit from all available features simply because they were not aware of them [150].

Factors related to workload and resource allocation were also central. Staff and resources availability and allocation were the main hurdle identified [9,34,51,55,70,85,102,104,152,181,183,192]. Adequate staffing is considered a prerequisite for successful adoption [2,61,77,78,92,185,189]. Some studies acknowledged that mHealth caused an increase in workload [4,41,195] mostly because of double data entry caused by lack of integration and interoperability [35,72,172], adjustment to new responsibilities and ways of working [48,79,80], and poor workflow adaptability [182]. Moreover, clinicians may refrain from adopting the tools altogether if they believe that they would increase their workload [5,37,174]. This perception is sometimes triggered by their experience with other health IT systems, which added to their workload [46]. At the same time, some studies reported no change in the overall workload because of mHealth adoption [10], whereas others suggested that such technologies can alleviate workload where clinicians' recruitment and

retention are challenging by improving efficiency [73] and providing additional support and resources [45,122,159,185,186].

Fit with the clinical practice and compatibility with workflow are also significant requirements for a successful adoption [9,59,84,114,120,136,163,166,181,184]; accordingly, proper planning and integration [8,10,61,73,182] and a good understanding of treatment processes [78,129,172] are essential to avoid any disruption for clinical practice. Clinicians' perceptions that these technologies might negatively impact their work processes can hinder adoption [46,53,80,141]. Such assessments are sometimes because of poor adaptability of the current routines to mHealth [88,182]. Nonetheless, mHealth adoption can also sometimes result in workflow modification, where an adaptation of working patterns is necessary to harness the potential of such tools [67,94,178]. These changes are mostly aimed at complementing routine care rather than replacing it [70,180], and reorganizing work to warrant routine practice.39,40,122,150

mHealth could enhance competitiveness through time and cost efficiencies, optimized work patterns [1,54,59,74,86,109,152,161,188,190,195], quicker access to care [91,137,159,162], and rapid triage and identification of cases that need urgent care thanks to the timely feedback that technologies such as digital patient monitoring enable [5,47,52,57,87,115,157]. Consequently, it can allow clinicians to prioritize by enabling them to focus more on patients that need assistance versus more stable patients [64,174]. Large scale rollout of such technologies also necessitates standardization, resulting in higher efficiency [177]. Unfortunately, there are still cases where such tools do not result in better efficiency in practice [94], mostly because of usability issues and difficulties with technology [108,110] and lack of EMR integration resulting in double work and reenter of data, which eliminates the efficacy gains achieved with the tools [44] and adds complexities to management [39]. Sometimes, efficiencies such as less in-clinic visits or phone calls come at the expense of a higher overall workload when there is no appropriate reimbursement [119]. Still, several studies suggested that the perceived higher efficiency can increase clinicians' intention to use mHealth [61,78,107,132,140,150,181].

Improved collaboration and coordination among clinicians were among the identified facilitators [1,52,68,109,150,152,186]. Well-planned coordination of services can increase adoption, especially when several teams or sites are involved [2,8,88,162,176]. Better care coordination was also sometimes the result of the introduction of such technology [87,194], mainly when new multidisciplinary and integrated teams are formed [10,39,50,55,56,59,156,172,188], and peer support through second opinion and new models of shared decision making are created [40,57,93,102,137,153,159,189]. Conversely, some studies report that this can sometimes result in more pressure on clinicians, as the tools increase the possibilities to coordinate and communicate with other staff members, adding to their already high workload [46], and as interprofessional collaboration can be challenging [85], sometimes resulting in lack of trust or conflicting opinions [69,188]. The lack of coordination and collaboration was also seen as a barrier is some studies [71,84,141,182,185].

Poor technical skills and experience create uncertainties about how the technology may work, thus they can be major hurdles for adoption [37,55,59,67,81,127,143,153,179,184,191], whereas users' familiarity with the technology may create confidence that may foster adoption [49,133,134,145,170]. The more IT-related knowledge and skills clinicians have, the lower their expected effort related to mHealth use becomes, resulting in an increase in their intention to use it [9,96,129,149]. Also, those with previous digital health experience are usually more willing to embrace mHealth than their counterparts that had not used such tools before [61,73,83,102,112,121,168]. However, it was also noted that in some cases, the fact that some clinicians use technology in their private life is not necessarily positively correlated with higher chances of technology adoption at the workplace [122,146]. It is suggested that the staff's technical skills need to improve to enable the efficient use of such new technologies [72].

Smooth integration of mHealth may necessitate changes in staff's roles and responsibilities [56,62,65,67,72], sometimes in the form of alignment of duties [48,86,152], role reassignment and redistribution [2,94], expanding existing staff members' responsibilities [85], or even the creation of additional functions or staff numbers to cover some of the new tasks related to mHealth management [40,68,71,74,77,79,88,90,103]. It was noted that in some cases, the tools' introduction resulted in a lack of clarity on roles demarcation [39,70,89,104,182], whereas clearly defined roles [61] and the presence of a local *champion* that can guide others on the technology use can contribute to a successful adoption [83,164]. The new tasks resulting from the use of such technologies are usually related to data analysis and interpretation [60,74,176], monitoring patient data and alerting the relevant staff accordingly [167], and also some other nonclinical tasks that were deemed sometimes undermining, such as equipment installation and troubleshooting [80,82,189]. The tools, moreover, allowed the delegation of more tasks to nursing staff in several studies, giving them more autonomy and empowering them in their role [78,169,183].

Leadership and institutional support were seen as a vital factor [5,9,95,127,132,134,157,182,188,192,196] and considered one of the most important facilitators of technology adoption [61,103,106,145,166,195]. Management support is crucial to facilitate the potential organizational changes that the new technologies entail, such as changes in roles and responsibilities [40], or changes in workflow [42,72,164], resource allocation [73,131,170], and proper training [111]. However, getting senior management support can be challenging at times [34,138,174], resulting in lack of recognition of clinicians' activities taken with mHealth tools [59]; this may be explained by a lack of proper understanding of mHealth from the management side [178] or a false perception that such tools would detract staff from their real work [156]. Lack of organizational support can be a barrier that slows down adoption [71,86].

Organizational infrastructure is a basic prerequisite for mHealth success [87,91,116,126,179]. Factors such as access to the internet, equipment, and suitable space and power play a key

role in whether or not clinicians would adopt such new technologies [4,47,51,69,77,93,124,127,153,154,163,169,181,187]. Poor infrastructure may hinder adoption [35,70,82,83,151,172,193], as clinicians who have no access to suitable equipment may refrain from using mHealth [2].

Process standardization and planning may facilitate the tools' uptake [45,73,86,88,149]. This can be achieved via streamlined procedures [39,80,160], process protocols and clear guidelines describing the practical details of integrating mHealth into clinical practice [40,168,185], and the presence of internal responsibility for facilitating this standardization [61,103,164]. Lack of planning or standardization of implementation strategies can hinder adoption as it can cause workflow challenges [5,44,46,67,82-84,155,167,189].

Staff nontechnical competence and qualifications also play a role in adoption [2,73,84,91,156,164,185]. Factors such as knowledge of medical terminology, a good command of the language in which the tool is offered, and the capacity to review large amounts of data and using the complex charts produced by some of these tools are paramount for successful adoption [4,36,109,176]. Given the shared decision-making models and higher collaboration enabled by mHealth, a potential hurdle may be the lack of confidence in the collaborators' clinical competence [39,51]. Another subsequent difficulty is the fear of exposing knowledge gaps [105,108,137] or being marginalized and undermined [80]. Conversely, the fact that such tools enable less experienced clinicians to access clinical resources can also be a facilitator [69].

The ability to efficiently manage and interpret the large amounts of data generated by mHealth, such as interpreting complex charts, may also impact adoption [176]. Data management–related challenges can hinder the use of the tools [51,177]. Factors such as information overload [60,62,72] and the integration of the generated data in the existing workflow can be challenging [53,167,182]. Other data-related risks, such as adverse events reporting and further handling, may also hinder adoption [38]. Although such new technologies increase the potential to combine data to enhance patient monitoring and improve clinical decision making, some of the available tools do not give clinicians the flexibility to customize data reporting according to their specific needs [36,120,183]. Facilitators include availability and access to required data [66,77,100,150], higher efficiency of data analysis [74,108], better patient care management because of the timely availability of data [75,78,115,157], and the better ability to measure outcome [73].

mHealth requires a change of paradigm that mostly results in changes to clinical practice [48,59,65,92,186,189,192]. This is not necessarily a barrier to adoption; on the contrary, some studies show that clinicians are aware of the change that the technology entails and have already prepared themselves for it [139]. This paradigm shift is linked to factors such as patients' self-monitoring and self-reporting, which necessitate new ways of treatment and care [10,72,162,185]. However, this redistribution of roles can sometimes be challenging [37,94,182]. For example, when a tool enables patients to access some of their test results before their care team, they can perceive this as an interference with established clinical practice [46].

Clinicians' perceptions of mHealth's impact on their autonomy and job security may also influence adoption [9,10,72,176,182,185,188]. Perceptions that the new tools compromise clinicians' autonomy, for example, by making their patients' treatment plans and outcomes more reachable to others and accordingly subject to more external control or criticism, may hinder adoption [62,116,130,140,141,186,188]. This can be a considerable barrier to adoption when care teams perceive the new technology as a threat to their own career and livelihood [55,72,141,151]. Equally, a tool has better chances of being adopted when perceived as a complement, not a substitute to clinicians' role [62]. Some studies report that clinicians feel that they need to renegotiate their professional identities in the face of the *empowered and informed patient* that is sometimes seen as undermining the authority and credibility of the care teams [10,62,72,80,182]. Conversely, it was also reported that mHealth can empower clinicians and help them be more autonomous, positively impacting adoption [124].

Clinicians' empowerment is tightly linked to the possibility of positively impacting their professional development and expertise because of the use of these new technologies, especially among nursing staff [62,72,124,162,169,188,189]. The educational benefits of mHealth for physicians can similarly encourage adoption [137,161]. The tools are perceived as enablers that prompt for best practice care, provide novel decision aids, and expand clinical knowledge [73,74,86,131].

Facilitating the adoption may be encouraged through proper incentives for clinicians [4,88,106,122,164]. Incentives such as awarding continuing medical education, adding mHealth use as an objective in employee appraisals, offering financial rewards through improved reimbursement schemes, and more clarity around medico-legal topics may encourage use [54,59,87,129,141,157,175,191].

Decision making can be a hurdle for adoption in the absence of a dedicated team or person responsible for digital health programs in the highly fragmented health care organizations [4,102,160,191]. This can also be an obstacle when the official decision makers do not involve practitioners in defining the aims and objectives of the introduction of an mHealth tool [43,71,72].

Social and Organizational Factors: Patient Related

Improvements in the quality and efficiency of care may positively impact clinicians' adoption of mHealth [3,5,44,52,61,63,64,66,69,83,86,100,107-109,120,122,125,127,140,166,168,175,182,186,196]. Such tools can improve the quality of patient care through better information access, improved disease control, personalized treatment plans, and more proactive support [2,36,37,40,42,47,48,55-57,72,78,80,88,92,93,103,114,115,119,130,157,159,160,162,174,184,188,190], although sometimes the perception that these new tools do not enhance patient care may hinder adoption [3,10]. Clinicians raised some concerns about the quality of patient reports, the possibility of overtreatment, or false positives being reported through the tools [38,183].

The impact of mHealth use on patient-clinician communication can also influence clinicians' adoption decision [47,88,

128,163,185,195]. This factor can be considered a facilitator when the tool enhances communication [3,5,50,58,59,66,67,75,77,78,82,115,150,172,174,175,182,189], but it can also be considered a barrier when clinicians perceive the tool as an obstruction to their communications with their patients [10,43,46,55,89,180]. Clinicians' concerns about digital communications are mostly about the loss of human contact, breaching patient privacy, medico-legal issues, unprofessional image, and patient's overreliance [41,72,79,80,90,156,160,190]. It was also emphasized that such tools should complement rather than replace face-to-face treatment and therapy [81,86,91].

Improving patients' access to care by removing time and space constraints may encourage clinicians' adoption [1,3,5,8,43,64,73,82,129,130,156,162,174,182,184,190]. This is especially true when the tools allow underserved patients, those residing in rural or remote areas, or suffering from a chronic condition, to access health care services [4,34,39,47,54,55,67,75,81,93,102,123,159,178,194]. mHealth may enable better access by eliminating or reducing travel burden [2,4,60,62,78,91,169,187,195].

From the clinicians' perspective, patient consent, comfort, and preference play an important role in adoption [2,9,39,49,90,104,122,123,132,153,185,192]. Several elements could impact patients' preferences, such as age, the complexity of the condition, access to technology, tech-savviness, or privacy concerns [1,43,52,53,60,174,176,180,184,191,195]. In some cases, patients may feel more comfortable to use mHealth than face-to-face care when they are treated for sensitive conditions such as HIV or sexual health [3,163].

It was reported that clinicians believe that mHealth may not be applicable or appropriate to all sorts of patients [9,61,68,88,90,91,103,189]. Consequently, it is important to have balanced selection criteria [71,79,89,162,182]. Some perceive the tools to be more appropriate for chronic and unstable patients that need more attention to support their stabilization [41,66], although others deemed the technology inappropriate for those with physical or psychological impairments, severely ill patients, and the ones unable to properly use technology [62,73,75,81,86,104,185]. However, it is important to note that restrictive inclusion criteria might prevent some patients who need the service from accessing it [71].

Clinicians are more likely to adopt mHealth when it empowers and engages patients, giving them more autonomy and assurance about their disease or condition management [5,34,44,48,62,73,77,78,88,89,115,157,166,175,180]. However, more evidence is needed to confirm such a positive impact on patient empowerment [128]. It is also worth noting that in some contexts, patients may initially be anxious from such increased empowerment, as they are afraid of taking responsibility. However, research suggests that their confidence may develop with long-term support [41]. Patient engagement might also be a barrier if they perceive mHealth as a burden, or when they do not feel that they need it [70,71]

Safety concerns can impact intention to use [72,103]. Perceived risks to patient safety can be a barrier to adoption, mainly when clinicians are concerned about factors such as device contamination, system reliability, clinical content accuracy, and self-diagnosing [10,63,81,179,190]. Conversely, adoption may be encouraged when mHealth increases patient safety through timeliness, early detection, or clear documentation [44,66,78,86,109,140,176,188,195].

The digital divide, defined in the Oxford dictionary [198] as "the gulf between those who have ready access to computers and the Internet, and those who do not," also plays a role in the adoption. Clinicians are concerned about patients that might be marginalized because they lack access to technology, the elderly that do not use smartphones, those who have literacy issues, or a lower living standard [49,53,55,60,73,75,79,81,84,120,123,138,185, 191]. A study reported that nurses do not see patients' age as a barrier [62].

Better patient education and awareness because of the use of mHealth tools may encourage adoption [52,53,60,75,86,88,162,164,168,183,190,199]. However, clinicians were concerned that the convenience of the new tools might result in patients' overreliance on their practitioner support [3,41,78,182]. Service abuse might occur when they overutilize the tool or try to access their care team after hours [156,169], or if they become too dependent on technology and fail to seek medical help in case of emergency [62,77].

Clinicians also pinpointed that data and surveillance-related anxiety might hinder adoption [140,190]. Patients might worry excessively because of the large amounts of data available through mHealth [46,128] or might feel watched because of the constant monitoring enabled by such tools [62,78]. Furthermore, the sustainability of mHealth services depends on several factors, such as the willingness of patients to keep using it [5], which might depend on the long-term availability of funding [167] and clinicians' long-term commitment [169]. It is also notable that clinicians might play a gatekeeping role for mHealth directly impacting adoption [97]; this may be driven by their willingness to protect their patients from any added burden [180].

Other Social and Organizational Factors

Concerns related to data privacy and security can be a barrier to adoption [9,39,67,84,95,108,117,132,143,158,174,177,185,191,192]. Worries about confidentiality, fear of inappropriate data use, anonymity, and medico-legal risks were the main drivers of this [2,3,10,37,47,49,52,53,59,98,100,102,110,123,128,130,152,160,163,167,178,182-184,189,193]. mHealth was perceived to be more prone to data security issues compared with other forms of digital health tools because of its portability and accessibility from personal devices [73,77,127]. Therefore, it is deemed important to have a safe tool that protects the data provided in it [38,61], work out liability issues in advance [60,131], provide data privacy training to clinicians [138], and have clearer legal guidance [161,162]. Interestingly, some studies reported that privacy concerns are not a key barrier to adoption, given that some clinicians that have high privacy concerns might still have high usage intentions [125,142,149].

Policy and regulations mostly related to malpractice protection, licensing, and credentialing, in addition to costs and reimbursement issues, can certainly impact clinicians' adoption of mHealth tools [9,10,37,61,73,95,121,123,130,141,151]. Unsuitable or inconsistent regulations and ambiguous policies

[5,35,63,155,159,179], restrictive directives [64,102], lack of policies and protocols [34,47,51,67,104,161,162], and lack of governmental coordination [4] may hinder adoption. Clear and appropriate regulations and guidelines [92,122,124, 146,168,178,190,193] and more proactive involvement of governments and medical professional associations [143,145,157] are essential for efficient adoption and sustainable services.

Clinicians' perceptions and attitudes toward technology may impact their decision to adopt the tools [5,35,69,107, 118,127,134,136,138,173]. Those who are lacking familiarity with mobile technologies, are resistant to change, or are risk averse may not use them [34,60,67, 85,108,117,174,186,195]; also, there is the perception that using a mobile phone at work may seem unprofessional [63,124,190]. Those with positive attitudes toward technology are more likely to adopt new tools [97,113]. In addition, their perception and attitudes toward mHealth specifically also affect their intention to use it [10,95,109,111,130,132,133,147,178,185,188]. Clinicians with negative attitudes toward mHealth are more reluctant to use it [143,155]. This is sometimes because of their perception that it will add to their workload [37,83], their uncertainty to what the introduction of such new tools would mean for their workflow [55,104,153,166], or their perception that it invades their privacy [47,65,77,161,188,190]. It is also important to note that personal attributes such as adaptability and the readiness to try new things may similarly impact the adoption decision [59,100,157].

The organizational culture and context can also impact the clinician's intention to use the tools [95,151,168], although some studies reported that it is not a meaningful barrier [130]. Prohibitive or unclear expectations around mobile phone use in the workplace may discourage adoption [42,63,76, 124,161,165,170,179]. Furthermore, an organizational culture that is resistant to change or risk averse may hinder the implementation of such new technologies [45,86,148,176]. A cultural shift might be needed to enable and foster the acceptance of mHealth use at the workplace and transition from paper-based systems to more use of digital tools [37,145,193].

Peer influence and endorsement are other factors that might impact clinicians' trust in mHealth and, accordingly, their adoption decision [2,9,125,142,170,175,182,196]. Equally, those who are *change-resistant* may also impact early adopters negatively [181]. Recommendations by reliable bodies such as scientific societies, renowned health care organizations such as the National Health Service, opinion leaders, internal champions, direct managers, or senior colleagues that promote the tools may foster adoption [38,51,61,67,99,105,128,146,161,163].

Financial aspects are typically barriers to adoption [70,101,152,168]. Lack of proper funding [36,71,86, 143,151,156,160,164,167] and compensation or reimbursement problems [2,3,5,9,35,51,54,56,60,61,84,100,119,123,128-130, 184,186] usually hinder clinicians' intention to use mHealth. In addition, low awareness of existing reimbursement schemes [102] and overcomplicated or inconsistent payment systems [39,64,67,141,159,162] may also be a barrier. Conversely, a suitable payment model and health insurance coverage may encourage adoption [8,67,68,77,92,122,131,182,195]. It is noteworthy that 1 study found that the financial disadvantages because of funding and reimbursement issues were compensated by the lower travel costs and higher efficiency generated by mHealth use [91].

Reducing organizational costs may positively impact clinicians' adoption as it helps them achieve budget efficiency [1,2,5,91,132,147,159,182]. However, uncertainties around cost-effectiveness [34,41,73,78,114] and the actual tool's or service's charge and affordability [9,38,39,51,53,55, 60,61,63,64,67,84,110,123,142,147,156,191] may hinder adoption.

Clinicians' perception that the timeliness and amount of the data generated by mHealth can enhance the evidence for benefit is a facilitator [85,89,108,109,115,159,169]. However, the perceived lack of a solid evidence base and proof of concept for clinical benefit resulting from mHealth use is considered a barrier to adoption [5,43,60,69,73,84,160,162,175,188]. There is a need for more research about the outcomes of such technologies use in clinical practice to help foster adoption [55,155,186].

The lack of awareness of mHealth tools may hinder adoption [73,120,151,175]. Active promotion of the tools' existence and objectives [9,55,56,150,156], and their benefits and impact on patient outcome may encourage their use [2,38,43,61,89,131,149,168,180,182].

Engaging users in the development, planning, and implementation phases may positively impact their adoption decision [68,86,135,169,172,183]. Enabling user feedback [38,52], collaborative involvement, and codesign [10,61] have shown to encourage adoption. Unfortunately, in some cases, clinicians are hardly asked for their input or involvement even though mHealth is one of their work tools [72,182].

Moderating Factors

Some of the included studies reported that moderating factors, such as age, gender, specialty, and years of professional experience, may have an impact on clinicians' adoption intentions [38,106]. However, other studies concluded that such moderating factors do not necessarily influence mHealth usage [117,127,196].

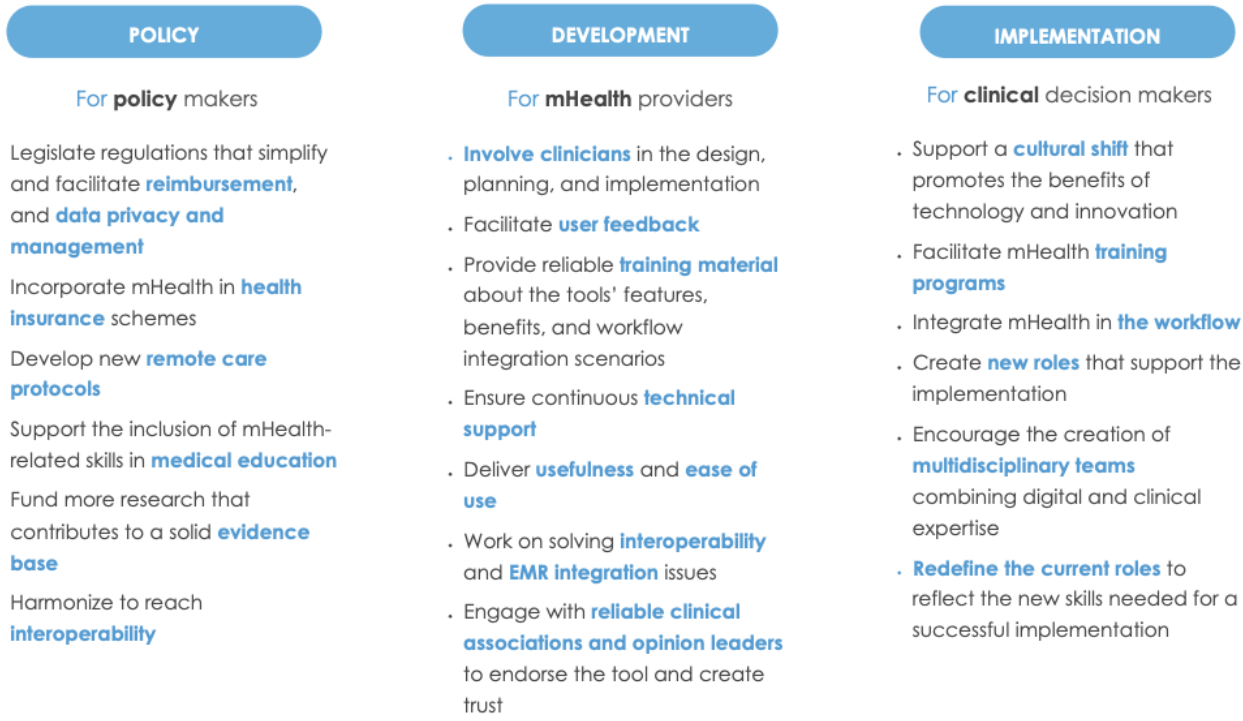
Younger clinicians typically have a more positive attitude toward such new technologies compared with their older counterparts [59,73,76,81,100,118,122,125,135,138], although some studies established that the age-gap does not play a role in adoption [142,143]. Also, clinicians with previous digital health experience seem to have more favorable attitudes toward mHealth adoption compared with their counterparts that have no previous experience [120,122,142].

Gender does not seem to be consistently reported as a moderating factor; 2 studies reported that female clinicians are more likely to accept the tools than their male counterparts [134,143], whereas 1 study reported the reverse [133]. The years of professional experience seem to negatively impact adoption [111,118].

Conclusions and Implications

The systematic review findings indicate important guidelines and areas that must be targeted regarding social and organizational practices to promote and foster clinicians' adoption of mHealth tools successfully. As shown in Figure 5, these implications can be split into 3 categories to address the actions needed from 3 key stakeholders: policymakers, mHealth providers, and clinical decision makers.

Figure 5. Implications for social and organizational practices. EMR: electronic medical record.



Policymakers can play a crucial role in unleashing the potential of mHealth in clinical practice. This can be achieved through regulations that simplify and facilitate reimbursement and address data privacy and management issues. Incorporating mHealth in health insurance schemes can help solve the cost and payment barriers and encourage not only clinicians' adoption but also patients' use. Developing new remote care protocols may help practitioners standardize these new services and better integrate them into their clinical practice. It is also important to support the inclusion of mHealth-related skills in official medical education to ensure that new graduates will be equipped with all the necessary capabilities to successfully run such new technologies. Funding more research that contributes to a solid evidence base about the clinical and efficiency benefits and the added value of the new tools can foster their acceptance. Coordinating the different stakeholders to streamline and harmonize technology in a way that helps reach interoperability would also ensure the successful implementation of such tools and solve the issue of additional workload that sometimes results from a double entry in the different systems.

Such policy implications echo the findings of other researchers. For example, Davis et al [183] addressed the barriers related to unclear legal liability and system interoperability. Gagnon et al [9] also discussed the importance of cost-related barriers and the need to address them.

Providers and developers of mHealth tools should always proactively involve clinicians in the design, planning, and implementation of their services to ensure that it fits well into clinical practice. Facilitating user feedback is key to warrant the relevance and sustainability of the tool. Providing reliable training material about the tools' features, benefits, and workflow integration scenarios may help clinicians better integrate the new tools into their daily practice. Delivering tools that are useful and ease of use, and ensuring continuous technical support, is crucial for smooth day-to-day usage and to overcome any technical issues that might push users to abandon the tool. Working on solving interoperability and EMR integration issues would help them emphasize the efficiency gains resulting from their services that are sometimes compromised because of the burden of double data entry when systems are not integrated properly. Furthermore, engaging with reliable clinical associations and opinion leaders to endorse the tool can help create trust and accelerate the adoption.

Recommendations for providers and developers of mHealth tools are aligned with Brewster et al [10], Davis et al [183], and Radhakrishnan et al [182] conclusions on the importance of the inclusion of clinicians in the development process to improve acceptance. Davis et al [183] also shed light on the importance of system interoperability and EHR integration to facilitate adoption.

Clinical decision makers in hospitals and clinics need to support a cultural shift that promotes the benefits of technology and innovation to encourage their staff to change their traditional ways of working and embrace the new modalities. Facilitating mHealth training programs may help clinical staff acquire the new skills needed to successfully adopt the new tools. In addition, integrating mHealth in the clinical workflow is key to avoid that the tools become more of a hurdle to the staff.

Encouraging the creation of multidisciplinary teams combining digital and clinical expertise and redefining the current roles to reflect the new skills needed to run the new technologies may contribute to a successful implementation. In some cases, the creation of new roles that support the implementation might be necessary.

In terms of implications for clinical decision makers, our findings are congruent with those of Duennebeil et al [149], who emphasized the importance of establishing standards and treatment processes and training programs that would enable the adoption of such new tools. Training, promotion, and redefinition of roles were also highlighted by Brewster et al [10] and Radhakrishnan et al [182].

Limitations and Recommendations for Future Research

Although this study contributes to the understanding of the factors impacting clinicians' adoption of mHealth, some limitations must be acknowledged. This review may not have included relevant studies that were not indexed in the searched databases, written in a language other than English, and grey literature searches that could have also allowed the identification of additional relevant insights. However, this study meant to concentrate on peer-reviewed scientific papers.

Moreover, this analysis only considered published studies, and no further contacts were made with the papers' authors to obtain extra information or to validate our thematic analysis. Consequently, it is possible that other mHealth adoption factors might have been missed. Future reviews could include studies in other languages to have a better grasp of any interregional or intercultural differences, and to have more studies in developed countries.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshot of Rayyan QCRI (Qatar Computing Research Institute).
[PNG File , 360 KB - mhealth_v8i2e15935_app1.png]

Multimedia Appendix 2
Critical Appraisal Skills Program checklist.
[PDF File (Adobe PDF File), 440 KB - mhealth_v8i2e15935_app2.pdf]

Multimedia Appendix 3
Critical appraisal of the included studies.
[XLSX File (Microsoft Excel File), 141 KB - mhealth_v8i2e15935_app3.xlsx]

Multimedia Appendix 4
Phases of thematic analysis after Braun and Clarke.
[PDF File (Adobe PDF File), 48 KB - mhealth_v8i2e15935_app4.pdf]

References

1. Armstrong AW, Kwong MW, Chase EP, Ledo L, Nesbitt TS, Shewry SL. Teledermatology operational considerations, challenges, and benefits: the referring providers' perspective. Telemed J E Health 2012 Oct;18(8):580-584. [doi: 10.1089/tmj.2011.0241] [Medline: 22881579]
2. Avey JP, Hobbs RL. Dial in: fostering the use of telebehavioral health services in frontier Alaska. Psychol Serv 2013 Aug;10(3):289-297. [doi: 10.1037/a0028231] [Medline: 22924798]
3. Anderson K, Francis T, Ibanez-Carrasco F, Globerman J. Physician's perceptions of telemedicine in HIV care provision: a cross-sectional web-based survey. JMIR Public Health Surveill 2017 May 30;3(2):e31 [FREE Full text] [doi: 10.2196/publichealth.6896] [Medline: 28559226]
4. Bhatta R, Aryal K, Ellingsen G. Opportunities and challenges of a rural-telemedicine program in Nepal. J Nepal Health Res Counc 2015;13(30):149-153. [Medline: 26744201]
5. Mileski M, Kruse CS, Catalani J, Haderer T. Adopting telemedicine for the self-management of hypertension: systematic review. JMIR Med Inform 2017 Oct 24;5(4):e41 [FREE Full text] [doi: 10.2196/medinform.6603] [Medline: 29066424]
6. Pavel M, Jimison HB, Wactlar HD, Hayes TL, Barkis W, Skapik J, et al. The role of technology and engineering models in transforming healthcare. IEEE Rev Biomed Eng 2013;6:156-177. [doi: 10.1109/RBME.2012.2222636] [Medline: 23549108]

7. Payne KF, Wharrad H, Watts K. Smartphone and medical related App use among medical students and junior doctors in the United Kingdom (UK): a regional survey. BMC Med Inform Decis Mak 2012 Oct 30;12:121 [FREE Full text] [doi: 10.1186/1472-6947-12-121] [Medline: 23110712]
8. Choi WS, Park J, Choi JY, Yang J. Stakeholders' resistance to telemedicine with focus on physicians: utilizing the Delphi technique. J Telemed Telecare 2019 Jul;25(6):378-385. [doi: 10.1177/1357633X18775853] [Medline: 29792080]
9. Gagnon MP, Ngangue P, Payne-Gagnon J, Desmartis M. m-Health adoption by healthcare professionals: a systematic review. J Am Med Inform Assoc 2016 Jan;23(1):212-220. [doi: 10.1093/jamia/ocv052] [Medline: 26078410]
10. Brewster L, Mountain G, Wessels B, Kelly C, Hawley M. Factors affecting front line staff acceptance of telehealth technologies: a mixed-method systematic review. J Adv Nurs 2014 Jan;70(1):21-33. [doi: 10.1111/jan.12196] [Medline: 23786584]
11. Hussein R, Khalifa A. Telemedicine in Egypt: SWOT analysis and future trends. GMS Medizinische Inform Biometrie und Epidemiol 2012;8(1):1-16 [FREE Full text] [doi: 10.3205/mibe000125]
12. Moffatt JJ, Eley DS. Barriers to the up-take of telemedicine in Australia--a view from providers. Rural Remote Health 2011;11(2):1581 [FREE Full text] [Medline: 21385004]
13. Walter Z, Lopez MS. Physician acceptance of information technologies: role of perceived threat to professional autonomy. Decis Support Syst 2008 Dec;46(1):206-215. [doi: 10.1016/j.dss.2008.06.004]
14. Xue Y, Liang H, Mbarika V, Hauser R, Schwager P, Getahun MK. Investigating the resistance to telemedicine in Ethiopia. Int J Med Inform 2015 Aug;84(8):537-547. [doi: 10.1016/j.ijmedinf.2015.04.005] [Medline: 25991059]
15. Gagnon MP, Desmartis M, Labrecque M, Car J, Pagliari C, Pluye P, et al. Systematic review of factors influencing the adoption of information and communication technologies by healthcare professionals. J Med Syst 2012 Feb;36(1):241-277 [FREE Full text] [doi: 10.1007/s10916-010-9473-4] [Medline: 20703721]
16. World Health Organization. mHealth: New Horizons for Health through Mobile Technologies. Switzerland: World Health Organization; 2011.
17. Rogers EM. Diffusion of Innovations. Fifth Edition. New York, NY: Free Press; 2003.
18. Straub ET. Understanding technology adoption: theory and future directions for informal learning. Rev Educ Res 2009;79(2):625-649. [doi: 10.3102/0034654308325896]
19. Goffman E. The Presentation of Self in Everyday Life. New York: Doubleday; 1956.
20. Pinch T. The invisible technologies of Goffman's sociology from the merry-go-round to the internet. Technol Cult 2010;51(2):409-424. [doi: 10.1353/tech.0.0456]
21. Garfinkel H. Studies in Ethnomethodology. Englewoods Cliffs, NJ: Prentice-hall, Inc; 1967.
22. Leonardi PM. Methodological guidelines for the study of materiality and affordances. In: Raza M, Jain S, editors. Routledge Companion to Qualitative Research in Organization Studies. New York: Routledge; 2017:279-290.
23. Bélanger F, Watson-Manheim MB. Virtual teams and multiple media: Structuring media use to attain strategic goals. Group Decis Negot 2006;15(4):299-321. [doi: 10.1007/s10726-006-9044-8]
24. Chudoba K, Wynn E, Lu M, Watson-Manheim MB. How virtual are we? Measuring virtuality and understanding its impact in a global organization. Inf Syst J 2005 Oct;15(4):279-306. [doi: 10.1111/j.1365-2575.2005.00200.x]
25. Jacob C, Sanchez-Vazquez A, Ivory C. Clinicians' role in the adoption of an oncology decision support app in Europe and its implications for organizational practices: qualitative case study. JMIR Mhealth Uhealth 2019 May 3;7(5):e13555 [FREE Full text] [doi: 10.2196/13555] [Medline: 31066710]
26. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009 Jul 21;6(7):e1000097 [FREE Full text] [doi: 10.1371/journal.pmed.1000097] [Medline: 19621072]
27. Higgins JP, Green S. Cochrane Handbook for Systematic Reviews of Interventions. New Jeresey: Wiley; 2011.
28. Jacob C, Ivory C, Sánchez-Vázquez A. CRD Database. 2018. Social and Material Factors Impacting Clinicians' Adoption of mHealth Solutions: A Systematic Review of the Literature URL: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018110175 [accessed 2019-07-30]
29. Schardt C, Adams MB, Owens T, Keitz S, Fontelo P. Utilization of the PICO framework to improve searching PubMed for clinical questions. BMC Med Inform Decis Mak 2007 Jun 15;7:16 [FREE Full text] [doi: 10.1186/1472-6947-7-16] [Medline: 17573961]
30. Merriam-Webster. Merriam Webster's Collegiate Dictionary. Massachusetts: Merriam-webster; 1997.
31. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. Syst Rev 2016 Dec 5;5(1):210 [FREE Full text] [doi: 10.1186/s13643-016-0384-4] [Medline: 27919275]
32. Critical Appraisal Skills Program. 2018. CASP Qualitative Checklist URL: https://casp-uk.net/casp-tools-checklists/
33. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
34. Catan G, Espanha R, Mendes RV, Toren O, Chinitz D. Health information technology implementation - impacts and policy considerations: a comparison between Israel and Portugal. Isr J Health Policy Res 2015;4:41 [FREE Full text] [doi: 10.1186/s13584-015-0040-9] [Medline: 26269740]

35. Chiang KF, Wang HH, Chien IK, Liou JK, Hung CL, Huang CM, et al. Healthcare providers' perceptions of barriers in implementing of home telecare in Taiwan: a qualitative study. Int J Med Inform 2015 Apr;84(4):277-287. [doi: 10.1016/j.ijmedinf.2015.01.007] [Medline: 25649842]
36. Chung C, Cook J, Bales E, Zia J, Munson SA. More than telemonitoring: health provider use and nonuse of life-log data in irritable bowel syndrome and weight management. J Med Internet Res 2015 Aug 21;17(8):e203 [FREE Full text] [doi: 10.2196/jmir.4364] [Medline: 26297627]
37. de Souza CH, Morbeck RA, Steinman M, Hors CP, Bracco MM, Kozasa EH, et al. Barriers and benefits in telemedicine arising between a high-technology hospital service provider and remote public healthcare units: a qualitative study in Brazil. Telemed J E Health 2017 Jun;23(6):527-532. [doi: 10.1089/tmj.2016.0158] [Medline: 27911667]
38. de Vries ST, Wong L, Sutcliffe A, Houÿez F, Ruiz CL, Mol PG, IMI Web-RADR Work Package 3b Consortium. Factors influencing the use of a mobile app for reporting adverse drug reactions and receiving safety information: a qualitative study. Drug Saf 2017 May;40(5):443-455 [FREE Full text] [doi: 10.1007/s40264-016-0494-x] [Medline: 28035492]
39. Egerton T, Nelligan R, Setchell J, Atkins L, Bennell KL. General practitioners' perspectives on a proposed new model of service delivery for primary care management of knee osteoarthritis: a qualitative study. BMC Fam Pract 2017 Sep 7;18(1):85 [FREE Full text] [doi: 10.1186/s12875-017-0656-7] [Medline: 28882108]
40. Esterle L, Mathieu-Fritz A. Teleconsultation in geriatrics: impact on professional practice. Int J Med Inform 2013 Aug;82(8):684-695. [doi: 10.1016/j.ijmedinf.2013.04.006] [Medline: 23746716]
41. Fairbrother P, Ure J, Hanley J, McCloughan L, Denvir M, Sheikh A, Telescot programme team. Telemonitoring for chronic heart failure: the views of patients and healthcare professionals - a qualitative study. J Clin Nurs 2014 Jan;23(1-2):132-144. [doi: 10.1111/jocn.12137] [Medline: 23451899]
42. Farrell M. Use of iPhones by nurses in an acute care setting to improve communication and decision-making processes: qualitative analysis of nurses' perspectives on iPhone use. JMIR Mhealth Uhealth 2016 May 31;4(2):e43 [FREE Full text] [doi: 10.2196/mhealth.5071] [Medline: 27246197]
43. Flynn D, Gregory P, Makki H, Gabbay M. Expectations and experiences of eHealth in primary care: a qualitative practice-based investigation. Int J Med Inform 2009 Sep;78(9):588-604. [doi: 10.1016/j.ijmedinf.2009.03.008] [Medline: 19482542]
44. Giraldo L, Schachner B, Luna D, Benítez S. Exploring nurses' perceptions and expectations toward a BCMA implementation using a mobile app and workstations as a change management strategy. Stud Health Technol Inform 2018;250:134-138. [Medline: 29857405]
45. Goedken CC, Moeckli J, Cram PM, Reisinger HS. Introduction of Tele-ICU in rural hospitals: changing organisational culture to harness benefits. Intensive Crit Care Nurs 2017 Jun;40:51-56. [doi: 10.1016/j.iccn.2016.10.001] [Medline: 28216177]
46. Grünloh C, Cajander A, Myreteg G. 'The Record is Our Work Tool!'- physicians' framing of a patient portal in Sweden. J Med Internet Res 2016 Jun 27;18(6):e167 [FREE Full text] [doi: 10.2196/jmir.5705] [Medline: 27349531]
47. Han KJ, Subramanian R, Cameron GT. Listen before you leap: Sri Lankan health professionals' perspectives on m-health. Health Informatics J 2019 Sep;25(3):858-866. [doi: 10.1177/1460458217725903] [Medline: 28825329]
48. Hanley J, Ure J, Pagliari C, Sheikh A, McKinstry B. Experiences of patients and professionals participating in the HITS home blood pressure telemonitoring trial: a qualitative study. BMJ Open 2013 May 28;3(5):pii: e002671 [FREE Full text] [doi: 10.1136/bmjopen-2013-002671] [Medline: 23793649]
49. Hanna L, May C, Fairhurst K. The place of information and communication technology-mediated consultations in primary care: GPs' perspectives. Fam Pract 2012 Jun;29(3):361-366. [doi: 10.1093/fampra/cmr087] [Medline: 22006040]
50. Hines M, Lincoln M, Ramsden R, Martinovich J, Fairweather C. Speech pathologists' perspectives on transitioning to telepractice: what factors promote acceptance? J Telemed Telecare 2015 Dec;21(8):469-473. [doi: 10.1177/1357633X15604555] [Medline: 26377120]
51. James S, Perry L, Gallagher R, Lowe J. Diabetes educators: perceived experiences, supports and barriers to use of common diabetes-related technologies. J Diabetes Sci Technol 2016 Sep;10(5):1115-1121 [FREE Full text] [doi: 10.1177/1932296816660326] [Medline: 27417141]
52. Jarvis-Selinger S, Bates J, Araki Y, Lear SA. Internet-based support for cardiovascular disease management. Int J Telemed Appl 2011;2011:342582 [FREE Full text] [doi: 10.1155/2011/342582] [Medline: 21822430]
53. Jimbo M, Shultz CG, Nease DE, Fetters MD, Power D, Ruffin MT. Perceived barriers and facilitators of using a Web-based interactive decision aid for colorectal cancer screening in community practice settings: findings from focus groups with primary care clinicians and medical office staff. J Med Internet Res 2013 Dec 18;15(12):e286 [FREE Full text] [doi: 10.2196/jmir.2914] [Medline: 24351420]
54. Armstrong AW, Kwong MW, Ledo L, Nesbitt TS, Shewry SL. Practice models and challenges in teledermatology: a study of collective experiences from teledermatologists. PLoS One 2011;6(12):e28687 [FREE Full text] [doi: 10.1371/journal.pone.0028687] [Medline: 22194887]
55. Kayyali R, Hesso I, Mahdi A, Hamzat O, Adu A, Nabhani Gebara S. Telehealth: misconceptions and experiences of healthcare professionals in England. Int J Pharm Pract 2017 Jun;25(3):203-209. [doi: 10.1111/ijpp.12340] [Medline: 28261891]

56. Khan NU, Rasheed S, Sharmin T, Ahmed T, Mahmood SS, Khatun F, et al. Experience of using mHealth to link village doctors with physicians: lessons from Chakaria, Bangladesh. BMC Med Inform Decis Mak 2015 Aug 5;15:62 [FREE Full text] [doi: 10.1186/s12911-015-0188-9] [Medline: 26242574]
57. Kim JW, Tiyyagura G, Langhan M. A qualitative analysis of general emergency medicine providers' perceptions on pediatric emergency telemedicine. Pediatr Emerg Care 2019 Dec;35(12):856-861. [doi: 10.1097/PEC.0000000000001067] [Medline: 28225376]
58. Kopanitsa G, Yampolsky V. Exploring barriers and opportunities for adoption of web portals in Russia. Stud Health Technol Inform 2016;221:87-91. [Medline: 27071883]
59. Tintorer DL, Domínguez JM, Pujol-Rivera E, Beneyto SF, Tuduri XM, Saigí-Rubió F. Keys to success of a community of clinical practice in primary care: a qualitative evaluation of the ECOPIH project. BMC Fam Pract 2018 May 9;19(1):56 [FREE Full text] [doi: 10.1186/s12875-018-0739-0] [Medline: 29743030]
60. Levine M, Richardson JE, Granieri E, Reid MC. Novel telemedicine technologies in geriatric chronic non-cancer pain: primary care providers' perspectives. Pain Med 2014 Feb;15(2):206-213 [FREE Full text] [doi: 10.1111/pme.12323] [Medline: 24341423]
61. Lord S, Moore SK, Ramsey A, Dinauer S, Johnson K. Implementation of a substance use recovery support mobile phone app in community settings: qualitative study of clinician and staff perspectives of facilitators and barriers. JMIR Ment Health 2016 Jun 28;3(2):e24 [FREE Full text] [doi: 10.2196/mental.4927] [Medline: 27352884]
62. MacNeill V, Sanders C, Fitzpatrick R, Hendy J, Barlow J, Knapp M, et al. Experiences of front-line health professionals in the delivery of telehealth: a qualitative study. Br J Gen Pract 2014 Jul;64(624):e401-e407 [FREE Full text] [doi: 10.3399/bjgp14X680485] [Medline: 24982492]
63. McNally G, Frey R, Crossan M. Nurse manager and student nurse perceptions of the use of personal smartphones or tablets and the adjunct applications, as an educational tool in clinical settings. Nurse Educ Pract 2017 Mar;23:1-7. [doi: 10.1016/j.nepr.2016.12.004] [Medline: 28137514]
64. Merchant KA, Ward MM, Mueller KJ, Rural Health Research & Policy Centers, Rural Policy Research Institute, RUPRI Center for Rural Health Policy Analysis, University of Iowa College of Public Health, Department of Health Management and Policy. Hospital views of factors affecting telemedicine use. Rural Policy Brief 2015 Apr 1(2015 5):1-4. [Medline: 26793811]
65. Bagot KL, Cadilhac DA, Bladin CF, Watkins CL, Vu M, Donnan GA, VSTASTUTE investigators. Integrating acute stroke telemedicine consultations into specialists' usual practice: a qualitative analysis comparing the experience of Australia and the United Kingdom. BMC Health Serv Res 2017 Nov 21;17(1):751 [FREE Full text] [doi: 10.1186/s12913-017-2694-1] [Medline: 29157233]
66. Moharra M, Almazán C, Decool M, Nilsson A, Allegretti N, Seven M. Implementation of a cross-border health service: physician and pharmacists' opinions from the epSOS project. Fam Pract 2015 Oct;32(5):564-567. [doi: 10.1093/fampra/cmv052] [Medline: 26148726]
67. Molfenter T, Boyle M, Holloway D, Zwick J. Trends in telemedicine use in addiction treatment. Addict Sci Clin Pract 2015 May 28;10:14 [FREE Full text] [doi: 10.1186/s13722-015-0035-4] [Medline: 26016484]
68. Molleda L, Bahamon M, St George SM, Perrino T, Estrada Y, Herrera DC, et al. Clinic personnel, facilitator, and parent perspectives of eHealth Familias Unidas in primary care. J Pediatr Health Care 2017;31(3):350-361 [FREE Full text] [doi: 10.1016/j.pedhc.2016.11.001] [Medline: 28012799]
69. Moloczij N, Mosley I, Moss KM, Bagot KL, Bladin CF, Cadilhac DA. Is telemedicine helping or hindering the delivery of stroke thrombolysis in rural areas? A qualitative analysis. Intern Med J 2015 Sep;45(9):957-964. [doi: 10.1111/imj.12793] [Medline: 25904209]
70. Morrow S, Daines L, Wiener-Ogilvie S, Steed L, McKee L, Caress A, et al. Exploring the perspectives of clinical professionals and support staff on implementing supported self-management for asthma in UK general practice: an IMPART qualitative study. NPJ Prim Care Respir Med 2017 Jul 18;27(1):45 [FREE Full text] [doi: 10.1038/s41533-017-0041-y] [Medline: 28720751]
71. Odeh B, Kayyali R, Nabhani-Gebara S, Philip N. Implementing a telehealth service: nurses' perceptions and experiences. Br J Nurs 2014;23(21):1133-1137. [doi: 10.12968/bjon.2014.23.21.1133] [Medline: 25426527]
72. Öberg U, Orre CJ, Isaksson U, Schimmer R, Larsson H, Hörnsten Å. Swedish primary healthcare nurses' perceptions of using digital eHealth services in support of patient self-management. Scand J Caring Sci 2018 Jun;32(2):961-970. [doi: 10.1111/scs.12534] [Medline: 28960451]
73. Puszka S, Dingwall KM, Sweet M, Nagel T. E-Mental health innovations for aboriginal and Torres Strait Islander Australians: a qualitative study of implementation needs in health services. JMIR Ment Health 2016 Sep 19;3(3):e43 [FREE Full text] [doi: 10.2196/mental.5837] [Medline: 27644259]
74. Rothstein JD, Jennings L, Moorthy A, Yang F, Gee L, Romano K, et al. Qualitative assessment of the feasibility, usability, and acceptability of a mobile client data app for community-based maternal, neonatal, and child care in rural Ghana. Int J Telemed Appl 2016;2016:2515420 [FREE Full text] [doi: 10.1155/2016/2515420] [Medline: 28070186]

75. Sandberg J, Trief PM, Izquierdo R, Goland R, Morin PC, Palmas W, et al. A qualitative study of the experiences and satisfaction of direct telemedicine providers in diabetes case management. Telemed J E Health 2009 Oct;15(8):742-750. [doi: 10.1089/tmj.2009.0027] [Medline: 19780691]
76. Beauregard P, Arnaert A, Ponzoni N. Nursing students' perceptions of using smartphones in the community practicum: a qualitative study. Nurse Educ Today 2017 Jun;53:1-6. [doi: 10.1016/j.nedt.2017.03.002] [Medline: 28324823]
77. Schneider T, Panzera AD, Martinasek M, McDermott R, Couluris M, Lindenberger J, et al. Physicians' perceptions of mobile technology for enhancing asthma care for youth. J Child Health Care 2016 Jun;20(2):153-163. [doi: 10.1177/1367493514556555] [Medline: 25427556]
78. Seto E, Leonard KJ, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Perceptions and experiences of heart failure patients and clinicians on the use of mobile phone-based telemonitoring. J Med Internet Res 2012 Feb 10;14(1):e25 [FREE Full text] [doi: 10.2196/jmir.1912] [Medline: 22328237]
79. Sharma U, Barnett J, Clarke M. Clinical users' perspective on telemonitoring of patients with long term conditions: understood through concepts of Giddens's structuration theory & consequence of modernity. Stud Health Technol Inform 2010;160(Pt 1):545-549. [Medline: 20841746]
80. Sharma U, Clarke M. Nurses' and community support workers' experience of telehealth: a longitudinal case study. BMC Health Serv Res 2014 Apr 10;14:164 [FREE Full text] [doi: 10.1186/1472-6963-14-164] [Medline: 24721599]
81. Sinclair C, Holloway K, Riley G, Auret K. Online mental health resources in rural Australia: clinician perceptions of acceptability. J Med Internet Res 2013 Sep 5;15(9):e193 [FREE Full text] [doi: 10.2196/jmir.2772] [Medline: 24007949]
82. Sturesson L, Groth K. Effects of the digital transformation: qualitative study on the disturbances and limitations of using video visits in outpatient care. J Med Internet Res 2018 Jun 27;20(6):e221 [FREE Full text] [doi: 10.2196/jmir.9866] [Medline: 29950290]
83. Taylor J, Coates L. Caring from a distance: the role of telehealth. Nurs Times 2015;111(28-29):18-20. [Medline: 26477231]
84. van Gaalen JL, van Bodegom-Vos L, Bakker MJ, Snoeck-Stroband JB, Sont JK. Internet-based self-management support for adults with asthma: a qualitative study among patients, general practitioners and practice nurses on barriers to implementation. BMJ Open 2016 Aug 26;6(8):e010809 [FREE Full text] [doi: 10.1136/bmjopen-2015-010809] [Medline: 27566627]
85. Varsi C, Ekstedt M, Gammon D, Børøsund E, Ruland CM. Middle managers' experiences and role in implementing an interactive tailored patient assessment eHealth intervention in clinical practice. Comput Inform Nurs 2015;33(6):249-257. [doi: 10.1097/CIN.0000000000000158] [Medline: 25988851]
86. Varsi C, Ekstedt M, Gammon D, Ruland CM. Using the consolidated framework for implementation research to identify barriers and facilitators for the implementation of an internet-based patient-provider communication service in five settings: a qualitative study. J Med Internet Res 2015 Nov 18;17(11):e262 [FREE Full text] [doi: 10.2196/jmir.5091] [Medline: 26582138]
87. Bello AK, Molzahn AE, Girard LP, Osman MA, Okpechi IG, Glassford J, et al. Patient and provider perspectives on the design and implementation of an electronic consultation system for kidney care delivery in Canada: a focus group study. BMJ Open 2017 Mar 2;7(3):e014784 [FREE Full text] [doi: 10.1136/bmjopen-2016-014784] [Medline: 28255097]
88. Vest BM, Hall VM, Kahn LS, Heider AR, Maloney N, Singh R. Nurse perspectives on the implementation of routine telemonitoring for high-risk diabetes patients in a primary care setting. Prim Health Care Res Dev 2017 Jan;18(1):3-13. [doi: 10.1017/S1463423616000190] [Medline: 27269513]
89. Wilhelmsen M, Høifødt RS, Kolstrup N, Waterloo K, Eisemann M, Chenhall R, et al. Norwegian general practitioners' perspectives on implementation of a guided web-based cognitive behavioral therapy for depression: a qualitative study. J Med Internet Res 2014 Sep 10;16(9):e208 [FREE Full text] [doi: 10.2196/jmir.3556] [Medline: 25208886]
90. Wynn R, Bergvik S, Pettersen G, Fossum S. Clinicians' experiences with videoconferencing in psychiatry. Stud Health Technol Inform 2012;180:1218-1220. [Medline: 22874406]
91. Zilliacus E, Meiser B, Lobb E, Dudding TE, Barlow-Stewart K, Tucker K. The virtual consultation: practitioners' experiences of genetic counseling by videoconferencing in Australia. Telemed J E Health 2010 Apr;16(3):350-357. [doi: 10.1089/tmj.2009.0108] [Medline: 20406122]
92. Carlisle K, Warren R. A qualitative case study of telehealth for in-home monitoring to support the management of type 2 diabetes. J Telemed Telecare 2013 Oct;19(7):372-375. [doi: 10.1177/1357633X13506512] [Medline: 24218347]
93. Cary MP, Spencer M, Carroll A, Hand DH, Amis K, Karan E, et al. Benefits and challenges of delivering tele-rehabilitation services to rural veterans. Home Healthc Now 2016 Sep;34(8):440-446. [doi: 10.1097/NHH.0000000000000441] [Medline: 27580283]
94. Casey M, Shaw S, Swinglehurst D. Experiences with online consultation systems in primary care: case study of one early adopter site. Br J Gen Pract 2017 Nov;67(664):e736-e743 [FREE Full text] [doi: 10.3399/bjgp17X693137] [Medline: 28993306]
95. Ghani MK, Jaber MM. Willingness to adopt telemedicine in major iraqi hospitals: a pilot study. Int J Telemed Appl 2015;2015:136591 [FREE Full text] [doi: 10.1155/2015/136591] [Medline: 26557848]

96. Duplaga M. Searching for a role of nursing personnel in developing landscape of eHealth: factors determining attitudes toward key patient empowering applications. PLoS One 2016;11(4):e0153173 [FREE Full text] [doi: 10.1371/journal.pone.0153173] [Medline: 27049525]
97. Gagnon MP, Orruño E, Asua J, Abdeljelil AB, Emparanza J. Using a modified technology acceptance model to evaluate healthcare professionals' adoption of a new telemonitoring system. Telemed J E Health 2012;18(1):54-59 [FREE Full text] [doi: 10.1089/tmj.2011.0066] [Medline: 22082108]
98. Hackl WO, Hoerbst A, Duftschmid G, Gall W, Janzek-Hawlat S, Jung M, et al. Crucial factors for the acceptance of a computerized national medication list: insights into findings from the evaluation of the Austrian e-Medikation pilot. Appl Clin Inform 2014;5(2):527-537 [FREE Full text] [doi: 10.4338/ACI-2014-04-RA-0032] [Medline: 25024766]
99. Hao H, Padman R. An empirical study of opinion leader effects on mobile technology implementation by physicians in an American community health system. Health Informatics J 2018 Sep;24(3):323-333. [doi: 10.1177/1460458216675499] [Medline: 30068266]
100. Holderried M, Hoeper A, Holderried F, Blumenstock G, Ernst C, Tropitzsch A. Attitudes toward e-Health: the otolaryngologists' point of view. Telemed J E Health 2018 Jun;24(6):425-432. [doi: 10.1089/tmj.2017.0158] [Medline: 29227206]
101. Jefee-Bahloul H, Duchen D, Barkil-Oteo A. Attitudes towards implementation of Store-and-Forward telemental health in humanitarian settings: survey of Syrian healthcare providers. Telemed J E Health 2016 Jan;22(1):31-35. [doi: 10.1089/tmj.2015.0021] [Medline: 26204132]
102. Jetty A, Moore MA, Coffman M, Petterson S, Bazemore A. Rural family physicians are twice as likely to use telehealth as urban family physicians. Telemed J E Health 2018 Apr;24(4):268-276. [doi: 10.1089/tmj.2017.0161] [Medline: 28805545]
103. Jury SC, Walker AM, Kornberg AJ. The introduction of web-based video-consultation in a paediatric acute care setting. J Telemed Telecare 2013 Oct;19(7):383-387. [doi: 10.1177/1357633X13506530] [Medline: 24218350]
104. Kato NP, Johansson P, Okada I, de Vries AE, Kinugawa K, Strömberg A, et al. Heart failure telemonitoring in Japan and Sweden: a cross-sectional survey. J Med Internet Res 2015 Nov 13;17(11):e258 [FREE Full text] [doi: 10.2196/jmir.4825] [Medline: 26567061]
105. Kifle M, Payton FC, Mbarika V, Meso P. Transfer and adoption of advanced information technology solutions in resource-poor environments: the case of telemedicine systems adoption in Ethiopia. Telemed J E Health 2010 Apr;16(3):327-343. [doi: 10.1089/tmj.2009.0008] [Medline: 20406120]
106. Adenuga KI, Iahad NA, Miskon S. Towards reinforcing telemedicine adoption amongst clinicians in Nigeria. Int J Med Inform 2017 Aug;104:84-96. [doi: 10.1016/j.ijmedinf.2017.05.008] [Medline: 28599820]
107. Kim S, Lee KH, Hwang H, Yoo S. Analysis of the factors influencing healthcare professionals' adoption of mobile electronic medical record (EMR) using the unified theory of acceptance and use of technology (UTAUT) in a tertiary hospital. BMC Med Inform Decis Mak 2016 Jan 30;16:12 [FREE Full text] [doi: 10.1186/s12911-016-0249-8] [Medline: 26831123]
108. Klack L, Ziefle M, Wilkowska W, Kluge J. Telemedical versus conventional heart patient monitoring: a survey study with German physicians. Int J Technol Assess Health Care 2013 Oct;29(4):378-383. [doi: 10.1017/S026646231300041X] [Medline: 24290330]
109. Kleinpell R, Barden C, Rincon T, McCarthy M, Rufo RJ. Assessing the impact of telemedicine on nursing care in intensive care units. Am J Crit Care 2016 Jan;25(1):e14-e20. [doi: 10.4037/ajcc2016808] [Medline: 26724303]
110. Koval PG, Kim JJ, Makhlouf T. Pharmacist perception of a mobile application audience response system for remote pharmacy continuing education participants. J Pharm Pract 2018 Aug 13:897190018792391. [doi: 10.1177/0897190018792391] [Medline: 30099934]
111. Kowitlawakul Y. The technology acceptance model: predicting nurses' intention to use telemedicine technology (eICU). Comput Inform Nurs 2011 Jul;29(7):411-418. [doi: 10.1097/NCN.0b013e3181f9dd4a] [Medline: 20975536]
112. Kuhn E, Eftekhari A, Hoffman JE, Crowley JJ, Ramsey KM, Reger GM, et al. Clinician perceptions of using a smartphone app with prolonged exposure therapy. Adm Policy Ment Health 2014 Nov;41(6):800-807. [doi: 10.1007/s10488-013-0532-2] [Medline: 24398700]
113. Kuo KM, Talley PC, Lee C, Yen Y. The influence of telemedicine experience on physicians' perceptions regarding adoption. Telemed J E Health 2015 May;21(5):388-394. [doi: 10.1089/tmj.2014.0091] [Medline: 25764024]
114. Lee SI, Park H, Kim JW, Hwang H, Cho EY, Kim Y, et al. Physicians' perceptions and use of a health information exchange: a pilot program in South Korea. Telemed J E Health 2012 Oct;18(8):604-612 [FREE Full text] [doi: 10.1089/tmj.2011.0261] [Medline: 22352898]
115. L'Esperance ST, Perry DJ. Assessing advantages and barriers to telemedicine adoption in the practice setting: A MyCareTeam(TM) exemplar. J Am Assoc Nurse Pract 2016 Jun;28(6):311-319. [doi: 10.1002/2327-6924.12280] [Medline: 26178417]
116. Liu CF, Cheng TJ. Exploring critical factors influencing physicians' acceptance of mobile electronic medical records based on the dual-factor model: a validation in Taiwan. BMC Med Inform Decis Mak 2015 Feb 7;15:4 [FREE Full text] [doi: 10.1186/s12911-014-0125-3] [Medline: 25889506]

117. Albrecht UV, Afshar K, Illiger K, Becker S, Hartz T, Breil B, et al. Expectancy, usage and acceptance by general practitioners and patients: exploratory results from a study in the German outpatient sector. Digit Health 2017;3:2055207617695135 [FREE Full text] [doi: 10.1177/2055207617695135] [Medline: 29942582]
118. Ly BA, Kristjansson E, Labonté R, Bourgeault IL. Determinants of the intention of Senegal's physicians to use telemedicine in their professional activities. Telemed J E Health 2018 Nov;24(11):897-898. [doi: 10.1089/tmj.2017.0276] [Medline: 29470109]
119. Mairesse GH, Braunschweig F, Klersy K, Cowie MR, Leyva F. Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association. Europace 2015 May;17(5):814-818. [doi: 10.1093/europace/euu390] [Medline: 25713012]
120. Miller KE, Kuhn E, Owen JE, Taylor K, Yu JS, Weiss BJ, et al. Clinician perceptions related to the use of the CBT-I Coach Mobile App. Behav Sleep Med 2019;17(4):481-491. [doi: 10.1080/15402002.2017.1403326] [Medline: 29120247]
121. Moore MA, Coffman M, Jetty A, Klink K, Petterson S, Bazemore A. Family physicians report considerable interest in, but limited use of, telehealth services. J Am Board Fam Med 2017;30(3):320-330 [FREE Full text] [doi: 10.3122/jabfm.2017.03.160201] [Medline: 28484064]
122. Morilla MD, Sans M, Casasa A, Giménez N. Implementing technology in healthcare: insights from physicians. BMC Med Inform Decis Mak 2017 Jun 27;17(1):92 [FREE Full text] [doi: 10.1186/s12911-017-0489-2] [Medline: 28655299]
123. Moskowitz A, Chan YY, Bruns J, Levine SR. Emergency physician and stroke specialist beliefs and expectations regarding telestroke. Stroke 2010 Apr;41(4):805-809 [FREE Full text] [doi: 10.1161/STROKEAHA.109.574137] [Medline: 20167910]
124. O'Connor S, Andrews T. Smartphones and mobile applications (apps) in clinical nursing education: a student perspective. Nurse Educ Today 2018 Oct;69:172-178. [doi: 10.1016/j.nedt.2018.07.013] [Medline: 30096510]
125. Okazaki S, Castañeda JA, Sanz S, Henseler J. Factors affecting mobile diabetes monitoring adoption among physicians: questionnaire study and path model. J Med Internet Res 2012 Dec 21;14(6):e183 [FREE Full text] [doi: 10.2196/jmir.2159] [Medline: 23257115]
126. Orruño E, Gagnon MP, Asua J, Abdeljelil AB. Evaluation of teledermatology adoption by health-care professionals using a modified Technology Acceptance Model. J Telemed Telecare 2011;17(6):303-307. [doi: 10.1258/jtt.2011.101101] [Medline: 21844171]
127. Putzer GJ, Park Y. Are physicians likely to adopt emerging mobile technologies? Attitudes and innovation factors affecting smartphone use in the Southeastern United States. Perspect Health Inf Manag 2012;9:1b [FREE Full text] [Medline: 22737094]
128. El Amrani L, Engberink AO, Ninot G, Hayot M, Carbonnel F. Connected health devices for health care in French general medicine practice: cross-sectional study. JMIR Mhealth Uhealth 2017 Dec 21;5(12):e193 [FREE Full text] [doi: 10.2196/mhealth.7427] [Medline: 29269336]
129. Rho MJ, Choi IY, Lee J. Predictive factors of telemedicine service acceptance and behavioral intention of physicians. Int J Med Inform 2014 Aug;83(8):559-571. [doi: 10.1016/j.ijmedinf.2014.05.005] [Medline: 24961820]
130. Rogove HJ, McArthur D, Demaerschalk BM, Vespa PM. Barriers to telemedicine: survey of current users in acute care units. Telemed J E Health 2012;18(1):48-53. [doi: 10.1089/tmj.2011.0071] [Medline: 22082107]
131. Sadoughi F, Erfannia L, Sancholi M, Salmani F, Sarsarshahi A. Teleradiology in Southeast Iran: Evaluating the Views of Senior Executives and Radiologists. Health Care Manag (Frederick) 2017;36(3):301-307. [doi: 10.1097/HCM.0000000000000162] [Medline: 28657915]
132. Saigi-Rubió F, Jiménez-Zarco A, Torrent-Sellens J. Determinants of the intention to use telemedicine: evidence from primary care physicians. Int J Technol Assess Health Care 2016 Jan;32(1-2):29-36. [doi: 10.1017/S0266462316000015] [Medline: 27472158]
133. Saigí-Rubió F, Torrent-Sellens J, Jiménez-Zarco A. Drivers of telemedicine use: comparative evidence from samples of Spanish, Colombian and Bolivian physicians. Implement Sci 2014 Oct 8;9:128 [FREE Full text] [doi: 10.1186/s13012-014-0128-6] [Medline: 25293651]
134. Sandholzer M, Deutsch T, Frese T, Winter A. Predictors of students' self-reported adoption of a smartphone application for medical education in general practice. BMC Med Educ 2015 May 21;15:91 [FREE Full text] [doi: 10.1186/s12909-015-0377-3] [Medline: 25994310]
135. Schmeer R, Behrends M, Kupka T, Meyenburg-Altwarg I, Marschollek M. Use and acceptance of mobile technology by hospital nurses in Germany. Stud Health Technol Inform 2016;225:944-945. [Medline: 27332422]
136. Sezgin E, Özkan-Yildirim S, Yildirim S. Understanding the perception towards using mHealth applications in practice. Inf Dev 2018;34(2):182-200. [doi: 10.1177/0266666916684180]
137. Sims MH, Fagnano M, Halterman JS, Halterman MW. Provider impressions of the use of a mobile crowdsourcing app in medical practice. Health Informatics J 2016 Jun;22(2):221-231. [doi: 10.1177/1460458214545896] [Medline: 25167866]
138. Smith PB, Buzi RS. Reproductive health professionals' adoption of emerging technologies for health promotion. Health Informatics J 2014 Dec;20(4):250-260. [doi: 10.1177/1460458213492525] [Medline: 25411221]
139. Asua J, Orruño E, Reviriego E, Gagnon MP. Healthcare professional acceptance of telemonitoring for chronic care patients in primary care. BMC Med Inform Decis Mak 2012 Nov 30;12:139 [FREE Full text] [doi: 10.1186/1472-6947-12-139] [Medline: 23194420]

140. Steinschaden T, Petersson G, Astrand B. Physicians' attitudes towards eprescribing: a comparative web survey in Austria and Sweden. Inform Prim Care 2009;17(4):241-248 [FREE Full text] [doi: 10.14236/jhi.v17i4.743] [Medline: 20359402]
141. Uscher-Pines L, Kahn JM. Barriers and facilitators to pediatric emergency telemedicine in the United States. Telemed J E Health 2014 Nov;20(11):990-996 [FREE Full text] [doi: 10.1089/tmj.2014.0015] [Medline: 25238565]
142. van Houwelingen CT, Barakat A, Best R, Boot WR, Charness N, Kort HS. Dutch nurses' willingness to use home telehealth: implications for practice and education. J Gerontol Nurs 2015 Apr;41(4):47-56. [doi: 10.3928/00989134-20141203-01] [Medline: 25486115]
143. Villalba-Mora E, Casas I, Lupiañez-Villanueva F, Maghiros I. Adoption of health information technologies by physicians for clinical practice: the Andalusian case. Int J Med Inform 2015 Jul;84(7):477-485. [doi: 10.1016/j.ijmedinf.2015.03.002] [Medline: 25823578]
144. Yaman H, Yavuz E, Er A, Vural R, Albayrak Y, Yardimci A, et al. The use of mobile smart devices and medical apps in the family practice setting. J Eval Clin Pract 2016 Apr;22(2):290-296. [doi: 10.1111/jep.12476] [Medline: 26552716]
145. Zailani S, Gilani MS, Nikbin D, Iranmanesh M. Determinants of telemedicine acceptance in selected public hospitals in Malaysia: clinical perspective. J Med Syst 2014 Sep;38(9):111. [doi: 10.1007/s10916-014-0111-4] [Medline: 25038891]
146. Zhang H, Cocosila M, Archer N. Factors of adoption of mobile information technology by homecare nurses: a technology acceptance model 2 approach. Comput Inform Nurs 2010;28(1):49-56. [doi: 10.1097/NCN.0b013e3181c0474a] [Medline: 19940621]
147. Ayatollahi H, Mirani N, Nazari F, Razavi N. Iranian healthcare professionals' perspectives about factors influencing the use of telemedicine in diabetes management. World J Diabetes 2018 Jun 15;9(6):92-98 [FREE Full text] [doi: 10.4239/wjd.v9.i6.92] [Medline: 29988886]
148. Brieux HM, Benitez S, Otero C, Luna D, Masud JH, Marcelo A, et al. Cultural problems associated with the implementation of eHealth. Stud Health Technol Inform 2017;245:1213. [Medline: 29295300]
149. Dünnebeil S, Sunyaev A, Blohm I, Leimeister JM, Krcmar H. Determinants of physicians' technology acceptance for e-health in ambulatory care. Int J Med Inform 2012 Nov;81(11):746-760. [doi: 10.1016/j.ijmedinf.2012.02.002] [Medline: 22397989]
150. Duhm J, Fleischmann R, Schmidt S, Hupperts H, Brandt SA. Mobile electronic medical records promote workflow: physicians' perspective from a survey. JMIR Mhealth Uhealth 2016 Jun 6;4(2):e70 [FREE Full text] [doi: 10.2196/mhealth.5464] [Medline: 27268720]
151. Alajlani M, Clarke M. Effect of culture on acceptance of telemedicine in Middle Eastern countries: case study of Jordan and Syria. Telemed J E Health 2013 Apr;19(4):305-311. [doi: 10.1089/tmj.2012.0106] [Medline: 23540280]
152. Ariens LF, Schussler-Raymakers FM, Frima C, Flinterman A, Hamminga E, Arents BW, et al. Barriers and facilitators to eHealth use in daily practice: perspectives of patients and professionals in dermatology. J Med Internet Res 2017 Sep 5;19(9):e300 [FREE Full text] [doi: 10.2196/jmir.7512] [Medline: 28874336]
153. Iacono T, Dissanayake C, Trembath D, Hudry K, Erickson S, Spong J. Family and practitioner perspectives on telehealth for services to young children with autism. Stud Health Technol Inform 2016;231:63-73. [Medline: 27782017]
154. Jamu JT, Lowi-Jones H, Mitchell C. Just in time? Using QR codes for multi-professional learning in clinical practice. Nurse Educ Pract 2016 Jul;19:107-112. [doi: 10.1016/j.nepr.2016.03.007] [Medline: 27428702]
155. Jeon J, Taneva S, Kukreti V, Trbovich P, Easty AC, Rossos PG, et al. Toward successful migration to computerized physician order entry for chemotherapy. Curr Oncol 2014 Apr;21(2):e221-e228 [FREE Full text] [doi: 10.3747/co.21.1759] [Medline: 24764707]
156. Loh P, Flicker L, Horner B. Attitudes toward information and communication technology (ICT) in residential aged care in Western Australia. J Am Med Dir Assoc 2009 Jul;10(6):408-413. [doi: 10.1016/j.jamda.2009.02.012] [Medline: 19560718]
157. Lapão LV, da Silva MM, Gregório J. Implementing an online pharmaceutical service using design science research. BMC Med Inform Decis Mak 2017 Mar 27;17(1):31 [FREE Full text] [doi: 10.1186/s12911-017-0428-2] [Medline: 28347304]
158. Lygidakis C, Wallace P, Tersar C, Marcatto F, Ferrante D, Vedova RD, et al. Download Your Doctor: implementation of a digitally mediated personal physician presence to enhance patient engagement with a health-promoting internet application. JMIR Res Protoc 2016 Mar 4;5(1):e36 [FREE Full text] [doi: 10.2196/resprot.5232] [Medline: 26944482]
159. Mueller KJ, Potter AJ, MacKinney AC, Ward MM. Lessons from tele-emergency: improving care quality and health outcomes by expanding support for rural care systems. Health Aff (Millwood) 2014 Feb;33(2):228-234. [doi: 10.1377/hlthaff.2013.1016] [Medline: 24493765]
160. Muigg D, Kastner P, Modre-Osprian R, Haluza D, Duftschmid G. Is Austria ready for telemonitoring? A readiness assessment among doctors and patients in the field of diabetes. Stud Health Technol Inform 2018;248:322-329. [Medline: 29726454]
161. Nerminathan A, Harrison A, Phelps M, Alexander S, Scott KM. Doctors' use of mobile devices in the clinical setting: a mixed methods study. Intern Med J 2017 Mar;47(3):291-298. [doi: 10.1111/imj.13349] [Medline: 27925381]
162. Odnoletkova I, Buysse H, Nobels F, Goderis G, Aertgeerts B, Annemans L, et al. Patient and provider acceptance of telecoaching in type 2 diabetes: a mixed-method study embedded in a randomised clinical trial. BMC Med Inform Decis Mak 2016 Nov 9;16(1):142 [FREE Full text] [doi: 10.1186/s12911-016-0383-3] [Medline: 27825340]

163. Bailey JV, Tomlinson N, Hobbs LJ, Webster R. Challenges and opportunities in evaluating a digital sexual health intervention in a clinic setting: Staff and patient views. Digit Health 2017;3:2055207617704272 [FREE Full text] [doi: 10.1177/2055207617704272] [Medline: 29942593]
164. Orchard J, Lowres N, Freedman SB, Ladak L, Lee W, Zwar N, et al. Screening for atrial fibrillation during influenza vaccinations by primary care nurses using a smartphone electrocardiograph (iECG): A feasibility study. Eur J Prev Cardiol 2016 Oct;23(2 suppl):13-20. [doi: 10.1177/2047487316670255] [Medline: 27892421]
165. Payne KF, Weeks L, Dunning P. A mixed methods pilot study to investigate the impact of a hospital-specific iPhone application (iTreat) within a British junior doctor cohort. Health Informatics J 2014 Mar;20(1):59-73. [doi: 10.1177/1460458213478812] [Medline: 24550565]
166. Possemato K, Kuhn E, Johnson EM, Hoffman JE, Brooks E. Development and refinement of a clinician intervention to facilitate primary care patient use of the PTSD Coach app. Transl Behav Med 2017 Mar;7(1):116-126 [FREE Full text] [doi: 10.1007/s13142-016-0393-9] [Medline: 27234150]
167. Quanbeck A, Gustafson DH, Marsch LA, Chih M, Kornfield R, McTavish F, et al. Implementing a mobile health system to integrate the treatment of addiction into primary care: a hybrid implementation-effectiveness study. J Med Internet Res 2018 Jan 30;20(1):e37 [FREE Full text] [doi: 10.2196/jmir.8928] [Medline: 29382624]
168. Ray KN, Felmet KA, Hamilton MF, Kuza CC, Saladino RA, Schultz BR, et al. Clinician attitudes toward adoption of pediatric emergency telemedicine in rural hospitals. Pediatr Emerg Care 2017 Apr;33(4):250-257. [doi: 10.1097/PEC.0000000000000583] [Medline: 26785087]
169. Shaw RJ, Kaufman MA, Bosworth HB, Weiner BJ, Zullig LL, Lee SD, et al. Organizational factors associated with readiness to implement and translate a primary care based telemedicine behavioral program to improve blood pressure control: the HTN-IMPROVE study. Implement Sci 2013 Sep 8;8:106 [FREE Full text] [doi: 10.1186/1748-5908-8-106] [Medline: 24010683]
170. Tahamtan I, Pajouhanfar S, Sedghi S, Azad M, Roudbari M. Factors affecting smartphone adoption for accessing information in medical settings. Health Info Libr J 2017 Jun;34(2):134-145. [doi: 10.1111/hir.12174] [Medline: 28406547]
171. Taylor A, Wade V, Morris G, Pech J, Rechter S, Kidd M, et al. Technology support to a telehealth in the home service: qualitative observations. J Telemed Telecare 2016 Jul;22(5):296-303. [doi: 10.1177/1357633X15601523] [Medline: 26362562]
172. Walker L, Clendon J. The case for end-user involvement in design of health technologies. J Telemed Telecare 2016 Dec;22(8):443-446. [doi: 10.1177/1357633X16670479] [Medline: 27799445]
173. Williamson KM, Muckle J. Students' perception of technology use in nursing education. Comput Inform Nurs 2018 Feb;36(2):70-76. [doi: 10.1097/CIN.0000000000000396] [Medline: 29084028]
174. Bidmead E, Marshall A. A case study of stakeholder perceptions of patient held records: the Patients Know Best (PKB) solution. Digit Health 2016;2:2055207616668431 [FREE Full text] [doi: 10.1177/2055207616668431] [Medline: 29942567]
175. Zhang Y, Koch S. Mobile health apps in Sweden: what do physicians recommend? Stud Health Technol Inform 2015;210:793-797. [Medline: 25991263]
176. Bramley G, Mangan C, Conroy M. Using telemonitoring to support personal care planning for adults with learning disabilities. J Telemed Telecare 2019 Dec;25(10):602-610. [doi: 10.1177/1357633X18784419] [Medline: 30016895]
177. Brown W, Giguere R, Sheinfil A, Ibitoye M, Balan I, Ho T, et al. Challenges and solutions implementing an SMS text message-based survey CASI and adherence reminders in an international biomedical HIV PrEP study (MTN 017). J Biomed Inform 2018 Apr;80:78-86 [FREE Full text] [doi: 10.1016/j.jbi.2018.02.018] [Medline: 29501908]
178. Chang F, Paramsothy T, Roche M, Gupta NS. Patient, staff, and clinician perspectives on implementing electronic communications in an interdisciplinary rural family health practice. Prim Health Care Res Dev 2017 Mar;18(2):149-160. [doi: 10.1017/S1463423616000414] [Medline: 27995826]
179. Charani E, Kyratsis Y, Lawson W, Wickens H, Brannigan ET, Moore LS, et al. An analysis of the development and implementation of a smartphone application for the delivery of antimicrobial prescribing policy: lessons learnt. J Antimicrob Chemother 2013 Apr;68(4):960-967 [FREE Full text] [doi: 10.1093/jac/dks492] [Medline: 23258314]
180. Cox A, Illsley M, Knibb W, Lucas C, O'Driscoll M, Potter C, et al. The acceptability of e-technology to monitor and assess patient symptoms following palliative radiotherapy for lung cancer. Palliat Med 2011 Oct;25(7):675-681. [doi: 10.1177/0269216311399489] [Medline: 21474620]
181. Ehrler F, Ducloux P, Wu DT, Lovis C, Blondon K. Acceptance of a mobile application supporting nurses workflow at patient bedside: results from a pilot study. Stud Health Technol Inform 2018;247:506-510. [Medline: 29678012]
182. Radhakrishnan K, Xie B, Berkley A, Kim M. Barriers and facilitators for sustainability of tele-homecare programs: a systematic review. Health Serv Res 2016 Feb;51(1):48-75 [FREE Full text] [doi: 10.1111/1475-6773.12327] [Medline: 26119048]
183. Davis MM, Freeman M, Kaye J, Vuckovic N, Buckley DI. A systematic review of clinician and staff views on the acceptability of incorporating remote monitoring technology into primary care. Telemed J E Health 2014 May;20(5):428-438 [FREE Full text] [doi: 10.1089/tmj.2013.0166] [Medline: 24731239]
184. Hickson R, Talbert J, Thornbury WC, Perin NR, Goodin AJ. Online medical care: the current state of 'eVisits' in acute primary care delivery. Telemed J E Health 2015 Feb;21(2):90-96. [doi: 10.1089/tmj.2014.0022] [Medline: 25474083]

185. Koivunen M, Saranto K. Nursing professionals' experiences of the facilitators and barriers to the use of telehealth applications: a systematic review of qualitative studies. Scand J Caring Sci 2018 Mar;32(1):24-44. [doi: 10.1111/scs.12445] [Medline: 28771752]
186. Kumar S, Merchant S, Reynolds R. Tele-ICU: efficacy and cost-effectiveness approach of remotely managing the critical care. Open Med Inform J 2013;7:24-29 [FREE Full text] [doi: 10.2174/1874431101307010024] [Medline: 24078857]
187. Lewis ER, Thomas CA, Wilson ML, Mbarika VW. Telemedicine in acute-phase injury management: a review of practice and advancements. Telemed J E Health 2012;18(6):434-445 [FREE Full text] [doi: 10.1089/tmj.2011.0199] [Medline: 22694296]
188. Li L, Cotton A. A systematic review of nurses' perspectives toward the telemedicine intensive care unit: a basis for supporting its future implementation in China? Telemed J E Health 2019 May;25(5):343-350. [doi: 10.1089/tmj.2018.0006] [Medline: 30036155]
189. Penny RA, Bradford NK, Langbecker D. Registered nurse and midwife experiences of using videoconferencing in practice: a systematic review of qualitative studies. J Clin Nurs 2018 Mar;27(5-6):e739-e752. [doi: 10.1111/jocn.14175] [Medline: 29149507]
190. Daniel F, Jabak S, Sasso R, Chamoun Y, Tamim H. Patient-physician communication in the era of mobile phones and social media apps: cross-sectional observational study on Lebanese physicians' perceptions and attitudes. JMIR Med Inform 2018 Apr 6;6(2):e18 [FREE Full text] [doi: 10.2196/medinform.8895] [Medline: 29625955]
191. Jungwirth D, Haluza D. Information and communication technology and the future of healthcare: results of a multi-scenario Delphi survey. Health Informatics J 2019 Mar;25(1):161-173. [doi: 10.1177/1460458217704256] [Medline: 28438103]
192. Ahmad F, Norman C, O'Campo P. What is needed to implement a computer-assisted health risk assessment tool? An exploratory concept mapping study. BMC Med Inform Decis Mak 2012 Dec 19;12:149 [FREE Full text] [doi: 10.1186/1472-6947-12-149] [Medline: 23253913]
193. Mishori R, Anastario M, Naimer K, Varanasi S, Ferdowsian H, Abel D, et al. mJustice: preliminary development of a mobile app for medical-forensic documentation of sexual violence in low-resource environments and conflict zones. Glob Health Sci Pract 2017 Mar 24;5(1):138-151 [FREE Full text] [doi: 10.9745/GHSP-D-16-00233] [Medline: 28351881]
194. Cunningham DL, Connors EH, Lever N, Stephan SH. Providers' perspectives: utilizing telepsychiatry in schools. Telemed J E Health 2013 Oct;19(10):794-799. [doi: 10.1089/tmj.2012.0314] [Medline: 23980938]
195. Bishop TF, Press MJ, Mendelsohn JL, Casalino LP. Electronic communication improves access, but barriers to its widespread adoption remain. Health Aff (Millwood) 2013 Aug;32(8):1361-1367 [FREE Full text] [doi: 10.1377/hlthaff.2012.1151] [Medline: 23918479]
196. Putzer GJ, Park Y. The effects of innovation factors on smartphone adoption among nurses in community hospitals. Perspect Health Inf Manag 2010 Jan 1;7:1b [FREE Full text] [Medline: 20697467]
197. Voncken-Brewster V, Tange H, Moser A, Nagykaldi Z, de Vries H, van der Weijden T. Integrating a tailored e-health self-management application for chronic obstructive pulmonary disease patients into primary care: a pilot study. BMC Fam Pract 2014 Jan 8;15:4 [FREE Full text] [doi: 10.1186/1471-2296-15-4] [Medline: 24400676]
198. Murray J. Oxford Dictionary Of English. UK: Oxford University Press; 2017.
199. Oudshoorn N, Rommes E, Stienstra M. Configuring the user as everybody: gender and design cultures in information and communication technologies. Sci Technol Hum Values 2004;29(1):30-63. [doi: 10.1177/0162243903259190]

Abbreviations

eHealth: electronic health
EHR: electronic health record
EMR: electronic medical record
IT: information technology
mHealth: mobile health
PICO: participants, intervention, comparators, and outcome framework
PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis
TAM: Technology Acceptance Model
UTAUT: unified theory of acceptance and use of technology

Edited by G Eysenbach; submitted 22.08.19; peer-reviewed by C Varsi, E Sezgin, C May; comments to author 02.11.19; revised version received 03.12.19; accepted 31.12.19; published 20.02.20.

Please cite as:
Jacob C, Sanchez-Vazquez A, Ivory C
Social, Organizational, and Technological Factors Impacting Clinicians' Adoption of Mobile Health Tools: Systematic Literature Review
JMIR Mhealth Uhealth 2020;8(2):e15935
URL: http://mhealth.jmir.org/2020/2/e15935/
doi:10.2196/15935
PMID:32130167

Original Paper

Operability, Acceptability, and Usefulness of a Mobile App to Track Routine Immunization Performance in Rural Pakistan: Interview Study Among Vaccinators and Key Informants

Shehla Zaidi[1,2], MBBS, MSc, PhD; Saqib Ali Shaikh[3], MBBS, MSc; Saleem Sayani[4], BA, MSc; Abdul Momin Kazi[1], MBBS, MPH; Adeel Khoja[5], MBBS, MSc; Syed Shahzad Hussain[1], BSN, MSc; Rabia Najmi[6], BDS, MSc

[1]Division of Woman and Child Health, Aga Khan University, Karachi, Pakistan

[2]Department of Community Health Sciences, Karachi, Pakistan

[3]Department of Health, Government of Sindh, Karachi, Pakistan

[4]E-Health Resource Centre, Aga Khan Development Network, Karachi, Pakistan

[5]Department of Medicine, Aga Khan University, Karachi, Pakistan

[6]Department of Community Health Sciences, Aga Khan University, Karachi, Pakistan

Corresponding Author:
Shehla Zaidi, MBBS, MSc, PhD
Department of Community Health Sciences
Aga Khan University
National Stadium Road
Karachi
Pakistan
Phone: 92 2134864852
Email: shehla.zaidi@aku.edu

Abstract

Background: There has been a recent spate of mobile health (mHealth) app use for immunizations and other public health concerns in low- and middle-income countries. However, recent evidence has largely focused on app development or before-and-after effects on awareness or service coverage. There is little evidence on the factors that facilitate adoption of mHealth programs, which is critical to effectively embed digital technology into mainstream health systems.

Objective: This study aimed to provide the qualitative experiences of frontline health staff and district managers while engaging with real-time digital technology to improve the coverage of routine childhood immunization in an underserved rural district in Pakistan.

Methods: An Android-based app was iteratively developed and used for a 2-year period in 11 union councils of the Tando Muhammad Khan district, an underserved rural district with poor immunization coverage in Pakistan. We used iterative methods to examine the (1) acceptability and operability of the app, (2) validity of the collected data, and (3) use of the collected data. In addition, we collected the barriers and enablers for uptake of the mHealth app. Each of these topics was further explored related to changes in work as well as the enabling factors for and barriers to app use. In-depth interviews were conducted with the 26 vaccinators posted in the 11 union councils and 7 purposively selected key informants (government district managers) involved with the Expanded Program for Immunization. Findings were triangulated in line with the three broad research areas.

Results: Digital immunization tracking was considered acceptable by vaccinators and district managers. Real-time immunization data were used to monitor vaccination volume, track children with incomplete vaccinations, develop outreach visit plans, correct existing microplans, and disburse a fuel allowance for outreach sessions. The validity of the app data was perceived to be superior to that of data from manual records. Ease of operability, satisfaction with data, personal recognition, links to field support, and a sense of empowerment served as powerful enablers. Taking twice the time to complete both manual and digital entries and outdated phones over time were considered constraints. An unintended knock-on effect was improved coordination and strengthening of Expanded Program for Immunization review platforms across district stakeholders through digitalized data.

Conclusions: Embedding digital technology into mainstream health systems relies on use by both end users and district stakeholders. Ease of operability, satisfaction with data reliability, personal recognition, links to field support, and empowerment are powerful enablers, whereas improved coordination as a result of easy, transparent data access can be an important by-product

of digitalization. Findings are relevant not only for wide-scale implementation of immunization tracking apps in Pakistan but also for informing the use of digital technology for results-based delivery by frontline health workers.

(JMIR Mhealth Uhealth 2020;8(2):e16081) doi:10.2196/16081

KEYWORDS

mHealth; immunization; digital technology; experience; health workers

Introduction

There has been a recent spate of mobile phone–led programs, known as mobile health (mHealth) [1], to tackle health care issues such as immunization, tuberculosis (TB), and malaria in low- and middle-income countries (LMICs). Mobile phones are used by 97 per 1000 people in LMICs [2], reaching remote communities that previously had little interaction with public authorities or private companies [3]. In rural Tanzania, mobile technology has been used to provide the current inventory of anti-malarial medicine to improve access to drugs and other medical supplies [4]. In rural Uganda, an app called TB Detect enables health care providers to access TB-related educational material [5]. Another area where mHealth is being increasingly applied is routine immunization services in LMICs. SMS reminders about immunization and the use of electronic registries to trace cases who missed vaccination are being trialed in an increasing number of LMICs in Latin America and Sub-Saharan Africa [6-16]. There is some evidence that these programs improve vaccination completion rates [6,8-16]. However, many have not progressed beyond the pilot phase, and evidence for the effectiveness of digital solutions is limited [17].

Despite the proliferation of mHealth apps, not all digital health programs perform as intended, and assessments of the technology, health systems, and behavioral factors need careful consideration [18]. In particular, mHealth programs that rely on the performance of health workers would benefit from qualitative research to understand the extent to which end users and decision makers are prepared to engage with mHealth technology [19,20]. Experience from high-income settings emphasizes a user-centric approach to the development of digital technology [21]. This is also an important consideration to assess the implementation of these technologies within LMICs. Technological factors such as internet access, data volume, and app usability can affect implementation [22]. In addition, other factors such as personal motivations for data use, work culture, and health system support should be reviewed when adopting mHealth programs.

In Pakistan, 66% of children are completely immunized; this is much lower than the country target of 90% set by the Global Vaccine Action Plan [23]. Routine childhood vaccinations are provided by a dedicated cadre of government-employed vaccinators at static health centers and during outreach visits to villages >5 km from the health center. Poor vaccinator performance, which is exacerbated by poor district supervision, has been a chronic issue for Pakistan's vaccine delivery system. A minimum of 1 vaccinator is allocated to each union council (UC), which is the smallest district administrative tier with a population of 10,000-20,000 people. Vaccinators are responsible for registering eligible children, providing vaccinations, updating Expanded Program on Immunization (EPI) cards, maintaining EPI records, and counseling parents for routine immunization awareness. The vaccinators are supplied with a motorbike, fuel support, and vaccines for routine immunization by the EPI program. UC–based EPI activities are administratively supervised by the district health office. However, paper records are poorly maintained and have questionable data. In addition, evidence suggests that vaccinators make too few outreach visits, provide little routine immunization education for parents, and maintain poor records [19]. Anecdotal evidence also suggests that vaccinators are resistant to supervision and often enjoy political patronage from local legislators protecting them from accountability on work performance [24]. In 2014, an app to track vaccinator movements through GPS was introduced across the populous Punjab province to ensure vaccinators made a sufficient number of outreach visits. Called e-Vaccs, it was designed, championed, and implemented by the government with provincially driven vertical accountability. Since then, policy commitment for digital immunization monitoring has also increased in other provinces, with the aim of effectively mobilizing the vaccinator workforce and moving away from relying on questionable paper-based records. However, a lack of the required systems support has stalled the roll-out process [20].

In this paper, we report the end-user experiences with a mobile app (Teeko, Aga Khan University Pediatrics Department, Pakistan) to track the delivery of routine childhood immunizations as well as the enablers and barriers for implementation in local health systems. Teeko is a mobile app that tracks vaccinators' routine immunization performance. It was co-designed with the sub-national government as part of a larger health system strengthening research program for routine childhood immunization and piloted in a rural district of Sindh, Pakistan in 2015-2017. The app generates quality real-time data, and its key features include GPS tracking of vaccinator outreach visits, digital records of the immunization volume at the static health center and during outreach visits, creation of the next scheduled immunization encounter, and identification of children who missed vaccination. We drew on the experiences of Teeko usage by vaccinators and district managers, including acceptability of the app, use of the digitalized data, perceptions of the data validity, and enabling factors and barriers for its adoption. We aim to inform how digital technology can be embedded within district health systems in LMICS.

Methods

Overview

Our study explored the experiences with an Android-based immunization app to improve vaccination coverage in a rural,

disadvantaged district of Pakistan. The overall objective was to evaluate the experiences of vaccinators and district managers during their use of the app to track routine immunization encounters. The specific objectives were to determine the acceptance and operability of the app as a tool for tracking vaccine encounters within the district health system, assess the data validity and data-related concerns of stakeholders, and understand how the technology is being used within the vaccine delivery system.

Setting

The mHealth initiative was part of a larger implementation research program to strengthen the health system and routine childhood immunization conducted by the Aga Khan University (AKU) in collaboration with the provincial EPI in the Tando Muhammad Khan (TMK) district in Sindh Province in 2015-2017 (Figure 1). This district had poor vaccination performance, with a Penta coverage rate of only 23% and PCV coverage of only 11% at the start of the study. A package of integrated interventions including a digital app was implemented based on formative research to identify interventions that was conducted at the start of the study. In addition to the mHealth intervention, other complementary interventions included facilitation of a district EPI review platform, microplanning training, fuel support routed through the district health office for outreach activities, and co-financing of EPI motorbikes for UCs lacking functional bikes for outreach sessions. Interventions were implemented in 2 district sub-divisions (Talukas) comprised of 11 UCs. The Teeko intervention was implemented over 24 months, after which vaccinator and district stakeholder interviews were conducted. The immunization program resulted in a significantly higher number of completed vaccinations at the intervention sites than at the control sites, as measured in terms of PENTA3 and PCV3 coverage (Table 1).

Figure 1. Map of the Tando Muhammad Khan (TMK) district in Sindh province, Pakistan, including locations of union councils (UCs) and Expanded Program on Immunization (EPI) centers.

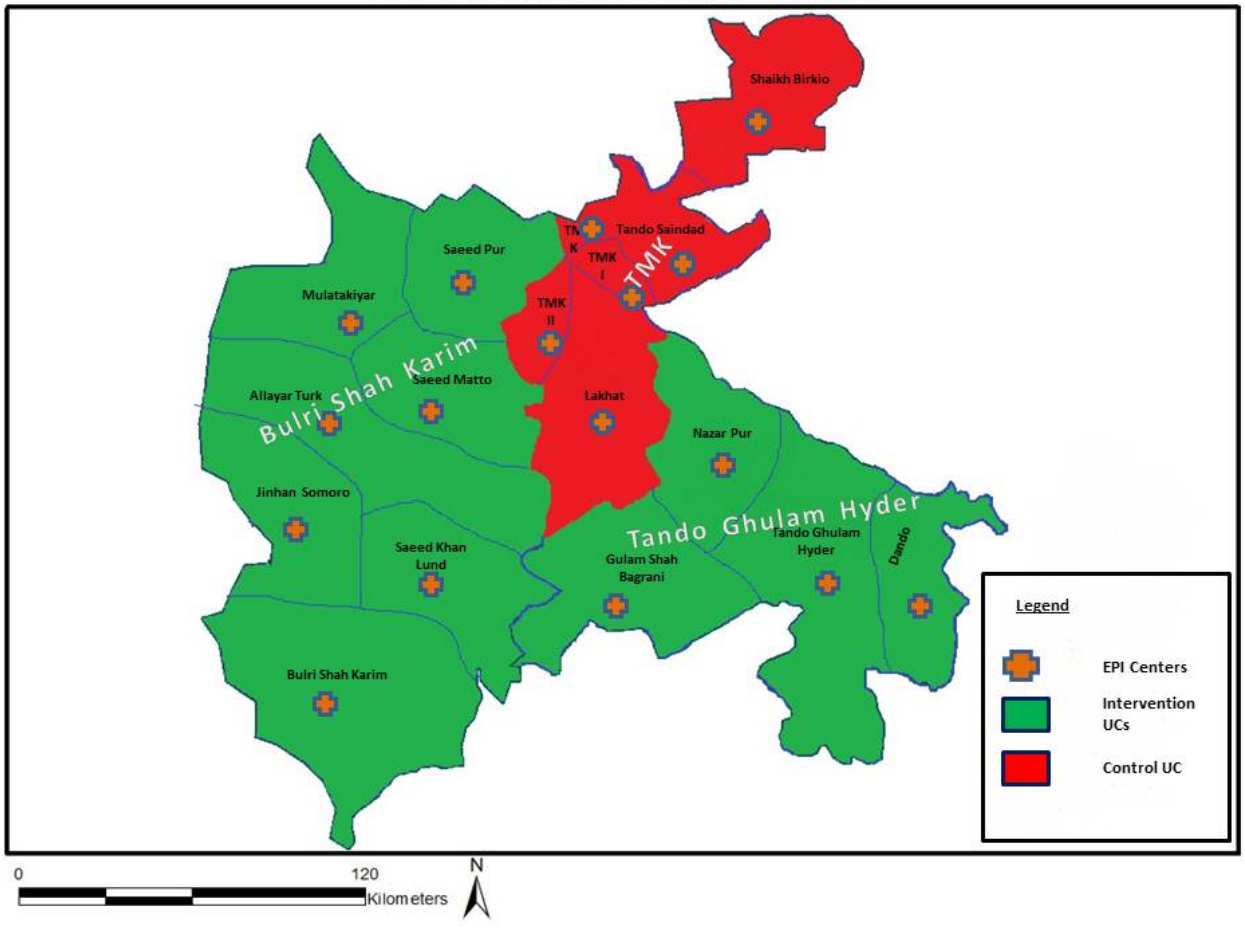


Table 1. Improvement in the vaccine coverage rate from 2014 to 2017 during the Health Systems Strengthening (HSS) immunization pilot study [19].

Vaccine	Intervention, %	Control, %	Difference, %	*P* value
PCV3				
2014	11	19	20	.001
2017	44	32	—	—
PENTA3				
2014	23	31	20	.001
2017	44	32	—	—

mHealth Intervention

Vaccinators and their sub-district and district EPI supervisors were provided with smartphones to track the immunization encounters. The app contained a list of UCs, villages, and health facilities assigned to each vaccinator. Vaccinators could access the app via unique access numbers to enter immunization data for the villages listed in their UCs (Figure 2). The app tracked vaccinator visits, vaccination volume at the static health center and outreach points, identified children that had missed a vaccination, tracked vaccine availability, and provided communication features for parents. The app had two components: data entry and a Web portal for data visualization.

Figure 2. Vaccinator using the Teeko app.

The immunization app was developed over a 6-month field testing period in 2014-2015 and was implemented in 2015-2017. The principal investigator (SZ) conducted a baseline assessment of routine immunization delivery in the district and identified the reporting of incomplete, questionable immunization EPI data and poor use in the TMK district [19]. During the assessment, management information system records were reviewed, and EPI officials, vaccinators, health workers, and health facility managers were interviewed. Further follow-up meetings were held with EPI provincial staff, the district health team, and vaccinators by the principal investigator (SZ) and a research specialist (SH) to identify intervention points within the EPI record flow that could be supported with an immunization tracking app, the support required for vaccinators and district health officers to use the app, and the health system interventions required to facilitate decision making. An in-house

technology firm (Aga Khan Development e-Resource Centre) was contracted for digital programming. App design and development were overseen by a steering committee chaired by the Provincial Director General of Health and comprised of the study principal investigator (SZ), a research specialist (SH), UNICEF, WHO, the EPI focal person for the TMK district, the District Health Officer for TMK, and a representative from the technology firm (SS). Using a participatory process, the following app features were identified: compulsory photo identification; defaulter (children who missed a vaccination) status using traffic light colors; alignment with EPI's management information system; client data to include the parents' national ID card numbers, household number, and village details; and adjustment for community migration. Meetings were held during the design phase and continued into the app roll-out, with recorded minutes. Iterations included the addition of new vaccines, identification of areas of misreporting, adjustment for vaccinations received outside the study area, and adjustment for household migration. To improve the technological features, the study team and technology partner field-tested different versions of the app with vaccinators and the district EPI focal person. Due to poor internet connectivity, the ability to upload data offline was added after the field testing. SMS messaging was poorly received and replaced with a robotic call. The study team randomly checked the photo entries and uploaded data for errors.

Finally, the app features included registration, immunization encounter record, offline data mode, vaccine stock management, awareness content, text messaging, a central database, and a Web portal.

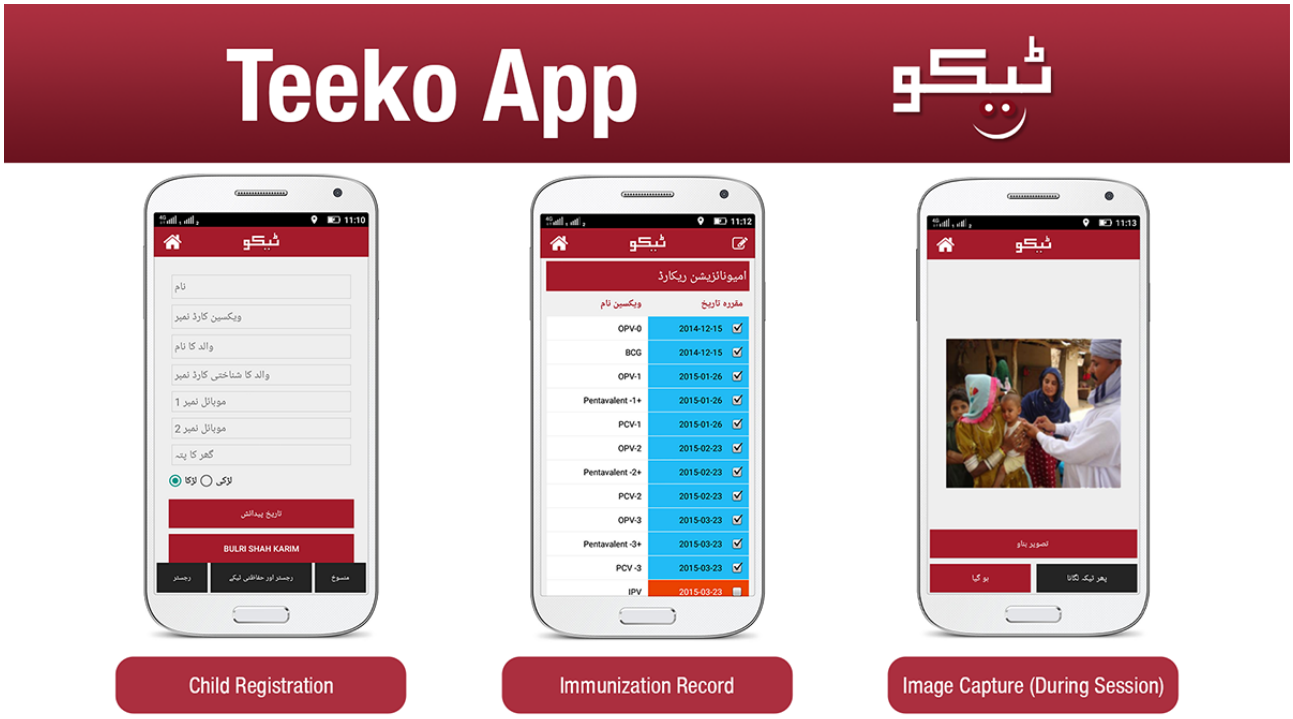
Registration

The vaccinator registered the child at the first encounter, entering the child's father's name, child's date of birth, household phone number, village name, and UC (Figure 2). This created an individual profile for the child. The child registration form was the same as the manually completed EPI child registration form. The data for the registered child was synced with the central database, in which all data were stored.

Immunization Encounter Record

The vaccinator then vaccinated the child and uploaded a mandatory photo of the vaccination or updated EPI card (Figure 3) as proof of vaccination. A GPS-based location was generated for the vaccination site. The app sent the immunization record data to the central server in real time.

Figure 3. Examples of registration, an immunization record, and the image capture view on the Teeko app.



Offline Data Mode

The app's offline feature allowed vaccination data to be recorded when internet connectivity was not available. The records were stored locally in the app and uploaded once an internet connection was restored during the outreach visit or at the health facility. Vaccinations could occur within the health facility or during an outreach visit.

Vaccine Inventory Management

To track inventory and ensure timely pick up of required supply, vaccinators could enter the amount of vaccine they had with them as well as the inventory at their respective health facilities.

Awareness Content

The app had certain communication features. A 60-second awareness video on routine immunization could be played by the vaccinator to educate the parents during a vaccination encounter.

Text Messaging

Following the vaccination, robotic calls and SMS messages about the routine immunization schedule and next visit were sent to the caregivers of each registered child.

Central Database

The central system (Figure 4) allowed the administrator to register all users (vaccinators, lady health workers, and viewers). In addition to during the vaccination encounters, the app occasionally sent the GPS coordinates of the vaccinators to the central database (Figure 5). If internet connectivity was not available, the coordinates were stored in the local database and later uploaded to the central database. The vaccinator directory listed the UC assigned to each vaccinator.

Figure 4. Flow of data through the Teeko app and Web portal.

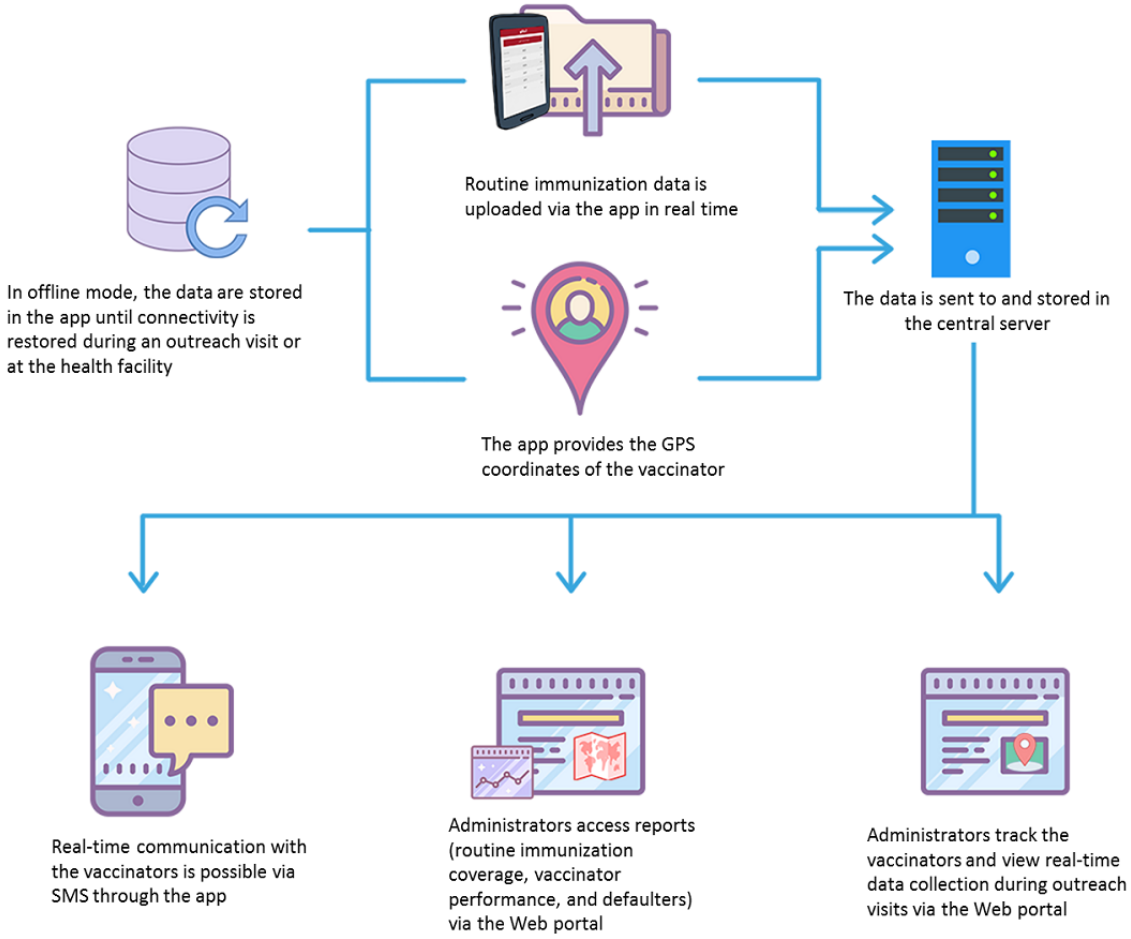


Figure 5. Vaccinator tracking screen in the Teeko Web portal.

Web Portal

Through the Web portal, the management and supervisory staff remotely monitored vaccinators' activities and movements in real time (Figure 5). The SMS Panel allowed the administrator to send an SMS to the vaccinators and lady health workers about meetings, schedules, and data corrections. The portal also generated district and UC reports on routine immunization coverage, defaulters, and individual vaccinator performance. These reports were generated based on formats already in use by the EPI Program.

Data Collection

We conducted semi-structured interviews with vaccinators and key informants (district managers) involved with EPI delivery (See Table 2). Data were collected and analyzed by trained researchers.

Table 2. Themes and tools used to explore the user experiences with digitalized immunization tracking and the key enabling factors

Themes	Tools	
	In-depth interviews with vaccinators	Key-informant interviews with district stakeholders
Acceptability and operability of the app	Use of key app features and app operability	Acceptability of the app within the district health system, enabling factors, and constraining factors
Validity of the app data	Perceptions of and concerns with the data validity	Perceptions of and concerns with the data validity
Use of the app data	Engaging with the app data, enabling factors, and constraining factors	Engaging with the app data, enabling factors, and constraining factors

Vaccinator Interviews

Semi-structured interviews were conducted covering the following topics: frequency of use of the app features; operability of and issues using the digital app; perceptions of the data validity and comparison with that of manually collected data; engagement with the app; and enabling factors and barriers for data use. Interviews were conducted with all 26 vaccinators working in the 11 UCs in which the digital app was implemented. All the vaccinators used the immunization app for at least 24 months. Individual interviews were conducted with each vaccinator in the local language and the privacy of a separate room.

District Stakeholder Interviews

In-depth interviews with key informants (district stakeholders) included the following topics: acceptability of the app to track immunizations conducted by the district heath team, perception of the data validity, and use of the information by district health management. For each topic, we also asked about how their work had changed after using the app and the enabling factors and barriers for app use. The topic guide was written in English and translated into the local Sindhi language. Interviews lasted 45 to 60 minutes and were conducted in the local language. Stakeholders from the district administration and district health office were purposively selected based on their key roles in EPI oversight or delivery. A total of 7 district stakeholders were interviewed, including the Deputy Commissioner (administrative head of the district and chair of the Polio-EPI district committee), Assistant Deputy Commissioner, District Health Officer, Assistant District Health Officer, District EPI Focal Person, District Superintendent of Vaccination, and Coordinator of the Lady Health Worker Program (rural community-based female health workers that assist with the awareness provision for routine immunization and mobilization of households for routine immunization sessions provided by vaccinators).

Ethical Considerations

Ethical approval for the study was obtained from the Ethical Review Committee of Aga Khan University Karachi, Pakistan (ERC number: 2818-Ped-ERC-13). Informed consent was obtained from all participants. Interviews were conducted on a voluntary basis. Each participant was ensured of the confidentiality of personal information. Personal information was anonymized for analyses and reporting through a coded interviewee number. The recorded data were kept in locked drawers and encrypted laptops to ensure data confidentiality.

Data Analysis

The interview information was transcribed in Sindhi and translated back into English. These were then checked for errors and manually analyzed. Three a priori themes were identified in line with the research objectives and used as the basis for inductive analysis: acceptability and operability of the app, data validity, and use of the app data (Table 2). Content analysis of the transcripts was undertaken, developing main codes in line with the a priori themes and further detailed coding based on grounded findings emerging from the narrative.

Results

Interview guides were used to report the results from the in-depth interviews. Textboxes 1 and 2 highlight the important findings from the vaccinator and district management interviews, respectively.

Vaccinators' End-User Experience

Table 3 lists specific responses provided by vaccinators during their interviews.

Acceptability of the App

Use of App Features

All 26 vaccinators used the app to record their vaccination encounters. Nearly all vaccinators (n=24) took post-vaccination photos of the children. Although some parents initially refused the photos, they eventually agreed after the vaccinators explained that the photo would be used for immunization verification and recording. Only two vaccinators reported that parents would not allow a photo under any circumstances, in which case a photo of the vaccination card was uploaded instead. These vaccinators were assigned to UCs that had pockets of the population with reports of prior vaccine refusal.

All the app features for routine immunization awareness including the awareness video, SMS alerts, and robotic calls were used by 18 vaccinators. Only the awareness videos were used by 6 vaccinators, and 2 vaccinators used only the SMS alert and robotic call features.

Operability

Of the 26 vaccinators, 25 reported that the app was easy to use and they could operate it without difficulty (Table 3). One vaccinator, who had a stroke-induced disability, needed his son's help to enter the data in the app. However, he also required assistance to manually complete data entry. Real-time data display in the format of the government EPI report was considered helpful for reading and relating to the data.

Vaccinators reported no instances of data loss from the app. Internet connectivity issues often occurred in the more remote villages, but the app allowed offline data entry. Then, vaccinators uploaded the data after they returned to the facility. The offline feature was particularly appreciated for its ability to prevent data loss (see Figure 4).

However, a few vaccinators reported being uncomfortable using the offline option and would have preferred real-time information uploads to the central database. Their reported concern was they might forget to upload pending data or be unable to upload pending data if the phone was damaged or stolen. However, there were no reports of phone damage or loss during the study.

Another reported issue was that, as the phones aged over the 24-month period, the phones would hang or freeze while using the app, making it difficult to enter data. Often, the phone had to be restarted, and there was a concern that unsaved data would be lost. The vaccinators wanted a replacement phone at least every 2 years to continue using the app.

Validity of the App Data

Most of the vaccinators (n=23) reported a high likelihood of error with manual documentation of outreach vaccination encounters. In practice, the data were entered based on recall in the EPI registers at the health care facilities rather than on site. Vaccinators recounted poorly recorded field data during prior measles outbreaks (before the Teeko app was available), resulting in an inability to target defaulters. They perceived that instant data entry through a mobile app generated a more accurate defaulter list.

Textbox 1. Important findings from the vaccinator interviews.

Acceptability of the App: Use of App Features

- All vaccinators used the app for vaccination encounters.
- Photos of the immunized child were uploaded more frequently than photos of the vaccination card.
- Most vaccinators used the videos, SMS, and robotic calls for immunization awareness education and routine follow-ups.
- Some vaccinators used only the videos for immunization awareness education.

Acceptability of the App: Operability

- Vaccinators considered it easy to operate.
- They could upload the data in villages without waiting for internet connectivity.
- The vaccinators preferred using the app over manual data entry.
- Issues included hanging of the phones after 2 years.

Validity of the App Data: Perceptions of Data Validity

- The vaccinators believed the accuracy of child registration and vaccination status was better than that of manual records.
- The photo verification was considered a key feature for accuracy.
- The vaccinators felt as if they were more likely to follow the monthly plan for visits because their supervisors monitored them via GPS tracking.

Validity of the App Data: Engagement With the Data

- Vaccinators could proactively identify and track defaulters.
- They could develop a monthly visit plan that could particularly target defaulters.
- Their performance could be tracked accurately by their supervisors using GPS tracking.

Use of the App Data: Enabling Factors

- Reporting of individual performance resulted in supervisory recognition and personal gratification in reaching targets.

Use of the App Data: Barriers

- Data entry via both the app and manual methods resulted in double the amount of work.

Textbox 2. Important findings from the key informant interviews with district management.

Acceptability of the App: Acceptability Within the District Health System

- The vaccinators were comfortable using the app.
- The Expanded Program for Immunization (EPI) supervisors found it easy to retrieve the data to monitor vaccinators and identify defaulters.
- The key informants requested to continue using the app and expand its use to other districts.
- The district was able to act as an example for other districts.

Acceptability of the App: Enabling Factors

- The district managers were interested in the app and expressed ownership of it.
- Data-driven accountability led to coordination across health programs and with the district administration.
- Data-driven accountability resulted in a demand for work recognition as well as fear of exposure.

Acceptability of the App: Barriers

- Additional effort to increase awareness of routine immunization was needed in high-defaulter areas.

Validity of the App Data: Perceptions of Data Validity

- GPS location of vaccinators provided reliable information, while previously checks were onerous.
- Vaccination volume and child details were very accurate and could be quickly verified.

Validity of the App Data: Engagement With the Data

- Real-time data was used to inform EPI monthly review meetings about the increasing vaccination volume and reduced number of defaulters.
- The monthly recognition of high-performing vaccinators and naming the poorly performing vaccinators encouraged sharing of experiences.

Use of the App Data: Enabling Factors

- The data enabled coordination across the district stakeholders.
- The individualized public recognition was considered the biggest motivator.
- The data encouraged competition among the vaccinators as well as sharing of lessons learned.
- The app data were used to release mobility support.

Use of the App Data: Barriers

- Political patronage is still an issue but better managed due to transparency of accountability and monitoring of the vaccinators in the target setting.

Table 3. Specific responses from the vaccinator interviews, organized by theme.

Theme	Examples of vaccinator responses
Acceptability of the app: Operability	"It is very easy to use, just like my own phone that I use, typing information on the phone is easy too... and we already knew how to take a picture and upload it..."
	"I never lose any of the data now, as the data is entered then and there in the outreach, ...first we used to write it on a piece of paper and bring it home and then enter it the next day at the health facility...there was a huge chance of error... "Teeko" data is very reliable data"
	"The application can save my data until I get internet signals but still, to avoid error due to this in future, a better connectivity in remote areas is needed..."
	"It's been two years now, mobiles phones should be replaced with new ones, ... they hang and shut down at times... Taking more time to make an entry in the field or transfer the data..."
Validity of the app data	"It is easy for me to find children who are overdue for their vaccination, I can see the due date for the next vaccination and reach the child"
Use of the app data	"The district administration has become more watchful and alert now... they can catch us not being in the field through their mobiles. now I believe that I am performing my duty with more honestly than I used to previously..."
	"During the last award ceremony, I was awarded first position by district-AKU team; my data recorded on "Teeko" application in the field also completely matched the manual data...I was overwhelmed"
	"I have been working for the last 35 years as a vaccinator and I feel that these two years were the ones where I performed my best. I feel very proud of myself"
	"Very easy application, but with manual (entry of records), it doubles my work; we have to make entries in both EPI (paper) registers and "Teeko"; this takes a lot of time"

The post-vaccination photograph was considered key to ensuring reliable data. Compared with the prior practice of checking the EPI records, the advantage of the photo feature was child verification. Vaccinators also reported that the GPS tracking of outreach visits resulted in greater vaccinator vigilance in conducting outreach sessions and improved the reliability of vaccination encounter reports. Vaccinators reported calls from their supervisors to check their location when the supervisors did not observe any field activity.

Use of the App Data

All vaccinators reported they mainly used the digital data to identify children overdue for their vaccinations. Vaccinators expressed ownership of the data and a feeling of empowerment when using the data to plan their monthly vaccination rounds. They also reported using the data to set target vaccination volumes.

All vaccinators also mentioned the use of the GPS feature by the district health office and deputy commissioner for vaccinator supervision. Vaccinators reported being questioned by the district supervisors if they turned off their mobile location or could not be seen moving in the field.

The vaccinators reported that the overriding motivator to use the app was the reporting of the performance level of each vaccinator. The vaccinators reported feeling gratified when the best performing vaccinators were publicly recognized during the review of individual performance levels in the monthly EPI meetings. All the vaccinators found it very satisfying to be noticed and praised by superior EPI officials and district officers. Most of the vaccinators reported that this motivated them to do their best. Others reported this was the first time they took their work seriously and found it a novel but satisfying experience to work toward targets rather than working to identify loopholes to avoid work.

A few vaccinators reported that the app increased their workload because they were also expected to manually document the EPI records in addition to documenting via the app.

Migration to digital records from manual recording was preferred by 23 of the 26 vaccinators, while 3 vaccinators wanted both manual and digital record keeping. All 26 vaccinators were willing to continue using the app in the future.

The vaccinators also mentioned the conditional fuel support provided by the district health office based on the number of monthly visits reported by the app. The vaccinators reported that the lack of fuel support made it difficult to conduct outreach sessions.

District Stakeholder Experiences

Findings from the key informant interviews with district stakeholders were categorized into the following thematic areas: acceptability of the app for routine immunization supervision by the district heath team, perception of data validity, and use of the app information by the district health management. Within each thematic area, the narrative reports were analyzed for changes in work after using the app, experiences with implementing the app, and the enabling factors for and barriers to app use. Table 4 lists specific responses provided by the district stakeholders during their interviews.

Table 4. Specific responses from the district stakeholder interviews, organized by theme.

Theme	Examples of district stakeholder responses
Acceptability of the app	"Good coordination between the Health and District Administration is seen, District Health Office helped AKU to pilot and develop "Teeko" while the Deputy Commissioner Office supported in making their planning work, also did field monitoring and addressing administrative issues"
	"Commissioner (district) requested to start the same project in his district, we were called to give a briefing on "Teeko" he was very impressed..."
	"Under the Health Department, EPI Provincial Program should adopt "Teeko" immediately...at least in the districts which are not performing up to mark"
Validity of the app data	"At first we used to follow vaccinators schedule, get hold of someone who knew the area, then try to find him in the field, now we see his location in "Teeko" application and reach him...it really saves a lot of time"
	"On looking at the data I send direction to vaccinators through "Teeko" (ap-plication) to correct it...they reply after getting it done"
Use of the app data	"If we took any disciplinary action against irregular or poor performing vaccinators, we faced political pressure at times and are threatened too, we then become helpless..."
	"Political involvement has always been an issue, but with sincere working, like with this "Teeko" project, we can overcome it."
	"At the office of Deputy Commissioner, in a formal ceremony with heads from the Teeko project and District Health Officer the best performing vaccinators were appreciated, they were given certificates, shields and gifts...everyone wanted to do more to earn this honor and respect...some of the vaccinators were so motivated that they even worked on Sundays to meet their target"
	"The vaccinator's data is assessed in the EPI meeting for future decisions & micro planning."
	"The vaccinators were offered motorcycles, they had to pay 50% while the project paid another 50%, it not only solved mobility issue, they owned a motorcycle as well...every month they (Vaccinators) get POL from District Health Office...the accountability made possible regular POL supply to vaccinators, which previously was not provided."
	"With mobility support and real monitoring, the routine immunization has improved in the outreach"

Acceptability of the App

Key informants from district management commonly reported that the vaccinators were comfortable using the app. District officials found it easy to retrieve routine immunization volume from their cell phones and computers, and the officials used the app to keep track of children who missed immunizations. The interviewees recounted poor vaccinator performance prior to using the app and attributed this to poor work attitudes, insufficient supervision from the supervisors, and a lack of fuel support and functional motorbikes for supervisory visits.

The stakeholders reported that the app led to increased coordination between the EPI and Lady Health Worker Program—the two important community outreach resources within the district heath system—and closer interaction regarding routine immunization between the District Health Office and the Deputy Commissioner's Office.

The health officials expressed an eagerness to continue the tracking initiative and anxiety that routine immunization coverage would decline again after closure of the project. The stakeholders also requested that the project be expanded to the other sub-divisions within the district. The district leadership reported feeling as if they could serve as an example for other districts in the province and were gratified that other districts requested demonstrations and sharing of lessons learned.

Validity of the App Data

Key informants reported that tracking a vaccinator in the field was challenging in routine practice. Immunization work plans provided by the vaccinators were not always accurate; they could make changes to the plans without prior notice to the district health office. Moreover, even when EPI supervisors verified the vaccinators' locations in the field, they needed assistance from local villagers familiar with the area. It was still possible that they would not successfully find the vaccinator. The district stakeholders appreciated that the app facilitated vaccinator tracking through its GPS feature. They were able to locate and reach vaccinators without delay.

The EPI district supervisors reported that they relied on the app data to provide supervisory instructions for the vaccinators related to routine immunization coverage and defaulter reports. The app data were considered superior in quality to manually collected data and were particularly used for corrective actions.

Use of the App Data

The key informants commonly reported that the main uses of the app data were improving the number of routine immunization encounters and locating defaulting children. In the past, it was challenging to hold the vaccinator cadre accountable for routine immunization performance, making it difficult to improve vaccination volume. Furthermore, disciplinary actions such as a "notice of explanation," for which employees must provide an explanation for an allegation of violation of company policies, rules, and procedures; "show cause letter," which asks the employee to provide a reason why they should not face a disciplinary action for a conduct or capacity issue in the workplace; and termination of irregular,

ghosting, or nonperforming vaccinators were not effective due to the political patronage of vaccinators by local legislators.

The key informants mentioned that regular EPI review meetings were convened at the district health office, and the meetings used the real-time app data. These meetings were often attended by the district health commissioner and assistant commissioner. During these meetings, vaccinator performance was reviewed, including that of poor performers. Vaccinators with high performance were also recognized separately in quarterly public ceremonies attended by district legislators. The stakeholders reported that the public recognition was instrumental for increasing motivation. They added that the review meetings provided a platform for vaccinators to learn from each other's experiences and promote healthy competition.

District stakeholders also expressed a sense of empowerment from using the app to make operational decisions to improve routine immunization in the district. They used the data to direct activities to areas with incomplete vaccination coverage. Real-time immunization data were also used to provide support for vaccinator mobility based on GPS-verified outreach visits.

Additionally, EPI motorbikes were provided by the district health office to the better performing vaccinators; these were co-financed by the project and the vaccinator. Both activities were undertaken during the monthly district EPI review meetings that were chaired by the District Health Officer.

Discussion

In LMICS, mHealth apps are increasingly used for immunizations and other public health concerns; however, recent evidence has largely focused on app development, dashboards, or the before-and-after effects on awareness or coverage [6,7,10,12,21-25]. Less evidence is available regarding end users' and decision makers' acceptance of and engagement with digital health technology. Bridging this evidence gap is critical to embed digital technology into mainstream health systems. In this paper, we report the qualitative experiences of frontline health staff and district managers in engaging with real-time, digital technology to improve the coverage of routine childhood immunization in an underserved rural district in Pakistan.

Using an iterative approach, we gathered information about the acceptability of the app for data collection and tracking vaccine delivery, perceptions about data validity, the extent that app data were used, and the engagement of care. We also identified the key factors for frontline staff to engage with digital technology. The app was commonly accepted by vaccinators and district supervisors to track vaccination encounters; however, the app features aimed at increasing parents' vaccination awareness were less commonly used. Lack of parental agreement for photograph verification of their children was not a major issue. Vaccinators found the app easy to operate, the fields were similar to those of EPI records, and the offline data recording feature was helpful in remote access areas. Double entry of both manual and digital records was considered time consuming, and aging phone technology created systems issues. District supervisors found the app data easy to access for quick verification of immunization activity and to provide supervisory direction. The ability for real-time tracking of both individual vaccinators and the entire team through the Web portal considerably reduced the time spent tracking vaccinators during outreach visits. This helped to not only accurately track the vaccinator but also identify vaccination coverage according to the geographical location. This drastically reduced the monitoring and tracking time during outreach. The increased availability of supervision time was then utilized for other monitoring and evaluation activities. In addition, the app-generated maps helped to finalize microplans and identify missed locations. The validity of the app data was considered superior to that of data from manual records by both the vaccinators and district supervisors; this perception was attributed to photo verification of the encounters. Opinions differed regarding what contributed to the improved data. The EPI supervisors attributed it to the transparency of vaccinator movements, while vaccinators felt that the ability to record immunization entries during the visits was better than using recall to manually record data later at the health facilities.

Real-time immunization data were mainly used to monitor vaccination volume, track children with incomplete vaccinations, develop outreach visit plans, alter existing microplans, and provide a results-based fuel allowance. A significant outcome was the initiation of regular monthly EPI review meetings by the district leadership. During these meetings, real-time data were used to review immunization progress. Data were also used to recognize both good and poor immunization performance per individual and across UCs and vaccinators. These findings are supported by those from a study in Nigeria that used GPS and geospatial data to track vaccinators [26,27]. They reported improvements in microplanning, monitoring, and immunization coverage, which were attributed to the technology-based support for performance monitoring that reduced erroneous entries and data fabrication by vaccinators. They also used GPS data to provide feedback to the outreach team and target missed geographical areas.

Our study also identified enablers that facilitated the use of digital immunization tracking. Recognition of individual performance, empowerment, and results linked to fuel support emerged as powerful motivators for the vaccinators to work towards target delivery rather than avoiding workload, as they had previously. For district management, key enablers included a sense of empowerment for reviewing and planning EPI delivery and enhanced transparency to counteract political patronage of vaccinators. A knock-on effect of the real-time verification data was improved coordination across different components of the district health systems.

Reviews of digital technology use in other settings have drawn on mixed methods including interviews, focus group discussions, and systems analysis of the app data. The evidence indicates that instant data availability for monitoring purposes, as observed with neglected tropical diseases [28], and ease of use and digital literacy of end users, as observed with oral cholera vaccinations [29], are important parameters for the successful trialing of digital apps. Poorly designed devices and inadequate cellular infrastructure have been noted as barriers for integrating apps into health systems [30]. Lessons learned from immunization registries in Latin American and Caribbean

countries indicate that digitalization must be useful to vaccinators for the data to be of good quality. Evidence on non-technological factors for health provider apps is still emerging. A study of a client data app for community health nurses in Ghana resulted in reasonably good acceptability due to the app's capacity to facilitate client follow-up and data reporting; however, the feasibility and usability of the app were hindered by high client volumes, staff shortages, and software and device challenges [31]. A study on an mHealth app for midwives in Ghana found low levels of user acceptance and a software design that did not match the end - user needs or work environment [32]. Another study that introduced an app for community health volunteers in Kenya found that acceptability improved after a period of initial anxiety; however, there were feasibility challenges related to battery drainage and difficulty keeping the phone charged [33]. Yet another study in South Africa with an app for mHealth workers to electronically track patients with multi-drug resistant TB found a high intent for use but low actual usage resulting from forgetfulness and low levels of responsibility for such work [34].

Our study provides timely evidence on the successful integration of an immunization tracking app to be used by vaccinators as Pakistan prepares to upscale digitalized immunization tracking. It also provides lessons for LMICS on technological and non-technological factors that require attention to contextualize health provider apps within the local health system. We contend that immunization performance tracking through digital technology needs essential acceptance by frontline health force, and mere vertical enforcement is not enough. Technological ease of operability, personal recognition, results-oriented mobility support, and empowerment to improvise microplanning are powerful individual-level factors, whereas data transparency and empowerment for district planning are key organizational-level enablers to embed digital tracking in vaccine delivery systems. While there is a proliferation of digital technologies in countries such as Pakistan, dedicated investment in e-governance for continuous, independent, rigorous evaluation is required to assess actual use in the field and validity of the data.

Strengths and Limitations

This study used iterative qualitative research methods for in-depth exploration of the digital technology interface with end users and decision makers within the health system. This iterative approach helped identify themes in an unexplored area and identified details that would have been missed in a more prescriptive quantitative study. Triangulation of the findings across vaccinators, supervisors, and district managers strengthened the analysis and helped draw out common convincing narratives. To limit bias, researchers who were not part of the intervention team undertook tool development and data collection.

A limitation of this study is the lack of quantitative assessment of the data generated by the app. A household vaccination coverage survey conducted as part of the larger health system strengthening immunization study found a significant difference in vaccination completion rates between the baseline and end timepoints across study control and intervention areas [35]. However, the app's impact cannot be separately quantified from the other components of the larger health systems intervention package. While several of the findings are specific to the study context, the study provides the key parameters for consideration during the current rollout of digital immunization interventions in Pakistan as well as lessons for the introduction of a health provider app in LMICS. Digital technology investments must be accompanied by independent rigorous evaluation for relevance to health systems.

Conclusions

Embedding digital technology into mainstream health systems relies on acceptance by both end users and district stakeholders. Ease of operability, satisfaction with reliable data, personal recognition, results-based field support, and empowerment are powerful enablers. An important by-product of digitalization can be improved coordination as a result of transparent, easy data access. The findings are relevant to not only the current upscaling of digital technology to track immunization in Pakistan but also the application of digital technology for results-based delivery by frontline health workers.

Acknowledgments

We thank Dr Hassan Murad Shah Director General Health Sindh; Zahoor Baloch, EPI Programme Sindh; Dr Nazir Baloch, Department of Health Sindh,; Dr Hafeez, Pasha District Health Office, Tando Muhammad Khan; Agha Abdul Rahim, DCO, Tando Muhammad Khan; Abdul Muqeet; and Tehniat Sheikh, Aga Khan Development Network E-Health Resource Centre. This work was supported by GAVI-The Vaccine Alliance (PP33961213A1).

Conflicts of Interest

None declared.

References

1. World Health Organization. Decade of Vaccines—Global Vaccine Action Plan 2011-2020 URL: https://www.who.int/immunization/global_vaccine_action_plan/DoV_GVAP_2012_2020/en/ [accessed 2020-01-10]
2. USAID. 2003 Oct. Immunization Essentials: A Practical Field Guide URL: http://pdf.usaid.gov/pdf_docs/Pnacu960.pdf [accessed 2020-01-10]

3. Stansfield SK, Walsh J, Prata N, Evans T. Chapter 54: Information to Improve Decision Making for Health. In: Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, editors. Disease control priorities in developing countries. New York, NY: The World Bank and Oxford University Press; 2006:1022.
4. Barrington J, Wereko-Brobby O, Ward P, Mwafongo W, Kungulwe S. SMS for Life: a pilot project to improve anti-malarial drug supply management in rural Tanzania using standard technology. Malar J 2010 Oct 27;9:298 [FREE Full text] [doi: 10.1186/1475-2875-9-298] [Medline: 20979633]
5. Labrique AB, Vasudevan L, Kochi E, Fabricant R, Mehl G. mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. Glob Health Sci Pract 2013 Aug;1(2):160-171 [FREE Full text] [doi: 10.9745/GHSP-D-13-00031] [Medline: 25276529]
6. Bangure D, Chirundu D, Gombe N, Marufu T, Mandozana G, Tshimanga M, et al. Effectiveness of short message services reminder on childhood immunization programme in Kadoma, Zimbabwe - a randomized controlled trial, 2013. BMC Public Health 2015 Feb 12;15:137 [FREE Full text] [doi: 10.1186/s12889-015-1470-6] [Medline: 25885862]
7. Domek GJ, Contreras-Roldan IL, O'Leary ST, Bull S, Furniss A, Kempe A, et al. SMS text message reminders to improve infant vaccination coverage in Guatemala: A pilot randomized controlled trial. Vaccine 2016 May 5;34(21):2437-2443 [FREE Full text] [doi: 10.1016/j.vaccine.2016.03.065] [Medline: 27026145]
8. Haji A, Lowther S, Ngan'ga Z, Gura Z, Tabu C, Sandhu H, et al. Reducing routine vaccination dropout rates: evaluating two interventions in three Kenyan districts, 2014. BMC Public Health 2016 Feb 16;16:152 [FREE Full text] [doi: 10.1186/s12889-016-2823-5] [Medline: 26880141]
9. Kaewkungwal J, Singhasivanon P, Khamsiriwatchara A, Sawang S, Meankaew P, Wechsart A. Application of smart phone in "Better Border Healthcare Program": a module for mother and child care. BMC Med Inform Decis Mak 2010 Nov 03;10:69 [FREE Full text] [doi: 10.1186/1472-6947-10-69] [Medline: 21047412]
10. Kazi A, Murtaza A, Kazi A, Khurram Z, Hussain K. Effect of mobile phone text messages reminders on uptake of routine immunization among children in Pakistan-study protocol for a randomized clinical trial. J Vaccines Vaccin 2016;7(333):2. [Medline: 29514773]
11. Kazi AM, Ali M, Zubair K, Kalimuddin H, Kazi AN, Iqbal SP, et al. Effect of Mobile Phone Text Message Reminders on Routine Immunization Uptake in Pakistan: Randomized Controlled Trial. JMIR Public Health Surveill 2018 Mar 07;4(1):e20 [FREE Full text] [doi: 10.2196/publichealth.7026] [Medline: 29514773]
12. Lund S, Nielsen BB, Hemed M, Boas IM, Said A, Said K, et al. Mobile phones improve antenatal care attendance in Zanzibar: a cluster randomized controlled trial. BMC Pregnancy Childbirth 2014 Jan 17;14:29 [FREE Full text] [doi: 10.1186/1471-2393-14-29] [Medline: 24438517]
13. Nguyen NT, Vu HM, Dao SD, Tran HT, Nguyen TXC. Digital immunization registry: evidence for the impact of mHealth on enhancing the immunization system and improving immunization coverage for children under one year old in Vietnam. Mhealth 2017;3:26 [FREE Full text] [doi: 10.21037/mhealth.2017.06.03] [Medline: 28828373]
14. Schlumberger M, Bamoko A, Yaméogo TM, Rouvet F, Ouedraogo R, Traoré B, et al. [Positive impact on the Expanded Program on Immunization when sending call-back SMS through a Computerized Immunization Register, Bobo Dioulasso (Burkina Faso)]. Bull Soc Pathol Exot 2015 Dec;108(5):349-354. [doi: 10.1007/s13149-015-0455-4] [Medline: 26498331]
15. Uddin MJ, Shamsuzzaman M, Horng L, Labrique A, Vasudevan L, Zeller K, et al. Use of mobile phones for improving vaccination coverage among children living in rural hard-to-reach areas and urban streets of Bangladesh. Vaccine 2016 Jan 4;34(2):276-283. [doi: 10.1016/j.vaccine.2015.11.024] [Medline: 26647290]
16. Wakadha H, Chandir S, Were EV, Rubin A, Obor D, Levine OS, et al. The feasibility of using mobile-phone based SMS reminders and conditional cash transfers to improve timely immunization in rural Kenya. Vaccine 2013 Jan 30;31(6):987-993 [FREE Full text] [doi: 10.1016/j.vaccine.2012.11.093] [Medline: 23246258]
17. Fadda M, Galimberti E, Fiordelli M, Romanò L, Zanetti A, Schulz PJ. Effectiveness of a smartphone app to increase parents' knowledge and empowerment in the MMR vaccination decision: A randomized controlled trial. Hum Vaccin Immunother 2017 Nov 02;13(11):2512-2521. [doi: 10.1080/21645515.2017.1360456] [Medline: 29125783]
18. LeFevre AE, Mohan D, Hutchful D, Jennings L, Mehl G, Labrique A, et al. Mobile Technology for Community Health in Ghana: what happens when technical functionality threatens the effectiveness of digital health programs? BMC Med Inform Decis Mak 2017 Dec 14;17(1):27. [doi: 10.1186/s12911-017-0421-9] [Medline: 28292288]
19. Zaidi S, Riaz A, Hussain SS, Omer SB, Ali A. Applying a governance barometer to vaccine delivery systems: Lessons from a rural district of Pakistan. Vaccine 2020 Jan;38(3):627-634. [doi: 10.1016/j.vaccine.2019.10.052]
20. Punjab Information Technology Board (PITB). Tracking Vaccinators (E-VACCS): Government of Punjab URL: https://www.pitb.gov.pk/tracking_evaccs
21. Ebile Akoh W, Ateudjieu J, Nouetchognou JS, Yakum MN, Djouma Nembot F, Nafack Sonkeng S, et al. The expanded program on immunization service delivery in the Dschang health district, west region of Cameroon: a cross sectional survey. BMC Public Health 2016 Aug 17;16(1):801 [FREE Full text] [doi: 10.1186/s12889-016-3429-7] [Medline: 27530488]
22. Braun R, Catalani C, Wimbush J, Israelski D. Community health workers and mobile technology: a systematic review of the literature. PLoS One 2013;8(6):e65772 [FREE Full text] [doi: 10.1371/journal.pone.0065772] [Medline: 23776544]

23. Calderón TA, Martin H, Volpicelli K, Frasso R, Díaz Arroyo EC, Gozzer E, et al. Understanding potential uptake of a proposed mHealth program to support caregiver home management of childhood illness in a resource-poor setting: a qualitative evaluation. Mhealth 2017;3:19 [FREE Full text] [doi: 10.21037/mhealth.2017.04.03] [Medline: 28607905]
24. JSI. Africa Routine Immunization System Essential. Improving the performance of routine immunization systems in Africa ? A case of the drivers of routine immunization system performance in Cameroon URL: https://3qvw4sd8qlr2o7003493odw1-wpengine.netdna-ssl.com/wp-content/uploads/2012/11/Arise_CameroonReport_final5081.pdf
25. JSI. 2018. Strengthening Immunization for the Urban Poor: Experiences and Lessons Learned from Five Country Studies URL: https://www.jsi.com/JSIInternet/Resources/publication/display.cfm?txtGeoArea=INTL&id=22079&thisSection=Resources [accessed 2020-01-10]
26. Barau I, Zubairu M, Mwanza MN, Seaman VY. Improving polio vaccination coverage in Nigeria through the use of geographic information system technology. J Infect Dis 2014 Nov 01;210 Suppl 1:S102-S110. [doi: 10.1093/infdis/jiu010] [Medline: 25316823]
27. Gammino VM, Nuhu A, Chenoweth P, Manneh F, Young RR, Sugerman DE, et al. Using geographic information systems to track polio vaccination team performance: pilot project report. J Infect Dis 2014 Nov 01;210 Suppl 1:S98-101. [doi: 10.1093/infdis/jit285] [Medline: 25316882]
28. Stanton M, Molineux A, Mackenzie C, Kelly-Hope L. Mobile Technology for Empowering Health Workers in Underserved Communities: New Approaches to Facilitate the Elimination of Neglected Tropical Diseases. JMIR Public Health Surveill 2016;2(1):e2 [FREE Full text] [doi: 10.2196/publichealth.5064] [Medline: 27227155]
29. Teng JE, Thomson DR, Lascher JS, Raymond M, Ivers LC. Using Mobile Health (mHealth) and Geospatial Mapping Technology in a Mass Campaign for Reactive Oral Cholera Vaccination in Rural Haiti. PLoS Negl Trop Dis 2014 Jul 31;8(7):e3050. [doi: 10.1371/journal.pntd.0003050]
30. Wallis L, Blessing P, Dalwai M, Shin SD. Integrating mHealth at point of care in low- and middle-income settings: the system perspective. Glob Health Action 2017 Jun;10(sup3):1327686 [FREE Full text] [doi: 10.1080/16549716.2017.1327686] [Medline: 28838302]
31. Rothstein JD, Jennings L, Moorthy A, Yang F, Gee L, Romano K, et al. Qualitative Assessment of the Feasibility, Usability, and Acceptability of a Mobile Client Data App for Community-Based Maternal, Neonatal, and Child Care in Rural Ghana. Int J Telemed Appl 2016;2016:2515420-2515414 [FREE Full text] [doi: 10.1155/2016/2515420] [Medline: 28070186]
32. Vélez O, Okyere PB, Kanter AS, Bakken S. A usability study of a mobile health application for rural Ghanaian midwives. J Midwifery Womens Health 2014 Jan 08;59(2):184-191 [FREE Full text] [doi: 10.1111/jmwh.12071] [Medline: 24400748]
33. van Heerden A, Sen D, Desmond C, Louw J, Richter L. App-Supported Promotion of Child Growth and Development by Community Health Workers in Kenya: Feasibility and Acceptability Study. JMIR Mhealth Uhealth 2017 Dec 05;5(12):e182 [FREE Full text] [doi: 10.2196/mhealth.6911] [Medline: 29208588]
34. Chaiyachati KH, Loveday M, Lorenz S, Lesh N, Larkan L, Cinti S, et al. A pilot study of an mHealth application for healthcare workers: poor uptake despite high reported acceptability at a rural South African community-based MDR-TB treatment program. PLoS One 2013 May 28;8(5):e64662 [FREE Full text] [doi: 10.1371/journal.pone.0064662] [Medline: 23724075]
35. Gavi-The Vaccine Alliance. Annual Progress Report 2018 URL: https://www.gavi.org/results/gavi-progress-reports/

Abbreviations

EPI: Expanded Program on Immunization
LMIC: low- and middle-income country
mHealth: mobile health
TB: tuberculosis
TMK: Tando Muhammad Khan
UC: union council

Edited by G Eysenbach; submitted 18.09.19; peer-reviewed by M Fiordelli, N Jarour, D Felt, J Boegner; comments to author 26.10.19; revised version received 31.10.19; accepted 16.12.19; published 13.02.20.

Please cite as:
Zaidi S, Shaikh SA, Sayani S, Kazi AM, Khoja A, Hussain SS, Najmi R
Operability, Acceptability, and Usefulness of a Mobile App to Track Routine Immunization Performance in Rural Pakistan: Interview Study Among Vaccinators and Key Informants
JMIR Mhealth Uhealth 2020;8(2):e16081
URL: https://mhealth.jmir.org/2020/2/e16081
doi:10.2196/16081
PMID:32053115

Original Paper

Feasibility of a Mobile Health Tool for Mothers to Identify Neonatal Illness in Rural Uganda: Acceptability Study

Shababa B Matin[1*], ScB, MSE; Allison Wallingford[1*], BS, MSE; Shicheng Xu[1*], BEng, MSE; Natalie Ng[1], BS, MSE; Anthony Ho[1], BS, MSE; Madison Vanosdoll[1], BSE, MSE; Peter Waiswa[2], MBChB, MPH, PhD; Alain B Labrique[3,4], MS, MHS, PhD; Soumyadipta Acharya[1], MBBS, MSE, PhD

[1]Center for Bioengineering Innovation and Design, Department of Biomedical Engineering, Johns Hopkins University, Baltimore, MD, United States

[2]School of Public Health, Makerere University, Kampala, Uganda

[3]Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, United States

[4]Global mHealth Initiative, Johns Hopkins University, Baltimore, MD, United States

[*]these authors contributed equally

Corresponding Author:
Soumyadipta Acharya, MBBS, MSE, PhD
Center for Bioengineering Innovation and Design
Department of Biomedical Engineering
Johns Hopkins University
Baltimore, MD,
United States
Phone: 1 4105167074
Email: acharya@jhu.edu

Abstract

Background: A shortage of community health workers to triage sick neonates and poor recognition of neonatal illness by mothers contribute significantly toward neonatal deaths in low- and middle-income countries. Providing low-resource communities with the tools and knowledge to recognize signs of neonatal distress can lead to early care-seeking behavior. To empower and educate mothers to recognize signs of neonatal illness, we developed a neonatal health assessment device consisting of a smartphone app and a wearable sensor (the NeMo system).

Objective: The aim of this study was to determine if mothers in rural Uganda were willing and able to use the NeMo system during the first week of their infant's life. We also assessed mothers' responses to the device's recommendation to seek care.

Methods: A total of 20 mothers were enrolled in the study after giving birth in the Iganga District Hospital. Each mother was trained to use the NeMo system to assess her infant for signs of illness before leaving the hospital and was given the NeMo system to use at home for 1 week. Throughout the week, the smartphone tracked the mothers' usage of NeMo, and the study team visited twice to observe mothers' ability to use NeMo. Each mother was interviewed at the end of 1 week to gather qualitative feedback on her experience with the NeMo system.

Results: In total, 18 mothers completed the study; 2 mothers were withdrawn during the week because of extenuating health circumstances. Moreover, 1 day after enrollment and training, 75% (15/20) of mothers used NeMo properly with no mistakes. Three days after enrollment and training, only 1 mother placed the wearable sensor improperly on her infant. On the final study day, only 1 mother connected the device improperly. Mothers used NeMo an average of 11.67 (SD 5.70) times on their own at home during the 5 full study days. Although the frequency of use per day decreased from day 1 to day 5 of the study (P=.04), 72% (13/18) of mothers used NeMo at least once per day. In total, 64% (9/14) of mothers who received an alert from the NeMo system to seek care for their infants either called the health care professional working with the study team or reused the system immediately and found no danger signs. All 18 mothers *agreed* or *strongly agreed* that the NeMo system was easy to use and helped them know when to seek care for their babies.

Conclusions: NeMo is a feasible and acceptable tool to aid mothers in rural Uganda to assess their infant's health.

(JMIR Mhealth Uhealth 2020;8(2):e16426) doi:10.2196/16426

KEYWORDS

newborn; neonatal health; community health workers; maternal behavior; Uganda; World Health Organization; mobile apps; telemedicine

Introduction

Background

An estimated 2.6 million neonatal deaths occur in the first month of life worldwide each year [1]. Roughly half of these deaths occur in the first 24 hours of life, with another 25% occurring in the first week of life [2,3]. Most of these deaths occur in low- and middle-income countries (LMICs) in community settings at home largely because of preventable causes such as sepsis, pneumonia, hypothermia, and complications of preterm birth, which could be prevented by timely identification of illness leading to early care-seeking behavior [2,4-9].

In Uganda, the neonatal mortality rate is estimated to be 27 per 1000 live births overall and 34 per 1000 in rural communities [10,11]. Like in other sub-Saharan African countries, a majority of neonatal deaths occur outside of the formal health system [12]. Poor recognition of neonatal illness is a major barrier for optimal care seeking by mothers [13]. An analysis of 64 neonatal deaths in eastern Uganda found that 54% occurred at home. Caretaker delay in problem recognition or in deciding to seek care was a major contributor to 50% of these deaths [14]. Many health care systems in LMICs, including Uganda, utilize village health teams (VHTs) of volunteer community health workers (CHWs) to visit mothers at home after they give birth to identify neonatal illness during the critical first week of life. In Bangladesh, neonatal assessment by a CHW has a sensitivity of 85% and a specificity of 75% in identifying infants 0-6 days old in need of admission to a facility [13]. Although CHW visits have been shown to lower the risk of neonatal death, only 5% of Ugandan neonates are visited in the first 48 hours of life because of the limited availability and bandwidth of CHWs [11,15].

Shifting the task of neonatal assessment and recognition of danger signs from CHWs to mothers is a promising strategy to improve early identification of neonatal illness [8,16]. However, the sensitivity of unassisted maternal recognition of symptoms of neonatal illness has been shown to be poor in developing countries [13,17,18]. Currently, the lack of knowledge and tools needed to evaluate neonatal health prevents families from identifying illness without CHW support.

The multidisciplinary team of students and faculty from the Johns Hopkins University Center for Bioengineering Innovation and Design (CBID), Johns Hopkins School of Public Health, and field partners from Makerere University in Uganda are developing an evidence-based system that we have named NeMo as a tool to guide mothers to identify danger signs of severe illness in their neonates. The goal of this system is to enable reliable and consistent assessment of neonates for identification of signs of illness to facilitate early referral of sick neonates, especially during the critical first week of life.

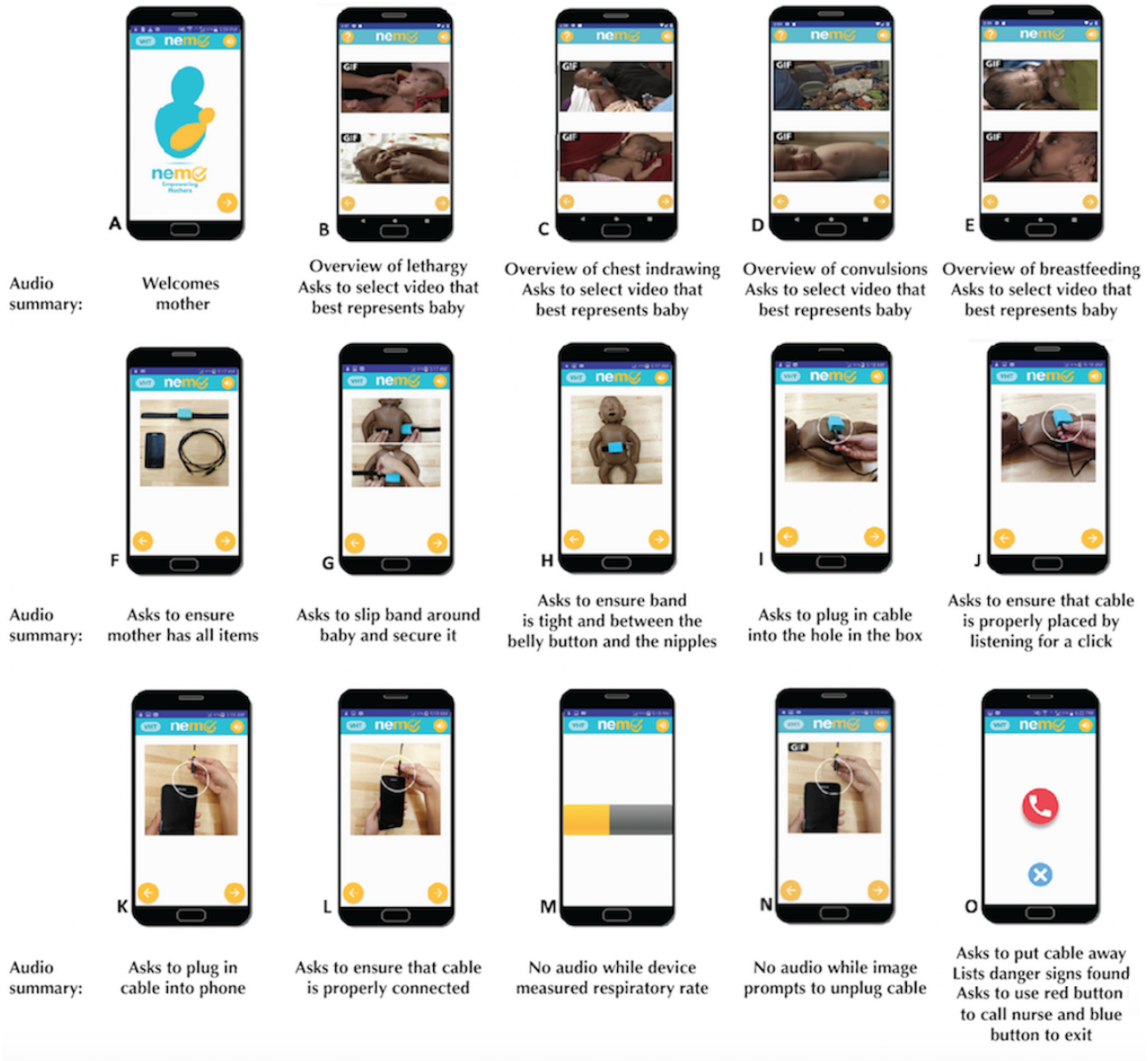
The NeMo System

NeMo is a two-part system designed to empower mothers to identify the 4 qualitative symptoms most indicative of severe neonatal illness using a smartphone preloaded with an interactive app (the NeMo app) as well as detect respiratory distress using a low-cost, wearable sensing band (the NeMo band) that measures breathing rate (Figure 1). NeMo aids assessment of 5 danger signs of neonatal illness through the use of the app and band two to three times a day. The Integrated Management of Childhood Illness guidelines published by the World Health Organization promote a set of general danger signs to identify neonatal illness [19]. A subset of these clinical signs including difficulty feeding, convulsions, movement only when stimulated, respiratory rate of 60 breaths per minute or more, and severe chest indrawing have been previously identified as some of the most valuable predictors of a 0-59 day-old infant requiring hospital care [20].

Figure 1. Smartphone connected by an audio cable to the NeMo band on a neonatal mannequin.

Mothers are instructed to use the NeMo system thrice a day, for the first week of their baby's life. The NeMo app interface has been previously described by Vanosdoll et al [21]. The app includes pictures, symbols, and audio recordings in the local language so that any mother, regardless of literacy, is able to navigate the app and examine her baby for signs of illness. The user interface of the NeMo app is shown in Figure 2. The steps are as follows: the initial home screen greets the mother and asks her to press the arrow to proceed with the assessment (Figure 2, A). The following 4 screens ask her to indicate the presence of the 4 qualitative danger signs in her infant: lethargy (Figure 2, B), chest indrawing (Figure 2, C), convulsions (Figure 2, D), and difficulty breastfeeding (Figure 2, E) by displaying 2 Graphic Interchange Format (GIF) images, one showing a newborn exhibiting the danger sign and one showing a healthy infant. The mother is asked to select the picture that best represents her newborn. Arrows, along with audio instruction, appear to direct the mother to move to the next or the previous screen once an image is selected. The following 7 screens use audio and visual instructions to guide the mother through properly placing the band around her baby and connecting the band and phone via the audio cord (Figure 2, F-L). The NeMo band connects to the smartphone through an audio cable via the headphone jack, which transmits signal for processing. The NeMo band uses a sensor housed in a plastic box with a silicone cover that is mounted on an elastic strap, the ends of which are attached using a generic hook-and-loop fastener similar to a Velcro closure. The sensor is fastened on top of the abdomen and detects abdominal movement to measure respiratory rate.

Figure 2. The user interface of the NeMo app.



Upon completion of band placement, the NeMo band measures respiratory rate for 1 minute while showing the progress on the screen (Figure 2, M). Once the measurement is complete, a screen with a GIF demonstrating audio cord removal appears (Figure 2, N). As the speaker is inherently disabled when the phone detects an audio jack connection, no audio can be heard for this instruction. When the cable is removed, reenabling audio, the final screen instructs the mother to remove and store

the device until the next use. The final screen of the app lists any danger signs detected and, if at least one danger sign is present, recommends that the mother seek medical attention for her baby. The final screen further recommends that the mother still seek care even if she believes her infant to be sick, but the device has not detected a danger sign. Two icons appear at the end of the audio recording. The mother can press the red phone icon to call a health care worker or press the blue X to close the app (Figure 2, O).

Objectives

We undertook a small-scale pilot study of the NeMo system to determine the acceptability and ease of use of the system in the home setting. The primary objective of the study was to understand the willingness of mothers in rural Ugandan villages to use the investigational device in a real-world scenario. We also hoped to better understand barriers to adoption to inform future iteration on and implementation of the system.

The study imitated a real-world scenario of a mother using the device in her home to assess her infant's health two to three times per day for the first week of life. The general research aim was to assess usage of the device by mothers after training to ascertain the NeMo system's level of acceptability with mothers. Specific research aims included determining the following:

1. Mothers' skill retention of correct device usage following an initial training session
2. Mothers' willingness to use the device at home
3. Mothers' initiative to seek care for their neonates based on NeMo's recommendations.

Methods

Study Sites and Collaborators

This study was undertaken in eastern Uganda in the Iganga-Mayuge districts over the course of 3 weeks. The population demographic in these two districts is considered representative of rural Uganda with regard to socioeconomic landscape, education levels, and neonatal mortality rates [14,22,23]. The study team was accompanied by a team of local health workers including nursing officers and midwives based out of Iganga District Hospital, who also acted as translators for the study team. Study coordination was aided by Uganda Development and Health Associates (UDHA). The study was approved by the Johns Hopkins Institutional Review Board (IRB#00191743), the Institutional Review Board of Makerere University School of Public Health, and The AIDS Support Organization in Uganda. Written consent was obtained from all participants and was available in Lusoga and English. Before the start of the study, the NeMo device's performance was validated in the Johns Hopkins Hospital nursery in a separate study (IRB#00117008) described elsewhere [24].

Study Design

The study involved recruitment of mothers in the Iganga District Hospital, training participants to use the NeMo system before discharge from the hospital, and lending participants the device to use for 1 week at home. The study team visited participants' homes twice during the week.

Participant Enrollment

Overall, 20 women who gave birth at Iganga District Hospital were enrolled before they were discharged from the hospital. The inclusion criteria of the study required that the participant must be aged 18-45 years, must be clinically stable, and must have a clinically stable infant under 7 days of age. The team selectively enrolled a diverse study cohort based on the following factors to best represent participants' differing socioeconomic status: distance of participant's residence from the hospital, number of antenatal care sessions attended, and cellphone access. Participants were told during recruitment that they would receive a small gift at the end of the study as a token of appreciation, with no mention of its value.

Training to Use the NeMo System

Participants were interviewed to obtain demographic information using a structured interview guide and trained to use the NeMo system before they were discharged from the hospital. Participants were first asked to identify sick children from a series of videos to assess baseline knowledge of illness, after which they received a short lesson on neonatal danger signs. Participants were then taught to use the NeMo system by answering the danger sign questions on the NeMo app when shown additional videos of sick and healthy children. Participants practiced placing the band on a neonatal mannequin and, finally, completed a full use of the system on their own babies. A detailed description of the training protocol can be found in Multimedia Appendix 1.

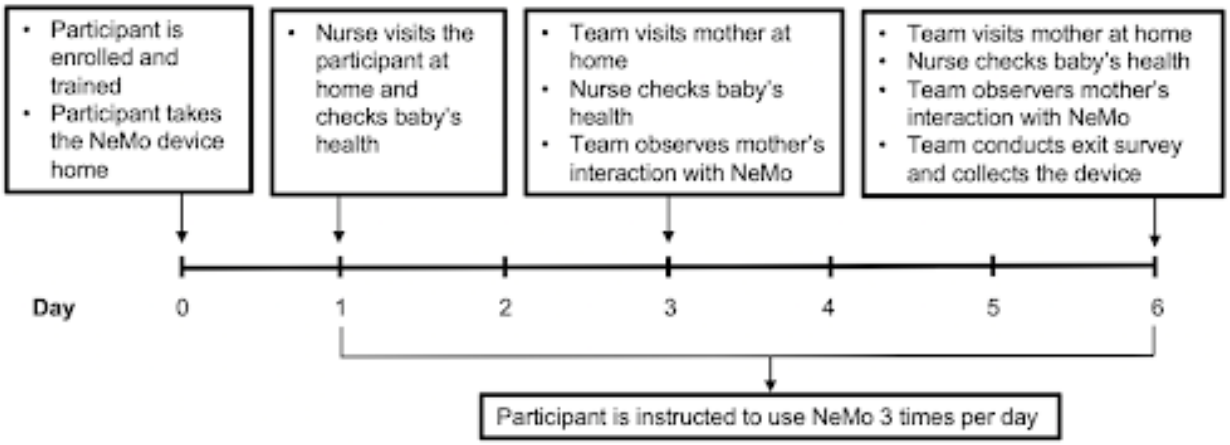
Device Usage in the Home

Upon completion of training, mothers were provided with a heavy-duty zip bag, as shown in Figure 3. The smartphone was loaded with the NeMo app, and all other apps were hidden to prevent confusion and improper use of the phone. Mothers were instructed to use NeMo three times each day (morning, noon, and night) to assess their baby's health daily during the first week of the baby's life. The study team members collected the zip bag and its contents at the end of the week. Each mother was provided an unused NeMo device to decrease the risk of cross-contamination between neonates.

A member of the health worker team visited the mothers in their homes on study day 1 to assess each baby's health and to observe the mothers using the device, address concerns, and correct any improper usage. The study team, accompanied by a health worker, visited mothers in their homes on study days 3 and 6 to observe device usage, conduct interviews, and assess each baby's health, as summarized in Figure 4. This framework was designed to mimic the recommended CHW postbirth visitation schedule. At no point during the visits were the mothers asked to use the device more frequently. Mothers received a small gift consisting of baby items, costing a total of 30,000 UGX (US $8) at the end of the study.

Figure 3. Equipment given to each study participant for the duration of the study: (A) 3.5-mm male-to-male TRRS audio cable, (B) Alcohol wipes, (C) NeMo device, (D) Smartphone charging cable with type-G adapter, and (E) Samsung Galaxy S5 smartphone.

Figure 4. Study protocol for each day of the study beginning with enrollment on day 0 and ending with exit on day 6.



Data Collection

During training, data on baseline assessment of danger sign knowledge and rounds of training video vignettes were collected. The study team collected qualitative feedback and responses from mothers using a Likert scale questionnaire and structured interview guides during each encounter, to assess insights related to device use.

During home visits, study team members observed device usage by the mother and recorded any mistakes. Incorrect use was immediately corrected following observation. During visits on days 3 and 6, a video recording was taken of the mother using the device for future reference.

The backend of the NeMo app recorded the mother's responses to the qualitative danger sign questions and the respiratory rate measured throughout the study period. Each screen opening and button press was time-stamped during each use. The mother was considered to have successfully completed a device use if the phone recorded an interaction with every single screen within the app.

Data Analysis

Training and Skill Retention

The average score on the danger signs baseline assessment was tested for significance using a *t* test. The null hypothesis of this *t* test was that mothers would score an average of 8/16 correct, as this is the most probable score through random guessing. One-way analysis of variance (ANOVA) was performed to detect significant differences in scores between rounds of video vignettes in phase 3 of training (Multimedia Appendix 1). Skill retention was determined as correct steps of use completed on observation.

Frequency of Use and Impressions of Device

Quantitative data, including mothers' number of uses tracked by the phone, time spent on each screen, and Likert scale responses, were analyzed by manual sorting and summarizing.

Repeated measures ANOVA was used to detect significant differences in device use frequency between study days, and posthoc Tukey tests were conducted to detect where those differences occurred. Qualitative data including the study team's observations about usage and mothers' interview responses were decoded and de-identified and then analyzed by employing themes identified a priori, including opportunities and barriers surrounding the NeMo system within the homes of new mothers.

Responses to Danger Sign Trigger

Danger sign triggers and the corresponding responses by mothers were summarized and categorized. Mothers' responses were analyzed through a qualitative discussion.

Results

Study Population Demographics

The study cohort consisted of mothers from 19 villages across the Iganga-Mayuge districts; distances between the mothers' homes and Iganga District Hospital stretched from 400 m to 24 km. During the 3-week study period, 20 mothers were recruited and 18 completed the study. Moreover, 2 participants were withdrawn in the course of the study because of extenuating health circumstances. Data collected from these 2 participants before they were withdrawn from the study, including day 0 interview responses, training results, and device uses, are included in these results. Background information from participants is shown in Table 1.

Table 1. Demographics of women enrolled in the study (N=20).

Characteristic	Values
Age (years), mean (SD)	27.2 (6.84)
Distance from hospital (km), mean (range)	7.78 (0.40-24)
Parity, mean (range)	3.5 (1-7)
First time mothers, n (%)	5 (25)
Own a phone, n (%)	11 (55)
Have ever used a smartphone, n (%)	8 (40)
Able to charge a phone, n (%)	18 (90)
Attended ANC[a], n (%)	19 (95)
ANC sessions attended, mean (range)	4 (0-5)
Knew danger sign, n (%)	
Failure to breastfeed	8 (40)
Convulsions	5 (25)
Breathing difficulty	2 (10)
Lethargy	2 (10)

[a]ANC: antenatal care.

Training Results

Training sessions were successfully completed by each of the study participants and took an average of 1.5-2.5 hours to complete. During the initial preassessment of baseline knowledge of neonatal illness (Multimedia Appendix 1), the average score on the initial danger sign knowledge assessment was 13.95 (SD 0.94) out of 16, which was significantly higher than random guessing (P<.001). However, 55% (11/20) of mothers were unable to list the correct presentation of illness despite correctly identifying that the baby in the video was sick. One-way ANOVA did not reveal a significant difference in mothers' average scores between the first, second, and third rounds (P=.36) of practicing danger sign identification using the NeMo app.

Table 2 summarizes correct task completion when the mother used NeMo for the first time on her baby during training on day 0. The two largest sources of error were incorrect placement of the band and failure to disconnect the audio cord from the phone at the end of the respiratory rate and temperature assessment. The largest contributing factor to incorrect band placement was failure to appropriately tighten the band around the baby's abdomen.

All mothers indicated that the voice directions in the app were understandable, and 75% (15/20) of the mothers indicated that they had learned at least one new neonatal danger sign. Following training, 100% (20/20) of mothers stated that they would feel comfortable using the device three times per day. During the study exit on the last day of the study, 83% (15/18) of mothers indicated that the training protocol they underwent on day 0 was sufficient to enable independent use of the device in their homes.

Table 2. Percentage of mothers who correctly completed each task during the observed uses on neonates.

Task	Mothers who correctly completed each task, n (%)			
	Day 0 (training)	Day 1	Day 3	Day 6
Unlocked the phone and opened the app	20 (100)	20 (100)	18 (100)	18 (100)
Navigated properly through the app	17 (85)	14 (70)	18 (100)	18 (100)
Correctly answered qualitative questions	20 (100)	20 (100)	18 (100)	18 (100)
Properly placed the device on the neonate's abdomen	6 (30)	18 (90)	17 (94)	18 (100)
Properly connected the audio cord to both audio jacks	16 (80)	20 (100)	18 (100)	17 (94)
Disconnected the audio cord from phone unprompted	7 (35)	18 (90)	18 (100)	18 (100)
Closed the app to acknowledge assessment finished	19 (95)	19 (95)	18 (100)	18 (100)

Skill Retention

During the day 1 visit, 75% (15/20) of mothers were able to properly execute all the steps of using the device on their infants in front of the health worker. The remaining 25% (5/20) of mothers were retrained by the visiting health worker. Mistakes with device placement included placing the device too loosely to obtain respiratory rate (1 mother), placing the box upside down on the abdomen (1 mother), and failing to unplug the connection cord from the phone without prompting (2 mothers). In addition, 3 mothers navigated the app improperly, which resulted in skipping the audio indicating if any danger signs had been detected. During the day 3 visit, only 5% (1/18) of mothers needed to be retrained, as they placed the sensor box upside down. Only 1 mother needed to be prompted to unplug the connection cord when observed on the day 6 visit.

Device Usage by Mothers

The 20 mothers enrolled in the study successfully completed the app a total of 252 times over the course of the study. On day 1 and day 3, the mother was asked to use the device while the study team observed, and this use was counted as a *prompted use*. The uses that the mother performed by herself at home, which were recorded by the phone, were counted as *unprompted uses*. On average, mothers performed 11.67 (SD 5.70) complete, unprompted uses per week-long study period. As the mother was prompted to use the device once on day 1 and day 3, we considered the ideal number of unprompted uses on these days to be two uses, compared with the ideal number of three unprompted uses on the other days. The difference between actual uses (mean 11.67, SD 5.70) compared with the ideal 13 times is not statistically significant (one-sample *t* test, P=.33). The frequency of use for each day has been normalized on a ratio of the ideal use of that day and presented in Figure 5 as the distribution of complete, unprompted uses by mothers on each day of the study.

There was a significant difference between the normalized frequency of unprompted use across the days of the study (repeated measures ANOVA, P=.005). A significant drop in normalized frequency was found between day 1 and day 7 of the study (posthoc Tukey test, P=.04); however, a significant difference was not found between any other 2 days. Figure 6 shows the distribution of the percentage of mothers who completed a device use 0, 1, 2, and 3 or more times each day.

Of the 18 participants who completed the study, 13 (72%) used NeMo consistently, completing a device use at least once per day. Only 2 participants skipped using NeMo for 2 or more consecutive days. In all, 9 mothers used the device more than the recommended three times a day at least once. From the exit survey, reasons for not using NeMo three times a day included social obligations outside the home, refusal to unwrap the baby on cold mornings, housework, caring for a sick child, and the phone being sent away for charging.

Mothers consistently used the device on their own at home, with most mothers using it at least once every day. Half of the mothers stated that they would like to use the system even more frequently than recommended because it helped them to monitor the health of their baby.

Figure 5. Box and whiskers plot of normalized unprompted uses expressed as a ratio of unprompted uses and expected number of uses. For example, on day 1, mothers on average used NeMo 1.25 times more than expected. Each point represents the ratio of uses by one participant on a corresponding day. Expected number of unprompted uses was 2 times on days 1 and 3 and 3 times on days 2, 4, and 5.

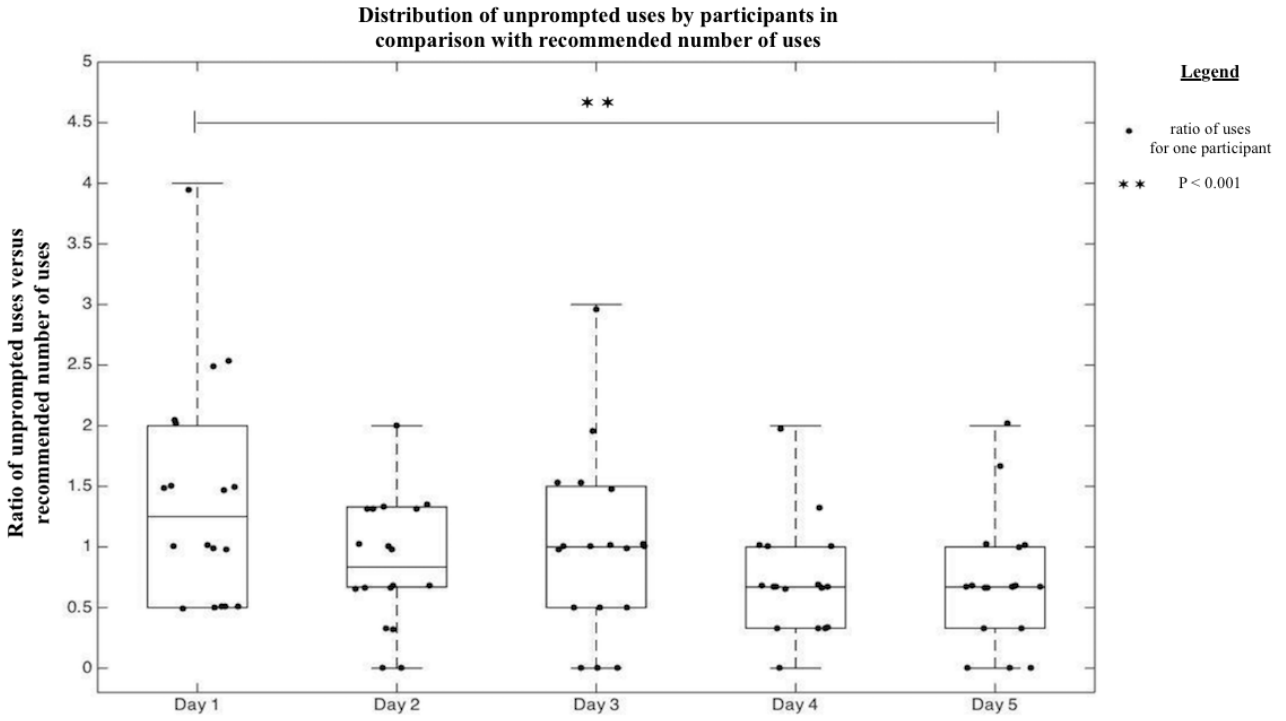
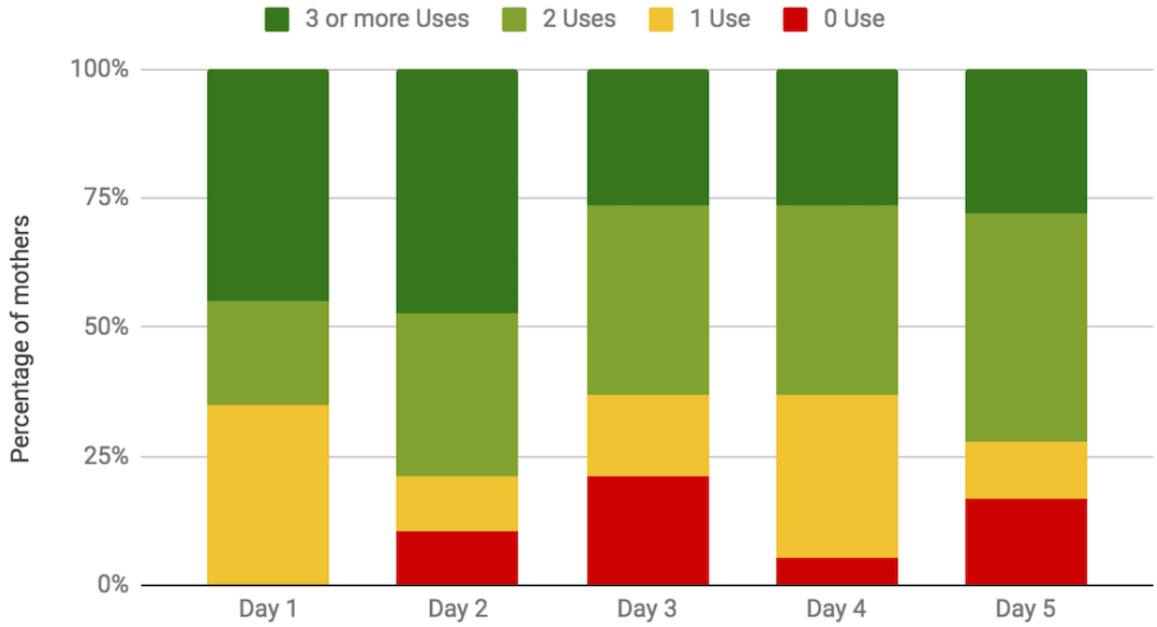


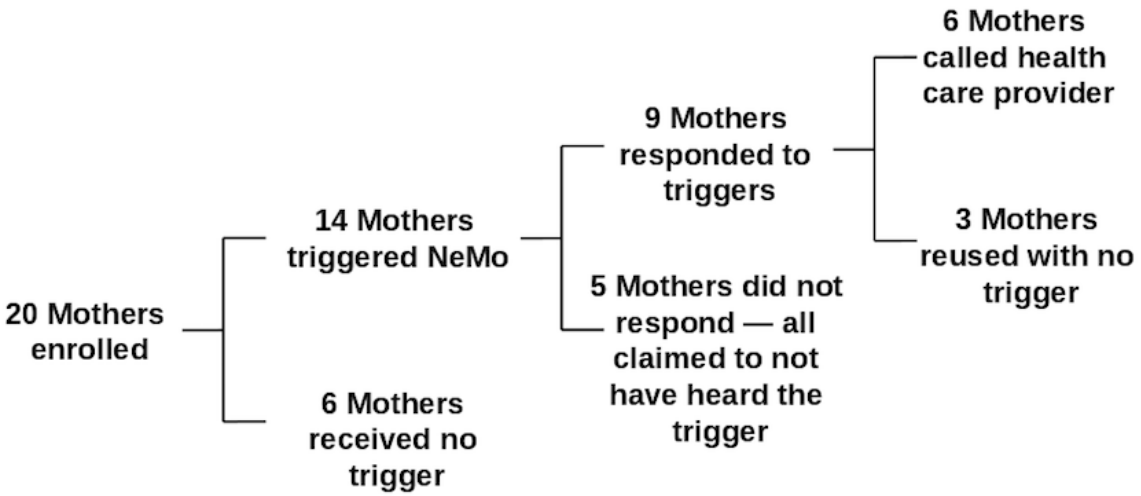
Figure 6. Distribution of the percentage of mothers who used the device unprompted 0 times, 1 time, 2 times, and 3 times or more, over the course of 5 days. Most mothers used NeMo 2 or more times a day, and very few mothers failed to use the device on any given day.



Neonatal Illness Assessment by Mothers at Home

In total, 14 mothers received a total of 63 triggers from the NeMo app warning them that their baby had an elevated respiratory rate; 5 of these mothers did not recall hearing the warning from the phone when asked about it during their follow-up interviews. None of these 5 babies were actually sick when assessed by the study nurse. In total, 9 mothers indicated that they were aware of a trigger. We considered the mother to have responded to the trigger if she either called the health care provider or reused NeMo on her baby to find that the baby was healthy. Figure 7 shows a summary of responses to triggers.

Figure 7. Summary of responses to NeMo danger sign triggers.

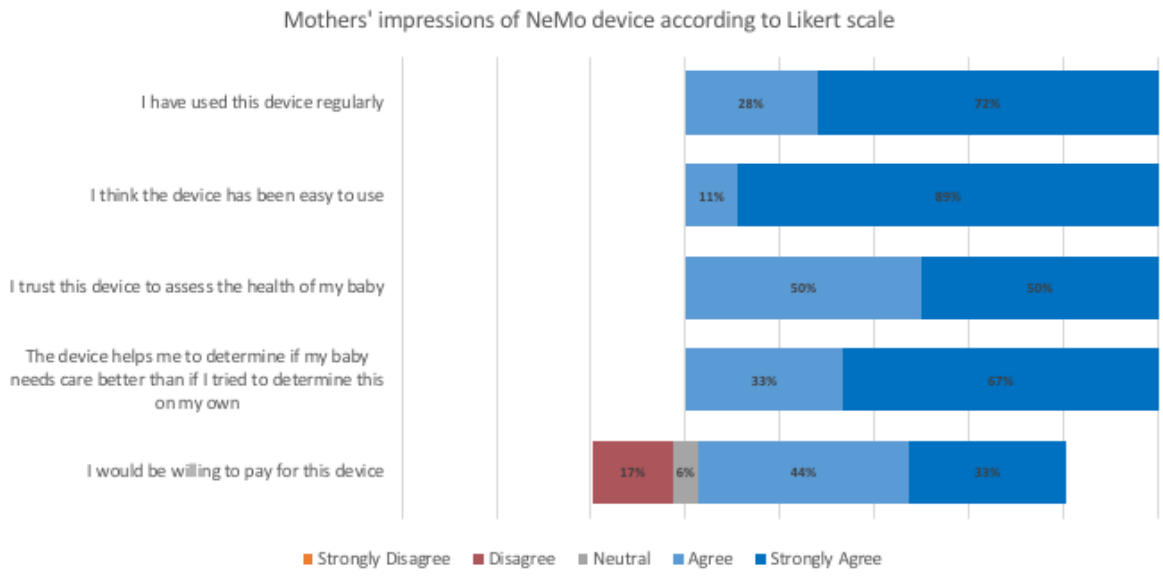


In total, 6 mothers contacted a health care provider following at least one of the triggers they received. One of the babies of a mother who called had a cord infection and was brought to Iganga District Hospital. In addition, another baby whose mother neither received a trigger from NeMo nor called was found during the day 1 visit to have a mild cord infection and was treated at home with medication and proper cord care. Another mother called the on-call health care professional out of concern for her baby's health without prompting from NeMo.

Impressions of Device

During the exit interview, each participant was asked about her experience with and impressions of the NeMo system using a Likert scale. Mothers' responses to each statement are shown in Figure 8.

Figure 8. Mothers' responses to Likert scale statements regarding their experience using the device after 6 days.



Willingness to Use

Using a composite scoring system (strongly agree=5 and strongly disagree=1), the statement "I have used the device regularly" had a composite score of 4.72 (median 5, IQR 1). The statement "I would trust this device to assess the health of my baby" had a composite score of 4.5 (median 4.5, IQR 1). All 18 mothers who completed the study answered that they would like to use the device again if they had another baby, and 94% (17/18) of mothers said that they would recommend using the device to other women in their village. During the exit survey, 5 mothers stated that they thought the device should be

used more than three times a day and suggested instead that recommended daily usage be increased to four or five times.

Throughout the study, mothers were encouraged to express their concerns and ask questions about the device. Few mothers expressed concerns about using the device. Common themes include concerns about the electrical safety of the device, potential stress to the baby caused by the band, and unwillingness to unwrap the baby to put the device on when the weather is cold. All of the reported concerns or questions were answered by the team when they were raised.

Ease of Use

All mothers *agree* or *strongly agree* that the device was easy to use, giving a composite score of 4.89 (median 5, IQR 0). All 18 mothers answered that they had become more comfortable using the device over the course of the study.

Perception of Usefulness

All mothers *agree* or *strongly agree* that the device helped them know when to seek care for their babies, resulting in a composite score of 4.66 (median 5, IQR 0). The most common reasons given for agreeing with this statement were that the device can assess breathing rate, which the mother cannot do on her own (4 mothers), and the device displays the danger signs (3 mothers). In total, 89% (16/18) of the participants who completed the exit survey said that other mothers would find the device useful.

Device Maintenance

Out of the 20 enrolled mothers, 11 (55%) were able to charge phones at home, whereas the rest needed to charge at a neighbor's house or nearby charging station up to 1.5 km from their home. During recruitment, 10% (2/20) of the mothers answered that they would have major difficulties (ie, have to travel a long distance or pay) and were, thus, provided with power banks to facilitate charging. Out of the 18 participants who completed the study, 11 (61%) charged the phone at least once during the study period. There were no adverse system events (including device breakage or loss of either phone or device) during the study despite 55% (10/18) of participants expressing concerns about losing or breaking the device. All devices remained intact and functional by day 6 when the devices were collected.

Discussion

Principal Findings

In this study, we assessed if mothers in rural Uganda were willing and able to use the NeMo system during the first week of their infant's life and if NeMo would trigger care-seeking behavior. Findings confirmed that mothers in rural Uganda would benefit from more education on recognizing signs of neonatal illness. The skill retention and usage results demonstrated that NeMo has a high level of usability and acceptability among mothers. Usability improvements could potentially increase the accuracy of the sensor and users' understanding of care-seeking recommendations.

Training and Skill Retention

Enrolled mothers could recognize a child in clear, visible distress as sick with significantly better accuracy than random guessing. However, most mothers were unable to list a specific reason for illness, which is in line with previous studies demonstrating poor knowledge of danger signs among women in community settings. Although mothers scored well when identifying very pronounced examples of neonatal distress shown during the training, education of specific danger signs is needed to enable early recognition of more subtle presentations of illness.

Mothers' ability to correctly use NeMo increased over the week through repeated use, showing that the overall system is intuitive to use. In this study, it was found that only the inability to consistently tighten and place the band arose as a primary usability concern. To obtain a signal, the sensor must be placed centrally on the neonate's abdomen (in between the nipples and midway between the umbilical cord and the nipples) and the band must be secured tightly around the baby, such that the outward movement of the baby's abdomen during a breath presses on the underside of the box (see Figure 1). Throughout the study, the team observed that erroneous respiratory rate readings resulted from incorrect band placements that were too loose or too tight, band placement on the chest rather than the abdomen, and poor audio jack connection to the device. In addition to a better training protocol, which better addresses band placement, other usability improvements such as reengineering of the band to eliminate memory burden for mothers must be made before any large-scale implementation efforts.

Willingness to Use

For NeMo to be an effective task-shifting tool, it must be well accepted by mothers such that they are willing to use the device regularly to assess their babies.

Mothers enrolled in our study consistently used the device on their own at home, with most mothers using it at least once every day. The average use at each day was at least two times. The study recommended mothers to use NeMo three times a day to ensure that enrolled babies were screened as often as possible without overburdening mothers. However, the use of NeMo even once a day greatly raises the frequency of neonatal screening during the first week of life. With 72% (13/18) of mothers using NeMo at least once every day, and the weekly average number of uses being 11.67 (SD 5.70), enrolled babies in the first week of life were being assessed approximately 10 times more with NeMo than they would have been within the current health care system in Uganda, where VHTs are overburdened and, thus, unavailable to carry out neonatal assessment with the recommended frequency. Therefore, NeMo has the potential to address this gap in the health care system.

A large number of mothers used the device more than the recommended three times on a given day of the study, especially on the first study day (Figure 5). The increased frequency of usage could be because of the novelty factor of NeMo among mothers, which must be considered in interpreting the generalizability of the usage results. Longer-term, large-scale studies are needed to assess the frequency of usage among

mothers in a community that has become familiar with the NeMo device. Usage in excess of three times per day may also reflect mothers' heightened anxiety about the health of their babies, especially in the first days of life, which may translate to frequent NeMo usage in a real-use case.

Behavior Change

NeMo's ability to task-shift neonatal assessment to mothers to reduce preventable neonatal deaths depends on its ability to initiate care-seeking behavior in mothers. Mothers' responses to its recommendations to seek care serve as indicators of the behavior change initiated by NeMo. The cases observed suggest that mothers who claimed to understand the device's audio recommendation to seek care are led to take further action to protect the baby's health.

During the study, the device signaled false-positive triggers for 13 mothers and one true-positive trigger for a sick neonate. Our observations suggest that many false positives were likely because of erroneous placement of the band. For all mothers who received a high respiratory rate trigger in the presence of the study team, it was observed that upon tightening of the band around the neonate, a normal respiratory rate was then recorded. Therefore, future iterations of the device require further considerations in human factors design that mitigate incorrect band placement and, thus, false-positive respiratory rate findings.

Out of the 14 mothers who received a trigger from the device, 5 claimed to have not heard the recommendation to seek care. Our posthoc analysis suggests that the app's audio and visual prompts to indicate the presence of a danger sign may have been unclear or too subtle, which may be responsible for some of these failures to acknowledge care-seeking recommendations. Modification of the app user interface to make the danger sign trigger more obvious may increase understanding of the danger sign trigger.

The remaining 64% (9/14) of mothers who received a trigger took action to further assess the baby's health, which the team interpreted as understanding and trusting the trigger. The team considers the mothers who used the device again immediately after the trigger to find no danger signs to have had an appropriate response to the trigger. The behavior of the 6 mothers who called the health care worker immediately following a trigger indicates NeMo's potential to lead mothers to seek care for sick newborns.

A major risk of the NeMo device is false negatives wherein the device would fail to detect a danger sign in a sick newborn, resulting in a mother not seeking care because of false reassurance from the device. The behavior of mothers in our small cohort does not show evidence that the device will deter mothers of sick infants from seeking care, although the study was not powered to detect such events; 1 mother even called the health care professional without prompting by the NeMo device.

Limitations of Study

This acceptability study gained preliminary evidence on the feasibility of NeMo implementation. Given the formative nature of the study, it was not powered to show effectiveness of the intervention. Rather, the objective of this study was to show proof-of-concept and to identify any major barriers to implementation so that a more rigorous randomized controlled trial (RCT) could be carried out based on the results.

The study was not able to assess the ability of mothers to identify qualitative danger signs aided by the NeMo app, as none of the babies of mothers enrolled displayed any of these danger signs, and none of the mothers answered in the NeMo app that her baby had a danger sign.

Mothers may have been influenced to use the device more or less frequently because of the intermittent visits by the health care provider and the study team. On one hand, mothers may have been reminded or encouraged to use the device by the presence of the study team. Conversely, the mothers may have been discouraged from assessing their infants on their own because the infant's health was assessed during the visit. The visits were limited to the days that a CHW would be expected to visit to simulate the reminders to use the device that a mother might be expected to receive in a real-use case. However, CHWs rarely visit as often as the recommended three times in the first week of life.

As a result of the sample size and the recruitment protocol, the generalizability of the study was limited. For example, being able to charge the smartphone was not among the selection criteria, and power banks were given to 2 mothers who expressed difficulty charging phones at home. Therefore, the willingness of mothers with difficulty accessing the power grid to go out of their way to use the device could not be determined.

This study was limited in its ability to assess the potential of the NeMo device to initiate care-seeking behavior in a real-use case in the local health care system. Mothers in the study who wished to seek care for their infants were provided with access to an on-call health care worker, rather than make a costly and arduous trip to a health center. We provided an on-call health care worker for the ethical consideration that using the NeMo device may burden mothers unnecessarily in the cases of false positives or may deter mothers from seeking care in the cases of false negatives. Studies have shown significant financial and sociocultural barriers to seeking medical care in the communities the NeMo device targets, such as financial constraints, distance from medical facilities, and reliance on traditional medicine [25].

Future Directions for the NeMo System

In light of the findings from this study, the next steps for the NeMo system include reengineering of the band to reduce the memory burden to mothers, reducing the occurrence of false-positive danger sign triggers and making it obvious to mothers that danger signs have been found in her baby. To facilitate implementation to scale, models that make smartphones accessible must be considered.

To accurately measure quantitative danger signs and prevent false-positive triggers, the user needs to place the NeMo band at the correct location and with appropriate tightness. Most mothers could perform the former task with the help of audio and visual directions but struggled with the latter. To guide

mothers to place the band consistently and correctly, a visual indicator on the band that reflects the tightness could be added. In addition, other visual indicators such as arrows indicating orientation of placement may also increase accuracy of device placement. To draw the mother's attention to any danger sign triggers, visual cues as well as audio alarms that indicate the appropriate danger signs may be added.

The requirement of a smartphone remains the biggest barrier to widespread implementation of NeMo. For implementation to scale, various business and public health models need to be investigated to make smartphones accessible to those who do not own one. Multiple models are currently being investigated by the research team for this purpose.

The larger implication of the implementation of a mobile health system like NeMo is the increased referral of neonates demonstrating danger signs. The NeMo system only addresses the creation of early care-seeking behavior. To save neonatal lives, a responsive supply chain of treatment must also be established.

Conclusions

The study presented here demonstrated acceptability and feasibility of mothers in a rural community using a NeMo device on their own at home. Mothers in rural eastern Uganda were willing to use the NeMo system to assess their infants frequently during the first week of life in a simulated use case. Mothers were able to understand how to use the NeMo system with minimal training and retained the skill to use the device for 6 days. Most importantly, the 9 mothers who claimed to have understood the device's trigger to seek care took steps to ensure the health of their infants, demonstrating the ability of the NeMo system to initiate early care seeking by mothers. These findings indicate mothers' increased awareness and understanding of neonatal illness, which suggests that NeMo could contribute to more referrals leading to higher neonatal survival rates. The results of this study also provide insights that will guide improvements in future prototypes of the NeMo system, for example, the next iterations of the NeMo system will incorporate a clearer danger sign trigger and assessment of an expanded set of danger signs (temperature and cord infection).

Implementation of the NeMo system has the potential to become a public health intervention by empowering and educating mothers to identify neonatal illness to promote early care-seeking behavior. Following further prototype iteration, the NeMo system will be introduced in the community in a large-scale RCT to validate the use of this intervention to reduce neonatal deaths in the home.

Acknowledgments

Funding for this research was provided by a grant from the Bill and Melinda Gates Foundation. This research was also supported by Johns Hopkins CBID, Johns Hopkins Center for Global Health, Makerere University School of Public Health, and UDHA.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Training protocol.
[DOCX File , 14 KB - mhealth_v8i2e16426_app1.docx]

References

1. World Health Organization. Neonatal Mortality URL: https://www.who.int/gho/child_health/mortality/neonatal_text/en/ [accessed 2019-09-16]
2. Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering Team. 4 million neonatal deaths: when? where? why? Lancet 2005;365(9462):891-900. [doi: 10.1016/S0140-6736(05)71048-5] [Medline: 15752534]
3. The United Nations Children's Fund (UNICEF). 2019 Sep. Neonatal Mortality URL: https://data.unicef.org/topic/child-survival/neonatal-mortality/ [accessed 2019-09-16] [WebCite Cache ID 77ppaFTWl]
4. Save the Children. 2001 May. State of the World's Mothers 2001 URL: https://www.savethechildren.org/content/dam/usa/reports/advocacy/sowm/sowm-2001.pdf [accessed 2019-09-18]
5. World Health Organization. First Global Review and Coordination Meeting on Integrated Management of Childhood Illness (IMCI). In: World Health Organization. 1997 Presented at: WHO/CHD'97; September 9-12, 1997; Santo Domingo, Dominican Republic URL: https://apps.who.int/iris/bitstream/handle/10665/64629/WHO_CHD_97.11.pdf?sequence=1&isAllowed=y
6. Black RE, Morris SS, Bryce J. Where and why are 10 million children dying every year? Lancet 2003 Jun 28;361(9376):2226-2234. [doi: 10.1016/S0140-6736(03)13779-8] [Medline: 12842379]
7. World Health Organization, UNAIDS. The World Health Report 2005: Make Every Mother and Child Count. Geneva, Switzerland: World Health Organization; 2005.
8. Bang AT, Bang RA, Reddy MH, Baitule SB, Deshmukh MD, Paul VK, et al. Simple clinical criteria to identify sepsis or pneumonia in neonates in the community needing treatment or referral. Pediatr Infect Dis J 2005 Apr;24(4):335-341. [doi: 10.1097/01.inf.0000157094.43609.17] [Medline: 15818294]

9. Darmstadt GL, El Arifeen S, Choi Y, Bari S, Rahman SM, Mannan I, Bangladesh Projahnmo-2 (Mirzapur) Study Group. Household surveillance of severe neonatal illness by community health workers in Mirzapur, Bangladesh: coverage and compliance with referral. Health Policy Plan 2010 Mar;25(2):112-124 [FREE Full text] [doi: 10.1093/heapol/czp048] [Medline: 19917652]
10. Uganda Bureau of Statistics. Kampala, Uganda: Uganda Bureau of Statistics; 2018. 2018 Statistical Abstract URL: https://www.ubos.org/wp-content/uploads/publications/05_2019STATISTICAL_ABSTRACT_2018.pdf [accessed 2019-09-16]
11. Kananura RM, Tetui M, Mutebi A, Bua JN, Waiswa P, Kiwanuka SN, et al. The neonatal mortality and its determinants in rural communities of Eastern Uganda. Reprod Health 2016 Feb 16;13:13 [FREE Full text] [doi: 10.1186/s12978-016-0119-y] [Medline: 26883425]
12. Lawn J, Osrin D, Adler A, Cousens S. Four million neonatal deaths: counting and attribution of cause of death. Paediatr Perinat Epidemiol 2008 Sep;22(5):410-416 [FREE Full text] [doi: 10.1111/j.1365-3016.2008.00960.x] [Medline: 18782248]
13. Choi Y, El Arifeen S, Mannan I, Rahman SM, Bari S, Darmstadt GL, Projahnmo Study Group. Can mothers recognize neonatal illness correctly? Comparison of maternal report and assessment by community health workers in rural Bangladesh. Trop Med Int Health 2010 Jun;15(6):743-753 [FREE Full text] [doi: 10.1111/j.1365-3156.2010.02532.x] [Medline: 20406425]
14. Waiswa P, Kallander K, Peterson S, Tomson G, Pariyo GW. Using the three delays model to understand why newborn babies die in eastern Uganda. Trop Med Int Health 2010 Aug;15(8):964-972 [FREE Full text] [doi: 10.1111/j.1365-3156.2010.02557.x] [Medline: 20636527]
15. McPherson R, Hodgins S. Postnatal home visitation: lessons from country programs operating at scale. J Glob Health 2018 Jun;8(1):010422 [FREE Full text] [doi: 10.7189/jogh.08.010422] [Medline: 29977530]
16. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L, Lancet Neonatal Survival Steering Team. Evidence-based, cost-effective interventions: how many newborn babies can we save? Lancet 2005;365(9463):977-988. [doi: 10.1016/S0140-6736(05)71088-6] [Medline: 15767001]
17. Geldsetzer P, Williams TC, Kirolos A, Mitchell S, Ratcliffe LA, Kohli-Lynch MK, et al. The recognition of and care seeking behaviour for childhood illness in developing countries: a systematic review. PLoS One 2014;9(4):e93427 [FREE Full text] [doi: 10.1371/journal.pone.0093427] [Medline: 24718483]
18. Abu-Shaheen A, AlFayyad I, Riaz M, Nofal A, AlMatary A, Khan A, et al. Mothers' and caregivers' knowledge and experience of neonatal danger signs: a cross-sectional survey in Saudi Arabia. Biomed Res Int 2019;2019:1750240 [FREE Full text] [doi: 10.1155/2019/1750240] [Medline: 31032336]
19. World Health Organization, Department of Child and Adolescent Health and Development, UNICEF. Handbook IMCI Integrated Management of Childhood Illness. Geneva, Switzerland: World Health Organization; 2005.
20. Opiyo N, English M. What clinical signs best identify severe illness in young infants aged 0-59 days in developing countries? A systematic review. Arch Dis Child 2011 Nov;96(11):1052-1059 [FREE Full text] [doi: 10.1136/adc.2010.186049] [Medline: 21220263]
21. Vanosdoll M, Ng N, Ho A, Wallingford A, Xu S, Matin SB, et al. A novel mobile health tool for home-based identification of neonatal illness in Uganda: formative usability study. JMIR Mhealth Uhealth 2019 Aug 15;7(8):e14540 [FREE Full text] [doi: 10.2196/14540] [Medline: 31418428]
22. Uganda Bureau of Statistics. Kampala, Uganda: Uganda Bureau of Statistics; 2017 Apr. National Population and Housing Census 2014. Area Specific Profiles: Iganga District URL: https://www.ubos.org/wp-content/uploads/publications/2014CensusProfiles/IGANGA.pdf [accessed 2019-09-17]
23. Uganda Bureau of Statistics. Kampala, Uganda: Uganda Bureau of Statistics; 2017 Apr. National Population and Housing Census 2014. Area Specific Profiles: Mayuge District URL: https://www.ubos.org/wp-content/uploads/publications/2014CensusProfiles/MAYUGE.pdf [accessed 2019-09-17]
24. Xu S, Ng N, Ho A, Vanosdoll M, Wallingford A, Matin SM. NeMo: Reducing delays in Identification of Neonatal Illness in Uganda. In: Oral Presentation from Johns Hopkins Engineering Design Day; May 7 Baltimore, MD. 2019 Presented at: Johns Hopkins Engineering Design Day; May 7, 2019; Johns Hopkins University.
25. Bazzano AN, Kirkwood BR, Tawiah-Agyemang C, Owusu-Agyei S, Adongo PB. Beyond symptom recognition: care-seeking for ill newborns in rural Ghana. Trop Med Int Health 2008 Jan;13(1):123-128 [FREE Full text] [doi: 10.1111/j.1365-3156.2007.01981.x] [Medline: 18291010]

Abbreviations

ANOVA: analysis of variance
CBID: Center for Bioengineering Innovation and Design
CHW: community health worker
GIF: Graphic Interchange Format
LMIC: low- and middle-income countries
RCT: randomized controlled trial
UDHA: Uganda Development and Health Associates

VHT: village health team

Edited by G Eysenbach; submitted 30.09.19; peer-reviewed by E Sezgin, G Klein; comments to author 23.10.19; revised version received 12.11.19; accepted 13.11.19; published 18.02.20.

Please cite as:
Matin SB, Wallingford A, Xu S, Ng N, Ho A, Vanosdoll M, Waiswa P, Labrique AB, Acharya S
Feasibility of a Mobile Health Tool for Mothers to Identify Neonatal Illness in Rural Uganda: Acceptability Study
JMIR Mhealth Uhealth 2020;8(2):e16426
URL: https://mhealth.jmir.org/2020/2/e16426
doi:10.2196/16426
PMID:32130174

Original Paper

A Men Who Have Sex With Men–Friendly Doctor Finder Hackathon in Guangzhou, China: Development of a Mobile Health Intervention to Enhance Health Care Utilization

Chunyan Li[1*], MSc; Yuan Xiong[2,3*], MSW; Hao Fong Sit[4], MSc; Weiming Tang[2,3,5], MD, PhD; Brian J Hall[4,6], PhD; Kathryn E Muessig[1], PhD; Chongyi Wei[7,8], DrPH; Huanyu Bao[2,3], MSc; Shufang Wei[2,3], MA; Dapeng Zhang[9], PhD; Guodong Mi[9], PhD; Fei Yu[9], MSW; Joseph D Tucker[2,3,10], MD, PhD

[1]Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States
[2]Social Entrepreneurship to Spur Health Global, Guangzhou, China
[3]University of North Carolina at Chapel Hill Project-China, Guangzhou, China
[4]Global and Community Mental Health Research Group, Department of Psychology, University of Macau, Macau, China
[5]Dermatology Hospital, Southern Medical University, Guangzhou, China
[6]Department of Health, Behavior and Society, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, United States
[7]Department of Health Behavior, Society, and Policy, Rutgers School of Public Health, Piscataway, NJ, United States
[8]Core Faculty, Rutgers Global Health Institute, Piscataway, NJ, United States
[9]Danlan Goodness, Beijing, China
[10]Department of Global Health and Development, London School of Hygiene and Tropical Medicine, London, United Kingdom
[*]these authors contributed equally

Corresponding Author:
Joseph D Tucker, MD, PhD
Social Entrepreneurship to Spur Health Global
University of North Carolina Chapel Hill Project-China
No 2 Lujing Road
Guangzhou, 510095
China
Phone: 86 13302391532
Email: jdtucker@med.unc.edu

Abstract

Background: Mobile health (mHeath)–based HIV and sexual health promotion among men who have sex with men (MSM) is feasible in low- and middle-income settings. However, many currently available mHealth tools on the market were developed by the private sector for profit and have limited input from MSM communities.

Objective: A health hackathon is an intensive contest that brings together participants from multidisciplinary backgrounds to develop a proposed solution for a specific health issue within a short period. The purpose of this paper was to describe a hackathon event that aimed to develop an mHealth tool to enhance health care (specifically HIV prevention) utilization among Chinese MSM, summarize characteristics of the final prototypes, and discuss implications for future mHealth intervention development.

Methods: The hackathon took place in Guangzhou, China. An open call for hackathon participants was advertised on 3 Chinese social media platforms, including Blued, a popular social networking app among MSM. All applicants completed a Web-based survey and were then scored. The top scoring applicants were grouped into teams based on their skills and content area expertise. Each team was allowed 1 month to prepare for the hackathon. The teams then came together in person with on-site expert mentorship for a 72-hour hackathon contest to develop and present mHealth prototype solutions. The judging panel included experts in psychology, public health, computer science, social media, clinical medicine, and MSM advocacy. The final prototypes were evaluated based on innovation, usability, and feasibility.

Results: We received 92 applicants, and 38 of them were selected to attend the April 2019 hackathon. A total of 8 teams were formed, including expertise in computer science, user interface design, business or marketing, clinical medicine, and public health. Moreover, 24 participants self-identified as gay, and 3 participants self-identified as bisexual. All teams successfully developed a prototype tool. A total of 4 prototypes were designed as a mini program that could be embedded within a popular Chinese social

networking app, and 3 prototypes were designed as stand-alone apps. Common prototype functions included Web-based physician searching based on one's location (8 prototypes), health education (4 prototypes), Web-based health counseling with providers or lay health volunteers (6 prototypes), appointment scheduling (8 prototypes), and between-user communication (2 prototypes). All prototypes included strategies to ensure privacy protection for MSM users, and some prototypes offered strategies to ensure privacy of physicians. The selected prototypes are undergoing pilot testing.

Conclusions: This study demonstrated the feasibility and acceptability of using a hackathon to create mHealth intervention tools. This suggests a different pathway to developing mHealth interventions and could be relevant in other settings.

(JMIR Mhealth Uhealth 2020;8(2):e16030) doi:10.2196/16030

KEYWORDS

mobile health; hackathon; crowdsourcing; men who have sex with men; MSM-friendly; health care utilization

Introduction

Background

Mobile health (mHealth)–based HIV and sexual health promotion interventions delivered through websites, text messages, or mobile apps are feasible and acceptable in reducing HIV risk behaviors and enhancing health care utilization among gay, bisexual, and other men who have sex with men (MSM) [1-4]. The use of these tools is especially feasible in low- and middle-income settings such as China, where smartphone ownership exceeded 68% in 2016 [5] and MSM face sexuality- and HIV-related discrimination and stigma in clinical settings [6-8]. However, most of the currently available mHealth intervention tools on the market were developed by the private sector for profit and have limited direct input from MSM communities [9,10], which may raise issues of acceptability and effectiveness of such tools among the target population.

Objectives

To fill the gap in engaging MSM communities in developing mHealth intervention tools to meet their specific needs in health care, we applied the crowdsourcing approach of a hackathon to solicit innovative designs of a mobile tool that aims to help MSM find, access, and utilize MSM-friendly health services. A hackathon is an intensive contest that brings together a diverse group of participants from multidisciplinary backgrounds to complete a health intervention–related task within a short period. Hackathons are an innovative approach to generate ideas from the target communities to address their needs [11,12].

Previous literature on health-related hackathons focused on translating biomedical innovations from laboratory settings or on general health care and health management [13-15]. A few hackathons focused on developing an mHealth intervention. The purpose of this paper was to describe a hackathon that aimed to develop an mHealth intervention to improve health care utilization (specifically HIV prevention and care) among Chinese MSM, summarize characteristics of the final prototypes, and discuss implications for future mHealth intervention development.

Methods

Pre-Hackathon Formative Work

Before this hackathon contest, in partnership with Social Entrepreneurship to Spur Health (SESH) and Blued (the largest gay social networking app in China), the Shenzhen University College of Mass Communication held a crowdsourcing contest from February 2018 to March 2018 for designing concepts of a mobile phone–based, MSM-friendly doctor mobile app. The contest generated 103 exceptional concepts about the name, logo, slogan, features, and functions of the MSM-friendly doctor mobile app.

We then conducted 4 focus group discussions with 38 MSM in Guangzhou and Shenzhen (July 2018), China, during which the researchers showed the participants a video of the concepts of an MSM-friendly doctor app platform; the platform's name, logo, slogan, and functions were designed by SESH based on the abovementioned crowdsourcing outputs. Participants were asked for feedback on refining the prototype design. A thematic analysis of the results of the focus group discussions indicated that MSM had unmet needs in health care utilization and such a mobile, MSM-friendly doctor finder tool would be beneficial to them for attaining better health. Focus group participants highlighted the following functions that they wanted to see in such a tool: (1) GPS location–based doctor finder, (2) mental health support, (3) information and access to pre- and postexposure prophylaxis, and (4) health education [16]. To develop an mHealth prototype for this MSM-friendly doctor finder, we organized an MSM-friendly doctor finder hackathon contest between October 2018 and April 2019. Key information of the formative work (including crowdsourcing outputs and feedback from focus group discussions) was presented to hackathon participants via images and text in the hackathon contest handbook. A detailed description of the implementation of this hackathon contest and its outputs is reported below.

Steering Committee Establishment

We invited 9 experts in psychology, public health, computer science, social media, and clinical medicine to serve as steering committee members. All committee members attended the hackathon contest and provided guidance and advice to participants. They were encouraged to communicate with hackathon participants, but they were instructed to avoid providing specific examples. The guidance for steering committee members was based on a previous hackathon-like event organized by SESH [17].

Participant Recruitment and Inclusion Criteria

An open call for hackathon participants was disseminated on Blued, a free messaging app (WeChat), and a Chinese blogging website (Weibo). The open call described the problem statement,

contest objectives, rules, timeline, and prizes (Textbox 1 and Figure 1). We encouraged individuals who self-identified as friendly to MSM and were interested in mobile app technology to sign up for the hackathon. All applicants were required to submit an application form that asked for information about demographics, professional background, personal interests, and self-reported strengths in terms of participating in a hackathon. Applicants were considered eligible for the hackathon if they met the following criteria: (1) aged 18 years or older, (2) interested in improving clinical services for MSM, and (3) were able to be physically present in Guangzhou during the entire hackathon.

Textbox 1. The problem statement and objectives presented in the hackathon manual (translated from the Chinese version).

The problem statement

Before your team starts to work, you need to fully understand the barriers that prevent gay people from accessing timely and appropriate health services, so that you can ensure your design will meet their needs. We suggest you speak with your gay friends to learn about their health care experience, or based on your own experience with providers, we advise you to think about the following questions:

- How did your gay friend (or you) find a gay-friendly doctor or a gay-friendly health institution (eg, clinic and hospital)?
- Was there any difficulty or problem that your friend (or you) encountered during the health care seeking process?
- How can we solve these difficulties?
- What are the characteristics or qualities that a gay-friendly doctor or health institute should have?
- How will the answers to the above questions be incorporated into your design and development of the Web-based platform?

What we expect

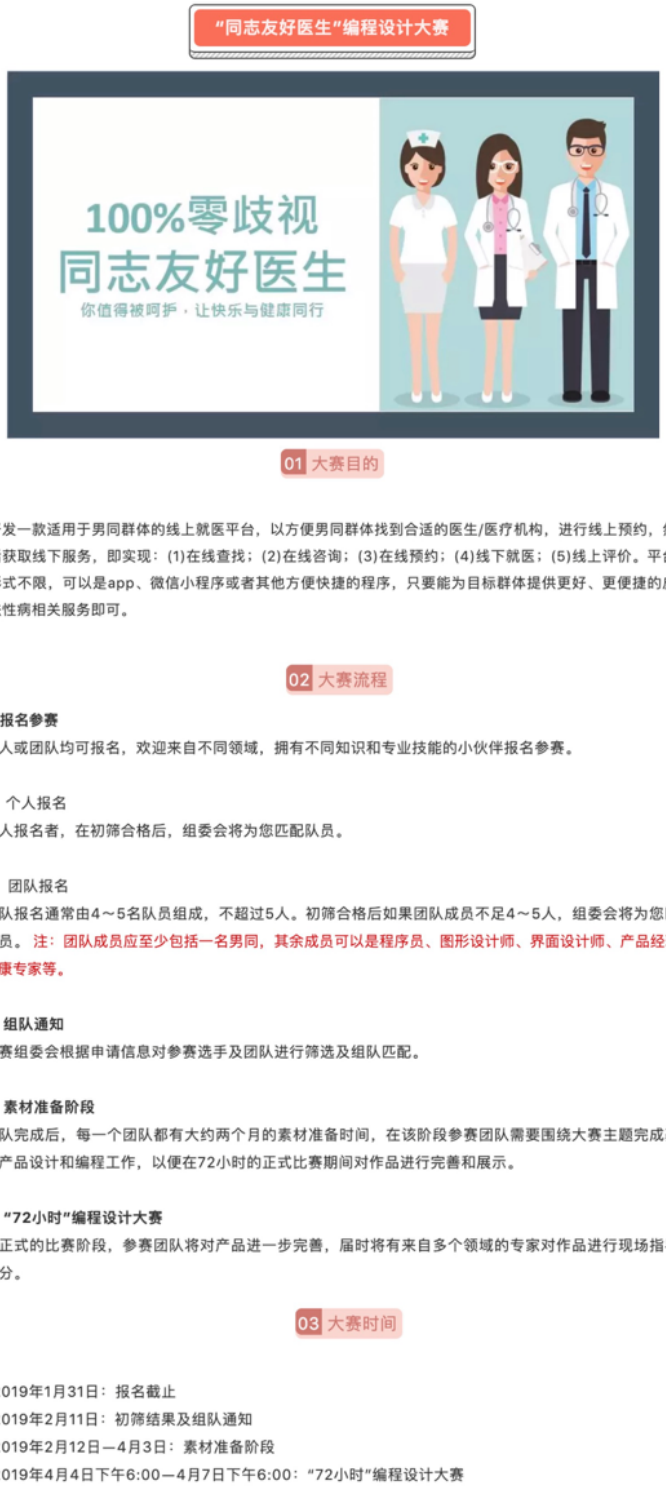
The overall goal of this contest is to develop a Web-based platform to help identify gay-friendly doctors and link gay people to better and timely health care, such as HIV- and sexually transmitted infections (STI)–related services. There is no restriction on the models of the platform. It can be in the form of a stand-alone app, mini programs built in WeChat, or other modes. Your project should include but not be limited to the following contents:

- Web-based searching: users will be able to search for STI doctors or dermatologists or search for related health clinics through the platform.
- Web-based counseling: users could consult the doctor in terms of signs, symptoms, or other health questions, or they could ask for support for disclosing to family or friends.
- Web-based appointment and/or offline visit: users could schedule an appointment on the Web for an offline service.
- Web-based feedback: after the offline service, users will be able to post feedback on their experience and comments to the doctor, which can be shared with other users.

Prizes

- Monetary prize: first prize of renminbi (RMB) 20,000 (approximately US $3000), second prize of RMB 10,000 (approximately US $1500), and third prize of RMB 3500 (approximately US $500).
- Internship: members from selected teams will be offered an internship at Blued.
- Priority admission: students who will graduate in 2019 will be prioritized for job admission at Blued.
- Gifts: every contest participant will receive a small gift.

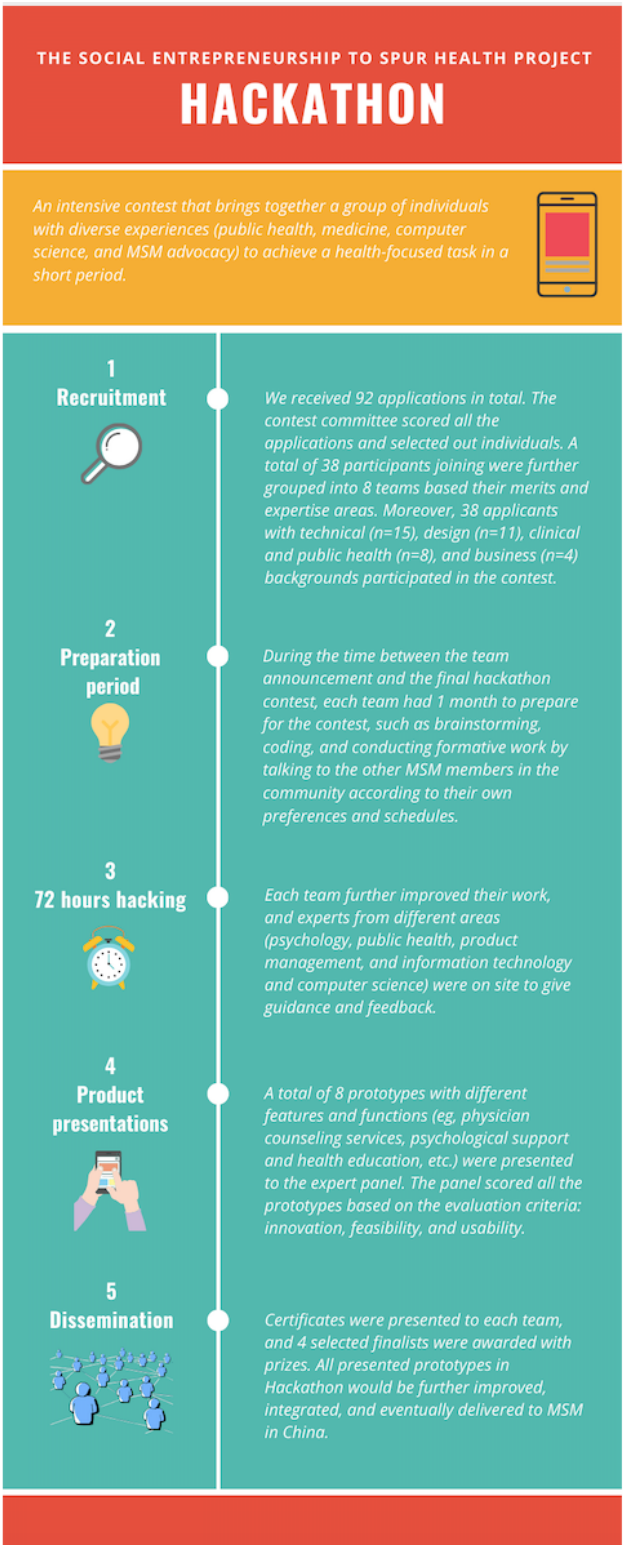
Figure 1. A screenshot of the call for applicants (advertised on Chinese social media). It introduced the health needs among men who have sex with men, expected functions of mobile health tools for enhancing health care utilization, procedure on how to apply, participants' eligibility criteria, timeline of the hackathon contest, and judging process.



Creating Teams

The flow of preparation for the hackathon contest is illustrated in Figure 2. Applicants were independently evaluated and scored from 0 to 10 by 3 members from the steering committee based on 3 criteria, including background (relevant academic or working experience and ever attended any MSM-related activity), professional skills (good at Photoshop and Python), and teamwork capacity ("as a team member, how you will contribute to your team?"). The 3 scores of the applicants were averaged and ranked, and the top 40 applicants were selected as finalists. Finalists were further grouped into 8 teams based on their merits and expertise areas. Each team had 4 to 5 members, including 2 members with computer science skills, 1 member or 2 members with design skills, and 1 member with medical or public health knowledge.

Figure 2. Flowchart of preparation for the hackathon event.



Hackathon Process

Considering the heavy workload of developing a complete mHealth app within a short period, each team was allowed to prepare for the hackathon 1 month before the in-person hackathon contest. During this 1 month, teams sketched concepts, conducted formative work to inform their designs, and started coding. An MSM-friendly hackathon manual (Multimedia Appendix 1) was shared with all participants, which provided information regarding the challenges MSM face when seeking health services and the hackathon process.

The final hackathon contest was held at a university building in Guangzhou, China. A total of 38 participants from the 8 teams attended the 72-hour in-person hackathon. Their transportation, accommodation, meals, and insurance were provided. Participants were instructed verbally and in writing in the hackathon manual (Multimedia Appendix 1) to follow all local laws and regulations during the hackathon contest and in the

design of their prototype. Teams were encouraged to communicate and exchange ideas with on-site mentors. Mentors included the 9 experts from the steering committee. At the end of the 72-hour hackathon, each team had 15 min to present their prototype to the judging panel and had 5 min for questions and answers.

Judging Process

In addition to the 9 members of the steering committee, a leader from a local MSM community–based organization was invited to join the judging panel. This 10-person judging panel evaluated the final prototypes based on the following criteria: (1) the prototype should have innovative features that aim to help MSM access Web-based and/or offline health care services (innovation), (2) the prototype should have a user-centered design (usability), and (3) the prototype should be feasible to use (assessed based on technical feasibility, compatibility with the local context, regulations and laws, and whether the prototype could provide sustainable motivation to doctors and MSM for using the tool). Each criterion was given equal weight and was assigned a score between 0 and 10. The final score for a prototype was up to 30 points in total.

Ethical Statement

This hackathon contest was not a research activity with human subjects. Data from the event were deidentified and not considered human subjects research. All applicants to the hackathon and the final participants were required to use nicknames throughout the contest. A disclosure of what information would be requested and how the information would be used was presented to the applicant before the applicant agreed to submit the application.

Results

Participants

We received 92 applications in total. After the application screening and evaluation by the members of the steering committee, 40 finalists were invited to attend the hackathon, of which 2 applicants dropped out before the final contest because of time conflicts. We chose to limit the hackathon contest to 40 participants (8 teams) primarily for feasibility and resource considerations regarding funding, venue size, and staff capacity.

Table 1 presents the characteristics of the final 38 participants. A total of 9 participants were from Guangzhou and Shenzhen in Guangdong Province. Moreover, 5 participants were from Beijing, and 5 participants were from Shanghai. In addition, 33 of 38 (87%) participants were men. Furthermore, of the 48 participants, 24 (64%) self-identified as gay, 3 identified as bisexual, and 8 identified as heterosexual. Participants' age ranged from 18 to 39 years, with 58% (22/48) of the participants aged between 18 and 23 years, with a median age of 23 years. Participants had diverse disciplinary backgrounds, including computer science (15/38, 40%), user interface/graphic design (11/38, 29%), clinical (5/38, 13%), business (4/38, 11%), and public health (15/28, 38%). Half of the participants had never participated in any MSM-related events or contests before.

Table 1. Demographic characteristics of the hackathon participants (N=38).

Variables	Value, n (%)
Province/city	
Guangdong	9 (24)
Beijing	5 (13)
Shanghai	5 (13)
Hebei	4 (11)
Shandong	3 (8)
Sichuan	3 (8)
Hunan	2 (5)
Hubei	2 (5)
Others (Zhejiang, Henan, Shanxi, Guangxi, and Liaoning)	5 (13)
Gender	
Male	33 (87)
Female	5 (13)
Sexual orientation	
Gay	24 (63)
Heterosexual	8 (21)
Bisexual	3 (8)
Do not want to disclose	3 (8)
Age (years)	
18-23	22 (58)
24-29	11 (29)
≥30	5 (13)
College students	
Yes	18 (47)
No	20 (53)
Background	
Computer science	15 (40)
Designing	11 (29)
Clinical	5 (13)
Business	4 (10)
Public health	3 (8)
Ever attended any men who have sex with men–related activity	
Yes	19 (50)
No	19 (50)

Final Products

All 8 teams developed a prototype tool by the end of the 72-hour contest. A total of 4 prototypes were designed as a mini program that could be embedded within a popular Chinese social networking app, and 3 prototypes were designed as stand-alone mobile apps. Moreover, 1 prototype adopted a more flexible structure that could be adjusted to multiple platforms, including webpages, mini programs, and/or built-in app functions. Some common functions across all the prototypes include Web-based doctor searching based on one's location (8 prototypes), health education (4 prototypes), Web-based health counseling with providers or lay health volunteers (6 prototypes), appointment scheduling (8 prototypes), and between-user communication (2 prototypes). All 8 prototypes included some designs of user privacy protection through offering anonymous counseling for both MSM and/or provider users

A total of 4 out of the 8 prototypes were selected as the finalists by the multidisciplinary judge panel based on the prototype's

innovation, usability, and feasibility (see Table 2 for detailed descriptions of the strengths and weaknesses of the first 4 prototypes). The prototype of the first prize winner (group 1) was designed as a cross-device Web-based platform that aims to recruit junior physicians and trained health counseling volunteers to provide Web-based text-based counseling services to MSM. It proposed multiple motivation strategies for physician engagement, such as MSM-friendly service trainings, continuation of medical education credit, and payment and bonus sharing mechanisms. At the same time, it allowed MSM users to start with a free trial period and then transition to fee-based services. The prototype of the second prize winner (group 2) integrated professional psychological counseling, peer support, and daily mood tracking into a single stand-alone app, which offers functions such as location-based physician recommendations, Web-based one-to-one counseling, and anonymous peer communication channel for social support.

Table 2. Awarded prototypes developed during the hackathon and their strengths and weaknesses identified by the judge panel.

Team	Prototype design	Strengths	Weaknesses
Group 1 (first)	A cross-device Web-based platform, recruiting junior physicians and lay health volunteers to provide services to men who have sex with men	Mobilize community resources: actively engages volunteers from local gay/HIV-related organizations; provide professional development opportunities: provides gay-friendly services training to physicians and provides multiple incentive mechanisms to motivate physician engagement (eg, continuing medical education credit and pay-for-service); financial sustainability: users will be able to try the service for free at first and then choose a payment plan for continuous services; compatibility: could be embedded within an existing gay social networking app	Difficulty in recruiting physicians to join at the very beginning, given the trainings required and free services offered at the beginning; the platform was not well developed by the end of the contest
Group 2 (second)	A stand-alone app, providing GPS location–based physician recommendation, Web-based counseling, and personal health record management	Addresses both physical and mental health care; social support: provides a platform for users to obtain peer support (anonymous forum to share experience and interact with others); health self-management: provides a platform for users to track their daily emotional status, with individual tailored feedback; user engagement: users can earn tokens via completing app activities, and use the tokens for rating physicians	Registration/log-in by users' mobile phone number may be less confidential; high human resource cost for complicated qualification review for content that will be published in the app
Group 3 (third)	A stand-alone app, providing physician referral to offline clinics, Web-based counseling, and AI[a]-enabled dermatology assessment	Innovative feature: has an AI-enabled dermatology assessment to identify users' specific needs; inclusion of both physicians and public health practitioners: offers a searching function for all types of health professionals (clinic-based providers and Centers for Diseases Prevention and Control-based providers) and gay health-related volunteers	Heavy cost and uncertain accuracy of AI-enabled disease assessment; highly complicated user interface and many functions within a single app
Group 4 (fourth)	A WeChat mini program that provides Web-based counseling, medical history and medication management, health education, and free testing tools	Formative research: the team conducted extensive formative research on unmet health needs among gay men before the contest; mobilize community resources: hiring both lay health volunteers (to answer gay-related questions that physicians may not understand) and medical professionals; innovative feature: live video streaming–enabled health education; HIV/sexually transmitted infections testing promotion: provides free testing toolkits that users could order from the platform	Too much individual knowledge-based education that somehow deemphasizes medical support; unsure whether there is medical support offered after self-testing

[a]AI: artificial intelligence.

The third prize winner (group 3) proposed a stand-alone app with a comprehensive range of functions, including Web-based counseling, referral, or appointment setting to offline health services, artificial intelligence–enabled dermatology assessment, health education, health self-management, and a search function for nearby physicians and MSM health-related volunteers. The fourth prize winner (group 4) designed a mini program embedded within a gay social networking app, including functions such as Web-based physician counseling, medical record and medication management, health education with MSM voluntary advisors, and HIV testing promotion through disbursing free testing toolkits. The remaining 4 prototypes (detailed descriptions are available in Multimedia Appendix 2) shared similar primary functions such as physician listings based on one's location and Web-based counseling or making an appointment for offline services, but these were less responsive to MSM's specific health needs as compared with the first 4 finalists.

After the contest, each team nominated 1 team member to be considered for an internship at Blued. These 8 nominees were then interviewed and assessed based on their professional background, performance at the contest, and other eligibility criteria (eg, time conflicts or noncompete clause). Ultimately, 5 nominees were selected by Blued for internships. Furthermore, the final 4 selected prototypes were all presented to Blued and were under technical review. A pilot study has been planned to test the acceptability and feasibility of the prototype of fourth prize winner (group 4) in an urban-based setting in central China.

Discussion

Principal Findings

Our hackathon event represents an innovative approach to engage multiple stakeholders to develop mHealth interventions. This hackathon event brought together diverse individuals to generate 8 complete prototypes that could help MSM access local health services. The major functions that were found innovative and responsive to MSM's specific health needs include Web-based counseling and appointment for offline services, provider training, engagement of MSM volunteers or peer support, and user's privacy considerations. This paper extends our knowledge in health intervention tool development for MSM by accelerating the translation of innovative intervention ideas from research findings to real-world application in middle-income settings such as China, thereby raising public awareness about the challenges faced by MSM in accessing health care services and engaging multiple community stakeholders in the health promotion process.

A Crowdsourcing Approach to Empower Community

Hackathons are a feasible approach to create tailored health interventions for marginalized populations such as MSM. Although the penetration rate of smartphones keeps rising in low- and middle-income countries where there are large numbers of sexual minorities [18], only a few interventions have incorporated the wisdom of MSM crowds into interventions [14]. Hackathons offer a platform for accelerating the development of digital solutions with input from multiple stakeholders, which could empower MSM communities and ultimately result in more effective interventions. Furthermore, a conventional public health intervention development process typically includes slower evolution from formative research to intervention design, pilot testing in a controlled environment, and eventual implementation [19]. In contrast, the hackathon approach bridges the gap among researchers, technology experts, and potential beneficiaries, while accelerating the translation of research-driven ideas into real-world solutions.

Hackathons may help to improve MSM community engagement in public health promotion. All 4 finalists focused on mobilizing MSM community resources through employing MSM as paid lay health advisors or unpaid voluntary peer supporters. This study provides a participatory approach to redress power imbalances among community, research, and technology partners. Previous mHealth interventions for HIV care services among MSM in Chinese settings were mainly delivered to MSM via preprogrammed messages or direct individual communication between MSM and trained interventionists, with little community mobilization [3,20,21]. Although 1 Web-based intervention with a component of peer support feature was found effective in promoting HIV testing among Chinese MSM in Chengdu, the selection and training of peers were still mainly driven by academic experts without sufficiently empowering the community to help identify and mobilize potential resources [2]. Even within the global literature, community mobilization has been traditionally used for developing in-person health interventions in low- and middle-income settings rather than being used for developing mHealth tools [22-24]. With the growth of digital health solutions, our project provides an innovative example of how to use hackathons as an effective and convenient way to mobilize MSM communities in generating mHealth solutions to meet their own health needs, which could further potentially reduce external stigma and self-stigma against sexual minority populations.

We found that all prototypes had a range of tools to safeguard MSM users' privacy, such as anonymous counseling, anonymous peer communication, and Snapchat messages, which allows MSM users to individualize account settings according to their perceived risk of breaching privacy. Formative research findings suggest that Chinese MSM prefer not to include any HIV- or gay-related identification in the appearance of mHeath intervention designs to avoid unintended disclosure of sexual orientation or HIV status [25]. A study found that including a feature of between-user communication is not universally accepted as some MSM perceived that such virtual relationships may exacerbate one's social isolation in real life [26].

Limitations

There are several limitations worth noting. First, this paper is a descriptive report of the hackathon's process and results. The winning prototypes were chosen but not yet tested in real-world settings. Although we collected and analyzed all judges' written comments on all final prototypes, we do not have robust qualitative or quantitative assessment data to comprehensively evaluate the 8 final prototypes. Second, the experience of a single hackathon within a single location, although the teams came from diverse backgrounds and geographic regions, may not reflect the diverse needs of MSM in China or elsewhere. Generalizing these findings to other settings should be done with caution. However, this paper breaks new ground in organizing and reporting hackathon events for mHealth intervention development in middle-income settings (advice for future events is reported in Textbox 2), which can help to set a solid foundation for future explorations.

Textbox 2. Advice for future hackathon events in similar contexts.

Challenges and potential solutions

- *Problem recruiting men who have sex with men (MSM) as judges (potential solution: including MSM who do not openly identify as gay):* Interventions developed with input from the target population are more likely to be attractive, engaging, and effective [27,28]. Although our hackathon contest engaged MSM as participants, judges, and steering committee members, we had difficulty in identifying openly gay hackathon judges. However, given the concerns about stigma toward sexual minority groups and ensuring privacy, we did not require that men disclose their sexual orientation to the hackathon organizing team. We included a range of potential stakeholders, including men who disclosed their sexual orientation and those who did not.
- *Problem recruiting sufficient number of participants with computer science/programming experience (potential solutions: (1) wide dissemination through Web-based platforms and pre hackathon planning and (2) allow for programming preparation before the actual Hackathon contest):* One of the primary goals of a hackathon contest is to develop a functional prototype, which requires a certain level of programming ability. Although most of our 8 teams finished the programming for their prototype by the end of the 72-hour contest, we had difficulty in recruiting people with technical experience in computer programming. In our hackathon, we partnered with Blued, a gay social networking company, to expand our recruitment strategies. We also allowed each team to start designing and programming 1 month before the actual contest, which partially compensated for this limitation.

Conclusions

Hackathons are a feasible approach to engage multiple community stakeholders in generating mHealth interventions. Similar community-based mHealth intervention development approaches could be used in other settings. More research is needed to evaluate the public health impact of the interventions.

Acknowledgments

The hackathon contest was funded by the National Institute of Allergy and Infectious Diseases (R01 grant AI114310-S1, R01 grant AI114310, and K24 grant AI143471), the National Institute of Mental Health (R34 grant MH119963), and the National Science Foundation of China (grant 81903371). There was no funding for authoring this paper, and the aforementioned sponsors were not involved in approving this paper. The authors thank all the people who contributed to the hackathon contest, including those who submitted applications for the hackathon. Specifically, the authors thank the 38 team members who attended the contest. The authors also thank the hackathon judges (Dr Na Liu from Beijing Genomics Institute, Dr Chunbo Ren from Central Michigan University, Mr Danyang Luo from Zhitong, Dr Ligang Yang from Guangdong Provincial Dermatology Hospital, Dr Lifang Li from South China University of Technology, and Dr Lu Zhong from City University of Hong Kong). The authors would also like to thank the staff at SESH Global, who helped organize the contest.

Conflicts of Interest

None declared.

Multimedia Appendix 1
MSM-friendly doctor hackathon contest manual (2019 Guangzhou, China).
[DOCX File , 700 KB - mhealth_v8i2e16030_app1.docx]

Multimedia Appendix 2
Final prototypes developed as part of the hackathon.
[DOCX File , 17 KB - mhealth_v8i2e16030_app2.docx]

References

1. Cheng W, Cai Y, Tang W, Zhong F, Meng G, Gu J, et al. Providing HIV-related services in China for men who have sex with men. Bull World Health Organ 2016 Mar 1;94(3):222-227 [FREE Full text] [doi: 10.2471/BLT.15.156406] [Medline: 26966334]
2. Mi G, Wu Z, Wang X, Shi CX, Yu F, Li T, et al. Effects of a quasi-randomized web-based intervention on risk behaviors and treatment seeking among HIV-positive men who have sex with men in Chengdu, China. Curr HIV Res 2015;13(6):490-496 [FREE Full text] [doi: 10.2174/1570162x13666150624104522] [Medline: 26105555]
3. Ruan Y, Xiao X, Chen J, Li X, Williams AB, Wang H. Acceptability and efficacy of interactive short message service intervention in improving HIV medication adherence in Chinese antiretroviral treatment-naïve individuals. Patient Prefer Adherence 2017;11:221-228 [FREE Full text] [doi: 10.2147/PPA.S120003] [Medline: 28228652]
4. Muessig KE, Bien CH, Wei C, Lo EJ, Yang M, Tucker JD, et al. A mixed-methods study on the acceptability of using eHealth for HIV prevention and sexual health care among men who have sex with men in China. J Med Internet Res 2015 Apr 21;17(4):e100 [FREE Full text] [doi: 10.2196/jmir.3370] [Medline: 25900881]

5. Poushter J, Bishop C, Chwe H. Pew Research Center. 2018 Jun 19. Social Media Use Continues to Rise in Developing Countries but Plateaus Across Developed Ones URL: https://assets.pewresearch.org/wp-content/uploads/sites/2/2018/06/15135408/Pew-Research-Center_Global-Tech-Social-Media-Use_2018.06.19.pdf [accessed 2019-08-31]
6. National Health and Family Planning Commission of People's Republic of China. UNAIDS. 2015 May. 2015 China AIDS Response Progress Report URL: http://www.unaids.org/sites/default/files/country/documents/CHN_narrative_report_2015.pdf [accessed 2019-08-31]
7. Wong NS, Mao J, Cheng W, Tang W, Cohen MS, Tucker JD, et al. HIV linkage to care and retention in care rate among MSM in Guangzhou, China. AIDS Behav 2018 Mar;22(3):701-710 [FREE Full text] [doi: 10.1007/s10461-017-1893-4] [Medline: 28849284]
8. Huang D, Hu Y, Wu G, Jia Y, Lu R, Xiao Y, et al. HIV prevention services and testing utilization behaviors among men who have sex with men at elevated risk for HIV in Chongqing, China. Biomed Res Int 2014;2014:174870 [FREE Full text] [doi: 10.1155/2014/174870] [Medline: 24783195]
9. Muessig KE, LeGrand S, Horvath KJ, Bauermeister JA, Hightow-Weidman LB. Recent mobile health interventions to support medication adherence among HIV-positive MSM. Curr Opin HIV AIDS 2017 Sep;12(5):432-441 [FREE Full text] [doi: 10.1097/COH.0000000000000401] [Medline: 28639990]
10. Hightow-Weidman LB, Muessig KE. New media challenges and opportunities. Sex Transm Infect 2017 Aug;93(5):309-310. [doi: 10.1136/sextrans-2016-052673] [Medline: 27888207]
11. World Health Organization. World Health Organization. Geneva: World Health Organization; 2018. Crowdsourcing in Health and Health Research: A Practical Guide URL: https://www.who.int/tdr/publications/year/2018/crowdsourcing-practical-guide/en/ [accessed 2019-08-31]
12. Wang JK, Roy SK, Barry M, Chang RT, Bhatt AS. Institutionalizing healthcare hackathons to promote diversity in collaboration in medicine. BMC Med Educ 2018 Nov 20;18(1):269 [FREE Full text] [doi: 10.1186/s12909-018-1385-x] [Medline: 30458759]
13. Ghouila A, Siwo GH, Entfellner JD, Panji S, Button-Simons KA, Davis SZ, DREAM of Malaria Hackathon Participants, et al. Hackathons as a means of accelerating scientific discoveries and knowledge transfer. Genome Res 2018 May;28(5):759-765 [FREE Full text] [doi: 10.1101/gr.228460.117] [Medline: 29650552]
14. Angelidis P, Berman L, Casas-Perez MD, Celi LA, Dafoulas GE, Dagan A, et al. The hackathon model to spur innovation around global mHealth. J Med Eng Technol 2016;40(7-8):392-399 [FREE Full text] [doi: 10.1080/03091902.2016.1213903] [Medline: 27538360]
15. DePasse JW, Carroll R, Ippolito A, Yost A, Santorino D, Chu Z, et al. Less noise, more hacking: how to deploy principles from MIT's hacking medicine to accelerate health care. Int J Technol Assess Health Care 2014 Jul;30(3):260-264. [doi: 10.1017/S0266462314000324] [Medline: 25096225]
16. Wu D, Huang W, Zhao P, Li C, Cao B, Wang Y, et al. A crowdsourced physician finder prototype platform for men who have sex with men in China: qualitative study of acceptability and feasibility. JMIR Public Health Surveill 2019 Oct 8;5(4):e13027 [FREE Full text] [doi: 10.2196/13027] [Medline: 31596245]
17. Tucker JD, Tang W, Li H, Liu C, Fu R, Tang S, et al. Crowdsourcing designathon: a new model for multisectoral collaboration. BMJ Innov 2018;4(2):46-50. [doi: 10.1136/bmjinnov-2017-000216]
18. Poushter J. Pew Research Center. 2016 Feb 22. Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies URL: http://www.pewglobal.org/2016/02/22/smartphone-ownership-and-internet-usage-continues-to-climb-in-emerging-economies/ [accessed 2019-08-31]
19. Riley WT, Glasgow RE, Etheredge L, Abernethy AP. Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise. Clin Transl Med 2013 May 10;2(1):10 [FREE Full text] [doi: 10.1186/2001-1326-2-10] [Medline: 23663660]
20. Guo Y, Hong YA, Qiao J, Xu Z, Zhang H, Zeng C, et al. Run4Love, a mHealth (WeChat-based) intervention to improve mental health of people living with HIV: a randomized controlled trial protocol. BMC Public Health 2018 Jun 26;18(1):793 [FREE Full text] [doi: 10.1186/s12889-018-5693-1] [Medline: 29940921]
21. Yang JP, Simoni JM, Dorsey S, Lin Z, Sun M, Bao M, et al. Reducing distress and promoting resilience: a preliminary trial of a CBT skills intervention among recently HIV-diagnosed MSM in China. AIDS Care 2018 Aug;30(sup5):S39-S48 [FREE Full text] [doi: 10.1080/09540121.2018.1497768] [Medline: 30628480]
22. Ziff MA, Harper GW, Chutuape KS, Deeds BG, Futterman D, Francisco VT, Adolescent Medicine Trials Network for HIV/AIDS Intervention. Laying the foundation for Connect to Protect: a multi-site community mobilization intervention to reduce HIV/AIDS incidence and prevalence among urban youth. J Urban Health 2006 May;83(3):506-522 [FREE Full text] [doi: 10.1007/s11524-006-9036-7] [Medline: 16739051]
23. Blanchard AK, Mohan HL, Shahmanesh M, Prakash R, Isac S, Ramesh BM, et al. Community mobilization, empowerment and HIV prevention among female sex workers in south India. BMC Public Health 2013 Mar 16;13:234 [FREE Full text] [doi: 10.1186/1471-2458-13-234] [Medline: 23496972]
24. Tedrow VA, Zelaya CE, Kennedy CE, Morin SF, Khumalo-Sakutukwa G, Sweat MD, et al. No 'magic bullet': exploring community mobilization strategies used in a multi-site community based randomized controlled trial: Project Accept (HPTN 043). AIDS Behav 2012 Jul;16(5):1217-1226 [FREE Full text] [doi: 10.1007/s10461-011-0009-9] [Medline: 21822627]

25. Zhang A, Reynolds NR, Farley JE, Wang X, Tan S, Yan J. Preferences for an HIV prevention mobile phone app: a qualitative study among men who have sex with men in China. BMC Public Health 2019 Mar 12;19(1):297 [FREE Full text] [doi: 10.1186/s12889-019-6617-4] [Medline: 30866880]
26. Mo PKH, Coulson NS. Are online support groups always beneficial? A qualitative exploration of the empowering and disempowering processes of participation within HIV/AIDS-related online support groups. Int J Nurs Stud 2014 Jul;51(7):983-993. [doi: 10.1016/j.ijnurstu.2013.11.006] [Medline: 24342449]
27. Brunton G, Thomas J, O'Mara-Eves A, Jamal F, Oliver S, Kavanagh J. Narratives of community engagement: a systematic review-derived conceptual framework for public health interventions. BMC Public Health 2017 Dec 11;17(1):944 [FREE Full text] [doi: 10.1186/s12889-017-4958-4] [Medline: 29228932]
28. Ceasar JN, Claudel SE, Andrews MR, Tamura K, Mitchell V, Brooks AT, et al. Community engagement in the development of an mHealth-enabled physical activity and cardiovascular health intervention (STEP it UP): Pilot focus group study. JMIR Form Res 2019 Jan 4;3(1):e10944 [FREE Full text] [doi: 10.2196/10944] [Medline: 30684422]

Abbreviations

AI: artificial intelligence
MSM: men who have sex with men
SESH: Social Entrepreneurship to Spur Health

Edited by G Eysenbach; submitted 03.09.19; peer-reviewed by H Wang, Y Wang, C Kurz; comments to author 19.10.19; revised version received 02.11.19; accepted 15.12.19; published 27.02.20.

Please cite as:
Li C, Xiong Y, Sit HF, Tang W, Hall BJ, Muessig KE, Wei C, Bao H, Wei S, Zhang D, Mi G, Yu F, Tucker JD
A Men Who Have Sex With Men–Friendly Doctor Finder Hackathon in Guangzhou, China: Development of a Mobile Health Intervention to Enhance Health Care Utilization
JMIR Mhealth Uhealth 2020;8(2):e16030
URL: http://mhealth.jmir.org/2020/2/e16030/
doi:10.2196/16030
PMID:32130189

Original Paper

Frequent Mobile Electronic Medical Records Users Respond More Quickly to Emergency Department Consultation Requests: Retrospective Quantitative Study

Kwang Yul Jung[1,2*], MD; SuJin Kim[2*], BA; Kihyung Kim[2], MS; Eun Ju Lee[3], MS; Kyunga Kim[2,4], PhD; Jeanhyoung Lee[5], ME; Jong Soo Choi[2,5], PhD; Mira Kang[2,5,6], MD, PhD; Dong Kyung Chang[2,5,7], MD, PhD; Won Chul Cha[2,5,8], MD

[1]Department of Emergency Medicine, Inha University School of Medicine, Incheon, Republic of Korea

[2]Department of Digital Health, Samsung Advanced Institute for Health Science & Technology, Sungkyunkwan University, Seoul, Republic of Korea

[3]Korea Health Industry Development Institute, Cheongju, Republic of Korea

[4]Statistics and Data Center, Research Institute for Future Medicine, Samsung Medical Center, Seoul, Republic of Korea

[5]Health Information and Strategy Center, Samsung Medical Center, Seoul, Republic of Korea

[6]Center for Health Promotion, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea

[7]Department Gastroenterology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea

[8]Department of Emergency Medicine, Samsung Medical Center, Seoul, Republic of Korea

[*]these authors contributed equally

Corresponding Author:
Won Chul Cha, MD
Department of Emergency Medicine
Samsung Medical Center
81, Irwon-ro, Gangnam-gu
Seoul, 06351
Republic of Korea
Phone: 82 1053866597
Fax: 82 221487899
Email: wc.cha@samsung.com

Related Article:

This is a corrected version. See correction statement: https://mhealth.jmir.org/2022/11/e43829

Abstract

Background: Specialty consultation is a critical aspect of emergency department (ED) practice, and a delay in providing consultation might have a significant clinical effect and worsen ED overcrowding. Although mobile electronic medical records (EMR) are being increasingly used and are known to improve the workflow of health care providers, limited studies have evaluated their effectiveness in real-life clinical scenarios.

Objective: For this study, we aimed to determine the association between response duration to an ED specialty consultation request and the frequency of mobile EMR use.

Methods: This retrospective study was conducted in an academic ED in Seoul, South Korea. We analyzed EMR and mobile EMR data from May 2018 to December 2018. Timestamps of ED consultation requests were retrieved from a PC-based EMR, and the response interval was calculated. Doctors' log frequencies were obtained from the mobile EMR, and we merged data using doctors' deidentification numbers. Pearson's product-moment correlation was performed to identify this association. The primary outcome was the relationship between the frequency of mobile EMR usage and the time interval from ED request to consultation completion by specialty doctors. The secondary outcome was the relationship between the frequency of specialty doctors' mobile EMR usage and the response time to consultation requests.

Results: A total of 25,454 consultations requests were made for 15,555 patients, and 252 specialty doctors provided ED specialty consultations. Of the 742 doctors who used the mobile EMR, 208 doctors used it for the specialty consultation process. After

excluding the cases lacking essential information, 21,885 consultations with 208 doctors were included for analysis. According to the mobile EMR usage pattern, the average usage frequency of all users was 13.3 logs/day, and the average duration of the completion of the specialty consultation was 51.7 minutes. There was a significant inverse relationship between the frequency of mobile EMR usage and time interval from ED request to consultation completion by specialty doctors (coefficient=–0.19; 95% CI –0.32 to –0.06; *P*=.005). Secondary analysis with the response time was done. There was also a significant inverse relationship between the frequency of specialty doctors' mobile EMR usage and the response time to consultation requests (coefficient=–0.18; 95% CI –0.30 to –0.04; *P*=.009).

Conclusions: Our findings suggest that frequent mobile EMR usage is associated with quicker response time to ED consultation requests.

(JMIR Mhealth Uhealth 2020;8(2):e14487) doi:10.2196/14487

KEYWORDS

electronic medical record; emergency department; mobile health; time efficiency

Introduction

Background

Specialty consultation is a critical aspect of emergency department (ED) practice [1]. Specialty consultation occurs when an ED doctor contacts a specialty doctor to decide the disposition of patients who require care beyond the scope of ED services. There are five types of specialty consultations: admission, seeking opinion, special procedures, transfer of care, and outpatient referrals [2].

A delayed response from the specialty doctor can cause disposition delay and contribute to ED crowding, which has been a critical public health concern [1,3-6]. It can also result in conflicts and misunderstanding among doctors, which can even lead to life-threatening outcomes for the patients and legal problems for the doctors [1]. Although many studies have suggested ways to manage consultation delays [2,7,8], consultation is still a laborious task. Strategies to reduce consultation delay should be considered and implemented.

Mobile Technology

Mobile electronic medical records (EMR) are being increasingly used by health care providers [9-11]. Several studies have reported that ubiquitous access to patient data through mobile EMRs and their portability in real-time can help doctors work more efficiently [12,13]. Studies conducted in EDs with mobile devices or mobile EMRs showed positive results for the improvement of clinical flow and efficiency [14-16]. However, given that mobile EMR usage has been generally low and varies among doctors [10,17,18], most studies evaluated the impact of mobile EMR using surveys or simulation methods [12,14-16]. To the best of our knowledge, none of the previous studies evaluated time efficiency in a real clinical setting for the frequency of mobile EMR usage.

Study Objectives

In this study, we aimed to determine the association between doctor's response duration to ED consultation requests and their frequency of mobile EMR use.

Methods

Study Setting

This retrospective study was conducted in the ED of Samsung Medical Center, Seoul, South Korea. The ED is part of a tertiary academic teaching hospital with 2000 inpatient beds and daily average outpatient visits of more than 9000 in 2018. The ED consists of 69 treatment beds and admits an average of 200 patients daily. The total number of ED cases in 2018 was approximately 79,000. The study protocol was reviewed and approved by the Samsung Medical Center Institutional Review Board (IRB #2019-01-113-001).

Mobile Electronic Medical Records

The hospital's EMR system, known as DARWIN (Data Analysis & Research Window for Integrated kNowledge), was launched in July 2016 with both PC and mobile versions. The mobile DARWIN (mDARWIN) is based on Android 2.3 Gingerbread (Google Inc, Mountain View, California, United States) and has Wi-Fi and 3G capabilities. It consists of the main menu, list-level features, and patient-level features. After logging in to the system using their identification number and password, users can select from the main menu to view a list-level feature or select a function. From each list-level feature, users can select patient-level features for more activities or leave and move to other list-level features. Each session closes either when a user logs out or after no activity has taken place for a certain amount of time. The mDARWIN also supports fingerprint log in and near-field communication.

Specialty Consultation Process

A specialty consultation involves three necessary steps: (1) sending a request; (2) responding to the request; and (3) answering the request (Figure 1). All consultations are requested through EMR except for the radiology department's interpretations of imaging findings, which is done via a PC messenger. When an ED doctor makes a specialty consultation request to a specific specialty department in the "Specialty consultation administration" window in the EMR, the written request is immediately sent via a mobile EMR notification and mobile text message to the on-call doctor in the department at the time of consultation request (Figure 2).

Figure 1. The specialty consultation process flow and outcome measurement of the study. The primary outcome was a measurement of the interval between consultation request and draft consultation note, while the secondary outcome used the interval between consultation request and response. ED: emergency department; EMR: electronic medical record.

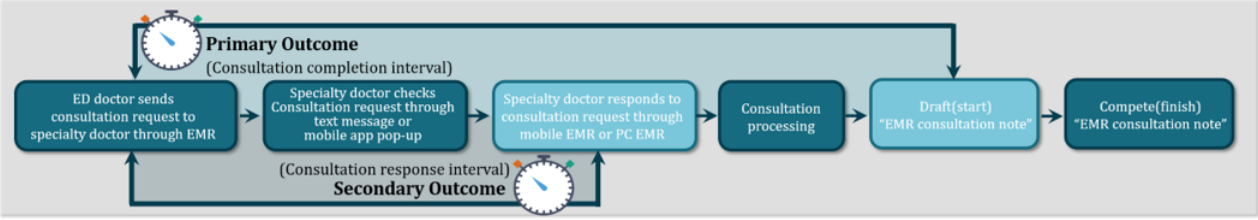
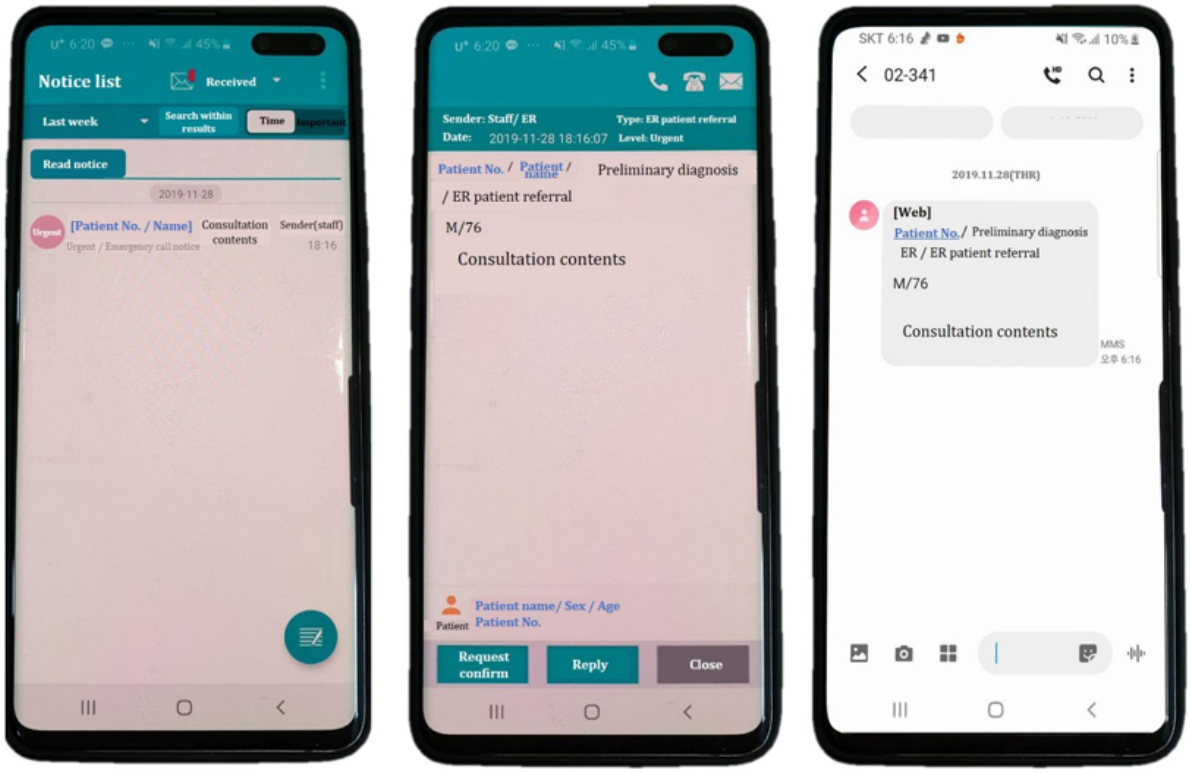


Figure 2. Screenshots of a consultation request made via mobile electronic medical record popup (left, middle) or text message (right).



The specialty doctor acknowledges the consultation, which is verified by opening the mobile EMR notification or using the nearest PC EMR at that time. Either of these two actions is recorded as a response in the "Specialty consultation administration," and the ED doctor is notified of the delivery of their consultation to the specialty doctor. The specialty doctor then goes to the ED and sees the patients. After examining the patients, the consultation note from the specialty doctor can be written only via PC-based EMR and not mobile EMR. The timestamp of drafting and completing the consultation note is recorded, and a completed consultation note by the specialty doctor is considered the closing of the consultation. The ED doctor can then make decisions on patient disposition according to the note.

Study Subjects

We analyzed specialty consultations for patients presented to the ED from May 2018 to December 2018. Patients who left without being examined or patients who were transferred directly to another location, like the delivery room, were excluded. Specialty consultations of radiology, pediatric, and emergency departments, which have different consultation processes, were also excluded. Doctors were categorized based on occupation (staff, fellows, and residents) and specialty (physician, surgeon, or another hospital-based group). The physician group consisted of internal medicine, the surgeon group was comprised of general surgery, neurosurgery, thoracic surgery, otolaryngology, ophthalmology, obstetrics/gynecology, orthopedic surgery, plastic surgery, and the urology department. The other hospital-based groups included critical-care medicine, dentistry, neurology, psychiatry, radio-oncology, and rehabilitation medicine. Consultations lacking time information due to missing consultation notes, or consulting without responses, were excluded.

Data Collection and Processing

Timestamp data on emergency consultations were retrieved from the EMR of the patients admitted to the ED during the study period. Data on three types of timestamps were collected: (1) time of consultation request by the ED doctor, which is recorded in the PC EMR by the requesting ED physician; (2) time of response made by the specialty doctor, which is recorded

in the EMR or mobile EMR by the requested specialty physician; and (3) time of drafting the consultation note by the specialty doctor, which is recorded when the specialty doctor selects "draft consultation note." Then, the time intervals were calculated, with time interval (1) to (3) defined as the consultation completion interval, and time interval (1) to (2) defined as the consultation response interval.

The frequency of mDARWIN usage was extracted from the log data. Frequency was defined as the sum of all event logs such as log in, selecting an option, log out, and other actions on the mDARWIN. The overall usage of individual features in the mDARWIN was examined by summarizing the usage frequencies of features from the log data. Timestamp data were merged with doctors' log frequency data using doctors' deidentification numbers. The merged data were then analyzed.

Outcome Measures and Sensitivity Analysis

The primary outcome was the relationship between the frequency of mDARWIN usage and the consultation completion interval. The drafting of the consultation note is considered to be the completion of the request. The ED physician then discharges the patients according to the consultation note. If the consultation note by the specialty physician advises further examinations, such as laboratory tests or additional radiological tests, the disposition decision will be delayed until the advised tests have been completed. The interval time from drafting the consultation note to finalizing the consultation note is determined by patient factors rather than workflow. Without a conclusion, answer of disposition, or additional examination of the consulted patient, the specialty physician cannot write a consultation note; the drafting of the consultation note, therefore, indicates the end of the consultation process.

Subanalysis was performed with the group of specialty doctors who had left log records between the timestamp of the ED consultation request and the timestamp for drafting the consultation note. We calculated the median mobile log frequency for this group and compared the median interval time between the high-frequency group (higher than the median frequency) and the low-frequency group (lower than the median frequency).

The secondary outcome was the relationship between the frequency of mDARWIN usage and the consultation response interval. The primary and secondary outcomes are depicted in Figure 1.

Statistical Analysis

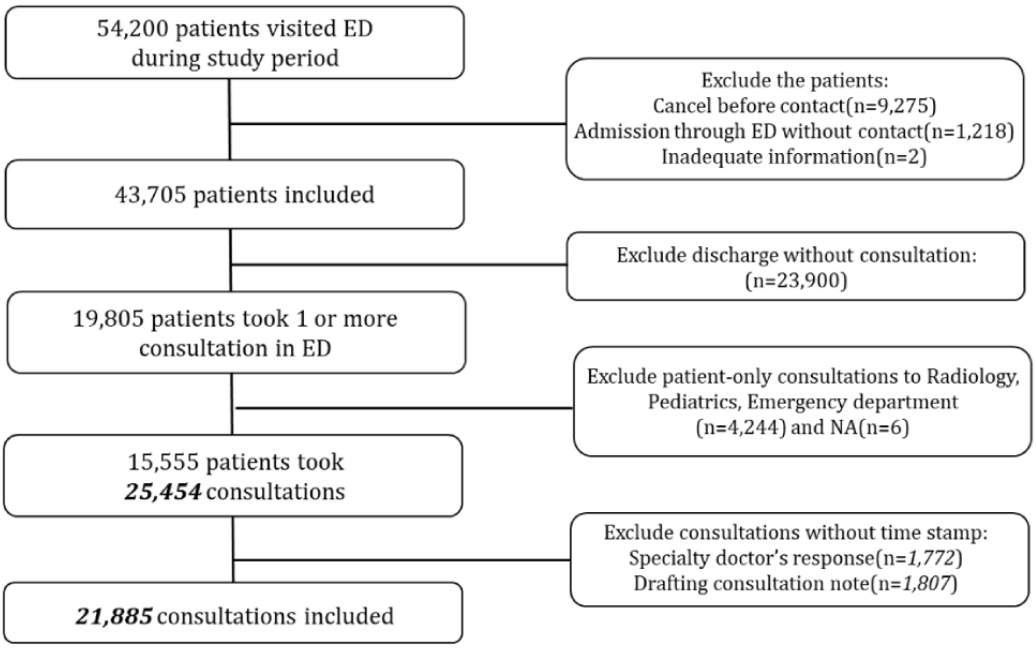
Continuous variables are expressed in terms of averages and standard deviations, and categorical variables are expressed in frequencies and percentages. To identify a correlation between frequency and time intervals, we performed Pearson's product-moment correlation and analyzed the summary of the linear model. The differences between the groups were examined using a one-tailed Student's *t* test for categorical variables. *P* values <.05 were considered significant. Data analyses were performed using R software version 3.4.2 (The R Project for Statistical Computing, Vienna, Austria).

Results

Characteristics of the Subjects

A total of 54,200 patients visited the ED during the study period. After excluding patients based on the exclusion criteria, 25,454 emergency consultations of 15,555 ED patients were included in the analysis. After excluding consultations lacking time information, 21,885 consultations were included in the analysis. Figure 3 presents the flowchart of subject inclusion. Multimedia Appendix 1 presents the demographics of the included subjects. Severity was assessed using the Korean Triage and Acuity Scale (KTAS), which was developed based on the Canadian Triage and Acuity Scale and is used across all Korean EDs. KTAS Level 1 indicates the highest acuity or severity of distress, and level 5 indicates the lowest [19].

Figure 3. Flowchart of patient inclusion in the specialty consultation process. ED: emergency department; NA: No information about consultation department.



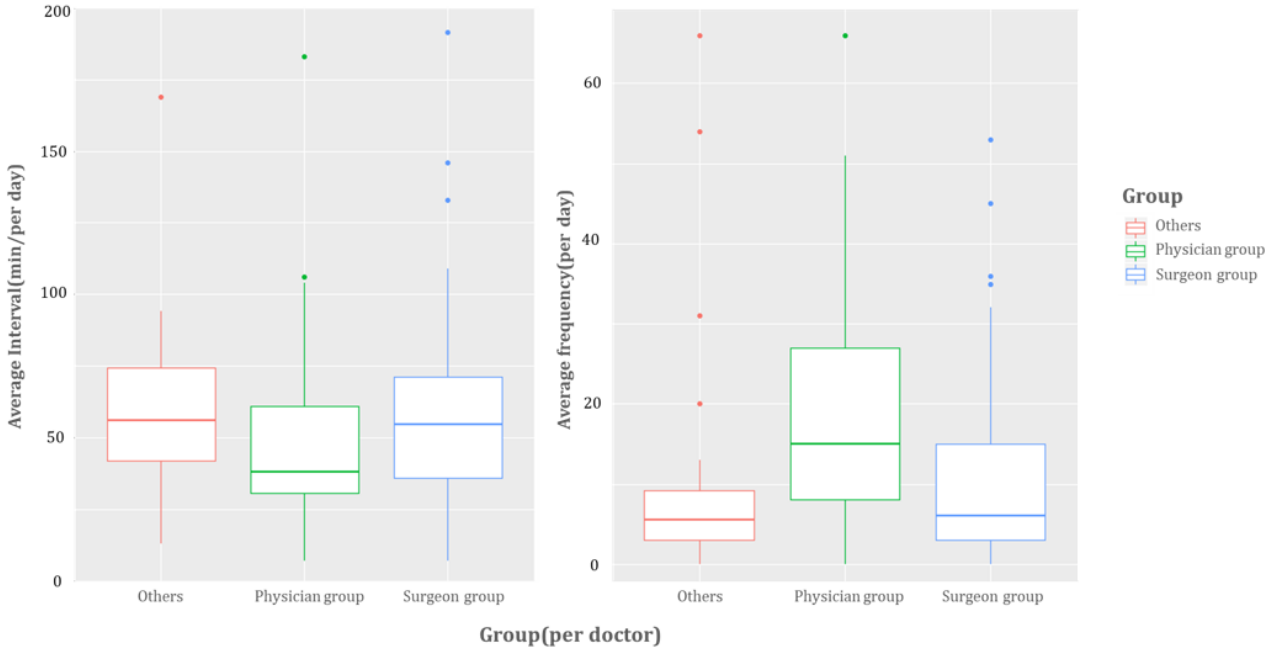
A total of 21,885 consultations were done, and 252 specialty doctors responded to these ED consultation requests. The specific departments of consultations are shown in Multimedia Appendix 2. The demographic characteristics of the doctors who provided consultations are shown in Table 1. Figure 4 provides mDARWIN usage patterns by group.

Table 1. Demographics of doctors related to specialty consultations.

Department	Position, n (%)	
	Staff and fellows	Resident
Physician group (n=86)	45 (52)	41 (48)
Surgeon group (n=120)	13 (11)	107 (89)
OHBP[a] group (n=46)	19 (41)	27 (59)

[a]OHBP: other hospital-based physician.

Figure 4. Median consultation completion interval and log frequency of doctors who used mobile electronic medical records in specialty consultation.



Log Data

During the study period, a total of 2,170,625 mobile EMR logs were created by 742 doctors of 39 specialty departments. Doctors included 218 professors (29%), 140 clinical fellows (19%), and 384 residents (52%). Of the 742 doctors, 208 used mobile EMR in the consultation process, and the following distribution was observed: physician group=34.6% (72/208), surgeon group=51.9% (108/208), and other hospital-based physician groups=13.5% (28/208). According to the mDARWIN usage pattern, the average log frequency of all users per day was 13.3, and the average time to complete the specialty consultation was 51.7 minutes. Among the three doctor groups, the physician group used mobile EMR more frequently (average usage=19.4) than the other groups, and the average period to complete the specialty consultation was the fastest at 45.3 minutes.

Pearson's Product-Moment Correlation

The results of the Pearson's product-moment correlation (Figure 5) showed that consultation completion interval time had a significant inverse relationship with mobile EMR usage frequency (coefficient=–0.19; 95% CI –0.32 to –0.06; *P*=.005). Subgroup analysis classified specialty doctors who had left mobile logs in the consultation completion interval by frequency using the median. The median frequency was 2834, and completion time for the specialty doctors with high frequency (over 2834) was 78 minutes, while the completion time was 84 minutes for specialty doctors with low frequency. The difference was not statistically significant (Multimedia Appendix 3).

The same analysis with different response interval times was performed to analyze the secondary outcome. There was a significant inverse relationship between the response interval time and mDARWIN usage frequency (coefficient=–0.18; 95% CI –0.30 to –0.04; *P*=.009) (Figure 6).

Figure 5. The correlation between consultation completion interval and mobile electronic medical record frequency. EMR: electronic medical record.

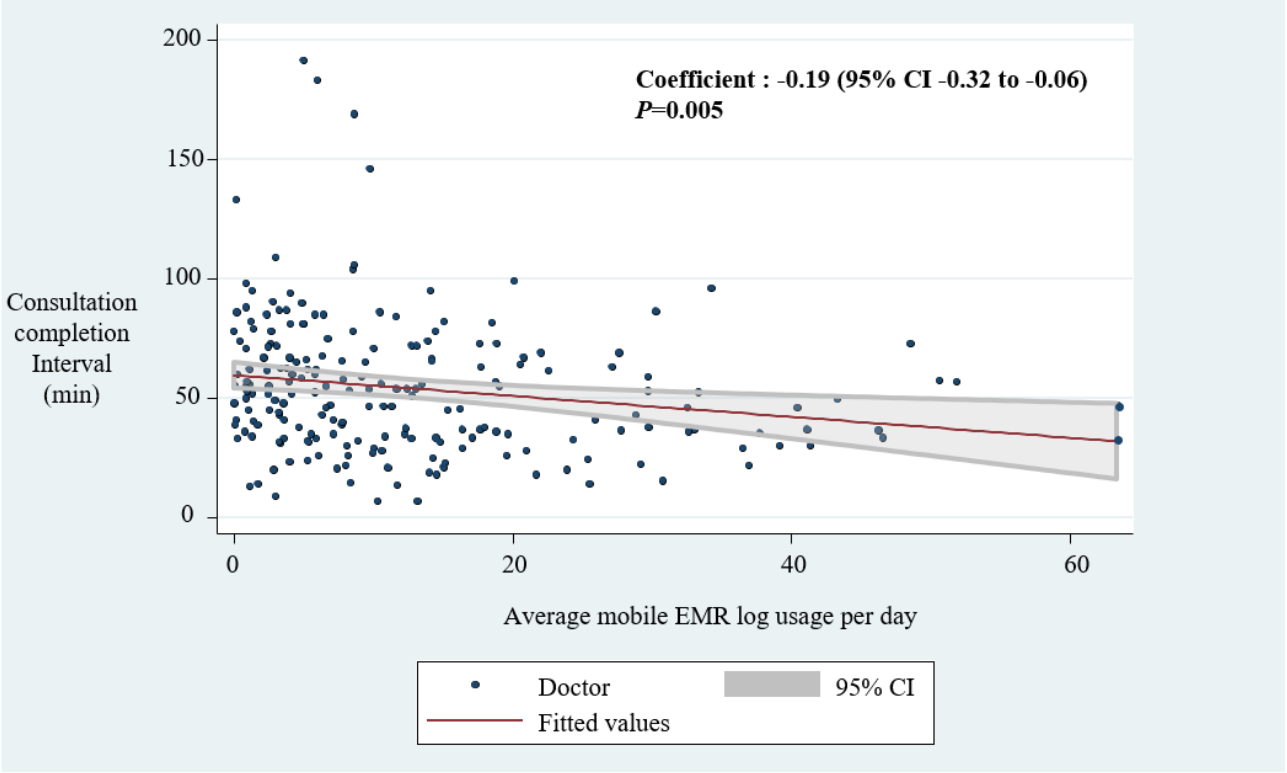
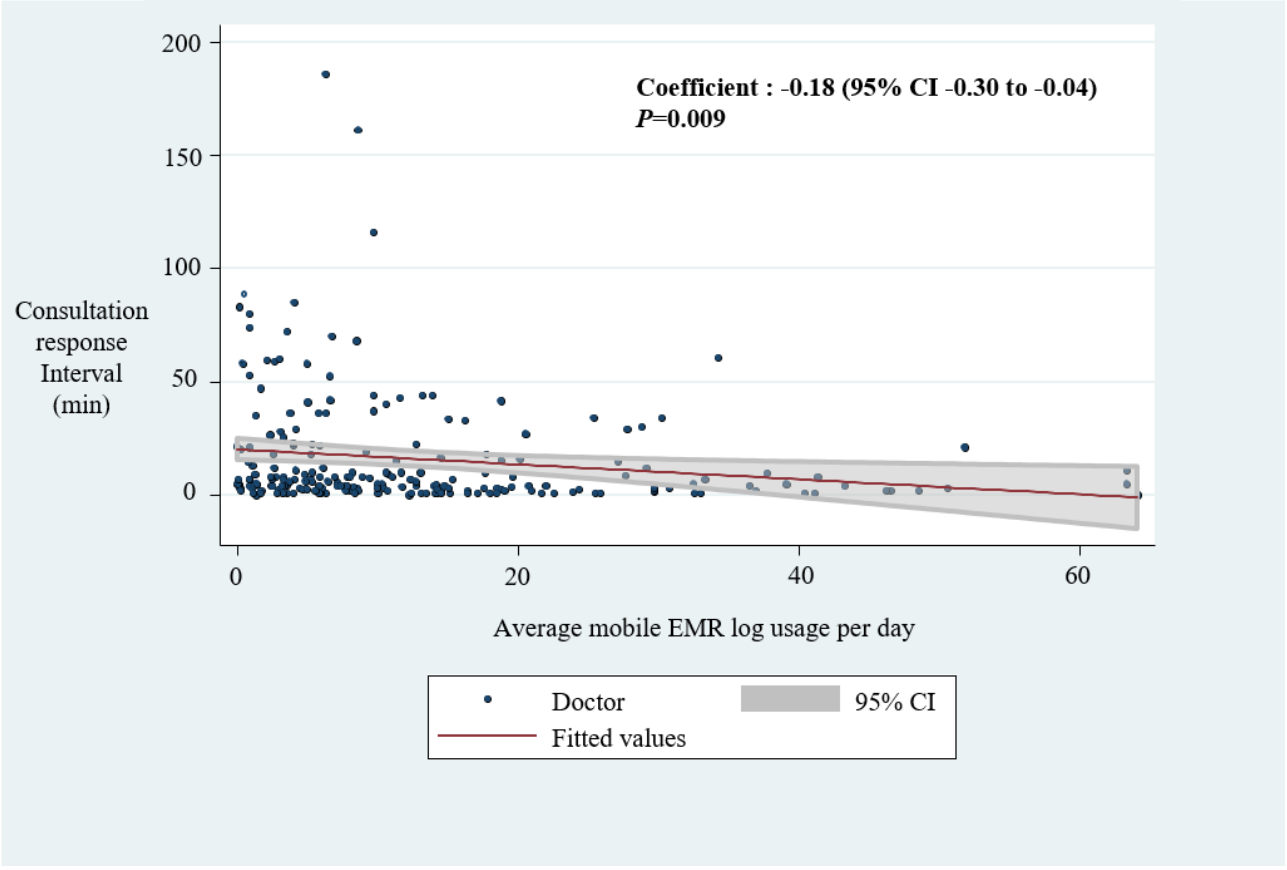


Figure 6. The correlation between consultation response interval and mobile electronic medical record frequency. EMR: electronic medical record.



Discussion

Principal Findings

This study aimed to explore the association between mobile EMR usage and specialty consultation time based on mobile EMR log data and EMR timestamp data. Our findings indicate that specialty doctors using mobile EMR frequently responded to ED consultation requests quicker and answered ED consultations with less time than the less frequent users (Figure 5 and Figure 6). This result implies that mobile EMR might be helpful in effectively managing consultation delays.

To ensure consistency in the results, we performed the subanalysis with specialty doctors who left log records between receiving the request and drafting the consultation note. Our findings showed consistent results on the association between time interval and mobile EMR usage frequency, for both primary and secondary outcome measures, without statistical insignificance (Appendix 3).

Because ED consultations are unpredictable, the specialty physician's actions after recognizing a consultation request vary from immediate to delayed, due to the demands of their daily jobs. Some specialty physicians could respond immediately and concentrate only on the ED consultation, while others inevitably dealt with ED consultations and other jobs simultaneously. In the analysis of real-world retrospective data, it is difficult to know whether all log data are related to ED consultation, even if log data appears in the interval between consultation requests and drafting consultation notes. Instead of cutting log data, we analyzed the total log data frequency. Nevertheless, the steps "response to request" and "drafting consultation note" after concluding the consultation process are unchangeable. For this reason, we analyzed the intervals between steps.

Mobile Electronic Medical Records in Real Emergency Department Flow

ED crowding is generally estimated by length of stay [20], and length of stay is affected by three factors: input, throughput, and output factors [21]. Delayed response to ED consultation is a crucial independent variable of throughput and output factors of ED overcrowding conceptualization [1,22]. In the initial stages of the implementation of computerized EMR, text messaging and the use of a consultation management application were suggested, both of which were efficient [7,8]. Considering the accelerated use of mobile EMR in the present times, this study suggests the effectiveness of ED consultations.

The adoption of a mobile device in health care practice has generally contributed to improvement in clinical workflow, timeliness of communication, and patient safety [15,23-25]. A previous study reported that mobile communication using WhatsApp messenger could reduce consultation delays [26]. However, to the best of our knowledge, this study is the first to reveal that workflow efficiency and mobile EMR usability, represented by response interval and log frequency, are positively related to real-life ED settings. The improvement might be attributable to the features of mobile technology, such as the immediate alarm function in the mobile device and ubiquitous accessibility to mobile EMR. Before the mobile EMR alarm system, most of the communication about ED consultation was done via text message and phone calls. Notification of consultation via mobile EMR has helped eliminate redundant communication and deliver the patient information in the mobile EMR itself. While communication through mobile messenger has a potential risk to the security of the patient's information when using personal devices [27,28], mobile EMR with access restriction is a much safer alternative for preventing confidentiality breaches.

As the contents of the mobile EMR to cover patient information is narrower than that of the EMR, it is important to consider the information covered in the mobile EMR. Different doctors and tasks require different contents [29]. Heavy information might result in fatigue, and light information might make the notification useless. Summarized patient information should be emphasized.

A previous study pointed out that doctors tended to underestimate mobile EMR objective improvement in response time, which resulted in its lower usability [15]. Of the 252 doctors included in this study, 17.4% of doctors (44/252) never used mobile EMR to manage consultations. There were several reasons for using only PC, such as not using an Android phone, unfamiliarity with the device, or not being aware of mobile EMR. It is difficult to determine the reasons for doctors not using mobile devices in this study. Surveying the nonuser group is a key to enhancing the usability of mobile EMR.

Limitations

This study has some limitations. First, as this study was a single-center and single-department study of its system, the findings have limited generalizability. However, consultation delay remains a challenge, with many limitations that need to be addressed [8,30]; the use of the mobile EMR system has been shown to be valuable in terms of evidence.

Second, because the results of this study were based on an analysis of mobile log data, the reasons for usage patterns were not considered. An additional mixed-methods analysis, such as a user interview or survey, might better explain the usefulness of a mobile EMR system in the consultation process [31], and further evaluation of its usability might provide a clearer picture.

Third, we could not determine the causality of log data because we analyzed the entire log dataset. Although the entire log sufficed to achieve the study aim, an observational study using the small cut log of mobile EMR would be needed to demonstrate the association between behavior and mobile EMR usage.

Conclusion

Our findings suggest that frequent usage of mobile EMR is associated with improvement in ED consultation delays.

Acknowledgments

This research was supported by the Basic Science Research Program through the National Research Foundation of Korea and funded by the Ministry of Education (grant number 2018R1C1B6002877).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Demographic characteristics of the patients receiving specialty consultations.
[PDF File (Adobe PDF File), 242 KB - mhealth_v8i2e14487_app1.pdf]

Multimedia Appendix 2
Number of consultation cases by department.
[PDF File (Adobe PDF File), 242 KB - mhealth_v8i2e14487_app2.pdf]

Multimedia Appendix 3
Comparison between high and low frequency users among specialty doctors who had left log records during the consultation completion interval.
[PDF File (Adobe PDF File), 346 KB - mhealth_v8i2e14487_app3.pdf]

References

1. Lee RS, Woods R, Bullard M, Holroyd BR, Rowe BH. Consultations in the emergency department: a systematic review of the literature. Emerg Med J 2008 Jan 01;25(1):4-9. [doi: 10.1136/emj.2007.051631] [Medline: 18156528]
2. Woods RA, Lee R, Ospina MB, Blitz S, Lari H, Bullard MJ, et al. Consultation outcomes in the emergency department: exploring rates and complexity. CJEM 2008 Jan;10(1):25-31. [doi: 10.1017/s1481803500009970] [Medline: 18226315]
3. Hoot NR, Aronsky D. Systematic review of emergency department crowding: causes, effects, and solutions. Ann Emerg Med 2008 Aug;52(2):126-136. [doi: 10.1016/j.annemergmed.2008.03.014] [Medline: 18433933]
4. Li G, Lau JT, McCarthy ML, Schull MJ, Vermeulen M, Kelen GD. Emergency department utilization in the United States and Ontario, Canada. Acad Emerg Med 2007 Jun;14(6):582-584 [FREE Full text] [doi: 10.1197/j.aem.2007.02.030] [Medline: 17470903]
5. Cha WC, Song KJ, Cho JS, Singer AJ, Shin SD. The Long-Term Effect of an Independent Capacity Protocol on Emergency Department Length of Stay: A before and after Study. Yonsei Med J 2015 Sep;56(5):1428-1436 [FREE Full text] [doi: 10.3349/ymj.2015.56.5.1428] [Medline: 26256991]
6. Shen Y, Lee LH. Improving the wait time to consultation at the emergency department. BMJ Open Qual 2018;7(1):e000131 [FREE Full text] [doi: 10.1136/bmjoq-2017-000131] [Medline: 29333496]
7. Kim MJ, Park JM, Je SM, You JS, Park YS, Chung HS, et al. Effects of a short text message reminder system on emergency department length of stay. Int J Med Inform 2012 May;81(5):296-302. [doi: 10.1016/j.ijmedinf.2012.01.001] [Medline: 22300639]
8. Cho SJ, Jeong J, Han S, Yeom S, Park SW, Kim HH, et al. Decreased emergency department length of stay by application of a computerized consultation management system. Acad Emerg Med 2011 Apr;18(4):398-402 [FREE Full text] [doi: 10.1111/j.1553-2712.2011.01039.x] [Medline: 21496143]
9. Kim J, Lee Y, Lim S, Lee J. How Are Doctors Using Mobile Electronic Medical Records? An In-Depth Analysis of the Usage Pattern. Stud Health Technol Inform 2017;245:1231. [Medline: 29295318]
10. Kim S, Lee K, Hwang H, Yoo S. Analysis of the factors influencing healthcare professionals' adoption of mobile electronic medical record (EMR) using the unified theory of acceptance and use of technology (UTAUT) in a tertiary hospital. BMC Med Inform Decis Mak 2016 Jan 30;16:12 [FREE Full text] [doi: 10.1186/s12911-016-0249-8] [Medline: 26831123]
11. Choi W, Park M, Hong E, Kim S, Ahn R, Hong J, et al. Early Experiences with Mobile Electronic Health Records Application in a Tertiary Hospital in Korea. Healthc Inform Res 2015 Oct;21(4):292-298 [FREE Full text] [doi: 10.4258/hir.2015.21.4.292] [Medline: 26618036]
12. Fleischmann R, Duhm J, Hupperts H, Brandt SA. Tablet computers with mobile electronic medical records enhance clinical routine and promote bedside time: a controlled prospective crossover study. J Neurol 2015 Mar;262(3):532-540 [FREE Full text] [doi: 10.1007/s00415-014-7581-7] [Medline: 25476692]
13. Burdette SD, Herchline TE, Oehler R. Surfing the web: practicing medicine in a technological age: using smartphones in clinical practice. Clin Infect Dis 2008 Jul 01;47(1):117-122. [doi: 10.1086/588788] [Medline: 18491969]
14. Rao AS, Adam TJ, Gensinger R, Westra BL. Study of the factors that promoted the implementation of electronic medical record on iPads at two emergency departments. AMIA Annu Symp Proc 2012;2012:744-752 [FREE Full text] [Medline: 23304348]

15. Duhm J, Fleischmann R, Schmidt S, Hupperts H, Brandt SA. Mobile Electronic Medical Records Promote Workflow: Physicians' Perspective From a Survey. JMIR Mhealth Uhealth 2016 Jun 06;4(2):e70 [FREE Full text] [doi: 10.2196/mhealth.5464] [Medline: 27268720]
16. Jung KY, Kim T, Jung J, Lee J, Choi JS, Mira K, et al. The Effectiveness of Near-Field Communication Integrated with a Mobile Electronic Medical Record System: Emergency Department Simulation Study. JMIR Mhealth Uhealth 2018 Sep 21;6(9):e11187 [FREE Full text] [doi: 10.2196/11187] [Medline: 30249577]
17. Wu I, Li J, Fu C. The adoption of mobile healthcare by hospital's professionals: An integrative perspective. Decision Support Systems 2011 Jun;51(3):587-596. [doi: 10.1016/j.dss.2011.03.003]
18. Ben-Assuli O. Electronic health records, adoption, quality of care, legal and privacy issues and their implementation in emergency departments. Health Policy 2015 Mar;119(3):287-297. [doi: 10.1016/j.healthpol.2014.11.014] [Medline: 25483873]
19. Kim JH, Kim JW, Kim SY, Hong DY, Park SO, Baek KJ, et al. Validation of the Korean Triage and Acuity Scale compare to Triage by Emergency Severity Index for emergency adult patient: Preliminary study in a tertiary hospital emergency medical center. J Korean Soc Emerg Med 2016 Oct;27(5):436-441 [FREE Full text]
20. Rathlev NK, Chessare J, Olshaker J, Obendorfer D, Mehta SD, Rothenhaus T, et al. Time series analysis of variables associated with daily mean emergency department length of stay. Ann Emerg Med 2007 Mar;49(3):265-271. [doi: 10.1016/j.annemergmed.2006.11.007] [Medline: 17224203]
21. Morley C, Unwin M, Peterson GM, Stankovich J, Kinsman L. Emergency department crowding: A systematic review of causes, consequences and solutions. PLoS One 2018;13(8):e0203316 [FREE Full text] [doi: 10.1371/journal.pone.0203316] [Medline: 30161242]
22. Yoon P, Steiner I, Reinhardt G. Analysis of factors influencing length of stay in the emergency department. CJEM 2003 May;5(3):155-161. [doi: 10.1017/s1481803500006539] [Medline: 17472779]
23. Wu R, Rossos P, Quan S, Reeves S, Lo V, Wong B, et al. An evaluation of the use of smartphones to communicate between clinicians: a mixed-methods study. J Med Internet Res 2011 Aug 29;13(3):e59 [FREE Full text] [doi: 10.2196/jmir.1655] [Medline: 21875849]
24. Przybylo JA, Wang A, Loftus P, Evans KH, Chu I, Shieh L. Smarter hospital communication: secure smartphone text messaging improves provider satisfaction and perception of efficacy, workflow. J Hosp Med 2014 Sep;9(9):573-578 [FREE Full text] [doi: 10.1002/jhm.2228] [Medline: 25110991]
25. Lo V, Wu RC, Morra D, Lee L, Reeves S. The use of smartphones in general and internal medicine units: a boon or a bane to the promotion of interprofessional collaboration? J Interprof Care 2012 Jul 09;26(4):276-282. [doi: 10.3109/13561820.2012.663013] [Medline: 22482742]
26. Gulacti U, Lok U, Hatipoglu S, Polat H. An Analysis of WhatsApp Usage for Communication Between Consulting and Emergency Physicians. J Med Syst 2016 Jun;40(6):130. [doi: 10.1007/s10916-016-0483-8] [Medline: 27083574]
27. Prochaska MT, Bird A, Chadaga A, Arora VM. Resident Use of Text Messaging for Patient Care: Ease of Use or Breach of Privacy? JMIR Med Inform 2015 Nov 26;3(4):e37 [FREE Full text] [doi: 10.2196/medinform.4797] [Medline: 26611620]
28. Moon BC, Chang H. Technology Acceptance and Adoption of Innovative Smartphone Uses among Hospital Employees. Healthc Inform Res 2014 Oct;20(4):304-312 [FREE Full text] [doi: 10.4258/hir.2014.20.4.304] [Medline: 25405067]
29. Prgomet M, Georgiou A, Westbrook JI. The impact of mobile handheld technology on hospital physicians' work practices and patient care: a systematic review. J Am Med Inform Assoc 2009;16(6):792-801 [FREE Full text] [doi: 10.1197/jamia.M3215] [Medline: 19717793]
30. Lee PA, Rowe BH, Innes G, Grafstein E, Vilneff R, Wang D, et al. Assessment of consultation impact on emergency department operations through novel metrics of responsiveness and decision-making efficiency. CJEM 2014 May;16(3):185-192. [doi: 10.2310/8000.2013.130973] [Medline: 24852581]
31. Sieverink F, Kelders S, Poel M, van Gemert-Pijnen L. Opening the Black Box of Electronic Health: Collecting, Analyzing, and Interpreting Log Data. JMIR Res Protoc 2017 Aug 07;6(8):e156 [FREE Full text] [doi: 10.2196/resprot.6452] [Medline: 28784592]

Abbreviations

DARWIN: Data Analysis & Research Window for Integrated kNowledge
ED: emergency department
EMR: electronic medical record
KTAS: Korean Triage and Acuity Scale
mDARWIN: mobile Data Analysis & Research Window for Integrated kNowledge

Edited by G Eysenbach; submitted 25.04.19; peer-reviewed by J Lee, C Fincham; comments to author 13.05.19; revised version received 07.10.19; accepted 16.12.19; published 14.02.20.

Please cite as:
Jung KY, Kim S, Kim K, Lee EJ, Kim K, Lee J, Choi JS, Kang M, Chang DK, Cha WC
Frequent Mobile Electronic Medical Records Users Respond More Quickly to Emergency Department Consultation Requests: Retrospective Quantitative Study
JMIR Mhealth Uhealth 2020;8(2):e14487
URL: http://mhealth.jmir.org/2020/2/e14487/
doi:10.2196/14487
PMID:32130157

Original Paper

Medication Management Apps for Diabetes: Systematic Assessment of the Transparency and Reliability of Health Information Dissemination

Zhilian Huang[1,2], MPH; Elaine Lum[1,3,4], Adv Prac Pharm, BPharm, MClinPharm, PhD; Josip Car[1], FRCP (Edin), FFPH, MSc, DIC, PhD, MD

[1]Centre for Population Health Sciences, Lee Kong Chian School of Medicine, Nanyang Technological University, Singapore, Singapore

[2]NTU Institute for Health Technologies, Interdisciplinary Graduate School, Nanyang Technological University, Singapore, Singapore

[3]Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Australia

[4]School of Clinical Sciences, Faculty of Health, Queensland University of Technology, Brisbane, Australia

Corresponding Author:
Zhilian Huang, MPH
Centre for Population Health Sciences
Lee Kong Chian School of Medicine
Nanyang Technological University
11 Mandalay Road
Clinical Sciences Building, Level 18
Singapore, 308322
Singapore
Phone: 65 65923945
Email: ZHUANG014@e.ntu.edu.sg

Abstract

Background: Smartphone apps are increasingly used for diabetes self-management because of their ubiquity and ability to help users to personalize health care management. The number of diabetes apps has proliferated in recent years, but only a small subset of apps that pose a higher risk are regulated by governmental agencies. The transparency and reliability of information sources are unclear for apps that provide health care advice and are not regulated by governmental agencies.

Objective: This study aimed to assess the transparency and reliability of information disseminated via diabetes apps against 8 criteria adapted from the Health On the Net code of conduct (HONcode) principles.

Methods: English-language diabetes-related terms were searched on a market explorer (42matters) on June 12, 2018. Apps with medication and blood glucose management features were downloaded and evaluated against the App-HONcode criteria adapted from the 8 HONcode principles: authoritative, complementarity, privacy, attribution, justifiability, transparency, financial disclosure, and advertising policy. Apps were profiled by operating platforms (ie, Android and iOS) and the number of downloads (ie, Android only: ≥100,000 downloads and <100,000 downloads).

Results: A total of 143 apps (81 Android and 62 iOS) were downloaded and assessed against the adapted App-HONcode criteria. Most of the apps on the Android and iOS platforms fulfilled between 2 and 6 criteria, but few (20/143, 14.0%) apps mentioned the qualifications of individuals who contributed to app development. Less than half (59/143, 39.2%) of the apps disclaimed that the information provided or app functions do not replace the advice of the health care provider. A higher proportion of iOS apps fulfilled 5 or more App-HONcode criteria compared with Android apps. However, Android apps were more likely to have the developer's email listed on the app store (Android: 75/81, 98%; and iOS: 52/62, 84%; *P*=.005) compared with iOS apps. Of the Android apps assessed, a significantly higher proportion of highly downloaded apps had a privacy and confidentiality clause (high downloads: 15/17, 88%; and low downloads: 33/64, 52%; *P*=.006) and were more likely to discuss their financial sources (high downloads: 14/17, 82%; and low downloads: 32/64, 50%; *P*=.03) compared with apps with a low number of downloads.

Conclusions: Gaps in the disclosure of the developer's qualification, funding source, and the complementary role of the app in disease management were identified. App stores, developers, and medical providers should collaborate to close these gaps and provide more transparency and reliability to app users. Future work can further examine the consent-seeking process for data collection, data management policies, the appropriateness of advertising content, and clarity of privacy clause of these apps.

(JMIR Mhealth Uhealth 2020;8(2):e15364) doi:10.2196/15364

KEYWORDS

health apps; digital health; diabetes; privacy; evidence-based guidance

Introduction

Background

Smartphone apps, software designed to run on mobile devices, have integrated into many aspects of daily lives and are increasingly used for disease management. For example, there are more than 2000 consumer apps to choose from to self-manage diabetes [1]. In contrast to Web-based information accessed from the computer, apps can help the user to conveniently access information with their portability and improved technological capabilities, such as increased human interaction, interoperability with other devices, and easy data collection. Health apps can have a multitude of uses, including offering advice on healthy living, communication with health care providers, and providing decision support through granular biometric data collection (eg, blood glucose) [2-4]. The adoption of health apps for chronic conditions such as diabetes is expected to grow [5]. There are currently 2.5 billion smartphone users in the world [6] and more than 300,000 health apps available for consumer download [5].

One main reason for the proliferation of health apps is the low barrier of entry for app developers to publish apps [3]. Although the 2 major app stores (ie, Apple and Google Play) review apps before publication (Multimedia Appendix 1), many apps that do not conform to the prereview checklist fall through the cracks and are published. The regulation of app stores also falls outside the purview of governmental agencies, such as purview of the Food and Drug Administration (FDA) [7]. Only a small subset of apps that can pose a higher risk and meet the regulatory definition of *device* are regulated by the FDA [8-10]. Therefore, apps with inaccurate content or advertisements may still be published and be available to consumers [11-13]. The lack of transparency regarding an app's source of content may compromise the reliability of the information it disseminates [9,14,15] and can potentially mislead or cause harm to patients who have low health literacy [16].

Concerns over the credibility and reliability of Web-based health information sources began to surface in the early days of internet usage [17,18]. The Health On the Net code of conduct (HONcode), which covers 8 principles (ie, authoritative, complementarity, privacy, attribution, justifiability, transparency, financial disclosure, and advertising policy) for website certification, was developed to help guide and standardize the reliability of health and medical information published on the internet [19]. Websites that were certified by the HONcode were assessed to be of higher quality and may reduce consumers' burden of searching for good-quality websites [20,21].

Objectives

As part of a larger study investigating the medication management features of diabetes apps [22], this study aimed to assess the transparency and reliability of information disseminated via these apps against 8 criteria adapted from the HONcode principles.

Methods

Development of App Assessment Criteria

We adapted the 8 HONcode principles (ie, authoritative, complementarity, privacy, attribution, justifiability, transparency, financial disclosure, and advertising policy) and termed it the App-HONcode criteria to suit the context of health apps and apps assessment. The initial versions of our criteria were piloted with highly downloaded (≥100,000 downloads) diabetes apps to refine and improve the clarity of the assessment criteria. Unclear statements were discussed among the app assessment team members until a consensus was reached. The *not applicable (N/A)* option was included for the assessment of *attribution* and *justifiability* to account for apps that did not provide health information within the app. The final assessment criteria are shown in (Table 1).

Table 1. Adapted Health On the Net code of conduct criteria for health app assessment.

Attribute	HONcode[a]	App-HONcode criteria	Options
Authoritative	The qualifications of the authors are indicated.	Does the app indicate the qualifications of specific individuals who developed or contributed to the development of the app?	Yes or no
Complementarity	Information should support, not replace, the doctor-patient relationship.	Is there a disclaimer stating or which implies that the information provided and/or app functions do not replace the health care provider's advice?	Yes or no
Privacy	Respect the privacy and confidentiality of personal data submitted to the site by the visitor.	Is there a privacy and confidentiality clause in the app?	Yes or no
Attribution	Cite the source(s) and date of published information on medical and health pages.	Are information sources in the app cited?	Yes, no, or N/A[b]
Justifiability	Justifiability: site must back up claims relating to benefits and performance.	Are the claims relating to benefits and performance in the app description backed up by evidence? (Answer *N/A* if there are no claims)	Yes, no, or N/A
Transparency	Accessible presentation and accurate email contact.	Are the developers contactable by email?	Yes or no
Financial disclosure	Identify funding sources.	Does the app indicate any funding sources? (*Yes* if the app is managed by a registered commercial company)	Yes or no
Advertising policy	Clearly distinguish advertising from editorial content.	Are advertorials distinguishable from content of the app?	Yes, no or no advertising

[a]HONcode: Health On the Net code of conduct.

[b]Not applicable.

App Selection and Assessment

As the app assessments were part of a larger study investigating medicines management functionalities of diabetes apps, a more detailed description of app selection and assessment can be found in another paper [22].

App Search Strategy

Diabetes terms in the English language were searched in the Google Play and Apple app stores via an app market explorer, 42matters [23], on June 12, 2018, to identify apps that were marketed for diabetes self-management. The search terms *(Diabetes OR Diabetic OR Diabetics) OR (glucose OR glycaemic OR glycemic OR blood sugar OR* HbA_{1c} *OR* A_{1c}*) OR insulin* were used to search app descriptions, and a list of app titles with descriptions was produced for screening.

App Selection

A random sample of 100 apps was first screened by 2 researchers (ZH and MLT) to ensure consistency in interpretation of the inclusion and exclusion criteria listed below. Differences in interpretations were resolved via consensus discussion with 2 other team members (EL and GJ). Random samples of apps were rescreened until an interrater agreement of above 80.0% was achieved.

Inclusion Criteria

The inclusion criteria were as follows: Apps with medication self-management features (ie, medication scheduling, reminders, tracking, information provision, and adherence review), apps with any blood glucose logging features, apps in the English language, free apps, and apps requiring payment.

Exclusion criteria

The exclusion criteria were as follows: Patient health portals linking to patients' electronic health records, apps that were not updated after January 1, 2017, intended only for health care professionals, insulin calculators/bolus correctors only, apps with exclusive blood glucose monitoring device tie-in requirement (ie, not permitting manual entry of blood glucose values), apps duplicated on the same platform, apps with regional restrictions, and technical problems (eg, crashes, screen hangs, unable to login, and unable to download).

App Assessments

Included apps were evaluated against the adapted App-HONcode criteria. In total, 5 team members (ZH, EL, GJ, CT, and MLT) underwent a calibration exercise to ensure consistency in criteria interpretation before the app assessments. Apps available on the iOS and Android platforms were treated as unique apps and assessed on both platforms because of possible differences in versions across platforms. The number of *yes* responses was summed up for each app to determine the number of App-HONcode criteria met. *N/A* responses for *attribution* and *justifiability* were treated as *not meeting the criteria* for a more conservative approach, whereas the *no advertising* response for *advertising policy* was treated as a *yes* (conforming to this principle).

Statistical Analyses

Apps were grouped by operating platform (ie, Android and iOS) and profiled according to each App-HONcode criterion using descriptive statistics. Only Android apps were further classified by the number of downloads (ie, ≥100,000 downloads and <100,000 downloads), as information on the number of downloads was not available for iOS apps. Pearson chi-square

test was used for comparisons between groups, and a 2-tailed Fisher exact test was used where the expected count was less than 5 in a group. Statistical significance was set at a *P* value of less than .05. All analyses were performed using SPSS (version 22; IBM Corp).

Results

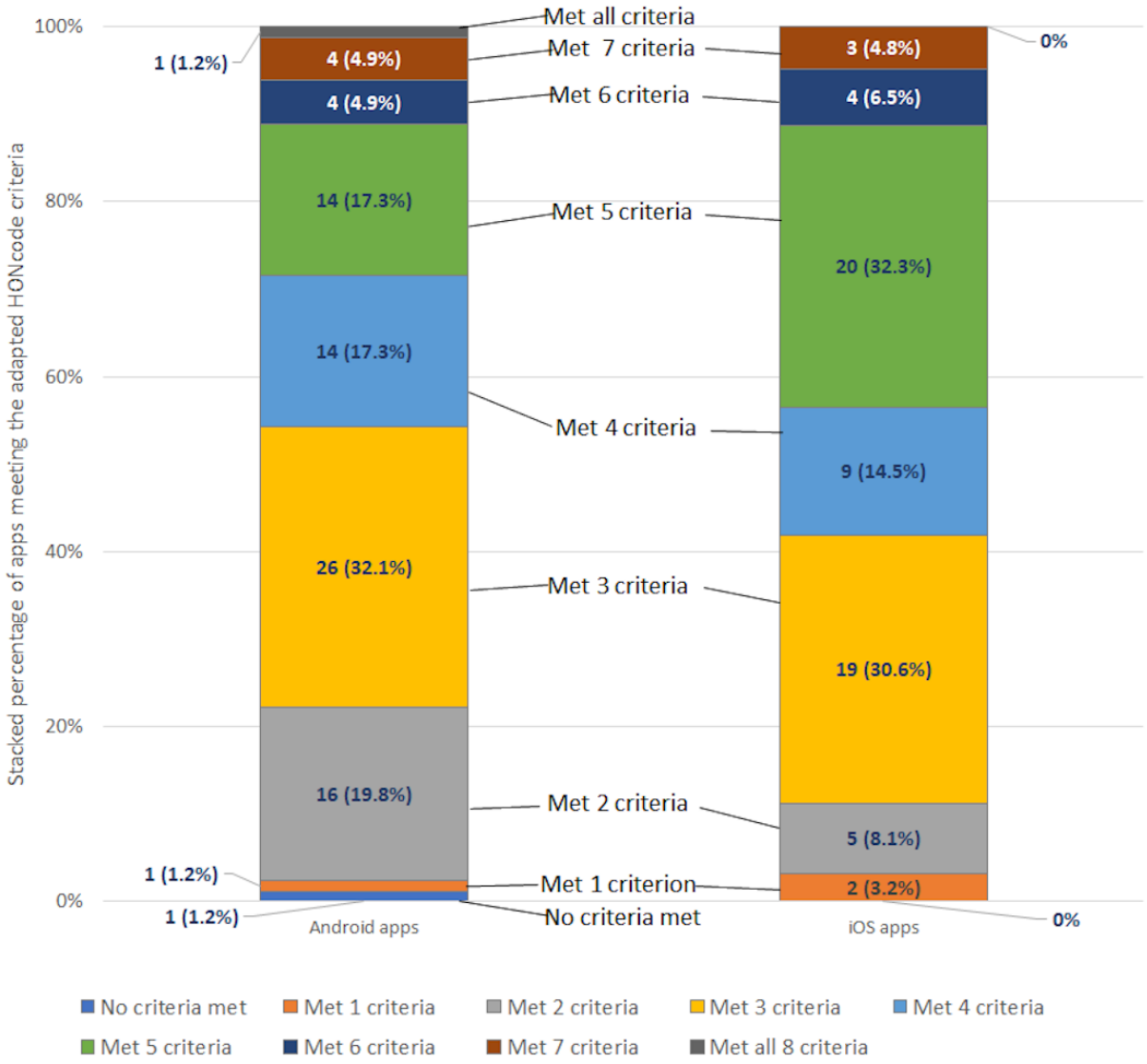
App Screening

We identified and downloaded 351 apps (191 Android and 160 iOS) after app title and description screening, of which 143 apps (81 Android and 62 iOS) met the inclusion criteria and were assessed against the app assessment criteria. The detailed app search results can be found in our study [22].

Characteristics of Included Apps

The number and proportion of the assessed apps meeting the App-HONcode criteria are shown in Figure 1. Most of the apps on the Android and iOS platforms fulfilled between 2 and 5 criteria; 1 Android app met all 8 criteria, whereas another did not meet any criteria. A higher proportion of apps published on the iOS platform met more App-HONcode criteria compared with apps on the Android platform. For example, 43.6% of iOS apps met at least five App-HONcode criteria compared with 28.3% of Android apps.

Figure 1. The number and proportion of diabetes apps meeting the App-HONcode app criteria. The number of Yes responses were summed up for each app to determine the number of app-HONcode criteria met. N/A responses for attribution and justifiability were treated as no, whereas the no advertising response for advertising policy was treated as a yes. HONcode: Health On the Net code of conduct.



The profile of app attributes grouped by platform is shown in Table 2. Few (20/143, 14.0%) apps mentioned the qualifications of individuals who contributed to app development. Less than half (56/143, 39.2%) of the apps had a disclaimer stating that the information provided/app functions do not replace a health care provider's advice, and approximately two-thirds (93/143, 65.0%) of apps had a privacy and confidentiality clause. Of the apps providing health or medical information or made claims on its efficacy, only one-third cited their information sources (15/42, 36%) and/or backed up the claims relating to benefits and performance in the app by evidence (7/23, 30%).

Table 2. Profile of app attribute grouped by platform.

HONcode[a] principle	App-HONcode criteria	All apps, n (%)	Android, n (%)	iOS, n (%)	*P* value
Authoritative	Does the app indicate the qualifications of specific individuals who developed or contributed to the development of the app?	20 (14.0)[b]	9 (11)[c]	11 (18)[d]	.33
Complementarity	Is there a disclaimer stating or which implies that the information provided and/or app functions do not replace the health care provider's advice?	56 (39.2)[b]	27 (33)[c]	29 (47)[d]	.12
Privacy	Is there a privacy and confidentiality clause in the app?	93 (65.0)[b]	48 (59)[c]	45 (73)[d]	.11
Attribution	Are information sources in the app cited?	15 (34)[e,f]	8 (36)[e,g]	7 (32)[e,h]	>.99[i]
Justifiability	Are the claims relating to benefits and performance in the app description backed up by evidence? (Answer *not applicable* if there are no claims)	7 (30)[e,j]	4 (29)[e,k]	3 (33)[e,l]	>.99[i]
Transparency	Are the developers contactable by email?	131 (91.6)[b]	79 (98)[c]	52 (84)[d]	.005[m]
Financial disclosure	Does the app indicate any funding sources? (*Yes* if the app is managed by a registered commercial company)	88 (61.5)[b]	46 (57)[c]	42 (68)[d]	.23
Advertising policy	There are no advertisements in the app	119 (83.2)[b]	64 (79)[c]	55 (89)[d]	.18
	Are advertorials distinguishable from content of the app?	18 (75)[n,o]	12 (71)[n,p]	6 (86)[n,q]	.63

[a]HONcode: Health On the Net code of conduct.

[b]N=143.

[c]N=81.

[d]N=62.

[e]Not applicable removed before statistical analysis and percentage computation.

[f]N=44.

[g]N=22.

[h]N=22.

[i]Two-tailed *P* value calculated using Fisher exact test, as the expected count is less than 5 in at least one group.

[j]N=23.

[k]N=14.

[l]N=9.

[m]Statistical significance *P*<.05 in the comparison between Android and iOS app features.

[n]Percentage is computed by dividing the number of apps with distinguishable advertisements with the total number of apps with advertisements.

[o]N=24.

[p]N=17.

[q]N=7.

There were no significant differences between the Android and iOS platforms in the proportion of apps fulfilling each criterion except for the principle of *transparency*. Android apps had a significantly higher proportion of apps with the developer's email listed on the Google play store compared with apps listed on the Apple store (Android: 75/81, 98%; and iOS: 52/62, 84%; *P*=.005). More than half (88/143, 61.5%) of the apps disclosed funding sources. Finally, most 119/143, 83.2%) of the assessed apps did not have advertisements; of apps with advertisements, three-fourths (18/24, 75%) were distinguishable from the content of the app.

Android Apps by Downloads

Table 3 shows the profile of app attribute grouped by a low (<100,000 downloads) and high number of downloads (≥100,000 downloads) for Android apps. There were no significant differences between apps with a low and high number of downloads in terms of the *authoritative*, *complementarity*, *attribution*, *justifiability*, *transparency*, and *advertising policy*. A significantly higher proportion of highly downloaded apps had a privacy and confidentiality clause (high downloads: 15/17, 88%; and low downloads: 33/64, 52%; *P*=.006) and were more likely to discuss their funding sources (high downloads: 15/17, 82%; and low downloads: 32/64, 50%;

Table 3. Profile of Android app attributes grouped by the number of downloads.

HONcode[a] principle	App-HONcode criteria	All Android apps, n (%)	<100,000 downloads, n (%)	≥100,000 downloads, n (%)	*P* value
Authoritative	Does the app indicate the qualifications of specific individuals who developed or contributed to the development of the app?	9 (11)[b]	8 (13)[c]	1 (6)[d]	.68[e]
Complementarity	Is there a disclaimer stating or which implies that the information provided and/or app functions do not replace the health care provider's advice?	27 (33)[b]	18 (28)[c]	9 (53)[d]	.08
Privacy	Is there a privacy and confidentiality clause in the app?	48 (59)[b]	33 (52)[c]	15 (88)[d]	.006[f]
Attribution	Are information sources in the app cited?	8 (36)[g,h]	7 (37)[g,i]	1 (33.3)[g,j]	>.99[e]
Justifiability	Are the claims relating to benefits and performance in the app description backed up by evidence? (Answer *not applicable* if there are no claims)	4 (29)[g,k]	3 (30)[g,l]	1 (25)[g,m]	>.99[e]
Transparency	Are the developers contactable by email?	79 (98)[b]	63 (98)[c]	16 (94)[d]	.38
Financial disclosure	Does the app indicate any funding sources? (*Yes* if the app is managed by a registered commercial company)	46 (57)[b]	32 (50)[c]	14 (82)[d]	.026[f]
Advertising policy	There are no advertisements in the app	64 (79)[b]	50 (78)[c]	14 (82)[d]	>.99[e]
	Are advertorials distinguishable from content of the app?	12 (71)[n,o]	11 (79)[n,p]	1 (33)[n,q]	.19[n]

[a]HONcode: Health On the Net code of conduct.

[b]N=81.

[c]N=64.

[d]N=17.

[e]Two-tailed *P* value calculated using Fisher exact test, as the expected count is less than 5 in at least one group.

[f]Statistical significance *P*<.05 in the comparison between Android and iOS app features.

[g]Not applicable removed before statistical analysis and percentage computation.

[h]N=22.

[i]N=19

[j]N=3.

[k]N=14.

[l]N=10.

[m]N=4.

[n]Percentage is computed by dividing the number of apps with distinguishable advertisements with the total number of apps with advertisements.

[o]N=17.

[p]N=14.

[q]N=3.

Discussion

Principal Finding

We evaluated 143 apps against 8 App-HONcode criteria to assess the transparency and reliability of information disseminated via diabetes apps. Most apps fulfilled between 2 and 5 assessment criteria, and only 1 Android app fulfilled all 8 criteria. Overall, a higher proportion of iOS apps fulfilled more App-HONcode criteria compared with Android apps, although the differences were not significant.

Many apps were not transparent in indicating the content source of the app. More than half of the assessed apps did not fulfill important criteria, such as indicating the qualifications of individuals involved in the app development and disclaiming that the app does not replace health care provider's advice. This concurs with a study assessing eczema apps, where only 15% of the app developers indicated their qualifications, and 46% disclaimed that the app does not replace the advice of the health care provider [24]. Although it may be challenging to indicate the qualifications of all individuals involved in the development of a complex app, the qualifications of the main content contributors and a representation of their collaborators should minimally be quoted to account for the content source of the app.

Approximately three-fourths of the assessed apps did not provide any health information. This was not surprising, as disease management apps tend to emphasize management aspects rather than educating the patient [1], which, in our view, presents a missed opportunity for patient education, which can be incorporated into apps. Of the apps that provided health information, only one-third cited the source of information. Few of the assessed apps had claims relating to the benefits and performance of the app. However, only one-third of these apps backed the claims with evidence. Apps or any consumer products with unsubstantiated claims have the potential to mislead and cause harm to the undiscerning consumer [16,25]. Therefore, it is imperative for app stores to check the veracity of claims used in the app description before its publication on the app stores.

Most apps had an email of the developer displayed, but the email address does not guarantee access to the app developer. We contacted the developers of apps that had access restrictions, and only 10% responded to our emails (2 emails sent a week apart). This percentage should be higher for apps that are accessible, but there is a possibility of inoperative email addresses being displayed on the app store. App stores should ensure the inclusion of a valid email address for all health apps for consumer inquiries.

Privacy breaches can erode consumers' trust in the app. Two-thirds of the apps assessed had a privacy and confidentiality clause. This was an improvement from a study published 6 years ago assessing the availability, scope, and transparency of mobile health (mHealth) app privacy policies on 600 commonly used mHealth iOS and Android apps [15]. One explanation for this improvement could be the changes made to the app store policies to improve the quality of apps over the years [26,27]. However, stricter scrutiny is required on the part of the app stores, given the absence of privacy policies in many of the assessed apps. Although there is an improvement in the presence of privacy policy of the English-language apps we assessed, those that are published on other platforms and in other languages may yield different assessment results.

Approximately 40% of the assessed apps did not have their funding sources indicated. The funding source of an app will affect its development, quality, and the services provided. This represents a gap in which app stores can play a role to improve the quality assurance of health apps. Advertisements were not present in 80% of the assessed apps. The proportion of apps with advertisements in our study may be lower, as we assessed the best version of apps requiring in-app payments for feature upgrades. Previous studies have shown that paid apps were not of higher quality compared with free apps [28,29]. Approximately one-third of the in-app advertisements were judged as being nondistinguishable from the content of the app. We did not scrutinize the appropriateness of the advertising content, which may present an additional gap in the quality and reliability of information disseminated via these apps.

The originators of the HONcode recently published an extension for apps—mHONcode—to cover the certification of health information disseminated on apps [30]. This was only available after we completed our app assessments, but there are minimal conceptual differences between our App-HONcode and the mHONcode. Our criteria were worded to minimize the subjectivity of assessment by different researchers.

Limitations

There were limitations to the study, despite attempts to minimize bias. First, the scope was limited to diabetes management apps because of being part of a larger study investigating the medication management features of diabetes apps. However, our findings are generalizable to other diabetes apps, as the apps were identified using a systematic search and selection strategy. Second, our assessment criteria may have underrated apps that do not provide health information (eg, medication logging apps). Even so, many apps were not transparent in data privacy and in clearly distinguishing the complementarity of the app (ie, not replacing the health care provider's advice). Third, the assessment may not reflect the current state of the apps because of constant app updates. However, we believe that our findings remain unchanged, as app updates were mainly for bug fixes and feature upgrades. Fourth, we neither assessed issues surrounding data management nor the content of privacy and confidentiality clauses, which may not accurately disclose the sharing of some personal information [31]. Finally, app assessments were subjective to researcher interpretation, although we attempted to reduce researcher bias by piloting the assessment and using a standardized patient profile when interacting with apps.

Implications and Future Research

The fulfillment of the 8 App-HONcode criteria are actionable, but not many developers may be aware of the need to indicate background information or to check the content of advertisements, as their main aim is to get the app published.

App developers and consumers would benefit from the availability of a standardized checklist to assess the information quality of health apps. It would be challenging for governments to regulate all health apps because of its ubiquity, pace of development, and ambiguity in definition. Therefore, app stores should play a larger role in making the transparency and reliability of information dissemination a basic requirement for app publication. As observed from our app assessments, owing to the higher barriers of entry currently set by the Apple app store (see Multimedia Appendix 1), it had a larger proportion of apps that fulfilled more App-HONcode criteria.

As health apps collect a lot more user data than the internet, the consent-seeking process for data collection and data management policies of these apps should be evaluated in the future. The appropriateness of advertising and clarity of privacy clauses should also be checked, for diabetes management and other chronic disease management apps in other languages and on other platforms, to provide a more complete landscape of the transparency and reliability of information disseminated and collected through these apps.

Conclusions

Our systematic app assessments of the transparency and reliability of health information disseminated in diabetes apps discovered gaps in the disclosure of the developer's qualification, funding source, and the complementary role of the app in disease management. App stores should play a larger role in scrutinizing app publication, as higher barriers of app entry will lead to the publication of apps with better disclosure of the app's content source. As the development of the App-HONcode criteria is preliminary, future work can further examine the consent-seeking process for data collection, data management policies, the appropriateness of advertising content, and the clarity of privacy clauses.

Acknowledgments

This study was funded by the Nanyang Technological University, Singapore, through (1) the Centre for Population Health Sciences, Lee Kong Chian School of Medicine, Nanyang Technological University, Singapore; (2) the Ageing Research Institute for Society and Education, Nanyang Technological University, Singapore; and (3) the Institute for Health Technologies, Nanyang Technological University, Singapore. The funder did not have direct involvement in the research including manuscript preparation, apart from employing the authors. The research presented in this paper is solely the responsibility of the authors and does not reflect the views of the funder. The authors wish to acknowledge Mr Geronimo Jimenez for his input in piloting and refining the app assessment criteria and Mr Geronimo Jimenez, Ms Christina Tan, and Ms My Linh Thai for their assistance in app assessment. ZH would like to acknowledge funding from the Nanyang Technological University Research Scholarship.

Authors' Contributions

ZH conceptualized and contributed to the development and refinement of the adapted HONcode app assessment criteria, screened apps, assessed apps, cleaned and analyzed data, interpreted data, and drafted and revised the manuscript. EL coconceptualized and provided critical input into the developed app assessment criteria, assessed apps, interpreted data, and revised the manuscript. JC conceptualized the study, obtained the funding, supervised the team, and provided critical input into all stages of the study and critical review of the draft manuscript. All authors reviewed and approved the final version of the manuscript before submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Selected pre-review app publication checklist of Apple and Google Play app stores.
[DOCX File , 38 KB - mhealth_v8i2e15364_app1.docx]

References

1. Huang Z, Soljak M, Boehm BO, Car J. Clinical relevance of smartphone apps for diabetes management: a global overview. Diabetes Metab Res Rev 2018 May;34(4):e2990. [doi: 10.1002/dmrr.2990] [Medline: 29431916]
2. Dayer L, Heldenbrand S, Anderson P, Gubbins PO, Martin BC. Smartphone medication adherence apps: potential benefits to patients and providers. J Am Pharm Assoc (2003) 2013;53(2):172-181 [FREE Full text] [doi: 10.1331/JAPhA.2013.12202] [Medline: 23571625]
3. West JH, Hall PC, Hanson CL, Barnes MD, Giraud-Carrier C, Barrett J. There's an app for that: content analysis of paid health and fitness apps. J Med Internet Res 2012 May 14;14(3):e72 [FREE Full text] [doi: 10.2196/jmir.1977] [Medline: 22584372]
4. Tran J, Tran R, White JR. Smartphone-based glucose monitors and applications in the management of diabetes: an overview of 10 salient 'apps' and a novel smartphone-connected blood glucose monitor. Clin Diabetes 2012;30(4):173-178. [doi: 10.2337/diaclin.30.4.173]

5. IQVIA. 2017 Nov 7. The Growing Value of Digital Health: Evidence and Impact on Human Health and the Healthcare System URL: https://www.iqvia.com/institute/reports/the-growing-value-of-digital-health [accessed 2019-06-03] [WebCite Cache ID 78qkViDOa]
6. Statista Research Department. Wayback Machine - Internet Archive. 2016. Number of Smartphone Users Worldwide From 2014 to 2020 (in Billions) URL: https://web.archive.org/web/20190704081902/https:/www.statista.com/statistics/330695/number-of-smartphone-users-worldwide/ [accessed 2019-07-04]
7. Food and Drug Administration. Wayback Machine - Internet Archive. 2015. Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff URL: https://web.archive.org/web/20190704082425/https://www.fda.gov/media/80958/download [accessed 2019-07-04]
8. Cortez NG, Cohen IG, Kesselheim AS. FDA regulation of mobile health technologies. N Engl J Med 2014 Jul 24;371(4):372-379. [doi: 10.1056/NEJMhle1403384] [Medline: 25054722]
9. Torous J, Roberts LW. Needed innovation in digital health and smartphone applications for mental health: transparency and trust. JAMA Psychiatry 2017 May 1;74(5):437-438. [doi: 10.1001/jamapsychiatry.2017.0262] [Medline: 28384700]
10. Bates DW, Landman A, Levine DM. Health apps and health policy: what is needed? J Am Med Assoc 2018 Nov 20;320(19):1975-1976. [doi: 10.1001/jama.2018.14378] [Medline: 30326025]
11. Huckvale K, Adomaviciute S, Prieto JT, Leow MK, Car J. Smartphone apps for calculating insulin dose: a systematic assessment. BMC Med 2015 May 6;13:106 [FREE Full text] [doi: 10.1186/s12916-015-0314-7] [Medline: 25943590]
12. Huckvale K, Car M, Morrison C, Car J. Apps for asthma self-management: a systematic assessment of content and tools. BMC Med 2012 Nov 22;10:144 [FREE Full text] [doi: 10.1186/1741-7015-10-144] [Medline: 23171675]
13. Chen J, Cade JE, Allman-Farinelli M. The most popular smartphone apps for weight loss: a quality assessment. JMIR Mhealth Uhealth 2015 Dec 16;3(4):e104 [FREE Full text] [doi: 10.2196/mhealth.4334] [Medline: 26678569]
14. Wicks P, Chiauzzi E. 'Trust but verify'--five approaches to ensure safe medical apps. BMC Med 2015 Sep 25;13:205 [FREE Full text] [doi: 10.1186/s12916-015-0451-z] [Medline: 26404791]
15. Sunyaev A, Dehling T, Taylor PL, Mandl KD. Availability and quality of mobile health app privacy policies. J Am Med Inform Assoc 2015 Apr;22(e1):e28-e33. [doi: 10.1136/amiajnl-2013-002605] [Medline: 25147247]
16. Ghaddar SF, Valerio MA, Garcia CM, Hansen L. Adolescent health literacy: the importance of credible sources for online health information. J Sch Health 2012 Jan;82(1):28-36. [doi: 10.1111/j.1746-1561.2011.00664.x] [Medline: 22142172]
17. Zhang Y, Sun Y, Xie B. Quality of health information for consumers on the web: a systematic review of indicators, criteria, tools, and evaluation results. J Assn Inf Sci Technol 2015;66(10):2071-2084. [doi: 10.1002/asi.23311]
18. Lee K, Hoti K, Hughes JD, Emmerton LM. Interventions to assist health consumers to find reliable online health information: a comprehensive review. PLoS One 2014;9(4):e94186 [FREE Full text] [doi: 10.1371/journal.pone.0094186] [Medline: 24710348]
19. Health On the Net. 1995. HONcode Certification URL: https://www.hon.ch/en/certification.html#principles [accessed 2019-07-04]
20. Taki S, Campbell KJ, Russell CG, Elliott R, Laws R, Denney-Wilson E. Infant feeding websites and apps: a systematic assessment of quality and content. Interact J Med Res 2015 Sep 29;4(3):e18 [FREE Full text] [doi: 10.2196/ijmr.4323] [Medline: 26420339]
21. Loy JS, Ali EE, Yap KY. Quality assessment of medical apps that target medication-related problems. J Manag Care Spec Pharm 2016 Oct;22(10):1124-1140 [FREE Full text] [doi: 10.18553/jmcp.2016.22.10.1124] [Medline: 27668561]
22. Huang Z, Lum E, Jimenez G, Semwal M, Sloot P, Car J. Medication management support in diabetes: a systematic assessment of diabetes self-management apps. BMC Med 2019 Jul 17;17(1):127 [FREE Full text] [doi: 10.1186/s12916-019-1362-1] [Medline: 31311573]
23. 42matters: Mobile App Intelligence. URL: https://42matters.com/ [accessed 2019-07-04]
24. van Galen LS, Xu X, Koh M, Thng S, Car J. Eczema apps conformance with clinical guidelines: a systematic assessment of functions, tools and content. Br J Dermatol 2019 Jun 9. [doi: 10.1111/bjd.18152] [Medline: 31179535]
25. Vladeck DC. Truth and Consequences: The Perils of Half-Truths and Unsubstantiated Health Claims for Dietary Supplements. J Public Policy Mark 2000;19(1):132-138. [doi: 10.1509/jppm.19.1.132.16948]
26. Apple Developer. 2019. App Store Review Guidelines URL: https://developer.apple.com/app-store/review/guidelines/ [accessed 2019-10-27]
27. Salim S. Digital Information World. 2019 Apr 18. Google Tweaks Its Policy With Aim to Improve 'App Quality' in Play Store URL: https://www.digitalinformationworld.com/2019/04/google-android-policy-improve-app-quality-in-play-store.html [accessed 2019-10-27]
28. Middelweerd A, Mollee JS, van der Wal CN, Brug J, te Velde SJ. Apps to promote physical activity among adults: a review and content analysis. Int J Behav Nutr Phys Act 2014 Jul 25;11:97 [FREE Full text] [doi: 10.1186/s12966-014-0097-9] [Medline: 25059981]
29. Bondaronek P, Alkhaldi G, Slee A, Hamilton FL, Murray E. Quality of publicly available physical activity apps: review and content analysis. JMIR Mhealth Uhealth 2018 Mar 21;6(3):e53 [FREE Full text] [doi: 10.2196/mhealth.9069] [Medline: 29563080]

30. Health On the Net. mHONcode: The New Certification of Health Mobile Applications URL: https://www.hon.ch/en/certification/app-certification-en.html [accessed 2019-07-04]
31. Huckvale K, Torous J, Larsen ME. Assessment of the data sharing and privacy practices of smartphone apps for depression and smoking cessation. JAMA Netw Open 2019 Apr 5;2(4):e192542 [FREE Full text] [doi: 10.1001/jamanetworkopen.2019.2542] [Medline: 31002321]

Abbreviations

FDA: Food and Drug Administration
HONcode: Health On the Net code of conduct
mHealth: mobile health

Edited by G Eysenbach; submitted 04.07.19; peer-reviewed by E Sezgin, S Baptista, T Hussain, F Fatehi; comments to author 21.10.19; revised version received 29.10.19; accepted 17.12.19; published 19.02.20.

Please cite as:
Huang Z, Lum E, Car J
Medication Management Apps for Diabetes: Systematic Assessment of the Transparency and Reliability of Health Information Dissemination
JMIR Mhealth Uhealth 2020;8(2):e15364
URL: http://mhealth.jmir.org/2020/2/e15364/
doi:10.2196/15364
PMID:32130163

Original Paper

Using Goal-Directed Design to Create a Mobile Health App to Improve Patient Compliance With Hypertension Self-Management: Development and Deployment

Huilong Duan[1], PhD; Zheyu Wang[1], BSc; Yumeng Ji[1], MSc; Li Ma[2], MSc; Fang Liu[2], MSc; Mingwei Chi[2], BSc; Ning Deng[1*], PhD; Jiye An[1*], PhD

[1]College of Biomedical Engineering and Instrument Science, Ministry of Education Key Laboratory of Biomedical Engineering, Zhejiang University, Hangzhou, China

[2]General Hospital of Ningxia Medical University, Yinchuan, China

[*]these authors contributed equally

Corresponding Author:
Ning Deng, PhD
College of Biomedical Engineering and Instrument Science
Ministry of Education Key Laboratory of Biomedical Engineering
Zhejiang University
38 Zheda Rd, Zhouyiqing Bldg 512
Yuquan Campus
Hangzhou
China
Phone: 86 571 2295 2693
Email: zju.dengning@gmail.com

Related Article:

This is a corrected version. See correction statement: https://mhealth.jmir.org/2020/5/e18859/

Abstract

Background: Hypertension is a lifestyle-induced chronic disease that threatens the lives of patients. Control of hypertension requires patients to follow self-management regimes; unfortunately, however, patient compliance with hypertension self-management is low, especially in developing countries. Improvement of patient compliance is premised on meeting patient needs. Mobile health apps are becoming increasingly popular for self-management of chronic diseases. However, few mobile apps have been designed to meet patient needs for hypertension self-management.

Objective: The goal of this study was to develop a mobile health app to improve patient compliance with hypertension self-management and evaluate the effectiveness of the app in terms of patient compliance.

Methods: The goal-directed design method was applied to guide study design. We divided the study into 4 stages. Stages 1 to 3 comprised the development process. To improve the applicability of the goal-directed design method to chronic disease management, we extracted elements of user models concerned with patient compliance and defined a concrete process for user modeling. In stage 1, personas of hypertensive patients were built using qualitative and quantitative methods. Clustering methods based on questionnaire responses were used to group patients. Qualitative interviews were conducted to identify the needs of different groups. In stage 2, several functional modules were designed to meet the needs of different groups based on the results from stage 1. In stage 3, prototypes of functional modules were designed and implemented as a real app. Stage 4 was the deployment process, in which we conducted a pilot study to investigate patient compliance after using the app. Patient compliance was calculated through the frequency with which they took blood pressure measurements. In addition, qualitative interviews were conducted to learn the underlying reasons for the compliance results.

Results: In stage 1, patients were divided into 3 groups based on 82 valid questionnaire responses. Eighteen patients from the different groups (7, 5, and 6 patients) were interviewed, and the needs of the groups were summarized as follows: improve self-management ability, enhance self-management motivation, and receive self-management support. In stages 2 and 3, 6 functional modules were designed and implemented based on specified needs, and the usability of the app was improved through

usability tests. In stage 4, 143 patients were recruited to use different versions of the app for 2 months. Results show that patient compliance improved as functional modules were added (P<.001) and was maintained at a high level (rate of 0.73). Interview results from 32 patients show that the design of the app met different needs; thus, patients were more compliant with it.

Conclusions: This study developed a mobile health app for hypertension self-management using the goal-directed design method. The app proved to be effective for improving patient compliance with hypertension self-management.

(JMIR Mhealth Uhealth 2020;8(2):e14466) doi:10.2196/14466

KEYWORDS

goal-directed design; smartphone; mobile health; patients; hypertension self-management; mobile phone

Introduction

Background

Chronic diseases are among the most prevalent and costly conditions worldwide [1]. Cardiovascular disease, cancer, chronic lung disease, and diabetes are four major chronic diseases that result in approximately 60% of global deaths [2], and hypertension is a leading cause of cardiovascular disease [3]. In China, more than 20% of the adults have hypertension, and more than 40% have prehypertension [4]. To improve the survival rate and life quality of hypertensive patients, long-term self-management along with supervision and intervention from doctors are essential [5]. Concretely, patients are required to take their medications as prescribed, change their behaviors to achieve a healthy lifestyle, and stick to a continuous self-monitoring regime of blood pressure (BP) measurements [6]. However, in practice, one significant obstacle is that patients do not always comply with the medical instructions for controlling their disease [7-9]. The World Health Organization has reported on the issue of noncompliance in treating prevalent chronic diseases such as hypertension, asthma, and diabetes [10]. Insufficient compliance may result in decreased treatment effectiveness or even treatment failure, which poses a great threat to health and life [11-13]. Although patients' awareness of the need for compliance has increased in recent years, much work remains to improve compliance in hypertensive patients [14-16].

The rapid development of mobile technologies and the popularity of smartphones fostered the development of an enormous number of mobile health (mHealth) apps. Such apps have the potential to improve patient compliance with chronic disease management [17]. For example, mHealth apps can provide personalized self-management strategies to users, allowing them to avoid the time and resource burdens imposed by the frequent interventions provided by health care providers [18]. In terms of hypertension, smartphone technology has been shown to help patients improve BP control [19] and medication compliance [20], mainly through functional modules such as home BP monitoring, medication reminders, and health education. Concretely, patients can use their smartphones to record measured BP, receive reminders to take medications in the form of notifications or short messages, and acquire health knowledge about hypertension. However, in practice, patients have various goals and need to use mHealth apps to self-manage their conditions [21]. Nonetheless, the functional designs of mHealth apps sometimes fail to meet patient needs, which results in reduced patient motivation for using these apps [22,23]. Improvement of patient compliance is premised on meeting patient needs [17]. Thus, mHealth apps demand systematic and theory-based design to meet patients' real needs for chronic disease management.

Design Methods of mHealth Apps

The existing design methods of mHealth apps mainly include traditional information technology (IT) design [24-27], activity-centered design [28], user-centered design [29], participatory design [30], and goal-directed design (GDD) [31]. These different design approaches consider user needs in different ways. Table 1 summarizes the characteristics of these methods. Compared with other methods, GDD concentrates on user goals instead of on the tasks or activities that users must accomplish [32]. Focusing on user goals can directly reveal user needs; in contrast, tasks or activities are intermediate steps that help users to reach their goals [31]. Therefore, to improve patient compliance by meeting their needs, GDD is the most appropriate of the existing design methods.

Table 1. Summary of common design methods for mHealth apps.

Method	Requirement analysis	Driving force	Multidisciplinary collaboration	User engagement	Applicable scope
TID[a]	Based on technical documents written by developers	Technical document	No	Low	User needs are clear and well defined
ACD[b]	Based on activities users would perform with the app	User activity	Yes	High	Pay attention to user experience, and focus on what activities should be enabled by the app
UCD[c]	Based on observation of user behaviors by guiding them to complete a series of user tasks concerned with the app	User task	Yes	High	Pay attention to user experience, and focus on what tasks users should perform with the app
PD[d]	Based on user decisions by inviting them to participate in the design process	User decision	Yes	Very high	Users have rich experience in using mHealth apps and are familiar with the design process
GDD[e]	Based on user goals when using the app	User goal	Yes	High	Pay attention to user goals, and user needs remain to be clearly defined

[a]TID: traditional information technology design.

[b]ACD: activity-centered design.

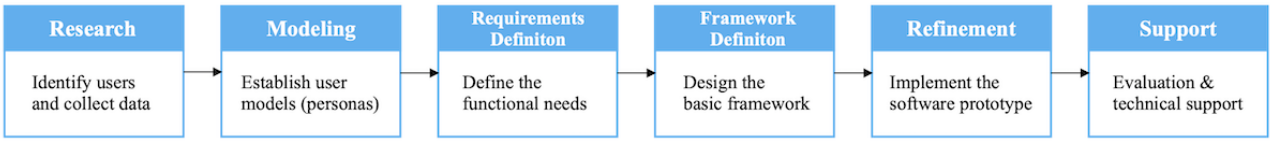
[c]UCD: user-centered design.

[d]PD: participatory design.

[e]GDD: goal-directed design.

The GDD design process can generally be divided into 6 phases: research, modeling, requirements definition, framework definition, refinement, and support. Figure 1 shows the workflow of the GDD design process. The research phase provides qualitative data about potential and/or actual users of the product through ethnographic field study techniques such as observation and contextual interviews. During the modeling phase, data discovered during the research phase are synthesized into user models. User models (personas) are detailed composite user archetypes that represent distinct groupings of behaviors, attitudes, aptitudes, goals, and motivations observed and identified during the research phase. For each primary persona, an analysis of the persona data and functional needs will be used during the requirements Definition phase. The output of this process is a requirements definition that provides a balance among different users. In the framework definition phase, software designers will create the overall product concept and define the basic frameworks for the product's behavior and visual design. The output of this process is an interaction framework definition, which provides a logical and rough structure for the details to come. The refinement phase is similar to the framework definition phase but has an increased focus on details and implementation. Finally, the support phase offers support during and after development because even a very well-conceived and validated design solution cannot possibly anticipate every development challenge and technical question [31]. To summarize, GDD requires the modeling process before concrete design, and the user models, which are called personas, can capture user skills, environments, behaviors, and goals, etc. All these aspects of personas are intended to capture user needs [32].

Figure 1. Workflow of the goal-directed design process.



Objectives

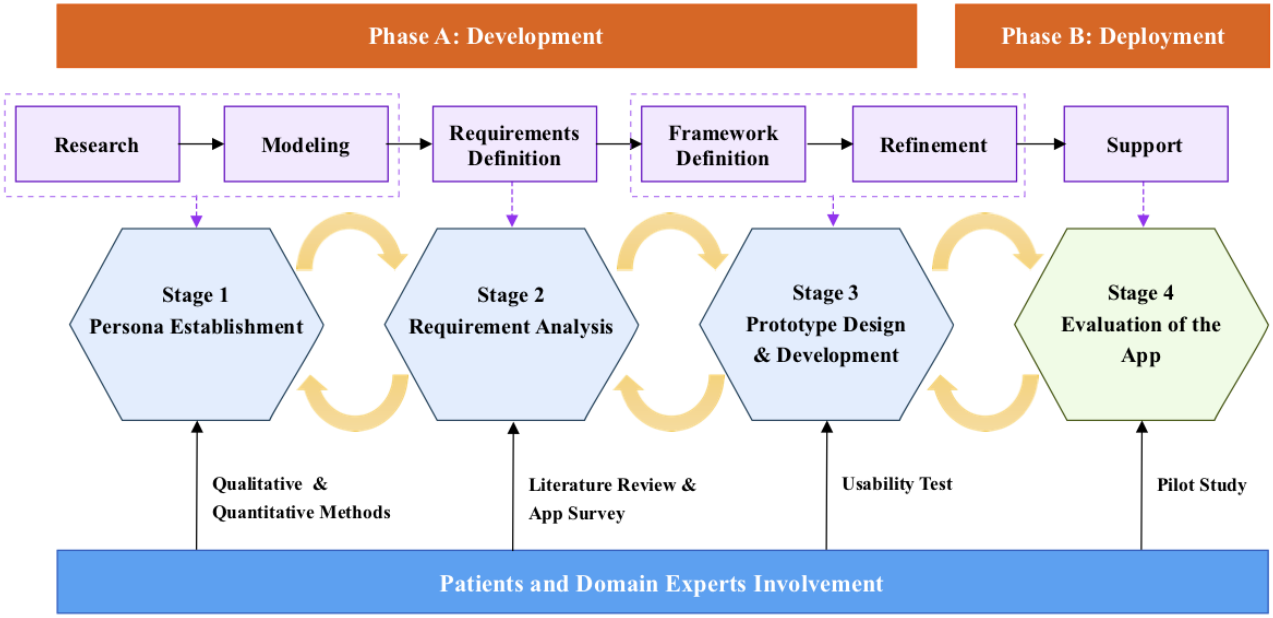
Although GDD is prominent for identifying user needs and has gradually been adopted in practice, relatively little research concentrates on using GDD in the field of chronic disease management [33,34]. In fact, to the best of our knowledge, to date, few studies have used a theory-based design method to develop an mHealth app, particularly one intended to improve patient compliance with hypertension self-management. Therefore, to identify the needs of hypertensive patients and improve their compliance with hypertension self-management, we designed and implemented the Blood Pressure Assistant (BPA), an innovative monitoring and feedback tool that supports hypertension self-management and can be installed on patients' smartphones. The GDD method was used to guide the design of BPA, and the end users (ie, hypertensive patients) were involved in the design process at an early stage. This paper describes the development process of BPA and the results of a pilot evaluation regarding patient compliance when using the BPA.

Methods

Study Design

This study was designed based on the GDD process. To simplify the design process and highlight the app evaluation, we made some modifications to the original GDD and divided the study into 4 iterative stages. Stages 1 to 3 covered the development phase, while stage 4 was the deployment phase. Figure 2 illustrates the complete study process and the comparison between the original GDD and our method. Stage 1 corresponds to the research and modeling phases, in which we used qualitative and quantitative methods to identify user personas. Stage 2 corresponds to the requirements definition phase, in which we defined the functional modules of BPA based on the identified user personas. Stage 3 corresponds to the framework definition and refinement phases, in which we designed the prototype of BPA based on the functional design and implemented it. Stage 4 corresponds to the support phase, in which we deployed BPA to the production environment and tested its effectiveness. Throughout the study process, patients and several domain experts (ie, experienced physicians) were involved, and they helped design the app and evaluate its effectiveness. The details of each phase are explained in the following sections.

Figure 2. Complete study process.



Participant Selection and Sampling

This study was conducted at the General Hospital of Ningxia Medical University, Ningxia Province. Participants in this study were outpatients and inpatients from the department of cardiology. Several physicians helped recruit patients into the study. The inclusion criteria were as follows: (1) aged 18 years or older, (2) a hypertension diagnosis with no other serious complications, (3) owned a smartphone and had home internet access, and (4) able to read and write in Chinese. Patients who met all the inclusion criteria were considered qualified to participate in the study. A random sampling method was applied by the researchers to ensure that the participating patients represented diverse personas.

Informed Consent and Ethical Consideration

After sampling, the researchers contacted the selected qualified patients, apprised them of the goal of the study, and promised that their personal information would be accessed only by the researchers or the domain experts. The patients who agreed to participate in the study were asked to sign informed consent forms. The domain experts signed informed consent forms as well. All procedures were performed in accordance with the ethical guidelines for biomedical research involving human subjects at Ningxia Medical University.

Goal-Directed Design Steps

Specified User Modeling Process of Goal-Directed Design

In our study design based on GDD, the first step is to model the users to establish their personas. However, the original user modeling process of GDD is generalized and abstract, which makes it difficult to use to specifically guide the design of mHealth apps for chronic disease management. Therefore, before using GDD to guide the design of BPA, we first specified the user modeling process of GDD for chronic disease management based on the following 2 points: (1) extracting user model elements specifically targeted to improve patient compliance with self-management regimes and (2) defining a concrete procedure for user modeling.

The authors of GDD indicated that user models can be described by 3 types of factors: demographic characteristics, domain expertise, and technical expertise [31]. We used evidence-based methods to extract specific elements of these factors from relevant studies and theories. Demographic characteristics are the most fundamental ways to describe users and usually include information such as gender, age, and occupation. With the development of mHealth technology in chronic disease management, several demographic characteristics have been

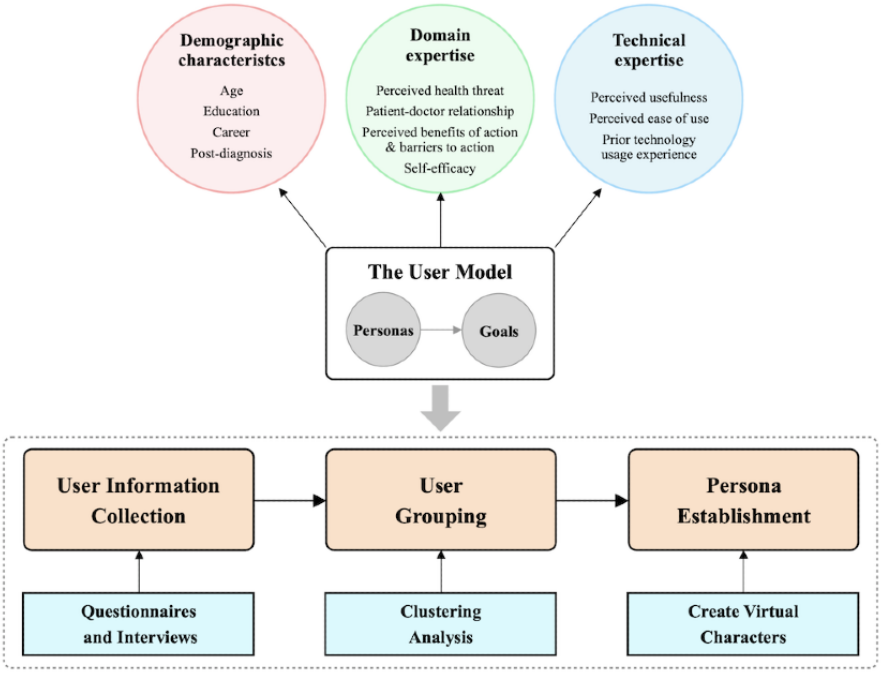
found to specifically affect the patient self-management compliance. LeRouge et al [34] found that changes in the physiological characteristics of elderly people such as vision, cognitive, memory, and learning ability led to additional requirements for the functional design of mHealth apps. Grindford et al [35] found educational attainment to be related to the acceptance of mHealth technology interventions. In addition, career status (if retired) and patient postdiagnosis have been shown to influence patient self-management experiences [36]. Therefore, we defined age, educational attainment, career status, and postdiagnosis as the specific elements of demographic characteristics.

Domain expertise refers to user proficiency in related fields. We summarized the domain expertise of chronic disease patients from a number of aspects. First, self-management reflects a patient's behavior in promoting, protecting, or maintaining their own health, and such behaviors can be explained by the health belief model (HBM) [37]. The HBM suggests that people's perceived health threats, perceived benefits of action and barriers to action, and their self-efficacy explain their engagement (or lack of it) in health promotion behavior [38]. In this study, a perceived health threat means patients' awareness of and concern for their hypertensive condition and its potential consequences. The perceived benefits of action and barriers to action refer to patients' awareness of the benefits of health behavior changes and their resistance to such changes. Self-efficacy reflects the extent of patients' beliefs in their ability to complete various tasks and reach the goal of controlling their hypertensive condition. Second, the positive effects of doctor-patient interactions for chronic disease management have long been established [39]. The doctor-patient relationship is an important factor that affects patients' acceptance of mHealth interventions [40]. We thus proposed perceived health threat, perceived benefits of action and barriers to action, self-efficacy, and doctor-patient relationship to be the specific elements of domain expertise.

In the mHealth field, technical expertise refers to user acceptance of and proficiency with mHealth technology. The technology acceptance model (TAM) [41] is a classic theoretical model that has been widely used to predict consumer acceptance of mHealth technology [42-44]. According to TAM, perceived usefulness and perceived ease of use are the two major cognitive determinants of health information technology use [45]. Perceived usefulness refers to the extent to which users believe that using a particular app would enhance their task performance. Perceived ease of use is the extent to which users believe that using a particular app would be easy [41]. Moreover, users' prior experiences with using technology can shape their beliefs about the new technologies [46]. Positive experiences may help patients feel more confident that they have the capabilities and resources to repeat that same performance with new technology [45,46]. Therefore, we defined perceived usefulness, perceived ease of use, and prior technology use experience as the specific elements of technical expertise.

After specifying the elements of the user model, we proposed the concrete user modeling procedure for our study based on the original GDD. The process for user modeling can be divided into 3 steps: (1) user information is collected through questionnaires and interviews based on the user model components, (2) statistic methods such as clustering analysis are used to group users and identify the personas and goals of each group, and (3) representative virtual characters (ie, persona) are created for each group describing their main characteristics and goals. Figure 3 shows the proposed user model and the concrete user modeling procedure for this study. Based on the specified user modeling process, we performed our 4-stage GDD method to guide the design of BPA.

Figure 3. Specified user model for improving compliance with hypertension self-management and the concrete user modeling procedure.



Stage 1: Persona Establishment

After participant recruitment, we used questionnaires to collect patient information based on the user model, including demographic characteristics, domain expertise, and technical expertise (see Multimedia Appendix 1 for original questionnaires). The demographic characteristics questionnaire was in the form of fill-in-the-blank and included 5 items: gender, age, educational attainment, career status, and postdiagnosis. The domain expertise questionnaire consisted of 2 parts: the Awareness Rate of Hypertension Knowledge Scale (ARHKS) [47] and the Compliance of Hypertensive Patients Scale (CHPS) [48]. ARHKS contains 8 items in the form of multiple choice and has been widely used in relevant studies. CHPS contains 10 items extracted from the original version using a 4-point Likert scale. ARHKS was originally in Chinese. CHPS was translated into Chinese, and its reliability and validity have been examined [49]. We merged the scores of CHPS and ARHKS to obtain a total score for the domain expertise. The technical expertise questionnaire contained 10 items extracted from our previous study and used a 5-point Likert scale; it was mainly intended to evaluate patient acceptance of mHealth technology for hypertension self-management [50].

We then explored patient expectations of using the mHealth app through qualitative interviews. The interview included 4 open questions that had previously been discussed and validated by one researcher and one physician. The validated questions are as follows: (1) How do you manage your high blood pressure? Is it effective? In what ways can you do better? (2) In what ways do you hope to get help? (3) Are you willing to use your smartphone for self-management of hypertension? Why or why not? (4) What problems do you expect the app to help you solve? The researchers conducted the interviews in separate face-to-face sessions with each patient using a semistructured approach in which the researchers were freely able to change the order of the questions and could ask follow-up questions to ensure that the respondents' answers were correctly understood. The interview was piloted on 3 patients to test content validity.

Using the questionnaire and interview results, we applied quantitative and qualitative methods to establish user personas. According to the specified user modeling process, a clustering analysis was first conducted to group the users. In this study, we chose the K-means algorithm and performed a clustering analysis on the domain expertise and technical expertise of the patients. Based on the grouping results, we then analyzed the differences between different groups regarding their demographic characteristics, domain expertise, technical expertise, and expectations of using the mHealth app. Finally, we created a virtual character (persona) for each group that reflected their characteristics and goals.

Stage 2: Requirement Analysis

In this stage, we defined what functional modules should be contained in BPA to meet patient needs and improve their compliance. We first investigated which functional modules have previously been included in existing mHealth apps from the literature and by examining real apps. We searched for literature on PubMed using a combination of terms relevant to mHealth technology for chronic disease management: "chronic disease," "hypertension," "mobile," "smartphone," "design," and "development." We searched for apps and downloaded them from the Tencent app store (one of the biggest app stores for Android apps in China) and the App Store (for iOS apps) using keywords "hypertension," "diabetes," "chronic disease," and "health." A total of 36 references and 37 apps were screened and analyzed (see Multimedia Appendix 2 for screened lists of references and apps). The concrete functional design was proposed corresponding to the established user personas. Different functional modules were designed to meet different patient needs, and design results were validated by the domain experts.

Stage 3: Prototype Design and Development

After identifying the functional modules of BPA, we designed the prototype and implemented it. First, we defined the main BPA interface, which organizes the concrete functional modules via the interface in different forms. We then designed a prototype of each functional module. We invited domain experts and patients to take part in the prototype development process. The experts evaluated the details of each functional module based on their knowledge and experience, and the patients were led by the researchers to join in the usability tests. After several iterations of the above 3 stages, we finally obtained a high-quality app prototype.

Stage 4: Prototype Evaluation

After BPA development, to further evaluate whether the app truly worked, we conducted a pilot study in which patients were provided with a copy of BPA installed on their own smartphones and were required to use it in their daily lives for 2 months. At the end of the trial period, we collected the patients' uploaded data, calculated their compliance with their self-management regimes, and conducted interviews with them to identify the reasons for the compliance results and gather suggestions for further improvement of BPA.

Data Analysis

Questionnaires were in the form of paper or online surveys. Paper questionnaires were collected and recorded into the database immediately after completion, while online questionnaires were automatically saved in the database. Disqualified questionnaires (with incomplete or contradictory answers) were discarded before the data analysis. All interviews were audiorecorded with the consent of the respondents, and all recordings were transcribed verbatim. The transcripts were generated, read, and open-coded using the NVivo 2.0 (QSR International) software package. Two researchers independently open-coded the transcripts. SPSS Statistics V20.0 (IBM Corp) and Python 3.0 were used for statistical analyses. Descriptive data is presented as counts and percentages. Multivariate analyses were conducted using Pearson chi-square tests for categorical variables and one-way analyses of variance for continuous variables. A P value of $<.05$ was considered statistically significance.

For the compliance analysis, in this study, patient compliance was defined as the ratio of actual frequency of BP measurements to the number required by the management plan. This metric

was proposed by the researchers and validated by the physicians. Figure 4 shows the calculation process, in which $C_i(d)$ corresponds to the compliance of user i on a specific day d.

Figure 4. Compliance of one user on a specific day.

$$C_i(d) = \min\left(\frac{actual\ num\ of\ BP\ measurements}{required\ num\ of\ management\ plan}, 1\right)$$

In the evaluation stage, we used 2 specific formulas based on the above formula to evaluate patient compliance. The first formula calculated the average compliance of all patients for each day using the different app versions. As shown in Figure 5, $C_{total}(d)$ corresponds to the average compliance of all groups for each version on a specific day d, and n corresponds to the total numbers of all groups for each version.

Figure 5. Average compliance of all groups for each version on a specific day.

$$C_{total}(d) = \frac{1}{n}\sum_{i=1}^{n} C_i(d)$$

The second formula calculated patient compliance during the entire trial for the different groups. As shown in Figure 6, C_g corresponds to the average compliance of each group for each version, n_g corresponds to the numbers of group g for each version, and q corresponds to the total days.

Figure 6. Average compliance of each group for each version.

$$C_g = \frac{1}{q}\frac{1}{n_g}\sum_{d=1}^{q}\sum_{i=1}^{n_g} C_i(d)$$

Results

Stage 1: Persona Establishment

A total of 90 questionnaires were distributed, and 82 valid questionnaires were collected. Answers to the domain expertise and technical expertise questionnaires were coded into points ranging from 0 to 50 and 0 to 60, respectively. The clustering results based on these 2 questionnaires are shown in Figure 7. These results demonstrated that hypertensive patients can be divided into 3 groups (the number of clusters was determined by the elbow method). A one-way analysis of variance showed that there were significant differences in domain and technical expertise among these 3 groups (P<.001). Based on the grouping results, we conducted statistical analyses on the demographic characteristics of different groups, and the results are shown in Table 2.

Figure 7. Clustering results on participant domain expertise and technical expertise.

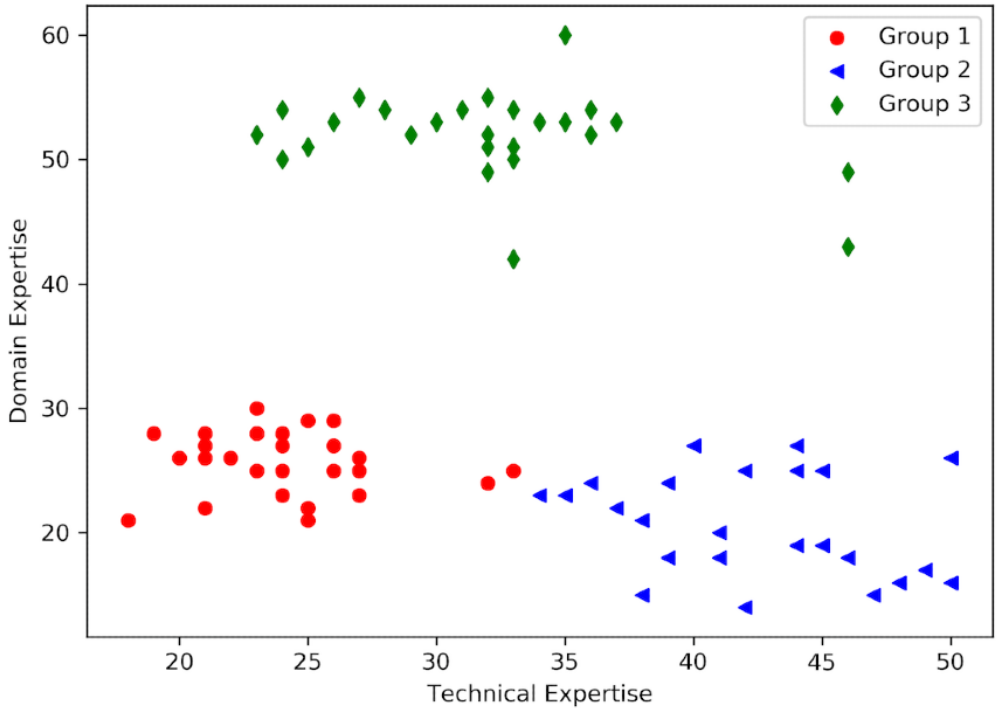


Table 2. Demographic characteristics of different groups.

Characteristics	Group 1 n=28	Group 2 n=26	Group 3 n=28	*P* value
Sex, n (%)				**.329**
Female	13 (46)	7 (27)	10 (36)	
Male	15 (54)	19 (73)	18 (64)	
Age in years, mean (SD)	53.8 (1.82)	49.7 (1.91)	62.3 (2.22)	<.001
Career, n (%)				**<.001**
Employed	6 (21)	19 (73)	10 (36)	
Self-employed/unemployed	15 (54)	7 (27)	3 (11)	
Retired	7 (25)	0 (0)	15 (54)	
Educational attainment, n (%)				**.002**
Secondary school and below	13 (46)	3 (12)	5 (18)	
High school	8 (29)	7 (27)	15 (54)	
Graduate and above	7 (25)	16 (62)	8 (29)	
Postdiagnosis, n (%)				**<.001**
<1 year	17 (61)	3 (12)	0 (0)	
1-5 years	11 (39)	16 (62)	5 (18)	
>5 years	0	7 (27)	23 (82)	

A total of 18 patients were interviewed; the numbers of interviewed patients from groups 1 to 3 were 7, 5, and 6, respectively. We coded user expectations of the mHealth app based on these interview results (Table 3). The most frequently mentioned expectation was increased communication between doctors and patients. Concretely, the patients hoped to receive self-management guidance from doctors and expected timely intervention when abnormal conditions occurred. On the other hand, some patients hoped to increase their disease cognition levels through self-management. They hoped to acquire health knowledge about hypertension and a professional analysis of their self-monitoring data. Moreover, some patients considered the mHealth app to be a convenient way to conduct self-management and expected it to provide functions such as step counting, online registration, wearable device support, and so on. In addition, patients who lacked smartphone experience suggested that the app should have high usability—for example, its functions and operation should be as simple as possible.

Table 3. Interview coding results.

User expectations and explanation	Group 1 n=7	Group 2 n=5	Group 3 n=6
Increasing communication between doctors and patients			
Doctors' guidance of self-management	7	1	3
Intervention of abnormal condition	1	2	4
Increase disease cognition level			
Acquire knowledge about hypertension	3	2	4
Professional analysis of their self-monitoring data	0	4	1
A convenient way for self-management			
Step counting	0	3	2
Timed reminder	5	3	0
Online registration	0	3	0
Wearable device support	0	3	1
High usability			
Simple operation	7	1	3
Simple function	4	1	2
Auto-uploading	1	3	1
Increasing fun	0	3	0

Based on the above results, we established personas for hypertension patients in the different groups (Table 4). The personas reflected the differences between hypertensive patients at the demographic, domain expertise, and technical expertise levels. The needs (goals) of these 3 groups of patients for using hypertension self-management apps can be summarized as follows: to improve their self-management ability, enhance their self-management motivation, and receive self-management support.

Table 4. Personas of hypertensive patients.

Characteristics and goals	Group 1	Group 2	Group 3
Age in years	50	45	65
Career	Self-employed/unemployed	Employed	Retired
Educational attainment	Secondary school and below	Graduate and above	High school
Postdiagnosis	<1 year	1-5 years	>5 years
Experience in using smartphone	Low	High	Medium
Perceived ease of use of smartphone	Low	High	Medium
Disease cognition level	Low	Medium	High
Self-management ability	None	Poor	Good
Expectations to use hypertension self-management apps	Self-management under the doctors' guidance; receive reminder of self-management; easy to use	Learn the disease progress; more fun in self-management; upload data automatically	Learn more knowledge related to hypertension; receive warning and intervention according to self-monitoring data
Goals	Improve self-management ability	Enhance self-management motivation	Receive self-management support

The patients in group 1 had a low level of disease cognition and lack of self-management experience. They wanted to manage their disease under the guidance of doctors and receive timely reminders and interventions. In addition, they demanded that the app must be easy to use because they lacked experience in using smartphones. Therefore, doctor supervision and an app with enhanced usability were the primary solutions to improving compliance of group 1.

The patients in group 2 were relatively young and better educated. They generally were more accepting of smartphone technology and had more experience in self-management, but they did not take their hypertensive condition seriously, and their compliance with medical orders was low. We considered providing self-management motivation to be the way to improve the compliance of group 2.

The patients in group 3 had a higher level of disease cognition and were capable of performing effective self-management at home. They wanted to learn more about their hypertension and receive feedback based on their self-monitoring data. Thus, further strengthening their self-management abilities and providing effective medical service support under abnormal conditions were the keys to improving compliance of group 3.

Stage 2: Requirements Analysis

The results of investigating functional modules in existing mHealth apps are shown in Table 5. These results demonstrated that a variety of functional modules designed in existing mHealth apps focus primarily on self-monitoring. Only some of the apps considered supervision and intervention from doctors. Based on the investigation results and established user personas, we proposed specific solutions to meet the needs of patients in different groups. For patients with the desire to improve their self-management ability, concrete and executable plans with reminder services as well as doctor supervision were essential. For patients with the desire to improve their self-management motivation, we aimed to inform them about their disease control situation and used some gamification designs to enhance their motivation. For patients with the desire to receive self-management support, providing health education and timely intervention under abnormal conditions were important.

Different functional modules were designed based on the proposed solutions. For patients who aimed to improve self-management ability, the management plan module was designed to provide guidance to patients on how to conduct self-management at home. Management plans were formulated by doctors through a telehealth system, and the system automatically split plans into daily tasks and sent them to the patients' smartphones. The management plan generally included BP and weight monitoring frequency, medication guidance, and advice on diets and exercise. Patients needed to record their health data according to the tasks, and the data would be sent to the doctors. The doctors needed to perform regular follow-ups with patients and adjust their management plans according to the uploaded health data. When the plans were changed, patients received new daily tasks on their smartphones instantly. In addition, a reminder service module was designed in order to prevent patients from forgetting to complete the tasks.

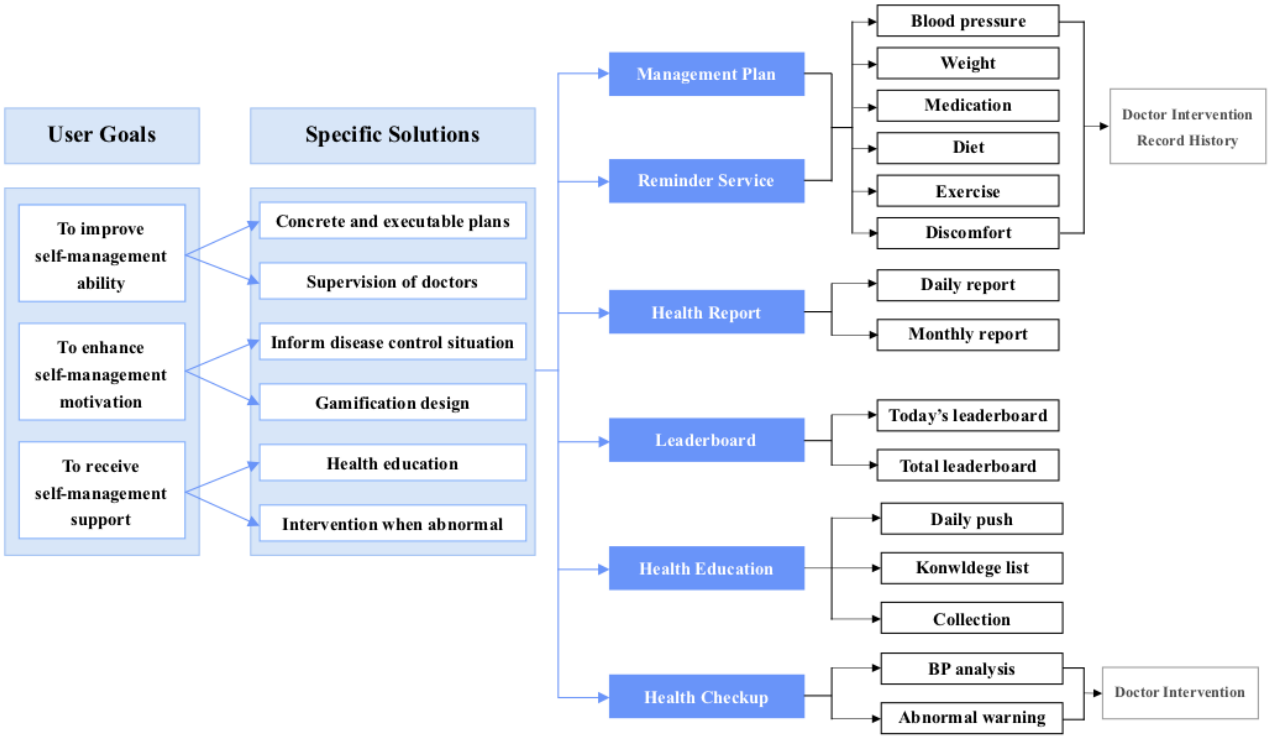
Table 5. Investigation results of functional modules in existing mHealth apps.

Category and functional module	References n=36	Apps n=37
Early detection: risk assessment	5	16
Disease cognition: health education	13	23
Lifestyle intervention		
Recipes	1	11
Exercise plan	2	3
Disease management and control		
Self-monitoring		
Blood pressure/blood glucose	36	37
Weight	27	21
Medication	12	35
Diet	8	14
Exercise	8	12
Statistical report	11	20
Reminder service	5	18
Abnormal warning	8	4
Intervention of doctors		
Short message service	12	7
Telephone follow-up	6	4
Online consultation	10	8
Gamification design		
Challenge and reward	4	0
Leaderboard	3	0
Social contact	5	10

For patients who aimed to enhance their self-management motivation, we designed the health report and leaderboard modules. The health report module provided daily and monthly reports to patients according to their health data. The leaderboard module aimed to provide motivation for self-management. All the behaviors of patients concerned with self-management were converted into scores, and patients could view their real-time leaderboards to compare themselves with other users though the app (with no identifiable data are used).

For patients who aimed to receive self-management support, the health education module provided health knowledge about chronic diseases to patients in various forms, and the health checkup module automatically analyzed the patients' recorded B*P* values and sent feedback to the patients. When a patient's B*P* value was abnormal, the doctors would be informed immediately through the system. The entire requirements analysis process is shown in Figure 8.

Figure 8. Complete requirements analysis process.

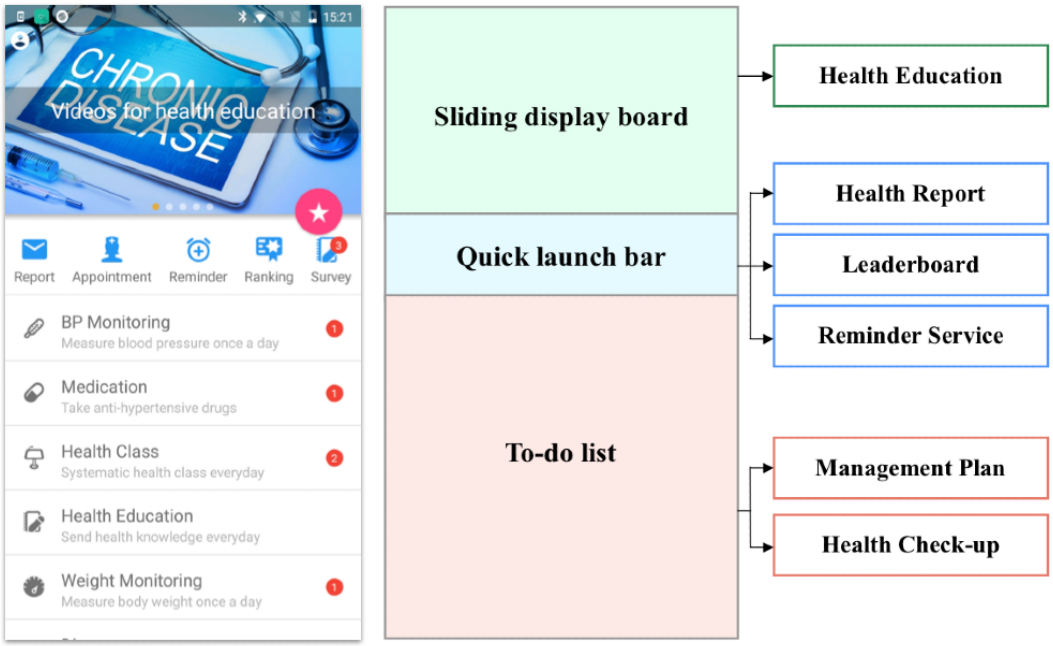


Stage 3: Prototype Design and Development

Main Interface

The resulting design for the main interface is shown in Figure 9. We divided the main interface into 3 parts: to-do list, sliding display, and quick launch bar. The to-do list mainly shows a list of tasks in the management plan, along with a brief introduction to each task. Users could clearly see the completion status of all the tasks via the list, which included a red highlight next to uncompleted tasks. By clicking on a specific row, users could enter the corresponding task interface of the management plan. The sliding display board shows daily updated health knowledge. Health knowledge shown by sliding the display effectively attracted users' attention while also serving as a quick entry point for reading the knowledge. Users could access the independent health education module to read knowledge as well (from the to-do list). The quick launch bar consisted of several small icons corresponding to different functional modules. Users could access the functional modules quickly by clicking on the icons. This part of the app was designed for less frequently used functional modules such as the leaderboard, health report, and reminder service.

Figure 9. Main Blood Pressure Assistant interface.



Management Plan Module

The management plan module appeared as a to-do list in the main interface of BPA. The list of daily tasks generated from the management plans formulated by doctors was grouped into 5 items: recording health data such as BP and weight, recording medication, recording diet, recording exercise, and recording uncomfortable symptoms. Each task was required to be completed at a specific time during each day. When users clicked on an item, a series of to-do cards for the current task would appear in a new interface. Patients only needed to input the required data and click on an OK button on the card to finish a task. After completing a task, the color and shape of the card would change, indicating the task's state transition. The input data were uploaded to the system database instantly so that doctors were able to remotely check up-to-date patient health records.

Reminder Service Module

The reminder service module was accessible from the quick launch bar or from within the management plan module. The reminder time was initially set based on the management plan, and when a time period elapsed, a dialog with the specific task would appear on the patients' screens, along with an audible alarm. Users who were unable to perform the tasks according to the default schedule could set a reminder, forming a customized schedule for their daily self-management tasks. In addition, users were free to reset or close the reminders.

Health Report Module

The health report module was accessible through the quick launch bar. Users received daily reports and a monthly report consisting of 3 parts: user's current health condition based on their historical data, uncompleted tasks, and the current day's (or current month's) score. Scores were calculated based on the completion status of provided tasks and on changes in health data. This functional module served to remind patients to accomplish any remaining tasks and motivated them to perform self-management tasks to achieve higher scores.

Leaderboard Module

Based on the scores obtained in the health report module, the leaderboard module provided competitive motivation for users by allowing them to compare their scores with those of other users. The module consisted of 3 parts: user's score, leaderboard among all users, and current user's rank among all users. In the daily leaderboard, users could view the top 30 users for the current day, while in the all-time leaderboard, users could view the top 30 users of all time. The design of leaderboard module applied a competitive strategy through persuasive technology [51] to motivate users to stick to their self-management regimes and strive for higher scores so their names would appear on leaderboards.

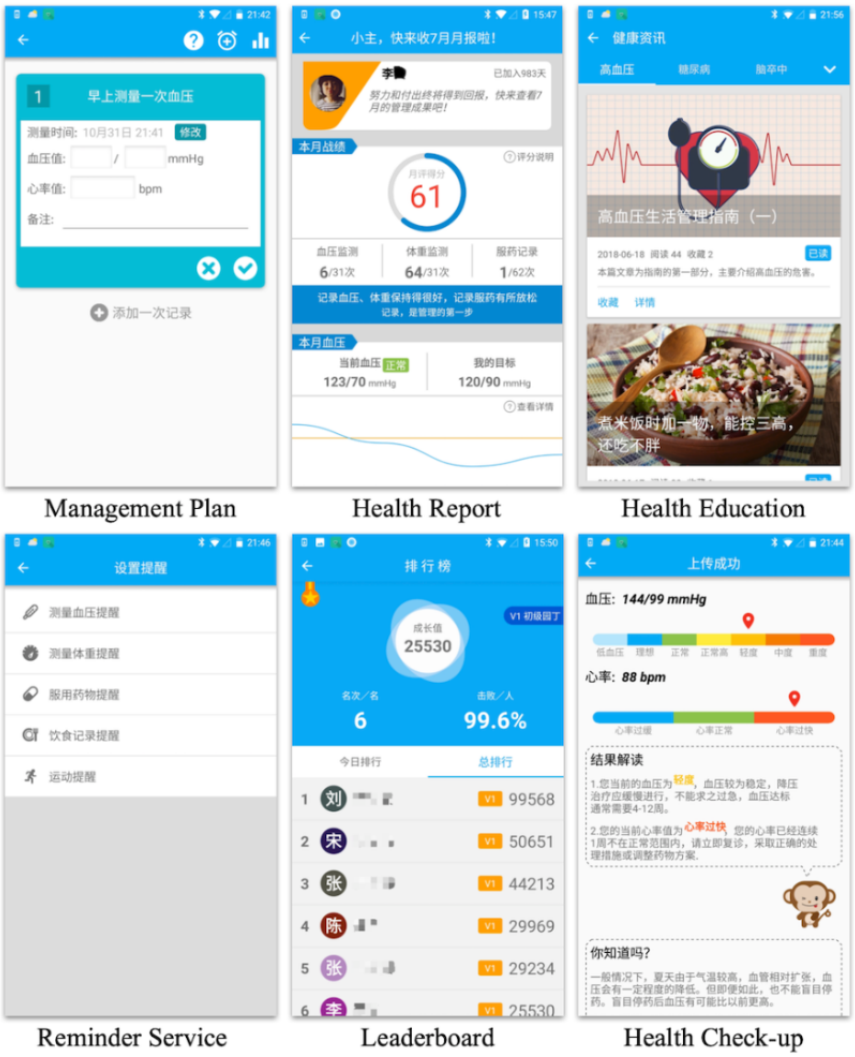
Health Education Module

Health education can improve disease awareness and help patients perform self-management more effectively. BPA provided 2 kinds of education. Educational articles and videos of common chronic diseases collected from the internet and vetted by the physicians covered all aspects of daily chronic disease management. Systematic educational material concerning hypertension based on guidelines and books was presented; this content was more professional and suitable for patients who wanted to learn more about their disease.

Health Check-Up Module

Patients' B*P* values are important indicators of their health condition. Each time a patient uploaded a B*P* value, the health check-up module would analyze that value by considering the patient's BP trends and their hypertension grade and return feedback to the patient. If the B*P* value was considered to be abnormal, a warning message would be sent to the patient, asking them to take a rest and measure their BP again in 20 minutes. All abnormal conditions were also sent to doctors immediately through the telehealth system. Doctors should pay close attention to abnormal patients and conduct interventions when appropriate. Figure 10 shows screenshots of the 6 functional modules in BPA (see Multimedia Appendix 3 for detailed screenshots).

Figure 10. Screenshots of the 6 functional modules in the Blood Pressure Assistant.



Stage 4: Evaluation

App Version and Patient Grouping

The development of BPA was an iterative process. We gradually recruited subjects as different functional modules were added to the app. Four versions of the app were released during the trial. Version 1 contained 3 main functional modules: management plan, reminder service, and health check-up. The other 3 modules were added in subsequent versions (Figure 11). Patients were required to use the different versions of the app for at least 2 months. A total of 143 patients completed the trial. We grouped all subjects according to the personas proposed in stage 1, and results are shown in Table 6.

Figure 11. Functional modules contained in each version.

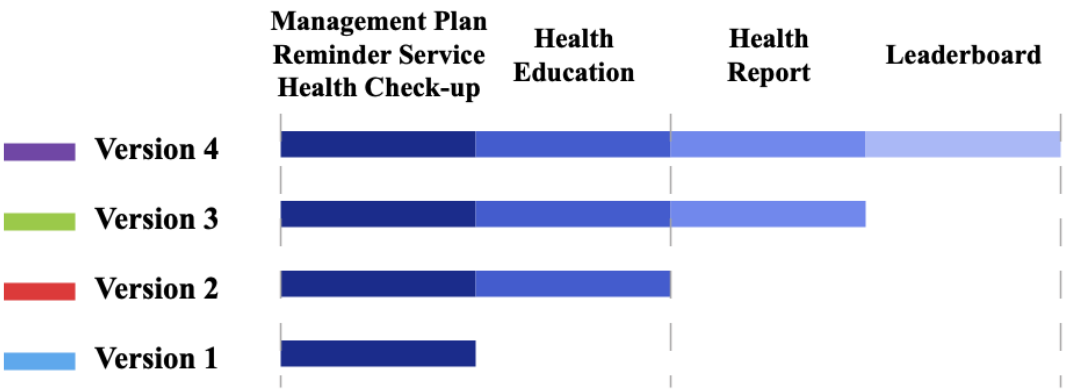


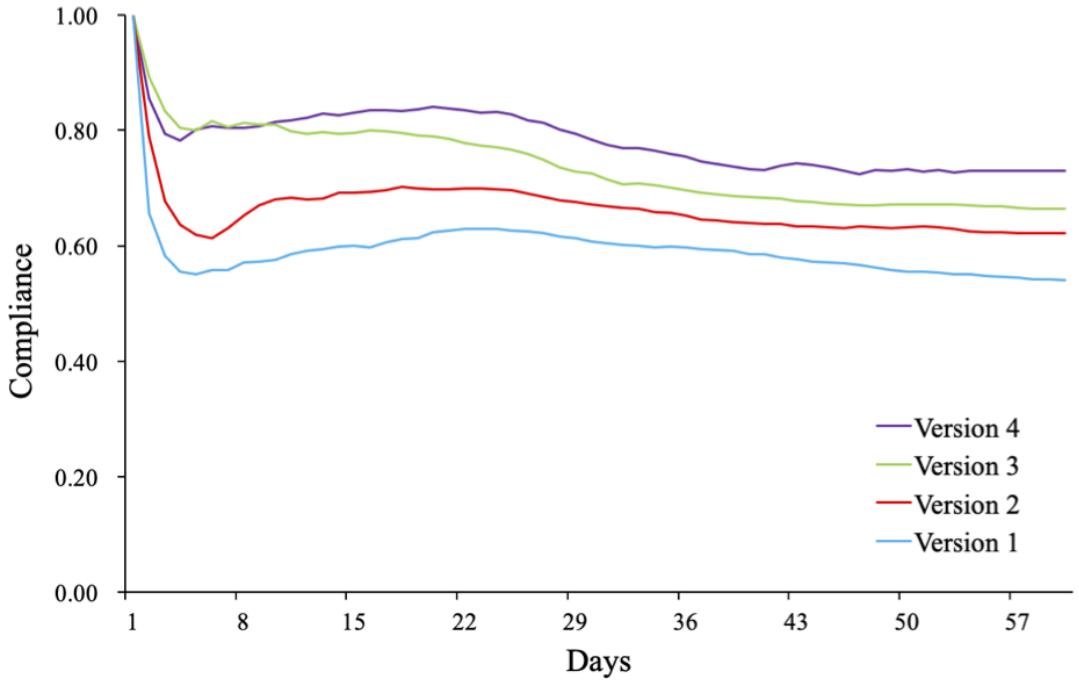
Table 6. Numbers of patients in the different groups.

Group	Version 1 n=36	Version 2 n=39	Version 3 n=36	Version 4 n=32
Group 1	11	14	14	11
Group 2	14	10	12	9
Group 3	11	15	10	12

Compliance Analysis

As mentioned in the data analysis section, we calculated the average compliance of all patients for each day using the different app versions. Each version was used for 2 months. Figure 12 shows the compliance trends of each version. The initial value of compliance was set to 1 on day 1. We can see that for all 4 versions, compliance first declined sharply and then gradually increased during the first week. The initial decline reflects the fact that patients were not familiar with the app and had not built trust in the doctors. The inflection point appeared on the third to the fifth day after becoming involved in the assisted self-management (ie, after starting to use the app), consistent with the time when the doctors conducted the telephone follow-up. This result indicates that timely doctor intervention can effectively alleviate user resistance during the initial stage when they receive new technology, thus improving their compliance. Compliance reached its highest level during the third week (except for the initial week) and slowly decreased to a stable level, indicating that time is another factor that affects patient compliance.

Figure 12. Compliance trends for each app over 2 months.



We calculated patient compliance during the trial for the different groups. Results show that patient compliance improved as functional modules were added to the app and was maintained at a high level (Table 7). Total compliance increased from 0.54 to 0.73, a significant difference (P<.001).

Table 7. Patient compliance among the different groups.

Group	Patient compliance				Analysis of variance	
	Version 1	Version 2	Version 3	Version 4	*F*-value	*P* value
Group 1	0.53	0.56	0.67	0.73	24.28	<.001
Group 2	0.39	0.51	0.50	0.59	14.64	<.001
Group 3	0.69	0.73	0.83	0.86	19.54	<.001
Average	0.54	0.62	0.66	0.73	11.30	<.001

To determine the reasons for patient compliance, we interviewed 32 patients from different groups who had used version 4 of the app. The interview included reasons for high or low compliance and suggestions for improving the app. Table 8 shows the coding results for the reasons mentioned in the interviews.

Table 8. Reasons for patient compliance from the interview.

Reason given	Group 1 n=11	Group 2 n=9	Group 3 n=12
Reasons for high compliance			
Received doctors' guidance	9	5	10
Reminders and supervision	7	7	3
Learned to control blood pressure	1	8	3
Enriched related knowledge	7	4	7
Enhanced pleasure	2	5	3
Easy to use	5	0	2
Reasons for low compliance			
Boring to record data	0	4	0
Did not know how to use the app	4	0	0
Did not have time	0	4	0

Reasons for High Compliance

Receiving doctors' guidance and enriching related knowledge were the most frequently mentioned reasons. The doctors' advice included the following: (1) for patients who had little experience in hypertension self-management, doctors taught the patients how to self-manage their disease and (2) for patients who had sufficient experience in hypertension self-management, doctors conducted timely interventions to help patients deal with abnormal conditions. Therefore, doctors played an important role in patient hypertension self-management, which can effectively improve patient compliance. In addition, health education can raise the self-management awareness of different groups, thus improving their compliance.

A total of 17 patients (mainly in groups 1 and 2) mentioned that the BPA app played a role by providing reminders and supervision. For patients who lacked experience in self-management, the reminder service in BPA reminded them to complete the daily tasks, and for patients who lacked motivation in self-management, regular follow-ups from doctors encouraged them to pay more attention to their self-management.

Twelve patients (mainly in group 2) agreed that BPA helped patients learn how to control their hypertension. Patients in group 2 were more highly educated and interested in learning more about their disease. The health report module was helpful for improving their compliance.

Ten patients mentioned that the app helped enhance the pleasure of self-management. The leaderboard module provided social support for patients and improved their compliance by indirectly improving their motivation. Seven patients (mainly in group 1) mentioned ease of use, which is considered particularly important for patients who lack smartphone experience.

Reasons for Low Compliance

Four users in group 2 mentioned that it was boring to record data. We considered integrating wearable devices with the app to simplify the recording process. However, the main reason for noncompliance is that patients have no intrinsic motivation to monitor their health indicators. Therefore, the solution to this problem is to further increase patient motivation.

Some patients did not know how to use the app. This aspect was mentioned by 4 users in group 1. Patients in this group had relatively low educational levels and often lacked experience using smartphones. Teaching them how to use the app during the initial period of management is the key to solving this problem.

Some patients said that they had no time to manage their disease. Four users in group 2 mentioned this problem. However, we think that an additional important reason is a lack of intrinsic motivation. Similar to the first reason, the path toward changing users' behaviors is to add extrinsic motivations that make them pay more attention to their disease management.

Suggestions for Further Improvement

Five patients suggested increasing communication between doctors and patients. The current BPA adopted a one-way form of communication—from doctors. However, patients wanted to be able to take the initiative to communicate with their doctors. Three patients suggested an online registration function to save time and improve treatment efficiency. In the current version of BPA, we have added this module, but its usability remains to be tested. Six patients hoped to automatically measure BP data using their smartphones instead of having to manually input the data after measuring their BP through wearable devices. This requirement stemmed from the fact that these patients often traveled for business, which made it difficult for them to monitor their BP regularly. Being able to use their smartphones to measure their BP might increase their self-monitoring frequency. However, due to the technological limitations, achieving accurate BP measurements using unmodified smartphones remains a future goal [52].

Discussion

Principal Findings

In this study, we designed an innovative mHealth app (BPA) for hypertension self-management and evaluated patient compliance with its use. To ensure that the app met patients' needs, we used the GDD method and involved patients in every stage of the design process. Three major patient goals (needs)

were identified: improve self-management ability, enhance self-management motivation, and receive self-management support. Different functional modules of BPA were designed based on the identified patient needs. To evaluate the effectiveness of the BPA app, we invited 143 patients to use different versions of BPA for 2 months. Patient compliance with BPA version 4 reached 73%, a favorable result. According to interviews, patients felt that BPA taught them how to take the right actions to manage their disease, and they felt encouraged when instructed by doctors. Results suggest that patients are willing to try new tools with new technologies if those tools are designed specifically for them. We also identified some problems existing in patient self-management of hypertension. Some of the reasons for low compliance were attributable to low motivation for disease management. Patients should be provided with additional extrinsic motivation in multiple ways. Another possible improvement for BPA was that it should help build a closer relationship between patients and doctors. A communication module could be added to the app to fulfill this need.

Comparison With Prior Work

To the best of our knowledge, this study is the first to explicitly use GDD principles to develop an mHealth app for hypertension self-management. To understand the innovation of our study, we compared it with 5 prior studies that used a theory-based design method in the chronic disease management field. The results are shown in Table 9. Among these studies, two (Fore et al [33] and our study) explicitly used GDD as the design method. LeRouge et al [34] investigated user-centered design as a methodological tool but also established user personas during the design process. Five of the studies ([34,53-55] and ours) designed smartphone apps for specific diseases. Two studies (Morita et al [55] and ours) provided evaluations of their design results. In addition, Wachtler et al [54] reported that their tool was being evaluated in a randomized controlled trial.

Table 9. Comparison of recent studies using theory-based design for disease management.

Study	Country	Design method	Objective	Disease	Sample size for design	Final output	Evaluation
Our study	China	GDD[a]	Improve patient compliance with hypertension self-management	Hypertension	90 questionnaires and 18 interviews	Smartphone app	Yes
Fore et al [33]	United States	GDD	Improve chronic illness care	Pediatric inflammatory bowel disease	10 patients, 10 caregivers, 10 physicians, and 6 nurses (interviews and observations)	Prototype of a learning health system	No
LeRouge et al [34]	China	UCD[b]	Identify user profiles and personas of an aging population	Diabetes	9 focus groups, interviews with 21 physicians and 9 nurses	Smartphone app	No
van der Weegen et al [53]	Netherlands	UCD	Stimulate physical activity of people with a chronic disease	Chronic obstructive pulmonary disease or type 2 diabetes	15 interviews with patients, 2 focus groups, 16 interviews with health care professionals, and discussion with several experts	Triaxial activity sensor along with smartphone app	No
Wachtler et al [54]	Australia	UCD	Improve treatment allocation for depression	Depression	2 focus groups with community sample (n=17) and 7 interviews with people with depressive symptoms	Smartphone app	No
Morita et al [55]	Canada	UCD	Support asthma self-management	Asthma	11 interviews and 5 usability tests	Web-based mHealth platform	Yes

[a]GDD: goal-directed design.

[b]UCD: user-centered design.

Compared with these prior works, our study was innovative in a few ways. User models (personas) were established based on elements concerned with patient compliance rather than simply considering all factors. Elements were extracted mainly from relevant theories such as HBM and TAM.

In the persona establishment stage, qualitative and quantitative methods were used together to identify user personas. Qualitative methods are appropriate for dividing users into specific groups, while quantitative methods are suitable for extracting the intrinsic needs of different groups.

Different functional modules were designed for different personas and integrated into a complete mHealth app by following a reasonable priority. For example, the management plan module appears in the most conspicuous position of the main interface because it is the most frequently accessed part. In contrast, the leaderboard module is accessible through the quick launch bar of the main interface because it is less frequently used and is designed primarily for experienced users.

Strengths

Our study has several strengths. First, it verified the viewpoint that patients should self-manage their disease under the direction of doctors [56]. Only in this way can patients conduct comprehensive self-management and have abnormal conditions handled in a timely manner. This approach also accounted for the reasons why BPA was more effective compared with other apps available in app stores.

Second, we involved experts and patients in the design process. Chronic disease patients consist primarily of elderly people who have special and additional disease self-management needs [34]. To better understand the needs of these patients, we used questionnaires and interviews to identify the different personas of different patient groups. These personas were used to guide the functional design. In addition, elderly people are less confident in the use of mobile technologies. As a result, more attention should be paid to the usability of such apps, which is an important factor affecting patient compliance. Inviting users to participate in the design process can help discover usability problems in a very early stage.

Third, we proposed a new compliance assessment method in which the self-monitoring frequency of BP was considered as an evaluation index for hypertension self-management compliance. The most common approach for measuring patient compliance has previously been to ask patients for their ratings of compliance behavior or acquire the information through standardized questionnaires [10]. However, such approaches may result in higher compliance levels than the true levels due to patient subjectivity and memory bias [57]. Compliance with medication regimes is the most evaluated index according to several studies [58-60] because that is the most direct indicator of compliance with the doctor's instructions. However, taking medicine on time is easier to perform than other self-management tasks [61]; consequently, such a metric cannot fully reflect the complete content of patients' self-management. Compared with other studies, we used the frequency with which patients self-monitor their B*P* values and collected the results automatically through the app. Thus, this evaluation result was more objective and practical over the long term. Although our study was only a preliminary trial, it helps set a benchmark that further research can refer to when assessing such apps.

Limitations and Future Works

One limitation of our study is that the number of recruited subjects for persona establishment was relatively small, and most were highly educated. Therefore, the generalizability of the study's results needs to be further confirmed. Another limitation is that the pilot study lasted for only 2 months; patient compliance over a longer period of time is unknown. The interview results show that a few patients with low compliance still exist, mainly due to a lack of intrinsic motivation. In addition, one other thing to note is that in eHealth enhanced chronic disease management, patient compliance is influenced by multiple factors such as well-designed self-management tools, community-based eHealth support, and a complete feedback loop between patients and doctors [62]. Our study focused on the functional design of self-management tools, which is one of the important factors influencing patient compliance.

In future work, we will include more patients and test for a longer time span. Comparison tests should be conducted to determine how much patient compliance is improved. We also plan to compare patient compliance as measured by this study's approach with compliance measured by a traditional approach, such as questionnaires, to further explore the practical validity of our approach. In addition, we need to find a way to further increase patient motivation for self-management.

Conclusions

The BPA app was shown to be an effective tool for hypertension self-management in terms of patient compliance. The GDD method was able to identify the different needs of different patients and guided functional design based on these needs. We learned from the study that efficient self-management of hypertension should be led by doctors. Usability is another important factor that should be considered during the development of apps. In addition, hypertensive patients should receive more extrinsic motivation in the management of their disease.

Acknowledgments

This study was supported by the National Key Research and Development Program of China (No 2018YFC0910503 and No 2017YFC0114105), the Key Research and Development Program of Ningxia Hui Autonomous Region of China (No 2018BFG02009), and the Open Fund of the Engineering Research Center of Cognitive Healthcare, Zhejiang Province (Sir Run Run Shaw Hospital), China (No 2018KFJJ02).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Original questionnaires.
[DOCX File , 20 KB - mhealth_v8i2e14466_app1.docx]

Multimedia Appendix 2
Screened lists of articles and apps in stage 2.
[DOCX File , 31 KB - mhealth_v8i2e14466_app2.docx]

Multimedia Appendix 3
Detailed screenshots in the Blood Pressure Assistant.
[PDF File (Adobe PDF File), 7674 KB - mhealth_v8i2e14466_app3.pdf]

References

1. World Health Organization. Global status report on noncommunicable diseases 2014 URL: http://apps.who.int/iris/bitstream/10665/148114/1/9789241564854_eng.pdf?ua=1 [accessed 2020-01-08]
2. Global Burden of Disease Group. Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980-2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet 2016 Oct 08;388(10053):1459-1544 [FREE Full text] [doi: 10.1016/S0140-6736(16)31012-1] [Medline: 27733281]
3. GBD 2015 Risk Factors Collaborators. Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet 2016 Oct 08;388(10053):1659-1724 [FREE Full text] [doi: 10.1016/S0140-6736(16)31679-8] [Medline: 27733284]
4. Wang Z, Chen Z, Zhang L, Wang X, Hao G, Zhang Z, China Hypertension Survey Investigators. Status of hypertension in China: results From the China Hypertension Survey, 2012-2015. Circulation 2018 May 29;137(22):2344-2356. [doi: 10.1161/CIRCULATIONAHA.117.032380] [Medline: 29449338]
5. Reynolds R, Dennis S, Hasan I, Slewa J, Chen W, Tian D, et al. A systematic review of chronic disease management interventions in primary care. BMC Fam Pract 2018 Jan 09;19(1):11 [FREE Full text] [doi: 10.1186/s12875-017-0692-3] [Medline: 29316889]
6. Whelton PK, Carey RM, Aronow WS, Casey DE, Collins KJ, Dennison HC, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension 2017 Nov 13;71(6):e127-e248. [doi: 10.1161/HYP.0000000000000065] [Medline: 29133356]
7. Martin LR, Williams SL, Haskard KB, Dimatteo MR. The challenge of patient adherence. Ther Clin Risk Manag 2005 Sep;1(3):189-199 [FREE Full text] [Medline: 18360559]
8. Beaglehole R, Epping-Jordan J, Patel V, Chopra M, Ebrahim S, Kidd M, et al. Improving the prevention and management of chronic disease in low-income and middle-income countries: a priority for primary health care. Lancet 2008 Sep 13;372(9642):940-949. [doi: 10.1016/S0140-6736(08)61404-X] [Medline: 18790317]
9. Vrijens B, Vincze G, Kristanto P, Urquhart J, Burnier M. Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories. BMJ 2008 May 17;336(7653):1114-1117 [FREE Full text] [doi: 10.1136/bmj.39553.670231.25] [Medline: 18480115]
10. Dal-Fabbro AL. Adherence to long term therapies: evidence for action. Cad Saúde Pública 2005 Aug;21(4):1297-1298. [doi: 10.1590/s0102-311x2005000400037]
11. Dunbar-Jacob J, Mortimer-Stephens MK. Treatment adherence in chronic disease. J Clin Epidemiol 2001 Dec;54(Suppl 1):S57-S60. [doi: 10.1016/s0895-4356(01)00457-7] [Medline: 11750211]
12. DiMatteo MR. Social support and patient adherence to medical treatment: a meta-analysis. Health Psychol 2004 Mar;23(2):207-218. [doi: 10.1037/0278-6133.23.2.207] [Medline: 15008666]
13. Ho PM, Magid DJ, Shetterly SM, Olson KL, Maddox TM, Peterson PN, et al. Medication nonadherence is associated with a broad range of adverse outcomes in patients with coronary artery disease. Am Heart J 2008 Apr;155(4):772-779. [doi: 10.1016/j.ahj.2007.12.011] [Medline: 18371492]
14. Ma C, Chen S, Zhou Y, Huang C. Treatment adherence of Chinese patients with hypertension: a longitudinal study. Appl Nurs Res 2013 Nov;26(4):225-231. [doi: 10.1016/j.apnr.2013.08.002] [Medline: 24050917]
15. Vrijens B, Antoniou S, Burnier M, de la Sierra A, Volpe M. Current situation of medication adherence in hypertension. Front Pharmacol 2017;8:100 [FREE Full text] [doi: 10.3389/fphar.2017.00100] [Medline: 28298894]
16. Tilea I, Petra D, Voidazan S, Ardeleanu E, Varga A. Treatment adherence among adult hypertensive patients: a cross-sectional retrospective study in primary care in Romania. Patient Prefer Adherence 2018;12:625-635 [FREE Full text] [doi: 10.2147/PPA.S162965] [Medline: 29731610]
17. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. J Med Internet Res 2015;17(2):e52 [FREE Full text] [doi: 10.2196/jmir.3951] [Medline: 25803266]
18. Wheeler TS, Michael Vallis T, Giacomantonio NB, Abidi SR. Feasibility and usability of an ontology-based mobile intervention for patients with hypertension. Int J Med Inform 2018 Nov;119:8-16. [doi: 10.1016/j.ijmedinf.2018.08.002] [Medline: 30342690]
19. Bengtsson U, Kjellgren K, Hallberg I, Lindwall M, Taft C. Improved blood pressure control using an interactive mobile phone support system. J Clin Hypertens (Greenwich) 2016 Feb;18(2):101-108 [FREE Full text] [doi: 10.1111/jch.12682] [Medline: 26456490]

20. Xiong S, Berkhouse H, Schooler M, Pu W, Sun A, Gong E, et al. Effectiveness of mHealth interventions in improving medication adherence among people with hypertension: a systematic review. Curr Hypertens Rep 2018 Aug 07;20(10):86. [doi: 10.1007/s11906-018-0886-7] [Medline: 30088110]
21. Dicianno BE, Henderson G, Parmanto B. Design of mobile health tools to promote goal achievement in self-management tasks. JMIR Mhealth Uhealth 2017 Jul 24;5(7):e103 [FREE Full text] [doi: 10.2196/mhealth.7335] [Medline: 28739558]
22. Matthew-Maich N, Harris L, Ploeg J, Markle-Reid M, Valaitis R, Ibrahim S, et al. Designing, implementing, and evaluating mobile health technologies for managing chronic conditions in older adults: a scoping review. JMIR Mhealth Uhealth 2016 Jun 09;4(2):e29 [FREE Full text] [doi: 10.2196/mhealth.5127] [Medline: 27282195]
23. Vo V, Auroy L, Sarradon-Eck A. Patients' perceptions of mHealth apps: meta-ethnographic review of qualitative studies. JMIR Mhealth Uhealth 2019 Jul 10;7(7):e13817 [FREE Full text] [doi: 10.2196/13817] [Medline: 31293246]
24. Rahimian V, Ramsin R. Designing an agile methodology for mobile software development: a hybrid method engineering approach. 2008 Presented at: 2008 Second International Conference on Research Challenges in Information Science; 2008; Marrakech p. 337-342. [doi: 10.1109/rcis.2008.4632123]
25. Jeong Y, Lee J, Shin G. Development process of mobile app SW based on agile methodology. 2008 Presented at: 10th International Conference on Advanced Communication Technology. Vol 1. IEEE; 2008; Gangwon-Do p. 362-366. [doi: 10.1109/icact.2008.4493779]
26. da Cunha TFV, Dantas V, Andrade R. SLeSS: a scrum and lean Six Sigma integration approach for the development of sofware customization for mobile phones. 2011 Presented at: 2011 25th Brazilian Symposium on Software Engineering; 2011; Sao Paulo p. 283-292. [doi: 10.1109/sbes.2011.38]
27. Abrahamsson P, Hanhineva A, Hulkko H. Mobile-D: an agile approach for mobile app development. In: Companion to the 9th Annual ACM SIGPLAN Conference on Object-Oriented Programming Systems, Languages, and Applications, Volume 1. New York: ACM Press; 2004:174.
28. Gifford B, Enyedy N. Activity centered design: towards a theoretical framework for CSCL. In: CSCL 99: Proceedings of the 1999 Conference on Computer Support for Collaborative Learning. Morristown: Association for Computational Linguistics; 1999:22.
29. Kangas E, Kinnunen T. Applying user-centered design to mobile application development. Commun ACM 2005 Jul 01;48(7):55. [doi: 10.1145/1070838.1070866]
30. Muller MJ. Participatory design: the third space in HCI. Hum Comput Interact Devel Process 2003;4235:165-185. [doi: 10.1201/9781410615862.ch54]
31. Cooper A. About Face: The Essentials of Interaction Design. Hoboken: John Wiley & Sons; 2014.
32. Williams A. User-Centered Design, Activity-Centered Design, and Goal-Directed Design. In: SIGDOC 09: Proceedings of the 27th ACM International Conference on Design of Communication. New York: ACM Press; 2009:1-9.
33. Fore D, Goldenhar LM, Margolis PA, Seid M. Using goal-directed design to create a novel system for improving chronic illness care. JMIR Res Protoc 2013 Oct 29;2(2):e43 [FREE Full text] [doi: 10.2196/resprot.2749] [Medline: 24168835]
34. LeRouge C, Ma J, Sneha S, Tolle K. User profiles and personas in the design and development of consumer health technologies. Int J Med Inform 2013 Nov;82(11):e251-e268. [doi: 10.1016/j.ijmedinf.2011.03.006] [Medline: 21481635]
35. Grindrod KA, Li M, Gates A. Evaluating user perceptions of mobile medication management applications with older adults: a usability study. JMIR Mhealth Uhealth 2014;2(1):e11 [FREE Full text] [doi: 10.2196/mhealth.3048] [Medline: 25099993]
36. Balduino ADFA, Mantovani MDF, Lacerda MR, Marin MJS, Wal ML. Experience of hypertensive patients with self-management of health care. J Adv Nurs 2016 Nov;72(11):2684-2694. [doi: 10.1111/jan.13022] [Medline: 27206159]
37. Rosenstock IM. The health belief model and preventive health behavior. Health Educ Behav 1974 Dec 01;2(4):354-386. [doi: 10.1177/109019817400200405]
38. Janz NK, Becker MH. The health belief model: a decade later. Health Educ Q 1984;11(1):1-47. [Medline: 6392204]
39. Kaplan SH, Greenfield S, Ware JE. Assessing the effects of physician-patient interactions on the outcomes of chronic disease. Med Care 1989 Mar;27(3 Suppl):S110-S127. [Medline: 2646486]
40. Koopman RJ, Petroski GF, Canfield SM, Stuppy JA, Mehr DR. Development of the PRE-HIT instrument: patient readiness to engage in health information technology. BMC Fam Pract 2014;15:18 [FREE Full text] [doi: 10.1186/1471-2296-15-18] [Medline: 24472182]
41. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q 1989 Sep;13(3):319-340. [doi: 10.2307/249008]
42. Kim J, Park H. Development of a health information technology acceptance model using consumers' health behavior intention. J Med Internet Res 2012;14(5):e133 [FREE Full text] [doi: 10.2196/jmir.2143] [Medline: 23026508]
43. Sun Y, Wang N, Guo X, Peng J. Understanding the acceptance of mobile health services: a comparison and integration of alternative models. J Electron Commer Res 2013;14(2):183-200 [FREE Full text]
44. Hung M, Jen W. The adoption of mobile health management services: an empirical study. J Med Syst 2012 Jun;36(3):1381-1388. [doi: 10.1007/s10916-010-9600-2] [Medline: 20878452]
45. Lim S, Xue L, Yen CC, Chang L, Chan HC, Tai BC, et al. A study on Singaporean women's acceptance of using mobile phones to seek health information. Int J Med Inform 2011 Dec;80(12):e189-e202. [doi: 10.1016/j.ijmedinf.2011.08.007] [Medline: 21956003]

46. Taylor S, Todd P. Assessing IT usage: the role of prior experience. MIS Q 1995 Dec;19(4):561. [doi: 10.2307/249633]
47. Fan C, Yu M, Chen Y. Survey on the awareness rate of hypertension knowledge in Zhejiang residents. Strait J Prev Med 2008;14(2):7-8.
48. Lahdenperä TS, Wright CC, Kyngäs HA. Development of a scale to assess the compliance of hypertensive patients. Int J Nurs Stud 2003 Sep;40(7):677-684. [doi: 10.1016/s0020-7489(02)00110-4] [Medline: 12965159]
49. Ping S. Effect of the Intervention Education on Self-Efficacy and Compliance of Hypertensive Patients in the Community [Thesis]. Beijing: Peking Union Medical College; 2006.
50. Dou K, Yu P, Deng N, Liu F, Guan Y, Li Z, et al. Patients' acceptance of smartphone health technology for chronic disease management: a theoretical model and empirical test. JMIR Mhealth Uhealth 2017 Dec 06;5(12):e177 [FREE Full text] [doi: 10.2196/mhealth.7886] [Medline: 29212629]
51. Oinas-Kukkonen H, Harjumaa M. Persuasive systems design: key issues, process model, and system features. Commun Assoc Inf Syst 2009;24(1):485-500. [doi: 10.17705/1CAIS.02428]
52. Chandrasekhar A, Kim C, Naji M, Natarajan K, Hahn J, Mukkamala R. Smartphone-based blood pressure monitoring via the oscillometric finger-pressing method. Sci Transl Med 2018 Mar 07;10(431) [FREE Full text] [doi: 10.1126/scitranslmed.aap8674] [Medline: 29515001]
53. van der Weegan S, Verwey R, Spreeuwenberg M, Tange H, van der Weijen T, de Witte L. The development of a mobile monitoring and feedback tool to stimulate physical activity of people with a chronic disease in primary care: a user-centered design. JMIR Mhealth Uhealth 2013;1(2):e8 [FREE Full text] [doi: 10.2196/mhealth.2526] [Medline: 25099556]
54. Wachtler C, Coe A, Davidson S, Fletcher S, Mendoza A, Sterling L, et al. Development of a mobile clinical prediction tool to estimate future depression severity and guide treatment in primary care: user-centered design. JMIR Mhealth Uhealth 2018 Apr 23;6(4):e95 [FREE Full text] [doi: 10.2196/mhealth.9502] [Medline: 29685864]
55. Morita PP, Yeung MS, Ferrone M, Taite AK, Madeley C, Stevens Lavigne A, et al. A patient-centered mobile health system that supports asthma self-management (breathe): design, development, and utilization. JMIR Mhealth Uhealth 2019 Jan 28;7(1):e10956 [FREE Full text] [doi: 10.2196/10956] [Medline: 30688654]
56. Kim HS, Cho JH, Yoon KH. New directions in chronic disease management. Endocrinol Metab (Seoul) 2015 Jun;30(2):159-166 [FREE Full text] [doi: 10.3803/EnM.2015.30.2.159] [Medline: 26194075]
57. Quilici J, Fugon L, Beguin S, Morange PE, Bonnet J, Alessi M, et al. Effect of motivational mobile phone short message service on aspirin adherence after coronary stenting for acute coronary syndrome. Int J Cardiol 2013 Sep 20;168(1):568-569. [doi: 10.1016/j.ijcard.2013.01.252] [Medline: 23462636]
58. Park LG, Howie-Esquivel J, Whooley MA, Dracup K. Psychosocial factors and medication adherence among patients with coronary heart disease: a text messaging intervention. Eur J Cardiovasc Nurs 2015 Jun;14(3):264-273. [doi: 10.1177/1474515114537024] [Medline: 24853566]
59. Strandbygaard U, Thomsen SF, Backer V. A daily SMS reminder increases adherence to asthma treatment: a three-month follow-up study. Respir Med 2010 Feb;104(2):166-171 [FREE Full text] [doi: 10.1016/j.rmed.2009.10.003] [Medline: 19854632]
60. Brath H, Morak J, Kästenbauer T, Modre-Osprian R, Strohner-Kästenbauer H, Schwarz M, et al. Mobile health (mHealth) based medication adherence measurement—a pilot trial using electronic blisters in diabetes patients. Br J Clin Pharmacol 2013 Sep;76 Suppl 1:47-55 [FREE Full text] [doi: 10.1111/bcp.12184] [Medline: 24007452]
61. Shetty AS, Chamukuttan S, Nanditha A, Raj RKC, Ramachandran A. Reinforcement of adherence to prescription recommendations in Asian Indian diabetes patients using short message service (SMS)--a pilot study. J Assoc Physicians India 2011 Nov;59:711-714. [Medline: 22616337]
62. Gee PM, Greenwood DA, Paterniti DA, Ward D, Miller LMS. The eHealth Enhanced Chronic Care Model: a theory derivation approach. J Med Internet Res 2015;17(4):e86 [FREE Full text] [doi: 10.2196/jmir.4067] [Medline: 25842005]

Abbreviations

ARHKS: Awareness Rate of Hypertension Knowledge Scale
BP: blood pressure
BPA: Blood Pressure Assistant
CHPS: Compliance of Hypertensive Patients Scale
GDD: goal-directed design
HBM: health belief model
IT: information technology
mHealth: mobile health
TAM: technology acceptance model

Edited by G Eysenbach; submitted 22.04.19; peer-reviewed by T Timmers, L Sheets, T Yano; comments to author 01.10.19; revised version received 19.11.19; accepted 16.12.19; published 25.02.20.

Please cite as:
Duan H, Wang Z, Ji Y, Ma L, Liu F, Chi M, Deng N, An J
Using Goal-Directed Design to Create a Mobile Health App to Improve Patient Compliance With Hypertension Self-Management: Development and Deployment
JMIR Mhealth Uhealth 2020;8(2):e14466
URL: http://mhealth.jmir.org/2020/2/e14466/
doi:10.2196/14466
PMID:32130161

Original Paper

Effect of a Mobile Phone–Based Glucose-Monitoring and Feedback System for Type 2 Diabetes Management in Multiple Primary Care Clinic Settings: Cluster Randomized Controlled Trial

Yeoree Yang[1,2], MD; Eun Young Lee[1], MD, PhD; Hun-Sung Kim[1,3], MD, PhD; Seung-Hwan Lee[1], MD, PhD; Kun-Ho Yoon[1,3], MD, PhD; Jae-Hyoung Cho[1,2], MD, PhD

[1]Division of Endocrinology and Metabolism, Department of Internal Medicine, Seoul St Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Republic of Korea

[2]Catholic Smart Health Care Center, The Catholic University of Korea, Seoul, Republic of Korea

[3]Department of Medical Informatics, College of Medicine, The Catholic University of Korea, Seoul, Republic of Korea

Corresponding Author:
Jae-Hyoung Cho, MD, PhD
Division of Endocrinology and Metabolism, Department of Internal Medicine, Seoul St Mary's Hospital
College of Medicine
The Catholic University of Korea
222 Banpo-daero, Seocho-gu
Seoul, 06591
Republic of Korea
Phone: 82 2 2258 6008
Email: drhopper@ikoob.com

Abstract

Background: Recent evidence of the effectiveness of mobile phone–based diabetes management systems is generally based on studies conducted in tertiary hospitals or professional diabetes clinics.

Objective: This study aimed to evaluate the clinical efficacy and applicability of a mobile phone–based glucose-monitoring and feedback system for the management of type 2 diabetes mellitus (T2DM) in multiple primary care clinic settings.

Methods: In this multicenter, cluster-randomized controlled, open trial, 13 primary care clinics in Seoul and other large cities in South Korea were voluntarily recruited. Overall, 150 (9 clinics) and 97 (4 clinics) participants with T2DM were assigned to the intervention and control groups, respectively (2:1 allocation). Every month, participants in both groups attended face-to-face physicians' consultation for the management of diabetes in the clinic. For the intervention group, participants were required to upload their daily self-monitoring of blood glucose (SMBG) results using the mobile phone app in addition to outpatient care for 3 months. The results were automatically transmitted to the main server. Physicians had to check their patients' SMBG results through an administrator's website and send a short feedback message at least once a week. At baseline and 3 months, both groups had anthropometry and blood tests, including hemoglobin A_{1c} (HbA_{1c}), and responded to questionnaires about treatment satisfaction and compliance.

Results: At 3 months, participants in the intervention group showed significantly more improvement in HbA_{1c} (adjusted mean difference to control −0.30%, 95% CI −0.50 to −0.11; *P*=.003) and fasting plasma glucose (−17.29 mg/dL, 95% CI −29.33 to −5.26; *P*=.005) than those in the control group. In addition, there was significantly more reduction in blood pressure, and the score regarding treatment satisfaction and motivation for medication adherence increased more in the intervention group than in the control group. In the subgroup analyses, the effect on glycemic control was more significant among younger patients and higher baseline HbA_{1c} levels.

Conclusions: The mobile phone–based glucose-monitoring and feedback system was effective in glycemic control when applied in primary care clinic settings. This system could be utilized effectively with diverse institutions and patients.

Trial Registration: Clinical Research Information Service (CRIS) https://tinyurl.com/tgqawbz

(JMIR Mhealth Uhealth 2020;8(2):e16266) doi:10.2196/16266

KEYWORDS

diabetes mellitus, type 2; primary care; mHealth; telehealth

Introduction

Background

Type 2 diabetes mellitus (T2DM) is a worldwide epidemic that is a major socioeconomic burden on the global health care system [1]. Poorly managed T2DM is associated with increased risks of micro and macrovascular complications and premature mortality. Therefore, it is important to steadily achieve the target levels of multiple risk factors, including hyperglycemia, hypertension, dyslipidemia, and obesity, to prevent diabetic morbidities and mortality [2]. Although diabetes is a lifestyle-related disease that requires daily self-management [3], the current diabetes management system largely depends on intermittent short face-to-face interviews at outpatient clinics and medication prescriptions. Consequently, it is not easy for patients to maintain constant care for diabetes in their daily lives.

There have been many attempts to introduce self-management support systems for patients with T2DM on the basis of information technologies (ITs), including Web-based interventions [4-7]. Since the introduction of the smartphone in 2007, mobile phone app-based monitoring systems have taken a major position as intervention modalities, and evidence of their effectiveness in diabetes management has also been accumulated in different types of groups [8-11]. However, previous positive results of mobile phone use in diabetes management were mostly reported by studies involving patients in tertiary hospitals or professional diabetes clinics [12,13]. A large number of patients with T2DM receive treatment at primary care clinics. Physicians at these clinics are not always experts on diabetes; furthermore, most of them have no experience with IT-based diabetes management systems. Implementation of IT-based systems into the primary care service is necessary and inevitable for sharing appropriate diabetes management systems and, ultimately, reducing diabetes-related complications [12]. Therefore, it is necessary to verify the effectiveness of mobile phone–based monitoring systems in primary care clinic settings, where there is a relative lack of specialized workforce and diabetes education environments compared with large hospitals.

Objectives

This study aimed to evaluate the clinical efficacy and applicability of an interactive, mobile phone–based monitoring and feedback system for T2DM management in primary care clinic settings by assessing its effect on glycemic control and other combined metabolic risk factors such as hypertension, dyslipidemia, and obesity. We also evaluated participants' treatment satisfaction and their motivation and knowledge related to long-term medication adherence in chronic diseases.

Methods

Study Design and Participants

We performed a 3-month, multicenter, cluster-randomized, open trial. Eligibility criteria for primary care clinics were being located in Seoul and other major cities in South Korea, having a patient pool with T2DM, and access to internet services at the clinic. At first, 17 clinics were voluntarily recruited after open research briefing. Among them, 4 clinics declined to participate, and 13 clinics were randomized (Multimedia Appendix 1). Clinics were the unit of randomization and intervention. A research statistician not involved with this study generated the random allocation sequence using SAS software, version 9.3 (SAS Institute Inc, Cary, the United States). Each clinic was sequentially allocated to an intervention or control group after registration with no masking. Finally, 9 and 4 (2:1 allocation) of the 13 primary care clinics were assigned to the intervention and control groups, respectively.

A notice about study methods and participant recruitment was posted on the bulletin board at each clinic. Subjects with T2DM who agreed to participate voluntarily in this clinical study were screened. Eligible subjects were over 18 years of age, had T2DM for at least one year, could use mobile phones or internet services at home, and had baseline hemoglobin A_{1c} (HbA_{1c}) levels between 7% (53 mmol/mol) and 10% (86 mmol/mol). We excluded subjects with type 1 diabetes and insulin pump users, subjects with any significant medical disease (such as active cancer, recent stroke, or myocardial infarction), subjects with severe diabetic complications (moderate to severe nonproliferative diabetic retinopathy, proliferative diabetic retinopathy, serum creatinine >1.5 or 1.4 mg/dL for men or women, respectively, or aspartate aminotransferase [AST] or alanine aminotransferase [ALT] levels >3× the upper normal limit), and subjects who had not been taking stable doses of diabetes medications during the 3 months before enrollment. Subjects of other clinical trials or plans could not participate in this study either.

This study was conducted according to the principles expressed in the Declaration of Helsinki. The protocol was reviewed and approved by the Public Institutional Bioethics Committee designated by the Ministry of Health and Welfare (P01-201504-11-002). Written informed consent was obtained from all participants. The study was registered with the Clinical Research Information Service (CRIS number: KCT 0002554).

Intervention

After screening, participants who met all inclusion criteria at the intervention clinic were registered on the medical staff website and downloaded a mobile phone app (Hicare smart K, Insung information). Then, the physicians of the primary care clinic educated participants on the individual management targets (glycemic, blood pressure [BP], lipid profile, and body weight) on the basis of the medical guidelines of the Korean Diabetes Association [14] and explained how to use the app

and all study instructions. In this study, we utilized a pre-existing diabetes management app. In addition, we upgraded a function to link the app data to the providers' main server. All participants in the intervention group were provided with a glucometer (GlucoNavii SD GlucoLink 0.3, SD Biosensor Inc) and 100 strips. Participants who satisfied all three of the following criteria were additionally provided with an electronic manometer (BP-1209, YH Medical Co): with hypertension for more than 1 year, taking hypertension medication for more than 3 months, and systolic or diastolic BP ≥140/90 at the screening.

Participants in the intervention group were required to upload the daily self-monitoring of blood glucose (SMBG) results using the mobile phone app for 3 months (Multimedia Appendix 2). As a coaching hospital center, we provided the general guidelines for SMBG measurements to all physicians in the primary care clinics. Because there is evidence that supports a correlation between higher SMBG frequency and lower HbA_{1c} [15,16], we established SMBG measurement guidelines to encourage more SMBG testing when the patient's HbA_{1c} level was high. Therefore, the minimum required number of SMBG measurements was determined on the basis of the participant's baseline HbA_{1c} level. Participants were advised to check the SMBG twice weekly when their HbA_{1c} level was <7% (53 mmol/mol) without oral hypoglycemic agents (OHAs); once daily when their HbA_{1c} level was <7% (53 mmol/mol) with OHA; at least once daily when their HbA_{1c} was between 7% to 8% (53-64 mmol/mol) with OHA or was >8% (64 mmol/mol) regardless of OHA; twice daily when their HbA_{1c} level was <7% (53 mmol/mol) with insulin treatment; and thrice daily when their HbA_{1c} level was ≥7% (53 mmol/mol) with insulin treatment. When participants checked their SMBG with the provided glucometer and brought it into contact with the mobile phone, the SMBG result was automatically inputted into the mobile phone app, using wireless transmission through a near-field communication system. Participants could also upload the data via manual input. The mobile phone then automatically transmitted the data to the main server. Participants were also required to input the mealtime when SMBG was checked and were requested to input their BP at least once a week. They could also input weight data on the mobile phone app.

The physicians of the primary care clinic had to check the accumulated participants' data and send short feedback messages via a password-protected staff website at least once a week. As a coaching hospital center, we provided a manual on how to recommend messages to each clinic. We also provided some examples of message templates in the administrator's website, where the physicians could select and send a message. The medical staff could select or modify the example template as desired. The main contents of the message were about praise or encouragement if participants' SMBG was almost within the target level, a reinformation of their glucose target level or advice for dietary control and exercise if their SMBG was almost above the target level, or an advice for the regular glucose checkup if they did not check the SMBG at the recommended level. Advice about dietary control and exercise was based on general guidelines such as reduce the carbohydrate and fruit intake and encourage postmeal exercise. If necessary, physicians could conduct additional direct phone call consultations, although it was not mandatory.

Every month, all study participants of the intervention and control groups visited the outpatient clinic and received face-to-face consultations for individual management target of risk factors (Multimedia Appendix 2). At this time, the physicians of the intervention clinic additionally provided the summarized result of accumulated information from the staff website to their patients and gave a consultation based on it.

Measures

All study participants in the intervention or control group received a baseline assessment for demographic information regarding age, sex, alcohol intake, cigarette smoking, past history, and medications. Baseline measurements of height, weight, waist circumference (WC), and BP were also conducted. Height and weight were measured in light clothing without shoes. An experienced nurse measured the WC with the participant standing erect with his or her arms at the side, keeping their feet wide open about 15 cm. BMI was calculated using the participant's height and weight (kg/m^2). BP was measured in the sitting position by the oscillometric method using an appropriate cuff after resting at least 5 min. A baseline fasting blood sample was obtained to measure the fasting plasma glucose (FPG), HbA_{1c}, creatinine, AST, ALT, total cholesterol, triglyceride, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein cholesterol. All blood samples were transported to a central laboratory (Green Cross Laboratories) for analysis. HbA_{1c} was measured through high-performance liquid chromatography.

Each monthly visit, physicians checked participants' vital signs, weight, WC, change in medications, and assessed safety and compliance with the study. At baseline and 3 months, all participants underwent the same measurements of anthropometry and laboratory tests to evaluate the efficacy of the trial.

Questionnaires

The questionnaires were given to the subjects twice, at baseline and 3 months, to evaluate participants' treatment satisfaction and adherence to chronic medications. The participants received the surveys in written form and self-conducted it in a separate clinic space. If they had difficulty in filling out the questionnaires, the primary care provider could give them help. Finally, the questionnaires were collected and analyzed by research statistician not involved with this study.

The Diabetes Treatment Satisfaction Questionnaire status version (DTSQs) was used to evaluate the participants' treatment satisfaction [17]. DTSQs contains 8 items scored on a 7-point scale from 6 (extremely satisfied) to 0 (very dissatisfied) points. Higher total scores indicate favorable treatment satisfaction. The 6-item Morisky Medication Adherence Scale (MMAS-6) was used to evaluate participants' motivation and knowledge related to long-term medication adherence in chronic diseases [18]. The response categories are yes or no for each item, with 1 point given to the desired state. If the total score for questions 1, 2, and 6 equals 0 or 1, this means that they have low motivation, whereas a total score of 2 or 3 refers to high

motivation for medication adherence. If the total score for questions 3, 4, and 5 equals 0 or 1, this means that they have low knowledge of medication adherence, and a total score of 2 or 3 refers to the high level of knowledge.

Outcomes

The primary efficacy outcome was the difference in mean change in HbA_{1c} from baseline to the 3-month follow-up between the two groups. The secondary efficacy outcomes were the difference of mean change from baseline to 3 months in FPG, weight, WC, BMI, systolic and diastolic BP, lipid profile, and the DTSQs and MMAS-6 questionnaire scores between the two groups.

Any adverse events were coded using the Medical Dictionary for Regulatory Activities, regarding the intervention, and were assessed by the medical staff at follow-up visits or by patient self-reporting.

Statistical Analysis

Calculation of the sample size was based on an expected 0.6% difference of change in HbA_{1c} (primary outcome) level between the intervention and control groups, with an SD of 0.8, an average cluster size of 25, and an intracluster correlation coefficient of .10, similar to a previous study [19]. As a result, a target sample of 100 participants per each group would achieve 80% power at a critical significance level of 0.05. A higher dropout rate was expected in the intervention group, so we planned to enroll more clinics and participants in the intervention group. Finally, we planned to enroll 150 participants at 9 intervention clinics and 100 participants at 4 control clinics.

The data were analyzed on an intent-to-treat basis of all assigned participants who completed the follow-up assessment at 3 months. For comparison of baseline differences between the two groups, independent *t* tests for continuous variables and chi-square tests for categorical variables were used. Continuous variables were expressed as means and SD or mean (95% CI). Categorical variables were expressed as numbers (%). To compare within-group differences (mean change from baseline) between baseline and 3 months, differences between pre and postintervention were examined using a paired *t* test. Analysis of covariance (ANCOVA) was used to compare mean changes in primary and secondary efficacy outcomes between the control and intervention groups (adjusted mean difference to control). Results were assessed using ANCOVA with a fixed effect for intervention, and age and respective baseline value as covariates to calculate a least-squares estimate of the treatment difference.

Furthermore, sensitivity analyses were assessed using the linear mixed model with fixed effects for age, sex, intervention, time (baseline and 3 months), respective baseline value, baseline value-by time interaction and intervention-by time interaction, and random effects with cluster (centers) and each participant. All analyses were two-tailed, and clinical significance was defined as $P<.05$. Statistical analyses were performed with the statistical package SPSS version 24.0 (SPSS Inc, Chicago, Illinois, the United States) or SAS version 9.3.

Results

Participant Disposition and Characteristics

Between March and June 2015, a total of 401 subjects were assessed for eligibility: 255 subjects at 9 intervention clinics and 146 subjects at 4 control clinics (Figure 1). Among them, 150 subjects at intervention clinics and 97 subjects at control clinics met all the criteria and participated in the study. Only 5 and 3 subjects in intervention and control clinics were lost during follow-up, respectively. No clinic stopped participating. Therefore, 239 final subjects were analyzed in this study: 145 subjects at 9 intervention clinics and 94 subjects at 4 control clinics.

The baseline characteristics of the participants in both groups are shown in Table 1. Both groups showed similar sex distributions. However, the mean age of the intervention group was 54.1 years, which was significantly lower than the 60.6 years of the control group. Although there were no significant differences in BMI and proportion of obesity (BMI ≥25 kg/m^2) between the 2 groups, the intervention group showed higher weight and WC compared with those in the control group. The subjects in the intervention group also had higher diastolic BP at baseline. The baseline HbA_{1c} was similar between the 2 groups, and mean HbA_{1c} was 7.9% in the intervention and 8.0% in the control group, respectively. In addition, baseline laboratory data showed almost no statistical differences between the 2 groups, except for the lower total cholesterol and HDL cholesterol levels in the intervention group. Baseline characteristics by each clinic in the control and intervention groups are shown in Multimedia Appendices 3 and 4.

Figure 1. Study enrollment and follow-up.

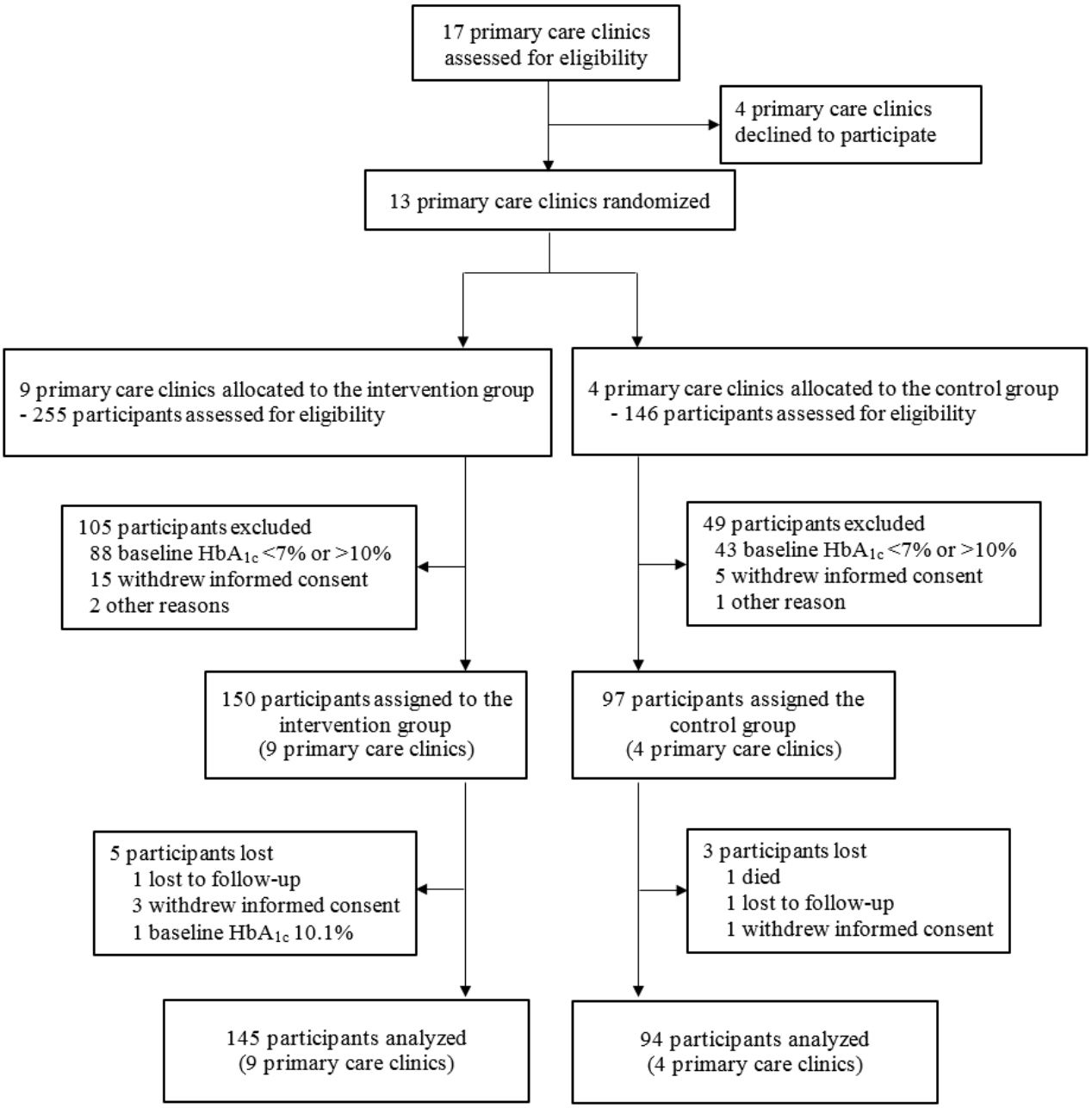


Table 1. Baseline characteristics of study participants.

Variable	Control group (n=97)	Intervention group (n=150)	*P* value
Age (years)			<.001
Mean (SD)	60.6 (10.2)	54.1 (10.1)	
<40, n (%)	4 (4)	10 (6.7)	
≥40 and <60, n (%)	36 (37)	93 (62.0)	
≥60, n (%)	57 (59)	47 (31.3)	
Male, n (%)	45 (46)	80 (53.3)	.29
Height (cm), mean (SD)	161.3 (9.1)	163.6 (9.5)	.06
Weight (kg), mean (SD)	67.2 (14.2)	70.6 (12.8)	.005
BMI (kg/m ^{2})			
Mean (SD)	25.7 (3.9)	26.3 (3.7)	.17
Obesity (BMI≥25), n (%)	52 (54)	97 (64.7)	.08
Waist circumference (cm), mean (SD)	87 (9.8)	89.5 (8.9)	.003
Systolic BP[a] (mmHg), mean (SD)	124.5 (11.9)	126.3 (10.9)	.17
Diastolic BP (mmHg), mean (SD)	74.1 (10.3)	77.3 (9)	.009
Diagnosis of hypertension, n (%)	57 (59)	92 (61.3)	.69
Diagnosis of dyslipidemia, n (%)	62 (64)	108 (72.0)	.18
Current smoker, n (%)	18 (19)	31 (20.7)	.69
FPG[b] (mg/dL), mean (SD)	147.9 (48.7)	150.7 (57.2)	.95
HbA_{1c}[c](%)			
Mean (SD)	7.9 (0.8)	8 (0.8)	.52
≥8%, n (%)	38 (39)	66 (44.0)	.45
Total cholesterol (mg/dL), mean (SD)	165 (30.5)	156.6 (29.8)	.02
Triglyceride (mg/dL), mean (SD)	165.3 (81.1)	160.3 (106.1)	.08
HDL[d] cholesterol (mg/dL), mean (SD)	51.1 (13.5)	46.9 (11)	.01
LDL[e] cholesterol (mg/dL), mean (SD)	94.5 (26.6)	89.6 (26.1)	.22
AST[f] (U/L), mean (SD)	25.9 (13)	27.4 (17.5)	.86
ALT[g] (U/L), mean (SD)	26.2 (15)	30.6 (22.5)	.16
Serum creatinine (mg/dL), mean (SD)	0.9 (0.2)	0.8 (0.2)	.09
DTSQs[h] score, mean (SD)	27.6 (6.1)	28.2 (6.2)	.35
MMAS-6[i] score, mean (SD)			
Total	4.7 (1.1)	4.4 (1.3)	.16
Motivation	2.3 (0.9)	2 (1)	.01
Knowledge	2.3 (0.6)	2.4 (0.7)	.09

[a]BP: blood pressure.

[b]FPG: fasting plasma glucose.

[c]HbA_{1c}: hemoglobin A_{1c}.

[d]HDL: high-density lipoprotein.

[e]LDL: low-density lipoprotein.

[f]AST: aspartate transaminase.

[g]ALT: alanine transaminase.

[h]DTSQs: Diabetes Treatment Satisfaction Questionnaire status version.

[i]MMAS-6: 6-item Morisky Medication Adherence Scale.

Changes in Glycemic Status

Table 2 shows the change in efficacy outcomes compared with baseline between the two groups at 3 months. The mean changes in efficacy outcomes from baseline in each clinic of the control and intervention groups are shown in Multimedia Appendices 5 and 6. At 3 months, both groups showed significant decreases in HbA_{1c} level compared with the baseline. Nevertheless, the intervention group showed significantly more reduction in HbA_{1c} compared with the control group, and the adjusted mean difference of change in HbA_{1c} between the two groups was −0.30% (95% CI −0.50% to −0.11%). The proportions of subjects who achieved HbA_{1c} <7% (53 mmol/mol) at 3 months were 33.8% (49/145) in the intervention and 24% (23/94) in the control group, respectively. Similar results were observed in the FPG level in both groups. The intervention group showed significantly more reduction in FPG (−7.29 mg/dL, 95% CI −29.33 to −5.26) than the control group. Sensitivity analysis showed constant statistical significance in all outcomes of HbA_{1c} and FPG.

Table 2. Changes in efficacy outcomes between control and intervention groups at 3 months.

Outcomes	Mean change from baseline		Adjusted mean difference to control[a], mean (95% CI)	*P* value[a]	*P* value for interaction (intervention x time)[b]
	Control group (n=94), mean (95% CI)	Intervention group (n=145), mean (95% CI)			
Glycemic parameters					
HbA_{1c}[c] (%)	−0.28 (−0.42 to −0.13)	−0.63 (−0.77 to −0.50)	−0.30 (−0.50 to −0.11)	.003[d]	.001[d]
HbA_{1c} (mmol/mol)	−3.02 (−4.62 to −1.42)	−6.93 (−8.38 to −5.48)	−3.32 (−5.50 to −1.15)	.003[d]	.001[d]
FPG[e] (mg/dL)	−2.41(−13.64 to 8.82)	−19.11 (−29.80 to −8.43)	−17.29 (−29.33 to −5.26)	.005[d]	.02[d]
Other metabolic parameters					
Weight (kg)	−0.88 (−2.65 to 0.90)	−0.63 (−1.02 to −0.24)	0.22 (−1.26 to 1.71)	.77	.35
WC[f] (cm)	−0.88 (−1.61 to −0.16)	−0.93 (−1.46 to −0.40)	0.30 (−0.62 to 1.22)	.52	.76
BMI (kg/m^2)	−0.41 (−1.21 to 0.40)	−0.26 (−0.40 to −0.11)	0.09 (−0.48 to 0.65)	.77	.34
Systolic BP[g] (mmHg)	3.55 (1.30 to 5.81)	−0.20 (−2.30 to 1.90)	−3.66 (−6.57 to −0.76)	.01[d]	.003[d]
Diastolic BP (mmHg)	0.68 (−0.94 to 2.30)	−2.02 (−3.47 to −0.57)	−2.77 (−4.92 to −0.62)	.01[d]	.08
Total cholesterol (mg/dL)	−2.77 (−8.01 to 2.48)	−3.06 (−6.73 to 0.60)	−3.81 (−10.04 to 2.42)	.23	.35
Triglyceride (mg/dL)	−16.88 (−30.14 to −3.62)	−16.72 (−31.36 to −2.08)	−8.27 (−25.89 to 11.27)	.38	.73
HDL[h] cholesterol (mg/dL)	0.24 (−1.35 to 1.84)	2.44 (1.16 to 3.73)	1.40 (−0.45 to 3.39)	.15	.20
LDL[i] cholesterol (mg/dL)	−0.16 (−4.60 to 4.28)	−2.99 (−6.03 to 0.04)	−4.46 (−9.62 to 0.69)	.09	.10
Questionnaires[j]					
DTSQs[k]	0.45 (−1.03 to 1.92)	2.40 (1.22 to 3.58)	2.21 (0.54 to 3.88)	.01[d]	.04[d]
MMAS-6[l]	0.06 (−0.15 to 0.28)	0.52 (0.31 to 0.74)	0.31 (0.05 to 0.57)	.02[d]	.02[d]
Motivation	0.04 (−0.11 to 0.20)	0.39 (0.23 to 0.54)	0.23 (0.03 to 0.42)	.02[d]	.01[d]
Knowledge	0.02 (−0.13 to 0.17)	0.14 (0.00 to 0.28)	0.12 (−0.03 to 0.28)	.12	.08

[a]Assessed using the analysis of covariance model with a fixed effect for intervention, and age and respective baseline value as covariates to calculate a least-squares estimate of the treatment difference.

[b]Assessed using the linear mixed model with fixed effects for age, sex, intervention, time (baseline and 3 months), respective baseline value, baseline value-by time interaction, intervention-by time interaction, and random effects with cluster (centers) and each participant.

[c]HbA_{1c}: hemoglobin A_{1c}.

[d]$P<.05$.

[e]FPG: fasting plasma glucose.

[f]WC: waist circumference.

[g]BP: blood pressure.

[h]HDL: high-density lipoprotein.

[i]LDL: low-density lipoprotein

[j]Higher DTSQs and MMAS-6 scores indicate a favorable state.

[k]DTSQs: Diabetes Treatment Satisfaction Questionnaire status version.

[l]MMAS-6: 6-item Morisky Medication Adherence Scale.

Effect on Other Metabolic Parameters Including Weight-Related Outcomes, Blood Pressure, and Dyslipidemia

During the 3-month follow-up, both groups showed different changes in various anthropometries and lipid parameters (Table 2). Although only the intervention group showed significant favorable changes in weight and HDL cholesterol compared with baseline, there were no statistically significant differences in the change of overall weight-related and lipid profile outcomes between the 2 groups. In contrast, the intervention group showed significantly more reduction in systolic and diastolic BP than the control group. However, with the sensitivity analysis, the statistical significance was lost in the change of diastolic BP.

Diabetes Treatment Satisfaction Questionnaire Status Version and 6-Item Morisky Medication Adherence Scale

DTSQs showed a significant rise only in the intervention group, resulting in a 2.21-point increase in the intervention group compared with the control group at 3 months (Table 2). Total MMAS-6 score was also significantly more increased in the intervention group, especially in the score related to motivation for long-term medication adherence. However, the knowledge aspect showed little difference between the two groups.

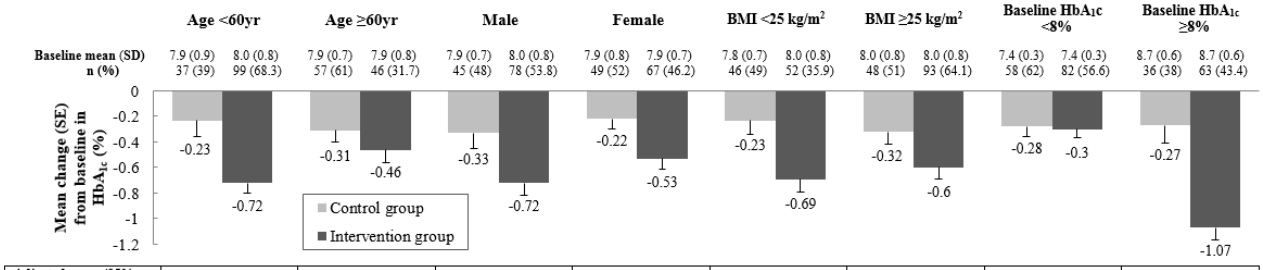
Subgroup Analyses of Changes in the Glycemic Status

We conducted subgroup analyses of the changes in glycemic status according to participant age, sex, BMI, and baseline HbA_{1c} level (Figure 2). Because of the difference in the baseline average age between the 2 groups, we divided each group into 2 subgroups: age <60 and ≥60 years. In the analysis of participants under 60 years of age, there were significantly reduced HbA_{1c} and FPG levels (Multimedia Appendix 7) in the intervention group, compared with those in the control group. However, there was little difference in these changes between the two groups in the analysis of participants 60 years and older.

In the subgroup analyses, according to sex, men showed significantly more reduction in HbA_{1c} level, whereas women showed significantly more reduction in FPG level compared with the control group. In the subgroup analyses according to BMI, the nonobese group (BMI <25 kg/m^2) showed significantly more reduction in HbA_{1c} level, whereas obese group (BMI ≥25 kg/m^2) showed significantly more reduction in FPG level compared with the control group.

Among participants with baseline HbA_{1c} levels lower than 8%, the intervention group did not show a difference in HbA_{1c} reduction compared with the control group, despite more reduction in FPG. However, among participants with baseline HbA_{1c} levels of 8% and higher, the intervention group showed the most significant reduction in HbA_{1c} and FPG compared with the modest change observed in the control group.

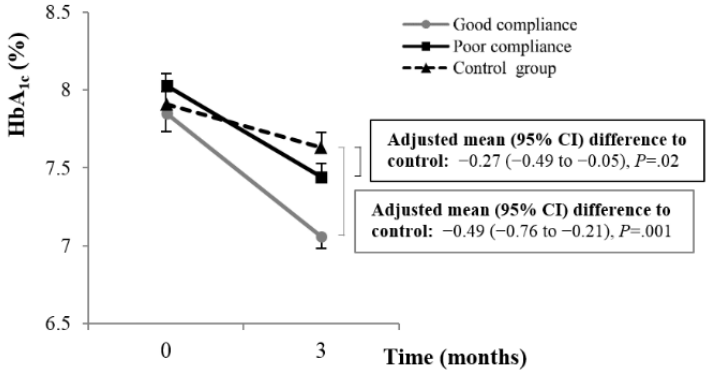
Figure 2. Subgroup analyses of changes in glycemic status by age, sex, BMI, and baseline hemoglobin A_{1c} (HbA_{1c}). Baseline data are expressed as mean (SD), and mean change of outcomes are expressed as mean (SE). The gray and black bars represent the control and intervention groups, respectively.



Changes in Glycemic Status According to Self-Monitoring of Blood Glucose Compliance

Figure 3 shows the changes in HbA_{1c} levels according to good and poor compliance with SMBG in the intervention group, compared with the control group. Compliance was calculated as the mean SMBG count/day (total numbers of SMBG count during the total study period divided by the study days for each participant). Participants with good compliance were defined as those with mean SMBG count/day ≥1, whereas those with SMBG count/day <1 were defined as having poor compliance. As a result, the participants with good compliance showed a higher reduction in HbA_{1c} than participants with poor compliance, although both good and poor compliance participants showed significantly more reduction in HbA_{1c} compared with the control group. In contrast, participants with good compliance only showed significantly more reduction in FPG than the control group, compared with the little change between the poor compliance group and the control group (Multimedia Appendix 8).

Figure 3. Changes in hemoglobin A_{1c} (HbA_{1c}) according to the self-monitoring of blood glucose compliance of the intervention group compared with the control group. Data are expressed as mean (SE).



Adverse Events

During the study, 12.4% (18/145) participants in the intervention group and 8% (8/94) participants in the control group reported a variety of symptoms, which were classified as adverse events (Table 3). The numbers of any adverse events did not differ significantly between the two groups. The most frequent events were elevated liver enzymes and hypoglycemia, which occurred only in the intervention group. However, all the reported symptoms were mild and temporary.

One participant in the control group died from cerebral infarction, which was classified as serious adverse events during the study period. However, there was no identified causality associated with the intervention system.

Table 3. Adverse events through 3 months.

Adverse events	Control group (n=94), n (%)	Intervention group (n=145), n (%)	*P* value
Any adverse events	8 (9)	18 (12.4)	.35
Elevated liver enzymes	5 (5)	12 (8.3)	
Renal impairment	2 (2)	1 (0.7)	
Mild hypoglycemia	0 (0)	5 (3.5)	
Serious adverse events			
Death	1 (1)[a]	0 (0)	

[a]Death from cerebral infarction.

Discussion

Principal Findings

In this study, we demonstrated the clinical effect of a mobile phone–based diabetes management system in multiple primary care clinics. Participants in the intervention group showed significantly more reduction in HbA_{1c} and FPG levels at 3 months compared with that of the control group. In addition to the improvement of glycemic status, there was also a significantly more reduction in BP and more improvement of participants' satisfaction and motivation for the management of the chronic disease. With the subgroup analyses, the effect on glycemic control was more significant in those with good compliance with SMBG, younger age (<60 years), and with poor glycemic status at baseline (HbA_{1c} ≥8%).

With the developments in IT, the method of monitoring glucose level has become simpler and more convenient for both patients with diabetes and their physicians [20]. There has been much evidence of the effects of Web- and mobile phone–based glucose-monitoring systems on diabetes management [21,22]. Nevertheless, most of the previous studies targeted patients under the care of tertiary hospitals and provided limited evidence in primary care clinic settings. Tertiary hospitals generally have a sufficient workforce, including professional diabetes specialists and skilled assistant medical teams. Also, with abundant educational experiences and professional equipment, the desirable and intended management could be easily achieved. However, the use of mobile phone–based diabetes management systems should spread to primary care clinics where these resources are insufficient. A previous study of a Web-based glucose-monitoring and feedback system showed that short motivational feedback messages, such as encouragement or simple recommendations, rather than complicated ones, were effective in glycemic control [23]. Thus, despite the lack of experience and resources, the use of mobile phone–based management systems at primary care clinics was likely to have a similar effect as tertiary hospitals.

In this study, the role of an experienced tertiary hospital was limited to the coaching center, and most clinics could use the system independently without much difficulty. As a result, there was no drop-out at participating clinics during the study period. At 3 months, we observed more statistically significant improvements in HbA_{1c} and FPG levels in the intervention group than in the control group, which demonstrates the clinical

effectiveness and applicability of this mobile health system in the primary care environment. The mean difference between intervention and control groups was −0.30%, which is slightly lower than that reported by a meta-analysis of tertiary hospitals (−0.4 to −0.67%) [22,24], and slightly higher than that reported in a recent Web-based study targeting primary care clinics in England (−0.24%) [25]. Interestingly, most of the intervention clinics showed similar results of glycemic improvement in the outcome analysis by each clinic, except for one intervention clinic (Multimedia Appendix 6). Although we could not precisely evaluate the physician's interaction with the participant in this study, it could be a determinant factor for the effective usage of this system [26]. Besides, participants with good compliance with SMBG showed more improvement in HbA_{1c} as in previous studies [27,28], and the mean difference in HbA_{1c} change was −0.49%. In this study, among the 145 participants in the intervention group, only 34 (23.4%) were classified as good compliance with SMBG. For a more effective application to primary care clinics, additional strategies for the improvement of compliance, such as a more accessible system or noninvasive methods for SMBG, are needed to provide positive results [29]. The questionnaire survey showed greater favorable changes in the satisfaction and motivation aspects for long-term medication adherence in the intervention group than in the control group. Previous studies reported the increased effectiveness of mobile phone–based management systems according to higher satisfaction and medication adherence [30,31]. These positive results are thought to have affected the positive effect of this study.

Interestingly, after the 3-month intervention, the intervention group also showed significantly more decrease in BP, along with improvement of glycemic status. Our intervention strategies for BP were limited to providing an electronic manometer to the participants with proven hypertension, and we recommended inputting their BP data at least once a week. In comparison, other metabolic parameters, including weight-related outcomes and dyslipidemia, did not show any effect. At baseline, the lipid profiles of both groups were controlled relatively well, and most participants were already taking statins. In addition, the input of weight data was not mandatory in the study. As a result, the impact on weight and lipid levels is thought to have been minimal. In the management of diabetes, it is essential to control various combined metabolic risk factors together to maximize the risk reduction of diabetic complications [32,33]. Therefore, more strategies for weight-related outcomes will need to be supplemented in the following studies.

Subgroup analyses showed little gender and BMI difference in glucose reduction. However, the effect on glycemic control was limited only to those under the age of 60 years. Since the study showed a baseline difference in age between the 2 groups, this finding suggests that our intervention effect in the reduction of HbA_{1c} and FPG was mostly attributable to participants under the age of 60 years. There is much evidence showing the effectiveness of Web- and mobile phone–based systems in elderly patients [10,34,35]. The reason why the mobile phone–based system had less impact on elderly patients in this study may be due to the lower socioeconomic and educational status of primary care patients compared with tertiary hospitals, which might be the particular situation in South Korea where the barriers to tertiary hospitals are lower than those of other countries [36]. In addition, subgroup analyses of baseline HbA_{1c} levels revealed a more significant reduction among participants with baseline HbA_{1c} levels of 8% and over. However, the difference in HbA_{1c} reduction between the control and the intervention groups was not observed in participants with baseline HbA_{1c} levels lower than 8%. In the previous study on the long-term effects of a Web-based glucose-monitoring system in patients with well-controlled diabetes (baseline HbA_{1c} <7%), the intervention group remained stable throughout the study with a low fluctuation of HbA_{1c} level, compared with the high fluctuation in the control group [23]. Therefore, expanded study periods are needed to evaluate long-term effects, especially in patients with well-controlled glycemic status.

Limitations

Our study has several limitations. First, as discussed previously, there was a significant age difference at baseline between the intervention and control groups, despite the randomized setting. The younger age of the intervention group may have a significant influence on compliance, providing more positive findings. On the basis of baseline characteristics by each clinic (Multimedia Appendices 3 and 4), we found that younger participants were mostly enrolled in intervention clinics compared with the control clinics. It might be because many of those who voluntarily participated in intervention clinics had more interest in the IT-based intervention and were younger than those in control clinics. Second, as a cluster-randomized open-label trial, variations in each medical team's interventions could cause bias. Finally, the follow-up duration was short, and only primary care clinics in large cities were targeted. Further studies targeting the primary care clinics in rural areas, where resources are more insufficient, and longer study periods are needed to provide extended evidence of mobile phone–based diabetes management systems. However, our research has the strength of being a well-designed and well-proceeded multicenter cluster-randomized controlled study with a relatively large number of clinics and participants. With a cluster-randomized setting, we could minimize the treatment contamination—a critical issue of educational intervention—between intervention and control participants [37].

Conclusions

In this study, we confirmed the clinical efficacy and applicability of a mobile phone–based diabetes-monitoring and feedback system in primary care clinics, which relatively lack the professional workforce and educational environment for chronic disease management. Younger patients with poor glycemic status (HbA_{1c} ≥8%) and good compliance with SMBG are those who may benefit the most from this intervention.

Acknowledgments

The authors thank all the participants, investigators, and trial staff who were involved in the conduct of the trial. This research was supported by the Information and Communications Technology (ICT) R&D Program of Ministry of Science, ICT and Future Planning (R0236-15-1007 telemedicine activation model development and substantiation) and the Creative Vitamin Project and by the Bio & Medical Technology Development Program of the National Research Foundation (NRF) funded by the Ministry of Science & ICT (NRF-2018M3A9E8021503).

Conflicts of Interest

None declared.

Multimedia Appendix 1
The 13 private clinics that participated in this study.
[DOCX File , 18 KB - mhealth_v8i2e16266_app1.docx]

Multimedia Appendix 2
Study design.
[DOCX File , 55 KB - mhealth_v8i2e16266_app2.docx]

Multimedia Appendix 3
Baseline characteristics by each clinic in the control group.
[DOCX File , 20 KB - mhealth_v8i2e16266_app3.docx]

Multimedia Appendix 4
Baseline characteristics by each clinic in the intervention group.
[DOCX File , 23 KB - mhealth_v8i2e16266_app4.docx]

Multimedia Appendix 5
Mean changes in efficacy outcomes from baseline in each clinic of the control group.
[DOCX File , 20 KB - mhealth_v8i2e16266_app5.docx]

Multimedia Appendix 6
Mean changes in efficacy outcomes from baseline in each clinic of the intervention group.
[DOCX File , 25 KB - mhealth_v8i2e16266_app6.docx]

Multimedia Appendix 7
Subgroup analyses of changes in fasting plasma glucose by sex, age, BMI, and baseline hemoglobin A1c.
[DOCX File , 65 KB - mhealth_v8i2e16266_app7.docx]

Multimedia Appendix 8
Changes in fasting plasma glucose according to the self-monitoring of blood glucose compliance of the intervention group compared with the control group.
[DOCX File , 67 KB - mhealth_v8i2e16266_app8.docx]

Multimedia Appendix 9
CONSORT EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2475 KB - mhealth_v8i2e16266_app9.pdf]

References

1. NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants. Lancet 2016 Apr 9;387(10027):1513-1530 [FREE Full text] [doi: 10.1016/S0140-6736(16)00618-8] [Medline: 27061677]
2. Ceriello A, Monnier L, Owens D. Glycaemic variability in diabetes: clinical and therapeutic implications. Lancet Diabetes Endocrinol 2019 Mar;7(3):221-230. [doi: 10.1016/S2213-8587(18)30136-0] [Medline: 30115599]
3. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of

Diabetes Educators, and the Academy of Nutrition and Dietetics. Clin Diabetes 2016 Apr;34(2):70-80 [FREE Full text] [doi: 10.2337/diaclin.34.2.70] [Medline: 27092016]
4. Meigs JB, Cagliero E, Dubey A, Murphy-Sheehy P, Gildesgame C, Chueh H, et al. A controlled trial of web-based diabetes disease management: the MGH diabetes primary care improvement project. Diabetes Care 2003 Mar;26(3):750-757. [doi: 10.2337/diacare.26.3.750] [Medline: 12610033]
5. Kwon HS, Cho JH, Kim HS, Song BR, Ko SH, Lee JM, et al. Establishment of blood glucose monitoring system using the internet. Diabetes Care 2004 Feb;27(2):478-483. [doi: 10.2337/diacare.27.2.478] [Medline: 14747232]
6. Cho JH, Kwon HS, Kim HS, Oh JA, Yoon KH. Effects on diabetes management of a health-care provider mediated, remote coaching system via a PDA-type glucometer and the internet. J Telemed Telecare 2011;17(7):365-370. [doi: 10.1258/jtt.2011.100913] [Medline: 21933896]
7. Pal K, Eastwood SV, Michie S, Farmer A, Barnard ML, Peacock R, et al. Computer-based interventions to improve self-management in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetes Care 2014 Jun;37(6):1759-1766. [doi: 10.2337/dc13-1386] [Medline: 24855158]
8. Istepanian RS, Zitouni K, Harry D, Moutosammy N, Sungoor A, Tang B, et al. Evaluation of a mobile phone telemonitoring system for glycaemic control in patients with diabetes. J Telemed Telecare 2009;15(3):125-128. [doi: 10.1258/jtt.2009.003006] [Medline: 19364893]
9. Cho JH, Lee HC, Lim DJ, Kwon HS, Yoon KH. Mobile communication using a mobile phone with a glucometer for glucose control in Type 2 patients with diabetes: as effective as an Internet-based glucose monitoring system. J Telemed Telecare 2009;15(2):77-82. [doi: 10.1258/jtt.2008.080412] [Medline: 19246607]
10. Kim HS, Lee KH, Kim H, Kim JH. Using mobile phones in healthcare management for the elderly. Maturitas 2014 Dec;79(4):381-388. [doi: 10.1016/j.maturitas.2014.08.013] [Medline: 25270725]
11. Goyal S, Nunn CA, Rotondi M, Couperthwaite AB, Reiser S, Simone A, et al. A mobile app for the self-management of type 1 diabetes among adolescents: a randomized controlled trial. JMIR Mhealth Uhealth 2017 Jun 19;5(6):e82 [FREE Full text] [doi: 10.2196/mhealth.7336] [Medline: 28630037]
12. Kim HS, Hwang Y, Lee JH, Oh HY, Kim YJ, Kwon HY, et al. Future prospects of health management systems using cellular phones. Telemed J E Health 2014 Jun;20(6):544-551 [FREE Full text] [doi: 10.1089/tmj.2013.0271] [Medline: 24693986]
13. Garabedian LF, Ross-Degnan D, Wharam JF. Mobile phone and smartphone technologies for diabetes care and self-management. Curr Diab Rep 2015 Dec;15(12):109 [FREE Full text] [doi: 10.1007/s11892-015-0680-8] [Medline: 26458380]
14. Korean Diabetes Association. 2013 Treatment Guidelines for Diabetes. website [FREE Full text]
15. Miller KM, Beck RW, Bergenstal RM, Goland RS, Haller MJ, McGill JB, T1D Exchange Clinic Network. Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D exchange clinic registry participants. Diabetes Care 2013 Jul;36(7):2009-2014 [FREE Full text] [doi: 10.2337/dc12-1770] [Medline: 23378621]
16. Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study. Diabetes Care 2011 Feb;34(2):262-267 [FREE Full text] [doi: 10.2337/dc10-1732] [Medline: 21270183]
17. Bradley C. Diabetes treatment satisfaction questionnaire. Change version for use alongside status version provides appropriate solution where ceiling effects occur. Diabetes Care 1999 Mar;22(3):530-532 [FREE Full text] [doi: 10.2337/diacare.22.3.530] [Medline: 10097946]
18. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. J Clin Hypertens (Greenwich) 2008 May;10(5):348-354 [FREE Full text] [doi: 10.1111/j.1751-7176.2008.07572.x] [Medline: 18453793]
19. Quinn CC, Shardell MD, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care 2011 Sep;34(9):1934-1942 [FREE Full text] [doi: 10.2337/dc11-0366] [Medline: 21788632]
20. Wildevuur SE, Simonse LWL. Information and communication technology-enabled person-centered care for the 'big five' chronic conditions: scoping review. J Med Internet Res 2015 Mar 27;17(3):e77 [FREE Full text] [doi: 10.2196/jmir.3687] [Medline: 25831199]
21. de Jong CC, Ros WJ, Schrijvers G. The effects on health behavior and health outcomes of internet-based asynchronous communication between health providers and patients with a chronic condition: a systematic review. J Med Internet Res 2014 Jan 16;16(1):e19 [FREE Full text] [doi: 10.2196/jmir.3000] [Medline: 24434570]
22. Wu Y, Yao X, Vespasiani G, Nicolucci A, Dong Y, Kwong J, et al. Mobile app-based interventions to support diabetes self-management: a systematic review of randomized controlled trials to identify functions associated with glycemic efficacy. JMIR Mhealth Uhealth 2017 Mar 14;5(3):e35 [FREE Full text] [doi: 10.2196/mhealth.6522] [Medline: 28292740]

23. Cho JH, Chang SA, Kwon HS, Choi YH, Ko SH, Moon SD, et al. Long-term effect of the internet-based glucose monitoring system on HbA1c reduction and glucose stability: a 30-month follow-up study for diabetes management with a ubiquitous medical care system. Diabetes Care 2006 Dec;29(12):2625-2631. [doi: 10.2337/dc05-2371] [Medline: 17130195]
24. Cui M, Wu X, Mao J, Wang X, Nie M. T2DM self-management via smartphone applications: a systematic review and meta-analysis. PLoS One 2016;11(11):e0166718. [doi: 10.1371/journal.pone.0166718] [Medline: 27861583]
25. Murray E, Sweeting M, Dack C, Pal K, Modrow K, Hudda M, et al. Web-based self-management support for people with type 2 diabetes (HeLP-Diabetes): randomised controlled trial in English primary care. BMJ Open 2017 Sep 27;7(9):e016009 [FREE Full text] [doi: 10.1136/bmjopen-2017-016009] [Medline: 28954789]
26. Schieber A, Kelly-Irving M, Génolini JP, Membrado M, Tanguy L, Fabre C, INTERMEDE Group. Integrating multidisciplinary results to produce new knowledge about the physician-patient relationship: a methodology applied to the INTERMEDE project. J Mix Methods Res 2017 Apr;11(2):174-201 [FREE Full text] [doi: 10.1177/1558689815588643] [Medline: 28491010]
27. Rho MJ, Kim SR, Kim H, Cho J, Yoon K, Mun SK, et al. Exploring the relationship among user satisfaction, compliance, and clinical outcomes of telemedicine services for glucose control. Telemed J E Health 2014 Aug;20(8):712-720. [doi: 10.1089/tmj.2013.0309] [Medline: 24901576]
28. Cho JH, Kim HS, Yoo SH, Jung CH, Lee WJ, Park CY, et al. An internet-based health gateway device for interactive communication and automatic data uploading: Clinical efficacy for type 2 diabetes in a multi-centre trial. J Telemed Telecare 2017 Jul;23(6):595-604. [doi: 10.1177/1357633X16657500] [Medline: 27381040]
29. Wagner J, Malchoff C, Abbott G. Invasiveness as a barrier to self-monitoring of blood glucose in diabetes. Diabetes Technol Ther 2005 Aug;7(4):612-619. [doi: 10.1089/dia.2005.7.612] [Medline: 16120035]
30. Kim HS, Choi W, Baek EK, Kim YA, Yang SJ, Choi IY, et al. Efficacy of the smartphone-based glucose management application stratified by user satisfaction. Diabetes Metab J 2014 Jun;38(3):204-210 [FREE Full text] [doi: 10.4093/dmj.2014.38.3.204] [Medline: 25003074]
31. Kim YJ, Rhee SY, Byun JK, Park SY, Hong SM, Chin SO, et al. A smartphone application significantly improved diabetes self-care activities with high user satisfaction. Diabetes Metab J 2015 Jun;39(3):207-217 [FREE Full text] [doi: 10.4093/dmj.2015.39.3.207] [Medline: 26124991]
32. Gæde P, Vedel P, Larsen N, Jensen GV, Parving H, Pedersen O. Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. N Engl J Med 2003 Jan 30;348(5):383-393. [doi: 10.1056/nejmoa021778]
33. del Cañizo-Gómez FJ, Moreira-Andrés MN. Cardiovascular risk factors in patients with type 2 diabetes. Do we follow the guidelines? Diabetes Res Clin Pract 2004 Aug;65(2):125-133. [doi: 10.1016/j.diabres.2003.12.002] [Medline: 15223224]
34. Bond GE, Burr R, Wolf FM, Price M, McCurry SM, Teri L. The effects of a web-based intervention on the physical outcomes associated with diabetes among adults age 60 and older: a randomized trial. Diabetes Technol Ther 2007 Feb;9(1):52-59 [FREE Full text] [doi: 10.1089/dia.2006.0057] [Medline: 17316098]
35. Lim S, Kang SM, Shin H, Lee HJ, Yoon JW, Yu SH, et al. Improved glycemic control without hypoglycemia in elderly diabetic patients using the ubiquitous healthcare service, a new medical information system. Diabetes Care 2011 Feb;34(2):308-313 [FREE Full text] [doi: 10.2337/dc10-1447] [Medline: 21270188]
36. Kim E, Kwon S, Xu K. Has income-related inequity in health care utilization and expenditures been improved? Evidence from the Korean National Health and Nutrition Examination Survey of 2005 and 2010. J Prev Med Public Health 2013 Sep;46(5):237-248 [FREE Full text] [doi: 10.3961/jpmph.2013.46.5.237] [Medline: 24137526]
37. Torgerson DJ. Contamination in trials: is cluster randomisation the answer? Br Med J 2001 Feb 10;322(7282):355-357 [FREE Full text] [doi: 10.1136/bmj.322.7282.355] [Medline: 11159665]

Abbreviations

ALT: alanine aminotransferase
ANCOVA: analysis of covariance
AST: aspartate aminotransferase
BP: blood pressure
DTSQs: Diabetes Treatment Satisfaction Questionnaire status version
FPG: fasting plasma glucose
HbA_{1c}: hemoglobin A_{1c}
HDL: high-density lipoprotein
ICT: Information and Communications Technology
IT: information technology
LDL: low-density lipoprotein
MMAS-6: 6-item Morisky Medication Adherence Scale
NRF: National Research Foundation
OHA: oral hypoglycemic agents
SMBG: self-monitoring of blood glucose

T2DM: type 2 diabetes mellitus
WC: waist circumference

Edited by G Eysenbach; submitted 14.09.19; peer-reviewed by Z Huang, G Signorelli, S Li, M Schuuring; comments to author 05.10.19; revised version received 14.12.19; accepted 24.01.20; published 26.02.20.

Please cite as:
Yang Y, Lee EY, Kim HS, Lee SH, Yoon KH, Cho JH
Effect of a Mobile Phone–Based Glucose-Monitoring and Feedback System for Type 2 Diabetes Management in Multiple Primary Care Clinic Settings: Cluster Randomized Controlled Trial
JMIR Mhealth Uhealth 2020;8(2):e16266
URL: http://mhealth.jmir.org/2020/2/e16266/
doi:10.2196/16266
PMID:32130172

Original Paper

A Mobile Health Team Challenge to Promote Stepping and Stair Climbing Activities: Exploratory Feasibility Study

Seaw Jia Liew[1], MEng; Alex Wilhelm Gorny[1], MBBS, MSc; Chuen Seng Tan[1,2], MSc, PhD; Falk Müller-Riemenschneider[1,2,3], MBBS, MSc, MD

[1]Saw Swee Hock School of Public Health, National University of Singapore, National University Health System, Singapore, Singapore

[2]Yong Loo Lin School of Medicine, National University of Singapore, National University Health System, Singapore, Singapore

[3]Institute of Social Medicine, Epidemiology and Health Economics, Charité - Universitätsmedizin, Berlin, Germany

Corresponding Author:
Falk Müller-Riemenschneider, MBBS, MSc, MD
Saw Swee Hock School of Public Health
National University of Singapore
National University Health System
Tahir Foundation Building (Block MD1)
12 Science Drive 2, #09-01v
Singapore, 117549
Singapore
Phone: 65 6601 3122
Email: ephmf@nus.edu.sg

Abstract

Background: Mobile health (mHealth) approaches are growing in popularity as a means of addressing low levels of physical activity (PA).

Objective: This study aimed to determine the validity of wearables in measuring step count and floor count per day and assess the feasibility and effects of a 6-week team challenge intervention delivered through smartphone apps.

Methods: Staff and students from a public university were recruited between 2015 and 2016. In phase 1, everyone wore a Fitbit tracker (Charge or Charge HR) and an ActiGraph for 7 days to compare daily step count estimated by the two devices under free-living conditions. They were also asked to climb 4 bouts of floors in an indoor stairwell to measure floor count which was compared against direct observation. In phase 2, participants were allocated to either a control or intervention group and received a Fitbit tracker synced to the Fitbit app. Furthermore, the intervention group participants were randomized to 4 teams and competed in 6 weekly (Monday to Friday) real-time challenges. A valid day was defined as having 1500 steps or more per day. The outcomes were as follows: (1) adherence to wearing the Fitbit (ie, number of days in which all participants in each group were classified as valid users aggregated across the entire study period), (2) mean proportion of valid participants over the study period, and (3) the effects of the intervention on step count and floor count determined using multiple linear regression models and generalized estimating equations (GEEs) for longitudinal data analysis.

Results: In phase 1, 32 of 40 eligible participants provided valid step count data, whereas all 40 participants provided valid floor count data. The Fitbit trackers demonstrated high correlations (step count: Spearman ρ=0.89; *P*<.001; floor count: Spearman ρ=0.98; *P*<.001). The trackers overestimated step count (median absolute error: 17%) but accurately estimated floor count. In phase 2, 20 participants each were allocated to an intervention or control group. Overall, 24 participants provided complete covariates and valid PA data for analyses. Multiple linear regressions revealed that the average daily steps was 15.9% higher for the intervention group (95% CI −8.9 to 47.6; *P*=.21) during the final two intervention weeks; the average daily floors climbed was 39.4% higher (95% CI 2.4 to 89.7; *P*=.04). GEE results indicated no significant interaction effects between groups and the intervention week for weekly step count, whereas a significant effect (*P*<.001) was observed for weekly floor count.

Conclusions: The consumer wearables used in this study provided acceptable validity in estimating stepping and stair climbing activities, and the mHealth-based team challenge interventions were feasible. Compared with the control group, the participants in the intervention group climbed more stairs, so this can be introduced as an additional PA promotion target in the context of mHealth strategies. Methodologically rigorous studies are warranted to further strengthen this study's findings.

(JMIR Mhealth Uhealth 2020;8(2):e12665) doi:10.2196/12665

KEYWORDS

behavior; health; physical activity; wearables

Introduction

Background

Low levels of physical activity (PA) can be attributed to societal development and modern workplaces, schools, and homes [1,2]. Physical inactivity has been identified as one of the leading risk factors for noncommunicable diseases, including obesity, diabetes, and heart diseases, and as a cause of preventable death [3,4]. Studies have demonstrated that even light PA can confer relevant health benefits among inactive individuals [5-11]. Simple measures that increase activities of daily living (eg, steps walked and stairs climbed) can be incorporated into daily life in public and work settings to provide health benefits [12-14]. Although stepping activities are a widely used target for PA promotion strategies [15,16], stair climbing has been identified as an actionable and time-saving approach; it is usually of greater intensity (ie, moderate-to-vigorous PA, MVPA) [17] and has been found to confer health benefits, such as improvements in cardiorespiratory fitness [18,19] and blood pressure [13]. Stair climbing and strategies to promote stair climbing may also be particularly appropriate among adults in Asia and metropolitan areas, which are densely populated with many high-rise buildings. Point-of-decision prompts have been widely used to encourage stair climbing at the population level [20]. However, in the long term, these strategies have not proven effective because people may have become habituated to these cues over time [21].

Today, electronic health and mobile health (mHealth) technologies (eg, wireless communication technologies, database server, sensors embedded in smartphone and wearable devices, and smartphone apps) enable us to objectively collect continuous PA and other contextual information under free-living conditions (ie, usual daily activities carried out in the community or at home). Moreover, improved design and enhanced digital connectivity have allowed more interactive and entertaining strategies for behavioral change to be developed [16,22-26]. For example, modern PA wearables and smartphone apps provide users with quantitative visual feedback on their PA level and empower them to continuously monitor and improve their behavior. Behavior change techniques (BCTs), such as goal setting, self-monitoring, and feedback, have been found effective in health promotion [27-29]. Moreover, gamified interventions have been shown to further improve user engagement and thereby potentially increase intervention effectiveness [30,31]. Examples include leaderboards, team-based performance feedback, or social and financial incentives, which have been shown to translate to better PA outcomes [32-34]. Feedback is a common BCT that can improve goal attainment through action planning [35] by giving explicit suggestions on when, where, and how to perform the action [36]. In addition to the continuous objective monitoring of diverse sensor-based information, mHealth technologies also enable the provision of continuous feedback in real time, which can be effectively integrated into daily routines and thus potentially increase the effectiveness of PA interventions in real-life settings.

Systematic reviews suggest that using pedometers paired with goal setting increased daily step count and resulted in decreases in body mass index and systolic blood pressure [15]. In the advent of consumer PA wearable devices beyond pedometers, there has been an increasing number of studies that investigated the effects of these wearables on promoting PA levels, in part with improvements in step count [37]. The potential of mHealth interventions on promoting stair climbing remains unstudied, despite the potentially greater health impact of this more intensive form of PA. With regard to the accuracy of consumer wearables to measure PA-related outcomes, previous validation studies have suggested that step count information from such devices may correlate well with established measures, but they may also under- or overestimate activity levels in absolute terms, which is an important consideration in setting appropriate goals or incentives [38,39]. The literature also suggests that the accuracy of different types of wearables differs considerably [38,40] and that fewer studies were conducted in free-living settings [38,41,42]. To the best of our knowledge, no published study has assessed consumer devices with regard to their accuracy of measuring stair climbing activities. This warrants further investigation before stair climbing activities can be incorporated as a target for mHealth interventions, aiming to promote PA.

Objectives

This feasibility study aimed to address some of these evidence gaps to guide the development of large-scale studies and health promotion initiatives in the future. The study included an assessment of the validity and feasibility of using an mHealth technology suite for the implementation of a real-time PA intervention to increase stepping and stair climbing activities among adults in the general population. The intervention to be tested comprised a team challenge, using a random team-forming approach to overcome two key limitations of team-based interventions: (1) scalability because of the need to identify and register a team, and (2) biases in findings when participants self-select team members [43]. The specific aims of this study were (1) to develop a multicomponent mHealth technology suite, which comprised PA wearables (ie, Fitbit Charge and Charge HR) and an interactive smartphone app supported by a Web-based data management system, (2) to determine the validity of these integrated wearables in measuring number of steps taken per day and number of floors climbed per day, and (3) to assess the feasibility and explore the effects of the team challenge intervention (ie, a pilot controlled trial) targeting adults at work or in a tertiary education setting from Monday to Friday. Leveraging several key BCTs [44], the team challenge adopted gamification features, such as feedback, social support, social incentive or reward, and self-monitoring, to facilitate PA behaviors.

Methods

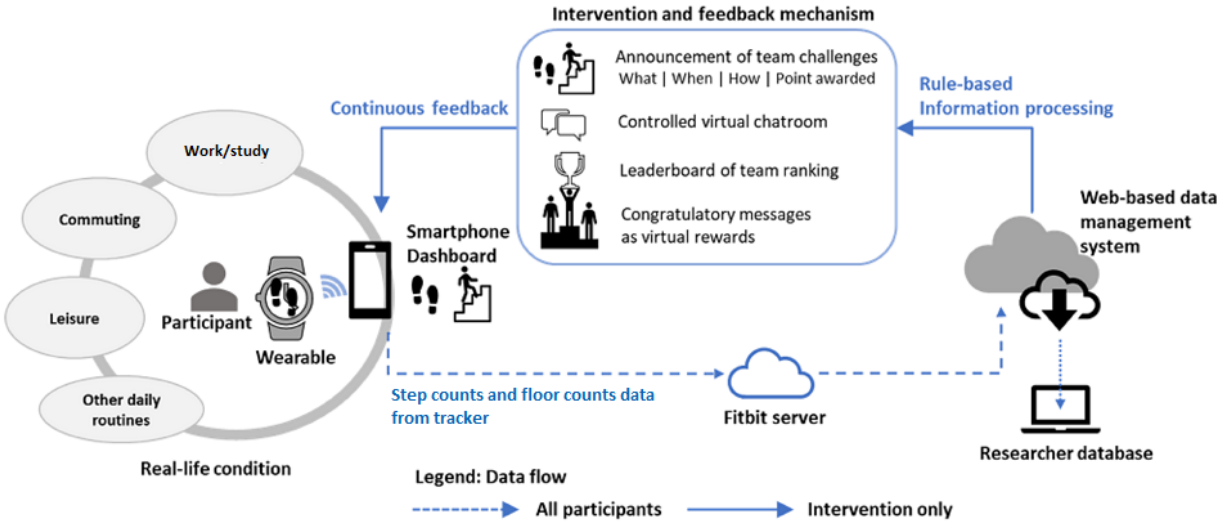
Study Participants

Recruitment of participants was conducted through posters, dissemination of e-flyers, and emails detailing the study objectives and inclusion and exclusion criteria through 4 faculties at the National University of Singapore from 2015 to 2016. Staff or students were deemed eligible if they (1) were aged 21 to 65 years, (2) free from physical disabilities or illnesses that would restrict normal activities, (3) were English literate, and (4) owned a smartphone that could support the use of a Fitbit tracker (Fitbit Charge or Charge HR). Potential participants were excluded if they intended to travel abroad for the duration of the study. Participants provided informed consent to participate in the study. The National University of Singapore Institutional Review Board approved the study protocol.

Study Design

This pilot study involved 3 sequential processes: (1) conceptualization of team challenge intervention delivered through a purposively developed multicomponent mHealth technology suite, which comprises consumer PA wearables, researcher-designed smartphone apps integrated with interactive gamification features, and a Web-based data management system as shown in Figure 1; (2) a validation study to determine the validity of the Fitbit wearables in measuring daily steps (ie, a step refers to lifting one's foot and putting it down in a different place) and floor count (ie, 1 floor count is equivalent to a 10 feet upward vertical displacement); and (3) a feasibility study (ie, a controlled pilot trial) that aimed to evaluate the real-time team challenge intervention integrated in the purposively developed mHealth system.

Figure 1. Internet and mobile health technologies to deliver team-based physical activity intervention and enhance user experience.



Mobile Health Technology Suite

Every participant recruited for the feasibility study was provided with a wearable device (either Fitbit Charge or Charge HR tracker at random) and the Fitbit proprietary app. However, only intervention group participants were registered for the additional use of the mHealth technology suite (Figure 1). The mHealth suite was realized through an integration of 3 major components: (1) Fitbit tracker and its proprietary app, (2) a purposively developed smartphone app with interactive functionalities, and (3) a Web-based data management unit. Fitbit was chosen for this study given the relative popularity the brand enjoyed at the time this pilot study was conducted. To complement the Fitbit tracker and the proprietary Fitbit app, a separate smartphone app and a Web portal compatible with the iOS and Android mobile systems were developed and linked with the Fitbit server through the application programming interface (API) provided by Fitbit. Furthermore, the apps sent push notifications and delivered in-app team challenges that aimed to engage intervention group participants in taking more steps and stairs every day. All smartphone apps and Web portal were password protected, and participants were asked not to input any personal information for the duration of the study. The data were downloaded from the Web portal by the research team at the end of the study.

Intervention

Team Formation

The intervention group participants were randomly assigned to smaller teams to avoid undue advantages of one team over the other. This study tested a team-based approach, which could potentially be replicated in large-scale settings (1) to promote team-based PA yet prevent high disparities in PA levels among teams; (2) to encourage PA and facilitate team forming in a real-world situation, especially in workplace or school settings when a person's PA buddies may not always be around in the same geographical locations; and (3) to create an avenue for individuals with a restricted social network to attempt team-based activities without the hassle of forming a physical team. The concept of anonymous sign up (nonregistering) of teams was implemented and tested in this pilot study because it helps to overcome the following two key limitations of commonly used team-based challenges: (1) scalability because

of the need to identify and register a team, and (2) biases related to self-selection of teams and team members [43].

Team-Based Challenges

The intervention comprised team-based challenges with multiple components (Textbox 1). Daily stepping and stairs climbed were quantified as the number of steps taken per day and the number of floors climbed per day, respectively. The challenges were designed to run on weekdays (from Monday to Friday) exclusively during the intervention period. All intervention group participants were randomly allocated into teams of equal size and prompted via smartphone push notifications to participate in the challenges. The intervention lasted 6 weeks, comprising repeated team-based challenges (weeks 1 and 4: steps challenge, weeks 2 and 5: stair climbing challenge, and weeks 3 and 6: steps challenge + lunchtime dash) that were prescheduled on a weekly basis. The lunchtime dash was a variation in which additional points were given for increase in step count and floor count during lunch hour.

Textbox 1. Features of the team challenge and purposively developed smartphone app.

Time of challenge: weekdays (Monday to Friday) 12 AM to 11:59 PM

Duration of challenge: 6 weeks

Types of challenges

- Weeks 1 and 4: steps challenge
- Weeks 2 and 5: stair climbing challenge
- Weeks 3 and 6: steps challenge + lunchtime dash (12 PM to 3 PM; additional points were awarded for steps taken and floors climbed during lunchtime)

Delivery of intervention: purposively developed smartphone app with interactive in-app features

- Prescheduled announcement of challenge: type, time, duration, and points awarded
- Virtual live chat: controlled message exchange among team members
- Leaderboard: visual feedback of weekly team ranking
- Virtual rewards: congratulatory message to the winning team

Gamification

Gamification (Multimedia Appendix 1) was adopted to motivate teams to compete to achieve goals and create a platform for team members to review their PA performance, communicate, and establish peer support to earn rewards for the team. In this study, in addition to delivering challenge-related notifications, the study app was developed to provide gamified features available only to the intervention group. To experience these gamification features, notifications were sent during the first 2 weeks of the intervention to remind the intervention group participants to synchronize their trackers with the study app. An individual's PA measures were converted to the team's performance scores.

Prescheduled Challenge Announcements

Actionable feedback was realized by providing explicit information about the weekly challenges: what (type of challenges; ie, stepping, stair climbing, or lunchtime dash challenge), when (dates and time of weekly challenge), how (type of PA and measures, such as step count or floor count), and reward (the associated scoring scheme and awarded points for every increase in the number of steps taken or floors climbed).

Real-Time Feedback

Team-level feedback on PA performance (daily step count or floor count) were delivered through weekly push notifications and also reflected on the leaderboard. An individual's PA statistics in terms of steps taken and stairs climbed were delivered in real time through the study app.

Virtual Chatroom

A virtual chatroom with an instant messaging feature was made available to all competing teams, but the exchange of short messages was restricted to only team members. Teammates remained anonymous throughout the study, and the exchange of messages was moderated by the research team.

Leaderboard

The leaderboard, a visual feedback of weekly team rankings, was made available to all intervention group participants.

Virtual Rewards

The incentives administered through our system were nonmaterial in nature. At the end of each challenge week, congratulatory messages were delivered to the winning team, and the final team ranking for the week was updated on the leaderboard.

Study Procedure

The study was organized into the following two main phases: (1) a validation study and (2) a feasibility study, that is, the evaluation of the controlled pilot trial, which consisted of the run-in (baseline), intervention, ending, and postintervention phases, as defined in Table 1.

Table 1. Definition of study phases in temporal order.

Study phase	Definition
Phase 1: validation study	
Validation of daily steps	• 7 days of wearing physical activity wearables in free-living conditions • Fitbit-measured step count data were compared with those measured using ActiGraph
Validation of floor count	• 4 bouts of upward stair climbing: 10 ft, 20 ft, 10 ft, and 20 ft in indoor stairwell (10 ft upward vertical displacement is equivalent to 1 floor count) • Fitbit-measured floor count data were compared with visual observation
Phase 2: feasibility study	
Run-in (baseline)	• 10 days (including weekdays and weekends) before group allocation when baseline step count and floor count measurements were established
Intervention	• 6 weeks of intervention (comprising 6 weekly challenges running from Monday to Friday) or 6 weeks of free living for the control group
Ending	• Last 10 weekdays (Monday to Friday of week 5 and week 6) of the intervention phase
Postintervention	• 5 weekdays after the intervention phase

Phase 1: Validation Study

Daily steps validation was conducted in free-living conditions for 7 consecutive days, whereas floor count validation involved 4 bouts of upward stair climbing in an indoor stairwell. Details on recruitment have been published in a previous paper [38]. Briefly, members of the university's staff and students were recruited through department-approved internal emails. All participants self-reported sociodemographic information through a Web-based questionnaire and completed measurements of height and weight necessary to initialize the devices used in the study. Each participant received a password-protected Fitbit mobile app, a Fitbit account that was identified using a unique subject identification number, and a wrist-worn Fitbit Charge or Charge HR that was linked to the Fitbit account. Participants were allowed to view their PA data from the Fitbit official dashboard, and they were advised to charge the wearable regularly. Subsequently, participants were brought to an indoor stairwell to validate the floor count function of the device. Each participant embarked on 4 separate bouts of climbing (upward): 10 ft, 20 ft, 10 ft, and, finally, 20 ft of vertical height, giving rise to a cumulative height climbed of 60 ft (ie, 10 ft is equivalent to 1 floor count) per person. Total floor count after each bout of climbing was read off the Fitbit display. Following stair climbing, participants were asked to wear an ActiGraph GT3X+ accelerometer on the right hip, concurrently with the wrist-worn Fitbit tracker, to provide 7 days' worth of steps data during waking hours. All participants received prompts to record their time of accelerometer use through a smartphone-based activity diary.

The ActiGraph-measured step count data in 60-second epochs were downloaded using ActiLife 6 software (ActiGraph, LLC), whereas the Fitbit-measured step count data were extracted from the Fitbit Web server using a developer's API issued by Fitbit. A valid day was defined as having accumulated 1500 steps or more taken per day [45] with 10 hours or more per day, restricted only to common wear time based on both ActiGraph and Fitbit tracker. Participants who provided 4 or more valid days [46] of ActiGraph and Fitbit data were included for the validation analysis.

Phase 2: Feasibility Study

The feasibility study was a controlled pilot trial with the following objectives: (1) to determine adherence to wearing the Fitbit (ie, number of days in which all participants in each group were classified as valid users aggregated across entire study period), (2) to determine the mean proportion of valid participants over the study period, and (3) to explore the effects of the team challenge intervention in promoting stepping and stair climbing among the completers (ie, participants who provided complete baseline information and valid Fitbit data at both baseline and ending phases). Recruitment was open to the existing participants who had completed the validation study as well as new participants. Newly recruited participants were also asked to complete the baseline questionnaire, and their height and weight were measured. All eligible participants entered the run-in (baseline) phase, which allowed new participants to familiarize themselves with using the Fitbit trackers and Fitbit app. All participants were assisted during the installation of the purposively developed study app at baseline. Despite this assistance, it was not possible to successfully install and enable the latest version of the study app on iOS devices and certain Android phones because of unresolvable incompatibility issues. As such, participants who successfully used the purposively developed study app were allocated to the intervention group. Participants who could not use the study app because of incompatibility were assigned to the control group. During the run-in period, app features (ie, team challenge, leaderboard, virtual chatroom, and reward) were not activated. After group allocation was determined, the intervention started for all intervention group participants at the same time. Both groups were then followed up for 6 weeks with an additional 1 week of free living (postintervention).

PA was measured using the Fitbit devices as the number of steps taken per day or the number of floors (10 ft) climbed per day. Baseline PA was quantified as the average number of steps taken per day or number of floors (10 ft) climbed per day during the run-in period. Ending PA was quantified as the average number of steps taken per day or number of floors (10 ft) climbed per day during the last 10 weekdays (ie, Monday to Friday on week 5 and week 6) of the 6-week intervention period. The main outcome was the difference between the intervention and control groups in terms of PA data from baseline to the ending phase. Additional outcomes were as follows: (1) adherence to Fitbit use (ie, number of days in which all participants in each group were classified as valid users aggregated across entire study period), and (2) the mean proportion of valid participants over the study period.

A valid day was defined as having accumulated 1500 steps or more per day [45]. Step count and floor count data from invalid days were not considered. Only participants who achieved 4 or more valid days of data [46] at both run-in (baseline) and ending phases were considered valid users and included in the analyses. On the basis that the team challenges were conducted on weekdays (ie, from Monday to Friday), the estimation of potential intervention effects used only PA data from weekdays.

Statistical Analysis

Phase 1: Analyses of Data From Validation Study

For the validation of daily steps taken per day, the assessment of the convergent validity of Fitbit compared with the ActiGraph was done on a day-to-day basis by aggregating the number of steps taken within each day. Spearman correlation coefficient (ρ) and intraclass correlation coefficient (ICC) were used to assess correlation and agreement, respectively, in step count data between ActiGraph and Fitbit. The Spearman ρ ranges from −1 (perfect negative correlation) to +1 (perfect positive correlation). An absolute Spearman correlation magnitude of 0.90 to 1.00 implied very high, 0.70 to 0.89 implied high, 0.50 to 0.69 implied moderate, 0.30 to 0.49 implied low, and 0.30 or less implied negligible correlation [39]. The agreement between measurements was interpreted based on the ICC estimate: greater than 0.90 implied excellent, 0.75 to 0.90 implied good, 0.50 to 0.75 implied moderate, and less than 0.50 implied poor agreement [40]. The median of absolute percentage error (MdAPE) between step count measured by Fitbit and ActiGraph was defined as the median of:

For the validation of floor count, the Spearman ρ and ICC estimate were used to assess correlation and agreement, respectively, in floor count data between visual observation and Fitbit. The MdAPE between floor count data obtained by Fitbit and visual observation was defined as the median of:

Phase 2: Analyses of Data From Feasibility Study

Binary baseline characteristics of completers were compared with noncompleters using Fisher exact test with a 2-sided *P* value and the prevalence ratio. Among the completers, comparisons between intervention and control groups were performed using Fisher exact test for categorical variables and Wilcoxon rank-sum test for continuous variables, where a 2-sided *P* value was reported for both tests.

Adherence

The proportion of valid participants on each observation day was defined by the number of participants who contributed valid step data on the day divided by the total number of participants (according to group). The adherence of each group was determined by calculating the rate ratio (RR) of the mean proportion of each group across the 40-day observation period. The difference in the mean proportion of valid users between the intervention and control groups was assessed using 2 independent sample *t* test.

Stepping and stair climbing activities were described as the average number of steps taken per day and average number of floors (10 ft) climbed per day, respectively. PA-related variables (ie, steps and floors) were log transformed to reduce their skewness and approximate normal distributions.

Intervention Effect at Ending Phase

The intervention effects between the intervention and control groups at the ending phase were estimated from multiple linear regression analyses on log-transformed average number of steps taken per day and log-trasnformed average number of floors (10 ft) climbed per day, respectively, with adjustment for baseline covariates (ie, gender, age, and respective baseline PA variables). After fitting the multiple linear regression models, the model assumptions were checked with residual diagnostics. The intervention effects were reported in terms of percent change in the average number of steps taken per day or average number of floors (10 ft) climbed per day between the 2 groups with the control group as the reference.

Intervention Effect at Each Challenge Week

Generalized estimating equations (GEEs) analyses were performed on the log-transformed average number of steps taken per day and log-transformed average number of floors (10 ft) climbed per day for each week during the intervention period to detect potentially different weekly intervention effects by taking into account the within-subject correlation of repeated weekly outcomes from the same individual. The multiple linear regression model with GEE was performed where an autoregressive working correlation matrix was specified, and the Huber-White estimator of variance was used to obtain a robust estimate for the standard error. We assessed the interaction between group status (ie, intervention group vs control group) and intervention week (ie, week 1 to week 6) with adjustment for baseline covariates (ie, gender, age, and respective baseline PA variables). When the interaction term was significant, a week-specific intervention effect was reported. On the other hand, if the interaction term was not significant, we reported the model that did not include the interaction term, and a common intervention effect across 6 weeks was reported instead. The model assumptions were checked with residual diagnostics. The intervention effects were reported in terms of percent change in the average number of steps taken per day or

number of floors (10 ft) climbed per day for each week compared with the control group.

This study was a feasibility study. Thus, sample size calculation was not performed. All statistical analyses were conducted using STATA 14.0 for Windows (Stata Corporation).

Results

Participants' Characteristics

Participants were staff and students from the National University of Singapore, recruited between 2015 and 2016 (Figure 2). A total of 40 eligible participants provided informed consent to participate in the validation study and completed the baseline assessment. In the phase 1 validation study, 80% (32/40 eligible participants) completed daily steps validation, whereas 100% (all 40 eligible participants) completed floor count validation. Of 40 participants, 23 (58%) further consented to participate in the subsequent feasibility study (phase 2). In addition, 18 participants were recruited, resulting in 41 eligible individuals for phase 2. Of the eligible participants, 1 participant subsequently declined participation, and 40 participants who completed the run-in period were allocated to the intervention (n=20) and control (n=20) groups. Of 40 participants, 29 (73%) completed the 6-week follow-up but 24 (60%; intervention group=11 and control group=13) participants were classified as completers if they provided complete exposure data and valid PA data at both baseline and ending phases. These 24 completers were included in the analyses of intervention effectiveness. Baseline characteristics of participants involved in the validation study and feasibility study are summarized in Table 2. No significant differences in the baseline characteristics were observed between the completers and the noncompleters in this study population (Multimedia Appendix 2).

Figure 2. Participant flow diagram.

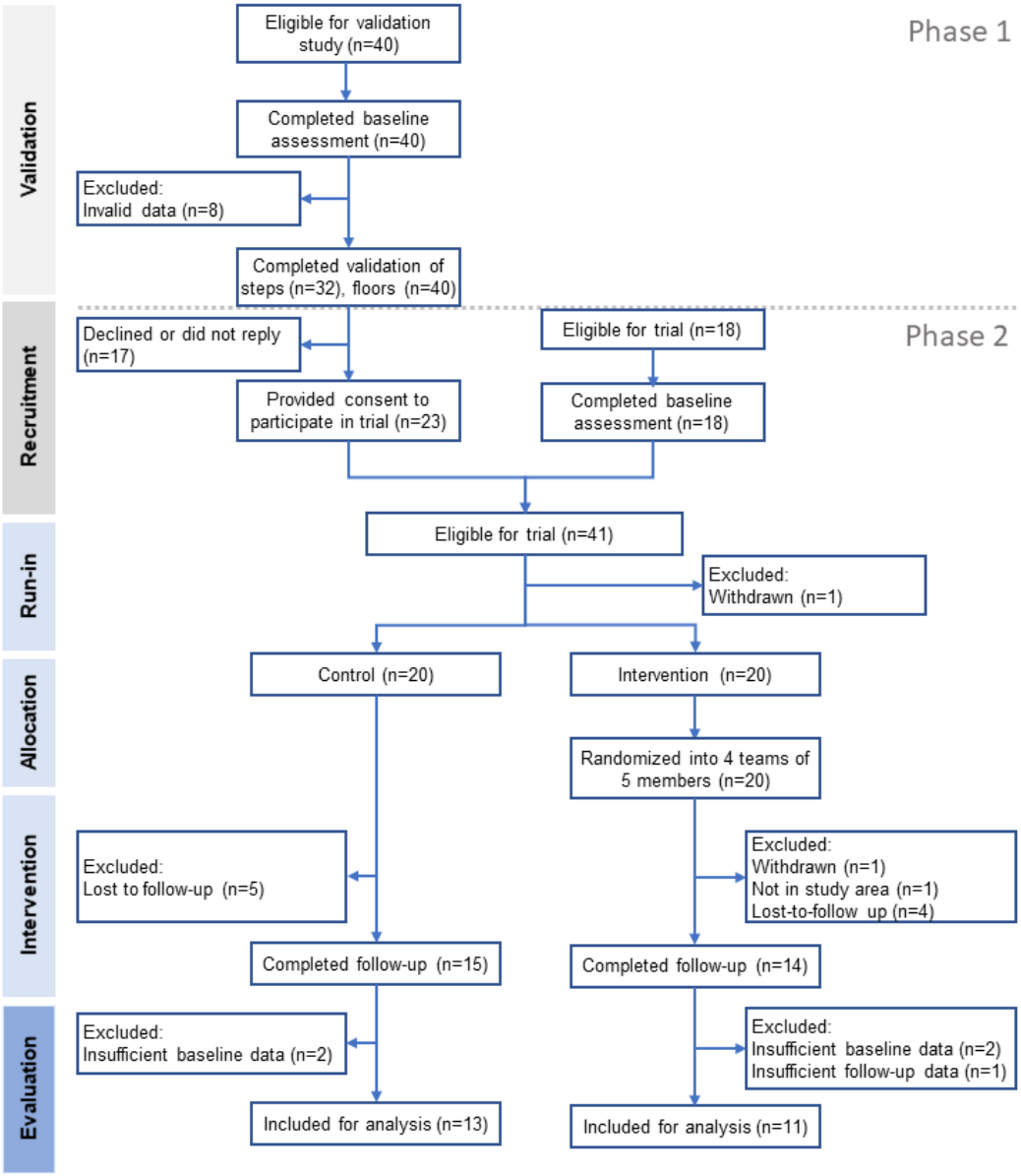


Table 2. Baseline characteristics of participants in validation (n=40) and pilot trial (n=24) included in analyses.

Baseline characteristics	Phase 1: validation study (N=40)	Phase 2: feasibility study (N=24)		
		Intervention group (n=11)	Control group (n=13)	*P* value[a]
Age (years), median (25th to 75th percentile)	24 (23-30)	28 (23-35)	28 (23-31)	.79
Gender, n (%)				**.03**
Female	20 (50)	4 (36)	11 (85)	
Male	20 (50)	7 (64)	2 (15)	
Ethnicity, n (%)				**.30**
Chinese	33 (82)	8 (73)	12 (92)	
Non-Chinese	7 (17)	3 (27)	1 (8)	
Education, n (%)				**.66**
Secondary[b]	15 (36)	4 (36)	3 (23)	
Tertiary or above	25 (62)	7 (64)	10 (77)	
Work status, n (%)				**>.99**
Studying	27 (67)	6 (54)	7 (54)	
Working	13 (32)	5 (45)	6 (46)	
Marital status, n (%)				**.63**
Not married	37 (92)	8 (73)	11 (85)	
Married	3 (7)	3 (27)	2 (15)	
Body mass index (kg/m^2), n (%)				**.14**
<18.5	1 (2)	0 (0)	2 (15)	
18.5-22.9	26 (65)	8 (73)	7 (54)	
23.0-24.9	7 (17)	1 (9)	4 (31)	
≥25.0	6 (15)	2 (18)	0 (0)	

[a]In Phase 2, feasibility study: for continuous variables, comparisons were performed by Wilcoxon rank-sum tests (medians); for categorical variables, Fisher exact tests were used.

[b]Secondary educational level included participants who completed A level or attended polytechnic school.

Results of Validation Study

A total of 32 participants provided 215 valid step count data pairs (measured by both ActiGraph and Fitbit) with an average of 6.7 (SD 0.6) valid data pairs. In the floor count validation study, each of the 40 participants provided 1 valid floor count data pair (direct observation vs measured by Fitbit; Table 3). A high and very high positive correlations between measurements in step and floor counts were observed, respectively. The level of agreement was good for number of steps taken per day and excellent for floor count. The MdAPE was less than 20% for step count and zero for floor count.

Table 3. Correlation, agreement, and error in measurements of steps (ActiGraph vs Fitbit) and floors (observation vs Fitbit).

Measurement characteristics	Daily steps[a] (n=32)	Floor count[b] (n=40)
Setting	7 days, free-living conditions	6 floors, research setting
Number of valid data pairs[c]	215	40
Number of valid data pairs provided by each participant, mean (SD)	6.7 (0.58)	4 (0)
Measurements output, median (25th-75th percentile)		
ActiGraph or observation	9503 (6392-12,479)[d]	6 (6-6)
Fitbit-measured	11,148 (8186-14,493)	6 (6-6)
Difference in measurements, median (25th-75th percentile)		
Fitbit vs ActiGraph or observation	1398 (643-2720)	0 (0-0)
Spearman correlation (ρ)	0.89[e]	0.98[e]
Intraclass correlation[f] (95% CI)	0.81 (0.45 to 0.91)[e]	0.96 (0.95 to 0.97)[e]
Median absolute percent error, median (25th-75th percentile)	17.13 (7.80-30.29)	0 (0-0)

[a]Daily steps were presented as the number of steps taken per day.

[b]One floor count is equivalent to 10 ft upward vertical displacement (presented as the number of floor).

[c]Valid data pairs referred to valid data points provided by both ActiGraph and Fitbit.

[d]ActiGraph-measured steps (presented as the number of steps taken per day).

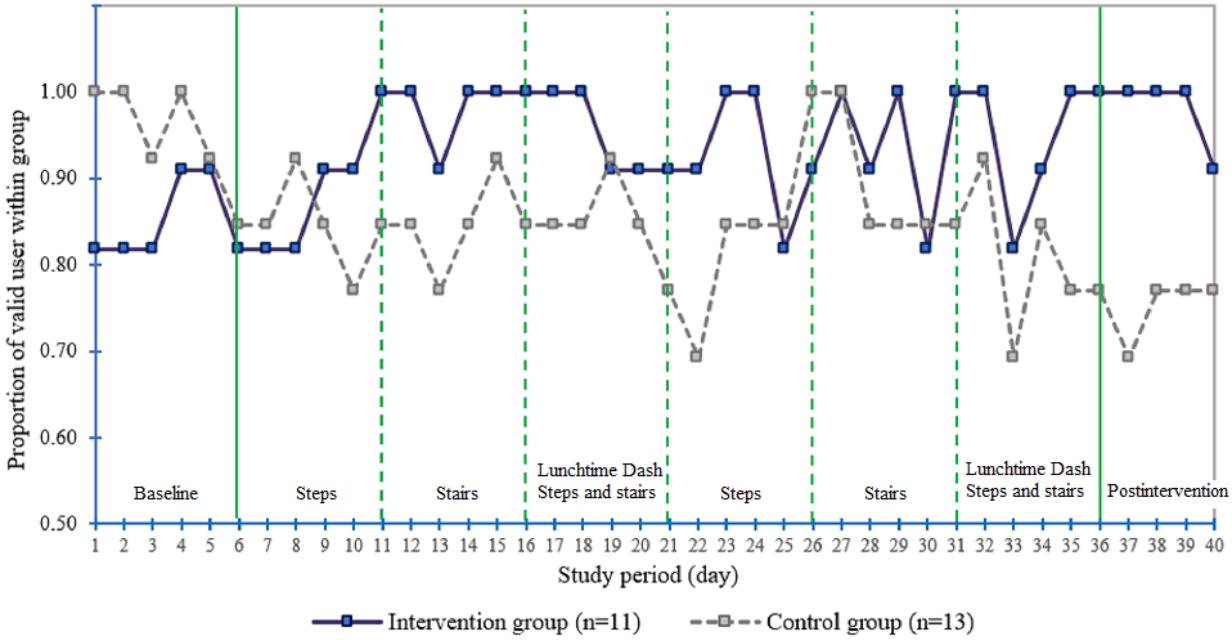
[e]*P*<.001.

[f]Intraclass correlation derived using 2-way mixed effects model for absolute agreement.

Wearable Use During the Study Period

The proportion of valid users over the 40-day study period within each group is described in Figure 3. At baseline, the proportion of valid users was somewhat higher among the controls; however, it decreased over time. On the contrary, the proportion of valid users in the intervention group was lower at baseline, but it increased after the introduction of the first team challenge and remained largely consistent throughout the study period. Over the 40 days of observation, the intervention group participants demonstrated a higher level of Fitbit use adherence. All intervention participants (11/11) were classified as valid in 18 of 40 days, whereas all control group participants (13/13) were valid participants in only 5 of 40 days (RR 3.6, 95% CI 1.5 to 9.1; *P*=.003). There was also a significant difference in the mean proportion of valid users between intervention and control groups (0.92 vs 0.83; *P*<.001).

Figure 3. Proportion of valid users (intervention, n=11; and control, n=13) over study phases.



Effects of the intervention

Table 4 presents the effects of the intervention on the average number of steps taken per day or number of floors (10 ft) climbed per day at the ending phase after adjusting for baseline PA variables, age, and gender. On average, the intervention group achieved 15.9% higher average number of steps taken per day (95% CI −8.9 to 47.6; *P*=.21) and 39.4% higher average number of floors (10 ft) climbed per day (95% CI 2.4 to 89.7; *P*=.04) than the control group at the ending phase.

Figure 4 depicts the average number of steps taken per day (upper panel) and number of floors (10 ft) climbed per day (lower panel) of the intervention period according to allocated group. The GEE results (Table 5) indicated that, on the one hand, there was no significant interaction effect between group status and intervention week with regard to average number of steps taken per day. Hence, the weekly intervention effect was similar across all 6 weeks (percentage change 9%; 95% CI −7.3 to 28.1; *P*=.30). On the other hand, a significant interaction between group status and intervention week (*P*<.001) was observed with regard to the average number of floors (10 ft) climbed per day. The percent change in the intervention group was significantly higher (percentage change 78.5%; 95% CI 20.8 to 163.8; *P*=.004) at week 5 (ie, the second stair climbing challenge) when compared with the control group.

Table 4. Average stepping and stair climbing activity of completers (n=24) as well as their intervention effect (percentage change).

Type of physical activity	Physical activity level by group, median (25th-75th percentile)		Intervention effect, (with respect to the control group)	
	Intervention group (n=11)	Control group (n=13)	Percentage change[a], (95% CI)	*P* value
Stepping activity (average number of steps taken per day)			**15.9 (−8.9 to 47.6)**	**.21**
Baseline	10,579 (8375-11,314)	10,207 (7745-12,345)		
Ending phase	8797 (8124-13,181)	8881 (7828-10,375)		
Stair climbing activity (average number of floors [10 ft] climbed per day)			**39.4 (2.4 to 89.7)**	**.04**
Baseline	11.8 (8.5-21.5)	14.8 (10.2-29.2)		
Ending phase	13.6 (9.9-23.3)	13.4 (10.3-14.4)		

[a]Multiple linear regressions adjusted for its baseline physical activity, age, and gender.

Figure 4. Average number of steps taken per day or number of floors (10 ft) climbed per day at baseline and across the 6-week intervention period.

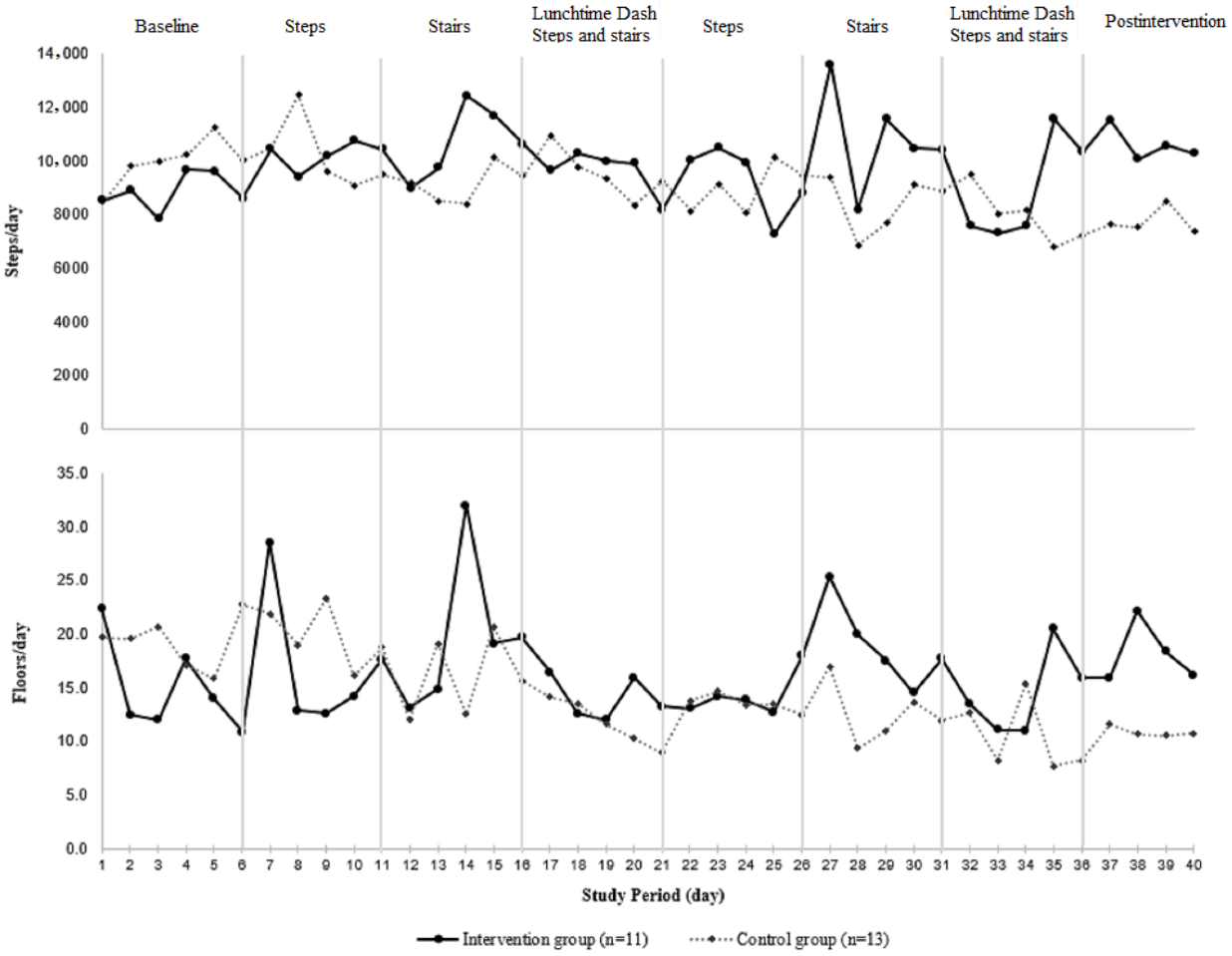


Table 5. Generalized estimating equation results for the average number of steps taken per day or number of floors (10 ft) climbed per day across each week during the 6-week intervention.

Physical activity	Intervention effect (with respect to the control group)		
	Percentage change[a]	95% CI	*P* value[b]
Stepping activity (weekly average number of steps taken per day)			
Weekly challenge			
Common effect across all weeks	9.0	−7.3 to 28.1	.30
Stair climbing activity (weekly average number of floors climbed per day)			
Weekly challenge			
Week 1 (steps)	−6.3	−35.5 to 36.2	.73
Week 2 (stairs)	18.2	−15.1 to 64.5	.32
Week 3 (steps+stairs)	24.9	−20.4 to 95.8	.33
Week 4 (step)	15.1	−23.5 to 73.2	.50
Week 5 (stairs)	78.5	20.8 to 163.8	.004
Week 6 (steps+stairs)	25.3	−8.3 to 71.1	.16

[a]Generalized estimating equation: (family: Gaussian; link: identity) analyses adjusted for its baseline physical activity, age, and gender.

[b]The interaction term (Group x week) has a *P* value of 0.12 and <.001 for stepping and stair climbing activities, respectively

Discussion

Principal Findings

This study describes the development of an mHealth-based team challenge intervention, including the validation of the integrated wearables with regard to the 2 main PA outcome measures: stepping and stair climbing activities. It also provides initial results from a controlled pilot trial on the feasibility and effectiveness of this real-time team challenge intervention when implemented among students and staff of a public university in Singapore. Findings from this study could inform large-scale mHealth strategies, such as the Singapore National Steps Challenge [47], on the potential integration of the team-based model and the focus on stair climbing in addition to stepping activities.

In summary, the validation study demonstrated that the Fitbit trackers provided acceptable validity in estimating daily step count and floor count, although the trackers overestimated step count in absolute terms. The controlled pilot trial demonstrated that the multicomponent mHealth technology suite designed to deliver real-time interventions was feasible. About 60% of the participants continued using the system and provided valid data for evaluation. Higher adherence was observed in the intervention group, and the team challenges resulted in more PA, especially stair climbing, when compared with the control group.

Considering the rapid innovations and adoption of consumer wearables and smartphone apps in monitoring PA behaviors, these mobile technologies require formal assessments to strengthen scientific basis and justify their application in measuring PA outcomes, such as the number of steps and flights of stairs. In terms of stepping activity under free-living conditions, we observed a high positive correlation and good agreement between the consumer wearables and a validated research grade accelerometer [48]. Consistent with a study that had systematically reviewed the accuracy of various Fitbit models, the Fitbit trackers used in this study demonstrated a similar tendency of overestimating daily steps and generated a measurement error of more than 10% [38]. In contrast, the review did not identify any study that has investigated the validity of Fitbit trackers on measuring stair climbing. Our study found a very high, positive correlation and excellent agreement between Fitbit-measured floor count and direct observation. This finding adds to the current literature that these consumer wearables accurately estimate stair climbing activities, offering additional value in PA continuous monitoring beyond stepping.

Stepping, a form of PA that often occurs at a lower intensity, has been a common target of mHealth interventions. However, fewer mHealth interventions using continuous monitoring via wearables or smartphones have investigated the potential of integrating higher intensity PA (ie, MVPA) into health promotion efforts. Stair climbing is of higher intensity and can be integrated into daily life [17]. Thus, it could be an efficient way to incorporate MVPA into daily routines, which has shown to result in improved cardiorespiratory fitness and health [18,19]. In view of the potential health benefits and the scarcity of the available evidence, our study investigated the feasibility of using consumer wearables to continuously monitor and promote stair climbing. This study extended the use of static point-of-decision prompts [20] and introduced stair climbing challenges in addition to the more commonly targeted stepping activities.

Despite the convenience of engaging in stepping and stair climbing and the almost effortless and low-cost use of wearables for monitoring such activities, it may not necessarily translate to regular use of these devices anywhere and anytime. Our study revealed that only 60% of participants continued using the trackers, and not all participants contributed valid PA data every day across the 40-day observation period. Although the proportion of valid participants in the control group declined over time, the intervention group demonstrated higher adherence to the use of the trackers, leading to more PA compared with the control group. In terms of stepping, although not significant, the controlled pilot trial suggested greater activity levels in the intervention group. These differences were mainly explained by a decline in stepping among the control group participants, whereas a small proportion of the intervention participants kept or slightly increased their average stepping level over time. After accounting for the correlation between repeated measurements, no significant increase in stepping with respect to weekly challenges was observed. The findings possibly reflect that the provision of self-monitoring alone through the use of wearables may not be sufficient to sustain participants' interest in PA. A systematic review has suggested that an increase in step count was predicted by behavioral change strategy, such as setting a step goal of 10,000 steps per day beyond just using the wearables [15]. A large-scale factorial randomized controlled trial conducted in Singapore further demonstrated that the use of wearables declined over time and that long-term financial incentives may be needed [49]. Our study provides some initial evidence that a simple, low-cost, and easy to implement team challenge intervention may hold some merits in promoting adherence to the use of wearables. In terms of stair climbing, we observed statistically significant increases in the use of stairs in the intervention group, especially during the second stair climbing challenge. This phenomenon could be partly explained by the fact that climbing stairs may have been seen as a less familiar health promotion target at the time of our study since strategies to promote PA via wearables and smartphones have traditionally focused on stepping goals [15,16]. When the intervention participants were exposed to the stair climbing challenges, they may have gradually become more receptive to the idea, considering the availability of many high-rise buildings and staircases in Singapore. Although we found some positive intervention effects through our use of nonregistered teams, we also recognize that the effects of the team-based intervention might have been different if the team members were friends or family members. Cohesion within each team will likely affect adherence to the intervention and shift the PA profile over time. Moreover, differences across the competing teams will likely be attributed to a complex interplay of social and environmental factors in real-life settings that need to be measured and accounted for in future evaluations. Furthermore, the dosage and timing of interventions delivered in real time require careful consideration. One study suggested that optimizing the number of challenges and feedback messages would potentially improve the engagement and adherence of participants [50]. It is

important to ensure that concise messages are presented to targeted users at the right time to minimize cognitive overload [51]. However, in our study, the effects of the number and timing of messages on PA maintenance were not assessed. Future studies are warranted to investigate this question.

In order to deliver effective promotion and monitoring of PA in free-living conditions, delivering meaningful BCTs becomes important. Systematic reviews have identified effective BCTs for health promotion. For instance, self-monitoring, feedback, and goal setting are among the most frequently used BCTs along with the use of commercial wearables in various mHealth strategies [25,50]. Recent studies suggested that strategies based on these BCTs reduced time spent in sedentary behavior [25] and were associated with greater intervention effectiveness for modifying PA and diet behaviors [52]. In addition, increases in intrinsic and extrinsic motivation through the use of reward systems, prompts, and cues have been reported to lead to a more regular use of wearable devices, as well as better adherence and self-management of chronic conditions [50]. Recognizing the growing capabilities of mobile technologies, there are opportunities to perform real-time behavioral assessments and facilitate timely support adapting to individuals' dynamic behavioral states. A recent systematic review suggested that just-in-time feedback that was goal oriented, actionable, and continuously available significantly improved health behavior [53]. Tailored feedback on users' current performance [54,55], gamified feedback, such as a leaderboard [31], and user engagement strategies, such as virtual rewards, social connectivity, and adaptive goal setting, have also been found promising in the promotion of PA [56,57]. In addition, studies have also demonstrated an increase in PA levels among the participants who received social incentives compared with participants who exercised alone and performed PA in social settings, such as teamwork and cooperation, compared with competition [58]. In spite of these various promising applications of BCTs in the context of promoting PA in free-living conditions, the potential of technology-enabled, real-time strategies has not been extensively explored [59]. Leveraging selected important BCTs, our study attempted to promote PA in real time through establishing a supportive team-based environment and incorporating feedback, social comparison, reward systems, and cues in addition to self-monitoring. Consistent with the current literature, BCTs may have led to positive stair climbing outcomes favoring the intervention group in our study. Although various BCTs hold potential for improving PA, individual BCTs remain largely underexplored, and it is unclear what combination of BCTs in mHealth interventions may lead to meaningful outcomes [25,60].

This study comprehensively describes the development and initial evaluation of a real-time mHealth team challenge intervention. Our findings suggest that the implementation of the team challenges using an mHealth suite is feasible. First, consumer wearables are readily available to provide a valid estimation of daily stepping and stair climbing activities. Second, mobile internet network connectivity in Singapore enables continuous and real-time monitoring of PA behaviors and allows delivery of in-time feedback about individual and team PA performance. Third, the nonregistering team–based approach adopted in the study helped to eliminate biases related to self-selection into competing teams and demonstrated some improvements in adherence to wearable use and activity levels over time. Fourth, the existing built environment in Singapore and many other metropolitan areas in Asia present opportunities for promoting stair climbing as an additional intervention target beyond traditional stepping-based targets. As such, stair climbing could be readily incorporated into health promotion programs as an effort to promote PA of higher intensity targeting the general adult population. However, we noted that the implementation of such mHealth strategies requires careful considerations. For instance, technical challenges, limited resources for the development or updating of study apps, and variability in smartphone settings prevented installation of the apps' final version on a larger proportion of participants' phones in our study.

Strengths and Limitations

This study demonstrated several strengths. First, we validated the wearables for stepping in free-living conditions and also investigated their validity in measuring stair climbing, which has not been studied based on our knowledge. Second, the inference about the effects of the intervention was established from a controlled study design. Third, the wearables were feasible for continuously collecting data on daily stepping and stair climbing activities. However, we also acknowledge several limitations. First, this is an exploratory feasibility study conducted in a single public university, mainly enrolling young to middle-aged educated adults. Thus, the findings have limited generalizability. Second, the intervention duration was short, and future studies will need to investigate long-term outcomes. Third, because of technical challenges in delivering the intervention via participants' iPhones and a small number of Android phones, we were not able to implement a randomized controlled trial but instead decided to allocate all iPhone users and the affected Android users to the control group. Although this decision may have led to differences between the intervention and control groups, the characteristics of the 2 groups were mostly comparable, and the differences at baseline were adjusted for during the analyses. This circumstance did not reflect the technology affinity of study participants in each group because our study team supported all participants in the installation process. Fourth, we did not collect information on participants' motivation and users' experience in relation to mHealth technology, but considering participants' interest to voluntarily enroll in this study, we assume that the groups' motivation was comparable. Finally, 40% of recruited participants did not provide valid data for the feasibility study in phase 2. The relatively large dropout rate of participants due to insufficient data hampered the assessment of the intervention's effectiveness. In this study, we deliberately chose to integrate consumer wearables to monitor study outcomes instead of the more common use of questionnaires or research-grade accelerometers for a few main reasons. For example, validated consumer wearables would likely provide more objective and accurate estimates of stepping and stair climbing than the typical PA questionnaires. These devices also enabled us to monitor outcomes over the entire intervention phase instead of the usual 4 to 7 days of monitoring that is

typically the case when using accelerometers. Moreover, using these mobile technologies allowed us to test a less resource-intensive approach to data collection that could be applied in large-scale population health initiatives.

Conclusions

The consumer wearables integrated into our mHealth suite provided acceptable validity in estimating stepping and stair climbing activities. The mHealth suite was feasible for implementing real-time team challenge interventions. Compared with the controls, the intervention participants performed more stair climbing, which could be introduced as an additional PA promotion target in the context of future mHealth strategies. Methodologically rigorous studies with larger sample size and long-term follow-up are warranted to strengthen this study's findings.

Acknowledgments

The National University of Singapore supported this study, and the institutional review board of the National University of Singapore approved the study protocol. The authors would like to thank Yusuf Shamir for his support in managing the Web-based data management systems, John Kuan Chow Leong and Omar Khalid for their contribution to app development, and all colleagues and students who participated in the study.

Authors' Contributions

FM-R and AWG conceived the study and designed the mHealth intervention. SJL and AWG recruited the participants and collected data for the validation and the evaluation studies, FM-R supervised the project implementation and data collection process. SJL and AWG performed statistical analyses. FM-R and CST contributed to and reviewed the statistical analyses and interpretation of findings. SJL drafted the manuscript, and all authors edited the manuscript and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Example of gamification features received by the intervention group.
[DOCX File , 113 KB - mhealth_v8i2e12665_app1.docx]

Multimedia Appendix 2
Comparison of baseline characteristics between non-completers (n=16) and completers (n=24).
[DOCX File , 35 KB - mhealth_v8i2e12665_app2.docx]

References

1. GBD 2015 Risk Factors Collaborators. Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet 2016 Oct 8;388(10053):1659-1724 [FREE Full text] [doi: 10.1016/S0140-6736(16)31679-8] [Medline: 27733284]
2. Knuth AG, Hallal PC. Temporal trends in physical activity: a systematic review. J Phys Act Health 2009 Sep;6(5):548-559. [Medline: 19953831]
3. Lee I, Shiroma EJ, Lobelo F, Puska P, Blair SN, Katzmarzyk PT, Lancet Physical Activity Series Working Group. Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. Lancet 2012 Jul 21;380(9838):219-229 [FREE Full text] [doi: 10.1016/S0140-6736(12)61031-9] [Medline: 22818936]
4. Booth FW, Laye MJ, Lees SJ, Rector RS, Thyfault JP. Reduced physical activity and risk of chronic disease: the biology behind the consequences. Eur J Appl Physiol 2008 Mar;102(4):381-390. [doi: 10.1007/s00421-007-0606-5] [Medline: 17987311]
5. Löllgen H, Böckenhoff A, Knapp G. Physical activity and all-cause mortality: an updated meta-analysis with different intensity categories. Int J Sports Med 2009 Mar;30(3):213-224. [doi: 10.1055/s-0028-1128150] [Medline: 19199202]
6. Wen CP, Wai JP, Tsai MK, Yang YC, Cheng TY, Lee M, et al. Minimum amount of physical activity for reduced mortality and extended life expectancy: a prospective cohort study. Lancet 2011 Oct 1;378(9798):1244-1253. [doi: 10.1016/S0140-6736(11)60749-6] [Medline: 21846575]
7. Moore SC, Patel AV, Matthews CE, de Gonzalez AB, Park Y, Katki HA, et al. Leisure time physical activity of moderate to vigorous intensity and mortality: a large pooled cohort analysis. PLoS Med 2012;9(11):e1001335 [FREE Full text] [doi: 10.1371/journal.pmed.1001335] [Medline: 23139642]
8. Sattelmair J, Pertman J, Ding EL, Kohl HW, Haskell W, Lee I. Dose response between physical activity and risk of coronary heart disease: a meta-analysis. Circulation 2011 Aug 16;124(7):789-795 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.110.010710] [Medline: 21810663]

9. Foulds HJ, Bredin SS, Charlesworth SA, Ivey AC, Warburton DE. Exercise volume and intensity: a dose-response relationship with health benefits. Eur J Appl Physiol 2014 Aug;114(8):1563-1571. [doi: 10.1007/s00421-014-2887-9] [Medline: 24770699]
10. Lee D, Pate RR, Lavie CJ, Sui X, Church TS, Blair SN. Leisure-time running reduces all-cause and cardiovascular mortality risk. J Am Coll Cardiol 2014 Aug 5;64(5):472-481 [FREE Full text] [doi: 10.1016/j.jacc.2014.04.058] [Medline: 25082581]
11. Ekelund U, Steene-Johannessen J, Brown WJ, Fagerland MW, Owen N, Powell KE, Lancet Physical Activity Series 2 Executive Committe, Lancet Sedentary Behaviour Working Group. Does physical activity attenuate, or even eliminate, the detrimental association of sitting time with mortality? A harmonised meta-analysis of data from more than 1 million men and women. Lancet 2016 Sep 24;388(10051):1302-1310. [doi: 10.1016/S0140-6736(16)30370-1] [Medline: 27475271]
12. Donath L, Faude O, Roth R, Zahner L. Effects of stair-climbing on balance, gait, strength, resting heart rate, and submaximal endurance in healthy seniors. Scand J Med Sci Sports 2014 Apr;24(2):e93-101. [doi: 10.1111/sms.12113] [Medline: 24033611]
13. Meyer P, Kayser B, Kossovsky MP, Sigaud P, Carballo D, Keller P, et al. Stairs instead of elevators at workplace: cardioprotective effects of a pragmatic intervention. Eur J Cardiovasc Prev Rehabil 2010 Oct;17(5):569-575. [doi: 10.1097/HJR.0b013e328338a4dd] [Medline: 20299999]
14. Bellicha A, Kieusseian A, Fontvieille A, Tataranni A, Charreire H, Oppert J. Stair-use interventions in worksites and public settings - a systematic review of effectiveness and external validity. Prev Med 2015 Jan;70:3-13. [doi: 10.1016/j.ypmed.2014.11.001] [Medline: 25449692]
15. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, et al. Using pedometers to increase physical activity and improve health: a systematic review. J Am Med Assoc 2007 Nov 21;298(19):2296-2304. [doi: 10.1001/jama.298.19.2296] [Medline: 18029834]
16. de Vries HJ, Kooiman TJ, van Ittersum MW, van Brussel M, de Groot M. Do activity monitors increase physical activity in adults with overweight or obesity? A systematic review and meta-analysis. Obesity (Silver Spring) 2016 Oct;24(10):2078-2091 [FREE Full text] [doi: 10.1002/oby.21619] [Medline: 27670401]
17. Teh KC, Aziz AR. Heart rate, oxygen uptake, and energy cost of ascending and descending the stairs. Med Sci Sports Exerc 2002 Apr;34(4):695-699. [doi: 10.1097/00005768-200204000-00021] [Medline: 11932581]
18. Allison MK, Baglole JH, Martin BJ, Macinnis MJ, Gurd BJ, Gibala MJ. Brief intense stair climbing improves cardiorespiratory fitness. Med Sci Sports Exerc 2017 Feb;49(2):298-307. [doi: 10.1249/MSS.0000000000001188] [Medline: 28009784]
19. Gillen JB, Martin BJ, MacInnis MJ, Skelly LE, Tarnopolsky MA, Gibala MJ. Twelve weeks of sprint interval training improves indices of cardiometabolic health similar to traditional endurance training despite a five-fold lower exercise volume and time commitment. PLoS One 2016;11(4):e0154075 [FREE Full text] [doi: 10.1371/journal.pone.0154075] [Medline: 27115137]
20. Sloan RA, Haaland BA, Leung C, Müller-Riemenschneider F. The use of point-of-decision prompts to increase stair climbing in Singapore. Int J Environ Res Public Health 2013 Jan 7;10(1):210-218 [FREE Full text] [doi: 10.3390/ijerph10010210] [Medline: 23296208]
21. Allais O, Bazoche P, Teyssier S. Getting more people on the stairs: the impact of point-of-decision prompts. Soc Sci Med 2017 Nov;192:18-27. [doi: 10.1016/j.socscimed.2017.09.006] [Medline: 28950159]
22. Jacobs RJ, Lou JQ, Ownby RL, Caballero J. A systematic review of eHealth interventions to improve health literacy. Health Informatics J 2016 Jun;22(2):81-98. [doi: 10.1177/1460458214534092] [Medline: 24916567]
23. Harrington RA, Arena R, Després JP, Ciarochi A, Croll E, Bloch KD, Committee for Scientific Sessions Programmingthe Global Congress on Physical Activity, American Heart Association Scientific Sessions 2013. More than 10 million steps in the right direction: results from the first American Heart Association scientific sessions walking challenge. Prog Cardiovasc Dis 2015;57(4):296-298. [doi: 10.1016/j.pcad.2014.09.009] [Medline: 25269063]
24. Schoeppe S, Alley S, van Lippevelde W, Bray NA, Williams SL, Duncan MJ, et al. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. Int J Behav Nutr Phys Act 2016 Dec 7;13(1):127 [FREE Full text] [doi: 10.1186/s12966-016-0454-y] [Medline: 27927218]
25. Direito A, Carraça E, Rawstorn J, Whittaker R, Maddison R. mHealth technologies to influence physical activity and sedentary behaviors: behavior change techniques, systematic review and meta-analysis of randomized controlled trials. Ann Behav Med 2017 Apr;51(2):226-239. [doi: 10.1007/s12160-016-9846-0] [Medline: 27757789]
26. Morrison LG, Yardley L, Powell J, Michie S. What design features are used in effective e-health interventions? A review using techniques from Critical Interpretive Synthesis. Telemed J E Health 2012 Mar;18(2):137-144. [doi: 10.1089/tmj.2011.0062] [Medline: 22381060]
27. Samdal GB, Eide GE, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. Int J Behav Nutr Phys Act 2017 Mar 28;14(1):42 [FREE Full text] [doi: 10.1186/s12966-017-0494-y] [Medline: 28351367]
28. Middleton KR, Anton SD, Perri MG. Long-term adherence to health behavior change. Am J Lifestyle Med 2013;7(6):395-404 [FREE Full text] [doi: 10.1177/1559827613488867] [Medline: 27547170]

29. Duff OM, Walsh DM, Furlong BA, O'Connor NE, Moran KA, Woods CB. Behavior change techniques in physical activity eHealth interventions for people with cardiovascular disease: systematic review. J Med Internet Res 2017 Aug 2;19(8):e281 [FREE Full text] [doi: 10.2196/jmir.7782] [Medline: 28768610]
30. Looyestyn J, Kernot J, Boshoff K, Ryan J, Edney S, Maher C. Does gamification increase engagement with online programs? A systematic review. PLoS One 2017;12(3):e0173403 [FREE Full text] [doi: 10.1371/journal.pone.0173403] [Medline: 28362821]
31. Johnson D, Deterding S, Kuhn K, Staneva A, Stoyanov S, Hides L. Gamification for health and wellbeing: a systematic review of the literature. Internet Interv 2016 Nov;6:89-106 [FREE Full text] [doi: 10.1016/j.invent.2016.10.002] [Medline: 30135818]
32. Patel MS, Volpp KG, Rosin R, Bellamy SL, Small DS, Fletcher MA, et al. A randomized trial of social comparison feedback and financial incentives to increase physical activity. Am J Health Promot 2016 Jul;30(6):416-424 [FREE Full text] [doi: 10.1177/0890117116658195] [Medline: 27422252]
33. Patel MS, Asch DA, Rosin R, Small DS, Bellamy SL, Eberbach K, et al. Individual versus team-based financial incentives to increase physical activity: a randomized, controlled trial. J Gen Intern Med 2016 Jul;31(7):746-754 [FREE Full text] [doi: 10.1007/s11606-016-3627-0] [Medline: 26976287]
34. Kullgren JT, Troxel AB, Loewenstein G, Asch DA, Norton LA, Wesby L, et al. Individual- versus group-based financial incentives for weight loss: a randomized, controlled trial. Ann Intern Med 2013 Apr 2;158(7):505-514 [FREE Full text] [doi: 10.7326/0003-4819-158-7-201304020-00002] [Medline: 23546562]
35. Gollwitzer PM. Implementation intentions: strong effects of simple plans. Am Psychol 1999;54(7):493-503. [doi: 10.1037/0003-066X.54.7.493]
36. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. Psychol Health 2011 Nov;26(11):1479-1498. [doi: 10.1080/08870446.2010.540664] [Medline: 21678185]
37. Coughlin SS, Stewart J. Use of consumer wearable devices to promote physical activity: a review of health intervention studies. J Environ Health Sci 2016 Nov;2(6) [FREE Full text] [doi: 10.15436/2378-6841.16.1123] [Medline: 28428979]
38. Feehan LM, Geldman J, Sayre EC, Park C, Ezzat AM, Yoo JY, et al. Accuracy of Fitbit devices: systematic review and narrative syntheses of quantitative data. JMIR Mhealth Uhealth 2018 Aug 9;6(8):e10527 [FREE Full text] [doi: 10.2196/10527] [Medline: 30093371]
39. Gorny AW, Liew SJ, Tan CS, Müller-Riemenschneider F. Fitbit charge HR wireless heart rate monitor: validation study conducted under free-living conditions. JMIR Mhealth Uhealth 2017 Oct 20;5(10):e157 [FREE Full text] [doi: 10.2196/mhealth.8233] [Medline: 29055881]
40. Straiton N, Alharbi M, Bauman A, Neubeck L, Gullick J, Bhindi R, et al. The validity and reliability of consumer-grade activity trackers in older, community-dwelling adults: a systematic review. Maturitas 2018 Jun;112:85-93. [doi: 10.1016/j.maturitas.2018.03.016] [Medline: 29704922]
41. Degroote L, de Bourdeaudhuij I, Verloigne M, Poppe L, Crombez G. The accuracy of smart devices for measuring physical activity in daily life: validation study. JMIR Mhealth Uhealth 2018 Dec 13;6(12):e10972 [FREE Full text] [doi: 10.2196/10972] [Medline: 30545810]
42. Farina N, Lowry RG. The validity of consumer-level activity monitors in healthy older adults in free-living conditions. J Aging Phys Act 2018 Jan 1;26(1):128-135. [doi: 10.1123/japa.2016-0344] [Medline: 28595019]
43. Chen R, Gong J. Can self selection create high-performing teams? J Econ Behav Organ 2018;148:20-33. [doi: 10.1016/j.jebo.2018.02.004]
44. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiyagarajan A, et al. Gamification for health promotion: systematic review of behaviour change techniques in smartphone apps. BMJ Open 2016 Oct 4;6(10):e012447 [FREE Full text] [doi: 10.1136/bmjopen-2016-012447] [Medline: 27707829]
45. Tudor-Locke C, Barreira TV, Schuna JM. Comparison of step outputs for waist and wrist accelerometer attachment sites. Med Sci Sports Exerc 2015 Apr;47(4):839-842. [doi: 10.1249/MSS.0000000000000476] [Medline: 25121517]
46. Trost SG, McIver KL, Pate RR. Conducting accelerometer-based activity assessments in field-based research. Med Sci Sports Exerc 2005 Nov;37(11 Suppl):S531-S543. [doi: 10.1249/01.mss.0000185657.86065.98] [Medline: 16294116]
47. HealthHub. National Steps Challenge Community Challenge URL: https://www.healthhub.sg/programmes/124/community-challenge [accessed 2019-11-06]
48. Lee JA, Williams SM, Brown DD, Laurson KR. Concurrent validation of the Actigraph gt3x+, Polar Active accelerometer, Omron HJ-720 and Yamax Digiwalker SW-701 pedometer step counts in lab-based and free-living settings. J Sports Sci 2015;33(10):991-1000. [doi: 10.1080/02640414.2014.981848] [Medline: 25517396]
49. Finkelstein EA, Haaland BA, Bilger M, Sahasranaman A, Sloan RA, Nang EEK, et al. Effectiveness of activity trackers with and without incentives to increase physical activity (TRIPPA): a randomised controlled trial. Lancet Diabetes Endocrinol 2016 Dec;4(12):983-995. [doi: 10.1016/S2213-8587(16)30284-4] [Medline: 27717766]
50. Sardi L, Idri A, Fernández-Alemán JL. A systematic review of gamification in e-Health. J Biomed Inform 2017 Jul;71:31-48 [FREE Full text] [doi: 10.1016/j.jbi.2017.05.011] [Medline: 28536062]

51. Nahum-Shani I, Smith SN, Spring BJ, Collins LM, Witkiewitz K, Tewari A, et al. Just-in-Time Adaptive Interventions (JITAIs) in mobile health: key components and design principles for ongoing health behavior support. Ann Behav Med 2018 May 18;52(6):446-462 [FREE Full text] [doi: 10.1007/s12160-016-9830-8] [Medline: 27663578]
52. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. Health Psychol 2009 Nov;28(6):690-701. [doi: 10.1037/a0016136] [Medline: 19916637]
53. Schembre SM, Liao Y, Robertson MC, Dunton GF, Kerr J, Haffey ME, et al. Just-in-time feedback in diet and physical activity interventions: systematic review and practical design framework. J Med Internet Res 2018 Mar 22;20(3):e106 [FREE Full text] [doi: 10.2196/jmir.8701] [Medline: 29567638]
54. Martin SS, Feldman DI, Blumenthal RS, Jones SR, Post WS, McKibben RA, et al. mActive: a randomized clinical trial of an automated mHealth intervention for physical activity promotion. J Am Heart Assoc 2015 Nov 9;4(11):pii: e002239 [FREE Full text] [doi: 10.1161/JAHA.115.002239] [Medline: 26553211]
55. Walsh JC, Corbett T, Hogan M, Duggan J, McNamara A. An mHealth intervention using a smartphone app to increase walking behavior in young adults: a pilot study. JMIR Mhealth Uhealth 2016 Sep 22;4(3):e109 [FREE Full text] [doi: 10.2196/mhealth.5227] [Medline: 27658677]
56. Poirier J, Bennett WL, Jerome GJ, Shah NG, Lazo M, Yeh H, et al. Effectiveness of an activity tracker- and internet-based adaptive walking program for adults: a randomized controlled trial. J Med Internet Res 2016 Feb 9;18(2):e34 [FREE Full text] [doi: 10.2196/jmir.5295] [Medline: 26860434]
57. Adams MA, Hurley JC, Todd M, Bhuiyan N, Jarrett CL, Tucker WJ, et al. Adaptive goal setting and financial incentives: a 2 × 2 factorial randomized controlled trial to increase adults' physical activity. BMC Public Health 2017 Mar 29;17(1):286 [FREE Full text] [doi: 10.1186/s12889-017-4197-8] [Medline: 28356097]
58. Chen Y, Pu P. HealthyTogether: Exploring Social Incentives for Mobile Fitness Applications. In: Proceedings of the Second International Symposium of Chinese CHI. 2014 Presented at: Chinese CHI'14; April 26-27, 2014; Toronto, Ontario, Canada p. 25-34. [doi: 10.1145/2592235.2592240]
59. O'Reilly GA, Spruijt-Metz D. Current mHealth technologies for physical activity assessment and promotion. Am J Prev Med 2013 Oct;45(4):501-507 [FREE Full text] [doi: 10.1016/j.amepre.2013.05.012] [Medline: 24050427]
60. Eckerstorfer LV, Tanzer NK, Vogrincic-Haselbacher C, Kedia G, Brohmer H, Dinslaken I, et al. Key elements of mHealth interventions to successfully increase physical activity: meta-regression. JMIR Mhealth Uhealth 2018 Nov 12;6(11):e10076 [FREE Full text] [doi: 10.2196/10076] [Medline: 30425028]

Abbreviations

API: application programming interface
BCT: behavior change technique
GEE: generalized estimating equation
ICC: intraclass correlation coefficient
MdAPE: median of absolute percentage error
mHealth: mobile health
MVPA: moderate-to-vigorous physical activity
PA: physical activity
RR: rate ratio

Edited by G Eysenbach; submitted 01.11.18; peer-reviewed by Y Liao, M Andrews, T Qian, S Smith ; comments to author 31.03.19; revised version received 31.05.19; accepted 22.10.19; published 04.02.20.

Please cite as:
Liew SJ, Gorny AW, Tan CS, Müller-Riemenschneider F
A Mobile Health Team Challenge to Promote Stepping and Stair Climbing Activities: Exploratory Feasibility Study
JMIR Mhealth Uhealth 2020;8(2):e12665
URL: https://mhealth.jmir.org/2020/2/e12665
doi:10.2196/12665
PMID:32014845

Original Paper

The Effect of Smartphone Apps Versus Supervised Exercise on Physical Activity, Cardiorespiratory Fitness, and Body Composition Among Individuals With Mild-to-Moderate Mobility Disability: Randomized Controlled Trial

Daniel Berglind[1], PhD; Diego Yacaman-Mendez[1], MSc, MD; Catharina Lavebratt[2], PhD; Yvonne Forsell[1], PhD

[1]Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden

[2]Department of Molecular Medicine and Surgery, Karolinska Institutet, Stockholm, Sweden

Corresponding Author:
Daniel Berglind, PhD
Department of Global Public Health
Karolinska Institutet
Solnavägen 1E
Eugeniavägen 3, Solna
Stockholm, SE-171 76
Sweden
Phone: +46 703644797
Email: daniel.berglind@ki.se

Abstract

Background: Adequate levels of physical activity (PA) and good cardiorespiratory fitness (CRF) are associated with profound health benefits for individuals with mobility disability (MD). Despite the vast amount of research published in the field of PA interventions, little attention has been given to individuals with MD.

Objective: The aim of this study was to examine the efficacy of an app-based versus a supervised exercise and health coaching program to support adults with MD to increase levels of PA, CRF, and improve body composition.

Methods: Participants with self-perceived MD, aged 18 to 45 years, were included in this 12-week parallel-group randomized controlled trial and allocated at random to an app-based intervention, using commercially available apps—the Swedish Military training app (FMTK), the Acupedo walking app, and the LogMyFood food photography app—or a supervised exercise and health coaching intervention, including 1 weekly supervised exercise session and healthy lifestyle coaching. The primary outcome was the level of moderate-to-vigorous PA (MVPA) measured with accelerometers. Secondary outcomes included CRF measured by a submaximal test performed on a stationary bicycle and body composition measured by bioelectrical impedance. All outcomes were measured at baseline, 6 weeks, and 12 weeks. Linear mixed-effect models were used to assess the between-group differences, as well as the within-group changes through time, in each intervention group.

Results: A total of 110 participants with MD were randomized to an app-based intervention (n=55) or a supervised exercise and health intervention (n=55). The mean age of participants was 34.9 years (SD 6.1), and 81.8% (90/110) of the participants were women. CRF showed a moderate increase in both groups after 12 weeks—1.07 (95% CI –0.14 to 2.27) mL/kg/min increase in the app-based group and 1.76 (95% CI 0.70 to 2.83) mLkg/min increase in the supervised exercise group. However, the intention-to-treat analysis showed no significant differences between the groups in MVPA or CRF after 12 weeks. Waist circumference was significantly lower in the app-based intervention group.

Conclusions: Commercially available apps increased levels of CRF and improved body composition over 12 weeks to the same extent as supervised exercise sessions, showing that both are equally effective. However, neither the app-based intervention nor the supervised exercise intervention increased MVPA.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 22387524; http://isrctn.com/ISRCTN22387524.

(JMIR Mhealth Uhealth 2020;8(2):e14615) doi:10.2196/14615

KEYWORDS

mobility disability; physical activity; cardiorespiratory fitness; exercise; randomized controlled trial; app; smartphone

Introduction

Background

In Sweden, approximately 23% of the population, between 16 and 84 years of age, reports some kind of disability, whereas 8% of the population suffers from mobility disability (MD), limiting their participation in society and ability to work. Health-related and social welfare costs for individuals with disabilities are the fastest growing expenditure by municipality in Sweden, and this represents 1.6% of the Swedish gross domestic product [1]. Often, individuals with MD suffer from social and health inequalities related to their condition, such as impaired access to health care services or social programs, lower employment rates, and higher risk of chronic diseases [2-4].

Although there are many known health benefits of physical activity (PA) and cardiorespiratory fitness (CRF), such as reduced risk for cardiovascular disease and improvement in markers of metabolic health [5,6], young adults with MD are less likely to engage in PA compared with their able-bodied peers [7,8]. In addition, obesity has been shown to be both a risk factor and a consequence of MD [9,10], and observational studies have shown that individuals with MD are not only more likely to suffer from obesity, but they are also more likely to be negatively impacted by its consequences [10].

Despite the vast amount of research published in the field of PA interventions over the past decades, little attention has been given to interventions aiming to increase PA and CRF among individuals with MD. Nevertheless, interventions focusing on PA and CRF for those with MD may be of particular importance, as there is evidence indicating that PA and CRF can confer additional health benefits for people with MD compared with the general population [11]. Additional evidence for the importance of high CRF in young adulthood comes from a recent prospective study, showing that higher CRF in young adulthood is associated with lower risk for receipt of a disability pension (from, eg, musculoskeletal causes) later in life, in a dose-response manner across all BMI categories [12]. To date, PA interventions targeting individuals with MD are limited to labor-intense supervised health programs targeting the elderly [13].

The few existing studies on PA and MD indicate that motivation for PA is high among individuals with MD and that barriers to PA engagement primarily include accessibility to tailored PA and a lack of knowledge on how to engage in PA [7,14]. Moreover, there is evidence that autonomy, goal setting, surveillance, support, and feedback are important factors for improving and maintaining healthy levels of PA in young adults with MD [14]. Consequently, factors beyond health benefits may be important to target when intervening on levels of PA and CRF in individuals with MD. Given that many people have busy lifestyles but still value access to health behavior programs that provide advice, information, feedback, and self-monitoring around the clock, app-based programs may be an attractive approach [15]. A recent meta-analysis showed modest evidence for effectiveness of smartphone apps to increase PA in the short term (up to 3 months) [16]. However, there is an inconsistency in the literature on the effects from multicomponent versus app-based PA interventions on health outcomes [17]. A preventive app-based PA intervention targeting individuals with MD has the potential to improve levels of PA, CRF, and the general health in this vulnerable group, to avert the progression to more severe disabilities and comorbidities and to thus reduce social and health care inequalities.

Objectives

The aim of this randomized controlled trial (RCT) was to evaluate the effects of commercially available apps compared with a supervised exercise and health program on levels of PA (primary outcome), CRF, and body composition.

Methods

Trial Design

The parallel-group RCT study presented in this paper was designed to examine the effects of an app-based program compared with a supervised exercise and health program on levels of PA. Secondary outcomes included CRF and body composition. The trial has been approved by the Ethical Review Board Stockholm (Dnr: 2017/1206-31/1) and registered in the ISRCTN registry (registration number: ISRCTN22387524) [18]. A detailed description of this trial has been published previously [19].

Participants

Participants were recruited from rehabilitation and primary care centers and from occupational health care within the Stockholm (Sweden) area. Recruitment started in May 2018, and the last 12-week measurements were finished in December 2018. All participants gave written consent before entering the trial. The eligibility criteria comprised the following: both sexes aged 18 to 45 years, who reported having experienced any mobility-related problems affecting their everyday life, for example, problems with dressing, performing household tasks, at transportation, personal hygiene tasks, or at work in the past 3 years before enrollment in the trial. Participants who were bound to a wheelchair or whose medical condition prevented them from moderate-intensity walking, as well as people unable to speak and read Swedish or who did not have access to a smartphone, were excluded.

Randomization

Group assignment was randomly generated, after the baseline measurements, via a block randomization procedure (in blocks of 2 to ensure an equal distribution of participants between the 2 treatment groups), using the SAS Proc Plan (SAS Institute Inc).

Blinding

This was an investigator-blinded study. The nature of the activities in the groups made blinding the participants

unmanageable. The assessment staff members were blinded to the intervention and remained separate from the intervention team. Participants were asked not to disclose their assigned group during the assessments.

Interventions

The treatment arms in the trial were designed with an intrinsic motivation strategy behavior change theory framework [20] to support participants to perform sustained changes in moderate-to-vigorous PA (MVPA) and CRF.

The App-Based Program

The app-based program was a 12-week walking and exercise program, delivered via commercially available smartphone apps, aiming to engage participants in at least 30 min of daily MVPA. Apps used were the Acupedo walking app, with inbuilt goal setting and feedback options, an individually tailored home-based bodyweight exercise app developed by the Swedish Military (FMTK), and the LogMyFood food photography app. Both the Acupedo and the FMTK apps encourage PA that can be detected as MVPA by hip-worn accelerometers. The intervention further included 3 face-to-face consultations, in groups of approximately 20 participants, where information on how to use the apps (session 1 at baseline), goal settings (session 2 at 6 weeks), and motivation to continue exercise (session 3 at 12 weeks) were discussed. At the 12-week follow-up, participants reported how often they had used the apps throughout the intervention (intervention adherence).

The Supervised Health Program

The supervised health program was based on the transtheoretical and sociocognitive models of behavior change [21]. It was a 12-week standard care exercise and health coaching program, delivered by health educators and personal trainers, including 1 weekly exercise session supervised by a personal trainer, with aerobic and strength exercises (a total of 12 sessions) and 3 meetings (baseline, week 6 and 12) with a health educator/dietitian. The personal meetings were based on a behavior change model with 4 core behavior change techniques (mobilizing social support for change, developing self-efficacy, goal setting, and self-monitoring), which are known to be effective in supporting individuals to improve healthy activity and dietary behaviors [22]. Dietary advice given to the participants followed the 4-step Step-wise Weight-determined Accumulative change Plan model [23].

PA goals and exercise programs were individualized and modified in response to baseline levels of CRF (VO_2max), illness, injury, or physical symptoms, in collaboration with the personal trainer. Each personal trainer session also included a short (5-10 min) motivation/feedback part. Participants were moreover encouraged to have an active lifestyle with at least 2 more weekly nonsupervised exercise sessions and to engage in a minimum of 30 min of daily MVPA.

Measurements

Measures on all outcomes were taken at baseline (week 0), midpoint (week 6), and at the end of the intervention (week 12). A Web-based survey was used to collect all questionnaire data. In addition to all outcome measures, the baseline assessment further included self-reported demographic and contact information, medical history, and living habits.

Primary Outcome

The primary outcome, between-group differences in minutes spent in MVPA per day at 12 weeks, was measured objectively, using Actigraph GT3X+ accelerometers, worn on the hip during all waking hours, for 7 consecutive days at each assessment. Sedentary time and light PA (LPA) were also measured by the accelerometer. Management and analyses of PA data followed best-practice and research recommendations [24]. Valid measurements included ≥10 hours wear time per day for ≥4 days. Vector magnitude ($\sqrt{X^2+Y^2+Z^2}$) was analyzed and recorded in 10-second epochs, converted to counts per minute (cpm). Wear time and classification of bouts were computed using ActiLife v.6.13.3, using an algorithm by Choi et al [25], and nonwear time was classified as nonzero counts for at least 60 min, with a maximum break of 2 min. We classified MVPA as more than 3208 cpm [26].

Secondary Outcomes

Cardiorespiratory Fitness

CRF was measured via a submaximal VO_2max test, performed on a stationary bicycle, according to the Ekblom-Bak cycle ergometer test [27], and presented in relative numbers as mL/kg/min.

Body Composition

Fat mass (kg) and fat-free mass (kg) were assessed via bioelectrical impedance [28], using an Omron model HBF-511B-E/HBF-511T-E. The physical tests further included height, weight, and waist circumference, measured by validated instruments, with the participants wearing light clothes to the nearest 0.1 kg and 0.5 cm, respectively.

Power Calculation

Power calculations for the primary outcome, between-group differences in minutes spent in MVPA per day at 12 weeks, were based on a 2-sided log-rank test at the 5% significance level. Under these assumptions, randomization of 80 individuals (40 individuals per group) provides 80% power to detect a between-group difference of 10 min of daily MVPA.

Statistical Analyses

Participant's baseline clinical and demographic characteristics are presented in Table 1, using frequencies and percentages for binary variables and mean and SD for continuous data.

Linear mixed-effect models (LMM) with a random intercept were fitted to estimate the between- and within-group differences for the main and secondary outcomes using time, group allocation, and their interaction as explanatory variables, adjusting for sex, and baseline VO_2max and BMI values as possible confounders in all models. Correlations because of paired data were modeled using an unstructured covariance matrix. To estimate the pairwise changes in each of the groups, correction for multiple tests was performed using the Bonferroni method.

Table 1. Baseline characteristics of the participants by randomization group.

Characteristics	App group (n=55)	Supervised exercise group (n=55)
Age (years), mean (SD)	35.6 (6.2)	34.5 (6.5)
Women, n (%)	47 (85)	43 (78)
Smoking, n (%)		
Daily smoking	3 (5)	2 (3)
Smoking occasionally	11 (20)	5 (9)
Education, n (%)		
Elementary school	3 (5)	2 (3)
High school	12 (21)	14 (25)
University	37 (67)	36 (65)
Moderate-to-vigorous physical activity (min/day), mean (SD)	48.4 (23.3)	40.3 (20.6)
Cardiorespiratory fitness, mean (SD)		
VO_2max, mL/kg/min	36.0 (7.9)	35.3 (8.7)
Body measures, mean (SD)		
Weight, kg	77.6 (20.4)	77.7 (17.3)
Height, cm	171.8 (9.4)	171.0 (9.3)
BMI, kg/m^2	26.3 (5.7)	27.2 (5.2)
Fat mass, kg	27.1 (12.5)	28.3 (11.9)
Fat-free mass, kg	49.1 (8.4)	51.4 (10.6)
Waist circumference, cm	86.9 (18.3)	84.6 (11.7)

No imputation of missing data was performed, and the mechanism of missing data is assumed to be at random, that is, missing data are not dependent on unobserved confounders. Given that LMM uses all the available information at baseline to calculate individual effects, estimations are also made for those lost to follow-up [29].

For the primary analysis, intention-to-treat analysis was conducted [19], on individuals according to group randomization [30]. We also ran per-protocol analyses, including those in the app group, who used the apps ≥5 days per week, and those in the supervised exercise group, who attended ≥10 exercise sessions. Further sensitivity analyses included comparisons of baseline characteristics of participants lost to follow-up by randomization group and by dropouts.

All statistical tests were calculated using a 2-tailed .05 significance level.

BMI was calculated as weight (kg)/height $(m)^2$. For MVPA and CRF, within- and between-group trajectories (from baseline to week 6 and 12) were calculated from a repeated measure mixed-effects model (time × group interactions) to explore the differences in MVPA and CRF at each time point between the groups. Change variables were created for between-group comparisons on changes in the primary and secondary outcomes from baseline to 6 and 12 weeks, respectively. All statistical analyses were performed using Stata/IC 15.1.

Consent for Publication

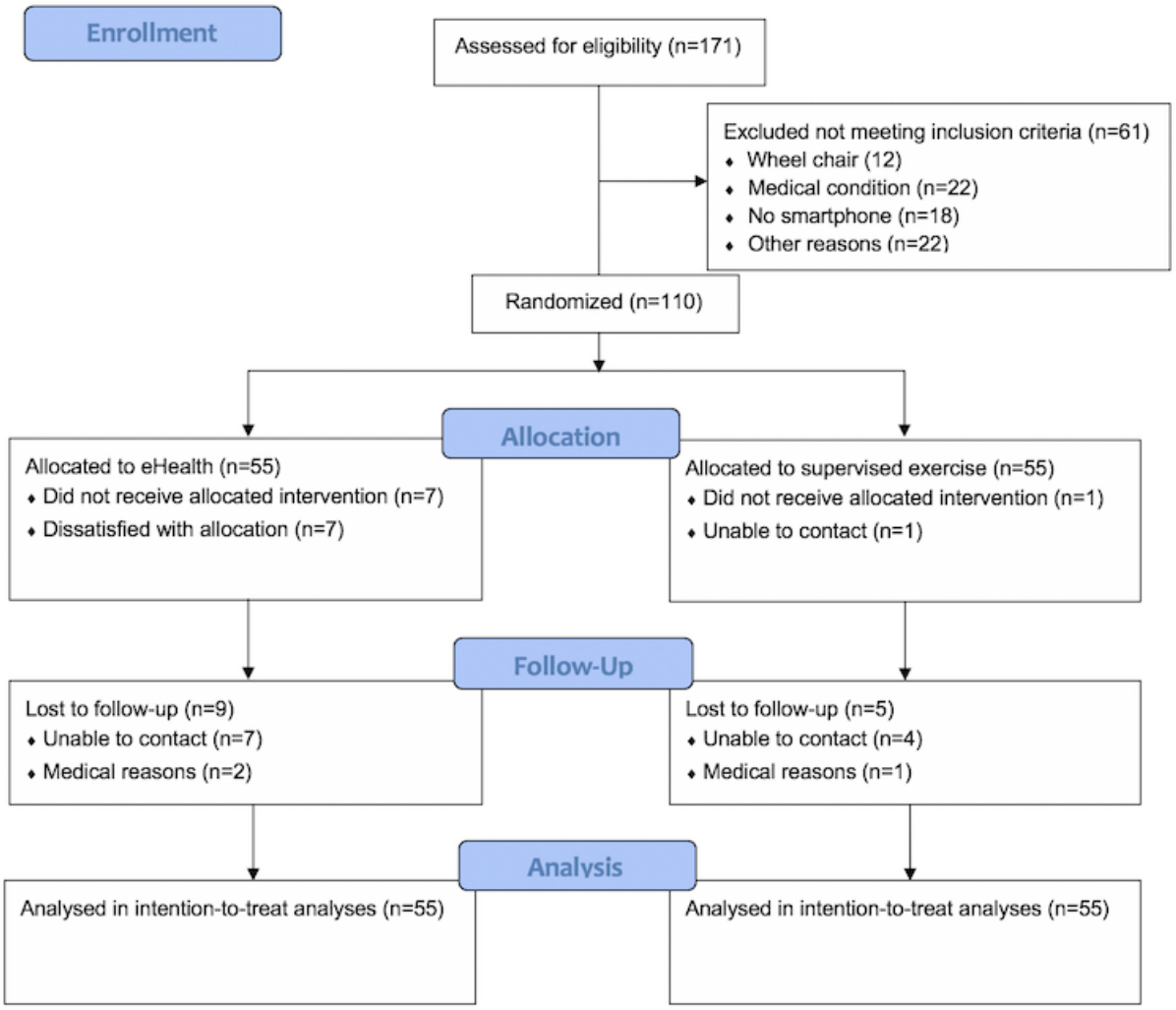
Published data will not contain any personal identification numbers. Thus, no single individual participating in the trial can be identified by published results.

Results

Study Participants

A participant flow diagram is shown in Figure 1. In total, 171 individuals were assessed for eligibility, of whom 61 were excluded because of being bound to a walker or wheelchair (n=12), having any medical condition not permitting moderate-intensity walking (n=22), not having access to a smartphone (n=18), or other reasons (n=10).

Figure 1. Flow chart according to Consolidated Standards for Reporting of Trials. eHealth: electronic health.



Intervention Adherence

A total of 36% (20/55) participants in the app group used the apps daily, 31% (17/55) for 5 to 6 days/week, 14% (8/55) for 3 to 4 days/week, and 19% (10/55) for less than 3 times/week. In the supervised exercise group, 45% (25/55) of the participants attended all 12 personal trainer exercise sessions, 29% (16/55) attended 11 exercise sessions, 7% (4/55) attended 10 exercise sessions, and the remaining 19% (10/55) attended 4 to 9 exercise sessions.

Participant's Baseline Characteristics

Baseline characteristics of the participants by randomization group are shown in Table 1. No differences were found between the groups with regard to baseline characteristics. A majority of the participants met the daily recommended minimal PA guideline of ≥150 min of MVPA/week [31]. Accelerometer wear time did not differ between the groups, 14.5 (SD 1.3) h/day and 14.1 (SD 1.1) h/day in the app and supervised exercise group, respectively. All the included participants reported mobility-related problems affecting their everyday life, and 88.2% of the participants reported a chronic illness defined as "problems causing work ability to be impaired or hindering other daily lives pursuits."

Between-Group Differences at 6 and 12 weeks

Between-group differences at 6 and 12 weeks in the primary outcome (MVPA) and secondary outcomes are shown in Figures 2 and 3 and in Table 2. No significant differences, except for waist circumference, were found between the groups for any of the outcomes at 12 weeks. Accelerometer wear time did not differ between the groups at 6 weeks—14.3 (SD 1.5) h/day and 14.4 (SD 1.4) h/day in the app and supervised exercise group, respectively—and 12 weeks—14.6 (SD 1.5) h/day and 14.5 (SD 1.4) h/day in the app and supervised exercise group, respectively. A total of 90% (41/45) and 92% (46/50) of participants in the app and supervised exercise group, respectively, met the PA recommendations at 12 weeks.

Figure 2. Levels of moderate-to-vigorous physical activity at each time point between the groups. Adjusted for sex, BMI, and maximal oxygen uptake (VO_2max). MVPA: moderate-to-vigorous physical activity.

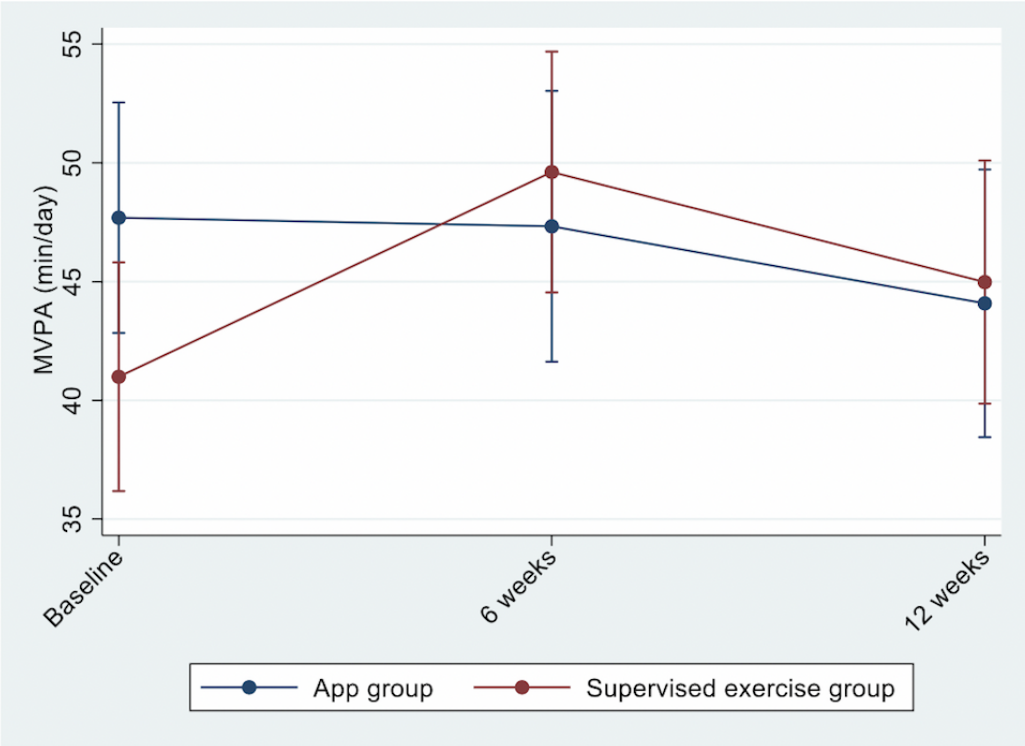


Figure 3. Levels of cardiorespiratory fitness (VO_2max) at each time point between the groups. Adjusted for sex, BMI, and VO_2max. MVPA: moderate-to-vigorous physical activity. VO_2max: maximal oxygen uptake.

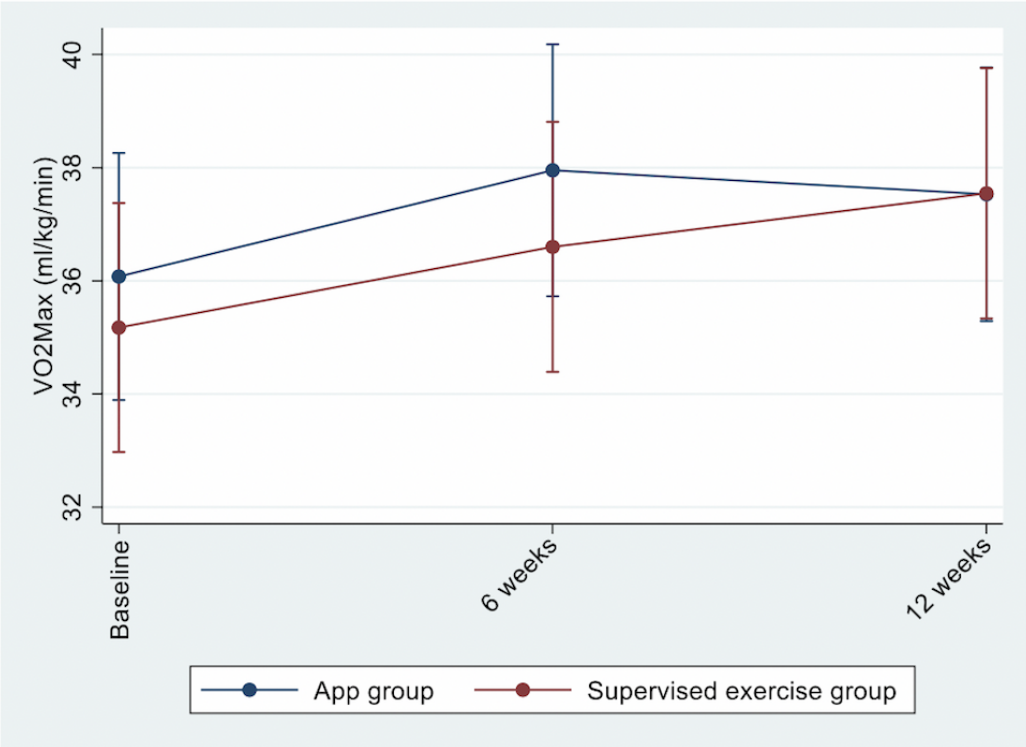


Table 2. Results of the intention-to-treat analysis. Mean difference of primary and secondary outcomes between the app group and the supervised exercise group, as well as within each treatment group (adjusted for sex, body mass index, and VO_2max; pairwise comparisons are adjusted using Bonferroni correction).

Outcomes	Between-group differences[a], beta coefficient, Δ (0 to 12 weeks)	Within-group differences			
		App group		Supervised exercise group	
		Beta coefficient, Δ (0 to 6 weeks)	Beta coefficient, Δ (0 to 12 weeks)	Beta coefficient, Δ (0 to 6 weeks)	Beta coefficient, Δ (0 to 12 weeks)
Moderate-to-vigorous physical activity, min/day	–5.71 (–12.91 to 1.47)	–2.25 (–10.40 to 5.90)	–6.17 (–14.28 to 1.95)	6.60 (–0.74 to 13.90)	1.37 (–6.06 to 8.81)
VO_2max, mL/kg/min	–0.53 (–2.40 to 1.34)	*1.32 (0.13 to 2.52)* [b]	1.07 (–0.14 to 2.27)	1.00 (–0.07 to 2.07)	*1.76 (0.70 to 2.83)* [c]
Weight, kg	–2.17 (–4.75 to 0.42)	0.15 (–0.35 to 0.66)	–0.03 (–0.53 to 0.47)	0.28 (–0.17 to 0.72)	–0.02 (–0.49 to 0.45)
BMI, kg/m^2	0.86 (–1.02 to 2.73)	–0.09 (–0.43 to 0.27)	–0.19 (–0.54 to 0.16)	–0.16 (–0.46 to 0.15)	*–0.40 (–0.72 to–0.07)*[d]
Fat mass, kg	–0.86 (–2.00 to 0.28)	–0.01 (–0.90 to 0.92)	0.20 (–0.72 to 1.20)	0.32 (–0.50 to 1.13)	*0.92 (0.09 to 1.75)* [b]
Fat-free mass, kg	–0.34 (–2.67 to 1.99)	0.77 (–0.65 to 2.19)	0.52 (–0.93 to 1.96)	–0.08 (–1.35 to 1.20)	–1.24 (–2.54 to 0.06)
Waist circumference, cm	*–4.27 (–7.78 to –0.76)*[b]	–0.16 (–1.90 to 1.57)	–0.75 (–2.49 to 0.99)	1.10 (–0.44 to 2.64)	–0.76 (–2.34 to 0.82)

[a]Reference: supervised exercise group.

[b]$P<.05$.

[c]$P<.001$.

[d]$P<.01$.

For the main outcome of MVPA, there was a nonsignificant reduction after 12 weeks of intervention, and no significant difference between the groups was observed. With respect to the secondary outcomes, there was a significant increase in CRF in both groups, but no significant difference between the treatment groups.

Changes in Outcomes From Baseline to 6 and 12 Weeks Within the Groups

Pairwise comparison of the changes in primary and secondary outcomes at 6 weeks and 12 weeks by randomization group are shown in Table 2. Participants in the supervised exercise group increased their levels of MVPA by 8%, whereas participants in the app group decreased their MVPA by 9%. VO_2max increased significantly, from baseline to 12 weeks, in both groups, 4% in the app group and 7% in the supervised exercise group. In the app group, 33 (33/38, 87%) participants met the PA recommendations at both baseline and 12 weeks, 2 (2/38, 5%) participants went from not meeting to meeting the PA recommendations, and 3 (3/38, 8%) participants went from meeting to not meeting the PA recommendations. In the supervised exercise group, 42 (42/50, 84%) participants met the PA recommendations at both baseline and 12 weeks, 6 (6/50, 12%) participants went from not meeting to meeting the PA recommendations, and 2 (2/50, 4%) participants went from meeting to not meeting the PA recommendations. Both groups showed decreases in weight and waist circumference from baseline to 12 weeks. However, only participants in the app group decreased their fat-free mass from baseline to 12 weeks.

Per-Protocol Analyses

Per-protocol analyses included those in the app group, who used the apps ≥5 days per week (20/39, 51%), and those in the supervised exercise group, who attended ≥10 exercise sessions (45/49, 92%). These analyses showed that those in the app group had a significantly higher VO_2max and lower BMI, waist circumference, and fat-mass compared with those in the supervised exercise group at 6 and 12 weeks. However, participants in the app group did not show any significant improvements from baseline to 6 and 12 weeks for any of the measured variables (Multimedia Appendix 1).

Sensitivity Analyses

Between-group differences from baseline to 12 weeks in the primary and secondary outcomes, including participants with complete data at 12 weeks (n=39 for the app group and n=49 for the supervised exercise group), showed similar results as the intention-to-treat analysis (Multimedia Appendix 1). There were no between-group differences in baseline characteristics of participants lost to follow-up by randomization group (Multimedia Appendix 1) and by dropouts (Multimedia Appendix 1).

Adverse Events

A total of 2 participants (1 in the app group and 1 in the supervised exercise group) cancelled participation in the trial because of illness. However, none of these illnesses were related to the intervention.

Discussion

Principal Findings

This single-centered RCT aimed to compare the effect of an app-based program and supervised exercise and health program among people with mild-to-moderate MD. We found a moderate increase in CRF after 12 weeks of follow-up in both groups. There was no significant difference between groups in our main outcome, time spent in MVPA, nor in CRF measured by VO_2max or most measurements of body composition (weight, BMI, fat mass, and fat-free mass). Participants randomized to the app-based intervention had a significantly lower waist circumference after 12 weeks of follow-up in the intention-to-treat analysis. However, the per-protocol analysis showed a significant difference in CRF and BMI between groups. The app-based intervention group had a lower BMI and higher CRF after 12 weeks of follow-up. Thus, a health program using commercially available health apps is a feasible intervention to improve health among people with mild-to-moderate MD.

Comparison With Previous Work

Current systematic review data indicate that app-based interventions to improve PA can be effective and that multicomponent interventions appear to be more effective than stand-alone app interventions [17]. However, there is a lack of randomized trials, and most previous studies have included older populations [32] or relied on self-reported measures of PA [17]. The discrepancy between self-reported and objectively measured PA is well established [33], and several app-based PA intervention studies show substantial increases in self-reported PA but not objectively (accelerometer) measured PA [34,35]. This lack of uniformity, in combination with the inaccuracy of self-reported data as a measure of PA, makes it difficult to compare and summarize outcomes across PA interventions.

PA interventions, using objective measures of PA, targeting individuals with MD are scarce. The LIFE intervention randomized 1635 sedentary 70- to 89-year-old men and women with MD to an exercise program, with supervised exercise 2 times per week and home-based exercise 3 to 4 times per week, or to a health educator program comprising workshops on topics relevant to older adults [13]. Through 2 years of follow-up, participants in the exercise group participated in an additional 40 min of light-intensity PA per week, assessed by accelerometry, compared with the health educator group. The between-group differences in self-reported PA were 104 min per week. This discrepancy between self-reported and objectively measured PA further highlights the importance to incorporate objective measures when evaluating the effectiveness of PA interventions [36]. Transferability of results from the LIFE study to this study is limited for several reasons. The LIFE study included an older population and did not assess time in MVPA or CRF, which has shown stronger associations to health outcomes in isotemporal substitution studies compared with LPA [37].

Meta-analysis data, including 12 RCTs, show that 3 aerobic/strength exercise sessions per week, for 30 to 60 min per session, can increase VO_2max by approximately 2.3 mL/kg/min [25]. Furthermore, supervised exercise 3 times per week has shown to increase VO_2max by approximately 6% over 12 weeks in adults [38]. This is somewhat comparable with the 2.5 mL/kg/min (7%) increase in VO_2max seen in this study, with only 1 supervised 60-min aerobic/strength exercise session per week.

Implications

Although the changes in PA were inconclusive, the changes in CRF (1.3 and 2.5 mL/min/kg increases in VO_2max for the app group and supervised exercise group, respectively) may translate into substantial long-term health benefits. In fact, a 1 mL/min/kg increase in VO_2max is associated with a 9% relative risk reduction of all-cause mortality (hazard ratio, 0.91; 95% CI 0.87 to 0.95) [39], which is a similar effect as a 10 cm reduction in waist circumference or a 10 mm/Hg reduction in systolic blood pressure [40]. Even though PA has effects on mortality independent of CRF, the opposite also holds true [41]. This further highlights the importance of the CRF improvements seen in this study. In addition, both protocols reduced waist circumference, fat mass, and BMI over 12 weeks, which are all important markers of health.

At baseline, participants in both groups had a slightly higher VO_2max and were substantially more active (>80% of the participants meeting the PA recommendations) compared with the general Swedish population [42-44]. This may, to some extent, explain why participants in both groups did not increase PA over the intervention period. Moreover, as further discussed in the Strengths and Limitations section, the high levels of PA at baseline may limit generalizability of findings in this study to the general population with MD [7].

The app intervention was designed to be simple for widespread implementation in a variety of communities and settings, as it requires no special equipment or previous exercise knowledge. Although apps have the potential to increase the reach of health behavior change interventions, our results mirror the recent research showing that few individuals will use an offered app consistently over time [45]. Surprisingly, those who used the app ≥5 times/week did not show greater changes in any measured variables, from baseline to 12 weeks, compared with those who used the apps less frequently. Instead, the per-protocol analyses showed that those who used the apps more frequently had higher baseline levels of CRF and lower fat mass and BMI; thus, there was less room for improvements.

Strengths and Limitations

A major strength of this study was the use of an RCT design to determine the effect of the use of commercially available apps compared with supervised exercise. Use of the apps during the intervention was ad libitum and not closely monitored, which reflects real-life app use, and contact with participants in the app group was minimal to reflect a real-world context and therefore increase generalizability. Furthermore, the primary and secondary outcomes were measured with objective measurements, in accordance with current recommendations

for evaluating the effectiveness of PA interventions [36], which further adds to the study's internal validity. Unlike the high attrition rate commonly observed in PA interventions, follow-up assessments were completed for 80% of participants, which represents a fairly high retention rate. As the study participants were aware of the study when they performed the baseline measurements of PA, it is most likely that they were more physically active than usual, which limits the comparison of baseline and outcome for PA measures. However, the CRF measures are reliable from baseline.

Some limitations of this study should be acknowledged. First, as participants were self-recruited from the community, they may not be fully representative of all people with MD, as shown by the high baseline levels of PA among the participants. Using free apps, instead of paid apps, may have increased contamination and/or cointerventions. There are also some limitations regarding our data collection. The participants began the intervention between December and May. Thus, changes in weather condition might have affected the levels of PA. However, there are data indicating that accelerometer-measured levels of PA may not be significantly affected by seasonality in populations living in high latitudes, such as Sweden [43]. In addition, we considered all valid MVPA observations from participants who provided 4 or more days of valid accelerometer data without considering the difference between weekdays and weekends. Both issues might introduce some bias in our analysis which, assuming successful randomization, would underestimate the effect of the intervention increasing the chance of type 2 error. Furthermore, the use of readily available apps precluded access to data on app utilization (we used self-reported data on app use).

The higher dropout in the app group (n=16), compared with the supervised exercise group (n=6), limited the statistical power to detect between-group differences. The initial power calculations were based on at least 40 participants, with measures on the primary outcome MVPA, in each group (n=39 in the app group at 12 weeks). However, 44% of the dropouts in the app group occurred directly after the randomization process because of dissatisfaction with the group allocation. Finally, the lack of a passive control group made it impossible to draw conclusions on whether apps can improve PA and CRF compared with not using apps. However, as stated in the aim of the study, the hypothesis of the study was to test to what extent commercially available apps can provide effects on PA and CRF compared with supervised exercise.

Conclusions

Commercially available apps increased levels of CRF and improved body composition over 12 weeks to the same extent as supervised exercise sessions. However, neither the app-based intervention nor the supervised exercise intervention increased MVPA.

Given the high degree of smartphone use in the population, the fact that an app-based intervention has the potential to increase reach at a low cost and the substantial health effects associated with an increased CRF [12,39], this intervention may be an alternative approach to increase physical health–related outcomes in individuals with mild-to-moderate MD.

Acknowledgments

The authors would like to acknowledge the participants, who gave time to take part in the study, and personnel from TWITCH Health Capital AB for help with the measures within the trial. This study was funded by the Swedish Research Council for Health, Working Life and Welfare (FORTE).

Authors' Contributions

DB contributed to study design, manuscript writing, and statistical analyses. DYM contributed to statistical analyses and manuscript editing. CL contributed to data interpretation and manuscript editing. YF contributed to study design, data interpretation, and manuscript editing. All authors have read and approved the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Tables, including appendix tables.
[DOCX File , 28 KB - mhealth_v8i2e14615_app1.docx]

References

1. The National Board of Health and Welfare. WHO MiNDbank. 2009. Swedish disability policy – service and care for people with functional impairments URL: https://www.mindbank.info/item/1201 [accessed 2019-11-22]
2. World Health Organization. World Report on Disability. Geneva, Switzerland: World Health Organization; 2011.
3. Ciol MA, Rasch EK, Hoffman JM, Huynh M, Chan L. Transitions in mobility, ADLs, and IADLs among working-age Medicare beneficiaries. Disabil Health J 2014 Apr;7(2):206-215 [FREE Full text] [doi: 10.1016/j.dhjo.2013.10.007] [Medline: 24680050]

4. Carroll DD, Courtney-Long EA, Stevens AC, Sloan ML, Lullo C, Visser SN, Centers for Disease ControlPrevention (CDC). Vital signs: disability and physical activity--United States, 2009-2012. MMWR Morb Mortal Wkly Rep 2014 May 9;63(18):407-413 [FREE Full text] [Medline: 24807240]
5. Warburton DE, Nicol CW, Bredin SS. Health benefits of physical activity: the evidence. Can Med Assoc J 2006 Mar 14;174(6):801-809 [FREE Full text] [doi: 10.1503/cmaj.051351] [Medline: 16534088]
6. McKinney J, Lithwick D, Morrison B, Nazzari H, Isserow S, Heilbron B. The health benefits of physical activity and cardiorespiratory fitness. B C Med J 2016 Apr;58(3):131-137 [FREE Full text]
7. Saebu M, Sørensen M. Factors associated with physical activity among young adults with a disability. Scand J Med Sci Sports 2011 Oct;21(5):730-738. [doi: 10.1111/j.1600-0838.2010.01097.x] [Medline: 20459465]
8. de Hollander EL, Proper KI. Physical activity levels of adults with various physical disabilities. Prev Med Rep 2018 Jun;10:370-376 [FREE Full text] [doi: 10.1016/j.pmedr.2018.04.017] [Medline: 29755934]
9. de Munter JS, Tynelius P, Ahlström G, Rasmussen F. The bidirectional association between body weight and mobility disability: a population-based cohort. Disabil Health J 2016 Oct;9(4):632-637. [doi: 10.1016/j.dhjo.2016.06.001] [Medline: 27528493]
10. Deshpande N, Metter EJ, Guralnik J, Bandinelli S, Ferrucci L. Predicting 3-year incident mobility disability in middle-aged and older adults using physical performance tests. Arch Phys Med Rehabil 2013 May;94(5):994-997 [FREE Full text] [doi: 10.1016/j.apmr.2012.10.032] [Medline: 23164980]
11. van der Ploeg HP, van der Beek AJ, van der Woude LH, van Mechelen W. Physical activity for people with a disability: a conceptual model. Sports Med 2004;34(10):639-649. [doi: 10.2165/00007256-200434100-00002] [Medline: 15335241]
12. Henriksson P, Henriksson H, Tynelius P, Berglind D, Löf M, Lee I, et al. Fitness and body mass index during adolescence and disability later in life: a cohort study. Ann Intern Med 2019 Feb 19;170(4):230-239 [FREE Full text] [doi: 10.7326/M18-1861] [Medline: 30743265]
13. Pahor M, Guralnik JM, Ambrosius WT, Blair S, Bonds DE, Church TS, LIFE study investigators. Effect of structured physical activity on prevention of major mobility disability in older adults: the LIFE study randomized clinical trial. J Am Med Assoc 2014 Jun 18;311(23):2387-2396 [FREE Full text] [doi: 10.1001/jama.2014.5616] [Medline: 24866862]
14. Saebu M, Sørensen M, Halvari H. Motivation for physical activity in young adults with physical disabilities during a rehabilitation stay: a longitudinal test of self-determination theory. J Appl Soc Psychol 2013;43(3):612-625. [doi: 10.1111/j.1559-1816.2013.01042.x]
15. Dennison L, Morrison L, Conway G, Yardley L. Opportunities and challenges for smartphone applications in supporting health behavior change: qualitative study. J Med Internet Res 2013 Apr 18;15(4):e86 [FREE Full text] [doi: 10.2196/jmir.2583] [Medline: 23598614]
16. Romeo A, Edney S, Plotnikoff R, Curtis R, Ryan J, Sanders I, et al. Can smartphone apps increase physical activity? Systematic review and meta-analysis. J Med Internet Res 2019 Mar 19;21(3):e12053 [FREE Full text] [doi: 10.2196/12053] [Medline: 30888321]
17. Schoeppe S, Alley S, van Lippevelde W, Bray NA, Williams SL, Duncan MJ, et al. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. Int J Behav Nutr Phys Act 2016 Dec 7;13(1):127 [FREE Full text] [doi: 10.1186/s12966-016-0454-y] [Medline: 27927218]
18. ISRCTN Registry. 2018. A Randomized Controlled Trial Evaluating Effects on Health for Individuals With Mobility Disability: eHealth vs Standard Care URL: http://www.isrctn.com/ISRCTN22387524 [accessed 2019-11-22]
19. Berglind D, Nyberg G, Willmer M, Persson M, Wells M, Forsell Y. An eHealth program versus a standard care supervised health program and associated health outcomes in individuals with mobility disability: study protocol for a randomized controlled trial. Trials 2018 Apr 27;19(1):258 [FREE Full text] [doi: 10.1186/s13063-018-2646-z] [Medline: 29703242]
20. Foster C, Richards J, Thorogood M, Hillsdon M. Remote and web 2.0 interventions for promoting physical activity. Cochrane Database Syst Rev 2013 Sep 30;9:CD010395. [doi: 10.1002/14651858.CD010395.pub2] [Medline: 24085594]
21. Bandura A. Health promotion by social cognitive means. Health Educ Behav 2004 Apr;31(2):143-164. [doi: 10.1177/1090198104263660] [Medline: 15090118]
22. Teixeira PJ, Carraça EV, Marques MM, Rutter H, Oppert J, de Bourdeaudhuij I, et al. Successful behavior change in obesity interventions in adults: a systematic review of self-regulation mediators. BMC Med 2015 Apr 16;13:84 [FREE Full text] [doi: 10.1186/s12916-015-0323-6] [Medline: 25907778]
23. Huseinovic E, Winkvist A, Bertz F, Brekke HK. Changes in food choice during a successful weight loss trial in overweight and obese postpartum women. Obesity (Silver Spring) 2014 Dec;22(12):2517-2523 [FREE Full text] [doi: 10.1002/oby.20895] [Medline: 25234605]
24. Migueles JH, Cadenas-Sanchez C, Ekelund U, Delisle Nyström C, Mora-Gonzalez J, Löf M, et al. Accelerometer data collection and processing criteria to assess physical activity and other outcomes: a systematic review and practical considerations. Sports Med 2017 Sep;47(9):1821-1845 [FREE Full text] [doi: 10.1007/s40279-017-0716-0] [Medline: 28303543]
25. Marsden DL, Dunn A, Callister R, Levi CR, Spratt NJ. Characteristics of exercise training interventions to improve cardiorespiratory fitness after stroke: a systematic review with meta-analysis. Neurorehabil Neural Repair 2013;27(9):775-788. [doi: 10.1177/1545968313496329] [Medline: 23884014]

26. Santos-Lozano A, Santín-Medeiros F, Cardon G, Torres-Luque G, Bailón R, Bergmeir C, et al. Actigraph GT3X: validation and determination of physical activity intensity cut points. Int J Sports Med 2013 Nov;34(11):975-982. [doi: 10.1055/s-0033-1337945] [Medline: 23700330]
27. Björkman F, Ekblom-Bak E, Ekblom Ö, Ekblom B. Validity of the revised Ekblom Bak cycle ergometer test in adults. Eur J Appl Physiol 2016 Sep;116(9):1627-1638 [FREE Full text] [doi: 10.1007/s00421-016-3412-0] [Medline: 27311582]
28. Kyle UG, Genton L, Karsegard L, Slosman DO, Pichard C. Single prediction equation for bioelectrical impedance analysis in adults aged 20--94 years. Nutrition 2001 Mar;17(3):248-253. [doi: 10.1016/s0899-9007(00)00553-0] [Medline: 11312069]
29. Fitzmaurice GM, Laird NM, Ware JH. Applied Longitudinal Analysis. Hoboken, NJ: Wiley; 2012.
30. Alshurafa M, Briel M, Akl EA, Haines T, Moayyedi P, Gentles SJ, et al. Inconsistent definitions for intention-to-treat in relation to missing outcome data: systematic review of the methods literature. PLoS One 2012;7(11):e49163 [FREE Full text] [doi: 10.1371/journal.pone.0049163] [Medline: 23166608]
31. Powell KE, King AC, Buchner DM, Campbell WW, DiPietro L, Erickson KI, et al. The scientific foundation for the physical activity guidelines for Americans, 2nd edition. J Phys Act Health 2018 Dec 17:1-11. [doi: 10.1123/jpah.2018-0618] [Medline: 30558473]
32. Muellmann S, Forberger S, Möllers T, Bröring E, Zeeb H, Pischke CR. Effectiveness of eHealth interventions for the promotion of physical activity in older adults: a systematic review. Prev Med 2018 Mar;108:93-110. [doi: 10.1016/j.ypmed.2017.12.026] [Medline: 29289643]
33. Schuna JM, Johnson WD, Tudor-Locke C. Adult self-reported and objectively monitored physical activity and sedentary behavior: NHANES 2005-2006. Int J Behav Nutr Phys Act 2013 Nov 11;10:126 [FREE Full text] [doi: 10.1186/1479-5868-10-126] [Medline: 24215625]
34. Marsaux CF, Celis-Morales C, Fallaize R, Macready AL, Kolossa S, Woolhead C, et al. Effects of a web-based personalized intervention on physical activity in European adults: a randomized controlled trial. J Med Internet Res 2015 Oct 14;17(10):e231 [FREE Full text] [doi: 10.2196/jmir.4660] [Medline: 26467573]
35. Wanner M, Martin-Diener E, Braun-Fahrländer C, Bauer G, Martin BW. Effectiveness of active-online, an individually tailored physical activity intervention, in a real-life setting: randomized controlled trial. J Med Internet Res 2009 Jul 28;11(3):e23 [FREE Full text] [doi: 10.2196/jmir.1179] [Medline: 19666456]
36. Silfee VJ, Haughton CF, Jake-Schoffman DE, Lopez-Cepero A, May CN, Sreedhara M, et al. Objective measurement of physical activity outcomes in lifestyle interventions among adults: a systematic review. Prev Med Rep 2018 Sep;11:74-80 [FREE Full text] [doi: 10.1016/j.pmedr.2018.05.003] [Medline: 29984142]
37. Grgic J, Dumuid D, Bengoechea EG, Shrestha N, Bauman A, Olds T, et al. Health outcomes associated with reallocations of time between sleep, sedentary behaviour, and physical activity: a systematic scoping review of isotemporal substitution studies. Int J Behav Nutr Phys Act 2018 Jul 13;15(1):69 [FREE Full text] [doi: 10.1186/s12966-018-0691-3] [Medline: 30001713]
38. Storer TW, Dolezal BA, Berenc MN, Timmins JE, Cooper CB. Effect of supervised, periodized exercise training vs self-directed training on lean body mass and other fitness variables in health club members. J Strength Cond Res 2014 Jul;28(7):1995-2006. [doi: 10.1519/JSC.0000000000000331] [Medline: 24276303]
39. Laukkanen JA, Zaccardi F, Khan H, Kurl S, Jae SY, Rauramaa R. Long-term change in cardiorespiratory fitness and all-cause mortality: a population-based follow-up study. Mayo Clin Proc 2016 Sep;91(9):1183-1188. [doi: 10.1016/j.mayocp.2016.05.014] [Medline: 27444976]
40. Kodama S, Saito K, Tanaka S, Maki M, Yachi Y, Asumi M, et al. Cardiorespiratory fitness as a quantitative predictor of all-cause mortality and cardiovascular events in healthy men and women: a meta-analysis. J Am Med Assoc 2009 May 20;301(19):2024-2035. [doi: 10.1001/jama.2009.681] [Medline: 19454641]
41. Davidson T, Vainshelboim B, Kokkinos P, Myers J, Ross R. Cardiorespiratory fitness versus physical activity as predictors of all-cause mortality in men. Am Heart J 2018 Feb;196:156-162. [doi: 10.1016/j.ahj.2017.08.022] [Medline: 29421008]
42. Ekblom-Bak E, Ekblom Ö, Andersson G, Wallin P, Söderling J, Hemmingsson E, et al. Decline in cardiorespiratory fitness in the Swedish working force between 1995 and 2017. Scand J Med Sci Sports 2019 Feb;29(2):232-239. [doi: 10.1111/sms.13328] [Medline: 30351472]
43. Hagströmer M, Rizzo NS, Sjöström M. Associations of season and region on objectively assessed physical activity and sedentary behaviour. J Sports Sci 2014;32(7):629-634. [doi: 10.1080/02640414.2013.844349] [Medline: 24102558]
44. Hagströmer M, Troiano RP, Sjöström M, Berrigan D. Levels and patterns of objectively assessed physical activity--a comparison between Sweden and the United States. Am J Epidemiol 2010 May 15;171(10):1055-1064. [doi: 10.1093/aje/kwq069] [Medline: 20406758]
45. Helander E, Kaipainen K, Korhonen I, Wansink B. Factors related to sustained use of a free mobile app for dietary self-monitoring with photography and peer feedback: retrospective cohort study. J Med Internet Res 2014 Apr 15;16(4):e109 [FREE Full text] [doi: 10.2196/jmir.3084] [Medline: 24735567]

Abbreviations

cpm: counts per minute

CRF: cardiorespiratory fitness
LMM: linear mixed-effect models
LPA: light physical activity
MD: mobility disability
MVPA: moderate-to-vigorous physical activity
PA: physical activity
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 05.05.19; peer-reviewed by G Signorelli, D Bond; comments to author 03.10.19; revised version received 14.10.19; accepted 22.10.19; published 04.02.20.

Please cite as:
Berglind D, Yacaman-Mendez D, Lavebratt C, Forsell Y
The Effect of Smartphone Apps Versus Supervised Exercise on Physical Activity, Cardiorespiratory Fitness, and Body Composition Among Individuals With Mild-to-Moderate Mobility Disability: Randomized Controlled Trial
JMIR Mhealth Uhealth 2020;8(2):e14615
URL: https://mhealth.jmir.org/2020/2/e14615
doi:10.2196/14615
PMID:32014846

Original Paper

Push Notifications From a Mobile App to Improve the Body Composition of Overweight or Obese Women: Randomized Controlled Trial

Alberto Hernández-Reyes[1*], MSc; Fernando Cámara-Martos[1*], PhD; Guillermo Molina Recio[2*], PhD; Rafael Molina-Luque[2*], MSc; Manuel Romero-Saldaña[3*], PhD; Rafael Moreno Rojas[1*], PhD

[1]Department of Bromatology and Food Technology, University of Córdoba, Córdoba, Spain

[2]Department of Nursing, School of Medicine and Nursing, University of Córdoba, Córdoba, Spain

[3]Department of Occupational Safety and Health, Córdoba City Hall, Córdoba, Spain

[*]all authors contributed equally

Corresponding Author:
Alberto Hernández-Reyes, MSc
Department of Bromatology and Food Technology
University of Córdoba
Campus Rabanales, Ed Darwin - Anexo
Córdoba, 14014
Spain
Phone: 34 957212001
Fax: 34 957212000
Email: hdezreyes2013@gmail.com

Abstract

Background: Technology—in particular, access to the Internet from a mobile device—has forever changed the way we relate to others and how we behave in our daily life settings. In recent years, studies have been carried out to analyze the effectiveness of different actions via mobile phone in the field of health: telephone calls, short message service (SMS), telemedicine, and, more recently, the use of push notifications. We have continued to explore ways to increase user interaction with mobile apps, one of the pending subjects in the area of mHealth. By analyzing the data produced by subjects during a clinical trial, we were able to extract behavior patterns and, according to them, design effective protocols in weight loss programs.

Objective: A clinical trial was proposed to (1) evaluate the efficacy of push notifications in an intervention aimed at improving the body composition of adult women who are overweight or obese, through a dietary procedure, and (2) analyze the evolution of body composition based on push notifications and prescribed physical activity (PA).

Methods: A two-arm randomized controlled trial was carried out. A sample size of 117 adult obese women attended a face-to-face, 30-minute consultation once a week for 6 months. All patients were supplied with an app designed for this study and a pedometer. The control group did not have access to functionalities related to the self-monitoring of weight at home, gamification, or prescription of PA. The intervention group members were assigned objectives to achieve a degree of compliance with diet and PA through exclusive access to specific functionalities of the app and push notifications. The same diet was prescribed for all patients. Three possible PA scenarios were studied for both the control and intervention groups: light physical activity (LPA), moderate physical activity (MPA), and intense physical activity (IPA). For the analysis of three or more means, the analysis of variance (ANOVA) of repeated means was performed to evaluate the effects of the intervention at baseline and at 3 and 6 months.

Results: Receiving notifications during the intervention increased body fat loss (mean -12.9% [SD 6.7] in the intervention group vs mean -7.0% [SD 5.7] in the control group; $P<.001$) and helped to maintain muscle mass (mean -0.8% [SD 4.5] in the intervention group vs mean -3.2% [SD 2.8] in the control group; $P<.018$). These variations between groups led to a nonsignificant difference in weight loss (mean -7.9 kg [SD 3.9] in the intervention group vs mean -7.1 kg [SD 3.4] in the control group; $P>.05$).

Conclusions: Push notifications have proven effective in the proposed weight loss program, leading women who received them to achieve greater loss of fat mass and a maintenance or increase of muscle mass, specifically among those who followed a program of IPA. Future interventions should include a longer evaluation period; the impact of different message contents, as well as message delivery times and frequency, should also be researched.

Trial Registration: ClinicalTrials.gov NCT03911583; https://www.clinicaltrials.gov/ct2/show/NCT03911583

(JMIR Mhealth Uhealth 2020;8(2):e13747) doi:10.2196/13747

KEYWORDS

exercise; text message; mobile phone; mHealth; health behavior; behavior maintenance; physical activity; push

Introduction

Mobile technology can be considered as being fundamental to our lives. Its presence is ubiquitous; estimates in 2019 have suggested that there will be around 4.1 billion intelligent devices globally, between mobile phones and tablets [1]. Furthermore, the wearable market is also a promising one, since the number of wearable devices connected worldwide is expected to jump to over 1.1 billion in 2022, while telecom technology will change from 4G to 5G [2]. Furthermore, this fact has changed the way we relate to each other, live, and work [3]. In 2014 there was a turning point in connectivity; for the first time, the amount of browsing through mobile devices exceeded that of desktop computers [4]. We can, therefore, dispense with the adjective *mobile* when we talk about *technology*, as both terms are already inseparable [3].

The health care field has not been alien to this revolution. The mHealth concept was born in 2000; the 2010 mHealth Summit held by the Foundation for the National Institutes of Health defined it as "the provision of health care services through mobile communication devices" [5]. Nowadays, around 40% of the 300,000 apps available in the major app stores are related to health, particularly those focused on disease monitoring and management [6].

Communication technology has evolved, taking us from making phone calls or sending short message service (SMS) text messages to developing telemedicine via Web or mobile apps as supports for clinical decision making or increasing the degree of adherence to treatments [7-9]. SMS text messaging has shown itself to be a great resource for delivering electronic reminders in practice and a highly feasible platform, since it is an older technology that can be used on any existing mobile phone. It has shown clear benefits in increasing adherence to treatment [10], preventing complications in chronic conditions [11], allowing communication between professionals [12], and helping in disease self-management [13], among others. In these situations, SMS text messaging has been used alone [11,12] or in combination with other technologies [13,14].

Push technology, however, has recently emerged in the mHealth sector because of its potential for improving pervasive functionalities in mobile health apps. It permits the delivery of timely updates and customized reminders to its users, with respect to the time sent and their contents. A push notification has been defined as being an event-based mechanism by which remote servers *push* events to mobile phone client apps [15]. This functionality offers auditory and visual alerts to inform users about an incoming message and invites them to act, even if the app sending the notifications is not currently in use [16]. Push notifications have proven to be effective in communication with professionals [17] and assessing health behavior patterns [18], but there is scant evidence of their effectiveness in interventions aimed at changing lifestyles.

Recent reviews confirm that providing digital solutions to people with an interest in health interventions improves the results obtained [19,20]. Some functions, such as self-monitoring, interaction between users, or setting objectives, have positive effects on health status [21]. In particular, self-evaluation is a characteristic that has shown encouraging results and has been the subject of study in clinical trials [22,23].

The role of physical activity (PA) in weight loss programs, as well as in the maintenance of weight loss in the long term, is fundamental [24] and has been confirmed in recent years through several systematic reviews [25,26]; this has revealed the existence of an inverse association between PA and body mass index (BMI).

Taking all of the above into account, a clinical trial was proposed to evaluate, as a primary outcome, the efficacy of push notifications in an intervention aiming to improve body composition—defined as loss of fat mass while maintaining or increasing muscle mass—of adult women who are overweight or obese. Assessing the evolution of body composition based on diet and prescribed PA was considered a secondary outcome.

Methods

Study Design: Overview

A two-arm randomized controlled trial of a 6-month intervention (ie, prescription of PA and diet) was carried out. The intervention group was comprised of women who received push notifications, while women assigned to the control group did not receive any. All the women in both groups followed the same diet. In addition, the women in the intervention group and the control group were randomly assigned to programs of PA of different intensities: light physical activity (LPA), moderate physical activity (MPA), or intense physical activity (IPA). The intervention group received push notifications with the aim of establishing a mechanism of control, gamification, and reminders of the PA prescribed in a face-to-face consultation. The control group, despite being recommended and prescribed corresponding PA, did not have a control and monitoring mechanism associated with push notifications. After enrollment, body composition variables were assessed every week for 24 weeks. The study protocol complied with the Declaration of Helsinki for medical studies and was approved by the bioethical committee of the University of Córdoba from the Department of Health at the Regional Government of Andalusia (Act No. 284, reference 4156). The protocol was registered at ClinicalTrials.gov (NCT03911583). This trial has been reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement and the CONSORT-Electronic and

Mobile HEalth Applications and onLine TeleHealth (EHEALTH) extension (see Multimedia Appendix 1).

Recruitment and Enrollment

The sample consisted of 117 Caucasian women from the region of Andalusia, Spain. Participants were recruited from a private health center, to which they came on their own initiative to undergo a weight loss program; women learned of the program either through ads published within the clinic itself or specific publicity in social networks. Data began to be collected on January 1, 2016, and lasted for a period of 2 years. All study participants were required to sign a written informed consent form.

Randomization

Participants were randomly assigned following a simple randomization procedure (ie, computerized random numbers) to intervention or control groups and to LPA, MPA, or IPA groups. Participants were randomized using a random-number generator in Microsoft Excel (Microsoft Corporation).

Sample Size Calculation

The primary outcome variable was fat mass loss after 6 months; the anticipated minimum difference in the average fat mass loss was 2% with an expected SD not exceeding 3.5% [27]. The study was designed to have at least 80% power and an alpha level set at .05, obtaining a sample size of 27 individuals in each of the intervention and control groups for a total of 54. A total of 90 women—45 in each group—was estimated to be necessary to mitigate the effect of possible dropouts during this trial.

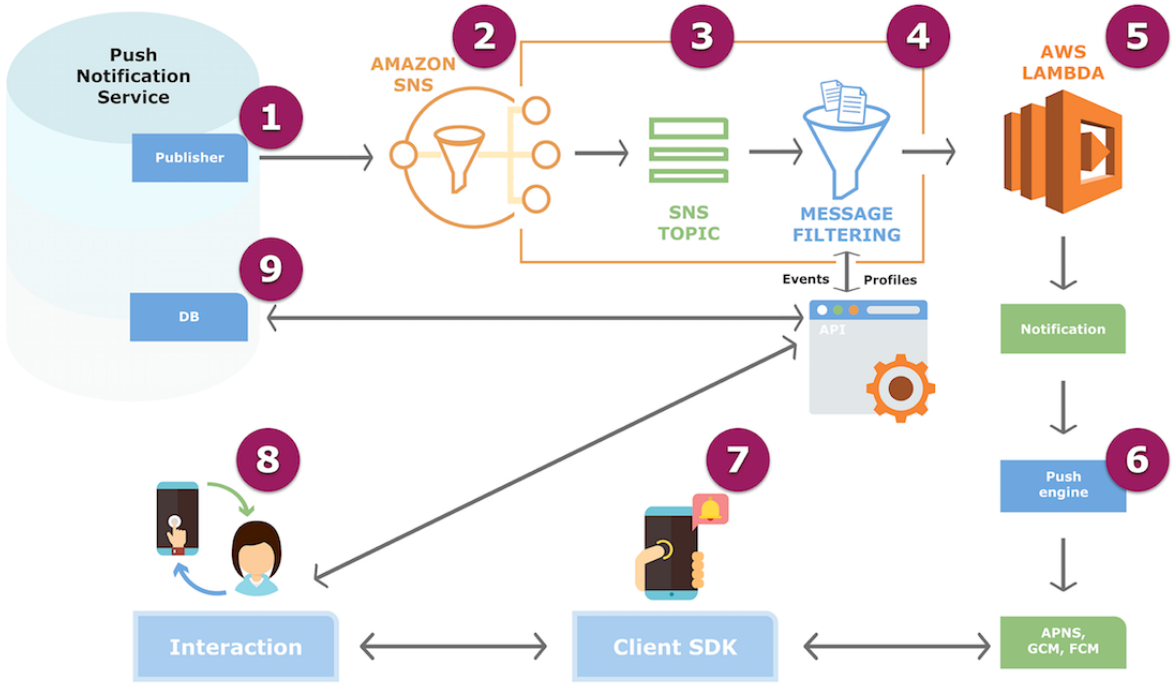
Push Notifications

Automatic push notifications (see Figure 1) were scheduled to be sent to the intervention group on specific days with personalized health-related and motivational messages; these messages aimed to provide comments to reinforce behavior modification and encourage interaction with the app.

The content of the feedback messages was extracted from a previously established library (see Textbox 1 and Multimedia Appendix 2) and was based on the following behavioral theories:

1. Health tips, where the primary tailoring goals are attention and peripheral processing [28].
2. PA tips, in this case attention and being informed [29].
3. Self-monitoring tips, where the primary tailoring goals are decision making and behavioral intention [30].

Figure 1. Push notification flow. The push notification service system works under the Amazon Simple Notification Service (SNS), which provides topics for push-based and many-to-many messaging. Using Amazon Web Services (AWS) Lambda functions from the SNS, messages are sent to a large number of subscriber end points via parallel processing. This process consists of eight steps. Step 1. The publisher sends push notifications from distributed systems. Step 2. Amazon SNS is activated to get fully managed publisher and subscriber messaging and event-driven computing service, including steps 3 and 4. Step 3. SNS Topic: message publishers are decoupled from subscribers by topic. Step 4. Message Filtering: messages are filtered according to subscription filters, which allows for personalization, and are delivered to clients, who connect to the database (DB) through an application programming interface (API). Step 5. AWS Lambda creates notifications and sends them to the client software development kit (SDK) engine through the Apple Push Notification service (APNs), Google Cloud Messaging (GCM), and Firebase Cloud Messaging (FCM). Step 6. The client SDK receives push notifications. Step 7. The user interacts with the push notification. Step 8. The interaction is recorded in the DB through the app's API.



Textbox 1. Main themes of the app message library.

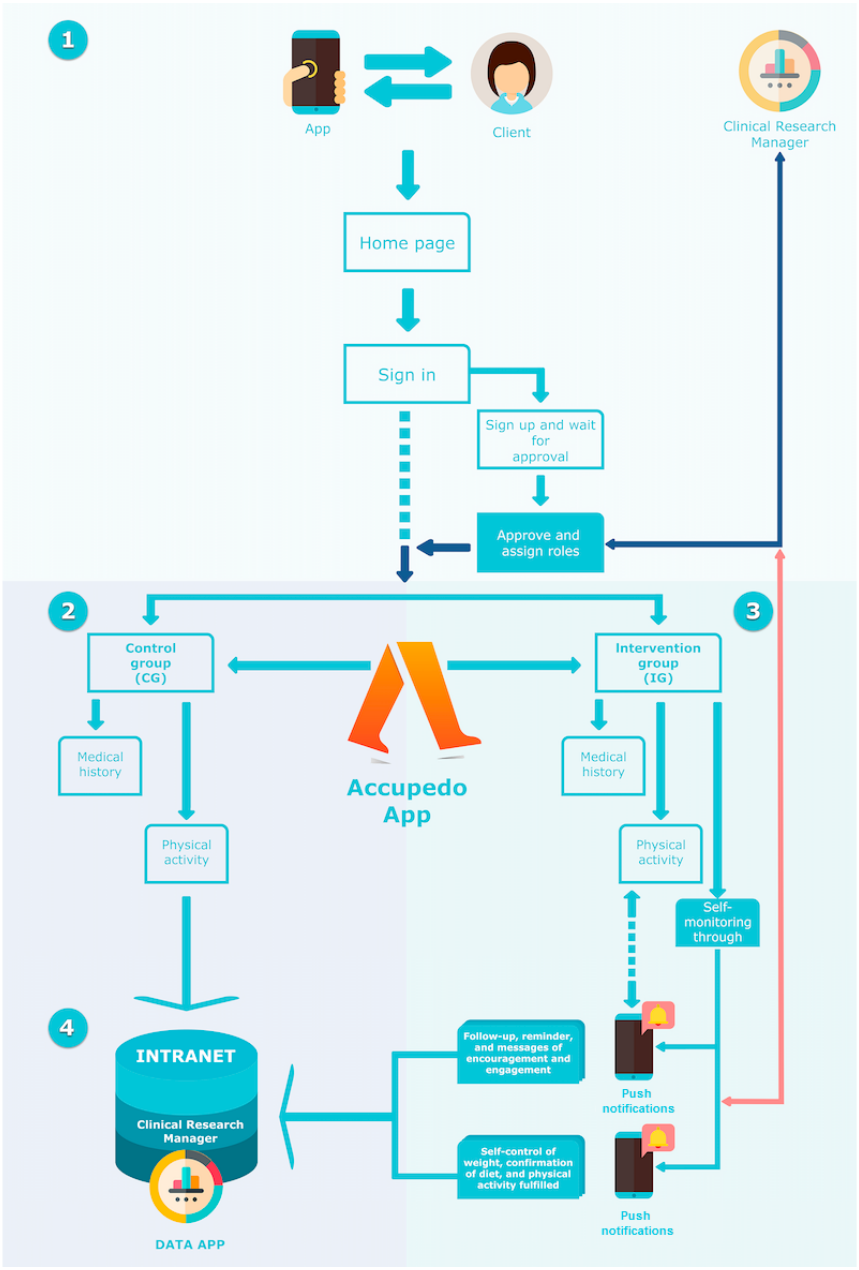
- Health tips
- Nutritional properties of specific foods
- Healthy options when it comes to selecting snacks
- Physical activity tips
- Examples of healthy habits
- Benefits of carrying out some protocols periodically
- Self-assessment tips: includes a specific menu for users to enter their weight at home—exclusive option for the intervention group

Randomized Test Design

The implementation of the methodology for sending push notifications (see Figure 2) was designed considering aspects collected in previous studies that mention, above all, the importance of the following: (1) patients' ability to select their preferred time for receiving notifications and (2) the increased effectiveness of notifications when delivered at times that do not interrupt the daily routine [31]. Based on these criteria, three time points were established at which the notifications would be sent to the patients in the intervention group: 08:30 (point 1)—the time point before going to work; 14:00 (point 2)—lunch time; and 20:00 (point 3)—the time when patients arrived home, before dinner. The first message was sent between points 1 and 2, according to the patients' preferences; patients who did not respond to the push notifications automatically received a notification at point 3.

The notifications were sent from an online tool developed specifically for this study. This tool allows the researcher to program push notifications and to check for who has responded and when (see Multimedia Appendix 3).

Figure 2. Implementation of push notifications in the study design. Step 1. Clients log in and the system recognizes the group to which each woman was assigned (control or intervention group). Step 2. Women in the control group are given access to their electronic medical record (ie, evolution in anthropometric indicators) and can register their physical activity (PA), including daily steps measured with the Accupedo app. Step 3. Women in the intervention group are given access to the same functionalities as those in the control group. In addition, they receive push notifications to increase self-control (ie, reminders, support messages, and request for registration of compliance with the dietary and PA plans). Step 4. All data are received and recorded in the Clinical Research Manager (Intranet).



Outcome Measures

Physical Activity

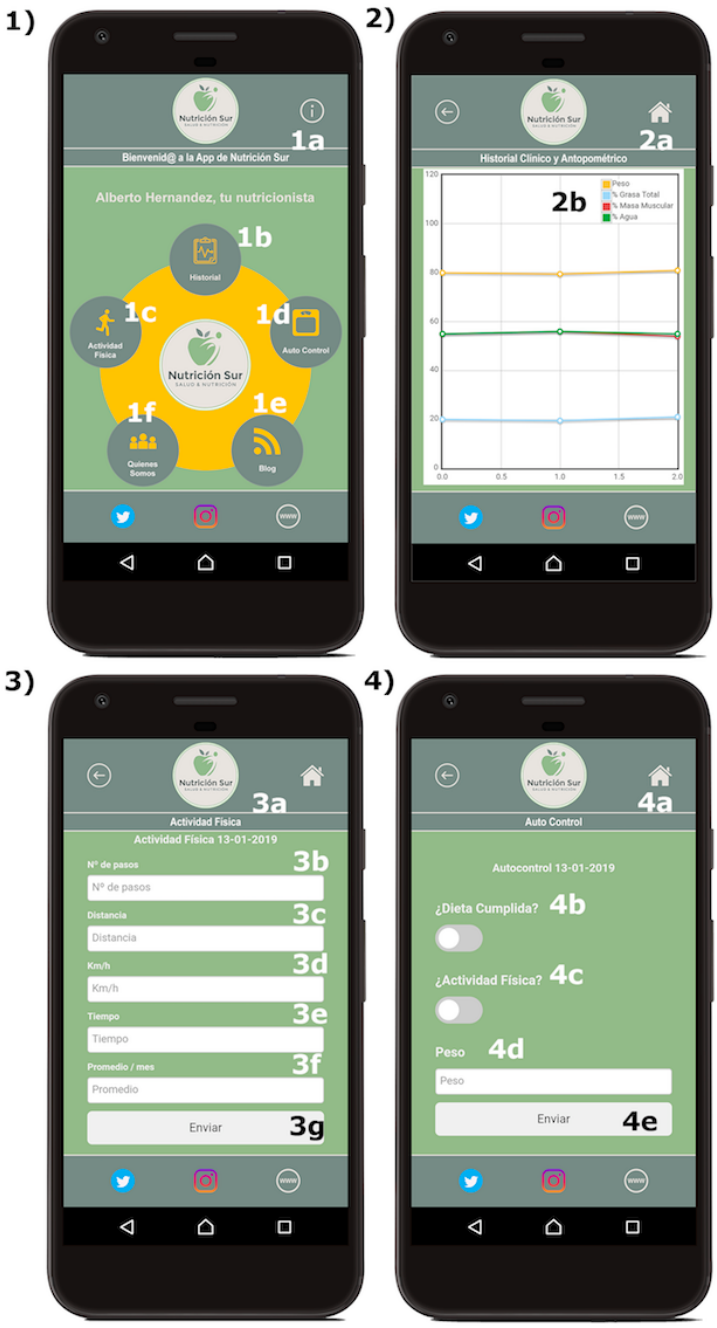
To estimate the degree of PA and sedentary activity at the beginning of the study, we used the long version of the International Physical Activity Questionnaire (IPAQ-long), which has been shown to be reliable and valid for estimating PA and sitting-down time [32]. To adjust for sedentary behavior and/or PAs outside working hours, the IPAQ-long was administered via interview at the beginning of the study and repeated at the end of the intervention. The Accupedo app—a pedometer app—was installed on the patients' mobile phones. This app is capable of tracking and storing information about daily PA in relation to walking or running; as well, it has been previously validated as a measure to encourage and motivate patients to reach a certain number of steps [33]. The purpose of the push notifications in this case was to encourage and remind patients of the objective that was previously established in the face-to-face consultation, regarding the number of steps. Patients had to report, within the app, the data obtained in Accupedo; this information was checked weekly in the consultation by the research team.

Self-Reporting

Self-evaluation was related to the women's behavior during each week. The women had to enter their weight in the app when they received the push notification. The objective was to

determine whether receiving a reminder and keeping track of weight made a difference among the women in the intervention group compared to the group of patients without access to this functionality (see Figure 3). Apps that offer self-evaluation features have previously demonstrated to help patients lose weight [34].

Figure 3. Screenshots of the full version of the app, including the self-control functionality for the intervention group. 1. Screenshot of the main menu. The following are translated from Spanish: 1a. Welcome to the Nutrición Sur app; 1b. Medical history; 1c. Physical activity; 1d. Self-control; 1e. About us; 1f. Blog. 2. Screenshot of the electronic medical record. The following are translated from Spanish: 2a. Medical and anthropometric history; 2b. Weight (orange), Total fat (blue), Muscle mass (red), Total water (green). 3. Screenshot of the physical activity record. The following are translated from Spanish: 3a. Physical activity; 3b. Number of steps; 3c. Distance; 3d. km/h; 3e. Time; 3f. Average/month; 3g. Submit. 4. Screenshot of the self-control page. The following are translated from Spanish: 4a. Self-monitoring; 4b. Diet fulfilled?; 4c. Physical activity?; 4d. Weight; 4e. Submit.



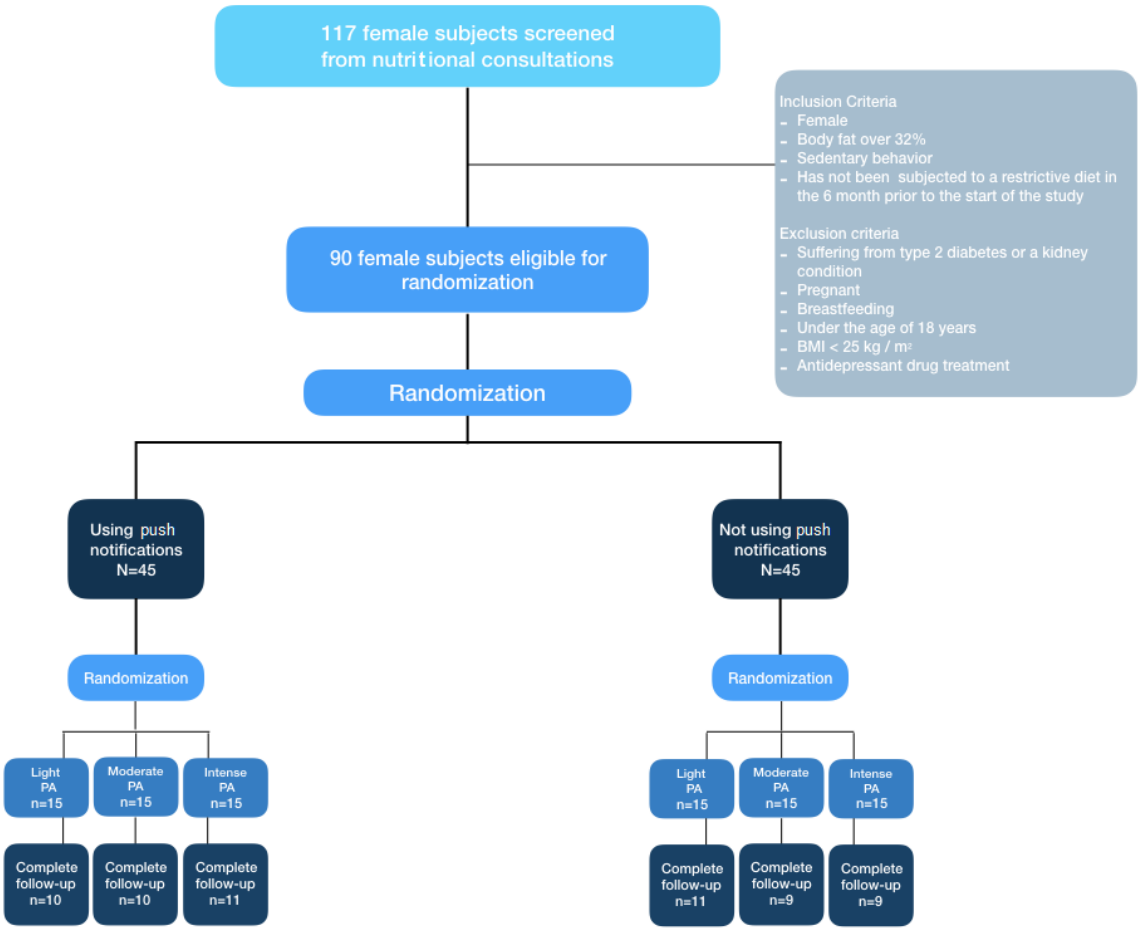
Eligibility Criteria: Inclusion and Exclusion

A flowchart of participants is shown in Figure 4. Of the 117 women who attended the consultations to lose weight, 27 (23.1%) did not meet the inclusion criteria, so the remaining 90 women (76.9%) were randomized into two groups: intervention group or control group. After this, the women in each group were randomly assigned to one of the three PA programs described previously. We decided to study a group of women, exclusively, because of differences from men with respect to body composition (ie, a higher percentage of fat mass) and metabolic response to PA plans (ie, lower capacity to build muscle mass) [35]. For this reason, and since the primary objective was to analyze the effect of push notifications, we decided not to include men. Another inclusion criterion was having at least 32% of total body fat at the start of the study

because this is the lowest limit that determines obesity in a woman, as the percentage of fat is considered a marker of obesity [36].

Women who had a metabolic illness and those who had previously been diagnosed with type 2 diabetes mellitus were excluded from the study. Exclusion criteria also included being pregnant or breastfeeding, being under the age of 18, and having a BMI of less than 25 kg/m^2. Finally, another exclusion criterion was taking antidepressant drugs, due to their possible role in the incidence of obesity in middle-aged women [37]. A total of 60 women out of 90 completed the follow-up evaluation, representing a retention rate of 67%. There were no statistical differences in the dropout rate between any of the groups.

Figure 4. Flowchart of participants. BMI: body mass index; PA: physical activity.



Study Variables and Measurements

Body fat, muscle mass, and water percentages, considering variable outcomes, were monitored and collected over time using multifrequency bioelectrical impedance with the BWB-800A electronic scale (Tanita Corporation of America), which was previously validated [38]. Standing height without shoes was measured to the nearest millimeter using the wall-mounted PORTROD stadiometer (Health o meter). The independent variables collected were age (years), height (cm), weight (kg), and BMI (kg/m^2). The anthropometric measurements were collected following the recommendations of the reference manual of standardized anthropometry [39].

For the PA, the strata proposed by Matthew were used [40]. Patients in MPA and IPA groups were instructed to perform aerobic exercises corresponding to energy expenditure induced by training of approximately 300-600 kcal/day. For PA to be considered MPA, women had to walk for 30-60 minutes every day or complete 7500-10,000 steps per day. On the other hand, to be considered IPA, patients had to carry out, in addition to the target set in the MPA group, IPA sessions of over 70% of VO_2max three times a week. Several members of the research team—nurses and a nutritionist—assessed the women in order to prescribe the adequate intensity of PA. This was based on heart rate, estimated using the Karvonen formula [41], and establishing the maximum heart rate of 220 - age (years). Adherence was monitored by weekly exercise records that were completed by participants and researchers.

With respect to diet, the daily energy requirements were determined by estimating the energy expenditure at rest through the formula proposed by Harris-Benedict (655.0955 + 9.5634 [weight in kg] + 1.8496 [size in cm] - 4.6756 [age in years]) [42] and multiplying the value obtained by a factor of 1.5 in those patients who did PA [43]. During a period of 24 weeks, all the participants followed a diet with the following distribution of macronutrients: 25%-30% protein, 40%-45% carbohydrates, and 30%-35% fat. A hypocaloric diet was designed, with a reduction of 500 kcal/day during the intervention period to

achieve a weekly weight loss of 400 grams; no vitamins or other nutritional supplements were prescribed. In order to be included in the study, each woman participated in a 1-hour seminar, in which a dietitian-nutritionist taught her the appropriate selection and preparation of food. The proposed menu was valid for 7 days, and at the weekly review appointment, the protocol for the current week was handed out. The energy and nutritional contributions were assessed through the Dietowin program and the weighing method [44].

The follow-up tests began during the first week of the diet and PA assignment. Body composition was measured after an overnight fast; the subject was then required to go to the center on the same day of the week at the same time, wearing the same clothes. Review appointments continued on a weekly basis until week 24, when all the variables were collected.

Statistical Analysis

The quantitative variables have been presented with the mean and SD, and the qualitative variables with frequencies and percentages.

To contrast the goodness of fit with a normal distribution of data from quantitative variables, the Kolmogorov-Smirnov test with the Lilliefors correction was used. For the bivariate hypothesis, the Student's *t* test was performed for two means, while for the qualitative variables the chi-square and Fisher exact tests were employed when necessary. Likewise, for the analysis of three or more means, the analysis of variance (ANOVA) of repeated means determined the effects of the intervention at baseline and at 3 and 6 months; the correlation between the quantitative variables was verified by the coefficient of Pearson correlation (r). Finally, if the normality or homoscedasticity criterion was not met for the ANOVA, the Kruskal-Wallis test was performed.

To adjust for the possible impact of PA on body composition and its possible role as a confounding factor, adjusted linear regressions were made for each body composition variable (percent body fat and muscle mass) and weight, calculating the standardized beta coefficients. To determine the goodness of fit of the models, the SE, the adjusted coefficient of determination, the F statistic, the linearity, and the residuals were analyzed.

For all statistical analyses, an alpha error of less than 5% was accepted ($P<.05$) and a 95% CI was calculated. For the statistical analysis, IBM SPSS Statistics software, version 22.0 (IBM Corp), was used.

Results

Characteristics of the Population Studied

The women studied had a mean age of 41.5 years (SD 11.3). With regard to body composition, in the first consultation we found an average weight of 82.6 kg (SD 14.5) (95% CI 78.8-86.3), average muscle mass of 44.7 kg (SD 5.1) (95% CI 43.4-46), and average body fat of 42.2% (SD 5.5) (95% CI 40.8-43.6) (see Table 1).

Table 1. Descriptive characteristics of participants randomized at baseline.

Variable	Total (N=60), mean (SD)	No push notifications (n=29), mean (SD)	Push notifications (n=31), mean (SD)	*P* value
Age (years)	41.5 (11.3)	40.3 (11.6)	42.9 (10.9)	.38
Height (m)	1.6 (0.1)	1.6 (0.1)	1.6 (0.1)	.77
Weight (kg)	82.6 (14.5)	84.8 (14.9)	80.5 (13.9)	.25
Body mass index (kg/m^2)	31.8 (5.3)	32.8 (5.3)	31.0 (5.3)	.19
Body fat (%)	42.2 (5.5)	43.4 (5.0)	41.0 (5.8)	.10
Muscle mass (kg)	44.7 (5.1)	45.0 (5.3)	44.4 (4.9)	.66
Water (%)	43.1 (3.9)	42.1 (3.3)	44.1 (4.2)	.05

No significant differences were found between the group that received notifications and the one that did not, with respect to the number of women who remained in the LPA group or engaged in MPA or IPA ($P>.05$). The baseline data according to whether the push notifications were sent or not are shown in Table 1.

Analysis of the Evolution of Body Composition Based on the Use of Push Notifications

The analysis of the variation in body composition in the study groups was based on the percentage changes between the measurements collected at baseline and at 3 and 6 months. A total of 3 months after the intervention, the group that received push notifications showed a significantly greater reduction in the percentage of body fat (-8.4% [SD 4.7], 95% CI -10.1 to -6.6; $P=.005$). For the rest of the anthropometric variables, although there was a greater decrease in the intervention group, the decreases were not significant with respect to the control group ($P>.05$).

However, this trend was not maintained after 6 months of the intervention. The women who received push notifications showed a greater improvement in their body composition than those who did not receive them; a higher decrease in body fat percentage ($P<.001$), a smaller reduction in muscle mass ($P<.05$), and a higher percentage increase in body water ($P<.05$) were observed (see Table 2).

Table 2. Variation of body composition.

Variable	At 3 months			At 6 months		
	No push notifications, mean (SD)	Push notifications, mean (SD)	*P* value	No push notifications, mean (SD)	Push notifications, mean (SD)	*P* value
Weight (kg)	-6.3 (3.3)	-7.1 (2.4)	.27	-7.1 (3.4)	-7.9 (3.9)	.39
Body mass index, (kg/m^2)	-2.1 (1.2)	-2.3 (1.0)	.56	-8.0 (3.7)	-9.1 (5.7)	.36
Body fat (%)	-5.0 (4.2)	-8.4 (4.7)	.005	-7.0 (5.7)	-12.9 (6.7)	<.001
Muscle mass (kg)	-2.6 (3.1)	-1.6 (4.1)	.27	-3.2 (2.8)	-0.8 (4.5)	.02
Water (%)	3.2 (3.3)	5.1 (4.5)	.07	4.8 (4.3)	8.0 (5.8)	.02

Analysis of the Evolution of Body Composition Based on the Use of Push Notifications and Physical Activity

At 3 months, it was found that there was no significant change in weight, nor in BMI or muscle mass, in women who remained in the LPA group. However, we observed a reduction in body fat percentage in women who received motivational messages during the intervention (-5.9% [SD 2.3], 95% CI -7.5 to -4.2) and a significantly elevated water percentage (3.4% [SD 1.3], 95% CI 2.4-4.3), compared to that in women who did not receive the messages.

With regard to women who performed some type of physical activity (ie, MPA and IPA), although a more favorable change was found among the women who received the push notifications, it was not significant (*P*>.05) (see Table 3).

The trend varied in the data collected at 6 months among the three study groups. Regarding sedentary women, it was found that the difference in body fat loss and water gain was significantly greater (*P*<.001 and *P*<.01, respectively) among women who received push notifications.

With respect to the group that did MPA, women in the control group showed greater modifications in all body composition variables, but they were only significant in the case of body fat (*P*<.01) (see Table 4).

Table 3. Evolution of body composition based on physical activity (PA) and push notifications at 3 months.

Variable	Light PA (n=21)			Moderate PA (n=19)			Intense PA (n=20)		
	No push notifications (n=11), mean (SD)	Push notifications (n=10), mean (SD)	*P* value	No push notifications (n=9), mean (SD)	Push notifications (n=10), mean (SD)	*P* value	No push notifications (n=9), mean (SD)	Push notifications (n=11), mean (SD)	*P* value
Weight (kg)	-4.8 (3.8)	-6.5 (2.0)	.22	-6.9 (2.9)	-8.1 (1.7)	.36	-7.5 (2.6)	-6.7 (3.2)	.66
Body mass index (kg/m^2)	-1.7 (1.5)	-2.1 (0.7)	.56	-2.3 (0.8)	-2.5 (0.9)	.84	-2.3 (0.9)	-2.2 (1.3)	.55
Body fat (%)	-2.3 (3.6)	-5.9 (2.3)	.02	-5.6 (3.5)	-6.8 (2.4)	.60	-8.0 (3.5)	-12.0 (5.7)	.07
Muscle mass (kg)	-2.8 (3.9)	-2.9 (2.4)	.71	-2.9 (2.3)	-3.7 (1.8)	.55	-2.1 (2.8)	1.6 (5.0)	.11
Water (%)	1.5 (2.5)	3.4 (1.3)	.04	3.1 (3.7)	4.2 (1.4)	.07	5.6 (2.4)	7.6 (6.9)	.30

Table 4. Evolution of body composition based on physical activity (PA) and push notifications at 6 months.

Variable	Light PA (n=21)			Moderate PA (n=19)			Intense PA (n=20)		
	No push notifications (n=11), mean (SD)	Push notifications (n=10), mean (SD)	*P* value	No push notifications (n=9), mean (SD)	Push notifications (n=10), mean (SD)	*P* value	No push notifications (n=9), mean (SD)	Push notifications (n=11), mean (SD)	*P* value
Weight (kg)	-5.6 (3.1)	-7.2 (1.9)	.07	-9.5 (2.3)	-11.4 (2.4)	.13	-10.0 (3.7)	-10.0 (4.3)	>.99
Body mass index (kg/m^2)	-5.3 (2.6)	-7.1 (2.0)	.09	-9.6 (2.3)	-9.5 (5.2)	.54	- 9.5 (4.3)	-10.6 (7.9)	.88
Body fat (%)	-1.2 (1.5)	-6.2 (2.1)	<.001	-8.1 (2.6)	-12.8 (2.6)	.002	-13.0 (3.7)	-19.0 (6.1)	.046
Muscle mass (kg)	-4.3 (2.2)	-3.0 (2.1)	.28	-3.6 (2.1)	-2.9 (1.9)	.24	-1.4 (3.4)	3.0 (5.3)	.08
Water (%)	1.2 (1.8)	4.1 (1.6)	.003	4.6 (3.2)	8.2 (2.1)	.02	9.3 (3.1)	11.4 (8.1)	.60

Finally, women who were referred to IPA and received push notifications had significantly greater reductions in the percentage of body fat (received notifications: -19.0% [SD 6.1], 95% CI -23.1 to -15; did not receive notifications: -13.0% [SD 3.7], 95% CI -15.5 to -10.5; *P*<.05). On the other hand, although no significant differences in muscle mass were found, muscle mass gain was observed in the intervention group.

Adjusted Regressions in Body Composition Modifications

The results shown in Table 5 confirm that the incorporation of push notifications had a different impact in body composition variables. Thus, we observed how receiving these notifications during the intervention lead to the weight loss increase (standardized beta=-.208) and helped to maintain or gain muscle mass (standardized beta=.266). However, the most important impact was observed on body fat, where loss occurred to a high degree (standardized beta=-.397).

Table 5. Multiple linear regression models.

Result variable and models[a] and measures they are adjusted for	Standardized beta	R^2[b]	SE	r[c]	*P* value
Weight lost at 6 months (kg)					
2.214 - 4.335 (MPA[d]- 4.219 (IPA[e]) - 1.487 (push notifications[f]) - 0.092 (weight at baseline)		**.393**	**2.812**	**.658**	**<.001**
MPA	-.564				
IPA	-.556				
Push notifications	-.208				
Weight at baseline	-.367				
Body fat lost at 6 months (%)					
1.443 - 6.720 (MPA) - 12.390 (IPA) - 5.379 (push notifications) - 0.058 (body fat at baseline)		**.743**	**3.461**	**.872**	**<.001**
MPA	-.462				
IPA	-.863				
Push notifications	-.397				
Body fat at baseline	-.047				
Muscle mass lost at 6 months (kg)					
5.769 - 0.029 (MPA) + 3.926 (IPA) + 2.062 (push notifications) - 0.226 (muscle mass at baseline)		**.416**	**2.985**	**.675**	**<.001**
MPA	-.003				
IPA	.478				
Push notifications	.266				
Muscle mass at baseline	-.294				

[a]Models are adjusted for age, weight at baseline, push notifications, percentage of fat at baseline, muscle mass at baseline, percentage of water at baseline, and physical activity (PA).

[b]R^2: coefficient of determination (goodness of fit).

[c]*r*: Pearson´s linear correlation.

[d]MPA: moderate physical activity (sedentary=0, moderate=1).

[e]IPA: intense physical activity (light=0, intense=1).

[f]Push notifications (no=0, yes=1).

Discussion

Principal Findings

As far as we know, this work has been the first clinical trial to study the impact of establishing a tracking and gamification system through push notifications in a weight loss program that included PA, combined with dietary treatment in face-to-face consultations, with a weekly tracking frequency over 6 months. From the results, we have extracted encouraging data. Introducing an mHealth strategy in patient consultation was shown to be, at the end of the trial period, a differentiating element: women receiving push notifications lost more weight, lost more total body fat, and had better muscle mass results than those who did not receive these notifications.

Comparison With Prior Work

Effects After 12 Weeks of the Push Notifications

In the first 3 months of the study, we found that push notifications only had an effect on total body fat and not on the rest of the anthropometric variables.

In the LPA groups, which only encouraged complying with the diet and carrying out weight control at home, push notifications triggered greater body fat loss, compared to the group who did not receive notifications. What differentiated the patients of this

group was their access via the app to a specific functionality called *self-monitoring*, a concept that allows the patient to restrict or cancel a response, which makes decision making possible [45]. The use of technology in a clinical trial of behavioral weight loss in a face-to-face intervention has previously been documented in the work of Polzien et al [46], who reported additional weight loss at 12 weeks of 2.1 kg in the group that had technological support; these data approximate those obtained in our study, since women who received push notifications lost 1.76 kg of additional weight in the LPA group.

We found important differences in applying mHealth technology in combination with face-to-face follow-ups when compared to resorting exclusively to an mHealth intervention. At 12 weeks, our trial subjects lost an average of 7.1 kg (SD 2.4), while participants in another intervention using only text messages lost an average of 1.6 kg (SD 2.6) [47].

Sending messages of encouragement results in an increase in PA in the short term. Although the data in the first 12 weeks show an improvement in the body composition of women who received notifications, this was not significant (P>.05). A previous study among sedentary women confirmed that an mHealth intervention helped increase PA, although there were no significant changes in BMI [48].

Effects After 24 Weeks of the Push Notifications

At 6 months, the women in the trial who received push notifications lost more fatty tissue and their fat-free mass behaved better (ie, muscle mass and total body water).

A study focusing on the effects of mobile phone-based support and weight loss found a difference in additional weight loss of 1.9 kg at 6 months between groups with and without technology [49]. This difference was greater than the 1.63 kg between women who did or did not receive push notifications in our study, despite the fact that patients were aware that they were being monitored. In previous studies, this aspect was seen to affect patients' behavior [50]. Our findings were similar to those obtained in the review by Hutchesson et al [51], who compared weight loss among participants assigned to an mHealth intervention (13 studies), finding that the additional characteristics led to an average weight loss difference of 1.46 kg.

The body composition variables of groups assigned to performing MPA and IPA improved, highlighting an increased loss of total body fat and better behavior in fat-free mass (ie, maintaining or gaining). Text messages (ie, push notifications) aimed at fulfilling an assigned PA protocol were effective in interventions of at least 6 months in duration. These results do not coincide with a study of the same duration [52], in which there was no monitoring in face-to-face consultations. Reinforcing the strategy to be followed in the consultation and using technology as a support may be more feasible. However, we found similar results in a study where subjects were monitored at a weekly frequency for 24 weeks [53].

The same conclusion made at 12 weeks on the effectiveness of text messaging and weight loss without face-to-face control can be extrapolated to longer periods of 24 weeks. Even though, in our study, patients monitored through push notifications and face-to-face consultations lost an average of 7.87 kg (SD 3.87), in studies that exclusively measured the effectiveness of mobile messaging and weight loss, the results were not so promising, as participants only lost an average of 1.27 kg (SD 6.51) [54,55].

Body Composition

Previous studies reported that decreases in muscle mass were restored over time after weight loss interventions [56,57]. Although the muscle mass loss was lower than that of total body fat, muscle maintenance should be monitored and prescribed even in weight loss programs. The subjects of our study who had a light or moderate exercise prescription (ie, walking) lost muscle mass at the end of the period. The explanation is that this kind of PA seems insufficient for mobilizing and stimulating muscle mass [58]. The group in our study that had an intense physical exercise prescription (ie, incorporating resistance training) was the only one that showed muscle mass gain at 6 months. These results provide evidence that a combined program of aerobic and resistance-type exercise helps to preserve muscle mass during weight loss, results that matched those of a recent review [59].

Our findings reveal that the prescription of PA results in significant body fat loss; the higher the intensity of PA, the greater the loss of fat at 6 months. While the LPA prescription implied a 6% fat loss at 6 months, the IPA subjects reached a fat loss of 19%. In addition, when analyzing the results among MPA and IPA subjects, we observed that IPA subjects lost an additional 7% of fat, whereas no significant weight loss was observed between the MPA and IPA groups. Our results are consistent with the existing literature [60]; although high-intensity training did not improve weight loss over 6 months compared to a lower intensity, the impact on fat loss was significant [61].

Limitations and Strengths

Although the sample size in this study is similar to that used in previous works [62,63], we carried out a randomization procedure that led to balanced arms; besides, the dropout pattern at 3 months was similar in the three groups. To avoid self-report bias, which was previously documented [64], the data collection records were checked by the research staff in face-to-face consultations on a weekly basis, in which women had to show her Accupedo status directly from their mobile phones. Key strengths include the use of an objective measure of PA, which has stronger associations with health behaviors than hypothetical methods and self-reported measures [65]. To understand the results in body composition and to be able to apply them in public health, our study included a combination of diet and PA and we had to demonstrate the difference in the change in muscle mass between diet, PA programs, or both [58]. In this work, we aimed to contribute to the growing interest in the field of mHealth, regarding improvement of body composition and the change in dynamics of disease prevention and treatment, through text messaging interventions [66]. This study abandons SMS technology to enter into a scenario of greater interaction between patients and their health, allowing feedback from the patients.

Although the number of women who completed the follow-up evaluation is greater than the estimated minimum sample size, the results should be interpreted with caution. In this sense, subsequent investigations with longer follow-up times, larger sample sizes, and with similar designs that allow us to corroborate the effectiveness found in this research would be necessary. Besides, more empirical research is needed to examine the effect of notification content and delivery times, as well as the purpose of user responsiveness, and to assess the impact of push notifications in other health care settings.

Conclusions

Push notifications have proven to be effective in the proposed weight loss program, leading to greater loss of fat mass and maintenance or increase of muscle mass among women who received it, specifically among those who followed a program of IPA. Future interventions should include a longer evaluation period; the impact of different message contents, as well as message delivery times and frequency, should also be researched.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2200 KB - mhealth_v8i2e13747_app1.pdf]

Multimedia Appendix 2
Main themes of the app message library.
[PPTX File , 46 KB - mhealth_v8i2e13747_app2.pptx]

Multimedia Appendix 3
Intranet developed for the study.
[PDF File (Adobe PDF File), 2956 KB - mhealth_v8i2e13747_app3.pdf]

References

1. Porter J, Huggins CE, Truby H, Collins J. The effect of using mobile technology-based methods that record food or nutrient intake on diabetes control and nutrition outcomes: A systematic review. Nutrients 2016 Dec 17;8(12):815 [FREE Full text] [doi: 10.3390/nu8120815] [Medline: 27999302]
2. Liu S. Statista. 2019 Mar 04. Wearable technology: Statistics & facts URL: https://www.statista.com/topics/1556/wearable-technology/ [accessed 2019-08-31]
3. Alonso-Arévalo J, Mirón-Canelo J. Revista Cubana de Información en Ciencias de la Salud (ACIMED). 2017. Aplicaciones móviles en salud: Potencial, normativa de seguridad y regulación URL: http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S2307-21132017000300005 [accessed 2019-12-28]
4. Eurostat. 2016 Dec 20. Internet use by individuals URL: http://ec.europa.eu/eurostat/documents/2995521/7771139/9-20122016-BP-EN.pdf/f023d81a-dce2-4959-93e3-8cc7082b6edd [accessed 2019-08-29]
5. Laxminarayan S, Istepanian RS. UNWIRED E-MED: The next generation of wireless and Internet telemedicine systems. IEEE Trans Inf Technol Biomed 2000 Sep;4(3):189-193. [doi: 10.1109/titb.2000.5956074] [Medline: 11026588]
6. Business Insider. 2017 Nov 07. IQVIA Institute for Human Data Science Study: Impact of digital health grows as innovation, evidence and adoption of mobile health apps accelerate URL: https://markets.businessinsider.com/news/stocks/iqvia-institute-for-human-data-science-study-impact-of-digital-health-grows-as-innovation-evidence-and-adoption-of-mobile-health-apps-accelerate-1007156018 [accessed 2019-08-29]
7. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. Am J Prev Med 2009 Feb;36(2):165-173. [doi: 10.1016/j.amepre.2008.09.040] [Medline: 19135907]
8. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile health technology-based health behaviour change or disease management interventions for health care consumers: A systematic review. PLoS Med 2013;10(1):e1001362 [FREE Full text] [doi: 10.1371/journal.pmed.1001362] [Medline: 23349621]
9. Molina Recio G, García-Hernández L, Molina Luque R, Salas-Morera L. The role of interdisciplinary research team in the impact of health apps in health and computer science publications: A systematic review. Biomed Eng Online 2016 Jul 15;15 Suppl 1:77 [FREE Full text] [doi: 10.1186/s12938-016-0185-y] [Medline: 27454164]
10. Thakkar J, Kurup R, Laba T, Santo K, Thiagalingam A, Rodgers A, et al. Mobile telephone text messaging for medication adherence in chronic disease: A meta-analysis. JAMA Intern Med 2016 Mar;176(3):340-349. [doi: 10.1001/jamainternmed.2015.7667] [Medline: 26831740]

11. Redfern J, Thiagalingam A, Jan S, Whittaker R, Hackett ML, Mooney J, et al. Development of a set of mobile phone text messages designed for prevention of recurrent cardiovascular events. Eur J Prev Cardiol 2014 Apr;21(4):492-499. [doi: 10.1177/2047487312449416] [Medline: 22605787]
12. Hao W, Hsu Y, Chen K, Li H, Iqbal U, Nguyen P, et al. LabPush: A pilot study of providing remote clinics with laboratory results via short message service (SMS) in Swaziland, Africa - A qualitative study. Comput Methods Programs Biomed 2015 Jan;118(1):77-83. [doi: 10.1016/j.cmpb.2014.10.005] [Medline: 25453385]
13. Casillas J, Goyal A, Bryman J, Alquaddoomi F, Ganz P, Lidington E, et al. Development of a text messaging system to improve receipt of survivorship care in adolescent and young adult survivors of childhood cancer. J Cancer Surviv 2017 Aug;11(4):505-516 [FREE Full text] [doi: 10.1007/s11764-017-0609-0] [Medline: 28364263]
14. Leightley D, Puddephatt J, Jones N, Mahmoodi T, Chui Z, Field M, et al. A smartphone app and personalized text messaging framework (InDEx) to monitor and reduce alcohol use in ex-serving personnel: Development and feasibility study. JMIR Mhealth Uhealth 2018 Sep 11;6(9):e10074 [FREE Full text] [doi: 10.2196/10074] [Medline: 30206054]
15. Warren I, Meads A, Srirama S, Weerasinghe T, Paniagua C. Push notification mechanisms for pervasive smartphone applications. IEEE Pervasive Comput 2014 Apr;13(2):61-71. [doi: 10.1109/mprv.2014.34]
16. Iqbal ST, Bailey BP. Effects of intelligent notification management on users and their tasks. In: Proceedings of the 26th Annual CHI Conference on Human Factors in Computing Systems. 2008 Presented at: 26th Annual CHI Conference on Human Factors in Computing Systems; April 5-10, 2008; Florence, Italy p. 93-102 URL: https://interruptions.net/literature/Iqbal-CHI08.pdf [doi: 10.1145/1357054.1357070]
17. Pielot M, Church K, de Oliveira R. An in-situ study of mobile phone notifications. In: Proceedings of the 16th International Conference on Human-Computer Interaction with Mobile Devices and Services. 2014 Presented at: 16th International Conference on Human-Computer Interaction with Mobile Devices and Services; September 23-26, 2014; Toronto, ON p. 233-242. [doi: 10.1145/2628363.2628364]
18. Gill S, Panda S. A smartphone app reveals erratic diurnal eating patterns in humans that can be modulated for health benefits. Cell Metab 2015 Nov 03;22(5):789-798 [FREE Full text] [doi: 10.1016/j.cmet.2015.09.005] [Medline: 26411343]
19. Armanasco AA, Miller YD, Fjeldsoe BS, Marshall AL. Preventive health behavior change text message interventions: A meta-analysis. Am J Prev Med 2017 Mar;52(3):391-402. [doi: 10.1016/j.amepre.2016.10.042] [Medline: 28073656]
20. Stephenson A, McDonough SM, Murphy MH, Nugent CD, Mair JL. Using computer, mobile and wearable technology enhanced interventions to reduce sedentary behaviour: A systematic review and meta-analysis. Int J Behav Nutr Phys Act 2017 Aug 11;14(1):105 [FREE Full text] [doi: 10.1186/s12966-017-0561-4] [Medline: 28800736]
21. Klasnja P, Pratt W. Healthcare in the pocket: Mapping the space of mobile-phone health interventions. J Biomed Inform 2012 Feb;45(1):184-198 [FREE Full text] [doi: 10.1016/j.jbi.2011.08.017] [Medline: 21925288]
22. van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. The development of a mobile monitoring and feedback tool to stimulate physical activity of people with a chronic disease in primary care: A user-centered design. JMIR Mhealth Uhealth 2013 Jul 02;1(2):e8 [FREE Full text] [doi: 10.2196/mhealth.2526] [Medline: 25099556]
23. Falk EB, O'Donnell MB, Cascio CN, Tinney F, Kang Y, Lieberman MD, et al. Self-affirmation alters the brain's response to health messages and subsequent behavior change. Proc Natl Acad Sci U S A 2015 Feb 17;112(7):1977-1982 [FREE Full text] [doi: 10.1073/pnas.1500247112] [Medline: 25646442]
24. Clark JE. Diet, exercise or diet with exercise: Comparing the effectiveness of treatment options for weight-loss and changes in fitness for adults (18-65 years old) who are overfat, or obese; systematic review and meta-analysis. J Diabetes Metab Disord 2015;14:31 [FREE Full text] [doi: 10.1186/s40200-015-0154-1] [Medline: 25973403]
25. Golubic R, Ekelund U, Wijndaele K, Luben R, Khaw K, Wareham NJ, et al. Rate of weight gain predicts change in physical activity levels: A longitudinal analysis of the EPIC-Norfolk cohort. Int J Obes (Lond) 2013 Mar;37(3):404-409 [FREE Full text] [doi: 10.1038/ijo.2012.58] [Medline: 22531093]
26. Liu F, Wang W, Ma J, Sa R, Zhuang G. Different associations of sufficient and vigorous physical activity with BMI in Northwest China. Sci Rep 2018 Sep 03;8(1):13120 [FREE Full text] [doi: 10.1038/s41598-018-31227-6] [Medline: 30177717]
27. Newton RL, Carter LA, Johnson W, Zhang D, Larrivee S, Kennedy BM, et al. A church-based weight loss intervention in African American adults using text messages (LEAN Study): Cluster randomized controlled trial. J Med Internet Res 2018 Aug 24;20(8):e256 [FREE Full text] [doi: 10.2196/jmir.9816] [Medline: 30143478]
28. Campbell MK, DeVellis BM, Strecher VJ, Ammerman AS, DeVellis RF, Sandler RS. Improving dietary behavior: The effectiveness of tailored messages in primary care settings. Am J Public Health 1994 May;84(5):783-787. [doi: 10.2105/ajph.84.5.783] [Medline: 8179049]
29. Bull FC, Kreuter MW, Scharff DP. Effects of tailored, personalized and general health messages on physical activity. Patient Educ Couns 1999 Feb;36(2):181-192. [doi: 10.1016/s0738-3991(98)00134-7] [Medline: 10223022]
30. Walther JB, Pingree S, Hawkins RP, Buller DB. Attributes of interactive online health information systems. J Med Internet Res 2005 Jul 01;7(3):e33 [FREE Full text] [doi: 10.2196/jmir.7.3.e33] [Medline: 15998624]
31. Bentley F, Tollmar K. The power of mobile notifications to increase well-being logging behavior. In: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems. New York, NY: ACM; 2013 Presented at: SIGCHI Conference on Human Factors in Computing Systems; April 27-May 2, 2013; Paris, France. [doi: 10.1145/2470654.2466140]

32. Hagströmer M, Oja P, Sjöström M. The International Physical Activity Questionnaire (IPAQ): A study of concurrent and construct validity. Public Health Nutr 2006 Sep;9(6):755-762. [doi: 10.1079/phn2005898] [Medline: 16925881]
33. Walsh JC, Corbett T, Hogan M, Duggan J, McNamara A. An mHealth intervention using a smartphone app to increase walking behavior in young adults: A pilot study. JMIR Mhealth Uhealth 2016 Sep 22;4(3):e109 [FREE Full text] [doi: 10.2196/mhealth.5227] [Medline: 27658677]
34. Thomas JG, Bond DS. Review of innovations in digital health technology to promote weight control. Curr Diab Rep 2014;14(5):485. [doi: 10.1007/s11892-014-0485-1] [Medline: 24664797]
35. Cardozo LA, Guzman C, Andrés Y, Torres M, Alejandro J. Nutrición clínica y dietética hospitalaria, Volume 36, Issue 3. 2016. Body fat percentage and prevalence of overweight-obesity in college students of sports performance in Bogotá, Colombia [Article in Spanish] URL: https://www.researchgate.net/profile/Luis_Cardozo4/publication/318351764_Porcentaje_de_grasa_corporal_y_prevalencia_de_sobrepeso-obesidad_en_estudiantes_universitarios_de_rendimiento_deportivo_de_Bogota_Colombia_Body_fat_percentage_and_prevalence_of_overweight-obesity_in_c/links/59655bd0aca27227d78c60e6/Porcentaje-de-grasa-corporal-y-prevalencia-de-sobrepeso-obesidad-en-estudiantes-universitarios-de-rendimiento-deportivo-de-Bogota-Colombia-Body-fat-percentage-and-prevalence-of-overweight-obesity-in.pdf [accessed 2019-12-28]
36. Forbes GB. Human Body Composition: Growth, Aging, Nutrition, and Activity. New York, NY: Springer-Verlag; 1987.
37. Svärd A, Lahti J, Rahkonen O, Lahelma E, Lallukka T. Obesity and psychotropic medication: A prospective register linkage study among midlife women and men. BMC Psychiatry 2016 Jun 06;16:185 [FREE Full text] [doi: 10.1186/s12888-016-0889-3] [Medline: 27267751]
38. Schubert MM, Seay RF, Spain KK, Clarke HE, Taylor JK. Reliability and validity of various laboratory methods of body composition assessment in young adults. Clin Physiol Funct Imaging 2019 Mar;39(2):150-159. [doi: 10.1111/cpf.12550] [Medline: 30325573]
39. Callaway W, Chumlea WC, Bouchard C, Himes JH, Lohman TG, Martin AD, et al. Circumferences. In: Lohman TG, Roche AF, Martorell R, editors. Anthropometric Standardization Reference Manual. Champaign, IL: Human Kinetics Books; 1988:44-45.
40. Matthew CE. Calibration of accelerometer output for adults. Med Sci Sports Exerc 2005 Nov;37(11 Suppl):S512-S522. [doi: 10.1249/01.mss.0000185659.11982.3d] [Medline: 16294114]
41. Karvonen J, Vuorimaa T. Heart rate and exercise intensity during sports activities: Practical application. Sports Med 1988 May;5(5):303-311. [doi: 10.2165/00007256-198805050-00002] [Medline: 3387734]
42. Harris JA, Benedict FG. A biometric study of human basal metabolism. Proc Natl Acad Sci U S A 1918 Dec;4(12):370-373 [FREE Full text] [doi: 10.1073/pnas.4.12.370] [Medline: 16576330]
43. Segal KR, Edano A, Abalos A, Albu J, Blando L, Tomas MB, et al. Effect of exercise training on insulin sensitivity and glucose metabolism in lean, obese, and diabetic men. J Appl Physiol (1985) 1991 Dec;71(6):2402-2411. [doi: 10.1152/jappl.1991.71.6.2402] [Medline: 1778939]
44. Dietowin. URL: http://www.dietowin.es/ [accessed 2019-12-28]
45. Baumeister RF, Vohs KD, Tice DM. The strength model of self-control. Curr Dir Psychol Sci 2016 Jun 24;16(6):351-355. [doi: 10.1111/j.1467-8721.2007.00534.x]
46. Polzien KM, Jakicic JM, Tate DF, Otto AD. The efficacy of a technology-based system in a short-term behavioral weight loss intervention. Obesity (Silver Spring) 2007 Apr;15(4):825-830 [FREE Full text] [doi: 10.1038/oby.2007.584] [Medline: 17426316]
47. Hebden L, Cook A, van der Ploeg HP, King L, Bauman A, Allman-Farinelli M. A mobile health intervention for weight management among young adults: A pilot randomised controlled trial. J Hum Nutr Diet 2014 Aug;27(4):322-332. [doi: 10.1111/jhn.12155] [Medline: 23992038]
48. Fukuoka Y, Vittinghoff E, Jong SS, Haskell W. Innovation to motivation: Pilot study of a mobile phone intervention to increase physical activity among sedentary women. Prev Med 2010;51(3-4):287-289 [FREE Full text] [doi: 10.1016/j.ypmed.2010.06.006] [Medline: 20600263]
49. Turner-McGrievy G, Tate D. Tweets, apps, and pods: Results of the 6-month Mobile Pounds Off Digitally (Mobile POD) randomized weight-loss intervention among adults. J Med Internet Res 2011 Dec 20;13(4):e120 [FREE Full text] [doi: 10.2196/jmir.1841] [Medline: 22186428]
50. Jacko JA, editor. Human Computer Interaction Handbook: Fundamentals, Evolving Technologies, and Emerging Applications. 3rd edition. Boca Raton, FL: CRC Press; 2012.
51. Hutchesson MJ, Rollo ME, Krukowski R, Ells L, Harvey J, Morgan PJ, et al. eHealth interventions for the prevention and treatment of overweight and obesity in adults: A systematic review with meta-analysis. Obes Rev 2015 May;16(5):376-392. [doi: 10.1111/obr.12268] [Medline: 25753009]
52. Gell NM, Wadsworth DD. The use of text messaging to promote physical activity in working women: A randomized controlled trial. J Phys Act Health 2015 Jun;12(6):756-763 [FREE Full text] [doi: 10.1123/jpah.2013-0144] [Medline: 25110303]
53. Fournier M, d'Arripe-Longueville F, Radel R. Testing the effect of text messaging cues to promote physical activity habits: A worksite-based exploratory intervention. Scand J Med Sci Sports 2017 Oct;27(10):1157-1165. [doi: 10.1111/sms.12730] [Medline: 27540899]

54. Steinberg DM, Levine EL, Askew S, Foley P, Bennett GG. Daily text messaging for weight control among racial and ethnic minority women: Randomized controlled pilot study. J Med Internet Res 2013 Nov 18;15(11):e244 [FREE Full text] [doi: 10.2196/jmir.2844] [Medline: 24246427]
55. Shapiro JR, Koro T, Doran N, Thompson S, Sallis JF, Calfas K, et al. Text4Diet: A randomized controlled study using text messaging for weight loss behaviors. Prev Med 2012 Nov;55(5):412-417. [doi: 10.1016/j.ypmed.2012.08.011] [Medline: 22944150]
56. Bosy-Westphal A, Schautz B, Lagerpusch M, Pourhassan M, Braun W, Goele K, et al. Effect of weight loss and regain on adipose tissue distribution, composition of lean mass and resting energy expenditure in young overweight and obese adults. Int J Obes (Lond) 2013 Oct;37(10):1371-1377. [doi: 10.1038/ijo.2013.1] [Medline: 23381557]
57. Gallagher D, Kelley DE, Thornton J, Boxt L, Pi-Sunyer X, Lipkin E, MRI Ancillary Study Group of the Look AHEAD Research Group. Changes in skeletal muscle and organ size after a weight-loss intervention in overweight and obese type 2 diabetic patients. Am J Clin Nutr 2017 Jan;105(1):78-84 [FREE Full text] [doi: 10.3945/ajcn.116.139188] [Medline: 27881389]
58. Tanaka NI, Murakami H, Aiba N, Morita A, Watanabe S, Miyachi M, Saku Control Obesity Program (SCOP) Study Group. Effects of 1-year weight loss intervention on abdominal skeletal muscle mass in Japanese overweight men and women. Asia Pac J Clin Nutr 2019;28(1):72-78 [FREE Full text] [doi: 10.6133/apjcn.201903_28(1).0011] [Medline: 30896417]
59. Cava E, Yeat NC, Mittendorfer B. Preserving healthy muscle during weight loss. Adv Nutr 2017 May;8(3):511-519 [FREE Full text] [doi: 10.3945/an.116.014506] [Medline: 28507015]
60. Swift DL, Johannsen NM, Lavie CJ, Earnest CP, Church TS. The role of exercise and physical activity in weight loss and maintenance. Prog Cardiovasc Dis 2014;56(4):441-447 [FREE Full text] [doi: 10.1016/j.pcad.2013.09.012] [Medline: 24438736]
61. Donnelly JE, Honas JJ, Smith BK, Mayo MS, Gibson CA, Sullivan DK, et al. Aerobic exercise alone results in clinically significant weight loss for men and women: Midwest exercise trial 2. Obesity (Silver Spring) 2013 Mar;21(3):E219-E228 [FREE Full text] [doi: 10.1002/oby.20145] [Medline: 23592678]
62. Morrison LG, Hargood C, Pejovic V, Geraghty AW, Lloyd S, Goodman N, et al. The effect of timing and frequency of push notifications on usage of a smartphone-based stress management intervention: An exploratory trial. PLoS One 2017;12(1):e0169162 [FREE Full text] [doi: 10.1371/journal.pone.0169162] [Medline: 28046034]
63. Turner-McGrievy GM, Wilcox S, Boutté A, Hutto BE, Singletary C, Muth ER, et al. The Dietary Intervention to Enhance Tracking with Mobile Devices (DIET Mobile) Study: A 6-month randomized weight loss trial. Obesity (Silver Spring) 2017 Aug;25(8):1336-1342 [FREE Full text] [doi: 10.1002/oby.21889] [Medline: 28600833]
64. Helmerhorst HJ, Brage S, Warren J, Besson H, Ekelund U. A systematic review of reliability and objective criterion-related validity of physical activity questionnaires. Int J Behav Nutr Phys Act 2012 Aug 31;9:103 [FREE Full text] [doi: 10.1186/1479-5868-9-103] [Medline: 22938557]
65. Ferrari P, Friedenreich C, Matthews CE. The role of measurement error in estimating levels of physical activity. Am J Epidemiol 2007 Oct 01;166(7):832-840. [doi: 10.1093/aje/kwm148] [Medline: 17670910]
66. Armanasco AA, Miller YD, Fjeldsoe BS, Marshall AL. Preventive health behavior change text message interventions: A meta-analysis. Am J Prev Med 2017 Mar;52(3):391-402. [doi: 10.1016/j.amepre.2016.10.042] [Medline: 28073656]

Abbreviations

ANOVA: analysis of variance
BMI: body mass index
CONSORT: Consolidated Standards of Reporting Trials
EHEALTH: Electronic and Mobile HEalth Applications and onLine TeleHealth
IPA: intense physical activity
IPAQ-long: long version of the International Physical Activity Questionnaire
LPA: light physical activity
MPA: moderate physical activity
PA: physical activity
SMS: short message service

Edited by C Dias; submitted 10.05.19; peer-reviewed by C Tejera Pérez, J Alvarez Pitti, C Carrion, R Ciptaningtyas, M Gaman, D Leightley; comments to author 19.08.19; revised version received 29.09.19; accepted 05.11.19; published 12.02.20.

Please cite as:
Hernández-Reyes A, Cámara-Martos F, Molina Recio G, Molina-Luque R, Romero-Saldaña M, Moreno Rojas R
Push Notifications From a Mobile App to Improve the Body Composition of Overweight or Obese Women: Randomized Controlled Trial
JMIR Mhealth Uhealth 2020;8(2):e13747
URL: http://mhealth.jmir.org/2020/2/e13747/
doi:10.2196/13747
PMID:32049065

Original Paper

Protecting Men Who Have Sex With Men From HIV Infection With an mHealth App for Partner Notification: Observational Study

Xiangyu Yan[1,2], PhD; Zuhong Lu[3], PhD; Bo Zhang[1,2], PhD; Yongjie Li[1,2], PhD; Wenjun Tang[1,2], MD; Lingling Zhang[4], ScD; Zhongwei Jia[2], PhD

[1]School of Public Health, Peking University, Beijing, China

[2]National Institute on Drug Dependence, Peking University, Beijing, China

[3]Biomedical Engineering, Southeast University, Jiangsu Province, China

[4]College of Nursing and Health Sciences, University of Massachusetts Boston, Boston, MA, United States

Corresponding Author:
Zhongwei Jia, PhD
National Institute on Drug Dependence
Peking University
38 Xueyuan Rd, Haidian District
Beijing,
China
Phone: 86 10 82802457
Email: urchinjj@163.com

Abstract

Background: Traditional partner notification methods have been implemented for HIV-infected patients, as well as HIV treatment, in order to identify people at risk of HIV infection, especially men who have sex with men (MSM), since they are more likely to have casual sex partners. These traditional methods have some limitations.

Objective: Our study focused on developing an mHealth app to improve partner notification in practice for MSM; the study then focused on evaluating the effects of the app.

Methods: We developed an mHealth app with different modules using Java and HTML5 and tested it in an MSM community to prevent HIV transmission. The HIV incidence stratified by different follow-up periods were calculated. Poisson regression and social networks were used to estimate the risk ratios and to identify the connection among MSM, respectively.

Results: In addition to the partner notification module, which is the kernel of the app, we developed a test result self-query module to enable MSM to get their approved test results in a timely manner, a prompt and warning module to alert users to protect themselves from high-risk conditions, and a health education module to teach users more skills regarding HIV/AIDS prevention. Over a 1-year duration, a total of 3186 MSM used the app, of which 678 had at least two HIV test results since becoming app users; they were included in the final analysis. Among 678 users, a total of 6473 self-queries and 623 partner notifications were recorded, which identified 180 social networks of MSM app users. Those who used the partner notification function were more likely to have self-queries (P<.001). The 678 MSM app users covered 296.47 person-years and contributed to 20 HIV seroconversions; the cumulative HIV infection incidence was estimated as 6.75 per 100 person-years (95% CI 4.38-10.01). We found that the longer the app was used, the lower the HIV incidence (>5 months vs ≤5 months: 2.22 per 100 person-years vs 6.99 per 100 person-years; risk ratio 0.32, 95% CI 0.12- 0.87).

Conclusions: The app developed in this study is consistent with the World Health Organization's sensitivity and confidentiality recommendations; it has the potential to reduce the risk of HIV infection among MSM.

(JMIR Mhealth Uhealth 2020;8(2):e14457) doi:10.2196/14457

KEYWORDS

partner notification; men who have sex with men; sexual network; mobile phone app

Introduction

HIV/AIDS is not only a serious infectious disease that endangers human health, but also a major global public health problem. In China, there were about 850,000 people reported to be living with HIV/AIDS in 2018; this number had increased rapidly over the years and is nearly double the number of about 440,000 people who were living with HIV/AIDS in 2011 [1,2]. Of the newly reported infections, 95.1% of people were infected through sexual transmission; 25.5% of them were men who have sex with men (MSM) and were infected though male-male sexual behaviors [3]. To control the spread of HIV effectively, providing antiretroviral therapy to people living with HIV/AIDS is a recommended method and is called *treatment as prevention* [4]. At present, antiretroviral therapy has covered about 75% of the reported HIV/AIDS cases worldwide and 80% of those in China, of which more than 90% were treated successfully [5,6]. However, as reported by the National Health Commission of China, about 30% of HIV-infected patients had not been found and did not know their HIV status [7]. As a result, they might not receive antiretroviral therapy and, therefore, this group comprises a tremendous number of latent sources of infection. As for MSM, the problem is particularly serious; because of the concealment of this subpopulation and stigma of HIV testing, it is difficult to find HIV-positive MSM in order to give them suitable treatment [8,9]. As most MSM seek sexual partners through Internet websites and software, such as Blued and Zank, including for one-night stands, they are more likely to hide their HIV status, which may increase the risk of HIV transmission [10,11]. Thus, it is important for them to know the risk of HIV infection and to know their real HIV status.

Partner notification is a public health measure that is recommended by the World Health Organization (WHO), in addition to *treatment as prevention*, to prevent and control HIV infection among HIV high-risk subpopulations, especially MSM [12-14]. Partner notification means that sexual partners should take the initiative to tell each other their HIV infection status; people living with HIV/AIDS, in particular, should tell their sexual partners their HIV status and encourage them to receive HIV testing [14]. A total of 67 countries already have policies about partner notification; it could be a valid way to help people identify their risk of HIV infection and promote HIV testing [14]. However, currently, the practicability of partner notification is limited to some extent. The existing partner notification methods, including traditional methods (ie, telephone or address contact), e-postcards sent by email as proposed by Deb Levine et al [15], and website-based partner notification methods [16,17], are aimed at giving HIV-positive individuals an opportunity to tell their sexual partners about their HIV status anonymously after sexual behaviors. As this has been the only type of notification method, partners of HIV-positive people have remained at high risk. In fact, implementing partner notification before sexual behaviors occur might be a fundamental way to avoid HIV transmission between two casual sexual partners and could be defined as primary prevention. However, this strategy has not yet been accepted in practice; one reason is that as a type of healthy behavior, implementing partner notifications is a long and difficult process, but most studies focus on short-term effects [18-20]. In addition, the lag and inconvenience of information exchange of existing partner notification methods was also a defect that needed to be improved [17].

Benefiting from the rapid development and popularization of the Internet, especially the rapid increase of health-related mobile phone apps, there are opportunities and techniques to achieve the goal of partner notification in advance of sexual behaviors [21,22]. In this study, we aim to design and develop a welcoming and convenient mHealth app with a main function of partner notification. We believe that this app could reduce the risk of HIV transmission among MSM. An observational study among app users was implemented to evaluate the effect of the app's functions.

Methods

mHealth App Design and Development Procedures

To meet the goal of promoting partner notification of HIV among MSM, an mHealth app was designed and developed. The app that we sought to develop had to meet the following functions and requirements:

1. Provide a feasible, easy, convenient technical solution to achieve the function of partner notification for MSM before they have sex.
2. Obtain and store users' HIV statuses and test dates, which can be used for partner notification in health centers by promoting HIV testing; HIV statuses can be approved and updated in a timely manner by health centers.
3. Allow users to query their HIV test results (ie, HIV status) conveniently and in a timely manner.
4. Protect users' privacy information in an effective, ethical, and nonobtrusive way.
5. Bring minimum economic and psychological burden, as well as a good user experience, to the users.

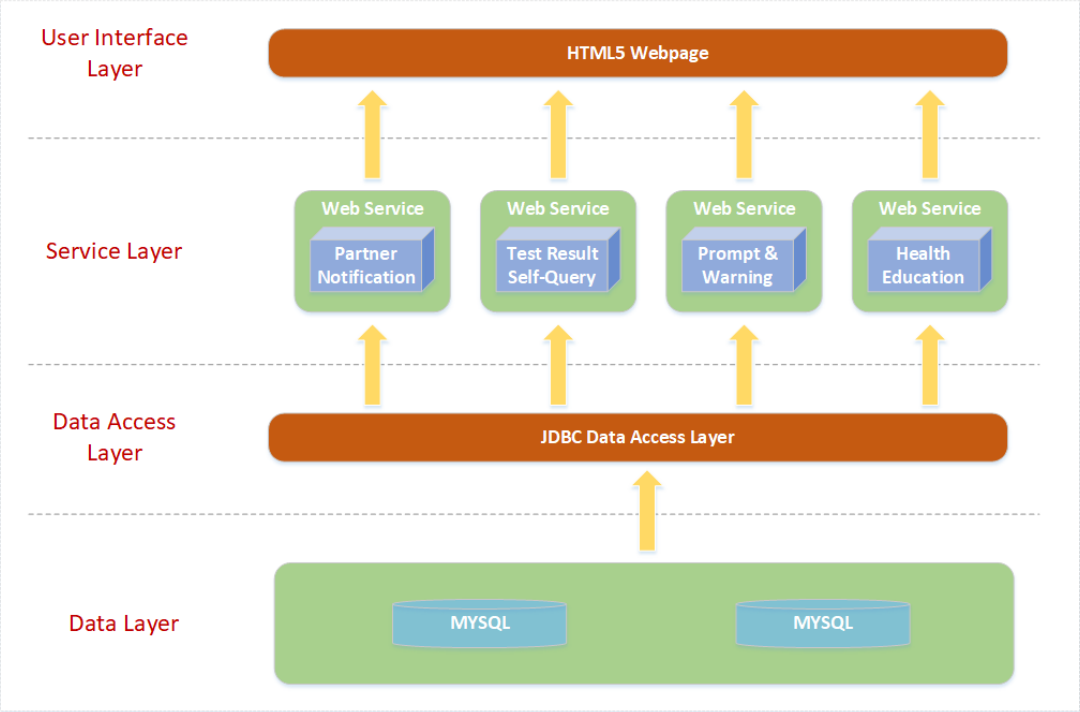
An interdisciplinary research and development team was formed to design and develop the app, including the following experts: HIV/AIDS epidemiologists, medical workers (ie, doctors and nurses), social workers, and software systems engineers. Team members had repeatedly discussed the implementation of the system functions and determined the final design scheme. The app was primarily developed in Java. The Web app technology was used to integrate some webpages, which combined the advantages of better human-computer interaction with cost-effectiveness in cross-platform development. These webpages were programmed and developed in HTML5.

To improve robustness of the app system, we designed and strengthened the app's infrastructure, architecture, and processing as follows. First, regarding the infrastructure, we set up system server hosts within the organization that provided HIV testing services. The operating system was Windows Server 2012. Second, we formed a four-layer architecture, including a data layer; a data access layer; a service layer, including four function modules; and a user interface layer (see Figure 1). Third, regarding processing, a log monitor module was set up within the app system to record any invalid inputs and queries by app users, such as incorrect phone number, which could be

used to optimize the system. To protect our data, we applied Hypertext Transfer Protocol Secure (HTTPS) communication over our system. The open-source Structured Query Language database MySQL was used for Web data storage, and the Message-Digest algorithm 5 (MD5) encryption technology was applied to encrypt the sensitive data in the database.

Two versions of the app for mobile phones running on iOS and on the Android operating system were developed; the functional webpages could also be accessed by Web browsers. After the completion of app development, we conducted internal and external testing; experts and staff on the project team tested and modified the system repeatedly to develop the final version of app to be used online. Engineers and testers, other than team members, were also invited to review code and test the app's function modules.

Figure 1. Application architecture. JDBC: Java Database Connectivity; SQL: Structured Query Language.



Observational Study Implementation

An observational study based on the app users' usage data was carried out to identify the connection among MSM and to evaluate the effectiveness of the app in reducing the risk of HIV infection. The study was implemented in Harbin, Heilongjiang province, China. Participants were enrolled into the study by the KangTong clinic for a period of 1 year between July 1, 2017, and June 30, 2018; the KangTong clinic is a community-based organization for MSM in Harbin and was the health center where app data were stored. The KangTong clinic also provided HIV testing services for the study; the clinic is the largest organization in Harbin that can provide testing services for MSM, except for hospitals and the local Center for Disease Control and Prevention (CDC).

The inclusion criteria for participants were as follows: (1) biologically male, (2) had oral or anal sex with men at least once during their lifetime, (3) 15 years of age or older, (4) had no difficulty using a mobile phone, on which the app must be installed, (5) willing to provide their mobile phone numbers to serve as the unique identification numbers of the app's self-query and partner notification functions, (6) willing to use the app's function modules, (7) willing to complete the questionnaire for the study, and (8) willing to complete the informed consent document. MSM who met all the inclusion criteria, but whose first HIV test results were positive, were also invited to register as app users and complete the questionnaire but were not included in the statistical analysis of HIV incidence.

When recruiting participants, the researchers and trained staff from the KangTong clinic publicized the app through online platforms (eg, WeChat, QQ, and Weibo) and offline venues (eg, the clinic, parks, and bars). The app's modules and their functions were introduced to all of the participants by trained staff. The participants were encouraged to use the app but were not obligated to do so. An electronic informed consent form was provided on the app when participants began to register. After completing the user registration, no specific instructions that would persuade them to use any particular module of the app were given to the participants; however, we observed them using the app in their own way to meet their needs. Participants were also invited to receive HIV testing provided by the KangTong clinic. When they made use of the provided HIV testing services, they needed to fill out a questionnaire containing basic demographic information and recent high-risk sexual behaviors, which they were informed of in the above electronic informed consent form. After completing an HIV test, the results and date were approved and input into the system by the clinic staff.

In order to protect participants' privacy and confidentiality, the recruitment process, HIV testing services, and participant

management after recruitment were all implemented one-to-one by the KangTong clinic's trained staff, and participants' real names were not collected during these processes. The HIV test results were communicated to the participants in two ways: first, by communicating the results to participants in person by the clinic's staff and, second, by allowing participants to query the results themselves through the app's function module. Though participants gave their phone numbers when they registered as app users, phone numbers would not be shown to clinic staff and staff would not call participants, in order to avoid disturbing them. The geographical locations collected by the app were also not shown to clinic staff.

Statistical Analysis

In this study, the app users who had at least two HIV test results during the 1-year period, and whose first HIV test results were negative after becoming registered users of the app, were included in the final analysis. The frequency and use of the app's different modules among these users were summarized. Because the frequency was not a normal distribution, medians and IQRs were calculated to describe the central tendency. The Mann-Whitney *U* test was used to test the difference in median frequencies between the two groups. The chi-square test was used to compare the basic characteristics among the MSM with the usage of different modules.

Several social networks were formed by users with at least two HIV test results and based on their connection with other MSM who were covered by the app's partner notification system. MSM who requested others' HIV statuses or whose statuses were requested by other MSM were the nodes of the networks identified by the transformed unique IDs. The directed edges in networks were built according to the request relationships. The nodes were weighted by the number of MSM they connected with, and the edges were weighted by the number of requests between two MSM in the same direction. Their HIV statuses (ie, HIV negative, HIV positive, and unknown status) were also distinguished in the network construction. In addition, HIV seroconversions were marked specifically in networks. We assumed that two MSM who were connected in the networks may be potential sexual partners.

The cumulative HIV incidence of the users with at least two HIV test results was calculated by dividing the total number of seroconversions by the total follow-up periods (ie, the period of time between one participant's first HIV test to his last HIV test, indicated by person-year). The HIV incidence of these users who used the app for 5 months or less or for more than 5 months was also calculated, of which 5 months was the median time of follow-up shown in the analysis of the study. Poisson regression was used to estimate the risk ratios (reported with 95% CIs and *P* values) of different follow-up periods and different modes of app usage. Because the enrollment time of each participant was different, the follow-up period for each participant was calculated individually. The date of HIV seroconversion was defined as the midway point between the last negative test date and the first positive test date. The users who used the app for more than 5 months were also included in the calculation for HIV incidence of those who used the app for 5 months or less; their follow-up periods were defined as 5 months (0.42 person-years). Regarding the calculation for HIV incidence of users who used the app for more than 5 months, their follow-up periods were the period of time between their first HIV test and their last HIV test.

A two-sided *P* value of .05 or less was regarded as significant. The data from the questionnaires, the self-queries, and the partner notification records that were linked by unique ID were double-checked in Microsoft Access, version 2013, and SPSS, version 21.0 (IBM Corp). Statistical analyses were done with SPSS, version 21.0 (IBM Corp). Network visualization was done with Cytoscape, version 3.5.1 (Cytoscape Consortium). Mapping was done with ArcGIS, version 10.0 (Esri).

Ethical Issues

This study was approved by the Peking University Institutional Review Board (IRB00001052-16016).

Results

App Development: Modules and Functions

The mHealth app named *Golden ark* was developed and contains four main modules: the *partner notification* module, the *test results self-query* module, the *prompt and warning* module, and the *health education* module.

Partner Notification Module

The app provides a function that allows users to request each other's HIV status from the health center. Figure 2 represents the framework of the partner notification system, which connects the app platform with the health center. The implementation of a request is divided into four steps:

1. User 1 sends a message to the health center requesting User 2's HIV status through the system; this is a very simple step where User 1 inputs User 2's phone number into the app's *Send new request* interface and then submits it.
2. After receiving the request, the health center converts it into a message that can be confirmed and approved by User 2 and sends the message to User 2's *Receive request* interface.
3. If User 2 agrees to show his HIV status to User 1, he must click on the *Agree* button on his *Receive request* interface within 24 hours; his status will then be sent to User 1. This is deemed a successful request. If User 2 clicks the *Disagree* button or refuses to deal with the request message within 24 hours, the request will be terminated and deemed an unsuccessful request.
4. User 1 can see the real-time processing results through his *Request history* interface as soon as User 2 has finished processing the request, which could have three outcomes: *Agree*, where User 2 agreed to share his recent HIV status; *Disagree*, where User 2 chose not to share his HIV status; and *Has yet to deal with*, where User 2 has not yet dealt with the request. The module's function can be implemented through several interfaces (see Figure 3, a, and Multimedia Appendix 1).

After the four steps, the two users' phone numbers, HIV status, the request status (ie, successful or not), and date are recorded

by the health center and can be linked to the two users' questionnaire information by their phone numbers.

We expect that when two MSM are deciding whether to meet, this friendly and convenient communication about HIV status via a social media app will help them decide, in a timely manner, whether to meet and have sex or not. If they use the function of partner notification and find out that one of them is HIV positive or HIV unknown, their meeting may be cancelled. In addition, if one user cannot get the other's HIV status or the other man has not had an HIV test for over 3 months, he is also more likely to cancel their meeting, thereby reducing his risk for HIV infection.

Figure 2. The framework of the partner notification system.

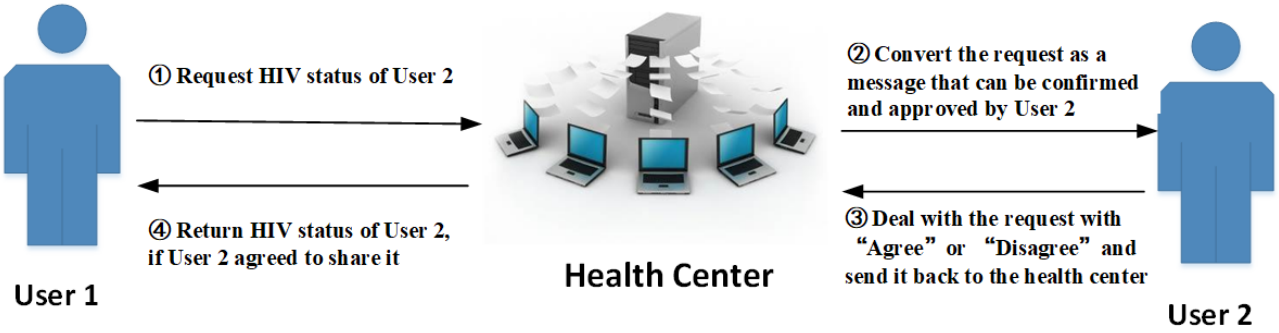
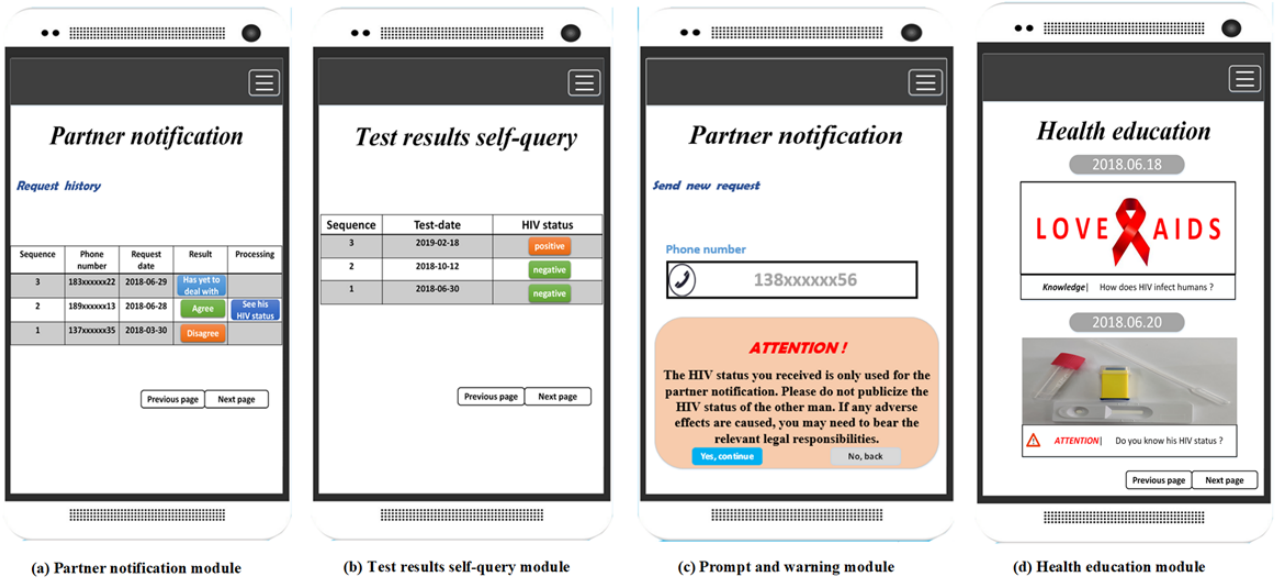


Figure 3. The interfaces of the app's four modules.



(a) Partner notification module (b) Test results self-query module (c) Prompt and warning module (d) Health education module

Test Results Self-Query Module

After completing the HIV test in the clinic, users can query their HIV test results through the app's *test results self-query* module from the health center—where all users' HIV test results are stored—just by clicking the module button on the interface. The test results that can be queried are approved by the health center and will be kept in the system; users can also look up their previous HIV test dates and results. For the convenience of users' queries, the records are arranged in reverse order according to the HIV test dates: the latest test record is listed at the top (see Figure 3, b). After every self-query, the user's phone number, HIV status, and self-query date are recorded by the health center and can be linked to the user's questionnaire information by their phone number. If the test result is positive, users can contact the health center for a follow-up consultation and help.

Prompt and Warning Module

On the basis of the self-query and partner notification module, a module aiming to give users some necessary prompts and warnings are embedded into the main functional module to alert users. This module contains two major parts: *dynamic prompt and warning* and *fixed prompt and warning*.

Dynamic Prompt and Warning

If one user's last HIV test result was HIV negative but he does not have a new result stored at the health center within the last 3 months—a 3-month interval is recommended by CDC [13]—the user will receive a prompt to persuade him to come to the health center for HIV testing (see Multimedia Appendix 2, a)

When one user (ie, User 1) requests to view the other user's (ie, User 2) HIV status, there are five request results possible:

1. User 2 refuses to show his HIV status to User 1: a *Disagree* or *Has yet to deal with* request result.
2. User 2 agrees to show his HIV status to User 1, but User 2 does not have any HIV test results stored in the health center's system: an unknown HIV status.
3. User 2 agrees to share his status, but User 2 is HIV positive.
4. User 2 agrees to share his status and the recent test result is HIV negative, however, the recorded result was 3 months ago.
5. User 2 agrees to share his status and has an HIV-negative test result recorded within the last 3 months.

According to the five possible request results, the system will give corresponding warning messages. For the first three results, the app module will send a warning message to User 1 to alert him to think carefully about dating User 2 and to pay attention to the potential risks (see Multimedia Appendix 2, b and c; the figures show the third situation as an example). For the fourth result, the module will alert User 1 that User 2's test result is overdue and he needs to be retested for HIV (see Multimedia Appendix 2, b and d). For the last result, the system will send a warning message to User 1 that alerts him to the possible window period and new infection of User 2 and advises him to use condoms to prevent potential risks of HIV and other sexually transmitted diseases (see Multimedia Appendix 2, b and e).

The above prompts and warnings are shown on User 1's *Partner's HIV status* interface when he uses the partner notification module.

Fixed Prompt and Warning

Two kinds of fixed prompts and warnings are set up on the app's interface to remind users to be more cautious and to pay attention to the security of their information. First of all, when one user uses the partner notification module and prepares to submit the mobile phone number of the man for whom he wants to request HIV status, a prompt will appear on the interface to warn him not to publicize the other man's HIV status (see Figure 3, c). In addition, when one user receives a request message on the *Receive request* interface, if he wants to click on the *Agree* button, he will receive a warning saying "If you click the 'Agree' button, your HIV status will be known by the other man; please be cautious" (see Multimedia Appendix 3).

Health Education Module

A health education module is provided to give users some necessary and timely health information to prevent them from engaging in high-risk behaviors (see Figure 3, d) This module also contains two parts: *Regular Intervention Information Dissemination* and *Dynamic Intervention Information Dissemination*.

Regular Intervention Information Dissemination

Health information will be disseminated to all users in the app regularly (ie, every week) to give users guidance on HIV prevention, such as basic knowledge about HIV/AIDS, skills in HIV/AIDS prevention, policies and regulations for AIDS patients, what and where services can be accessed, and so on.

Dynamic Intervention Information Dissemination

Based on the user's request behaviors (ie, frequency, successful or not, and so on) and his HIV status, as well as the HIV status of the men to whom he sent requests, the system may determine that the user is in a high-risk state. If so, the system will send reminders to the user, in a timely manner on the app's interface, about paying attention to his security regarding sexual behaviors, the correct method of condom use, the use of the HIV self-testing kit, and nearby HIV testing institutions.

App Data Collection and Management

The app users' data are collected from three sources:

1. The regular questionnaires users fill in before their application for HIV testing services, which are stored in the database automatically after they submit them through the app.
2. The approved HIV status and testing date for each HIV test, which are input into the system by the health center's trained staff and stored in the database for the app's partner notification module: users cannot input the test results themselves.
3. The self-query behaviors (ie, self-query records), the interactive behaviors (ie, partner notification records) of users, and the geographical locations of the usage of the two modules are automatically stored in the database when these modules are used.

The three kinds of data are linked by users' phone numbers that were used for registration, which became their unique IDs.

All of the data are stored in an encrypted database by the health center's stand-alone server in case of information leakage and illegal use. The reason we use phone numbers as unique IDs is that phone numbers are convenient and easy for users to remember as their unique usernames for registration and log-in; this is very common for most apps in China for managing users. Because users' phone numbers are private information, we encrypt this field when we store it in the database. When we export the data for analysis, this field will be replaced by a 16-bit string made up of random letters and numbers as the transformed unique IDs.

The kinds of information we collect, how we use and protect the information, as well as the possible risks are written in the informed consent form. All users need to sign the electronic informed consent form when they register.

Observational Study

From July 1, 2017, to June 30, 2018, 3186 MSM were recorded in the health center's self-query records and/or partner notification records. Of the 3186 MSM, there were 678 users (21.28%) with at least two HIV test results since becoming app users. There were 20 seroconversions found among these 678 users (2.9%).

Of the 678 users, a total of 6473 self-queries (median 6, IQR 2-12) and 623 partner notifications (median 2, IQR 1-3) were recorded. MSM who had used the partner notification function were likely to have more self-queries than those who did not (P<.001) (see Table 1). Most (4740/7096, 66.80%) of the self-queries and partner notifications occurred in Harbin,

Heilongjiang province, where the health center was located. Over the 1-year study period, usage location of the two function modules covered all of mainland China, except six provinces—Qinghai, Tibet, Gansu, Ningxia, Guizhou, and Guangxi—and was distributed centrally in eastern China (see Figure 4).

Table 1. Usage frequency of functions by the app users.

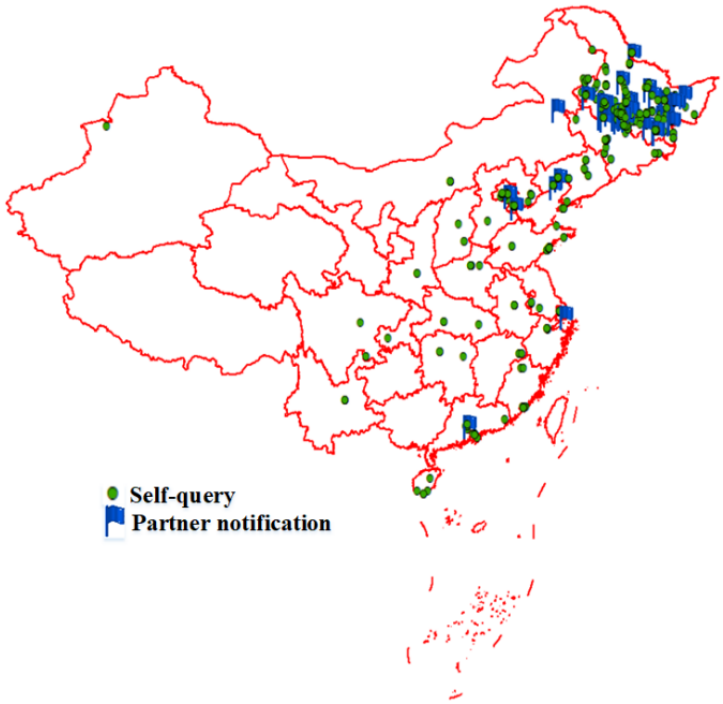
Function	Total	Never used partner notification (self-query only)	Had used partner notification	Mann-Whitney *U*	*P* value
Self-query					
MSM[a], n (%)	662 (100)	424 (64.0)	238 (36.0)		
Frequency, n (%)	6473 (100)	3340 (51.60)	3133 (48.40)	35,443	<.001[b]
Frequency, median (IQR)	6 (2-12)	5 (2-10)	9 (4-16)		
Partner notification					
MSM, n (%)	254 (100)	0 (0)	254 (100)		
Frequency, n (%)	623 (100)	0 (0)	623 (100)	N/A[c]	N/A
Frequency, median (IQR)	2 (1-3)	N/A	2 (1-3)		

[a]MSM: men who have sex with men.

[b]Significant at $P<.05$.

[c]N/A: not applicable.

Figure 4. Location distribution of the self-queries and partner notifications.



Most of the 678 users were unmarried (536/678, 79.1%), permanent residents (423/678, 62.4%), Han (648/678, 95.6%), living in the local area for more than 2 years (518/678, 76.4%), and had university-level education or above (447/678, 65.9%). Most of the users were homosexual, however, a sizable proportion (130/678, 19.2%) were bisexual MSM. In terms of seeking sexual partners, most of the MSM always used the Internet and some mobile apps to do so (555/678, 81.9%) instead of offline venues, such as gay bars, parks, bathrooms, and so on. The proportions of MSM who were insertive only when having anal sex versus those who had both insertive and receptive roles were similar (273/678, 40.3% vs 250/678, 36.9%) and were both higher than those who were receptive only (155/678, 22.9%). Among the 678 users, 254 (37.5%) of them had used the partner notification function (see Table 2).

Table 2. Basic characteristics of the app users.

Characteristics	Total (N=678), n (%)	Never used partner notification (self-query only) (N=424), n (%)	Had used partner notification (N=254), n (%)	Chi-square (df)	*P* value
MSM[a] (N=678)	678 (100)	424 (62.5)	254 (37.5)		
Age (years)				**0.1 (2)[b]**	**.94**
<25	171 (25.2)	109 (25.7)	62 (24.4)		
25-40	267 (39.4)	167 (39.4)	100 (39.4)		
>40	217 (32.0)	139 (32.8)	78 (30.7)		
Missing data	23 (3.4)	9 (2.1)	14 (5.5)		
Marital status				**0.9 (2)[b]**	**.64**
Married	105 (15.5)	70 (16.5)	35 (13.9)		
Unmarried	536 (79.1)	331 (78.1)	205 (81.3)		
Divorced or widowed	32 (4.7)	20 (4.7)	12 (4.8)		
Missing data	5 (0.7)	3 (0.7)	2 (0.8)		
Registered residence				**10.2 (1)**	**.001[c]**
Permanent residents	423 (62.4)	245 (57.8)	178 (70.1)		
Migrant	255 (37.6)	179 (42.2)	76 (29.9)		
Ethnicity				**0.007 (1)[b]**	**.93**
Han	648 (95.6)	404 (95.3)	244 (96.1)		
Minority	26 (3.8)	16 (3.8)	10 (3.9)		
Missing data	4 (0.6)	4 (0.9)	0 (0)		
Residence time in local area (years)				**6.8 (1)**	**.009[c]**
≤2	160 (23.6)	114 (26.9)	46 (18.1)		
>2	518 (76.4)	310 (73.1)	208 (81.9)		
Education				**1.1 (2)**	**.58**
Junior high school or below	92 (13.6)	62 (14.6)	30 (11.8)		
High school	139 (20.5)	85 (20.0)	54 (21.3)		
University or college or above	447 (65.9)	277 (65.3)	170 (66.9)		
Sexual orientation				**0.9 (3)**	**.83**
Homosexuality	485 (71.5)	305 (71.9)	180 (70.9)		
Heterosexuality	19 (2.8)	10 (2.4)	9 (3.5)		
Bisexuality	130 (19.2)	82 (19.3)	48 (18.9)		
Uncertain	44 (6.5)	27 (6.4)	17 (6.7)		
Place for seeking sexual partners				**10.7 (1)**	**.001[c]**
Internet or software app	555 (81.9)	363 (85.6)	192 (75.6)		
Offline venues (eg, bars and parks)	123 (18.1)	61 (14.4)	62 (24.4)		
Sex role				**6.2 (2)**	**.045[c]**
Insertive only	273 (40.3)	162 (38.2)	111 (43.7)		
Receptive only	155 (22.9)	110 (25.9)	45 (17.7)		
Both	250 (36.9)	152 (35.8)	98 (38.6)		

[a]MSM: men who have sex with men.

[b]Missing data were not included in the test.

[c]Significant at $P<.05$.

Compared with the MSM who only used the self-query function, MSM who had used the partner notification function were more likely to be permanent residents (178/254, 70.1% vs 245/424, 57.8%, $P=.001$), be living in the local area for more than 2 years (208/254, 81.9% vs 310/424, 73.1%, $P=.009$), and take on the insertive role when having anal sex (111/254, 43.7% vs 162/424, 38.2%, $P=.045$). Though the Internet and mobile apps were the main ways for seeking sexual partners, the proportion of MSM in the partner notification group who sought sexual partners in some offline venues was higher than that of the self-query-only group (62/254, 24.4% vs 61/424, 14.4%, $P=.001$) (see Table 2).

Overall, 180 networks were constructed among 254 users with at least two HIV test results (254/678, 37.5%) and other users they connected with (see Figure 5). Though most of the networks had just two nodes, there were still several larger networks; the common feature of these networks was that they all had one user with a high degree of centrality (ie, number of edges connecting a node to other nodes in the network) requesting the HIV status of other MSM. Some HIV-negative MSM frequently requested the HIV status of other MSM; this occurred a maximum of 55 times with 47 MSM involved. The MSM with a high degree of centrality from almost all of the larger networks were HIV negative. In addition, by using the app and forming networks, we are able to not only achieve our purpose of carrying out research on the 678 target users, but we can also find the relationships among more MSM in addition to the target MSM (see Figure 6, a). If we only focus on the connections among the 678 MSM, there were only 43 networks formed by 109 users with at least two HIV test results (109/678, 16.1%). However, based on the actual situation recorded by the app, this could extend to 180 networks with 254 users with at least two HIV test results and they could find more MSM that connect with them (see Figure 6, b).

Figure 5. Networks formed by the app's partner notification module.

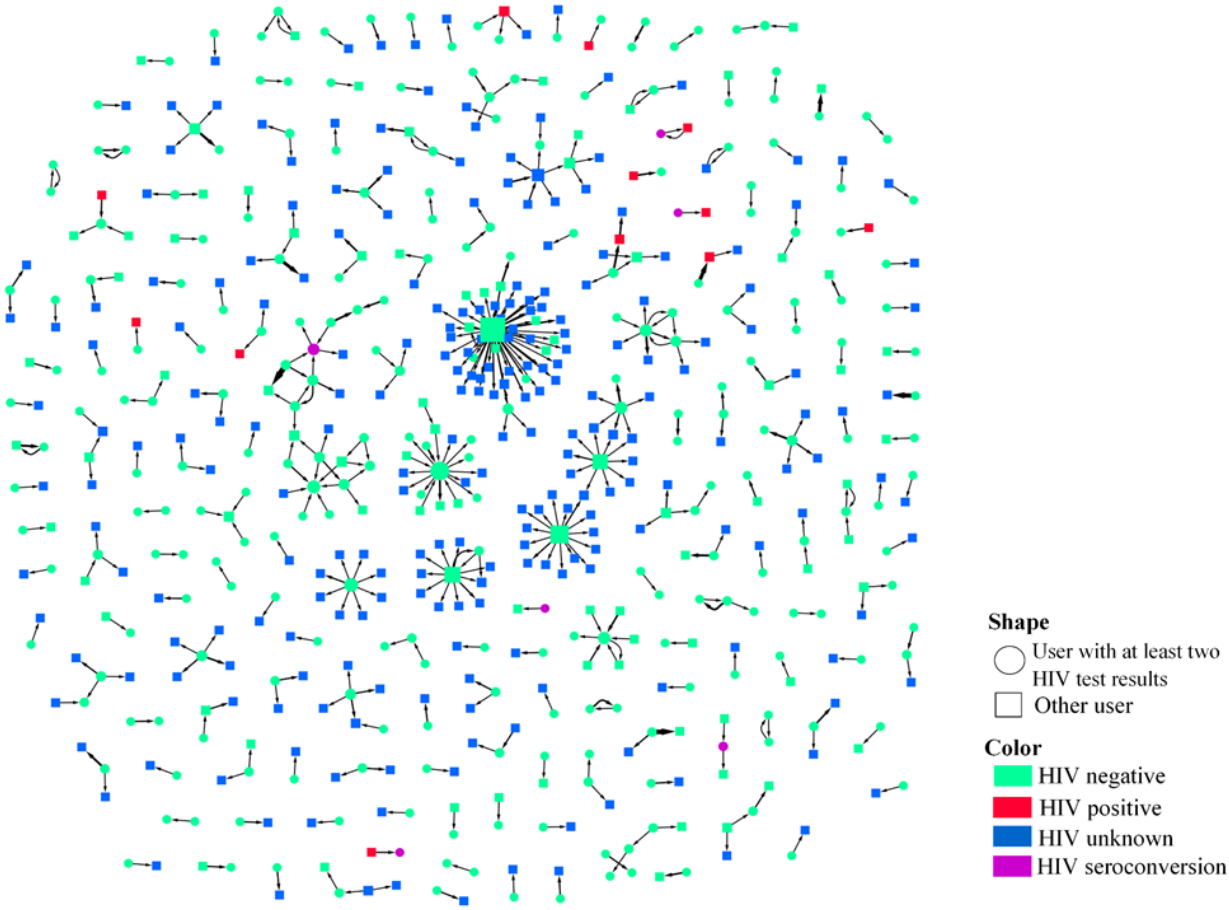
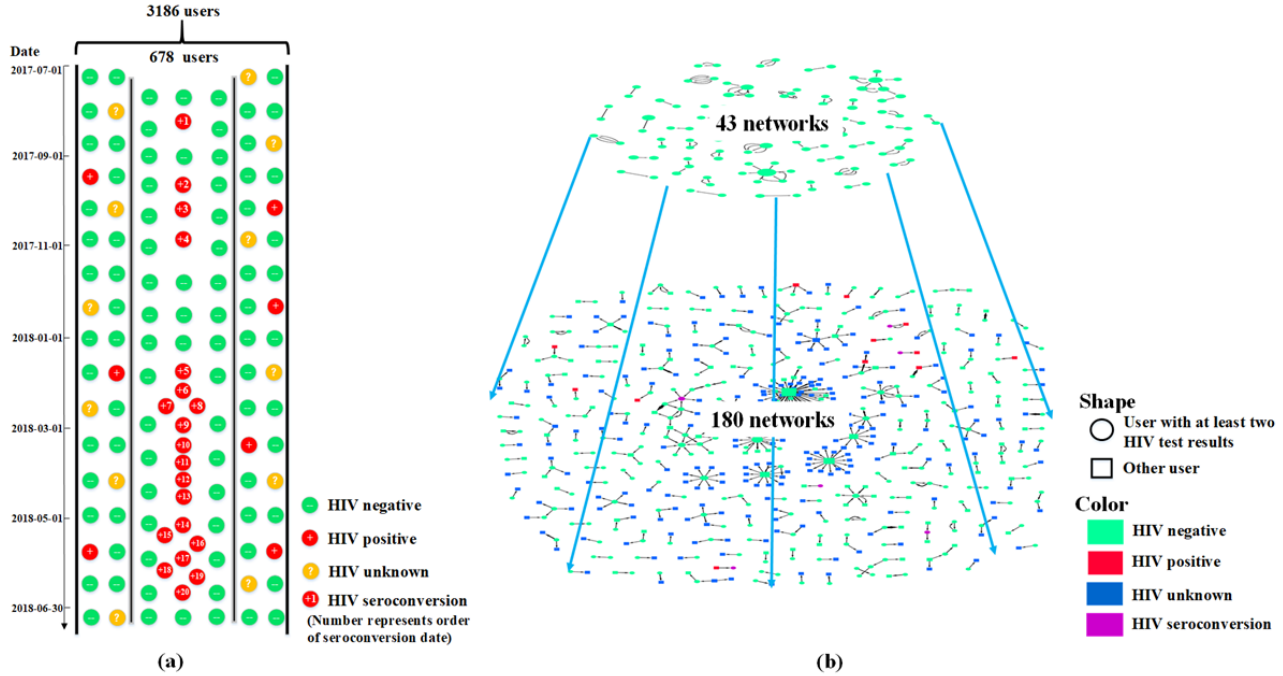


Figure 6. Extension of men who have sex with men (MSM) users and the two-tier networks.



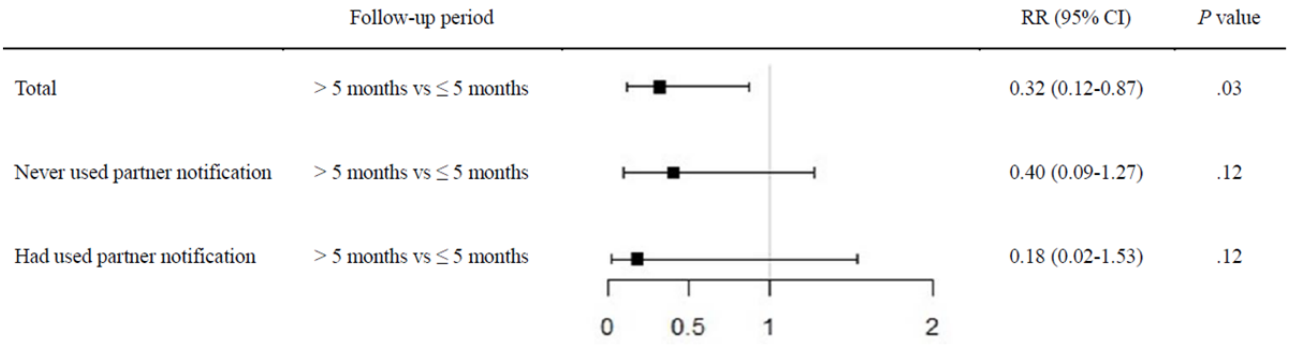
The median follow-up period for the 678 MSM was 5.05 months (IQR 2.82-7.64). The cumulative HIV incidence was 6.75 per 100 person-years (95% CI 4.38-10.01). Of the 20 seroconversions, 6 MSM (30%) had used the partner notification module while the other 14 MSM (70%) only used the self-query module. No significant differences in HIV incidence were found between MSM who had not used the partner notification module (ie, who just used the self-query function) and MSM who had used it. The difference in HIV incidence among MSM with a follow-up period of 5 months or less, or more than 5 months, between the two groups was also not significant (see Table 3). However, regardless of whether this module is used, longer usage (ie, >5 months) of the app could reduce HIV incidence compared with a follow-up of 5 months or less (incidence: 2.22 per 100 person-years vs 6.99 per 100 person-years; risk ratio 0.32, 95% CI 0.12-0.87, *P*=.03) (see Figure 7).

Table 3. HIV incidence of app users.

Follow-up period	Total (N=678)	Never used partner notification (self-query only) (N=524)	Had used partner notification (N=254)	Risk ratio (95% CI) (used vs never used)	*P* value
Total				**0.78 (0.27-2.29)**	**.65**
MSM[a] (N=678), n (%)	678 (100)	524 (77.3)	254 (37.5)		
Seroconversion, n (%)	20 (2.9)	14 (2.7)	6 (2.4)		
Person-years	296.47	177.53	118.94		
Incidence per 100 person-years (95% CI)	6.75 (4.38-10.01)	7.89 (4.73-12.52)	5.04 (2.37-9.81)		
≤5 months				**0.52 (0.06-4.68)**	**.56**
MSM (N=678), n (%)	678 (100)	524 (77.3)	254 (37.5)		
Seroconversion, n (%)	15 (2.2)	10 (1.9)	5 (2.0)		
Person-years	214.48	130.83	83.65		
Incidence per 100 person-years (95% CI)	6.99 (4.26-10.95)	7.64 (4.20-13.06)	5.98 (2.63-12.24)		
>5 months				**0.64 (0.25-1.66)**	**.36**
MSM (N=678), n (%)	348 (51.3)	283 (41.7)	142 (20.9)		
Seroconversion, n (%)	5 (1.4)	4 (1.4)	1 (0.7)		
Person-years	225.01	131.36	93.65		
Incidence per 100 person-years (95% CI)	2.22 (0.98-4.55)	3.05 (1.24-6.67)	1.07 (0.26-3.94)		

[a]MSM: men who have sex with men.

Figure 7. HIV infection risk between different periods of follow-up. RR: risk ratio.



Discussion

Principal Findings

The mHealth app with four modules seemed to be favored by MSM. Over a 1-year project duration, the app reached 3186 MSM, of which 678 uploaded at least two HIV test results and 37.5% used the partner notification function. The *partner notification* module provided a system connecting MSM and the health center, which could enable the function of sharing HIV statuses between potential sexual partners, after permission was given, in a way that preserved privacy. Such a module can enable partner notification before two MSM meet and have sex, and it can minimize embarrassment and anxiety after meeting. It is well aligned with the WHO's guidelines for sensitivity and confidentiality [23]. The *test results self-query* module enabled MSM to get the approved test results in time and to seek further guidance and intervention. In addition, the approved results provided a trustworthy source of users' HIV statuses when they used the *partner notification* function, which was also aligned with the *Know Your Status* theme of World AIDS Day 2018 [24]. The *prompt and warning* module and the *health education* module are two important auxiliary modules that can protect users from high-risk behaviors and teach users more skills in HIV/AIDS prevention. Taking advantage of the rapid development of the Internet and health-related mobile apps, this app and the app-based intervention have been developed to be much more convenient, user friendly, and cost-effective than traditional methods, and is easier to implement; the app is an expansion of the traditional behavior intervention mode, which focuses on education [25,26].

Our study has explored a new method of partner notification that could be implemented before high-risk sexual behaviors occur. In 2016, the WHO's evidence-based guidelines recommended assisted HIV partner notification services. This

refers to the assistance of consenting HIV-positive clients by a trained provider to disclose their status or to anonymously notify their sexual partners of their potential exposure to HIV infection and offer voluntary HIV testing services. These notification services could increase HIV testing among partners of HIV-positive people and result in a high proportion of HIV-positive people being diagnosed and linked to care [14,27-30]. However, some limitations might challenge the effectiveness of assisted partner notification: first, it attaches importance to the notification after sexual behavior has occurred, which might not prevent HIV transmission to the partners of HIV-positive individuals; second, assisted partner notification emphasizes the participation of health workers, which requires more time, human, and economic resources, and HIV-positive individuals might not be willing to cooperate [31,32]. Our method of partner notification could overcome these limitations to some extent. As well, two auxiliary modules of the app might intensify the effect of partner notification and MSM's sense of healthy self-responsibility, which could facilitate the transition from secondary prevention to primary prevention of HIV transmission among MSM.

Based upon connections and communications among MSM, the social networks were formed and analyzed to show the true epidemiologic behaviors among MSM. The networks formed by the partner notification connections could help find more MSM and their connections, which are more real, objective, and comprehensive than the connections found by traditional observational or cohort studies. Some much bigger networks were marked and the MSM with a high degree of centrality were more active than the MSM they were connected with. Though the MSM with a high degree of centrality were almost all HIV negative in our study, their active behaviors might put them at high risk of HIV infection; if they turned out to be HIV positive, active sources of infection would emerge. Thus, the MSM with a high degree of centrality in the network should be given a targeted intervention. The network was not only the reflection of the MSM's connection, as peer pressure and peer norms might also exist in social networks; several studies have shown that relying on the connections and communications among the members of the networks could promote behavior change and reduce the risk of HIV transmission [33-35]. Therefore, the networks formed by true epidemiologic data could be used to detect individual risk behaviors to make targeted policies for HIV control among MSM.

In this study, we were glad to find that the risk of HIV infection was decreasing. The cumulative HIV incidence was 6.75 per 100 person-years (95% CI 4.38-10.01), which was slightly lower than 7.1 per 100 person-years —the incidence of a cohort study with an intensive preventive intervention for MSM in Beijing, China [36]. The longer the app was used, the lower the risk of seroconversion. More than 5 months of app usage could reduce the HIV incidence to a much lower level of 2.22 per 100 person-years (95% CI 0.98-4.55), which was lower than the reported incidence in most regions of China and showed the potential effect of the app in reducing MSM's HIV infection risk [37]. In addition, the users of the app may naturally expand the intervention to more MSM than expected. In our study, the 254 users with at least two HIV test results connected with more MSM with no or only one HIV test result. The connections could be a process of expanding the reach of the intervention; it would encourage the other MSM to adopt this mode and to get regular HIV testing, which may increase the effect.

Limitations

Though the app has good application values, several limitations exist. We did not apply the intervention of HIV testing intervals to users, so some users' HIV testing intervals were too long to truly reflect their current HIV status. For some MSM with high-frequency sexual behaviors, the 3-month interval set in the app's prompt and warning module may be a bit longer. A dynamic adjusted prompt and warning interval based on the user's social network and HIV testing frequency is needed in the module. Another limitation was that, to some extent, the follow-up period of the study was short so there may exist a bias leading to misestimation of the HIV incidence. In addition, the only health center in this study was limited in its capability to provide enough services and spread the app to a much larger MSM population in a short time, which was also less convenient for MSM living in different cities.

Future Research Prospects

In future research, the following improvements will be made:

1. Improving the app functions to give more specific prompts and health education and to set some limits in search and match frequencies for app users with positive and unknown HIV statuses.
2. A new HIV testing model will be introduced to the health center to make the testing more convenient. In that model, app users will make an appointment to receive the HIV rapid test reagent kit from the health center, which can be sent to their home. After self-testing, users need to take photos of the test reagent kit and upload them through the app interface. The health center staff will review the photos and input the HIV status and date into the app system, which can then be used for test result self-query and partner notification.
3. More sexually transmitted diseases, such as syphilis, hepatitis B, and hepatitis C, will be included in testing services, the self-query module, and the partner notification module to ensure maximum protection levels for MSM.
4. More health centers in additional cities will be included in future studies to improve the convenience of testing services. We will recruit a larger number of MSM participants and increase the follow-up period to verify the effect of the intervention via the app. A consolidated database will be set up to collect and summarize the data from different health centers and to make the self-query and partner notification functions possible across health centers and cities.
5. We will try to cooperate with some popular MSM dating geosocial networking apps to attract more users and expand the population that our intervention can reach.

Conclusions

To our knowledge, our study is the first of its kind to provide an app to achieve mutual querying of HIV status between two MSM before sexual behaviors, with the integration of HIV

testing, partner notification, health center services, and social networks. We are optimistic that our app will be accepted by MSM users and that it will promote partner notification and reduce the risk of HIV infection. This app has the potential to help health care policy makers make targeted policies for HIV control among MSM.

Acknowledgments

We thank the staff from the KangTong clinic for their efforts in participant recruitment, app daily management, and providing HIV testing services. This work was supported by the National Natural Science Foundation of China (91546203, 91846302).

Authors' Contributions

XY, ZL, and ZJ were responsible for the development of the app and the observational study design. XY, LZ, and ZJ contributed to writing the report. XY and BZ contributed to data analysis. XY, BZ, WT, and YL contributed to the app development and data management. ZJ, the corresponding author, had full access to all data in the study and had the final responsibility for publication submission decisions.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The other interfaces of the partner notification module.
[PNG File , 545 KB - mhealth_v8i2e14457_app1.png]

Multimedia Appendix 2
The interfaces of the dynamic prompt and warning module.
[PNG File , 623 KB - mhealth_v8i2e14457_app2.png]

Multimedia Appendix 3
The other interfaces of the fixed prompt and warning module.
[PNG File , 182 KB - mhealth_v8i2e14457_app3.png]

References

1. NCAIDS, NCSTD, China CDC. Update on the AIDS/STD epidemic in China in 2011 and progress in major prevention and control work. Chin J AIDS STD 2011 Feb;18(2):64. [doi: 10.13419/j.cnki.aids.2012.02.007]
2. NCAIDS, NCSTD, China CDC. Update on the AIDS/STD epidemic in China the third quarter of 2018. Chin J AIDS STD 2018 Nov;24(11):1075. [doi: 10.13419/j.cnki.aids.2018.11.01]
3. NCAIDS, NCSTD, China CDC. Update on the AIDS/STD epidemic in China in December 2017. Chin J AIDS STD 2018 Feb;24(02):111. [doi: 10.13419/j.cnki.aids.2018.02.01]
4. Lou J, Hu P, Qian H, Ruan Y, Jin Z, Xing H, et al. Expanded antiretroviral treatment, sexual networks, and condom use: Treatment as prevention unlikely to succeed without partner reduction among men who have sex with men in China. PLoS One 2017;12(4):e0171295 [FREE Full text] [doi: 10.1371/journal.pone.0171295] [Medline: 28406992]
5. Miles to Go: Closing Gaps, Breaking Barriers, Righting Injustices. Geneva, Switzerland: UNAIDS; 2018. URL: http://www.unaids.org/sites/default/files/media_asset/miles-to-go_en.pdf [accessed 2019-04-19] [WebCite Cache ID 77kinAmy0]
6. Progress in AIDS Prevention and Treatment in China.: NCAIDS; 2018 Nov 23. URL: http://ncaids.chinacdc.cn/xxgx/yqxx/201811/t20181123_197488.htm [accessed 2019-04-19] [WebCite Cache ID 77khZoySO]
7. Press Conference on the Progress of HIV/AIDS Prevention and Treatment in China.: National Health Commission of China; 2018. URL: http://www.scio.gov.cn/xwfbh/gbwxwfbh/xwfbh/wsb/Document/1642083/1642083.htm [accessed 2019-04-19] [WebCite Cache ID 77khf6k2D]
8. Knight R, Karamouzian M, Salway T, Gilbert M, Shoveller J. Online interventions to address HIV and other sexually transmitted and blood-borne infections among young gay, bisexual and other men who have sex with men: A systematic review. J Int AIDS Soc 2017 Nov;20(3):e25017 [FREE Full text] [doi: 10.1002/jia2.25017] [Medline: 29091340]
9. Lorenc T, Marrero-Guillamón I, Llewellyn A, Aggleton P, Cooper C, Lehmann A, et al. HIV testing among men who have sex with men (MSM): Systematic review of qualitative evidence. Health Educ Res 2011 Oct;26(5):834-846. [doi: 10.1093/her/cyr064] [Medline: 21873612]
10. Li Q, Liu Y, Zhou Z, Li S, Luo F, Li D, et al. Online sex-seeking behaviors among men who have sex with men: Implications for investigation and intervention. AIDS Behav 2012 Aug;16(6):1690-1698. [doi: 10.1007/s10461-011-0005-0] [Medline: 21785872]

11. Prost A, Chopin M, McOwan A, Elam G, Dodds J, Macdonald N, et al. "There is such a thing as asking for trouble": Taking rapid HIV testing to gay venues is fraught with challenges. Sex Transm Infect 2007 Jun;83(3):185-188 [FREE Full text] [doi: 10.1136/sti.2006.023341] [Medline: 17229791]
12. The Lancet. Partner notification for preventing HIV infection. Lancet 1991 Nov 02;338(8775):1112-1113. [doi: 10.1016/0140-6736(91)91968-z]
13. NCAIDS, NCSTD, China CDC. Guidelines on HIV/AIDS Prevention Interventions for Men Who Have Sex With Men. 2016. URL: http://ncaids.chinacdc.cn/xxgx/jszl/201804/W020180419452122183283.pdf [accessed 2019-04-19] [WebCite Cache ID 77kgC0qhf]
14. Guidelines on HIV Self-Testing and Partner Notification: Supplement to Consolidated Guidelines on HIV Testing Services. Geneva, Switzerland: World Health Organization; 2016 Dec. URL: https://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/ [accessed 2019-04-19] [WebCite Cache ID 77kgdOoIt]
15. Levine D, Woodruff AJ, Mocello AR, Lebrija J, Klausner JD. inSPOT: The first online STD partner notification system using electronic postcards. PLoS Med 2008 Oct 21;5(10):e213 [FREE Full text] [doi: 10.1371/journal.pmed.0050213] [Medline: 18942887]
16. Zhong F, Xu HF, Cheng WB, Meng G, Wen F, Liu Q. Easy Tell™: An innovative online sexual partner notification system based on Internet and mobile phone. Chin J AIDS STD 2012 Jan;18(01):41-44. [doi: 10.13419/j.cnki.aids.2012.01.002]
17. Pellowski J, Mathews C, Kalichman MO, Dewing S, Lurie MN, Kalichman SC. Advancing partner notification through electronic communication technology: A review of acceptability and utilization research. J Health Commun 2016 Jun;21(6):629-637 [FREE Full text] [doi: 10.1080/10810730.2015.1128020] [Medline: 27144318]
18. Ye S, Xiao Y, Jin C, Cassell H, Blevins M, Sun J, et al. Effectiveness of integrated HIV prevention interventions among Chinese men who have sex with men: Evaluation of a 16-city public health program. PLoS One 2012;7(12):e50873 [FREE Full text] [doi: 10.1371/journal.pone.0050873] [Medline: 23300528]
19. Tang W, Mao J, Liu CC, Mollan K, Li HC, Wong T, SESH study group. Crowdsourcing health communication about condom use in men who have sex with men in China: A randomised controlled trial. In: Proceedings of the Lancet-Chinese Academy of Medical Sciences (CAMS) Health Summit. 2016 Oct Presented at: The Lancet-Chinese Academy of Medical Sciences (CAMS) Health Summit; October 30-31, 2016; Beijing, China. [doi: 10.1016/s0140-6736(16)32000-1]
20. Tang S, Tang W, Meyers K, Chan P, Chen Z, Tucker JD. HIV epidemiology and responses among men who have sex with men and transgender individuals in China: A scoping review. BMC Infect Dis 2016 Oct 20;16(1):588 [FREE Full text] [doi: 10.1186/s12879-016-1904-5] [Medline: 27765021]
21. Lunden I. TechCrunch. 2015 Jun 03. 6.1B smartphone users globally by 2020, overtaking basic fixed phone subscriptions URL: https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-2020-overtaking-basic-fixed-phone-subscriptions/ [accessed 2019-04-19] [WebCite Cache ID 77khtwnAw]
22. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiyagarajan A, et al. Gamification for health promotion: Systematic review of behaviour change techniques in smartphone apps. BMJ Open 2016 Oct 04;6(10):e012447 [FREE Full text] [doi: 10.1136/bmjopen-2016-012447] [Medline: 27707829]
23. US Agency for International Development (USAID), FHI 360's Strengthening HIV/AIDS Response Partnership with Evidence-Based Results (SHARPER) Project. FHI 360. 2014. Facebook over face-to-face time: Using social media to access hard-to-reach populations of men who have sex with men in Ghana URL: https://www.fhi360.org/sites/default/files/media/documents/Facebook%20over%20face-to-face%20time.pdf [accessed 2019-04-19] [WebCite Cache ID 77ki89hEf]
24. World Health Organization. 2018. World AIDS Day URL: https://www.who.int/campaigns/world-aids-day/world-aids-day-2018 [accessed 2019-04-19] [WebCite Cache ID 77kiCqtKq]
25. García-Gómez JM, de la Torre-Díez I, Vicente J, Robles M, López-Coronado M, Rodrigues JJ. Analysis of mobile health applications for a broad spectrum of consumers: A user experience approach. Health Informatics J 2014 Mar;20(1):74-84. [doi: 10.1177/1460458213479598] [Medline: 24550566]
26. Statista. 2018. Global mobile health app downloads 2013-2017 URL: https://www.statista.com/statistics/625034/mobile-health-app-downloads/ [accessed 2019-04-19] [WebCite Cache ID 77kiLAQE1]
27. Brown LB, Miller WC, Kamanga G, Nyirenda N, Mmodzi P, Pettifor A, et al. HIV partner notification is effective and feasible in sub-Saharan Africa: Opportunities for HIV treatment and prevention. J Acquir Immune Defic Syndr 2011 Apr 15;56(5):437-442 [FREE Full text] [doi: 10.1097/qai.0b013e318202bf7d] [Medline: 22046601]
28. Landis SE, Schoenbach VJ, Weber DJ, Mittal M, Krishan B, Lewis K, et al. Results of a randomized trial of partner notification in cases of HIV infection in North Carolina. N Engl J Med 1992 Jan 09;326(2):101-106. [doi: 10.1056/NEJM199201093260205] [Medline: 1445500]
29. Rosenberg NE, Mtande TK, Saidi F, Stanley C, Jere E, Paile L, et al. Recruiting male partners for couple HIV testing and counselling in Malawi's option B+ programme: An unblinded randomised controlled trial. Lancet HIV 2015 Nov;2(11):e483-e491. [doi: 10.1016/s2352-3018(15)00182-4]
30. Cherutich P, Golden M, Wamuti B, Richardson B, Asbjornsdottir K, Otieno F, aPS Study Group. Effectiveness of partner services for HIV in Kenya: A cluster randomized trial. In: Proceedings of the Conference on Retroviruses and Opportunistic

Infections. 2016 Presented at: Conference on Retroviruses and Opportunistic Infections; February 13-16, 2016; Boston, MA.
31. Carballo-Dieguez A, Remien R, Benson DA, Dolezal C, Decena CU, Blank S. Intention to notify sexual partners about potential HIV exposure among New York City STD clinics' clients. Sex Transm Dis 2002 Aug;29(8):465-471. [doi: 10.1097/00007435-200208000-00006] [Medline: 12172531]
32. Tsega A, Udeagu C, Begier EM. A comparison of partner notification effectiveness in African-, Caribbean-, and United States-born HIV-infected Blacks in New York City. AIDS Patient Care STDS 2012 Jul;26(7):406-410. [doi: 10.1089/apc.2011.0313] [Medline: 22663166]
33. Broadhead RS, Heckathorn DD, Grund JC, Stern LS, Anthony DL. Drug users versus outreach workers in combating AIDS: Preliminary results of a peer-driven intervention. J Drug Issues 1995 Jul;25(3):531-564. [doi: 10.1177/002204269502500303]
34. Tucker JD, Peng H, Wang K, Chang H, Zhang S, Yang L, et al. Female sex worker social networks and STI/HIV prevention in South China. PLoS One 2011;6(9):e24816 [FREE Full text] [doi: 10.1371/journal.pone.0024816] [Medline: 21931856]
35. Watt MH, Maman S, Jacobson M, Laiser J, John M. Missed opportunities for religious organizations to support people living with HIV/AIDS: Findings from Tanzania. AIDS Patient Care STDS 2009 May;23(5):389-394 [FREE Full text] [doi: 10.1089/apc.2008.0195] [Medline: 19335171]
36. Jia Z, Huang X, Wu H, Zhang T, Li N, Ding P, et al. HIV burden in men who have sex with men: A prospective cohort study 2007-2012. Sci Rep 2015 Jul 02;5:11205 [FREE Full text] [doi: 10.1038/srep11205] [Medline: 26135810]
37. Zhang L, Chow EPF, Jing J, Zhuang X, Li X, He M, et al. HIV prevalence in China: Integration of surveillance data and a systematic review. Lancet Infect Dis 2013 Nov;13(11):955-963. [doi: 10.1016/s1473-3099(13)70245-7]

Abbreviations

CDC: Center for Disease Control and Prevention
HTTPS: Hypertext Transfer Protocol Secure
MD5: Message-Digest algorithm 5
MSM: men who have sex with men
SQL: Structured Query Language
WHO: World Health Organization

Edited by G Eysenbach; submitted 20.04.19; peer-reviewed by J Clark, R Ali, M Gaman, J Farzi; comments to author 29.09.19; revised version received 22.11.19; accepted 29.11.19; published 19.02.20.

Please cite as:
Yan X, Lu Z, Zhang B, Li Y, Tang W, Zhang L, Jia Z
Protecting Men Who Have Sex With Men From HIV Infection With an mHealth App for Partner Notification: Observational Study
JMIR Mhealth Uhealth 2020;8(2):e14457
URL: http://mhealth.jmir.org/2020/2/e14457/
doi:10.2196/14457
PMID:32130147

Original Paper

Using Text Messaging to Improve Access to Prenatal Health Information in Urban African American and Afro-Caribbean Immigrant Pregnant Women: Mixed Methods Analysis of Text4baby Usage

Tenya M Blackwell[1], BS, MS, DrPH; LeConte J Dill[2], MPH, DrPH; Lori A Hoepner[1], MPH, DrPH; Laura A Geer[1], MHS, PhD

[1]Department of Environmental and Occupational Health Sciences, SUNY Downstate Health Sciences University, School of Public Health, Brooklyn, NY, United States

[2]Department of Social and Behavioral Sciences, College of Global Public Health, New York University, New York, NY, United States

Corresponding Author:
Tenya M Blackwell, BS, MS, DrPH
Department of Environmental and Occupational Health Sciences
SUNY Downstate Health Sciences University
School of Public Health
450 Clarkson Avenue
Brooklyn, NY
United States
Phone: 1 7182703101
Email: tblackwell@arthurasheinstitute.org

Abstract

Background: The Text4baby (T4B) mobile health (mHealth) program is acclaimed to provide pregnant women with greater access to prenatal health care, resources, and information. However, little is known about whether urban African American and Afro-Caribbean immigrant pregnant women in the United States are receptive users of innovative health communication methods or of the cultural and systematic barriers that inhibit their behavioral intent to use T4B.

Objective: This study aimed to understand the lived experiences of urban African American and Afro-Caribbean immigrant pregnant women with accessing quality prenatal health care and health information; to assess usage of mHealth for seeking prenatal health information; and to measure changes in participants' knowledge, perceptions, and behavioral intent to use the T4B mHealth educational intervention.

Methods: An exploratory sequential mixed methods study was conducted among pregnant women and clinical professionals for a phenomenological exploration with focus groups, key informants, interviews, and observations. Qualitative themes were aligned with behavioral and information technology communications theoretical constructs to develop a survey instrument used. repeated-measures pre- and post-test design to evaluate changes in participants' knowledge, attitudes, and beliefs, of mHealth and T4B after a minimum of 4 weeks' exposure to the text message–based intervention. Triangulation and mixing of both qualitative and quantitative data occurred primarily during the survey development and also during final analysis.

Results: A total of 9 women participated in phase 1, and 49 patients signed up for T4B and completed a 31-item survey at baseline and again during follow-up. Three themes were identified: (1) patient-provider engagement, (2) social support, and (3) acculturation. With time as a barrier to quality care, inadequate patient-provider engagement left participants feeling indifferent about the prenatal care and information they received in the clinical setting. Of 49 survey participants, 63% (31/49) strongly agreed that T4B would provide them with extra support during their pregnancy. On a Likert scale of 1 to 5, participants' perception of the usefulness of T4B ranked at 4.26, and their perception of the compatibility and relative advantage of using T4B ranked at 4.41 and 4.15, respectively. At follow-up, there was a 14% increase in participants reporting their intent to use T4B and a 28% increase from pretest and posttest in pregnant women strongly agreeing to speak more with their doctor about the information learned through T4B.

Conclusions: Urban African American and Afro-Caribbean immigrant pregnant women in Brooklyn endure a number of social and ecological determinants like low health literacy, income, and language that serve as barriers to accessing quality prenatal

health care and information, which negatively impacts prenatal health behaviors and outcomes. Our study indicates a number of systematic, political, and other microsystem-level factors that perpetuate health inequities in our study population.

(JMIR Mhealth Uhealth 2020;8(2):e14737) doi:10.2196/14737

KEYWORDS

Text4baby; mHealth; pregnancy; text messaging; health information; prenatal health; disparities

Introduction

Poor Birth Outcomes in Brooklyn, New York

Women and children of color in Brooklyn, New York, suffer inequities in health because of disproportionately higher rates of adverse birth outcomes such as low birth weight (LBW) and preterm birth. In 2014, the overall LBW (<2500 kg) rate for Brooklyn was 8.2% compared with 8.5% for all of New York City and 8.1% for the state of New York [1,2]. In 2012, the national rate for LBW was at 7.99% [3]. African American women have a 3 to 4 times higher risk than non-Hispanic/Latino whites for adverse infant health outcomes such as LBW [4], and according to Martins et al, infants born to non-Hispanic black women have the highest rates of LBW (13.1%), 2 or more times greater than that for infants born to women of other race and ethnic groups [4].

The Role of Communication

Health communication researchers attest that the public health community has a limited understanding of what health communication can offer to the elimination of health inequities [5]. Evidence shows that health communication can increase the intended audience's knowledge and awareness of a health issue, problem, or solution; influence perceptions, beliefs, and attitudes that may change social norms; prompt action; demonstrate or illustrate healthy skills; reinforce knowledge, attitudes, or behavior; show the benefit of behavior change; advocate a position on a health issue or policy; increase demand or support for health services; refute myths and misconceptions; and strengthen organizational relationships [5].

However, Freimuth and Quinn assert that health communication alone, without environmental support, is not effective at sustaining behavioral changes at the individual level [6]. High-quality communication and a positive patient-provider relationship are critical components of patient-centered quality care [7]. Furthermore, engaged patients who communicate with their providers are more likely to be treated with respect, receive adequate health information, and engage in health behaviors such as physical activity and healthy dietary behaviors [8,9].

Pregnant Women and Mobile Health

Mobile health (mHealth) has evolved as the branch of electronic health broadly defined as the use of mobile computing and communication technologies in health care and public health [10]. It has over the last decade become a new tool used in the delivery of health services for disease management and prevention in a variety of health arenas and as an innovative means to supplement traditional health communications targeting doctors, nurses, patients, or even the lay population [11].

Available literature displays use of mHealth for smoking cessation [12], physical activity [13], diet and weight loss [14], and managing chronic disease such as diabetes [15]. mHealth text messaging services (SMS) have impacted pregnant women in a number of ways.

Research in Canada, Saudi Arabia, and Argentina show pregnant women positively benefiting from the use of mHealth through increased access to prenatal health services, improved information-seeking behaviors, and has provided support throughout pregnancy with increased prenatal health knowledge and improved access to care [16-18]. Pregnant women or those caring for their first child are highly likely to use mHealth to increase their prenatal health information–seeking behaviors as they have a stronger need and desire to obtain pregnancy- and child health–related information [8,19,20].

Much of the current literature around mHealth for pregnant women examines participants' interests, acceptance, and the feasibility of text messaging for improving perinatal and postnatal care. For many immigrant populations, language and speech are important factors of consideration for any health communication endeavor either through providers or through technology. A recent cross-sectional study in Germany highlights the importance of culturally tailored text messaging and the consideration of users' health beliefs and health literacy levels in message development [21]. Similarly, in a systematic review, researchers underline the importance of the accommodation of local languages and preferences in the content of effective text messaging programs [22].

Dobson et al's qualitative study corroborates the benefits of culturally tailored mHealth programs for improved diet and exercise in pregnant women [22]; the feasibility and acceptability of a text messaging program aimed at smoking cessation for pregnant women [16] demonstrates that high acceptance and perceived feasibility of mHealth indicate a willingness to use and benefit from such services.

These studies provide a framework for this work and depict the need to first understand users' perceptions, acceptance, and overall intent to use mHealth for the purpose of accessing prenatal health information.

Text4baby

Despite a high level of activity and interest around text messaging apps, the documented evidence on their effectiveness remains limited [23]. The Text4baby (T4B) program was designed to offer support, improve health literacy, increase expectations for successful pregnancy, build the knowledge and skills to manage one's own health, and prevent health risks by avoiding behavioral risk factors including smoking and drinking. Launched in 2012, it is a US mHealth information text

messaging service led by the US Centers for Disease Control and Prevention that sends free text messages to women who are pregnant or have children younger than 1 year, providing them with information and reminders to improve their health and the health of their babies [17].

Research on T4B has focused primarily on the content and frequency of the T4B messages in comparison with messages from other pregnancy-related apps [17]. Enrollment and health literacy among potential T4B participants have also been a focus of T4B evaluation [24], along with its use to promote influenza vaccination among pregnant women [18], and for the design of interventions to improve physical activity in pregnant women [25].

Evans et al [26] emerged as a seminal empirical investigator of the impact of T4B on knowledge and behavioral outcomes of pregnant women. The earliest research published was a pilot study conducted with pregnant women in Fairfax County, Virginia, who presented for care at their local health department [17,27]. Through a randomized controlled trial (RCT), Evans et al found increased odds of participants feeling prepared for motherhood in those exposed to T4B versus normal prenatal care [26,28]. In other works, Evans et al [26] conducted an RCT of a group of military health service participants. Researchers sought to evaluate differences in adequate use of prenatal care, as defined by the Adequacy of Prenatal Care Utilization Index, in T4B participants compared with participants not receiving the T4B messages; however, others attest the study's ability to accurately measure true behavior change [27].

Effective health behavioral change programs should be guided by strong theoretical models [29-32]. To date, few mHealth and text messaging studies have adequately incorporated the use of theory to examine the impact, acceptance, feasibility, and behavioral intent to use mHealth. The current landscape of mHealth and T4B research using information technology (IT) theories is limited [33]. There are many factors that can influence the use of technology as a channel for prenatal health information within low-income urban and immigrant populations, and researchers strongly point to the need for multidisciplinary frameworks that capture the complexities of using mobile sources in health information behaviors [34].

Marton and Chun [35] demonstrate that an integration of theoretical perspectives from the health sciences, social sciences, communication, and information sciences research is necessary to fully understand this complex behavior. This study will leverage theoretically motivated constructs from research in consumer behavior and health information and communications technology to assess participants' knowledge, attitudes, beliefs, and behavioral intent to use T4B. Our research will add to the current body of literature around T4B by first assessing its impact on participants' perceptions of its feasibility, acceptance, compatibility, and usefulness. We seek to further fill empirical gaps by utilizing theoretically motivated constructs to examine our study populations' intent to use the T4B program for prenatal health information. This will allow practitioners and program developers to predict the use of the T4B program in this population to design better strategies that encourage its use for maternal health education and risk communication in ethnically, culturally, and socioeconomically diverse immigrant communities in Brooklyn. Therefore, our research demonstrates how theory and explicit testing of mediators can be used for evaluations of T4B [36]. See Figure 1.

Figure 1. Screenshot of Text4baby messages.

Theoretical Underpinnings

Previous works on the individual adoption of ITs have identified that a number of consumer characteristics and perceptions influence adoption of IT [13]. A recent systematic review of consumer health technology acceptance research points to studies that have assessed the effects of age, income, and education on health technology acceptance; however, theoretical constructs have not yet been fully considered in consumer health technology acceptance studies [13,37]. A combination of the Theory of Planned Behavior [38,39] and Technology Acceptance Model was used to examine the influence of participants' subjective norms and perceived behavioral control (attitudes and beliefs) on their ability and intention to use T4B [40,41]. Constructs from Roger's Diffusion of Innovation Theory were also explored in identifying valuable predictors for T4B intent [42]. In this research, our goal was to understand what it is like to be an urban and/or immigrant pregnant woman with accessing prenatal health care and information in Brooklyn, New York, and to utilize behavioral and technology assimilation of theoretical constructs in tandem with qualitative data to develop a survey instrument to measure pregnant women's knowledge, perceptions, and behavioral intent to use the T4B health communication program.

The overall purpose of this study was to test a maternal health education intervention (T4B) to see if it improves access to prenatal health care and information, improves prenatal health-seeking behaviors in pregnant women, and determines the likelihood that pregnant women in central Brooklyn would adopt T4B as a viable channel for prenatal health information. The underlying assumptions are that patients' knowledge about mHealth and T4B, their attitudes toward text messaging for prenatal health, their subjective and normative beliefs about prenatal health information sources, their perceptions on the usefulness and compatibility of T4B, and factors such as satisfaction and visibility of T4B will affect their acceptance of and behavioral intent to use the T4B program for improved access to prenatal and maternal health care and information.

Research Site

Study participants were recruited from the SUNY Downstate Medical Center University Hospital located in the East Flatbush section of Brooklyn, New York. East Flatbush is a community located in the central region of Brooklyn with a population of 154,575 persons. A total of 88.00% (136,026/154,575) of the population of East Flatbush is black, with 53% of residents born outside the United States, and almost 10% are reported to have limited English proficiency. In East Flatbush, 15.6% of live births receive late or no prenatal care, and according to the NYC Department of Health and Mental Hygiene, 1 in 8 births in this population are delivered preterm. The Maternal Fetal Medical Division of the Department of Obstetrics and Gynecology at Downstate provides perinatal and gynecological services for pregnant and nonpregnant black and Afro-Caribbean women. This location was chosen because of its vastly diverse urban and immigrant black population with migrants from a number of Afro-Caribbean countries including Haiti; Trinidad; and Jamaica, West Indies. Our research at this location offers an opportunity to study different social and cultural perspectives from subgroups within the black community and how these differences shape pregnant women's experiences in Brooklyn, New York. This site is also a location where scientists, physicians, and researchers hold expertise in risk communication of reproductive health issues, perinatal epidemiology, and environmental exposure assessment specifically with the use of biological markers. Geer et al, while characterizing important environmental risk factors in our target population, have indicated a need for further study and exposure reduction efforts tailored specifically to this community [43]. Our research at this site will expound the knowledge on innovative risk communication and health promotion efforts that are most suitable and receptive for the population of pregnant women. The authors have chosen not to use a pseudonym for the research site/research partner. Some scholars [44] agree that removing identifying information erases important contextual information that is valuable to the research. To not anonymize location of the research recognizes that SUNY Downstate sits within specific social, historical, cultural, environmental, geographical, and symbolic moments and meanings [45].

The study and protocol were approved by the Institutional Review Boards of the State University of New York Downstate Medical Center. Each participant signed an informed consent form before participation.

This study used multiple methods of inquiry including both qualitative phenomenology and IT constructs to explore the views of pregnant women in Brooklyn, New York, on prenatal health care and text messaging programs such as T4B to inform the development of a quantitative instrument to measure changes in their knowledge, attitudes, beliefs, and intent to use T4B.

Methods

Overview

A sequential mixed approach [46] was used to first gain knowledge about the experiences of urban African American and Afro-Caribbean immigrant pregnant women with accessing prenatal health care and prenatal health information at an urban metropolitan health center in New York City. We also sought to understand participants' perceptions about the use of mHealth and the T4B text messaging program as a source of prenatal health information and resources. We then conducted a repeated-measures pre- and post-test design study to measure changes in participants' knowledge, attitudes, and beliefs on key prenatal health behaviors, perceptions, and intent to use the T4B text messaging program.

Recruitment and Sampling

The sampling techniques for the qualitative phase were driven by the study's socioecological framework, which was used to aid in the exploration and discovery of factors that serve as barriers or facilitators of access to prenatal care and the use of mHealth communications among pregnant women in this community. Sample participants were pregnant women receiving prenatal care and clinical providers of prenatal health care services at SUNY Downstate. Various nonprobability sampling techniques were used during the early phase of inquiry. We used purposeful maximum variation sampling to recruit pregnant

participants who (1) were aged 18 to 45 years, (2) owned a cell phone with text messaging capabilities, and (3) could communicate fluently in English. Creswell and Plano Clark [47] render that maximum variation sampling captures the variation in experiences and perspectives from study participants. They further specify that if participants are purposefully chosen to be different at onset, then the variation in views will be reflected and will provide a more comprehensive picture of the phenomena under study [47]. We also chose purposive sample for participants who were able to communicate fluently in English as we found that participants from our target population who were not proficient in speaking or reading English showed difficulty in understanding consent forms and pretest survey questions. Many patients at Downstate who primarily spoke Haitian creole attempted to use a mobile interpretation app to translate the survey but naturally were unsuccessful. Therefore, we only recruited participants with adequate English proficiency. Expert sampling is a type of purposive sampling technique that is used as expert elicitation—acquiring knowledge from professionals who possess a particular expertise [48]. We used this form of purposive sampling to select clinicians from the obstetrics and gynecology clinic at Downstate Medical Center with experience providing prenatal care services to our study population as key informants to our study.

Their expert perspective helped broaden our scope of understanding the experiences of pregnant women through the eyes of both patients and providers.

A total of 22 participants agreed to be in the study; however, 9 women were successfully recruited and participated in 2 focus groups, 1 one-on-one interview, and 2 key informant interviews. For phenomenological research, Creswell et al [49] recommend a range of 5 to 25 participants; Fitzgerald et al [50] recommend a minimum sample size of 6. Our overall sample size of 9 falls within the recommendations of these qualitative research scholars. Moreover, 7 of the 9 participants were patients at the clinic.

The 2 key informants were clinical staff yielding a total of 9 participants for the descriptive phenomenology. Participants were directly approached by the study investigator while waiting to be seen at the clinic. They were initially recruited to participate in semistructured focus groups; however, difficulty with coordinating and scheduling focus groups at the convenience of the pregnant patients led to one-on-one in-depth interviews with patients as an alternative for data collection. Qualitative data collection took place from March 2016 to June 2016.

A standard demographic survey was completed during the consent process to gather data on participant age, education level, country of origin, race, ethnicity, insurance provider, and marital status. A total of 2 discussion guides were created for patients and providers to guide the focus groups and interviews with open-ended questions and probes to introduce selected a priori themes: (1) access and barriers to prenatal health care and information; (2) health disparities and the built environment; (3) cultural, familial, and social relationships; (4) knowledge, attitudes, beliefs, and use of mHealth and T4B; and (5) health information–seeking behaviors and sources.

Qualitative Data Collection

Focus groups and one-on-one interviews with pregnant women took place in a secured location at Downstate, and for convenience, they were scheduled to coincide with patients' prenatal visits. Key informant interviews took place at informant's offices. Interviews averaged between 60 and 90 min, with time allotted for refreshments for the pregnant participants. Participants gave oral responses to the set of open-ended questions. We completed a total of 2 focus groups and 1 in-depth interview with patients and 2 separate key informant interviews with providers. Data collection ended once saturation was reached and no new information emerged as interviews transpired. Interview data were triangulated with 3 patient observations in the natural setting of the clinic environment. Participant observations offer researchers an opportunity to gain a firsthand encounter with the phenomena under interest rather than relying solely on a secondhand account provided by participants [51]. We conducted 3 patient observations in the clinic waiting areas during the data collection phase. We observed patient engagement, attitudes, temperament, and the receipt of prenatal health education provided from a registered nurse educator from Downstate. Participants' observation also permitted within-method triangulation and increased validation of the dataset [51]. Care was taken to ensure research ethics, protecting patients' anonymity, confidentiality, and respecting their wishes were met. Moms received a US $20 Target gift card and a round trip metro transit card (worth US $5.50) as incentive. Participants provided written consent to participate and agreed to be audio recorded during the interviews.

Quantitative Data Collection

A convenience sample of 49 pregnant women was recruited during standard visits to undergo the T4B mHealth intervention. Inclusion criteria were the same for phases 1 and 2 to include pregnant women receiving care at SUNY Downstate, aged 18 to 45 years, who owned a cell phone with text messaging capabilities and were able to communicate in English. Participants were recruited while waiting for care in either the clinic triage area and while waiting to see the doctor after triage or waiting to receive a sonogram. Thematic findings generated from the qualitative analysis were aligned with constructs from consumer behavior, communications technology, and diffusion theories to develop a 32-item survey for a repeated-measures test of perceived usefulness, perceived behavioral control, and relative advantage of using T4B.

The instrument was a self-administered questionnaire that leveraged the constructs from other validated instruments [27] while also drawing on the suggested theoretical measures used for research on technology acceptance [39,43], consumer behavior [42], and mobile technology diffusion [33,52]. The 32-item survey is a composite of 8 scales representing 8 dependent variables and was administered as a pre-/post-test to assess changes in participants' perceptions regarding the statements. Following consent, participants were invited to use their mobile phones to enroll in the T4B program and partake

in 2 surveys, 1 on the day of recruitment and a second follow-up survey after a minimum of 4 weeks of receiving the text messages. Recruitment for the quantitative phase took place between October 2016 and March 2017 and continued on a rolling basis until the minimum desired number of participants was reached. Upon receiving consent, we administered the pretest survey and then assisted participants to follow the steps for signing up for T4B. After which, participants provided contact information to be reached after 4 weeks to complete a posttest survey during a subsequent prenatal visit. After a minimum of 4 weeks, participants were contacted to coordinate with their next prenatal visit to complete the follow-up survey. The posttest survey was identical to the initial baseline survey with the addition of 1 item to assess participants' self-report of actual reading of the text messages. Participants received a US $20 gift card and a roundtrip transit card (worth US $5.50) for their participation.

Quantitative Measures and Instrumentation

Attitudes Scale

This scale contained a battery of questions to assess participants' attitudes regarding key prenatal health behaviors such as diets, taking prenatal vitamins, smoking, drinking, and seeking prenatal care and information through mHealth. Participants were asked to rate their agreement with a series of statements on a 5-point Likert scale of 1 to 5 from "strongly disagree" to "strongly agree." The scale contained 8 items. The minimum possible score for the attitude scale was 8, and the maximum score was 40. A higher score was a reflection of a more strongly positive attitude toward the behavioral statements captured in the items.

Beliefs Scale

The beliefs scale contained 2 items that measured participants' subjective norm—the perceptions of family, peers, and persons of influence—on the use of mHealth and T4B to obtain prenatal health information.

The scale had a minimum score of 2 and a maximum score of 10. Variables specific to beliefs were adapted from previous studies of behavioral factors influencing text messaging intention [42]. Example belief variables included the following: "family and friends who are important to me would welcome using Text4baby for prenatal health information," and they were measured on a 5-point scale ranging from strongly disagree to strongly agree.

Perceived Usefulness Scale

The perceived usefulness construct contained 6 items to assess the degree to which participants perceived T4B to be useful to them. The maximum score possible for the scale was 30. Participants were asked to rate their agreement with statements such as "Info from Text4baby will help me ask more questions to the doctors and nurses at the clinic" and "online sources are useful for searching for prenatal health information."

Perceived Ease of Use Scale (Behavioral Control)

A 7-item scale was used to measure participant's perceived behavioral control for using mHealth and if they find mHealth easy to engage. With a maximum score of 35, example measures included the following: "it is easy for me to get prenatal health information on my mobile phone" and "I have all the skills and knowledge I need to use the Text4baby program."

Compatibility Scale

The compatibility scale was a 2-item scale that contained questions to assess the degree to which participants utilize mobile technology, particularly text messaging to communicate throughout their daily lives. Measured on a 5-point Likert scale, the compatibility scale asked questions such as "I communicate regularly with friends and family through text messages."

Relative Advantage Scale

We wanted to assess whether participants perceived T4B to be advantageous to them for the purposes of acquiring prenatal health information and resources. The relative advantage scale containing 3 items was also measured on a Likert scale. Example measures included "using Text4baby will allow me to reach healthier prenatal health goals" and "Text4baby messages will be a better source of prenatal health information for me."

Visibility Scale

The lack of awareness or visibility of T4B was a huge concept that was discovered during the qualitative phase of this study. Many of the participants had not heard of T4B despite its widespread promotion and local advertisement. We chose to assess visibility with a 2-item scale that contained a battery of questions to assess participants' agreement on whether they have seen or heard of others using T4B or if people they know depend more on the internet and mHealth for health information.

Intent

Unlike other studies [33], we did not assess the strength of the previously mentioned constructs in predicting participants' behavioral intent to use T4B; however, we measured behavioral intent using 2 items to determine the level of agreement with statements such as "I plan to use Text4baby for prenatal health care and information measured on a 5-point Likert scale of 'strongly disagree' to 'strongly agree'."

See Tables 1 and 2 for a description of survey questionnaire components and corresponding alpha coefficients.

Table 1. Questionnaire components by scale.

Scale	Item	Components measured	Theoretical origin	Response options
Attitude	1-8	Feelings on health behaviors like smoking, drinking, diet, health care utilization	TPB[a]	Strongly disagree–strongly agree
Perceived Usefulness	11-16	Intrinsic motivations to use T4B[b] due to perceived benefits of using	TAM[c]	Strongly disagree–strongly agree
Perceived Ease of Use	17-23	Behavioral control and abilities to use text messaging for prenatal health info	TPB, TAM	Strongly disagree–strongly agree
Compatibility	24-25	Perceptions whether text messaging and T4B fits into the everyday lives	DOI[d]	Strongly disagree–strongly agree
Relative advantage	26-28	Perceptions of the benefits of using T4B	DOI	Strongly disagree–strongly agree
Visibility	29-30	knowledge and awareness of T4B	DOI	Strongly disagree–strongly agree
Intent	31-32	Plans and intentions to use T4B	TPB, TAM DOI	Strongly disagree–strongly agree

[a]TPB: Theory of Planned Behavior.

[b]T4B: Text4baby.

[c]TAM: Technology Acceptance Model.

[d]DOI: Diffusion of Innovation Theory.

Table 2. Cronbach alpha coefficients for questionnaire by scale.

Scale	Alpha coefficient	Items, n	Mean scale rank[a]
Attitude scale	.661	8	—[b]
Beliefs scale	.883	2	4.08
Perceived Usefulness scale	.835	6	4.26
Perceived Ease of Use scale	.718	7	3.95
Compatibility scale	.806	2	4.41
Relative advantage scale	.880	3	4.15
Visibility scale	.193	2	—
Intent scale	.914	2	4.28

[a]Mean rank on a scale of 1-5 strongly disagree–strongly agree analyzed by Wilcoxon sign rank test.

[b]Not applicable.

Analysis

Qualitative Data Analysis

A total of 5 qualitative data sources were generated from the focus groups and interviews. Audio recordings from each interview were transcribed and uploaded using the NVivo (version 11.0 QSR International) [53] qualitative data management software. To ensure analytic rigor, we followed Colaizzi's 7-step phenomenological approach for extracting, organizing, and analyzing our narrative dataset [54]. With this approach, significant statements made by interviewees were taken from the transcripts and grouped together to formulate themes that describe key elements of experiencing the phenomenon, or area being studied Creswell et al [49]. Significant statements are those most outstanding comments, sentences, or quotes taken from participants that describe how they experienced the phenomenon [54]. Subsequently, similar significant statements are placed into clusters of meanings (or themes).

A total of 392 significant statements were extracted from 5 transcripts and broken into 9 a priori theme clusters. These clusters of significant statements were then coded using coding methods described by Miles et al [55] and analyzed to identify emergent themes.

Quantitative Data Analysis

SPSS version 24 (IBM) was used to analyze the quantitative dataset. The 32- items in the instrument were analyzed both as single Likert-type items in which frequency distributions, measures of central tendency, and variance were among the descriptive statistics used to summarize the variables. The 7 subscales were also analyzed as composite Likert scales in which nonparametric tests of comparison were run. Reliability of each scale—defined as how well a set of items within a scale measured the same underlying constructs—was determined based on the internal reliability using Cronbach alpha coefficient [56]. Changes in participants' attitudes and perceptions as a result of exposure to T4B messages between baseline and follow-up were analyzed using a matched-pairs Wilcoxon sign-ranked test. We chose this statistical test over a paired

sample *t* test because of the ordinal nature of the Likert-type subscales.

Results

Overview

A total of 58 participants were successfully recruited from the OB/GYN clinic at SUNY Downstate Medical Center for this study. Moreover, 9 participants, including 7 pregnant women and 2 clinicians, participated in the qualitative phase, and 49 pregnant women participated in phase 2 and completed the pretest and posttest surveys. The average age of the participants (n=49) was 28 years. Approximately two-thirds (63%) of the participants were US born, whereas the remaining were born in either Trinidad and Tobago; Haiti; or Jamaica, West Indies (36.7%). In addition, 15 participants (30.6%) reported that they were married, and 65.3% of the participants reported not being married or living with partner. Of the 38 participants, 38.8% had a high school diploma or the equivalent general education diploma, 20.4% attended technical school, and 14.3% reported having a 4-year college degree. A high proportion (87.8%) of participants had public health insurance such as Medicaid or Family Health Plus, whereas 4.1% (n=2) of the participants reported having private insurance through an employer. See Tables 3 and 4 for demographic characteristics of focus group and survey participants.

Table 3. Demographic characteristics of patients participating in focus groups and interviews.

Demographics	Value, n (%)
Maternal age	
20-29	4 (57)
30-39	2 (29)
40-45	1 (14)
Maternal education	
High school diploma or GED[a]	3 (43)
Technical school	1 (14)
College, 4-year degree	3 (43)
Maternal ethnicity	
African American	6 (86)
Hispanic	1 (14)
Maternal country of birth	
United States	2 (29)
Jamaica	2 (29)
Haiti	2 (29)
Trinidad	1 (13)
Maternal marital status	
Married	0 (0)
Not married	7 (100)
Maternal insurance type	
Public	6 (86)
Private	1 (14)

[a]GED: general education diploma.

Table 4. Demographic characteristics of patients participating in the survey.

Demographics	Value, n (%)
Age (years; n=49)	
<20	3 (6)
20-34	38 (77)
35+	6 (12)
Education (n=38)	
Some high school	2 (4)
High school diploma or GED[a]	19 (39)
Technical school	10 (20)
College, 4-year degree	7 (14)
Ethnicity (n=47)	
African American	22 (45)
Caribbean West Indian	24 (49)
Other	1 (2)
US born (n=49)	
Yes	31 (63)
No	18 (37)
Marital status (n=47)	
Married	15 (31)
Single	32 (65)
Insurance (n=45)	
Public	43 (88)
Private	2 (4)

[a]GED: general education diploma.

Prenatal Experiences With the US Health Care System

A total of 3 major themes were garnered from the interviews and observations: (1) inadequate patient-provider engagement, (2) social support, and (3) acculturation. Our qualitative findings showed that time served as a huge barrier impeding an adequate level of engagement and communication between pregnant women and clinicians at the Downstate prenatal health clinic. Participants reported expending a large amount of time—sometimes more than 4 and 5 hours from arrival to departure waiting for prenatal care. This often left many of them feeling frustrated, impatient, and with a poor temperament regarding the care they receive. One participant described dissatisfaction with her experiences, with waiting times for care creating great amount of frustration with the prenatal health system:

> *I get here earlier and then you're still here until 1 in the afternoon you know…Like…I don't understand that part…*

Another participant chimed:

> *and after…being somewhere for 4 or 5 hours you just wanna eat and go home*

This caused huge barriers in communication and engagement between pregnant women and providers. During an observation in the waiting areas, we noticed high levels of frustration marked by signs of huffing and puffing, constant complaints, restlessness, and high irritability, as captured in this observation field note:

> *Patients were very irate with the wait time – says "its miserable in here." They report that the doctors are very good and very thorough with providing information and addressing concerns when asked but having to wait so long; being pregnant, tired and hungry made them very angry.*

Participant 2 from focus group #2 described the actual amount of time spent in the office with doctors as "like an assembly line":

> *I feel, every time I come here I'm drained...I'm there...say the appointment starts from 10 o'clock...I'm there at 8 o'clock...and I'm still there to 1 o'clock...hmp...just to see him for four minutes.*

As patients are moved in and out so quickly, women felt as though they are not given enough opportunity to speak with their doctors and ask questions or given sufficient time to engage with providers in a manner that leads to acquiring information

or addressing any concerns they may have. They are reluctant to engage. When asked about the relationship between themselves and the doctor, the women in this study perceived that "here…there's so much of a rush…they don't put too much time in to do that." Some participants expressed a desire for clinicians to "be more communicative" and articulated dissatisfaction with their care as captured in the following statement:

> *Well I think the doctors need to be more…umm like communicative with the patients, not just come and then just check you and then {oh ok everything is fine I will give you like another appointment like next week}…that's not good.*

We found differences of perception between participants who were either US born, who had migrated to the United States less than 2 years, or within 5 years or greater. Discontent over the quality of prenatal care and information received came predominantly from younger participants, those born in the United States, and those more acculturated. Notably, the attitudes and experiences of participants who were newer immigrants were much more positive. Potentially, their increased exposure to the systematic and structural racism known to perpetuate the US health care industry have led to such negative perspective of their prenatal health experiences. With regard to the prenatal care she receives, 1 participant who migrated more recently expressed:

> *I'm from the Caribbean so…that seems like…top of the class to me…I'm from Trinidad…so I am content, it would too that I have never seen better than this. So my experience would be different so to me its ok…its great*

During the key informant interviews, clinical providers described the practices at Downstate and reported that immigrant and pregnant women have a great deal of access to prenatal care through various insurance programs such as New York State Medicaid and other pregnancy assistance programs such as Prenatal Care Assistance Program (PCAP), a prenatal care program developed to provide comprehensive perinatal care to low-income, high-risk pregnant women. Informants shared that women migrated from various countries—many Caribbean and African countries—presenting in their third term of pregnancy and near delivery. One clinician explained:

> *Many walk in here straight off a plane. They're far gone in the pregnancy and then umm with NO insurance.*

There was emphasis on women appearing for services late in the pregnancy for the provision of care despite the lack of health insurance.

The provider also added:

> *We had a subset of patients who would travel here from out of the country, they would come here and a lot of them had their prenatal records, they would get emergency Medicaid, deliver, have their postpartum visit and then leave and go home*

Social programs such as state Medicaid and PCAP make provisions for women who are pregnant to qualify for access to prenatal care. However, although such programs facilitate access to clinical prenatal care, we found that the women in our study more importantly emphasized the social determinants of prenatal health, including social systems and mHealth that provided support and information and improved participants' prenatal health-seeking behaviors.

Women noted that the advice, information, and support from their circle of family, friends, and other pregnant women in Web-based chat groups made them feel more prepared for motherhood. For many women, the internet or other mHealth apps were a major source of prenatal health information. In the current age of mobile and digital technology, it is not surprising that interviewees unanimously mentioned extensive use of the internet, Google, and sites such as BabyCenter as primary go-to sources for prenatal health information and also to fact-check doctors. Participants were attracted to online forums and groups for pregnant women "with whom participants could relate" and communicate with to share and learn from others' experience:

> *Sometimes you go in the chat rooms...you see people doing their methods of what works...but...it gives you something, it gives you a little more confidence too sometimes...you know...just to see the same amount of weeks or people going through the same symptoms that I am...*

Similarly, a second participant expounded:

> *Yea there's this app called baby prep baby pregnancy or something app, I have it on my phone...You talk to people all over the world...and all you have to do is put in your due date, they'll like link you up with a bunch of people who are in your time in your pregnancy...and everybody have the same similarities...you know going through the same thing so you'll feel more comfortable hearing from other people...around your time or whatever but doctor wise...I don't know*

There was a sense of trust, comfort, and pleasure with being able to go online for information, and many of the participants spoke of the increased access they have via their mobile phones. The women showed strongly positive attitudes toward the use of T4B and articulated that receiving push messages targeted specifically to their stages of pregnancy as a benefit that would even save them time from seeking information on their own.

Quantitative Findings

Attitudes and Beliefs Statements

In general, initial attitudes toward T4B and key prenatal health behaviors were mostly neutral among pregnant women in the study, as indicated by a mean rank score of 3.71 on the attitude scale (alpha coefficient .661). A score of 4 would indicate overall agreement. Survey results show that approximately 10% of respondents neither agreed nor disagreed with the statements on the scale. Approximately 84% of the participants strongly agreed with the statement that eating 5 or more fruits and vegetables per day is important to the health of their baby, which reflect a 22% increase from pre- and post-test (P=.02). After T4B exposure, there was a 26% increase in the amount of women who strongly agreed that visiting their health care

provider on a regular basis will help them be a healthy new mother (*P*=.03). There was also a 38% increase (*P*=.03) between presurvey and postsurvey in the proportion of participants who strongly agreed that using T4B will help them to have more support during pregnancy. During posttest, 51.0% of survey respondents strongly agreed with the statement "text4baby will help me to get new information about prenatal health" as opposed to 39% during pretest—reflecting an increase of nearly 27%. Although many participants neither agreed nor disagreed on whether relatives and those close to them would support the use of mHealth and T4B (20%), after exposure results showed a 12% increase in those who strongly agreed with that statement.

Perceived Usefulness and Perceived Behavioral Control Statements

The perceived usefulness of T4B improved in survey respondents after exposure to the text messages. Initially, a moderate proportion of participants neither agreed nor disagreed that the T4B messages will help to have a healthier pregnancy (26.5%). During the same time, 28.6% of respondents strongly agreed. However, at posttest, the proportion of participants who strongly agreed increased to 46.9% (*P*=.02). These results indicate a positive shift in attitude regarding T4B's usefulness. In contrast, strong agreement with the statement "online sources are helpful for searching prenatal health information" declined from initial testing to follow-up (from 46.9% to 40.8%). At the same time, the proportion of respondents who neither agreed nor disagreed increased from 6.1% to 14.3%, indicating a shift to more neutral attitudes in the usefulness of T4B. The proportion of women who believed that they find it easy to receive prenatal health information on their mobile phone increased slightly from 57.1% to 59.2%. In addition, the proportion of women who strongly agreed that T4B messages will allow them to have greater control over their prenatal health care increased by 56% between pretest and posttest from 28.6% of participants to 51% (*P*=.02). However, in contrast, there was a slight increase in strong agreement that "I have the skills needed to use Text4baby," and there was an increase from 4% to 14% in those having no opinion on that statement. Approximately 10% of the women surveyed agreed that reading English is sometimes difficult for them.

Compatibility, Relative Advantage, and Visibility Statements

A large percentage (85%) of respondents either agreed or strongly agreed with the compatibility of T4B messages by self-reporting regular use and communication via text messaging. A small portion (6%) either disagreed or strongly disagreed with the statement "I communicate regularly with friends and family through text messages," suggesting high usage of text messaging for communication and a strong compatibility with T4B's mode of disseminating information. Participant's perceptions about the relative advantage of using T4B improved after receiving the T4B messages. Overall, participants agreed (mean score 4.15) with the items on the relative advantage scale. There were significant increases in the proportion of respondents who strongly agreed with the statement "using Text4baby will allow me to reach healthier prenatal health goals" and the proportion of respondents who initially had no opinion, indicated by them neither agreeing nor disagreeing with the statement decreased from 10% and 16% before using T4B to 6.1% post T4B. T4B had low visibility within our study participants. A small percentage (8.2%) reported having seen or heard of someone using T4B. A larger proportion of respondents neither agreed nor disagreed (30.6%) and others either disagreed or strongly disagreed (24.5% and 16.3%, respectively) about having seen or heard of T4B use.

Behavioral Intent to Use Text4baby

Study participants largely reported their intent to use the T4B program (rank score 4.28). A total of 47% and 46%, respectively, agreed and strongly agreed that they plan to use T4B for accessing prenatal health care and information.

Similarly, 91.8% of the participants strongly agreed to speak more to their doctor about information they learn through T4B.

Discussion

Mixed Findings and Implications (for Research, Policy, and Practice)

The number of mHealth educational interventions for pregnant women is rapidly evolving, but research in this area—although growing— is still limited. Before this study, there existed no knowledge as to what determinants influenced T4B usage intentions and if participants' attitudes, beliefs, and perceptions would improve as a result of receiving the text messages. There are no studies that theoretically measure constructs of consumer health behavior, technology acceptance, and diffusion to conceptualize intent to use the T4B mHealth program. This is the first study to examine changes in attitudes, beliefs, and perceptions among urban African American and Afro-Caribbean immigrant pregnant women after exposure to T4B, and it provides novel insights by examining how T4B usage intentions may be influenced by perceived usefulness, relative advantage, perceived behavioral controls, and its compatibility within this study's population.

Despite the growing number of research endeavors investigating mHealth and T4B [9,57,58], none have used a sequential exploratory mixed methods design incorporating qualitative phenomenology followed by repeated-measures pre-/post-test design around T4B intervention. Our investigation revealed that pregnant women often felt that the information they received during prenatal visits was not adequate at meeting their health communication needs; however, they believed that mHealth and T4B could increase their access to health care and information. When asked how receptive they were to using T4B and receiving prenatal health text messages on their cellphones, respondents replied:

> *I wouldn't mind that cause...these phones now a days who don't have messages just popping up out of everywhere; yea I think it great cause instead of like going to google...and trying to type you just receive a text and they tell you click the link I think it's easier*

Survey respondents were later asked to rate on a 5-point Likert scale their level of agreement with the statement "Text4baby will help me to get new information about prenatal health."

Although 51% of the participants strongly agreed, approximately 10% of the participants remained neutral after having received the T4B messages. A 2012 study of pregnant women attending public hospitals and antenatal care centers in Argentina found that a vast majority (95.9%) of the women reported willingness to receive SMS messages during pregnancy [59]. A study of pregnant women and health care professionals also revealed that pregnant women believed 3 SMS messages per week was an appropriate and preferred dose of SMS message to receive during pregnancy [9].

We found that pregnant women often placed greater value on their social support system over clinical prenatal care services for complete and quality care. This included family, peers, social networks, and online communities for pregnant women and government social programs such as the Woman, Infant, and Children nutritional assistance programs. This was most notable as many women expressed great dissatisfaction with the lack of engagement they have with providers. Other researchers have suggested that one potential explanation for improved outcomes amongst pregnant black women is the provision of social support, coping strategies, and stress reduction through group prenatal care [60].

With regard to care and information, responds alluded to using mHealth as a support to check information provided to them by doctors:

> *I even look up certain things that I don't feel that's right that the doctor, whatever the doctor say I look it over just to make sure they not giving the wrong information cause you know sometimes...people do make mistakes...you know...but...but just to make sure I'm ok and my baby's is safe...I'll look it over...do the research...that's...that's what it's about the internet is everything for me lol.*

Our findings extend prior research [61] which showed that quality prenatal care must equally weigh on other nonclinical factors, such as interpersonal care processes like attitude and emotional support; and structure of care including access and physical setting; and care provider characteristics as a part of quality clinical prenatal care. Overall, our findings corroborate with others to confirm high acceptability [16] and feasibility [17] for T4B and similar text messaging interventions for pregnant women. Given the high population of Afro-Caribbean immigrants with limited English proficiency and multiple dialects spoken, we believe that a tailored mHealth program should be considered for this population to supplement access to information and resources. Patient-centered approaches that leverage partnerships between health care providers and community-based organizations could provide patients with access to culturally competent doulas and other community health workers in a novel way to increase engagement, support, and educational opportunities during pregnancy.

Future Implications

This research has a number of important implications for research, policy, and practice around mHealth and T4B. First, it provides a framework for more robust evaluation of the effects of T4B in this population of pregnant women by fostering an examination and prediction of T4B use through an initial assessment of patients' knowledge and perceptions regarding its use. Second, the study of consumer health behavior and IT uses the factors associated with mHealth, and text message use provides strategic targets for prevention and intervention through the design of cogent strategies that encourage its use among patients at Downstate.

New York State Department of Health is currently in year 3 of a 5-year endeavor to redesign health care delivery systems for residents in the State Delivery Systems Reform Incentive Payment program. There is a renewed focus on nonclinical social determinants of health and the provision of value-based care by community health organizations that provide health education and promotion services for people with low socioeconomic status. This research implies opportunities for health policy decisionmakers to further investigate, develop, and implement nontraditional patient-centered prenatal health care services that are better positioned to address the many health, education, and communication barriers faced by low income pregnant women in Brooklyn New York. This research also implies the use of mHealth and text messaging to communication environmental health and prenatal risk assessment messages for women in Brooklyn; and for environmental and population health surveillance as early warning signs of emerging public health threats, and as emergency information systems in natural disasters or pandemics [36].

Strengths and Limitations

The strengths of this study include the robust survey; sampling and analysis methods; and the triangulation of the qualitative data with focus groups, key informants, and observations. In addition, the development of a survey based on theoretically driven constructs of technology acceptance, innovation diffusion, and theory of planned behavior offers added strength. There are a number of limitations to this study, namely, the small sample size and the use of convenience sample, which can introduce sampling biases such as nonresponse and selection bias. This does not allow us to generalize to other populations of pregnant women; however, results may be indicative to similar urban and immigrant populations. The nature of pretest and posttest designs can also introduce biases due to response shift and maturation.

Conclusions

T4B is a text messaging program that provides prenatal care messages to pregnant women and new mothers. It uses a partnership model with health care facilities often serving as local implementation partners [36]. Although mHealth interventions have been proposed as effective solutions to improve maternal and neonatal health [56], this study showed that the use of mHealth for prenatal health information was quite common, whereas internet searches, Google, and pregnancy-related app usage was most widespread. Receiving prenatal health electronic messages through texting is a positive avenue and highly compatible to provide pregnant women in central Brooklyn with information; however, more research with a larger population and direct modeling of testing of the theoretical constructs is needed to fully assess the perceived

usefulness and relative advantage of T4B in this population. Although there was moderate intent to use the T4B program possibly because of its facilitation in women accessing information, gaining more control, and reaching healthier pregnancy goals, it is important that any mHealth endeavor must first be designed and tailored with the inclusion of those targeted to ensure that the messages and content are relevant and for a specific place-based population.

Acknowledgments

This study presents the original dissertation research funded by the University Hospital of Brooklyn SUNY Downstate Medical Center President's Health Disparities fund. The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of SUNY Downstate Medical Center. The authors would like to thank the clinicians and staff in the Department of Obstetrics and Gynecology at SUNY Downstate as well as their graduate research assistant Ludmila Ferruzzi for their support of this work. The authors especially like to thank the study participants for their time and effort.

Conflicts of Interest

None declared.

References

1. Li W, Huynh M, Lee E. New York City Department of and Mental Hygiene. Summary of Vital Statistics, 2014 URL: https://www1.nyc.gov/assets/doh/downloads/pdf/vs/2014sum.pdf [accessed 2018-10-29] [WebCite Cache ID 73Xn7AfCI]
2. New York State Department of Health. New York State Health Indicator Report - Percentage Low Birth Weight URL: https://www.health.ny.gov/statistics/chac/birth/b37.htm [accessed 2018-10-30] [WebCite Cache ID 73Xo5H4oA]
3. Martin J, Hamilton BE, Osterman MJ, Curtin SC, Matthews TJ. Births: final data for 2012. Natl Vital Stat Rep 2013 Dec 30;62(9):1-68 [FREE Full text] [Medline: 25671704]
4. Matthews TJ, MacDorman MF, Thoma ME. Infant mortality statistics from the 2013 period linked birth/infant death data set. Natl Vital Stat Rep 2015 Aug 06;64(9):1-30 [FREE Full text] [Medline: 26270610]
5. Thomas SB, Fine MJ, Ibrahim SA. Health disparities: the importance of culture and health communication. Am J Public Health 2004 Dec;94(12):2050. [doi: 10.2105/ajph.94.12.2050] [Medline: 15612166]
6. Freimuth VS, Quinn SC. The contributions of health communication to eliminating health disparities. Am J Public Health 2004 Dec;94(12):2053-2055. [doi: 10.2105/ajph.94.12.2053] [Medline: 15569949]
7. Attanasio L, Kozhimannil KB. Patient-reported communication quality and perceived discrimination in maternity care. Med Care 2015 Oct;53(10):863-871 [FREE Full text] [doi: 10.1097/MLR.0000000000000411] [Medline: 26340663]
8. Guendelman S, Broderick A, Mlo H, Gemmill A, Lindeman D. Listening to communities: mixed-method study of the engagement of disadvantaged mothers and pregnant women with digital health technologies. J Med Internet Res 2017 Jul 05;19(7):e240 [FREE Full text] [doi: 10.2196/jmir.7736] [Medline: 28679489]
9. Huberty J, Dinkel D, Beets MW, Coleman J. Describing the use of the internet for health, physical activity, and nutrition information in pregnant women. Matern Child Health J 2013 Oct;17(8):1363-1372. [doi: 10.1007/s10995-012-1160-2] [Medline: 23090284]
10. Cené CW, Roter D, Carson KA, Miller ER, Cooper LA. The effect of patient race and blood pressure control on patient-physician communication. J Gen Intern Med 2009 Sep;24(9):1057-1064 [FREE Full text] [doi: 10.1007/s11606-009-1051-4] [Medline: 19575270]
11. Roter DL, Stewart M, Putnam SM, Lipkin M, Stiles W, Inui TS. Communication patterns of primary care physicians. J Am Med Assoc 1997;277(4):350-356. [Medline: 9002500]
12. Rai A, Chen L, Pye J, Baird A. Understanding determinants of consumer mobile health usage intentions, assimilation, and channel preferences. J Med Internet Res 2013 Aug 02;15(8):e149 [FREE Full text] [doi: 10.2196/jmir.2635] [Medline: 23912839]
13. Free C, Phillips G, Felix L, Galli L, Patel V, Edwards P. The effectiveness of M-health technologies for improving health and health services: a systematic review protocol. BMC Res Notes 2010 Oct 06;3:250 [FREE Full text] [doi: 10.1186/1756-0500-3-250] [Medline: 20925916]
14. Free C, Whittaker R, Knight R, Abramsky T, Rodgers A, Roberts IG. Txt2stop: a pilot randomised controlled trial of mobile phone-based smoking cessation support. Tob Control 2009 May;18(2):88-91. [doi: 10.1136/tc.2008.026146] [Medline: 19318534]
15. Fukuoka Y, Vittinghoff E, Jong SS, Haskell W. Innovation to motivation--pilot study of a mobile phone intervention to increase physical activity among sedentary women. Prev Med 2010;51(3-4):287-289 [FREE Full text] [doi: 10.1016/j.ypmed.2010.06.006] [Medline: 20600263]
16. Aranda-Jan CB, Mohutsiwa-Dibe N, Loukanova S. Systematic review on what works, what does not work and why of implementation of mobile health (mHealth) projects in Africa. BMC Public Health 2014 Mar 21;14:188 [FREE Full text] [doi: 10.1186/1471-2458-14-188] [Medline: 24555733]

17. US Department of Health and Human Services. 2014. Using Health Text Messages to Improve Consumer Health Knowledge, Behaviors, and Outcomes URL: https://www.hrsa.gov/sites/default/files/archive/healthit/txt4tots/environmentalscan.pdf [accessed 2015-03-24]
18. Gazmararian JA, Yang B, Elon L, Graham M, Parker R. Successful enrollment in Text4Baby more likely with higher health literacy. J Health Commun 2012;17(Suppl 3):303-311. [doi: 10.1080/10810730.2012.712618] [Medline: 23030578]
19. Ferrer-Roca O, Cárdenas A, Diaz-Cardama A, Pulido P. Mobile phone text messaging in the management of diabetes. J Telemed Telecare 2004;10(5):282-285. [doi: 10.1258/1357633042026341] [Medline: 15494086]
20. Wallwiener S, Müller M, Doster A, Laserer W, Reck C, Pauluschke-Fröhlich J, et al. Pregnancy eHealth and mHealth: user proportions and characteristics of pregnant women using Web-based information sources-a cross-sectional study. Arch Gynecol Obstet 2016 Nov;294(5):937-944. [doi: 10.1007/s00404-016-4093-y] [Medline: 27084763]
21. Jang J, Dworkin J, Hessel H. Mothers' use of information and communication technologies for information seeking. Cyberpsychol Behav Soc Netw 2015 May;18(4):221-227. [doi: 10.1089/cyber.2014.0533] [Medline: 25803204]
22. Dobson R, Whittaker R, Bartley H, Connor A, Chen R, Ross M, et al. Development of a culturally tailored text message maternal health program: TextMATCH. JMIR Mhealth Uhealth 2017 May 20;5(4):e49 [FREE Full text] [doi: 10.2196/mhealth.7205] [Medline: 28428159]
23. Abroms LC, Johnson PR, Heminger CL, Van Alstyne JM, Leavitt LE, Schindler-Ruwisch JM, et al. Quit4baby: results from a pilot test of a mobile smoking cessation program for pregnant women. JMIR Mhealth Uhealth 2015 Jan 23;3(1):e10 [FREE Full text] [doi: 10.2196/mhealth.3846] [Medline: 25650765]
24. Bahanshal S, Coughlin S, Liu B. For You and Your Baby (4YYB): adapting the centers for disease control and prevention's Text4Baby program for Saudi Arabia. JMIR Res Protoc 2017 Mar 28;6(2):e23 [FREE Full text] [doi: 10.2196/resprot.5818] [Medline: 28246065]
25. Bushar JA, Kendrick JS, Ding H, Black CL, Greby SM. Text4baby influenza messaging and influenza vaccination among pregnant women. Am J Prev Med 2017 Dec;53(6):845-853 [FREE Full text] [doi: 10.1016/j.amepre.2017.06.021] [Medline: 28867143]
26. Evans WD, Wallace JL, Snider J. Pilot evaluation of the text4baby mobile health program. BMC Public Health 2012 Dec 26;12:1031 [FREE Full text] [doi: 10.1186/1471-2458-12-1031] [Medline: 23181985]
27. Huberty J, Rowedder L, Hekler E, Adams M, Hanigan E, McClain D, et al. Development and design of an intervention to improve physical activity in pregnant women using Text4baby. Transl Behav Med 2016 Jun;6(2):285-294 [FREE Full text] [doi: 10.1007/s13142-015-0339-7] [Medline: 27356999]
28. Remick AP, Kendrick JS. Breaking new ground: the text4baby program. Am J Health Promot 2013;27(3 Suppl):S4-S6 [FREE Full text] [doi: 10.4278/ajhp.27.3.c2] [Medline: 23286662]
29. van Velthoven MH, Majeed A, Car J. Text4baby - national scale up of an mHealth programme. Who benefits? J R Soc Med 2012 Nov;105(11):452-453 [FREE Full text] [doi: 10.1258/jrsm.2012.120176] [Medline: 23257962]
30. Ybarra ML, Holtrop JS, Bağci Bosi AT, Emri S. Design considerations in developing a text messaging program aimed at smoking cessation. J Med Internet Res 2012 Jul 24;14(4):e103 [FREE Full text] [doi: 10.2196/jmir.2061] [Medline: 22832182]
31. Lichtenstein E, Zhu S, Tedeschi GJ. Smoking cessation quitlines: an underrecognized intervention success story. Am Psychol 2010;65(4):252-261 [FREE Full text] [doi: 10.1037/a0018598] [Medline: 20455619]
32. Johnson WD, Diaz RM, Flanders WD, Goodman M, Hill AN, Holtgrave D, et al. Behavioral interventions to reduce risk for sexual transmission of HIV among men who have sex with men. Cochrane Database Syst Rev 2008(3):CD001230. [doi: 10.1002/14651858.CD001230.pub2] [Medline: 18646068]
33. Gaglio B, Smith TL, Estabrooks PA, Ritzwoller DP, Ferro EF, Glasgow RE. Using theory and technology to design a practical and generalizable smoking reduction intervention. Health Promot Pract 2010 Sep;11(5):675-684. [doi: 10.1177/1524839908324778] [Medline: 19116418]
34. Almatari A, Noorminshah A, Ali S. Journal of Information Systems Research and Innovation (JISRII)5 (2013). 2013. Factors influencing students' intention to use mlearning URL: https://seminar.utmspace.edu.my/jisri/download/Vol5/Pub1_Factors_to_Use_Mobile_learning.pdf
35. Marton C, Wei Choo C. A review of theoretical models of health information seeking on the web. J Doc 2012 Apr 20;68(3):330-352. [doi: 10.1108/00220411211225575]
36. Sondaal SF, Browne JL, Amoakoh-Coleman M, Borgstein A, Miltenburg AS, Verwijs M, et al. Assessing the effect of mHealth interventions in improving maternal and neonatal care in low-and middle-income countries: a systematic review. PLoS One 2016;11(5):e0154664 [FREE Full text] [doi: 10.1371/journal.pone.0154664] [Medline: 27144393]
37. Warren J, Kvasny L, Hecht M, Burgess D, Ahluwalia J, Okuyemi K. Barriers, control and identity in health information seeking among African American women. J Health Dispar Res Pract 2009;3(3):5 [FREE Full text]
38. Ajzen I. From Intention to Actions: A theory of Planned Behavior. In: Action Control. New York, NY: Springer; 1985:a.
39. Ajzen I. The theory of planned behavior. Organizational Behavior and Human Decision Processes 1991 Dec;50(2):179-211. [doi: 10.1016/0749-5978(91)90020-t]
40. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q 1989 Sep;13(3):319-340. [doi: 10.2307/249008]

41. Davis FD. User acceptance of information technology: system characteristics, user perceptions and behavioral impacts. Int J Man Mach Stud 1993 Mar;38(3):475-487. [doi: 10.1006/imms.1993.1022]
42. Rogers E. Diffusion of innovations5.1.38 (2003). 2003. Elements of diffusion URL: https://teddykw2.files.wordpress.com/2012/07/everett-m-rogers-diffusion-of-innovations.pdf
43. Geer LA, Persad MD, Palmer CD, Steuerwald AJ, Dalloul M, Abulafia O, et al. Assessment of prenatal mercury exposure in a predominately Caribbean immigrant community in Brooklyn, NY. J Environ Monit 2012 Mar;14(3):1035-1043. [doi: 10.1039/c2em10835f] [Medline: 22334237]
44. Thomson D, Bzdel L, Golden-Biddle K, Reay, Trish & Estabrook, Carole A. Central questions of anonymization: a case study of secondary use of qualitative data. Forum Qual Soc Res 2005;6(1):- [FREE Full text]
45. Dill LJ. "Wearing My Spiritual Jacket": the role of spirituality as a coping mechanism among African American youth. Health Educ Behav 2017 Oct;44(5):696-704. [doi: 10.1177/1090198117729398] [Medline: 28882071]
46. Hubbard W, Sandmann L. Using diffusion of innovation concepts for improved program evaluation. Journal of Extension 2007:154-161.
47. Yu CH. Designing and Conducting Mixed Methods Research. In: Organizational Research Methods. Thousand Oaks, CA: Sage Publications; Aug 15, 2008:801-804.
48. Leard Dissertation. Purposive Sampling URL: http://dissertation.laerd.com/purposive-sampling.php
49. Creswell JW, Hanson WE, Clark Plano VL, Morales A. Qualitative research designs. Counsel Psychol 2016 Jun 30;35(2):236-264. [doi: 10.1177/0011000006287390]
50. Fitzgerald EM, Cronin SN, Boccella SH. Anguish, yearning, and identity: toward a better understanding of the pregnant Hispanic woman's prenatal care experience. J Transcult Nurs 2016 Sep;27(5):464-470. [doi: 10.1177/1043659615578718] [Medline: 25838327]
51. Merriam S, Tisdell EJ. Qualitative Research: A Guide to Design and Implementation, 4th Edition. New York: Wiley Inc; 2015:-.
52. Phan K, Daim T. Exploring technology acceptance for mobile services. J Ind End Manag 2011 Jul 14;4(2). [doi: 10.3926/jiem.2011.v4n2.p339-360]
53. Evans W, Nielsen PE, Szekely DR, Bihm JW, Murray EA, Snider J, et al. Dose-response effects of the text4baby mobile health program: randomized controlled trial. JMIR Mhealth Uhealth 2015;3(1):e12 [FREE Full text] [doi: 10.2196/mhealth.3909] [Medline: 25630361]
54. Colaizzi PF. Psychological research as the phenomenologist views. In: Existential-Phenomenological Alternatives for Psychology. Oxford United Kingdom: Oxford University Press; 1978:48-71.
55. Miles M, Huberman M, Saldana J. Sage publications. 2013. Qualitative data analysis URL: http://www.theculturelab.umd.edu/uploads/1/4/2/2/14225661/miles-huberman-saldana-designing-matrix-and-network-displays.pdf
56. Geer LA, Curbow BA, Anna DH, Lees PS, Buckley TJ. Development of a questionnaire to assess worker knowledge, attitudes and perceptions underlying dermal exposure. Scand J Work Environ Health 2006 Jun;32(3):209-218 [FREE Full text] [doi: 10.5271/sjweh.1001] [Medline: 16804624]
57. Foster J, Miller L, Isbell S, Shields T, Worthy N, Dunlop AL. mHealth to promote pregnancy and interconception health among African-American women at risk for adverse birth outcomes: a pilot study. Mhealth 2015;1:20 [FREE Full text] [doi: 10.3978/j.issn.2306-9740.2015.12.01] [Medline: 28293578]
58. Cormick G, Kim NA, Rodgers A, Gibbons L, Buekens PM, Belizán JM, et al. Interest of pregnant women in the use of SMS (short message service) text messages for the improvement of perinatal and postnatal care. Reprod Health 2012;9:9 [FREE Full text] [doi: 10.1186/1742-4755-9-9] [Medline: 22866753]
59. Sword W, Heaman MI, Brooks S, Tough S, Janssen PA, Young D, et al. Women's and care providers' perspectives of quality prenatal care: a qualitative descriptive study. BMC Pregnancy Childbirth 2012 Apr 13;12:29 [FREE Full text] [doi: 10.1186/1471-2393-12-29] [Medline: 22502640]
60. Scott KA, Britton L, McLemore MR. The ethics of perinatal care for black women: dismantling the structural racism in "Mother Blame" narratives. J Perinat Neonatal Nurs 2019;33(2):108-115. [doi: 10.1097/JPN.0000000000000394] [Medline: 31021935]
61. Whittaker R. Issues in mHealth: findings from key informant interviews. J Med Internet Res 2012;14(5):e129 [FREE Full text] [doi: 10.2196/jmir.1989] [Medline: 23032424]

Abbreviations

IT: information technology
LBW: low birth weight
mHealth: mobile health
RCT: randomized controlled trial
T4B: Text4baby

Edited by G Eysenbach; submitted 17.05.19; peer-reviewed by J Constantin, P Ware, C Calyx; comments to author 10.07.19; revised version received 01.11.19; accepted 16.12.19; published 13.02.20.

Please cite as:
Blackwell TM, Dill LJ, Hoepner LA, Geer LA
Using Text Messaging to Improve Access to Prenatal Health Information in Urban African American and Afro-Caribbean Immigrant Pregnant Women: Mixed Methods Analysis of Text4baby Usage
JMIR Mhealth Uhealth 2020;8(2):e14737
URL: http://mhealth.jmir.org/2020/2/e14737/
doi:10.2196/14737
PMID:32053117

Original Paper

The Implementation of a Text Messaging Intervention to Improve HIV Continuum of Care Outcomes Among Persons Recently Released From Correctional Facilities: Randomized Controlled Trial

Breana J Uhrig Castonguay[1], MPH; Andrew E Cressman[2,3], ScM; Irene Kuo[4,5], MPH, PhD; Rudy Patrick[6], MPH; Claudia Trezza[4], MPH; Alice Cates[4], MS; Halli Olsen[4], MPH; James Peterson[4,5], EdD, MHS; Ann Kurth[7], CNM, MPH, PhD; Lauri B Bazerman[8], MS; Curt G Beckwith[8,9], MD

[1]University of North Carolina Center for AIDS Research, Lineberger Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States

[2]The Center for Prisoner Health and Human Rights, Providence, RI, United States

[3]Brown University School of Public Health, Providence, RI, United States

[4]Milken Institute School of Public Health, George Washington University, Washington, DC, United States

[5]District of Columbia Center for AIDS Research, Washington, DC, United States

[6]Division of Infectious Diseases and Global Public Health, Department of Medicine, University of California, San Diego, La Jolla, CA, United States

[7]Yale University School of Nursing, New Haven, CT, United States

[8]The Miriam Hospital, Providence, RI, United States

[9]Division of Infectious Diseases, Alpert Medical School of Brown University, Providence, RI, United States

Corresponding Author:
Breana J Uhrig Castonguay, MPH
University of North Carolina Center for AIDS Research
Lineberger Cancer Center
University of North Carolina at Chapel Hill
135 Dauer Drive
Room 313, CB 7440
Chapel Hill, NC, 27599
United States
Phone: 1 9198432532
Email: bcastonguay@unc.edu

Abstract

Background: Previously incarcerated individuals have suboptimal linkage and engagement in community HIV care. Mobile health (mHealth) interventions have been shown to be effective in addressing these gaps. In Washington, District of Columbia (DC), we conducted a randomized trial of an SMS text messaging–based mHealth intervention (CARE+ Corrections) to increase linkage to community HIV care and antiretroviral treatment adherence among HIV-infected persons involved in the criminal justice system.

Objective: This study aimed to describe the SMS text messaging–based intervention, participant use of the intervention, and barriers and facilitators of implementation.

Methods: From August 2013 to April 2015, HIV-positive incarcerated individuals were recruited within the DC Department of Corrections, and persons released in the past 6 months were recruited within the community via street-based recruitment, community partnerships, and referrals. Participants were followed for 6 months and received weekly or daily SMS text messages. Formative research resulted in the development of the content of the messages in 4 categories: HIV Appointment Reminders, Medication Adherence, Prevention Reminders, and Barriers to Care following release from jail. Participants could customize the timing, frequency, and message content throughout the study period.

Results: Of the 112 participants enrolled, 57 (50.9%) were randomized to the intervention group and 55 (49.1%) to the control group; 2 control participants did not complete the baseline visit, and were dropped from the study, leaving a total of 110 participants

who contributed to the analyses. Study retention was similar across both study arms. Median age was 42 years (IQR 30-50), 86% (49/57) were black or African American, 58% (33/57) were male, 25% (14/57) were female, and 18% (10/57) were transgender. Median length of last incarceration was 4 months (IQR 1.7-9.0), and median lifetime number of times incarcerated was 6.5 (IQR 3.5-14.0). Most participants (32/54, 59%) had a baseline viral load of <200 copies/mL. Nearly all participants (52/57, 91%) chose to use a cell phone provided by the study. The most preferred Appointment Reminder message was *Hey how you feeling? Don't forget to give a call and make your appointment* (19/57, 33%). The most preferred Medication Adherence message was *Don't forget your skittles!* (31/57, 54%), and 63% (36/57) of participants chose to receive daily (vs weekly) messages from this category at baseline. The most preferred Prevention Reminder message was *Stay strong. Stay clean* (18/57, 32%). The most preferred Barriers to Care message was *Holla at your case manager, they're here to help* (12/57, 22%). Minor message preference differences were observed among participants enrolled in the jail versus those from the community.

Conclusions: Participants' ability to customize their SMS text message plan proved helpful. Further large-scale research on mHealth platforms is needed to assess its efficacy among HIV-infected persons with a history of incarceration.

Trial Registration: ClinicalTrials.gov NCT01721226; https://clinicaltrials.gov/ct2/show/NCT01721226

(JMIR Mhealth Uhealth 2020;8(2):e16220) doi:10.2196/16220

KEYWORDS

criminal justice; incarcerated populations; HIV; acquired immunodeficiency syndrome; mHealth; anti-HIV agents; medication adherence; retention in care; implementation science

Introduction

Background

In 2016, more than 6.6 million adults—or 1 in 38 in the United States—were involved in the criminal justice (CJ) system [1]. The domestic CJ-involved population is disproportionately impacted by HIV, with an estimated HIV prevalence of 1.3% in correctional facilities [2]. In addition, people living with HIV (PLWH) experience high rates of incarceration—an estimated 14% of all persons with HIV are released from a correctional facility annually [3]. Although correctional facilities have been identified as important venues for HIV testing [4-6], HIV treatment [6,7], and reducing HIV-related health disparities [8], PLWH experience poor outcomes along the HIV care continuum after release from correctional facilities. A systematic review illustrated that after release, PLWH had worse linkage to care, retention in care, antiretroviral therapy (ART) receipt, and viral suppression than during incarceration and compared with nonincarcerated populations [9]. Recent evidence demonstrates the utility of technology-based interventions to reach this vulnerable population and to improve ART adherence [10,11].

Ownership of smartphones in the United States has greatly increased from 35% in 2011 to 81% in 2019 [12]. However, smartphone ownership varies by socioeconomic status. For example, smartphone ownership was 71% among persons earning less than US $30,000 per year compared with 95% among persons earning more than US $75,000 per year [12]. Despite these variations, smartphone ownership is increasing and has stimulated the development of mobile health (mHealth) apps to address a wide range of health outcomes from postnatal care [13] to the self-management of long-term illnesses, such as diabetes [14].

A variety of mHealth interventions have been implemented to address HIV/AIDS outcomes among PLWH [15]. Forrest et al [16] proposed a framework that divides mHealth interventions for HIV prevention and care into 3 groups: (1) patients (ie, medication reminders); (2) health systems (ie, evaluation of HIV care delivery and data collection); and (3) populations (ie, mass public health campaigns). However, to date individual-level SMS text messaging remains the primary mode of delivery [15]. A meta-analysis published in 2017 found that interventions with SMS reminders significantly improved HIV appointment attendance, ART adherence, and biological outcomes (ie, CD4 count and HIV viral load) [17]. As a result, there has been substantial interest in developing mHealth interventions to improve HIV outcomes among high-risk populations [18-28].

Objectives

The National Institute on Drug Abuse funded the Seek, Test, Treat, and Retain (STTR) research initiative to improve the identification, linkage, and engagement in care of HIV-infected vulnerable persons [29]. Within this STTR initiative, 4 studies evaluated mHealth interventions, and a summary of the challenges using mobile phones has been previously reported [10]. In this paper, we characterize the implementation barriers and facilitators for developing an SMS intervention (CARE+ Corrections) among PLWH involved in the CJ system. To assist with future SMS text messaging interventions in this population, we report on lessons learned, share our SMS text message library, discuss optimal timing and frequency of SMS text messaging, and provide training materials to support the introduction of smartphone technology.

Methods

Study Design

The CARE+ Corrections study was a randomized, controlled, and longitudinal pilot study in Washington, District of Columbia (DC), and it has been described in detail elsewhere [30-32]. Briefly, the study examined the feasibility and preliminary efficacy of the CARE+ intervention among HIV-infected persons with a history of incarceration. Recruitment occurred in the DC Department of Corrections (DOC) facilities (housing both men and women) and within the community via street-based recruitment, community partnerships, and referrals.

Participants recruited in the DOC had anticipated release dates within 6 weeks, whereas participants recruited in the community had been recently released from a jail, prison, or halfway house within the previous 6 months. Study participants were followed for 6 months and outcomes of interest were linkage to HIV care, and achieving HIV viral suppression. To be eligible to receive the intervention, participants needed to pass a basic literacy test to ensure they would be able to read the CARE+ SMS text messages.

The CARE+ intervention was delivered to study participants randomized to the intervention arm and included 2 components: (1) a one-time computerized counseling session called CARE+ Corrections, which was adapted for CJ populations from the CARE+ tool [33,34]; and (2) an SMS text messaging intervention (CARE+ Corrections SMS) that was delivered to study participants in the community. Focusing on the second component in this paper only, CARE+ Corrections SMS comprised daily or weekly scheduled SMS text messages delivered to a cell phone.

Participants were offered the choice of using a basic Android smartphone provided by the study with SMS capability or a monthly US $25 reimbursement to cover texting expenses if they preferred to use their own SMS texting–capable phone. Study phones were provided at no cost to participants (further information about the cell phone plans are detailed elsewhere) [10]. Each participant was allowed 1 replacement phone during the course of the study to account for lost or stolen phones. If a phone was broken and it was deemed not the participant's fault, that is, a software problem, the participant received a new phone, and this was *not* considered to be part of the one-replacement-phone policy. If participants lost their replacement phones, they were encouraged to find another phone to use for the duration of the study and were provided the monthly US $25 reimbursement.

Study staff set up the SMS intervention on participant's cell phones using an SMS platform website and completed a registration form that included the participant's new phone number (or existing one if using their own phone), a participant-chosen nickname (real names were not used to protect privacy of participants), and SMS text message preferences on content and frequency. If participants wanted to make changes to their SMS plan during follow-up visits, a follow-up form was completed by study staff on the SMS platform website.

SMS Content Development

Formative work conducted in Washington, DC, and Providence, Rhode Island, informed the content of the CARE+ Corrections SMS text messages [30]. The final SMS library included 4 categories with 9 prewritten messages and the ability to customize a message within each category. (See Multimedia Appendix 1 for the full SMS text message library.) We addressed the following 4 content categories.

HIV Appointment Reminders

Messages focused on reminding participants to attend their prescheduled HIV care appointment or reminded participants to schedule a new appointment.

Medication Adherence

This comprised message reminders to take their HIV medications. Messages varied from highlighting the importance of medications to, *keep your body strong and healthy* to reaching out to caseworkers to ask for help with medication adherence.

HIV Prevention Reminders

Participants chose to receive a message on safe sex practices or tips and mantras to avoid substance use.

Barriers to Care

Messages focused on areas participants may need help with when leaving the correctional system, such as finding housing, employment, etc. This category was adapted from the formative work to include specific resources found in Washington, DC, eg, providing the actual phone number of the office that helps returning citizens find employment within the message.

CARE+ Corrections study staff worked with an SMS vendor (Dimagi, Cambridge, MA) to create an SMS platform for automated text messaging. The initial SMS platform delivered messages from all 4 content areas in a single message thread at a preset frequency and in a single communication. Before study initiation, study staff members conducted pilot testing of the platform and concluded that greater flexibility in the frequency of messaging was required. Staff members indicated that receiving all messages in a single thread led to message fatigue and content was often overlooked, given multiple messages needed to be read at the same time. In response to this feedback, the SMS vendor was able to adapt the platform to allow participants to choose the frequency of messaging (daily versus weekly), timing of messaging (eg, am or pm), and ability to change messaging content in each category (Table 1), with slight variations in 2 message content categories: HIV Appointment Reminder and Barriers to Care.

Frequency for the HIV appointment reminder message depended on the date of the participant's appointment and the Barriers to Care message was only available once per week to participants during the first month of the intervention or, if reincarcerated during the study period, 1 month following reentry into the community.

Table 1. SMS message content details, customization, time options, and frequency.

Message category	Able to write own custom text message	Time options	Able to customize text message frequency options	Able to change options during follow-up
HIV appointment reminder	✓[a]	• 8:00 am • 10:00 am • 12:00 pm • 2:00 pm • 5:00 pm • 8:00 pm	X[b] Message sent on the basis of appointment date: 19, 14, 7, 3, 2, and 1 day before HIV appointment date	✓
Medication adherence	✓	• 8:00 am • 10:00 am • 12:00 pm • 2:00 pm • 5:00 pm • 8:00 pm	✓ Choice of daily or weekly option	✓
Prevention reminder	✓	• 8:00 am • 10:00 am • 12:00 pm • 2:00 pm • 5:00 pm • 8:00 pm	✓ Choice of daily or weekly option	✓
Barriers to care	✓	X	X Message sent weekly during the first month of the intervention or if reincarcerated, one month following reentry into the community	X

[a]✓: Yes, participants were able to customize this area

[b]X: No, participants were unable to customize this area.

Data Analysis

We generated descriptive statistics (eg, frequency, mean, and/or median) of characteristics of study participants in the intervention arm and their message preferences (content, time, and frequency) throughout the study using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA).

Human Subjects Review

The George Washington University and The Miriam Hospital Institutional Review Boards approved the CARE+ Corrections Study and the US Office of Human Research Protections reviewed it.

Results

Demographics

Of 219 persons assessed for eligibility, 112 (51.1%) were enrolled and randomized. Of those enrolled, 57 (50.9%) were randomized to the CARE + Corrections intervention group and 55 (49.1%) to the control group; two control participants did not complete the baseline visit, and were therefore dropped from the study, leaving a total of 110 participants who contributed to the analyses. Study retention was similar across both study arms. Although 41 of 110 (37.3%) experienced reincarceration during the 6-month follow-up period, 96 of 110 (87.3%) completed all three study visits. This paper will focus on the experience of the 57 individuals randomized to the intervention group (Table 2).

Most participants (37/57, 65%) were enrolled in the community after recent release from a correctional facility. The median age was 42 years (IQR 30-50). Most (49/57, 86%) were black or African American and male (33/57, 58%), with 25% (14/57) being female and 18% (10/57) being male-to-female transgender. The participants' median length of last incarceration was 4 months (IQR 1.7-9.0), and the median number of times of being incarcerated throughout their lifetime was 6.5 times (IQR 3.5-14.0).

Table 2. Characteristics of intervention arm (n=57) at baseline.

Characteristic	Values
Enrollment location, n (%)	
Community	37 (65)
District of Columbia Department of Corrections	20 (35)
Gender, n (%)	
Male	33 (58)
Female	14 (25)
Transgender (male to female)	10 (18)
Race/ethnicity, n (%)	
Non-Hispanic black/African American	49 (86)
Non-Hispanic white	2 (3)
Other	6 (11)
Age (years), median (IQR)	42 (30-50)
Sexual orientation, n (%)	
Heterosexual or straight	45 (78)
Homosexual, gay, or lesbian	6 (11)
Bisexual	6 (11)
Education, n (%)	
≤High school	49 (86)
>High school	8 (14)
Housing stability, n (%)	
Stable	45 (79)
Unstable	12 (21)
Drug dependence (Texas Christian University score)[a], n (%)	
No (9-11)	25 (44)
Yes (12-18)	32 (56)
Ever injection drug use , n (%)	
No	47 (82)
Yes	10 (18)
Injection drug use in the 3 months before last incarceration[b], n (%)	
No	6 (60)
Yes	4 (40)
Ever noninjection drug use, n (%)	
No	9 (16)
Yes	48 (84)
Noninjection drug use in 3 months before last incarceration[c], n (%)	
No	15 (31)
Yes	33 (69)
Depressive symptoms (Center for Epidemiological Studies Depression Scale-10) , n (%)	
No	29 (51)
Yes	28 (49)
Length of last incarceration (months), median (IQR)	4 (1.7-9.0)

Characteristic	Values
Number of times in jail/prison, lifetime[c], median (IQR)	6.5 (3.5-14.0)
Study baseline viral load[d], n (%)	
<200 copies/mL	32 (59)
≥200 copies/mL	22 (41)
Cell phone choice , n (%)	
CARE+ phone	52 (91)
Personal phone	5 (9)

[a]12 months before last incarceration.

[b]Among 10 participants reporting ever injection drug use.

[c]Among 48 participants reporting ever noninjection drug use.

[d]Among 54 participants.

Implementation Logistics at Study Start-Up

Cell Phone Logistics

Most participants (52/57, 91%) chose to use a cell phone provided by the study (Table 2); of those participants, nearly two-thirds (35/52, 67%) required a replacement phone during the follow-up period. Most replacement phones (30/35, 86%) were provided because of reported loss or theft of the phone. Only 14% (5/35) of replacement phones were provided because of a faulty phone and did not count toward the participant's one-replacement-phone policy. At the end of the study, participants were asked to return their study phones; however, more than 90% (47/52) of participants kept the phone provided by the study (they reported not having their phone at the final visit).

Service Interruptions and Billing/Overage Issues

As nearly two-third of the phones provided by the study had to be replaced because of loss or theft, many were left without service while waiting for a replacement phone. In addition, reincarceration led to service disruptions. To avoid intervention interruptions because of phone issues, study staff had regular clinic hours in a known location throughout the duration of the study and participants knew to drop-in regarding any issues with phones. Furthermore, participants knew which community partners were affiliated with the CARE+ study, and study staff would receive calls from participants at these community partner locations to schedule appointments for phone replacements.

We used a pooled minutes cell phone plan, in which all phone lines shared available minutes, to account for some participants using more minutes and others less. Using this model, the study never went over its total allotted monthly minutes. Several participants exceeded their monthly minute allotments, and if the amount was significant, study staff would call the participant and review the participant's cell phone plan. In 2 instances, participants used smartphone services that incurred additional fees (eg, downloading apps and calling 411 for information). In both cases, study staff worked with participants to call one of the community partners instead for information and inform participants that downloading apps on the study phone was not allowed. In addition, study staff worked with the phone carrier to limit the downloading of apps on study phones.

Mobile Health in an Older Population

As the median age of CARE+ Corrections participants was 42 years, study staff recognized that cell phone training for smartphones would be required for some study participants. During the initial session, study staff assessed participants' knowledge and ability in using the smartphones provided by the study and found that the majority of participants required 1-on-1 training before the initiation of the intervention. Study staff developed a 5- to 10-min cell phone training module that was delivered during the baseline visit (see Multimedia Appendix 2). The training module was interactive and included instructions on how to turn the phone on and off, entering information for contacts, opportunities to practice sending SMS text messages and making telephone calls, and instructions for using the talk-to-text option. We provided ongoing support at all follow-up appointments, including reviewing the training again at in-person visits.

Participant Preferences: Message Content and Preferred Frequency

Participants had the option of customizing the content, timing, and frequency of the SMS text messages by the 4 topic areas.

HIV Appointment Reminder Message Preferences

The most popular message chosen at baseline for the HIV appointment reminder message (see Table 3) was, *Hey how you feeling? Don't forget to give a call and make your appointment* (19/57, 33%), followed by *Don't forget your appointment – it's important* (11/57, 19%) and *You're worth it – remember your clinic appointment* (8/57, 14%).

A total of 3 participants created custom message content at baseline, such as, *Dr. [name] on [date]* (see Multimedia Appendix 3 for other custom messaging). The most popular message time chosen at baseline was 8:00 am (20/57, 35%), followed by 12:00 pm (12/57, 21%). During follow-up, 28% (16/57) and 14% (8/57) of participants made changes to message content and time, respectively. The most popular message content changes during follow-up were to choose, *Don't forget your appointment – it's important* (5/17, 29%) and *Your health comes first – go to your appointment* (5/17, 29%). The most popular message time changes during follow-up were to choose 8:00 am (3/9, 33%) and 10:00 am (3/9, 33%).

Table 3. HIV appointment reminder messaging.

Messaging options, HIV appointment reminder	Values, n (%)
Message content	
Hey how you feeling? Don't forget to give a call and make your appointment [a]	*19 (33)*
Don't forget your appointment – it's important	*11 (19)*
You're worth it – remember your clinic appointment	*8 (14)*
Your doctor wants you to come to your appointment	5 (9)
Your health comes first – go to your appointment	4 (7)
Your doctors are here to help you –go to your appointment	4 (7)
Custom message content	3 (5)
Call your case manager – he/she can help you get to clinic	2 (4)
Going to the clinic helps you stay healthy	1 (2)
Can't remember when your next appointment is? Call the clinic to find out	0 (0)
Total	57 (100)
Message time	
8:00 am	*20 (35)*
12:00 pm	*12 (21)*
10:00 am	11 (19)
5:00 pm	6 (11)
2:00 pm	4 (7)
8:00 pm	4 (7)
Total	57 (100)

[a]Italics indicate the 3 most popular messages and 2 most popular message time options at baseline.

Medication Adherence Message Preferences

The most popular message chosen at baseline was *Don't forget your skittles!* (31/57, 54%), followed by, *Meds keep your body strong and healthy* (10/57, 18%) and *Hey, take your vitamins!* (7/57, 12%; Table 4).

A participant created a custom message at baseline and wanted us to include a smiley face within the message, *Hey [name] don't forget those mones! :)* The most popular message times chosen at baseline were 10:00 am (17/57, 30%) and 8:00 am (15/57, 26%). At baseline, most participants chose daily message frequency (36/57, 63%). During follow-up, 21% (12/57), 18% (10/57), and 14% (8/57) of participants made changes to message content, time, and frequency, respectively. The most popular message content change during follow-up was to create custom message content (3/12, 25%). The most popular message frequency change during follow-up was from weekly to daily (7/8, 88%).

Table 4. Medication adherence messaging.

Messaging options, medication adherence	Values, n (%)
Message content	
Don't forget your skittles! [a]	*31 (54)*
Meds keep your body strong and healthy	*10 (18)*
Hey, take your vitamins!	*7 (12)*
You got to play to win. So don't forget your meds	3 (5)
The best way to stay healthy is to take your meds on time and the right way	2 (4)
Give meaning to your life … Now!	2 (4)
Custom message content	1 (2)
Your meds may not work anymore if you forget to take them	1 (2)
Adherence to meds means taking the right dose at the right time	0 (0)
Call your case manager—he/she can help you find ways to remember to take your meds	0 (0)
Total	57 (100)
Message time	
10:00 am	*17 (30)*
8:00 am	*15 (26)*
8:00 pm	14 (25)
5:00 pm	4 (7)
2:00 pm	4 (7)
12:00 pm	3 (5)
Total	57 (100)
Message frequency	
Daily	*36 (63)*
Weekly	21 (37)
Total	57 (100)

[a]Italics indicate the 3 most popular messages, 2 most popular message time options, and most popular message frequency option at baseline.

Prevention Reminder Message Preferences

The most popular message chosen at baseline was, *Stay strong. Stay clean* (18/57, 32%), followed by *Safe sex is important. Use a condom* (8/57, 14%) and *Be smart. Use a condom* (7/57, 12%; Table 5).

A total of 2 participants created custom content at baseline (see Multimedia Appendix 3). For 1 participant, the custom message of *Keep your eyes on your own work* was a saying his father used often to help the participant remember to stay focused on what matters.

When the messages were categorized as substance use prevention, safe sex, or custom content, most participants (31/57, 54%) chose substance use content. The most popular message times chosen at baseline were 8:00 am (13/57, 23%) and 8:00 pm (12/57, 21%). At baseline, most participants chose weekly message frequency (31/57, 54%). During follow-up, 26% (15/57), 28% (16/57), and 18% (10/57) of participants made changes to message content, time, and frequency, respectively. The most popular message time change during follow-up was to 10:00 am (7/18, 39%). The most popular message frequency change during follow-up was from weekly to daily (9/13, 69%).

Table 5. Prevention reminder messaging.

Messaging options, prevention reminders	Values, n (%)
Message content	
Stay strong. Stay clean [a,b]	*18 (32)*
Safe sex is important. Use a condom [c]	*8 (14)*
Be smart. Use a condom [c]	*7 (12)*
One day at a time. Just for today, don't use[b]	6 (10)
Did you read "Get your Freak on for Dummies"—it says you must wear a rubber![c]	5 (9)
Staying clean is most important. Call your case manager for help[b]	4 (7)
If you are using, you may forget your meds[b]	3 (5)
Don't forget to wrap it or don't give it up![c]	3 (5)
Custom message content	2 (4)
Protect yourself and your partner. Use a condom[c]	1 (2)
Total	57 (100)
Message time	
8:00 am	*13 (23)*
8:00 pm	*12 (21)*
2:00 pm	11 (19)
10:00 am	10 (18)
5:00 pm	7 (12)
12:00 pm	4 (7)
Total	57 (100)
Message frequency	
Weekly	*31 (54)*
Daily	26 (46)
Total	57 (100)

[a]Italics indicate the 3 most popular messages, 2 most popular message time options, and most popular message frequency option at baseline.

[b]Substance use prevention content.

[c]Safe sex content.

Barriers to Care Message Preferences

The most popular messages chosen at baseline for the Barriers to Care messaging (Table 6) were *Holla at your case manager, they're here to help* (12/57, 21%), *Hey! Stay linked to your clinic so you can get your meds and care* (9/57, 16%), *Get help for your housing: call (XXX) XXX-XXXX [Local CBO that helps with housing]* (9/57, 16%), and *Check on job and training programs today* (9/57, 16%).

More participants chose to create custom content for this message category compared with the other categories (see Multimedia Appendix 3). For example, a custom message, *Hey don't forget your parole appointment on [date]*, highlighted the importance of incarceration-related priorities and other custom messages focused on positivity, such as *Keep hope alive!*, *We love you!* and *Stay positive!* The most popular message times chosen at baseline were 10:00 am (17/57, 30%) and 8:00 am (16/57, 28%).

Table 6. Barriers to care messaging.

Messaging options, barriers to care	Values, n (%)
Message content	
Holla at your case manager, they're here to help [a,b,c]	*12 (21)*
Hey! Stay linked to your clinic so you can get your meds and care [b]	*9 (16)*
Get help for your housing: call xxx-xxx-xxxx [b,c]	*9 (16)*
Check on job and training programs today [c]	*9 (16)*
Remember to get a case manager: call xxx-xxx-xxxx	7 (12)
Custom message content	5 (9)
Get help getting your entitlement/insurance programs: call xxx-xxx-xxxx	3 (5)
Can't get your prescriptions? Call your clinic or case manager	2 (3)
Need a ride to your appointment? Call your case manager at xxx-xxx-xxxx	1 (2)
Call transportation services so you can get to your clinic visits: call xxx-xxx-xxxx	0 (0)
Total	57 (100)
Message time	
10:00 AM	*17 (30)*
8:00 AM	*16 (28)*
2:00 PM	10 (18)
8:00 PM	7 (12)
5:00 PM	4 (7)
12:00 PM	3 (5)
Total	57 (100)

[a]Italics indicate the 3 most popular messages and 2 most popular message time options at baseline.

[b]The 3 most popular message content options among those enrolled in the community.

[c]The 3 most popular message content options among those enrolled in the District of Columbia Department of Corrections.

Results by Enrollment Site

There were minor differences in message preferences between those enrolled in the community (released from a correctional facility within the last 6 months) versus those enrolled in the DC DOC. For the prevention reminder messaging, the most popular messages chosen at baseline among those enrolled in the community were *Stay strong. Stay clean* (9/37, 24%), *Safe sex is important. Use a condom* (5/37, 14%), *Be smart. Use a condom* (5/37, 14%), and *One day at a time. Just for today, don't use* (5/37, 14%). The most popular messages chosen at baseline among those enrolled in jail were *Stay strong. Stay clean* (9/20, 45%), *Safe sex is important. Use a condom* (3/20, 15%), and *Did you read "Get your Freak on for Dummies"—it says you must wear a rubber!* (3/20, 15%). Among the barriers to care messages, the most popular messages chosen at baseline among those enrolled in the community were, *Holla at your case manager, they're here to help* (8/37, 22%), *Hey! Stay linked to your clinic so you can get your meds and care* (7/37, 19%), and *Get help for your housing: call (XXX) XXX-XXXX* (5/37, 14%). Participants enrolled in the jail were more likely to choose *Check on job and training programs today* (5/20, 25%), *Holla at your case manager, they're here to help* (4/20, 20%), and *Get help for your housing: call (XXX) XXX-XXXX* (4/20, 20%).

Discussion

Principal Findings

HIV-infected individuals with a history of incarceration represent a vulnerable community in need of innovative interventions to address many barriers to HIV care and adherence to ART. We were able to implement an SMS-based intervention and report lessons learned for implementation and message preferences. This knowledge will be invaluable to others delivering SMS interventions in this vulnerable population.

Lessons Learned

As reported elsewhere [10], challenges implementing mHealth technologies for CJ-involved population include service interruptions, billing/overage issues, and users' experience with an SMS text messaging platform that is automated. Adding to this knowledge, during implementation of CARE+ SMS, we learned the following: (1) the importance of pilot testing the intervention and adapting the intervention for the population; (2) cell phone implementation considerations; and (3) providing an array of message delivery preferences (ie, frequency and timing).

Pilot Testing and Adapting to Your Population

The study team saw huge improvements to the CARE+ Corrections intervention after pilot testing the intervention. Recognizing the significance of customization (ie, timing and frequency) of messaging to avoid message fatigue, the study team was able to make changes to the SMS platform before intervention implementation to provide study participants more flexibility.

Adapting the SMS text message library to accurately reflect the common experiences for the population was essential. For example, study participants were more likely to choose a substance use message versus the safe sex message under the Prevention Reminder category. This reflected what has been previously observed among incarcerated persons facing a 3- to 8-fold increased risk of drug-related death, 1 to 2 weeks following release compared with 3 to 12 weeks following release [35]. Future interventions should review the literature, engage with community-based organizations (CBOs), and conduct formative research with the population to inform message development to identify unique barriers and resources for the population of interest.

In addition, as our study population was older, adapting the implementation strategy to meet the needs of older participants was essential to effective implementation of the SMS text message plan. On the basis of previous literature [10,36,37], we recognized that additional cell phone training would be required for some study participants and developed a simple in-person training (see Multimedia Appendix 2). This was consistent with previous literature, in which a 2016 review of designing, implementing, and evaluating mHealth solutions among older adults highlighted the importance of ease of use of the mobile platform and an understanding of technical literacy of the user [38]. Furthermore, in-person contact helped to facilitate familiarizing the older population with mobile platforms. In our study, participants received 1-on-1 support with the initial setup of the CARE+ SMS program during their baseline visit. Another option for future mHealth interventions among older populations would be to use YouTube videos to further build rapport among study participants and build mobile skills [39].

Cell Phone Implementation Considerations

The Android smartphones provided by the study were highly desirable; however, participants' chaotic personal environments impacted smartphone retention. Most CARE+ participants opted to receive the phone provided by the study; however, most required a replacement phone and almost all kept their phone at the end of the study. In contrast, another STTR study reported 100% of users discarded the inexpensive, older model flip phone [10]. Future mHealth interventions, if possible, should continue to provide smartphones but consider budgeting more funds for cell phone replacement, given the likelihood of phone replacements. If the budget to provide a cell phone is not available and/or sustainable, an idea for future interventions would be to use Web-based telephone services (ie, Google Voice and WhatsApp) to continue sending SMS text messages via email when cell phone service is turned off, as was used in another STTR site [10].

Leveraging community partnerships proved very useful to avoid cell phone service interruptions because of lost or faulty phones. In addition to having regular office/study hours at the CARE+ community site, CARE+ staff identified contacts at multiple popular CBOs to provide participants with options for study engagement. Participants knew which community partners were affiliated with CARE+ and study staff would receive calls from participants at these community partner locations to set up appointments for phone replacements. This also proved useful for study retention purposes.

Identifying economic solutions with the cell phone carrier reduced economic burden on study budget. Using the pooled minutes approach provided the much-needed flexibility for CARE+ study participants, as some used very little of the suggested minutes allotted per month whereas others went over consistently. Future interventions should consider the pooled minutes approach to avoid overage issues and work with carriers to turn off specific apps and phone options that could incur monthly charges. Furthermore, incorporating cost-effectiveness analyses using templates [40], such as the one used by Reback et al [41] to evaluate a substance use and HIV risk reduction SMS intervention, will provide useful information for the feasibility of mHealth interventions at the population level.

Message Frequency and Customization

Previous research has indicated that SMS interventions with 1 or more daily messages demonstrated *smaller* effects than interventions that only sent messages weekly [42]; however, CARE+ participant preferred more frequent SMS text messages. At baseline, participants were more likely to choose to receive the message every day instead of once per week. Furthermore, during follow-up, a large proportion of participants changed their message frequency option from weekly to daily.

Few chose to create their own message. We believe this could reflect the success and importance of the formative work, adequately reflecting the messages they wanted to receive. However, even with few selecting to create their own message, providing this as an option is important, as interventions that allow for message customization are more effective at promoting adherence to ART than those that send uniform messages to all participants [42].

For those who did create custom messages (see Multimedia Appendix 3), they provided us insights into missed messaging opportunities for future SMS interventions for persons with a history of incarceration. For example, a custom message reminded the participant of the participant's parole appointment and thus highlighted the potential of adding community supervision—related reminder options to the Barriers to Care content area. Highlighting CJ status within the message was in contrast to our initial study goals of avoiding mentioning either HIV or CJ status. Future research is needed to explore the breadth and effectiveness of CJ-focused messaging.

Differences by Enrollment Site

Participants who were enrolled in the jail chose different Barriers to Care messaging compared with those participants enrolled in the community—highlighting the differences in barriers encountered at 2 different time points (immediate release versus

up to 6 months before release from jail). The popularity of messages about seeking housing and job training programs among jail enrollees versus community-enrolled participants could be because of the fact that the latter may have had more time in the community to address these needs. This is supported by the literature, with persons immediately released from correctional facilities reporting transitional challenges, such as not knowing how to find shelter and feeling dumped into the city, unsure where to spend their first night [43]. Immediate needs following reentry can also vary by gender, with men reporting finding a job and education as most important immediately, whereas women identified shelter and substance abuse as their top priorities [44]. Future interventions should consider the timing of release from a correctional setting and choose Barriers to Care messaging that reflects the timing of release.

Limitations

Although this study provides important details for future mHealth interventions among this vulnerable population, this study had several limitations. First, this study reported on the intervention arm of a pilot feasibility study. Given the small sample size, we lacked that statistical power to make between-group comparisons (eg, gender, race, and enrollment site), limiting our ability to inform mHealth interventions among specific populations. In addition, our SMS platform website (Dimagi) was a 1-way text service; thus, we could not evaluate engagement in the SMS intervention or confirm receipt of the SMS text messages. Furthermore, this study was limited to programming data (from Dimagi) and the experiences of study staff. Future mHealth intervention studies would benefit from larger sample sizes to evaluate messaging preference among various sociodemographic variables and qualitative research to better understand the specifics of SMS interventions that work well for the target population.

Conclusions

In this paper, we report the implementation of an SMS intervention for HIV-infected persons with a history of incarceration. Highlighting the implementation of a real-world application of an mHealth platform, subsequent programs working with the same or other vulnerable populations can use the findings, methodology, and trainings to implement and benefit from our lessons learned.

Acknowledgments

The authors would like to acknowledge funding from the National Institutes of Health and National Institute on Drug Abuse (R01DA030747 and T32DA023356) and institutional support from the University of North Carolina (UNC)—Chapel Hill Center for AIDS Research (P30AI50410), Providence/Boston Center for AIDS Research (P30AI042853), and the DC Center for AIDS Research (P30AI117970). The authors would also like to acknowledge CARE+ team members Anthony Rawls and Avery Barber, DC DOC partners (Drs Beth Mynett and Reena Chakraborty), and community-based partners for their support and assistance in conducting this work. In addition, the authors would like to acknowledge Lorin Bruckner with the UNC Davis Library, who assisted with the data visualization (Table 1), and Sable Watson for manuscript editing support. Finally, the authors would like to thank the study participants without whom this work would not be possible.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CARE+ Corrections SMS Messaging Library.
[DOCX File , 22 KB - mhealth_v8i2e16220_app1.docx]

Multimedia Appendix 2
How to Use Your Droid 4.
[DOCX File , 319 KB - mhealth_v8i2e16220_app2.docx]

Multimedia Appendix 3
CARE+ Customized Messages at Baseline.
[DOCX File , 20 KB - mhealth_v8i2e16220_app3.docx]

Multimedia Appendix 4
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1643 KB - mhealth_v8i2e16220_app4.pdf]

References

1. Kaeble D, Cowhig M. Bureau of Justice Statistics. Washington, D.C: US Department of Justice, Bureau of Justice Statistics; 2018 Apr. Correctional Populations in the United States, 2016 URL: https://www.bjs.gov/content/pub/pdf/cpus16.pdf [accessed 2019-12-05]

2. Maruschak LM, Bronson J. Bureau of Justice Statistics. Washington, DC: US Department of Justice, Bureau of Justice Statistics; 2017 Aug. HIV in Prisons, 2015 - Statistical Tables URL: https://www.bjs.gov/content/pub/pdf/hivp15st.pdf [accessed 2019-12-05]
3. Spaulding AC, Seals RM, Page MJ, Brzozowski AK, Rhodes W, Hammett TM. HIV/AIDS among inmates of and releasees from US correctional facilities, 2006: declining share of epidemic but persistent public health opportunity. PLoS One 2009 Nov 11;4(11):e7558 [FREE Full text] [doi: 10.1371/journal.pone.0007558] [Medline: 19907649]
4. Beckwith CG, Nunn A, Baucom S, Getachew A, Akinwumi A, Herdman B, et al. Rapid HIV testing in large urban jails. Am J Public Health 2012 May;102(Suppl 2):S184-S186 [FREE Full text] [doi: 10.2105/AJPH.2011.300514] [Medline: 22401524]
5. Welcome to CDC stacks. Atlanta, GA: Centers for Disease Control and Prevention; 2009 Jan. HIV Testing Implementation Guidance for Correctional Settings URL: https://stacks.cdc.gov/view/cdc/5279 [accessed 2019-12-05]
6. Beckwith CG, Zaller ND, Fu JJ, Montague BT, Rich JD. Opportunities to diagnose, treat, and prevent HIV in the criminal justice system. J Acquir Immune Defic Syndr 2010 Dec;55(Suppl 1):S49-S55 [FREE Full text] [doi: 10.1097/QAI.0b013e3181f9c0f7] [Medline: 21045600]
7. Meyer JP, Cepeda J, Wu J, Trestman RL, Altice FL, Springer SA. Optimization of human immunodeficiency virus treatment during incarceration: viral suppression at the prison gate. JAMA Intern Med 2014 May;174(5):721-729 [FREE Full text] [doi: 10.1001/jamainternmed.2014.601] [Medline: 24687044]
8. Rich JD, DiClemente R, Levy J, Lyda K, Ruiz MS, Rosen DL, Centers for AIDS Research at the Social and Behavioral Sciences Research Network, Centers for AIDS Research–Collaboration on HIV in Corrections Working Group. Correctional facilities as partners in reducing HIV disparities. J Acquir Immune Defic Syndr 2013 Jun 1;63(Suppl 1):S49-S53 [FREE Full text] [doi: 10.1097/QAI.0b013e318292fe4c] [Medline: 23673887]
9. Iroh PA, Mayo H, Nijhawan AE. The HIV care cascade before, during, and after incarceration: a systematic review and data synthesis. Am J Public Health 2015 Jul;105(7):e5-16. [doi: 10.2105/AJPH.2015.302635] [Medline: 25973818]
10. Christopoulos KA, Cunningham WE, Beckwith CG, Kuo I, Golin CE, Knight K, et al. Lessons learned from the implementation of seek, test, treat, retain interventions using mobile phones and text messaging to improve engagement in HIV care for vulnerable populations in the United States. AIDS Behav 2017 Nov;21(11):3182-3193 [FREE Full text] [doi: 10.1007/s10461-017-1804-8] [Medline: 28578543]
11. Krishnan A, Cravero C. A multipronged evidence-based approach to implement mHealth for underserved HIV-infected populations. Mob Media Commun 2017;5(2):194-211. [doi: 10.1177/2050157917692390]
12. Pew Research Center. 2019 Jun 12. Mobile Fact Sheet URL: https://www.pewresearch.org/internet/fact-sheet/mobile/ [accessed 2019-12-05]
13. Dol J, Richardson B, Tomblin Murphy G, Aston M, McMillan D, Campbell-Yeo M. Impact of mHealth interventions during the perinatal period on maternal psychosocial outcomes: a systematic review protocol. JBI Database System Rev Implement Rep 2019 Jul 25. [doi: 10.11124/JBISRIR-D-19-00003] [Medline: 31356572]
14. de Jongh T, Gurol-Urganci I, Vodopivec-Jamsek V, Car J, Atun R. Mobile phone messaging for facilitating self-management of long-term illnesses. Cochrane Database Syst Rev 2012 Dec 12;12:CD007459 [FREE Full text] [doi: 10.1002/14651858.CD007459.pub2] [Medline: 23235644]
15. Mehraeen E, Safdari R, Mohammadzadeh N, Seyedalinaghi SA, Forootan S, Mohraz M. Mobile-based applications and functionalities for self-management of people living with HIV. Stud Health Technol Inform 2018;248:172-179. [Medline: 29726434]
16. Forrest JI, Wiens M, Kanters S, Nsanzimana S, Lester RT, Mills EJ. Mobile health applications for HIV prevention and care in Africa. Curr Opin HIV AIDS 2015 Nov;10(6):464-471. [doi: 10.1097/COH.0000000000000198] [Medline: 26352394]
17. Mayer JE, Fontelo P. Meta-analysis on the effect of text message reminders for HIV-related compliance. AIDS Care 2017 Apr;29(4):409-417 [FREE Full text] [doi: 10.1080/09540121.2016.1214674] [Medline: 27477580]
18. Belzer ME, Naar-King S, Olson J, Sarr M, Thornton S, Kahana SY, Adolescent Medicine Trials Network for HIV/AIDS Interventions. The use of cell phone support for non-adherent HIV-infected youth and young adults: an initial randomized and controlled intervention trial. AIDS Behav 2014 Apr;18(4):686-696 [FREE Full text] [doi: 10.1007/s10461-013-0661-3] [Medline: 24271347]
19. Dowshen N, Kuhns LM, Gray C, Lee S, Garofalo R. Feasibility of interactive text message response (ITR) as a novel, real-time measure of adherence to antiretroviral therapy for HIV+ youth. AIDS Behav 2013 Jul;17(6):2237-2243. [doi: 10.1007/s10461-013-0464-6] [Medline: 23546844]
20. Belzer ME, MacDonell KK, Clark LF, Huang J, Olson J, Kahana SY, Adolescent Medicine Trials Network for HIV/AIDS Interventions. Acceptability and feasibility of a cell phone support intervention for youth living with HIV with nonadherence to antiretroviral therapy. AIDS Patient Care STDS 2015 Jun;29(6):338-345 [FREE Full text] [doi: 10.1089/apc.2014.0282] [Medline: 25928772]
21. Garofalo R, Kuhns LM, Hotton A, Johnson A, Muldoon A, Rice D. A randomized controlled trial of personalized text message reminders to promote medication adherence among HIV-positive adolescents and young adults. AIDS Behav 2016 May;20(5):1049-1059 [FREE Full text] [doi: 10.1007/s10461-015-1192-x] [Medline: 26362167]

22. Lewis MA, Uhrig JD, Bann CM, Harris JL, Furberg RD, Coomes C, et al. Tailored text messaging intervention for HIV adherence: a proof-of-concept study. Health Psychol 2013 Mar;32(3):248-253. [doi: 10.1037/a0028109] [Medline: 22545972]
23. Reback CJ, Ling D, Shoptaw S, Rohde J. Developing a text messaging risk reduction intervention for methamphetamine-using MSM: research note. Open AIDS J 2010 May 14;4:116-122 [FREE Full text] [doi: 10.2174/1874613601004030116] [Medline: 20657827]
24. Reback CJ, Grant DL, Fletcher JB, Branson CM, Shoptaw S, Bowers JR, et al. Text messaging reduces HIV risk behaviors among methamphetamine-using men who have sex with men. AIDS Behav 2012 Oct;16(7):1993-2002 [FREE Full text] [doi: 10.1007/s10461-012-0200-7] [Medline: 22610370]
25. Ingersoll K, Dillingham R, Reynolds G, Hettema J, Freeman J, Hosseinbor S, et al. Development of a personalized bidirectional text messaging tool for HIV adherence assessment and intervention among substance abusers. J Subst Abuse Treat 2014 Jan;46(1):66-73 [FREE Full text] [doi: 10.1016/j.jsat.2013.08.002] [Medline: 24029625]
26. Ingersoll KS, Dillingham RA, Hettema JE, Conaway M, Freeman J, Reynolds G, et al. Pilot RCT of bidirectional text messaging for ART adherence among nonurban substance users with HIV. Health Psychol 2015 Dec;34S:1305-1315 [FREE Full text] [doi: 10.1037/hea0000295] [Medline: 26651472]
27. Rana AI, van den Berg JJ, Lamy E, Beckwith CG. Using a mobile health intervention to support HIV treatment adherence and retention among patients at risk for disengaging with care. AIDS Patient Care STDS 2016 Apr;30(4):178-184 [FREE Full text] [doi: 10.1089/apc.2016.0025] [Medline: 27028183]
28. Norton BL, Person AK, Castillo C, Pastrana C, Subramanian M, Stout JE. Barriers to using text message appointment reminders in an HIV clinic. Telemed J E Health 2014 Jan;20(1):86-89 [FREE Full text] [doi: 10.1089/tmj.2012.0275] [Medline: 24160900]
29. Chandler R, Gordon MS, Kruszka B, Strand LN, Altice FL, Beckwith CG, et al. Cohort profile: seek, test, treat and retain United States criminal justice cohort. Subst Abuse Treat Prev Policy 2017 May 16;12(1):24 [FREE Full text] [doi: 10.1186/s13011-017-0107-4] [Medline: 28511680]
30. Beckwith C, Castonguay BU, Trezza C, Bazerman L, Patrick R, Cates A, et al. Gender differences in HIV care among criminal justice-involved persons: baseline data from the care+ corrections study. PLoS One 2017;12(1):e0169078 [FREE Full text] [doi: 10.1371/journal.pone.0169078] [Medline: 28081178]
31. Kuo I, Liu T, Patrick R, Trezza C, Bazerman L, Castonguay BJ, et al. Use of an mHealth Intervention to Improve Engagement in HIV Community-Based Care Among Persons Recently Released from a Correctional Facility in Washington, DC: A Pilot Study. In: Proceedings of the 12th International Conference on HIV Treatment and Prevention Adherence. 2017 Presented at: IAPAC'17; June 4-6, 2017; Miami, FL. [doi: 10.1007/s10461-018-02389-1]
32. Kuo I, Liu T, Patrick R, Trezza C, Bazerman L, Castonguay BJ, et al. Use of an mHealth intervention to improve engagement in HIV community-based care among persons recently released from a correctional facility in Washington, DC: a pilot study. AIDS Behav 2019 Apr;23(4):1016-1031. [doi: 10.1007/s10461-018-02389-1] [Medline: 30627850]
33. Skeels M, Kurth A, Clausen M, Severynen A, Garcia-Smith H. CARE+ user study: usability and attitudes towards a tablet pc computer counseling tool for HIV+ men and women. AMIA Annu Symp Proc 2006:729-733 [FREE Full text] [Medline: 17238437]
34. Spielberg F, Kurth AE, Severynen A, Hsieh Y, Moring-Parris D, Mackenzie S, et al. Computer-facilitated rapid HIV testing in emergency care settings: provider and patient usability and acceptability. AIDS Educ Prev 2011 Jun;23(3):206-221. [doi: 10.1521/aeap.2011.23.3.206] [Medline: 21696240]
35. Merrall E, Kariminia A, Binswanger IA, Hobbs MS, Farrell M, Marsden J, et al. Meta-analysis of drug-related deaths soon after release from prison. Addiction 2010 Sep;105(9):1545-1554 [FREE Full text] [doi: 10.1111/j.1360-0443.2010.02990.x] [Medline: 20579009]
36. Parker SJ, Jessel S, Richardson JE, Reid MC. Older adults are mobile too!Identifying the barriers and facilitators to older adults' use of mHealth for pain management. BMC Geriatr 2013 May 6;13:43 [FREE Full text] [doi: 10.1186/1471-2318-13-43] [Medline: 23647949]
37. Watkins I, Xie B. eHealth literacy interventions for older adults: a systematic review of the literature. J Med Internet Res 2014 Nov 10;16(11):e225 [FREE Full text] [doi: 10.2196/jmir.3318] [Medline: 25386719]
38. Matthew-Maich N, Harris L, Ploeg J, Markle-Reid M, Valaitis R, Ibrahim S, et al. Designing, implementing, and evaluating mobile health technologies for managing chronic conditions in older adults: a scoping review. JMIR Mhealth Uhealth 2016 Jun 9;4(2):e29 [FREE Full text] [doi: 10.2196/mhealth.5127] [Medline: 27282195]
39. Nundy S, Dick JJ, Goddu AP, Hogan P, Lu CE, Solomon MC, et al. Using mobile health to support the chronic care model: developing an institutional initiative. Int J Telemed Appl 2012;2012:871925 [FREE Full text] [doi: 10.1155/2012/871925] [Medline: 23304135]
40. UNAIDS. AIDSinfo | UNAIDS. Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2000 Oct. Costing Guidelines for HIV Prevention Strategies URL: http://data.unaids.org/publications/irc-pub05/jc412-costguidel_en.pdf [accessed 2019-12-05]
41. Reback CJ, Fletcher JB, Leibowitz AA. Cost effectiveness of text messages to reduce methamphetamine use and HIV sexual risk behaviors among men who have sex with men. J Subst Abuse Treat 2019 May;100:59-63. [doi: 10.1016/j.jsat.2019.02.006] [Medline: 30898329]

42. Finitsis DJ, Pellowski JA, Johnson BT. Text message intervention designs to promote adherence to antiretroviral therapy (ART): a meta-analysis of randomized controlled trials. PLoS One 2014;9(2):e88166 [FREE Full text] [doi: 10.1371/journal.pone.0088166] [Medline: 24505411]
43. Binswanger IA, Nowels C, Corsi KF, Long J, Booth RE, Kutner J, et al. 'From the prison door right to the sidewalk, everything went downhill,' a qualitative study of the health experiences of recently released inmates. Int J Law Psychiatry 2011;34(4):249-255. [doi: 10.1016/j.ijlp.2011.07.002] [Medline: 21802731]
44. Freudenberg N, Daniels J, Crum M, Perkins T, Richie BE. Coming home from jail: the social and health consequences of community reentry for women, male adolescents, and their families and communities. Am J Public Health 2008 Sep;98(9 Suppl):S191-S202. [doi: 10.2105/ajph.98.supplement_1.s191] [Medline: 18687613]

Abbreviations

ART: antiretroviral therapy
CBO: community-based organization
CJ: criminal justice
DC: District of Columbia
DOC: Department of Corrections
mHealth: mobile health
PLWH: people living with HIV
STTR: Seek, Test, Treat, and Retain
UNC: University of North Carolina

Edited by G Eysenbach; submitted 12.09.19; peer-reviewed by S Graham, YH Kwan; comments to author 09.10.19; revised version received 19.10.19; accepted 20.10.19; published 13.02.20.

Please cite as:
Uhrig Castonguay BJ, Cressman AE, Kuo I, Patrick R, Trezza C, Cates A, Olsen H, Peterson J, Kurth A, Bazerman LB, Beckwith CG The Implementation of a Text Messaging Intervention to Improve HIV Continuum of Care Outcomes Among Persons Recently Released From Correctional Facilities: Randomized Controlled Trial
JMIR Mhealth Uhealth 2020;8(2):e16220
URL: https://mhealth.jmir.org/2020/2/e16220
doi:10.2196/16220
PMID:32053119

Original Paper

International ResearchKit App for Women with Menstrual Pain: Development, Access, and Engagement

Jiani Wang[1], MSc; Alizé A Rogge[1], MSc; Mike Armour[2], PhD; Caroline A Smith[2], PhD; Christopher R D'Adamo[3], PhD; Claudia R Pischke[4], PhD; Hung-Rong Yen[5,6], PhD; Mei-Yao Wu[6], PhD; Ari Ojeda Ocampo Moré[7], PhD; Claudia M Witt[1,3,8*], MD, MBA; Daniel Pach[1,8*], MD

[1]Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Institute for Social Medicine, Epidemiology and Health Economics, Berlin, Germany

[2]NICM Health Research Institute, Western Sydney University, Sydney, Australia

[3]Center for Integrative Medicine, School of Medicine, University of Maryland, Baltimore, MD, United States

[4]Institute of Medical Sociology, Centre for Health and Society, Medical Faculty, Heinrich Heine University Düsseldorf, Düsseldorf, Germany

[5]School of Chinese Medicine, China Medical University, Taichung, Taiwan

[6]Department of Chinese Medicine, China Medical University Hospital, Taichung, Taiwan

[7]Integrative Medicine and Acupuncture Division, University Hospital, Federal University of Santa Catarina, Florianópolis, Santa Catarina, Brazil

[8]Institute for Complementary and Integrative Medicine, University Zurich and University Hospital Zurich, Zurich, Switzerland

[*]these authors contributed equally

Corresponding Author:
Daniel Pach, MD
Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Institute for Social Medicine, Epidemiology and Health Economics
Luisenstraße 57
Berlin, 10117
Germany
Phone: 49 30450529011
Email: daniel.pach@charite.de

Abstract

Background: Primary dysmenorrhea is a common condition in women of reproductive age. A previous app-based study undertaken by our group demonstrated that a smartphone app supporting self-acupressure introduced by a health care professional can reduce menstrual pain.

Objective: This study aims to evaluate whether a specific smartphone app is effective in reducing menstrual pain in 18- to 34-year-old women with primary dysmenorrhea in a self-care setting. One group of women has access to the full-featured study app and will be compared with 2 control groups who have access to fewer app features. Here, we report the trial design, app development, user access, and engagement.

Methods: On the basis of the practical implications of the previous app-based study, we revised and reengineered the study app and included the ResearchKit (Apple Inc) framework. Behavior change techniques (BCTs) were implemented in the app and validated by expert ratings. User access was estimated by assessing recruitment progress over time. User evolution and baseline survey respondent rate were assessed to evaluate user engagement.

Results: The development of the study app for a 3-armed randomized controlled trial required a multidisciplinary team. The app is accessible for the target population free of charge via the Apple App Store. In Germany, within 9 months, the app was downloaded 1458 times and 328 study participants were recruited using it without external advertising. A total of 98.27% (5157/5248) of the app-based baseline questions were answered. The correct classification of BCTs used in the app required psychological expertise.

Conclusions: Conducting an innovative app study requires multidisciplinary effort. Easy access and engagement with such an app can be achieved by recruitment via the App Store. Future research is needed to investigate the determinants of user engagement, optimal BCT application, and potential clinical and self-care scenarios for app use.

Trial Registration: ClinicalTrials.gov NCT03432611; https://clinicaltrials.gov/ct2/show/NCT03432611 (Archived by WebCite at http://www.webcitation.org/75LLAcnCQ).

(JMIR Mhealth Uhealth 2020;8(2):e14661) doi:10.2196/14661

KEYWORDS

dysmenorrhea; mHealth; mobile applications; acupressure; pain; behavior change techniques (BCTs); ResearchKit; recruitment

Introduction

Background

In recent years, increasing smartphone access has enabled the advancement and widespread use of smartphone apps [1,2]. Apps are a promising tool for people with a wide variety of health conditions and may be particularly useful to guide and support individuals in the self-management of these conditions [3,4]. A recent systematic review on apps in pain management concluded that apps might be beneficial for patients, particularly in an outpatient setting, but that there is a need for more scientific knowledge [5]. Furthermore, in an Australian national survey on mobile health (mHealth) in women with polycystic ovary syndrome [6], current evidence-based information was considered to be the most desirable app feature. Thus, an app with evidence-based information on menstrual pain might be of great value for patients suffering from this common problem.

Menstrual disorders are highly prevalent among women of reproductive age, and especially in young women; they commonly include period pain and mood disturbances [7]. Primary dysmenorrhea is defined as menstrual pain in the absence of underlying pathology, with the pain commonly starting within 3 years of menarche (the first menstrual period) [8]. A characteristic symptom of primary dysmenorrhea is crampy, colicky spasms of pain below the belly button, occurring within 8 to 72 hours of menstruation and peaking within the first few days as menstrual flow increases [9]. Many women with dysmenorrhea also experience other menstrual-related symptoms such as back pain, headaches, bowel changes, nausea, and vomiting [9]. Primary dysmenorrhea has significant negative impacts on education [7] and productivity at work [10]. Current menstrual health literacy and understanding of effective self-care strategies for menstrual symptoms are often poor [11].

In a previous randomized pragmatic trial (trial registration: ClinicalTrials.gov NCT01582724) [12] for women with menstrual pain, a total of 221 women were randomly assigned to 1 of 2 study groups. Both groups received the study app and a short introduction by a health care professional. Although the intervention group had access to acupressure-based features, including visual and written instructions on how to apply self-acupressure before and during menstruation, the control group did not. In addition, the app could send regular reminders to start the acupressure or to fill in questions. For both groups, the app was used to collect the study-related data and support the management of the menstrual period with a simplistic period calendar. Users in the self-acupressure group reported a significant reduction in the mean pain intensity and reported less pain medication intake in comparison with the usual care control group. In addition, two-thirds of the women still used the app and continued to apply self-acupressure after 6 months [12]. Owing to the fast-developing mHealth technology, it was difficult to keep these noteworthy study results relevant for actual implementation. This was, in part, because of the user experience and because the underlying technology soon became outdated. Therefore, a complete modernization and reengineering of the app and the development of a new corresponding trial that examines its effect over a longer duration than undertaken in the initial trial were necessary.

In 2015, Apple Inc introduced ResearchKit as an open-source framework to support clinical researchers conducting structured mobile app–based health studies [1]. This free and reusable framework can simplify the integration of patient recruitment, the consent process, and the data collection in an mHealth study app. A modernization and reengineering of the previous study app using the ResearchKit framework, new software tools, and design guidelines for broader functionalities and an up-to-date interface would allow to verify the study results from our previous trial on a larger scale and in a real-life self-care setting in several different countries across the world. To our knowledge, no ResearchKit app-based interventional studies have been previously conducted targeting women with menstrual pain. By implementing this ResearchKit app, it would be possible to improve self-care for menstrual pain by encouraging users to change their behavior and regularly apply self-care activities, such as exercise, yoga, or self-acupressure.

Michie et al defined the smallest, observable, replicable intervention component with the potential to bring about change in behavior as behavior change techniques (BCTs) [13]. BCTs have been widely applied in electronic health interventions. A prior ResearchKit app-based observational study evaluated the decision making in patients with acute anterior cruciate ligament ruptures [14] and suggested that it might be possible to maintain users' motivation by providing instant feedback and relevant treatment information. In another study aimed at reducing alcohol consumption via an app [15], self-monitoring, goal setting, action planning, and feedback in relation to goals were identified as BCTs with the greatest potential to reduce alcohol use. A review on apps targeting persons with poor control of type 2 diabetes mellitus also suggests that the majority of BCTs employed are those for the promotion of self-regulatory behavior [16]. However, there is a lack of data for expert validation of BCTs implemented in apps for menstrual pain.

From the recruitment perspective, previous ResearchKit-based studies predominantly used Web-based recruitment. Web-based recruitment has the potential advantage of reaching a broader population quickly, whereas conventional recruitment is usually time consuming and costly. However, the broad reach can potentially bring in people who are not the target population of a particular mHealth study [17]. In an interventional ResearchKit study, enrollment before eligibility screening (number of App Store visits and downloads) and after baseline questions are indicators for user engagement. However, this important measurement has not been widely reported in previous mHealth studies yet.

Objectives

To address the questions raised above and to gain a greater understanding for conducting mHealth trials, we report the development, user access, and user engagement of our ResearchKit-based study app for an ongoing pragmatic randomized controlled trial (RCT) [18] on menstrual pain.

Methods

Study App and Study Design

Technical Development of the Study App

The development of the app was started with the aim to modernize the design and technology of the study app *AKUD* (2012-2015) for a new 3-armed study in a self-recruitment self-care setting.

The study app *Luna.* (Luna, period) was developed in a collaborative project by the Institute of Complementary and Integrative Medicine of the University of Zurich, Switzerland, the Institute for Social Medicine, Epidemiology and Health Economics, Charité – Universitätsmedizin Berlin, Germany, and Smart Mobile Factory, Berlin, Germany, based on Apple's ResearchKit modular concept. The app was coded in Swift 4 with initial full support for English and German and prepared for easy deployment of other languages, such as simplified and traditional Chinese. The design followed the iOS Human Interface Guidelines (2017) and targets young women. The team involved in the development included iOS and back-end developers, designers, medical doctors, public health researchers, psychologists, and experts on integrative medicine and health.

Behavior Change Techniques in the Study App

The development of user interaction and feedback wording was based on the previous app. However, during the development of the new app, we used the BCT taxonomy (BCTTv1), according to Michie et al [19], to document BCTs employed in the app. For example, the BCT *goal setting* was implemented to promote the goal of completing certain self-care activities. In addition, bar charts that recorded change in pain and activities were set up based on the BCT *self-monitoring*. The app was developed in English. During the adaption to German and Chinese, the content of the app was always translated with care to ensure that the respective underlying BCTs were not affected.

For the scientific description of an mHealth intervention, a proper description of BCTs implemented in the app is important. For this, expert validation is essential. At a later stage after the app development was completed, 2 psychologists who were not part of the development team independently rated the individual app features to validate the proper use of BCTs according to the BCTTv1 [19]. We compared the list of BCTs (that were intended to be implemented in the app) of 1 app development team member with the rating results of these 2 psychologists. Where there was disagreement regarding which BCT was used in the app, a final agreement was reached in a consensus meeting between the 3 raters (Table 1).

Table 1. App features and corresponding behavior change techniques implemented.

App features	Wording and app content	BCTs[a] (rating)
Introduction to baseline survey	"Hello! To get to know you better, we would like to ask you some more questions. All of your data will be kept strictly confidential and anonymous."	No BCTs
Baseline survey finished	"Thank you for your patience. Now we have all the necessary baseline information. You can start with the study."	No BCTs
Notification of doing interventions/fulfilling surveys	"Time to do some activities for your period pain and record your progress."	Prompts/cues (7.1)
When a survey has been finished	"Well Done!"	Social reward (10.4)
In-app reminder of finishing survey during task days	"Missing Answers. Keep going with the questions, this can help you see your progress."	Prompts/cues (7.1)
In-app reminder for acupressure	"Apply acupressure. On days where you have pain, we recommend at least twice a day."	Prompts/cues (7.1)
When the timer for acupressure finished (for all 6 points)	"Well Done! Keep on taking care of yourself."	Social reward (10.4)
Guide for nontask days	"New questions will appear five days before your next period."	Prompts/cues (7.1)
Instructions of when to apply acupressure	When to Apply Acupressure. Instructions of when to apply acupressure (time, frequency).	Goal setting (behavior) (1.1); action planning (1.4)
Instructions of how to apply acupressure	How to Apply Acupressure. Instructions of how to apply acupressure (position, strength, and feeling).	Instructions on how to perform a behavior (4.1)
An image and location for each acupressure point	Image and description of locations of acupressure 3 points: spleen 6, liver 3, large intestine 4.	Instructions on how to perform a behavior (4.1); demonstration of behavior (6.1)
Instruction video for self-acupressure	An instruction animation for self-acupressure on 3 points: spleen 6, liver 3, large intestine 4.	Instructions on how to perform a behavior (4.1); demonstration of behavior (6.1)
Self-care recommendation	"Evidence-based information with references of 5 self-care recommendations: exercises; dietary supplementations; heating pad/hot water bottle; yoga; medication."	Information about health consequences (5.1); credible source (9.1)
Timer for self-acupressure: 1 minute for each point	A counting down timer with a picture of the corresponding acupressure point.	Goal setting (behavior) (1.1); instructions on how to perform a behavior (4.1); demonstration of behavior (6.1)
Dashboard screen	Dashboard screen, including period calendar, diagrams, and charts reviewing pain and survey questions, and a function button for period start/end.	Feedback on behavior (2.2); self-monitoring of behavior (2.3); self-monitoring of outcome(s) of behavior (2.4); feedback on outcome(s) of behavior (2.7)
Journal screen: calendar	Journal screen in calendar view, including period calendar that also displays the completion of survey questions.	Prompts/cues (7.1)
Journal screen: questions	Journal screen in questions view, including a list of survey questions with the date.	No BCTs
Self-care screen	Self-care screen, including a list and icon images for 5 self-care recommendations.	No BCTs

[a]BCT: behavior change technique.

Privacy and Data Security

Privacy and data security were considered high priorities during app development. User data collected by the app are encrypted and transferred anonymously. We adhere to the principle of data minimization [20] and collect only data that are absolutely necessary to answer the research questions. Personally identifiable information (PII), such as the name and signature collected during the informed consent procedure provided by Apple ResearchKit, is stored only on the user's iPhone and will not be sent to the back end. The individual person owning the iPhone (the study participant) will not be identifiable by the data transferred to the study server. A token will be created as an identifier to label the individual study data. Moreover, an app passcode is implemented to avoid unintended access to the app. Collection of information by the app can be stopped at any time by withdrawing from the study, using a specific button in the app's settings, and uninstalling the app. Data will be collected anonymously. In addition, the study team of the coordinating office in Germany is supervised by the data protection officer of the Charité—Universitätsmedizin Berlin. The other participating centers are supervised by their respective institutions.

Study Design

We will conduct a 3-armed, randomized pragmatic trial [18,21] to evaluate whether the smartphone app is effective in reducing menstrual pain in 18- to 34-year-old women with primary dysmenorrhea. We will compare the group of women who has access to the full-featured study app with 2 control groups who have access to fewer app features. After within-app verification of eligibility for the study, eligible women will be randomly allocated to one of the 3 groups in a 1:1:1 ratio. The potential group allocations are as follows: full-featured app version (self-care information + self-acupressure feature), control intervention I (only self-care information feature), or control intervention II (only self-acupressure feature). The app contains the interventions for all 3 groups, but the content is only unlocked and presented to the user depending on their group allocation. Study participants can use the app for the whole study duration of 12 menstruation cycles. The primary outcome of the study is the mean pain intensity measured with the in-app numerical rating scale (NRS) ranging from 0, *no pain*, to 10, *most intense pain imaginable*, on the painful days during the sixth menstruation after starting the intervention (approximately 6 months from trial start depending on cycle length). It will be calculated by adding up the daily values from the start of the menstruation until the end of bleeding and then dividing them by the number of days with available values. NRS is a common measure of pain intensity that has been utilized in many previous studies [22-24], including studies of menstrual pain [25,26]. Secondary outcome measures are described in more detail on ClinicalTrials.gov (NCT03432611).

The decisions on study design of this trial are based, in part, on decisions of the stakeholder advisory group from the corresponding previous trial and its results [12]. As no member of the study team was specialized in gynecology, this expertise was represented by a gynecologist appointed to the advisory group. Our stakeholder advisory group included a female gynecologist, a 16-year-old woman with dysmenorrhea, a female teacher, 2 acupuncture experts, and a mind-body medicine expert [27].

Intervention Components

Furthermore, 5 days before the anticipated start of the menstruation until the end of bleeding, notifications from the app will remind all the groups of participating women to complete questions and perform self-care activities, such as self-acupressure or yoga, depending on the group allocation.

The self-care feature will offer information on self-care for menstrual pain, including evidence-based information about exercise, nutrition and dietary supplementation, heating pad/hot water bottle, yoga, and when to consult a doctor and regarding how primary dysmenorrhea is treated in most cases (see Multimedia Appendix 1).

The acupressure feature will offer detailed written and multimedia descriptions of the acupressure to be used for menstrual pain (see Multimedia Appendix 2). A total of 3 acupressure points will be described that should be massaged bilaterally, if possible, twice a day, up to 5 times per day, starting from 5 days before menstruation until the end of menstruation. Each point should be massaged for 1 min (ie, altogether 6 min should be spent for 1 acupressure session). A visual timer for the acupressure will indicate desirable length of acupressure. In addition, an in-app notification on the app's dashboard will remind users to practice acupressure during painful days at least twice daily.

The acupressure intervention resulted from a written consensus process with international acupuncture experts from China, Germany, and the United States of America [27] and was already evaluated in an RCT previously conducted by our group demonstrating effectiveness of the intervention [12]. The acupuncture points SP6 (Sanyinjiao), LI4 (Hegu), and LR3 (Taichong) were chosen during this process.

Participants are allowed to continue with their own usual care (medical and nonmedical) during the study.

Participants and Group Allocation

We aim to recruit 594 young women with primary dysmenorrhea. The sample size estimation is based on the comparison of the group receiving the full-featured app (self-care information + self-acupressure) with the group receiving the app version without the self-care information (control intervention II) regarding the primary outcome (NRS after 6 menstrual cycles) that will be treated as a continuous variable. Our previous study showed a mean group difference of 1.4 on the NRS and a standard deviation of 2.15 at the sixth menstrual cycle after the onset of the trial.

Assuming that self-care information has a smaller impact on pain than acupressure, we hypothesize a difference of 0.8 on the NRS between groups. To detect a mean difference of 0.8 point on the NRS after 6 menstrual cycles between the group receiving the full-featured app (with a common standard deviation of 2.15 observed in our previous study) and control intervention II, applying a 2-sided *t* test with a power of 80% and an adjusted alpha of .025, a total of 139 participants will be needed per group (417 women for the 3 arms together). Taking into account a dropout rate of approximately 30% (based on our previous study after 6 cycles), 198 participants per group will be needed (total 594 women).

The eligibility criteria resemble the criteria of our previous study. Women owning an iPhone will be included if they have primary dysmenorrhea, are between the ages of 18 and 34 years, report moderate or severe menstrual pain ≥6 on the NRS; 0=*no pain at all*, 10=*most intense pain imaginable*), and report no existing or planned pregnancy within the next 12 months. During the app-based eligibility screening, the inclusion and exclusion criteria will be assessed by 12 compulsory eligibility questions (Table 2). After the determination of eligibility and obtaining informed consent, participants will be asked to complete the baseline survey before they receive access to the app features depending upon the respective study group allocation. We will use a server-based randomization table created by a statistician using the RANUNI random number generator of the SAS/STAT version 9.2 (SAS Inc) [28]. Participating women will be randomized in a 1:1:1 ratio by block randomization with a fixed block length.

Table 2. Eligibility questions.

Eligibility questions	Question type	Criteria
Are you a woman over 18 and below 35 years old?	Yes/no	If no, exclude
Do you suffer from period pain or menstrual cramps during every menstrual cycle?	Yes/no	If no, exclude
Do you suffer from your period pain on more than 5 days outside the period?	Yes/no	If yes, exclude
Do you think your pain started during your teenage years?	Yes/no	If no, exclude
Do you have any prior history of a gynecological disease that is known to be a reason for your period pain?	Yes/no	If yes, exclude
Did you have a period within the last 6 weeks?	Yes/no	If no, exclude
Is your cycle length between 3 and 6 weeks?	Yes/no	If no, exclude
How strong was the most severe pain without medication during your last period?	Numerical on a pain scale from 0 to 10	If <6, exclude
Are you willing to see a doctor when (1) your pain is getting worse than usual, (2) pain medication is not helping, and (3) when you have pain well before or well after the period?	Yes/no	If no, exclude
Are you pregnant?	Yes/no	If yes, exclude
Do you plan to be pregnant within the next 12 months?	Yes/no	If yes, exclude
Is this your iPhone?	Yes/no	If no, exclude and message the user because of data protection, the app should be used only on your own iPhone

Efficacy-Effectiveness Continuum

From a methodological point of view, a clinical trial provides more evidence on the effectiveness of an intervention using a pragmatic trial design or on the efficacy side using an explanatory trial design [29,30]. Pragmatic trials are usually considered to study interventions in a real-world setting, whereas explanatory trials are usually designed to investigate interventions in an ideally controlled setting. The PRECIS-2 is a wheel-format tool that helps researchers to consider trial design as more effectiveness or efficacy focused including 9 domains: eligibility criteria, recruitment, setting, organization, flexibility (delivery), flexibility (adherence), follow-up, primary outcome, and primary analysis [31]. The PRECIS-2 scoring system ranges from 1 (most explanatory) to 5 (most pragmatic).

During the design phase of the trial, PRECIS served as a tool to make better informed design decisions [32]. We used the PRECIS-2 tool to assess our app-based trial's positioning on the pragmatic-explanatory continuum. The authors independently scored the 9 dimensions.

User Enrollment

The primary recruitment strategy focuses on self-referral through the Apple App Store. On the basis of our experience from the previous trial and the associated stakeholder engagement [12,27], we anticipate that an app-based study for menstrual pain would meet wide acceptance among young women in Germany. Furthermore, we assume that no external advertising (such as posters in public transport or on campus) will be needed for recruitment. A Web-based press release on the Charité university homepage was published on February 28, 2018, (in German and English language), highlighting the results of the previous trial, while also mentioning the new study with the updated app, including a link to the App Store. The media coverage of the app is observed regularly by the study team, using Google search with keywords "selfcare + period pain + Luna," "selfcare + Luna," "app + period pain," "acupressure + period pain" (in German: "Selbsthilfe + Regelschmerzen + Luna," "Selbsthilfe + Luna," "app + Regelschmerzen," "Akupressur + Regelschmerzen").

The app use will be free of charge; no financial compensation will be provided for participating in the study.

Potential future recruitment strategies will include traditional and Web-based recruitment methods that are also adapted to the respective study sites. These will include information about the ongoing study on printed posters or information leaflets or in social media. In addition, if accepted by the Apple App Store editorial team, we will inform potential users about the study app with the *App of the day* feature option of the Apple App Store for the category *Health and Fitness*.

User Engagement

When users install and open the study app for the first time, they will be briefly introduced to the study and encouraged to participate. For potential participants who wish to continue, an app-based anonymous eligibility screening and more detailed information about the study will be provided. After the consent process, participants will finish the app-based baseline survey to unlock the intervention interface. This process is based on the onboarding process of Apple's ResearchKit framework [33]. User flow and conversion rates will be calculated based on the number of downloads, the number of eligible users, and the number of users who finish the baseline survey and enter the study.

In the baseline survey, general information relevant for menstrual pain will be assessed, such as age, education, individual exercise behavior, length of period and level of pain experienced during the period, and use of hormonal contraceptives and pain medications (Table 3). A *skip* button is available for a selection of questions and allows users to skip questions they do not want to answer. User engagement will be measured by usage of *skip* button and baseline survey respondent rate.

Table 3. Baseline questions.

Baseline questions and answer field	Skip button
Your age	**X**[a]
_____ years	
BMI calculated from height and weight	**X**
Your height: ____ cm	
Your body weight: ____ kg	
What is the highest level of education you have completed so far?	**X**
High school or above	
Other	
How long is your cycle usually (the time from the first day of period until the beginning of the next period)?	**__**[b]
_____ days	
How long is your period usually?	**—**
_____ days	
What kind of period pain and discomfort do you usually experience? (multi-choice possible)	**X**
Stomach cramps	
General pain in lower belly	
Lower back pain	
Headache	
Nausea/Vomiting	
Other symptoms, namely _____	
Do you use hormonal contraceptives (eg, birth control pills, hormone patch, vaginal ring, or hormonal IUD[c])?	**X**
No	
Yes	
If yes, why do you use hormonal contraceptives?	
I use hormonal contraceptives because of my period pain.	
I use hormonal contraceptives for contraception.	
I use hormonal contraceptives because of other reasons (for example, acne).	
If yes, which hormonal contraceptives are you using? _____	
If yes, how long have you been using hormonal contraceptives? for ____ months and ____ years	
Have you ever been pregnant?	**X**
No	
Yes	
If yes, number of pregnancies:____	
If yes, number of births:____	
How intense was the average period pain of the painful days during your last period?	**—**
0 1 2 3 4 5 6 7 8 9 10 (0=no pain at all, 10=most intense pain imaginable)	
During your last period, how intense was the worst period pain you experienced?	**—**
0 1 2 3 4 5 6 7 8 9 10 (0=no pain at all, 10=most intense pain imaginable)	
On how many days have you had period pain during your last period?	**X**
_____ days	
On how many days were you absent from work or education due to period pain during your last period?	**X**
_____ days	

Baseline questions and answer field	Skip button
Have you taken any medication for your period pain?	
No	X
Yes ->if yes, which one: _____	
Which self-care activities have you done during the previous month because of your period pain? (multi-choice possible)	**X**
No actions	
Fitness/Gymnastics	
Jogging/Running	
Acupressure	
Yoga	
Autogenic training	
Herbal medicine	
Meditation/Relaxation	
Homeopathy	
Local supply of heat	
Food supplements	
Tea	
Others: _____	
Which self-care activities have you done during the previous month because of other reasons than your period pain? (multi-choice possible)	**X**
No actions	
Fitness/gymnastics	
Jogging/running	
Acupressure	
Yoga	
Autogenic training	
Herbal medicine	
Meditation/relaxation	
Homeopathy	
Local supply of heat	
Food supplements	
Tea	
Others: _____	
When did you have your last period? Please enter the data of the first day of your last period.	**—**
__.__.____	

[a]X: skip button enabled.

[b]—: skip button disabled.

[c]IUD: intrauterine device.

Statistical Analysis

The PRECIS-2 score was calculated by summing up the means of each dimension based on the rating results of 11 raters; meanwhile, standard deviations were calculated to show the variability.

For the BCT ratings, the interrater reliability among BCT raters was assessed by intraclass correlations (ICCs) [34,35].

For the assessment of user access, we used the data generated by App Analytics [33] (Apple Inc) to descriptively show the source of product page views and number of downloads.

To assess user engagement, the user conversion rate and the baseline survey response data were calculated using descriptive statistics (frequencies, percentages, means, and standard deviations). The baseline survey variables were extracted from

the back-end database and only the missing values of the baseline survey (*skipped* questions) were used for the calculation of the proportion of actually skipped questions among all skippable questions to interpret the user engagement.

All collected data were analyzed with SPSS version 22.0 (SPSS Inc).

Ethics

The app is prepared for international use and can be currently (October 2019) downloaded in the German App Store and will later be made available in the App Stores of the other participating centers. The study database, the app server, and the primary study center are based in Berlin, Germany. The study was approved by the university's ethics committee (Charité—Universitätsmedizin Berlin approval Number EA1/364/16). The trial was registered at ClinicalTrials.gov (NCT03432611).

The participation of the study sites in Taichung, Taiwan (approval letter Number CMUH107-REC1-120 by Ethics Committee of China Medical University and Hospital); Sydney, Australia (approval number H13175 by Western Sydney University Human Research Ethics Committee); Florianopolis, Brazil (approval number 3.583.066 by Ethics Committee of Federal University of Santa Catarina), and Baltimore, United States is currently being processed.

Results

Study App and Study Design

The study app is a result of multidisciplinary efforts. The launch of the study app in the App Store will mark the beginning of the fully app-based study: users will be recruited via the Apple App Store, eligibility and consent will be processed by the study app, different self-care interventions will be guided by corresponding app features, and the follow-up will be recorded by app-based survey questions (Figure 1). Detailed screenshots, which depict the user flow in more detail, are listed in Multimedia Appendix 3.

The study app will display the intervention components (self-acupressure and self-care information) selectively according to the group allocation. The core features *Dashboard*, *Journal*, and *More* (Figure 2) will be accessible to all users. The *Dashboard* will display feedback according to study progress and answers of survey questions and a prediction of the next period start date. The *Journal* feature will contain a period calendar and an overview of the progress on the survey questions. With the *More* feature, users will be able to set personal identification number lock and notification time. Users' cycle information, the signed consent form, and a link to the privacy policy will also be displayed there.

Figure 1. Study design. ITT: intention to treat; PP: per protocol.

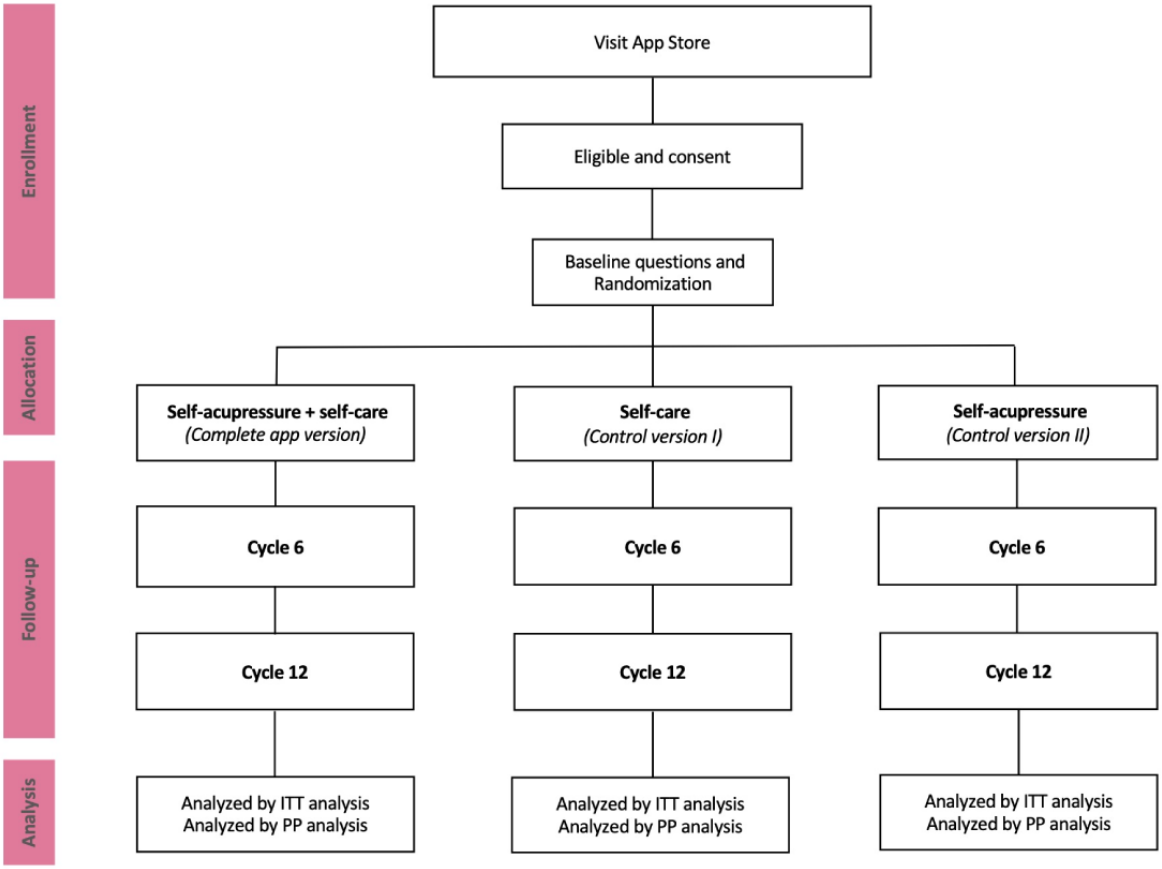
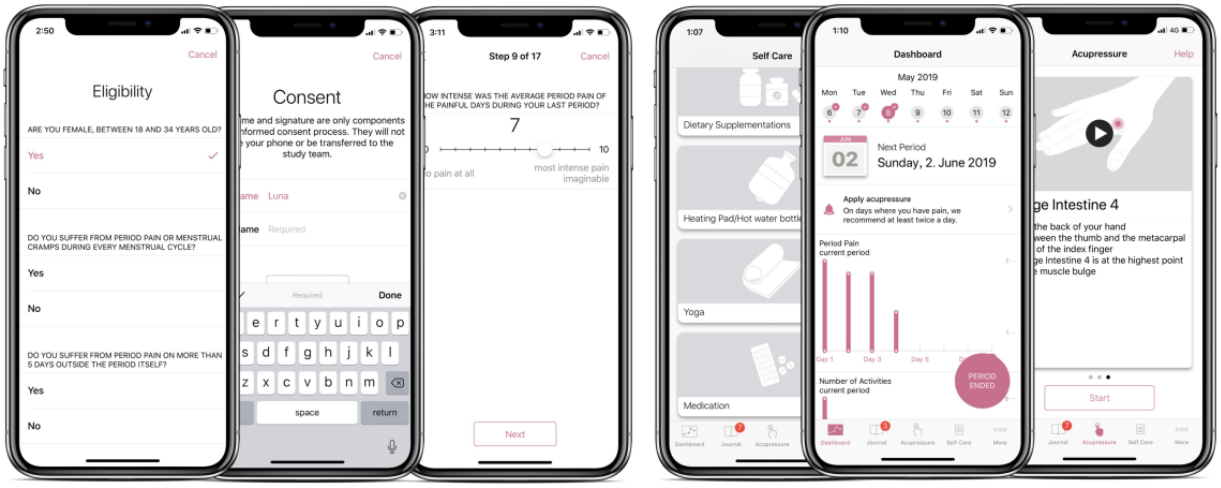


Figure 2. Screenshots of the study app.



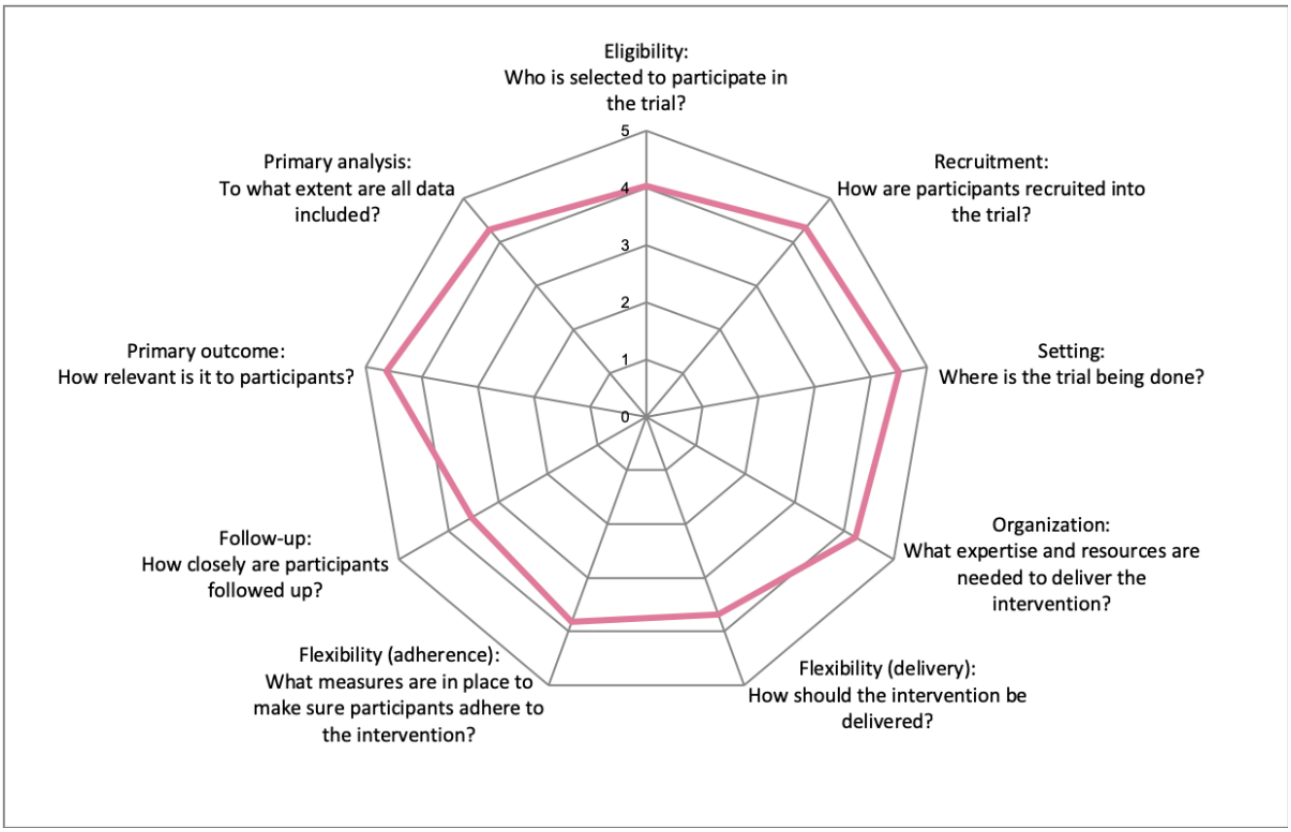
Behavior Change Technique Ratings

To validate whether the BCTs implemented in the app were properly applied, a developer rating (JW) was compared with ratings of 2 psychologists with BCT expertise (CRP and AR) who had experienced the finalized full-featured app but who had not been part of the app development process. The interrater agreement between the 2 psychologists showed an excellent ICC (ICC=0.954; 95% CI 0.87-0.98). However, the overall interrater agreement including all raters was poor (ICC=0.442; 95% CI 0.07-0.78), that is, the ratings of the BCTs used during the development by the study team, did not correspond well with the ratings of the 2 psychologists. There was no significant difference between ICCs at the item level and the cluster level based on the BCTs taxonomy (v1) [19]. The final agreement that was reached in a consensus meeting is shown in Table 2. Overall, 12 BCTs were identified in the study app. The most frequently implemented BCTs are prompts/cues (5 times), instructions on how to perform behavior (4 times), and demonstration of the behavior (3 times).

Efficacy-Effectiveness Continuum Rating

On the basis of the rating results of all authors, all 9 dimensions of the PRECIS-2 tool are defined more on the pragmatic side (Figure 3). Thus, this app-based RCT can be considered as a pragmatic trial.

Figure 3. PRECIS-2 rating results of the study design.

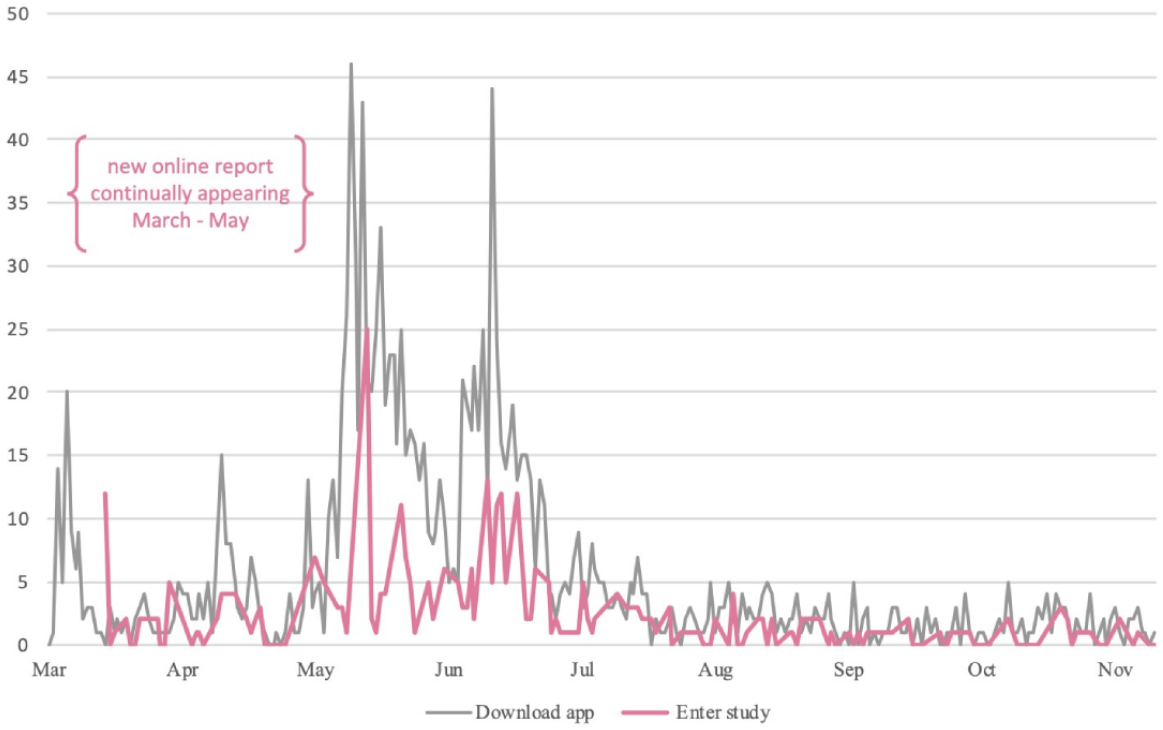


User Enrollment

Trial recruitment started in February 2018 with the launch of the ResearchKit-based study app in the German App Store. The Web-based press release was well received by the public and the media. By observation of media coverage via Google search during the following 10 weeks, 65 articles or blog entries of pharmacy or health-related websites citing the press releases in English and German could be detected. Overall, 2 printed newspapers reported about this app-based study in German. An increase of media coverage could be observed from March to May 2018. In the weeks following the press release, the app showed continuous increase in both downloads and the number of users (Figure 4).

After 38 weeks in the app store (from February 19, 2018, to November 13, 2018), there were 1458 downloads and 328 users were included into the study (22.5%). On average, we recruited around 8 study participants per week with a peak between May and June after the press release (22 new users per week). Approximately 60% (195/328) of the participants were recruited within these 2 months.

Figure 4. App downloads and new users per day.



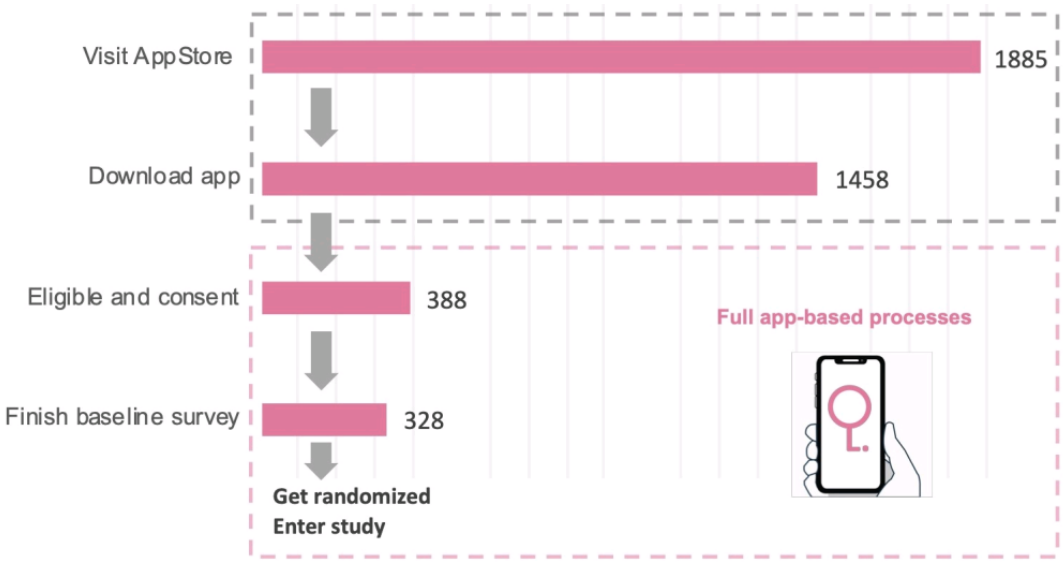
User Engagement

During the first 38 weeks of recruitment, the App Store's preview of the app was viewed 1885 times. Although 75% of the app's product page viewers found the app by searching the App Store, 25% found the app by App Store browsing, app referral, or Web referral. The app was downloaded 1458 times. A total of 388 (27%) users passed the 12-question eligibility screening and agreed to consent; 328 of the 388 users (85%) completed the 16-question baseline survey and were recruited to the study. Figure 5 displays the user evolution [14].

For 11 of 16 baseline questions, the *skip* button can be used because these questions are either not related to the primary outcome of the study or their data are not essential for the proper functioning of the app. The usage of the *skip* button of a study sample (328 users) was calculated to evaluate the user engagement in the app-based survey.

Almost all questions of the baseline survey were answered (data completeness of 98.27%; 5157/5248). A total of 276 users (276/328, 84.1%) answered all 16 baseline questions and never used the skip button. Only 3% of the data based on the skippable questions were missing. The question asking for discomfort/symptoms during the period was answered by all users (response rate 100%). For free-text fields, 105 (105/328, 32.0%) of the users provided details about their discomfort/symptoms during their period; 269 (269/328, 82.0%) users provided details about their medication for the question asking about the period pain-related medical history.

Figure 5. User evolution.



Discussion

Principal Findings

By using the ResearchKit framework, we successfully developed a study app for a fully app-based pragmatic RCT for young women with primary dysmenorrhea. The app is easily accessible via self-referral and can be used as a self-care and study tool for a highly relevant condition. The available data already indicate a high level of user engagement with the study app. We also realized that the early involvement of behavioral science experts is of great importance for the development of app-based trials.

In a young population that widely uses smartphones, a digital intervention, such as the study app, provides low entry barriers. It offers easy access to evidence-based self-care information for menstrual pain and tools to improve healthy behavior. We believe that recruitment is not only influenced by the app itself but also by the way of communicating the study. We observed a substantial increase in recruitment rates following the publication of a press release on our university's websites and corresponding media coverage. A causal relationship in the recruitment increase seems to be very probable. After 5 months without actively communicating the study with media or information material, we still could observe a basic recruitment of about 1 new study participant per day.

Almost all research or self-care apps include BCT elements, such as prompts/cues to fill in questionnaires (self-monitoring) or to engage in app- specific intervention components. Dialog boxes are also used to give feedback on behavior or to promote self-belief [19]. However, the adequate implementation and the proper description of the applied BCTs are not easy to achieve. Therefore, it is important to involve psychologists or behavioral scientists in the design and development of an app [36,37]. The review of the use of the BCT taxonomy during the development of the trial revealed some discrepancies between the study team members and the psychologists that were involved in the ratings. For future studies, the behavior change wheel framework by Michie et al [38] will be applied before the app development to improve the design and implementation of app-based interventions [39]. Moreover, the mechanisms and efficacy of BCTs implemented need to be further explored in mHealth research settings.

As in our previous mHealth studies, the app and trial simultaneously shaped each other during the trial design and app development process. In conventional RCTs, the trial intervention and outcomes are usually very standardized as they are described in the study protocol. However, during the development and coding process of the study app, we regularly made adaptations of the study protocol because of technical and design aspects. For example, during the development process, we realized that the digitally collected data can be used to give the users an overview of study progress and symptom improvement that subsequently became part of the intervention strategy. Branching within a question (the answer of an item impacts the next question choices) and combining different question types were not possible with the standard ResearchKit framework. Moreover, baseline questions had to be limited to reduce the time spent until finalization of onboarding, that is, the whole process from introduction, eligibility screening, and participant consent until completion of baseline survey and the random allocation to the respective intervention group. However, the final onboarding process in our research app was longer than what users of consumer apps might usually accept. This could have resulted in a loss of potential study participants. Some baseline questions typical for research studies, such as questions about partnership and income, were omitted because of privacy concerns. It was not necessary to collect body weight and height as PII data, as they were only used for BMI calculation on the user's iPhone and not transferred to the study backend. The study design also impacted some technical decisions. For instance, to limit recall bias, questions that required daily answers before and during the period will expire after 7 days. Moreover, the way symptoms are measured or tracked in an app is limited to validated and commonly used outcomes. NRS or Likert scales are used instead of more consumer-oriented approaches, such as individualized icons or

emojis to record mood or pain. This might limit the user experience.

Limitations

In addition to the limitation of the development process already described above, several other related limitations have to be taken into account. The decision to focus on Apple's iOS only enabled the use of Apple ResearchKit and avoided the difficulties associated with developing for 2 operating systems simultaneously, as was done in our previous trials [12,27]. Owing to this decision, only women using an iPhone can participate in the study, which consequently might introduce selection bias and therefore limit the generalizability of the study. Moreover, the impact of technical updates (ie, ResearchKit and iOS updates) or other potential adaptations of the app during the course of the study is not clear yet, but these adaptations will be thoroughly reported in the results paper of the trial.

Our study is also subject to some limitations from the access perspective. The numbers of App Store's visitors and downloads are generated by Apple's App Analytics, which we do not control. This is the only source to estimate the number of subjects interested in our study because of our anonymous study design. However, we think that it is important to also include App Analytics' data despite its nonstudy purpose. Taking advantage of these resources from the mHealth ecosystem might help future app-based studies. To be eligible to use our study app, individuals who downloaded the app had to pass our 12-question eligibility screening that is based on our relatively strict inclusion and exclusion criteria. However, for the assessment of user evolution, we could only record the number of eligible users who gave consent because of ResearchKit's design restrictions and our privacy rules. As a result, we lack knowledge about the reasons for ineligibility. In addition, although the participant's eligibility and survey data underwent comparably strict plausibility checks that we have implemented in the app, fake users and fraud registration for the study cannot be completely ruled out. However, our fully remote study allows user behavior in a real-life setting [12,21,40]. Additional plausibility checks will be developed before the analysis of the results. Another way to access the app could be on recommendation of a gynecologist and/or family physician within a therapeutic setting. Further study is required to make a definite conclusion about the extent to which the app might be of use in such a setting.

Data on user engagement in our study are limited so far. The only indicator we currently use for assessing engagement is based on the completion and response of the baseline questions. Commercial apps often use analytic tools to track user interaction with the app. These data can be used for the evaluation of engagement [41], the optimization of the app, or the addition of new features. In a study setting with strict privacy considerations, we do not use these tools. In addition, adherence would be a good measurement for user engagement. Data about adherence is not available yet but will be considered as an outcome of the study.

Comparison With Prior Studies

The study app and the app-based trial result from adaptation and amendments of our previous *AKUD* trial [12,27]. The inclusion criteria of the research population are based on the previous trial but were modified to meet the necessities of remote recruitment. In the previous *AKUD* trial, participants were recruited through onsite recruitment by 1 study center in Berlin, Germany facilitated by advertisements (posters, flyers, leaflets, students email lists, and subway advertisements). Baseline data were recorded with paper-and-pencil surveys. This way, it took 20 months to reach the recruitment target of 221 participants [12,27]. With the ResearchKit-based study app, we are now able to reach participants across Germany.

For the assessment of access of app studies, Anguera et al [40] reported the recruitment number, whereas Zens et al [14] reported the consent/download rate. The percentage of consented participants (27%) in our trial is lower than in other ResearchKit studies [14,42,43]. The mPower study [42] reported 35% consent/download rate, whereas the *Back on Track* study [14] reported 58%. The differences might be explained by the observational character of these studies and the application of a comparably strict eligibility process in our study with 12 eligibility questions.

User adherence and survey response rate are usually considered to be the measurements for evaluating engagement in app studies [40,44,45]. However, as adherence data of the current trial are not available in the current stage of the study, the baseline survey response is used as a proxy for engagement.

The ResearchKit framework has been used for studies for many health conditions, such as asthma [43], acute anterior cruciate ligament ruptures [14], and Parkinson disease [42] since its launch in 2015 [46]. To our knowledge, no ResearchKit clinical trial for pain conditions has been conducted yet. Thurnheer et al [5] reported 15 studies without ResearchKit and their efficacy in a systematic review of app-based studies for pain management. App-based studies have been conducted both for acute pain such as acute needle stick pain [47] and acute pain before coronarography [48] and for chronic pain such as chronic cancer pain [49], neck pain [50], and low back pain [24,51]. No mHealth-based interventional trial has been conducted for examining the influence of an app promoting health behavior and the use of acupressure on menstrual pain [5,52] so far. Regarding the high prevalence of menstrual pain and the increasing ownership of smartphones [12,53,54], our trial might provide data that can have practical public health implications.

Conclusions

Conducting an evidence-based and up-to-date app study requires multidisciplinary efforts. The resulting ResearchKit-based study app for menstrual pain is accessible for the target population with positive user engagement. However, future research is necessary to investigate the determinants of user engagement, optimal BCT application, and potential clinical scenarios for app use.

Acknowledgments

We thank Beatrice Eden, Iris Bartsch, and Stefanie Helmer for app testing, and all participating women for their study participation. This is an investigator-initiated trial. The app development has been supported by a starting grant of the University of Zurich to Claudia Witt. Mike Armour and Caroline Smith: As a medical research institute, the National Institute of Complementary Medicine (NICM) Health Research Institute receives research grants and donations from foundations, universities, government agencies, and industry. Sponsors and donors provide untied and tied funding for work to advance the vision and mission of the Institute. This study was not specifically supported by donor or sponsor funding to NICM.

Conflicts of Interest

The app has been developed for research purposes and is not a commercial product. The authors do not have any financial stake in the success of the app.

Multimedia Appendix 1
Self care feature.
[PDF File (Adobe PDF File), 216 KB - mhealth_v8i2e14661_app1.pdf]

Multimedia Appendix 2
Acupressure feature.
[PDF File (Adobe PDF File), 275 KB - mhealth_v8i2e14661_app2.pdf]

Multimedia Appendix 3
Screenshots and user flow to enter the study.
[PDF File (Adobe PDF File), 1343 KB - mhealth_v8i2e14661_app3.pdf]

Multimedia Appendix 4
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 577 KB - mhealth_v8i2e14661_app4.pdf]

References

1. Chan YY, Bot BM, Zweig M, Tignor N, Ma W, Suver C, et al. The asthma mobile health study, smartphone data collected using ResearchKit. Sci Data 2018 May 22;5:180096 [FREE Full text] [doi: 10.1038/sdata.2018.96] [Medline: 29786695]
2. Firth J, Torous J, Nicholas J, Carney R, Pratap A, Rosenbaum S, et al. The efficacy of smartphone-based mental health interventions for depressive symptoms: a meta-analysis of randomized controlled trials. World Psychiatry 2017 Oct;16(3):287-298 [FREE Full text] [doi: 10.1002/wps.20472] [Medline: 28941113]
3. McKay FH, Cheng C, Wright A, Shill J, Stephens H, Uccellini M. Evaluating mobile phone applications for health behaviour change: a systematic review. J Telemed Telecare 2018 Jan;24(1):22-30. [doi: 10.1177/1357633X16673538] [Medline: 27760883]
4. Lucht M, Bredenkamp R, Boeker M, Kramer U. Uniklinik Freiburg. Freiburg; 2013. Health and Supply Apps URL: https://www.uniklinik-freiburg.de/fileadmin/mediapool/09_zentren/studienzentrum/pdf/Studien/150331_TK-Gesamtbericht_Gesundheits-und_Versorgungs-Apps.pdf [accessed 2019-12-13]
5. Thurnheer SE, Gravestock I, Pichierri G, Steurer J, Burgstaller JM. Benefits of mobile apps in pain management: systematic review. JMIR Mhealth Uhealth 2018 Oct 22;6(10):e11231 [FREE Full text] [doi: 10.2196/11231] [Medline: 30348633]
6. Boyle JA, Xu R, Gilbert E, Kuczynska-Burggraf M, Tan B, Teede H, et al. Ask PCOS: identifying need to inform evidence-based app development for polycystic ovary syndrome. Semin Reprod Med 2018 Jan;36(1):59-65. [doi: 10.1055/s-0038-1667187] [Medline: 30189452]
7. Armour M, Parry K, Manohar N, Holmes K, Ferfolja T, Curry C, et al. The prevalence and academic impact of dysmenorrhea in 21,573 young women: a systematic review and meta-analysis. J Womens Health (Larchmt) 2019 Aug;28(8):1161-1171. [doi: 10.1089/jwh.2018.7615] [Medline: 31170024]
8. Coco AS. Primary dysmenorrhea. Am Fam Physician 1999 Aug;60(2):489-496 [FREE Full text] [Medline: 10465224]
9. Proctor M, Farquhar C. Diagnosis and management of dysmenorrhoea. Br Med J 2006 May 13;332(7550):1134-1138 [FREE Full text] [doi: 10.1136/bmj.332.7550.1134] [Medline: 16690671]
10. Schoep ME, Adang EM, Maas JW, de Bie B, Aarts JW, Nieboer TE. Productivity loss due to menstruation-related symptoms: a nationwide cross-sectional survey among 32 748 women. BMJ Open 2019 Jun 27;9(6):e026186 [FREE Full text] [doi: 10.1136/bmjopen-2018-026186] [Medline: 31248919]
11. Armour M, Parry K, Al-Dabbas MA, Curry C, Holmes K, MacMillan F, et al. Self-care strategies and sources of knowledge on menstruation in 12,526 young women with dysmenorrhea: A systematic review and meta-analysis. PLoS One 2019;14(7):e0220103 [FREE Full text] [doi: 10.1371/journal.pone.0220103] [Medline: 31339951]

12. Blödt S, Pach D, Eisenhart-Rothe SV, Lotz F, Roll S, Icke K, et al. Effectiveness of app-based self-acupressure for women with menstrual pain compared to usual care: a randomized pragmatic trial. Am J Obstet Gynecol 2018 Feb;218(2):227.e1-227.e9 [FREE Full text] [doi: 10.1016/j.ajog.2017.11.570] [Medline: 29155036]
13. Michie S, Abraham C, Eccles MP, Francis JJ, Hardeman W, Johnston M. Strengthening evaluation and implementation by specifying components of behaviour change interventions: a study protocol. Implement Sci 2011 Feb 07;6:10. [doi: 10.1186/1748-5908-6-10] [Medline: 21299860]
14. Zens M, Woias P, Suedkamp NP, Niemeyer P. 'Back on Track': A mobile app observational study using Apple's ResearchKit framework. JMIR Mhealth Uhealth 2017 Feb 28;5(2):e23 [FREE Full text] [doi: 10.2196/mhealth.6259] [Medline: 28246069]
15. Garnett C, Crane D, West R, Brown J, Michie S. Identification of behavior change techniques and engagement strategies to design a smartphone app to reduce alcohol consumption using a formal consensus method. JMIR Mhealth Uhealth 2015 Jun 29;3(2):e73 [FREE Full text] [doi: 10.2196/mhealth.3895] [Medline: 26123578]
16. Kebede MM, Liedtke TP, Möllers T, Pischke CR. Characterizing active ingredients of eHealth interventions targeting persons with poorly controlled type 2 diabetes mellitus using the behavior change techniques taxonomy: scoping review. J Med Internet Res 2017 Oct 12;19(10):e348 [FREE Full text] [doi: 10.2196/jmir.7135] [Medline: 29025693]
17. Lane TS, Armin J, Gordon JS. Online recruitment methods for web-based and mobile health studies: a review of the literature. J Med Internet Res 2015 Jul 22;17(7):e183 [FREE Full text] [doi: 10.2196/jmir.4359] [Medline: 26202991]
18. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, CONSORT group, Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. Br Med J 2008 Nov 11;337:a2390 [FREE Full text] [doi: 10.1136/bmj.a2390] [Medline: 19001484]
19. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013 Aug;46(1):81-95. [doi: 10.1007/s12160-013-9486-6] [Medline: 23512568]
20. European Parliament and Council of the European Union. EUR-Lex. 2016 Apr 27. REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679 [accessed 2019-12-13] [WebCite Cache ID 78C4f3H8O]
21. Witt CM. Efficacy, effectiveness, pragmatic trials--guidance on terminology and the advantages of pragmatic trials. Forsch Komplementmed 2009 Oct;16(5):292-294 [FREE Full text] [doi: 10.1159/000234904] [Medline: 19887807]
22. Heapy AA, Higgins DM, Goulet JL, LaChappelle KM, Driscoll MA, Czlapinski RA, et al. Interactive voice response-based self-management for chronic back pain: the COPES noninferiority randomized trial. JAMA Intern Med 2017 Jun 1;177(6):765-773 [FREE Full text] [doi: 10.1001/jamainternmed.2017.0223] [Medline: 28384682]
23. Choi S, O'Hare T, Gollish J, Paul JE, Kreder H, Thorpe KE, et al. Optimizing pain and rehabilitation after knee arthroplasty: a two-center, randomized trial. Anesth Analg 2016 Nov;123(5):1316-1324. [doi: 10.1213/ANE.0000000000001469] [Medline: 27749351]
24. Huber S, Priebe JA, Baumann K, Plidschun A, Schiessl C, Tölle TR. Treatment of low back pain with a digital multidisciplinary pain treatment app: short-term results. JMIR Rehabil Assist Technol 2017 Dec 4;4(2):e11 [FREE Full text] [doi: 10.2196/rehab.9032] [Medline: 29203460]
25. Witt CM, Reinhold T, Brinkhaus B, Roll S, Jena S, Willich SN. Acupuncture in patients with dysmenorrhea: a randomized study on clinical effectiveness and cost-effectiveness in usual care. Am J Obstet Gynecol 2008 Feb;198(2):166.e1-166.e8. [doi: 10.1016/j.ajog.2007.07.041] [Medline: 18226614]
26. Wade C, Wang L, Zhao WJ, Cardini F, Kronenberg F, Gui SQ, et al. Acupuncture point injection treatment of primary dysmenorrhoea: a randomised, double blind, controlled study. BMJ Open 2016 Jan 5;6(1):e008166 [FREE Full text] [doi: 10.1136/bmjopen-2015-008166] [Medline: 26733563]
27. Blödt S, Schützler L, Huang W, Pach D, Brinkhaus B, Hummelsberger J, et al. Effectiveness of additional self-care acupressure for women with menstrual pain compared to usual care alone: using stakeholder engagement to design a pragmatic randomized trial and study protocol. Trials 2013 Apr 11;14:99 [FREE Full text] [doi: 10.1186/1745-6215-14-99] [Medline: 24499425]
28. SAS Support. Cary, NC, USA SAS/STAT version 9.2 URL: http://support.sas.com/rnd/app/stat/9.2/stat92resources.html [accessed 2019-12-13]
29. Witt CM, Aickin M, Baca T, Cherkin D, Haan MN, Hammerschlag R, Effectiveness Guidance Documents Collaborators. Effectiveness Guidance Document (EGD) for acupuncture research - a consensus document for conducting trials. BMC Complement Altern Med 2012 Sep 6;12:148 [FREE Full text] [doi: 10.1186/1472-6882-12-148] [Medline: 22953730]
30. Wieland LS, Berman BM, Altman DG, Barth J, Bouter LM, D'Adamo CR, et al. Rating of included trials on the efficacy-effectiveness spectrum: development of a new tool for systematic reviews. J Clin Epidemiol 2017 Apr;84:95-104 [FREE Full text] [doi: 10.1016/j.jclinepi.2017.01.010] [Medline: 28188898]
31. Loudon K, Zwarenstein M, Sullivan FM, Donnan PT, Gágyor I, Hobbelen HJ, et al. The PRECIS-2 tool has good interrater reliability and modest discriminant validity. J Clin Epidemiol 2017 Aug;88:113-121. [doi: 10.1016/j.jclinepi.2017.06.001] [Medline: 28603007]

32. Bellmann-Strobl J, Pach D, Chang Y, Pasura L, Liu B, Jäger S, et al. The effectiveness of acupuncture and mindfulness-based stress reduction (MBSR) for patients with multiple sclerosis associated fatigue – A study protocol and its rationale for a randomized controlled trial. Eur J Integr Med 2018;20(5):6-15. [doi: 10.1016/j.eujim.2018.04.001]
33. Apple Developer. Cupertino, CA, USA ResearchKit Human Interface Guidelines URL: https://developer.apple.com/design/human-interface-guidelines/researchkit/overview/introduction/ [accessed 2019-05-07] [WebCite Cache ID 78BzShgCr]
34. Michie S, Wood CE, Johnston M, Abraham C, Francis JJ, Hardeman W. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). Health Technol Assess 2015 Nov;19(99):1-188 [FREE Full text] [doi: 10.3310/hta19990] [Medline: 26616119]
35. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. J Chiropr Med 2016 Jun;15(2):155-163 [FREE Full text] [doi: 10.1016/j.jcm.2016.02.012] [Medline: 27330520]
36. Kataria S, Ravindran V. Digital health: a new dimension in rheumatology patient care. Rheumatol Int 2018 Nov;38(11):1949-1957. [doi: 10.1007/s00296-018-4037-x] [Medline: 29713795]
37. Concannon TW, Fuster M, Saunders T, Patel K, Wong JB, Leslie LK, et al. A systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research. J Gen Intern Med 2014 Dec;29(12):1692-1701 [FREE Full text] [doi: 10.1007/s11606-014-2878-x] [Medline: 24893581]
38. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011 Apr 23;6:42 [FREE Full text] [doi: 10.1186/1748-5908-6-42] [Medline: 21513547]
39. Fulton EA, Brown KE, Kwah KL, Wild S. StopApp: using the behaviour change wheel to develop an app to increase uptake and attendance at NHS stop smoking services. Healthcare (Basel) 2016 Jun 8;4(2):pii: E31 [FREE Full text] [doi: 10.3390/healthcare4020031] [Medline: 27417619]
40. Anguera JA, Jordan JT, Castaneda D, Gazzaley A, Areán PA. Conducting a fully mobile and randomised clinical trial for depression: access, engagement and expense. BMJ Innov 2016 Jan;2(1):14-21 [FREE Full text] [doi: 10.1136/bmjinnov-2015-000098] [Medline: 27019745]
41. Osborn CY, van Ginkel JR, Rodbard D, Heyman M, Marrero DG, Huddleston B, et al. One Drop | Mobile: An Evaluation of Hemoglobin A1c Improvement Linked to App Engagement. JMIR Diabetes 2017 Aug 24;2(2):e21 [FREE Full text] [doi: 10.2196/diabetes.8039] [Medline: 30291059]
42. Bot BM, Suver C, Neto EC, Kellen M, Klein A, Bare C, et al. The mPower study, Parkinson disease mobile data collected using ResearchKit. Sci Data 2016 Mar 3;3:160011 [FREE Full text] [doi: 10.1038/sdata.2016.11] [Medline: 26938265]
43. Chan YY, Wang P, Rogers L, Tignor N, Zweig M, Hershman SG, et al. The Asthma Mobile Health Study, a large-scale clinical observational study using ResearchKit. Nat Biotechnol 2017 Apr;35(4):354-362 [FREE Full text] [doi: 10.1038/nbt.3826] [Medline: 28288104]
44. Bakker D, Rickard N. Engagement in mobile phone app for self-monitoring of emotional wellbeing predicts changes in mental health: MoodPrism. J Affect Disord 2018 Feb;227:432-442. [doi: 10.1016/j.jad.2017.11.016] [Medline: 29154165]
45. Torous J, Staples P, Slaters L, Adams J, Sandoval L, Onnela JP, et al. Characterizing smartphone engagement for schizophrenia: results of a naturalist mobile health study. Clin Schizophr Relat Psychoses 2017 Aug 4. [doi: 10.3371/CSRP.JTPS.071317] [Medline: 28777029]
46. Dorsey ER, Chan YF, McConnell MV, Shaw SY, Trister AD, Friend SH. The use of smartphones for health research. Acad Med 2017 Feb;92(2):157-160. [doi: 10.1097/ACM.0000000000001205] [Medline: 27119325]
47. Stinley NE, Norris DO, Hinds PS. Creating mandalas for the management of acute pain symptoms in pediatric patients. Art Therapy 2015;32(2):46-53. [doi: 10.1080/07421656.2015.1028871]
48. Guétin S, Brun L, Deniaud M, Clerc J, Thayer JF, Koenig J. Smartphone-based music listening to reduce pain and anxiety before coronarography: a focus on sex differences. Altern Ther Health Med 2016 Jul;22(4):60-63. [Medline: 27548494]
49. Sun Y, Jiang F, Gu JJ, Wang YK, Hua H, Li J, et al. Development and testing of an intelligent pain management system (IPMS) on mobile phones through a randomized trial among Chinese cancer patients: a new approach in cancer pain management. JMIR Mhealth Uhealth 2017 Jul 25;5(7):e108 [FREE Full text] [doi: 10.2196/mhealth.7178] [Medline: 28743681]
50. Lee M, Lee SH, Kim T, Yoo H, Kim SH, Suh D, et al. Feasibility of a smartphone-based exercise program for office workers with neck pain: an individualized approach using a self-classification algorithm. Arch Phys Med Rehabil 2017 Jan;98(1):80-87. [doi: 10.1016/j.apmr.2016.09.002] [Medline: 27693421]
51. Irvine AB, Russell H, Manocchia M, Mino DE, Glassen TC, Morgan R, et al. Mobile-Web app to self-manage low back pain: randomized controlled trial. J Med Internet Res 2015 Jan 2;17(1):e1 [FREE Full text] [doi: 10.2196/jmir.3130] [Medline: 25565416]
52. Portelli P, Eldred C. A quality review of smartphone applications for the management of pain. Br J Pain 2016 Aug;10(3):135-140 [FREE Full text] [doi: 10.1177/2049463716638700] [Medline: 27583140]
53. Götz FM, Stieger S, Reips U. Users of the main smartphone operating systems (iOS, Android) differ only little in personality. PLoS One 2017;12(5):e0176921 [FREE Full text] [doi: 10.1371/journal.pone.0176921] [Medline: 28467473]

54. Mikolasek M, Witt CM, Barth J. Adherence to a mindfulness and relaxation self-care app for cancer patients: mixed-methods feasibility study. JMIR Mhealth Uhealth 2018 Dec 6;6(12):e11271 [FREE Full text] [doi: 10.2196/11271] [Medline: 30522990]

Abbreviations

BCT: behavior change technique
ICC: intraclass correlation
mHealth: mobile health
NICM: National Institute of Complementary Medicine
NRS: numerical rating scale
PII: personally identifiable information
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 01.06.19; peer-reviewed by C Reis, T Janmohamed; comments to author 30.08.19; revised version received 21.10.19; accepted 12.11.19; published 11.02.20.

Please cite as:
Wang J, Rogge AA, Armour M, Smith CA, D'Adamo CR, Pischke CR, Yen HR, Wu MY, Moré AOO, Witt CM, Pach D
International ResearchKit App for Women with Menstrual Pain: Development, Access, and Engagement
JMIR Mhealth Uhealth 2020;8(2):e14661
URL: https://mhealth.jmir.org/2020/2/e14661
doi:10.2196/14661
PMID:32058976

Original Paper

From “Step Away” to “Stand Down”: Tailoring a Smartphone App for Self-Management of Hazardous Drinking for Veterans

Daniel Blonigen[1], PhD; Brooke Harris-Olenak[1], PhD; Eric Kuhn[1], PhD; Keith Humphreys[1], PhD; Christine Timko[1], PhD; Patrick Dulin[2], PhD

[1]Department of Veterans Affairs Palo Alto Health Care System, Menlo Park, CA, United States

[2]University of Alaska-Anchorage, Anchorage, AK, United States

Corresponding Author:
Daniel Blonigen, PhD
Department of Veterans Affairs Palo Alto Health Care System
795 Willow Road
MPD-152
Menlo Park, CA, 94025
United States
Phone: 1 6504935000 ext 27828
Email: daniel.blonigen@va.gov

Abstract

Background: US military veterans who screen positive for hazardous drinking during primary care visits may benefit from a mobile app. Step Away is an evidence-based mobile intervention system for the self-management of hazardous drinking. However, Step Away was not designed for veterans, and differences between veterans and civilians could limit the reach and effectiveness of the app with this population.

Objective: The primary objective of this study was to repurpose Step Away to address the needs and preferences of the veteran primary care population. The Method for Program Adaptation through Community Engagement (M-PACE) model was used to guide the adaptation process. This model can serve as a generalizable approach that other researchers and intervention developers can follow to systematically tailor mobile health tools for a new population.

Methods: Veteran patients who screened positive for hazardous drinking during a primary care visit (n=12) and peer providers employed by the US Veterans Health Administration (n=11) were recruited to systematically review Step Away and provide feedback on its content and presentation via Web-based surveys and a semistructured interview. Participant feedback was reviewed through an iterative process by key stakeholders who adjudicated which suggested modifications to the app could enhance engagement and effectiveness with veterans while maintaining program integrity.

Results: Usability ratings of the individual modules of Step Away were uniformly positive across patients and peers, as was the perceived utility of the app overall. Personalized feedback on the health consequences and costs of drinking, options for customization, and the measurement-based care capabilities of the app were viewed as facilitators of engagement. Conversely, lengthy text, small font, and a lack of interactive features were viewed as potential barriers with the older primary care population. Modifications to create a veteran version of the app (*Stand Down: Think Before You Drink*) included altering the appearance of the app to incorporate more veteran-centric content, adding links and options for resources and activities for veterans, and reducing the amount of text and adding veteran-specific references and common concerns and triggers for drinking in this population.

Conclusions: The M-PACE model provided a systematic approach to repurpose Step Away to fit the needs and preferences of veteran primary care patients who engage in hazardous drinking. Stand Down may serve as an innovative, low-cost means of expanding access to care for veterans who engage in hazardous drinking.

(JMIR Mhealth Uhealth 2020;8(2):e16062) doi:10.2196/16062

KEYWORDS

veterans; hazardous drinking; Step Away; Stand Down; peer support

Introduction

Overview

The evidence for various smartphone apps to improve users' mental health is expanding [1,2]. Nonetheless, for many mobile apps, the patient population for which they were developed and validated differs in important ways from subpopulations that may also benefit from these apps. To cite one of many possible examples, an app developed on a young adult sample would not necessarily be as appealing to the elderly population, thus creating barriers to implementation [3]. Consequently, tailoring mobile apps to maximize reach and effectiveness with new populations defined by demographic and life experience factors is essential. In this paper, we outline a systematic approach to tailoring a mobile app for populations for which it was not originally designed [4]. To illustrate this approach, we describe a mobile-based intervention system for self-management of drinking problems–*Step Away* [5-8]–that was originally developed for the general population. We outline our efforts to repurpose Step Away's content and presentation to fit the characteristics, needs, and preferences of US veterans to maximize engagement and effectiveness with this population.

Hazardous Drinking Among US Veterans: Using Mobile Apps to Improve Access to Care

Hazardous drinking—a pattern of alcohol use that increases an individual's risk for negative health consequences—is a significant public health problem and financial burden on health care systems and the society at large [9]. Hazardous drinking is commonly assessed using the Alcohol Use Disorder Identification Test for Consumption (AUDIT-C) [10], which is also an effective screening questionnaire for identifying those with a past-year diagnosis of an alcohol use disorder (AUD) [11]. In the US Veterans Health Administration (VHA), 15% to 30% of veterans screen positive for hazardous drinking on the AUDIT-C during a primary care visit; however, most of these patients do not obtain treatment for their drinking despite wide availability of these services in VHA [12].

Mobile apps offer an innovative and low cost means of expanding access to care for veterans who engage in hazardous drinking. Such apps have the benefit of overcoming key barriers to care access. For example, an app would make appointments unnecessary, thus reducing the burden on both the VHA (eg, staffing) and patients (eg, travel costs) [13,14]. Providing veterans with an option for care that is private, self-directed, and available as needed can also address the stigma that many patients have in regard to alcohol use treatment [15]. There is a need for an evidence-based mobile app that is customized and targeted toward veterans to help them reduce or abstain from alcohol use.

Step Away: Mobile App for Hazardous Drinking

Step Away is a mobile-based intervention program for individuals who want to reduce or abstain from drinking but are unable or unwilling to receive in-person care [5,16]. Development of Step Away was guided by the empirically supported alcohol interventions of motivational enhancement and cognitive-behavioral therapies, particularly relapse prevention and community reinforcement approaches [17,18]. For example, the app provides a comprehensive assessment of drinking patterns, personalized feedback to enhance awareness of drinking-related problems, tracking progress toward drinking goals, and in-the-moment tools to help manage cravings and triggers. Step Away is applicable to individuals with a range of alcohol use severity as it allows a choice of either moderation or abstinence as a drinking goal.

Published research on Step Away has focused exclusively on the prototype version. In a pilot randomized controlled trial of 54 adults with an AUD diagnosis, the use of the prototype version was associated with significant reductions in heavy drinking days and drinks per drinking day over 6 weeks and more percentage days abstinent relative to use of a Web-based program (Drinker's Check-up) plus bibliotherapy [7]. On the basis of the usability ratings and system usage data, the prototype was subsequently modified, named "Step Away," and is now available for download on iPhones and other iOS (iPhone Operating System) platform mobile devices [19]. Step Away contains 10 modules: (1) drinking patterns, (2) goals, (3) rewards, (4) cravings, (5) strategies, (6) support persons, (7) reminders, (8) high risk, (9) moods, and (10) new activities. Step Away also includes a *Get Help* feature that provides strategies and resources for individuals who need immediate assistance to manage cravings or other problems, and Daily and Weekly Interviews to help individuals monitor their alcohol use and track progress toward their drinking goal [16]. The acceptability and usability of the current version of Step Away has not been reported, though recent unpublished work from New Zealand and the United States indicates that acceptability of this version is high (P Dulin, personal communication).

Tailoring Step Away for US Veterans

Step Away was not designed for US veterans *per se*. Differences between veterans and civilians highlight the value of repurposing Step Away to address the characteristics, needs, and preferences of veterans. For example, modifications to the appearance of mobile health (mHealth) tools to include references to military culture can increase the likelihood that a veteran will identify with the program's content and engage with the tool [20]. Differences in the demographics and mental health needs of veterans (vs civilians) may also be relevant. To date, the development and validation of Step Away has been limited to adults aged 18 to 45 years, whereas the majority of veterans who screen positive for hazardous drinking during a primary care visit are in mid-to-late life [21,22]. Consequently, less text or larger font may be needed to facilitate usability among the older veteran population [3]. Relative to young adults, older adults who engage in hazardous drinking also struggle with more comorbid medical conditions [23] and may therefore benefit from feedback on the health consequences of drinking. Finally, the rate of trauma exposure and the comorbidity between hazardous drinking and posttraumatic stress disorder is higher among veterans than in the general population [24]. Therefore, references to the association between trauma and alcohol use may enhance the relevance of the app for some veterans.

This Study

The objective of this study was to repurpose the Step Away mobile intervention system to create a version of the app that would maximize engagement and effectiveness with US veterans. To achieve this objective, we applied the Method for Program Adaptation through Community Engagement (M-PACE) model [4]. M-PACE is a systematic approach to soliciting comprehensive feedback from stakeholders on potential changes to an intervention to address differences in a target population and deciding on which changes to implement. Per the M-PACE model, incorporating consumer feedback into the adaptation of an intervention, along with feedback from relevant experts and program facilitators, results in improved acceptability and utility of the intervention while maintaining program fidelity. The goal is to enhance engagement of the intervention in a new population without diluting the intervention's effectiveness.

The long-term goal of this research program is to integrate the use of a veteran version of Step Away with telephone support from peer providers. Such providers would be veterans who are currently in recovery from addiction and have been trained to serve other veterans who are actively struggling with these issues. By encouraging utilization of the app and monitoring Veterans' progress toward their recovery goals, a peer provider can provide supportive accountability to patients who use Step Away, thus increasing the reach and sustainability of this app with the veteran population [25]. Therefore, the samples for this study were veteran patients who screened positive for hazardous drinking during a VHA primary care visit and peer providers who serve veterans with addiction.

Methods

Participants

Patients

VHA administrative data were used to identify eligible patients who received a positive screen on the AUDIT-C (scores of >4 for women and >5 for men) during a visit to a VHA primary care clinic between July and October 2017. A total of 150 eligible patients were sent a study invitation letter in the mail; patients who did not respond to the letter were called approximately 1 week later. Overall, 81 patients (81/150, 54.0%) opted out, 33 (33/150, 22.0%) did not respond to a voicemail message, and 13 (13/150, 8.7%) were unable to be reached because of their message inbox being full or the phone number listed in patients' medical records being incorrect or not in service. Furthermore, 23 patients (23/150, 15.3%) were able to be reached and expressed interest in the study. Among this pool of interested patients, quota sampling based on gender, age, and race and ethnicity was used to select a representative sample of VHA primary care patients who screened positive for hazardous drinking. A total of 13 patients were initially enrolled, and 1 withdrew, yielding a sample of 12 (see sample characteristics in Table 1). Patient participants were mostly male (11/12, 92%), white (non-Hispanic; 7/12, 58%), college educated (9/12, 75%), and 58.9 years old, on average (SD 19.4). At the time of enrollment, 4 participants reported that they were currently receiving mental health treatment for mental health issues; none of them reported receiving treatment for addiction. Per AUDIT-C scores from the administrative records, patients reported a moderate level of drinking problems (mean 6.3, SD 2.4; out of a possible score of 12).

Table 1. Sample characteristics.

Variable	Patients (N=12)	Peers (N=11)
Gender, n (%)		
Male	11 (92)	9 (82)
Female	1 (8)	2 (18)
Race and ethnicity, n (%)		
African American/black	4 (33)	1 (9)
White (non-Hispanic)	7 (58)	7 (64)
Hispanic	0 (0)	3 (27)
Other	3 (25)	0 (0)
Age, mean (SD)	58.9 (19.4)	48.3 (9.4)
Education (highest level), n (%)		
High school diploma/General Equivalency Degree	1 (8)	5 (46)
Some college	2 (17)	3 (27)
4-year college/university	5 (42)	2 (18)
Graduate degree	4 (33)	1 (9)
Smartphone comfort level (1-5 scale), mean (SD)	4.5 (0.8)	4.4 (0.9)
1=very uncomfortable, n (%)	0 (0)	0 (0)
5=very comfortable, n (%)	8 (67)	7 (64)
Device used during the study, n (%)		
Personal device	8 (67)	5 (46)
Study-provided iPod Touch	4 (33)	6 (55)

Peer Providers

A convenience sample of peer providers was recruited across 5 VHA facilities. Peer providers were eligible if they were veterans, worked with other veterans with alcohol use problems, and had been employed by VHA for at least 6 months. Approximately 71 peer providers were informed about the study through passive recruitment strategies, that is, mass emails to provider listservs and phone and in-person meetings with teams of peer support specialists and addiction therapists) rather than individual contacts. Overall, 13 peer providers contacted the study staff to express an interest and were enrolled, 2 of whom ultimately withdrew, yielding a sample of 11 (see sample characteristics in Table 1). Provider participants were mostly male (9/11, 82%), were white (non-Hispanic; 7/11, 64%), had at least some college education (6/11, 55%), and were 48.3 years old on average (SD 9.4 years). In addition, 3 participants were employed by the VHA as addiction therapists, and 8 were employed as peer support specialists. Among them, 5 participants reported working in their position for less than 3 years, and 6 participants reported working in their position for 3 years or more.

Procedures

Method for Program Adaptation Through Community Engagement Steps

The M-PACE model guided adaptation of Step Away for the veteran population [4]. The first step involved creation of a steering committee with members who represented key stakeholders in adaptation of the intervention—that is, researchers, practitioners, program developers, and patients. Specifically, the committee for this study comprised 12 individuals: 6 research investigators (experts on addiction among veterans, evidence-based treatments for AUD, and mHealth), the app developer (PLD), 4 VHA administrators and clinicians in primary care–mental health integration and peer support services at both the local and national levels, and a representative of a Veteran and Family Engagement Council. The second step of the M-PACE model involved implementing the program as originally designed with patients and providers who will ultimately use the adapted intervention. This study's target users were veterans who screened positive for hazardous drinking during primary care visits and peer providers who would provide telephone-based care to veterans using the app. The third step involved systematically soliciting feedback and suggestions for change from patients and providers, using both qualitative and quantitative research methods. Surveys with open-ended and scaled items were used to assess likes, dislikes, and recommendations for change during the course of the intervention and soon after its completion. The fourth step involved summarizing the quantitative and qualitative data and reviewing results with the steering committee. During the fifth step—adjudicating participants' feedback—each suggestion for change was evaluated using 3 criteria: importance (degree to which the change will improve effectiveness of the intervention), feasibility (degree to which additional burden would be placed on patients, providers, or program developers), and congruence

(degree to which the suggested changes work with or against the core change features of the intervention). After evaluating each suggestion, the steering committee decided whether to implement the suggested change.

Data Collection

After enrollment, patients and providers completed a baseline interview to assess demographics and rate their comfort using a smartphone on a 5-point scale (1=*very uncomfortable*, 5=*very comfortable*). Both patients and peer providers reported a high level of comfort in using these devices (see Table 1). Patients were also queried on their current receipt of mental health or addiction treatment, and peer providers were queried on their length of employment in the VHA. A research assistant (RA) then assisted participants with downloading the unmodified Step Away app to their iPhone (the app was only available on the iOS platform at the time) or a study-provided iPod Touch. The majority of patients used their personal device (8/12, 67%), whereas the majority of peer providers borrowed an iPod Touch (6/11, 55%). Participants were asked to use the app daily for 10 days, reviewing an average of 1 of the 10 modules per day, and to complete daily surveys (sent via email using REDCap) to provide feedback on each module's usability. Participants were provided with a written guide to direct their review of the individual modules. This approach to data collection increases participants' accurate recall of feelings and reactions to program material and obtains suggestions that are specific to elements of a program (eg, a given module) rather than generalized across program material [4]. The daily surveys consisted of 5 items involving quantitative ratings of the usefulness (1=*not at all useful*, 5=*very useful*) and difficulty of using a certain Step Away module (1=*not at all difficult*, 5=*very difficult*), and 3 open-ended questions asking what the participant liked, what they disliked, and what they would change about the module. With exception of the *Reminders* module, usability ratings for modules were completed by a majority of participants (see Table 2). Semistructured interviews were conducted by phone 2 weeks after enrollment to obtain global feedback from participants on the perceived utility of Step Away, facilitators and barriers to engagement with the app, and suggested modifications to enhance engagement and effectiveness with veteran primary care patients. App usage data were extracted from the app during the 2-week period to validate participants' use of the app during their participation. Owing to limited Wi-Fi availability, 5 participants who borrowed an iPod Touch did not have their app usage data uploaded to the Cloud-based storage system where app usage was being tracked. Therefore, data on app usage were available for 18 participants (9 patients and 9 peers). These participants launched an average of 5.3 (SD=4.2) of the 10 app modules and reviewed the app for an average of 150.2 min (SD=43.3) over the 2-week period. Patient participants were paid US $25 for the follow-up interview, US $5 per Web-based survey, and an additional US $25 if they completed all 10 Web-based surveys. All participant procedures were approved by the local institutional review board.

Table 2. Usability ratings of the Step Away modules from veteran patients and peer providers.

Module	Total sample		Patients		Peers		Sample responses to free-text questions	
	Usefulness, mean (SD)	Difficulty, mean (SD)	Usefulness, mean (SD)	Difficulty, mean (SD)	Usefulness, mean (SD)	Difficulty, mean (SD)	Liked	Disliked/would change
Drinking patterns[a]	3.76 (0.9)	1.88 (1.1)	3.63 (0.9)	1.86 (1.2)	3.90 (0.7)	1.90 (0.9)	"Allows user to see how much they drink and the financial cost of drinking." [Peer-004]	"Shorten, simplify. I find alcoholics are impatient while actively drinking." [Peer-002]
Goals[b]	4.06 (0.9)	1.88 (0.8)	3.67 (1.1)	1.86 (0.9)	4.44 (0.7)	1.89 (0.8)	"Health and money as benefits of not drinking." [Patient-001]	"Explanations were very long." [Patient-005]
Rewards[c]	3.76 (1.3)	1.62 (1.2)	3.38 (1.1)	1.06 (0.2)	4.11 (1.4)	2.11 (1.5)	"Allows for custom input for rewards." [Peer-012]	"Add reward choices that will appeal to lower income vets." [Patient-008]
Cravings[d]	4.21 (1.1)	1.64 (1.2)	3.83 (1.3)	1.50 (0.8)	4.50 (0.8)	1.75 (1.4)	"You can isolate and identify specific triggers." [Peer-013]	"A lot of reading and less interacting in this step." [Peer-012]
Strategies[e]	4.00 (1.2)	1.93 (1.3)	4.00 (1.0)	1.57 (1.1)	4.00 (1.4)	2.29 (1.5)	"Good variety of strategies." [Patient-003]	"Seemed aimed at heavy drinkers." [Patient-008]
Support persons[f]	3.81 (1.0)	1.41 (0.7)	3.63 (1.1)	1.56 (0.9)	4.00 (1.1)	1.25 (0.5)	"Actually putting in the number and email of the person." [Peer-001]	"Prompt user to check in with someone every day." [Peer-006]
Reminders[g]	3.60 (1.1)	1.60 (1.1)	3.29 (1.1)	1.71 (1.3)	4.33 (0.6)	1.33 (0.6)	"Different ways to personalize reasons for change (eg, photos of loved ones)." [Patient-003]	"More text space to provide reasons for change." [Patient-010]
High risk[h]	3.75 (0.9)	1.33 (0.8)	3.67 (0.8)	1.00 (0.0)	3.83 (0.9)	1.67 (1.0)	"Allows me to see what time I am more at risk to drink." [Peer-009]	"Provide link to supports as way to deal with high-risk times." [Patient-013]
Moods[i]	3.94 (0.7)	1.34 (0.6)	3.86 (0.7)	1.14 (0.4)	4.00 (0.7)	1.50 (0.7)	"Keeps weekly track of fluctuations in mood." [Patient-011]	"More information regarding graphs." [Patient-010]
New activities[j]	4.23 (0.8)	1.54 (0.9)	4.40 (0.9)	1.40 (0.9)	4.13 (0.8)	1.63 (0.9)	"Easy to customize. Allows you to plan ahead for a high-risk time." [Peer-013]	"Expand to track activities taken up instead of drinking." [Patient-010]

[a] $N_{Total\ sample}=21$, $N_{Patients}=11$, $N_{Peers}=10$.

[b] $N_{Total\ sample}=18$, $N_{Patients}=9$, $N_{Peers}=9$.

[c] $N_{Total\ sample}=17$, $N_{Patients}=8$, $N_{Peers}=9$.

[d] $N_{Total\ sample}=14$, $N_{Patients}=6$, $N_{Peers}=8$.

[e]$N_{Total\ sample}$=15, $N_{Patients}$=8, N_{Peers}=7.

[f]$N_{Total\ sample}$=16, $N_{Patients}$=8, N_{Peers}=8.

[g]$N_{Total\ sample}$=10, $N_{Patients}$=7, N_{Peers}=3.

[h]$N_{Total\ sample}$=12, $N_{Patients}$=6, N_{Peers}=6.

[i]$N_{Total\ sample}$=16, $N_{Patients}$=7, N_{Peers}=9.

[j]$N_{Total\ sample}$=13, $N_{Patients}$=5, N_{Peers}=8.

Data Analysis

Descriptive statistics were calculated for quantitative items from the daily surveys and the follow-up interview. Textual data from the open-ended questions of the daily surveys and the follow-up interviews were analyzed using techniques for rapid qualitative analysis recommended by Hamilton [26]. Specifically, 2 RAs reviewed responses to the daily surveys, listened to the audio recordings from the semistructured interviews, and took detailed notes using a template to summarize responses to the survey and interview questions and document preliminary themes related to facilitators and barriers to engagement and suggested modifications. The RAs then copied these notes into an Excel matrix to compare the preliminary themes for each question (columns) across participants (rows). This matrix was organized such that the summary of participants' response to a question and the preliminary theme were entered into each cell. Furthermore, 2 study investigators independently reviewed the composite matrix of these summarized responses to identify global themes in the data corresponding to domains of facilitators and barriers to engagement and suggested modifications to enhance the engagement and effectiveness of Step Away among veterans who engaged in hazardous drinking. The investigators then met to review their independently derived lists of themes and engaged in a consensus process to rectify disagreements and finalize the themes in each of these domains.

Results

Usability Ratings of the Step Away Modules

Table 2 provides the daily survey ratings of each Step Away module in terms of usefulness and difficulty. In general, the modules were rated as moderate-to-high in usefulness and low in difficulty. Table 2 also provides sample responses to the free-text questions regarding what participants liked, what they disliked, and what they would change about each module. The suggestions for change typically followed directly from what participants reported disliking about a module; therefore, responses to those questions were combined for summarizing and reporting. Across modules, participants reported liking the ability to customize and personalize information as well as the ability of different modules to track changes in the information that users provided. Aspects of the modules that participants tended to dislike or would change pertained to the heavy amount of reading, a desire for the module to interact more with the user, and expanding the extent to which modules could track the information entered by the user. Notably, across modules, responses to the free-text questions addressed themes of money and finances (eg, liking how the app highlighted the financial costs of drinking and suggestions to add options for recreational activities for low-income veterans).

Perceived Utility of Step Away

When asked, "Will the app help veterans reduce the amount they drink or how often they drink?," 22 of the 23 participants answered affirmatively. When asked, "How likely are you to continue using Step Away?," 15 of the 23 participants indicated plans to continue using the app or said they would continue to use it if it were available on their personal phone. Patient participants noted the benefits for increasing their access to care and ability to monitor their drinking over time:

> *It would help. Not a lot of people are in an area where there's availability for help. It's helped me already.* [Patient-009]

> *It's good because you can put in the exact number of drinks and track your progress. I think I personally drank less while using it.* [Patient-011]

Peer participants also noted the benefits of the app for reducing a patients' drinking, although they added that this would depend on another person keeping the patient accountable for using it:

> *If they have a solid support system that reminds them of using the app it would be helpful.* [Peer-002]

> *Yes, it will hold them accountable and help them. As long as they're reminded to use it, it would help.* [Peer-010]

Facilitators and Barriers to Engagement With Step Away

Regarding facilitators to their engagement with Step Away, participants noted the (1) reminders on high-risk times and situations; (2) encouraging rewards for reaching one's drinking goals; (3) personalized feedback, particularly around the financial costs and health consequences of alcohol use; (4) ability to customize one's drinking goal and other features of the app; and (5) measurement capabilities, such as the app's ability to track one's drinking and progress toward their drinking goal (see Table 3). In terms of barriers to engagement with the app, participants noted (1) key features of Step Away that felt hidden or insufficiently highlighted (eg, the *Get Help* feature and options for customization), (2) concerns that some aspects of the interface could limit user engagement (eg, not user-friendly for elderly patients because of the small font size, not enough visuals and graphics and the app is *text heavy*), and (3) privacy concerns that were insufficiently acknowledged.

Table 3. Facilitators and barriers to engagement with Step Away.

Themes	Sample quotations
Facilitator	
Reminders on high-risk times and situations	"[I like that it] provides education and awareness of risky situations and times of drinking." [Patient-005]; "I like that it reminded me when I was coming up on a time I was going to drink." [Peer-006]
Encouraging rewards for reaching drinking goals	"Rewards for milestones reached were helpful. Sometimes veterans don't know what to do for themselves as a reward instead of drinking. Typically, they would go out and have a drink." [Peer-001]
Personalized feedback regarding financial costs and health consequences of alcohol use	"Information about amount of money spent on alcohol was useful" [Peer-004]; "Good information in terms of caloric impact of my drinking and how alcohol may be affecting my problems with weight control." [Patient-013]
Ability to customize one's drinking goal and various app features	"It allowed me to set up a schedule to be notified; it engaged me and helped me be involved…it made it more personalized." [Patient-008]; "I like that it gives a choice of moderation. That makes it helpful for people who might not want to fully quit but still want help." [Peer-011]
Measurement capabilities (eg, ability of app to track drinking and progress toward goals)	"If you want to change something, measure it. [The app] helps vets pay attention to what they're doing and keep track of progress so they have an idea of what they need to change." [Patient-010)
Barrier	
Key features appeared hidden or were insufficiently highlighted: The "Get Help" feature; more options for customization	"I tend not to click on help icons. One reason is because I typically don't find the answer I'm looking for and another is because I did not feel the need to use the feature." [Patient-010]
Concerns that some aspects of the interface could limit user engagement: Not user-friendly for elderly patients (eg, small font size); "Text heavy"—not enough visuals and graphics.	"It was hard to read. It would be nice if they could be magnified for people with older eyes." [Patient-013]; "I don't think it would be helpful for vets who are actively drinking. Too much reading." [Peer-004]
Privacy concerns insufficiently acknowledged	"Trust issues with government and VA. Fear of breach of confidentiality. Those who are new to sobriety might be overwhelmed." [Peer-002]; "Provide a rationale as to why we are putting contacts in, for example, including that [providing personal information] typically helps people for reasons x, y, and z; otherwise it could be triggering." [Patient-005]

Suggested Modifications to Enhance Engagement and Effectiveness of Step Away Among Veterans

The qualitative interviews yielded themes to enhance engagement and effectiveness of Step Away with the veteran population (see Multimedia Appendix 1, Column 1 for a bulleted outline of the suggested modifications). One theme focused on modifying the appearance and design of the app to include more veteran-centric content. Another theme related to the need to revise the text to increase the usability and relevance of the app for older and/or lower-income veterans. Other veteran-centric modifications included adding links to resources and services for veterans in crisis or seeking treatment; adding information on drinking problems among veterans; adding more preprogrammed response options relevant to veteran preferences and needs; and addressing potential privacy concerns among veterans such as whether the app data would be entered into patients' Veterans Affairs (VA) medical records. Although many suggestions focused on how to repurpose the app for veterans *per se*, other modification themes focused on ways to increase the usability of the app more generally. For example, participants suggested more orientation to the app when users set up the program; more use of graphics to track progress toward one's drinking goal over time; more interactive features, and increasing access and engagement with the app content more generally.

Adjudicating the Suggested Modifications to Step Away

Following the analyses, 2 meetings with the steering committee were convened. The first meeting (daylong) was held in person, with remote members attending by phone. Committee members downloaded Step Away to their iPhones or a study-provided iPod Touch to review the app before the meeting. During the meeting, a demonstration of Step Away's content and functionality was given by the lead author. Participant feedback and other summary findings were then reviewed, and the suggested modifications to Step Away were discussed and operationalized. Committee members were asked to evaluate the suggested modifications according to 3 criteria: *importance*—the degree to which the change could enhance Step Away's effectiveness and engagement with the veteran primary care population; *feasibility*—how burdensome the change would be to veterans, peer providers, and/or app developers; and *congruence*—did the change work with or against the core components of Step Away.

Following this meeting, a list of proposed changes to Step Away to create a veteran version of the app was drafted by the lead (DMB) and senior authors (PLD) and emailed to committee members. Members rated each of the proposed changes in terms

of whether it was (1) *essential*, (2) *nice to have, but not essential*, or (3) *not essential* to incorporate into the veteran version of the app. Proposed changes that received a rating of *essential* by a majority of the committee members and were retained in the final list are shown in Multimedia Appendix 1. Changes that were not viewed as *essential* by a majority of committee members included many of the interactive features that were suggested by participants—for example, voiceover audio, educational games, and link to an online forum. These changes were viewed by the committee as too costly and resource intensive to incorporate into the app's format and were therefore not included into the final list of changes.

Creating the Veteran Version of Step Away (Stand Down: Think Before You Drink)

The lead and senior authors had a series of meetings to review the progress on the planned changes, discuss and edit wireframes of the changes, and conduct beta testing of the initial versions of the revised app. To solicit feedback on specific content that was being considered for inclusion in the app, a meeting was convened with members of the Veteran and Family Engagement Council at the local facility. This council assists with the development and implementation of projects and initiatives at the facility to ensure that the perspectives of veterans and their family members are incorporated. After all the changes to Step Away were completed and beta tested by the lead author and an RA, a second meeting of the steering committee was convened by phone. Before this meeting, an initial version of the repurposed app—*Stand Down: Think Before You Drink* (or *Stand Down*)—was made available to members for review. In the military, *Stand Down* refers to a period of recovery after a state of high alert; and among veterans, the term also refers to multiday events in providing them with resources, services, and referrals to additional services. During the meeting, major changes to the app were reviewed and feedback was solicited from the committee members regarding additional changes to be made to the app. On the basis of this feedback, minor changes were made to Stand Down, and the app was launched for research use in the iTunes store [27].

Discussion

Principal Findings

The goal of this study was to use the M-PACE model to repurpose the Step Away mobile intervention system for US veterans. In particular, we sought to create a version of the app that would enhance engagement and effectiveness with veterans in primary care who screened positive for hazardous drinking, many of whom are in mid-to-late life [21,22]. A key advantage of using the M-PACE model was the ability to obtain feedback on both the individual modules of Step Away and global feedback on the app. Feedback on both facilitators and barriers to engagement with Step Away was critical to this process, which helped the Steering Committee adjudicate which modifications to this app were most essential and how best to implement them.

One strength of the app from the perspective of participants was the personalized feedback provided via the *DrinkingPatterns* module. Personalized, norm-based feedback is viewed as an essential component of brief interventions for drinking problems [12] and is a feature not currently incorporated into other mobile apps for drinking problems for veterans [28]. Feedback on the financial costs and health consequences of drinking were highlighted by participants and the steering committee as common concerns of the target population that should be emphasized in the veteran version of the app. These issues are now highlighted to a greater extent in Stand Down than in Step Away. Another perceived strength of the app was the ability of users to customize the content to fit their needs and preferences, such as their drinking goal, rewards, nondrinking activities, and reminders. Such a personalized approach to care is consistent with a broader shift in addiction and mental health treatment toward more recovery-oriented and patient-centered approaches to care designed around patients' unique goals and priorities for care [29,30]. To this end, Stand Down includes more preprogrammed recreational activities for veterans including a list of organizations that support veteran activities and events. The measurement-based care capabilities of Step Away in terms of tracking users' alcohol use over time and progress toward their drinking goal was also viewed as a strength by participants. Consistent with a broader effort in VHA and the addiction treatment literature of measurement-based care [31], this feature of Step Away was expanded in Stand Down by showing users' weekly progress toward their drinking goal on the home screen.

One potential barrier to engagement with Step Away was both the size and the amount of text throughout the app's modules. Small font size may be particularly salient for the target population, given that many veterans treated in primary care in VHA are mid-to-late life and may have visual impairments [32]. Consistent with this, prior research has recommended using larger font on mHealth tools targeted toward older adults [3]. Relatedly, other research has suggested minimizing text in mHealth tools when possible to mitigate the potential for fatigue [33]. Accordingly, a key modification to create the Stand Down app involved a careful review of the app's text files to identify opportunities to shorten descriptions, break up long paragraphs, and enumerate key information. These changes, along with more proactive presentation of app content via the Message of the Day, were intended to enhance the overall usability of the app for the target population.

In addition to modifying Step Away to address the characteristics of the veteran population and increase its usability, other changes involved alterations to the *look and feel* of the app to incorporate more veteran-centric content. For example, we replaced both the app icon and the splash page that users would see when they launch the app with an image of an American flag (see Multimedia Appendix 1), embedded videos of veterans describing their recovery from drinking problems, and rebranded the app name. These changes are unlikely to have an adverse impact on the effectiveness of the Step Away program and may have the benefit of increasing the extent to which veterans identify with the app. This approach to tailoring an mHealth tool for the veteran population was employed successfully in a recent study that modified a Web-based intervention for anxiety and depression for rural veterans [20]. This study extends this principle of adapting mHealth tools for

veterans to mobile apps and to the treatment of hazardous drinking in this population.

Strengths, Limitations, and Future Directions

The design of this study included a number of strengths, many of which are inherent to the M-PACE model. Specifically, we used a mixed-methods approach to data collection to obtain comprehensive feedback from key consumers (veteran patients and peer providers) on the unmodified app. Drawing on the principles of community-based participatory research [34], a diverse set of stakeholders with expertise in addiction, evidence-based treatments for AUD, primary care–mental health integration, and mHealth was used to adjudicate the suggested changes to Step Away. Furthermore, the iterative and systematic approach to adjudication helped to identify which changes to the app can maximize its effectiveness with veterans while also being feasible to implement and congruent with the core components of Step Sway [4]. These benefits of the M-PACE model notwithstanding, there may be opportunities to extend the model by incorporating elements from the field of instructional design [35]. For example, cycles of formative evaluation are common in instructional design models as they allow for revisions of mHealth tools before implementation. Such an approach could be incorporated into the M-PACE model after the adjudication process by soliciting feedback on the new tool with the same consumers who initially reviewed the unmodified tool. This would permit assessment of whether the suggested modifications were incorporated sufficiently or whether further revisions to the mHealth tool are needed prior to its implementation with the target population.

Among the study limitations, the patient feedback was based on a sample from a single VA Health Care System, which may not generalize to the perceptions of veterans in other clinics and geographical regions. This limitation was somewhat countered by soliciting feedback from peer providers across multiple geographical regions in the United States. Furthermore, a minority of both the patient and peer providers who were contacted about the study agreed to participate; for patients, this may reflect the fact that many veterans who screen positive for alcohol use problems are not interested in receiving help. Consequently, feedback from these highly self-selected groups may not be representative of the larger samples of veterans and providers who could conceivably use the app. A larger sample size of both patients and peer providers may also have been advantageous. However, a substantial portion of the participant feedback involved qualitative data, and sample sizes of 10 or more are often sufficient for reaching thematic saturation and conducting group comparisons in qualitative research [36,37]. The modest launch rate (5.3 out of the 10 app modules) and the lower number of daily surveys completed for some of the Step Away modules (eg, *Reminders*) also suggests that participants may not have reviewed the full menu of tools available in Step Away. Potentially, this modest level of app usage may be improved by the modifications that were made through the M-PACE process. Finally, this study did not provide data on the acceptability or utility of the Stand Down app. Pilot testing of this veteran-focused app is a critical next step in this program research. Should it prove effective in future research for improving the drinking outcomes of veterans engaging in hazardous drinking, subsequent implementation research should focus on how best to enhance the reach of the app with the target population. Our involvement of key stakeholders at the national level of VHA in this early stage of this program of research should ultimately facilitate such efforts.

Conclusions

We used the M-PACE model to repurpose the Step Away mobile intervention system to target the characteristics, needs, and preferences of veterans who are identified in primary care settings as engaging in hazardous drinking. We envision the approach outlined here as a generalizable method that other researchers can follow to systematically tailor an mHealth tool to maximize engagement and effectiveness of an app with a patient population for which the app was not originally designed. Ultimately, the use of Stand Down may serve as an innovative, low-cost means of overcoming barriers to access and engagement in alcohol use treatment among veteran primary care patients. Our preliminary study of this app would benefit from a follow-up study in a larger population and involving patients across multiple VA medical centers.

Acknowledgments

This work was supported by a Department of Veterans Affairs Health Services Research and Development grant awarded to DMB (PPO 16-305). CT and KH were supported by Senior Research Career Scientist Awards from the Department of Veterans Affairs Health Services Research and Development (RCS-00-001 and RCS-14-141, respectively). The views expressed are those of the authors and do not necessarily reflect those of the VHA.

Conflicts of Interest

PLD is the primary owner of Here & Now Systems, LLC—the company that developed the Step Away mobile app as well as the veteran version of this app (Stand Down: Think Before You Drink). There are no other conflicts to report.

Multimedia Appendix 1
Modifications to Step Away to create a veteran version of the app (“Stand Down: Think Before You Drink”).
[DOCX File , 6242 KB - mhealth_v8i2e16062_app1.docx]

References

1. Armstrong CM, Hoyt T, Kinn JT, Ciulla RP, Bush NE. Mobile behavioral health applications for the military community: evaluating the emerging evidence base. Best Pract Mental Health 2017;13(1):106-119 [FREE Full text]
2. Kuhn E, Kanuri N, Hoffman JE, Garvert DW, Ruzek JI, Taylor CB. A randomized controlled trial of a smartphone app for posttraumatic stress disorder symptoms. J Consult Clin Psychol 2017 Mar;85(3):267-273. [doi: 10.1037/ccp0000163] [Medline: 28221061]
3. Kuerbis A, Mulliken A, Muench F, A. Moore A, Gardner D. Older adults and mobile technology: factors that enhance and inhibit utilization in the context of behavioral health. Ment Health Addict Res 2017;2(2). [doi: 10.15761/MHAR.1000136]
4. Chen EK, Reid MC, Parker SJ, Pillemer K. Tailoring evidence-based interventions for new populations: a method for program adaptation through community engagement. Eval Health Prof 2013 Mar;36(1):73-92 [FREE Full text] [doi: 10.1177/0163278712442536] [Medline: 22523308]
5. Dulin PL, Gonzalez VM, King DK, Giroux D, Bacon S. Smartphone-based, self-administered intervention system for alcohol use disorders: theory and empirical evidence basis. Alcohol Treat Q 2013;31(3) [FREE Full text] [doi: 10.1080/07347324.2013.800425] [Medline: 24347811]
6. Dulin PL, Gonzalez VM, Campbell K. Results of a pilot test of a self-administered smartphone-based treatment system for alcohol use disorders: usability and early outcomes. Subst Abus 2014;35(2):168-175 [FREE Full text] [doi: 10.1080/08897077.2013.821437] [Medline: 24821354]
7. Gonzalez VM, Dulin PL. Comparison of a smartphone app for alcohol use disorders with an internet-based intervention plus bibliotherapy: a pilot study. J Consult Clin Psychol 2015 Apr;83(2):335-345 [FREE Full text] [doi: 10.1037/a0038620] [Medline: 25622202]
8. Giroux D, Bacon S, King DK, Dulin P, Gonzalez V. Examining perceptions of a smartphone-based intervention system for alcohol use disorders. Telemed J E Health 2014 Oct;20(10):923-929 [FREE Full text] [doi: 10.1089/tmj.2013.0222] [Medline: 25243480]
9. Whiteford HA, Degenhardt L, Rehm J, Baxter AJ, Ferrari AJ, Erskine HE, et al. Global burden of disease attributable to mental and substance use disorders: findings from the Global Burden of Disease Study 2010. Lancet 2013 Nov 9;382(9904):1575-1586. [doi: 10.1016/S0140-6736(13)61611-6] [Medline: 23993280]
10. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Arch Intern Med 1998 Sep 14;158(16):1789-1795. [doi: 10.1001/archinte.158.16.1789] [Medline: 9738608]
11. Bradley KA, DeBenedetti AF, Volk RJ, Williams EC, Frank D, Kivlahan DR. AUDIT-C as a brief screen for alcohol misuse in primary care. Alcohol Clin Exp Res 2007 Jul;31(7):1208-1217. [doi: 10.1111/j.1530-0277.2007.00403.x] [Medline: 17451397]
12. Bradley KA, Ludman EJ, Chavez LJ, Bobb JF, Ruedebusch SJ, Achtmeyer CE, et al. Patient-centered primary care for adults at high risk for AUDs: the Choosing Healthier Drinking Options In primary CarE (CHOICE) trial. Addict Sci Clin Pract 2017 May 17;12(1):15 [FREE Full text] [doi: 10.1186/s13722-017-0080-2] [Medline: 28514963]
13. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. J Med Internet Res 2013 Nov 15;15(11):e247 [FREE Full text] [doi: 10.2196/jmir.2791] [Medline: 24240579]
14. Prentice JL, Dobson KS. A review of the risks and benefits associated with mobile phone applications for psychological interventions. Can Psychol 2014;55(4):282-290. [doi: 10.1037/a0038113]
15. Rapp RC, Xu J, Carr CA, Lane DT, Wang J, Carlson R. Treatment barriers identified by substance abusers assessed at a centralized intake unit. J Subst Abuse Treat 2006 Apr;30(3):227-235 [FREE Full text] [doi: 10.1016/j.jsat.2006.01.002] [Medline: 16616167]
16. Blonigen DM, Harris-Olenak B, Haber JR, Kuhn E, Timko C, Humphreys K, et al. Customizing a clinical app to reduce hazardous drinking among veterans in primary care. Psychol Serv 2019 May;16(2):250-254. [doi: 10.1037/ser0000300] [Medline: 30407060]
17. Miller WR, Rollnick S. Motivational Interviewing. Third Edition. New York, NY: Guilford Press; 2013.
18. Blonigen DM, Finney JW, Wilbourne P, Moos RH. Psychosocial treatments for substance use disorders. In: Nathan PE, Gorman JM, editors. A Guide to Treatments that Work. Fourth Edition. New York: Oxford University Press; 2015:731-761.
19. Here and Now Systems LLC. Step Away: Mobile Intervention for Alcohol Addiction URL: http://itunes.apple.com [accessed 2019-12-17]
20. Abraham TH, Marchant-Miros K, McCarther MB, Craske MG, Curran GM, Kearney LK, et al. Adapting coordinated anxiety learning and management for veterans affairs community-based outpatient clinics: iterative approach. JMIR Ment Health 2018 Aug 22;5(3):e10277 [FREE Full text] [doi: 10.2196/10277] [Medline: 30135051]
21. Funderburk JS, Maisto SA, Wade MJ, Kenneson A, Campbell CE. Clinical course of alcohol use in veterans following an AUDIT-C Positive Screen. Mil Med 2014 Nov;179(11):1198-1206. [doi: 10.7205/MILMED-D-14-00071] [Medline: 25373041]

22. Takahashi T, Lapham G, Chavez LJ, Lee AK, Williams EC, Richards JE, et al. Comparison of DSM-IV and DSM-5 criteria for alcohol use disorders in VA primary care patients with frequent heavy drinking enrolled in a trial. Addict Sci Clin Pract 2017 Jul 18;12(1):17 [FREE Full text] [doi: 10.1186/s13722-017-0082-0] [Medline: 28716049]
23. Timko C, Kong C, Vittorio L, Cucciare MA. Screening and brief intervention for unhealthy substance use in patients with chronic medical conditions: a systematic review. J Clin Nurs 2016 Nov;25(21-22):3131-3143 [FREE Full text] [doi: 10.1111/jocn.13244] [Medline: 27140392]
24. Fuehrlein BS, Mota N, Arias AJ, Trevisan LA, Kachadourian LK, Krystal JH, et al. The burden of alcohol use disorders in US military veterans: results from the National Health and Resilience in Veterans Study. Addiction 2016 Oct;111(10):1786-1794. [doi: 10.1111/add.13423] [Medline: 27061707]
25. Ray JM, Kemp LL, Hubbard A, Cucciare MA. Developing a peer support protocol for improving veterans' engagement to computer-delivered cognitive behavioural therapy. Behav Cogn Psychother 2017 May;45(3):253-265. [doi: 10.1017/S1352465816000539] [Medline: 28325175]
26. Hamilton A. Health Services Research & Development - Veterans Affairs. 2013 Dec 11. Qualitative Methods in Rapid Turn-Around Health Services Research URL: https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=780 [accessed 2019-12-17]
27. Here & Now Systems LLC. mobile application software. Stand Down: Think Before You Drink URL: http://itunes.apple.com
28. US Department of Veterans Affairs (VA). App Store - Apple. VetChange URL: http://itunes.apple.com [accessed 2019-12-17]
29. Kuehn BM. Veterans health system cited by experts as a model for patient-centered care. J Am Med Assoc 2012 Feb 1;307(5):442-443. [doi: 10.1001/jama.2012.47] [Medline: 22298663]
30. Marchand K, Oviedo-Joekes E. Prioritizing the patient in patient-centered addictions treatment. Addiction 2017 Mar;112(3):466-467. [doi: 10.1111/add.13680] [Medline: 28168794]
31. Dollar KM, Kirchner JE, DePhilippis D, Ritchie MJ, McGee-Vincent P, Burden JL, et al. Steps for implementing measurement-based care: implementation planning guide development and use in quality improvement. Psychol Serv 2019 Jul 18. [doi: 10.1037/ser0000368] [Medline: 31318240]
32. Schubert MC, Gimmon Y, Millar J, Brewer KJ, Roberts D, Shelhamer M, et al. Veterans have greater variability in their perception of binocular alignment. PLoS One 2018;13(12):e0209622 [FREE Full text] [doi: 10.1371/journal.pone.0209622] [Medline: 30586453]
33. Batterham PJ, Calear AL. Preferences for internet-based mental health interventions in an adult online sample: findings from an online community survey. JMIR Ment Health 2017 Jun 30;4(2):e26 [FREE Full text] [doi: 10.2196/mental.7722] [Medline: 28666976]
34. Wallerstein N, Duran B. Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. Am J Public Health 2010 Apr 1;100(Suppl 1):S40-S46. [doi: 10.2105/AJPH.2009.184036] [Medline: 20147663]
35. Hilgart MM, Ritterband LM, Thorndike FP, Kinzie MB. Using instructional design process to improve design and development of internet interventions. J Med Internet Res 2012 Jun 28;14(3):e89 [FREE Full text] [doi: 10.2196/jmir.1890] [Medline: 22743534]
36. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. Field Methods 2006;18(1):59-82. [doi: 10.1177/1525822X05279903]
37. Hennink MM, Kaiser BN, Marconi VC. Code saturation versus meaning saturation: How many interviews are enough? Qual Health Res 2017 Mar;27(4):591-608. [doi: 10.1177/1049732316665344] [Medline: 27670770]

Abbreviations

AUD: alcohol use disorder
AUDIT-C: Alcohol Use Disorder Identification Test for Consumption
iOS: iPhone Operating System
M-PACE: Method for Program Adaptation through Community Engagement
mHealth: mobile health
RA: research assistant
VA: Veterans Affairs
VHA: Veterans Health Administration

Edited by C Dias; submitted 29.08.19; peer-reviewed by J McKay, A Gual, J Taylor, I Savolainen; comments to author 30.09.19; revised version received 11.11.19; accepted 14.11.19; published 13.02.20.

Please cite as:
Blonigen D, Harris-Olenak B, Kuhn E, Humphreys K, Timko C, Dulin P
From "Step Away" to "Stand Down": Tailoring a Smartphone App for Self-Management of Hazardous Drinking for Veterans
JMIR Mhealth Uhealth 2020;8(2):e16062
URL: http://mhealth.jmir.org/2020/2/e16062/
doi:10.2196/16062
PMID:32053118

Original Paper

Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries

Clarence Baxter[1,2*], MPH; Julie-Anne Carroll[1,2*], PhD; Brendan Keogh[3*], PhD; Corneel Vandelanotte[4*], PhD

[1]School of Public Health and Social Work, Faculty of Health, Queensland University of Technology, Kelvin Grove, Queensland, Australia

[2]Institute of Health and Biomedical Innovation, Queensland University of Technology, Kelvin Grove, Queensland, Australia

[3]Digital Media Research Centre, Creative Industries Faculty, Queensland University of Technology, Kelvin Grove, Queensland, Australia

[4]School of Health, Medical and Applied Sciences, Central Queensland University, Rockhampton, Queensland, Australia

[*]all authors contributed equally

Corresponding Author:
Clarence Baxter, MPH
School of Public Health and Social Work
Faculty of Health
Queensland University of Technology
Victoria Park Road
Kelvin Grove, Queensland, 4059
Australia
Phone: 61 488539311
Email: c.baxter@hdr.qut.edu.au

Abstract

Background: More than a million health and well-being apps are available from the Apple and Google app stores. Some apps use built-in mobile phone sensors to generate health data. Clinicians and patients can find information regarding safe and effective mobile health (mHealth) apps in third party–curated mHealth app libraries.

Objective: These independent Web-based repositories guide app selection from *trusted* lists, but do they offer apps using ubiquitous, low-cost smartphone sensors to improve health? This study aimed to identify the types of built-in mobile phone sensors used in apps listed on curated health app libraries, the range of health conditions these apps address, and the cross-platform availability of the apps.

Methods: This systematic survey reviewed three such repositories (National Health Service Apps Library, AppScript, and MyHealthApps), assessing the availability of apps using built-in mobile phone sensors for the diagnosis or treatment of health conditions.

Results: A total of 18 such apps were identified and included in this survey, representing 1.1% (8/699) to 3% (2/76) of all apps offered by the respective libraries examined. About one-third (7/18, 39%) of the identified apps offered cross-platform Apple and Android versions, with a further 50% (9/18) only dedicated to Apple and 11% (2/18) to Android. About one-fourth (4/18, 22%) of the identified apps offered dedicated diagnostic functions, with a majority featuring therapeutic (9/18, 50%) or combined functionality (5/18, 28%). Cameras, touch screens, and microphones were the most frequently used built-in sensors. Health concerns addressed by these apps included respiratory, dermatological, neurological, and anxiety conditions.

Conclusions: Diligent mHealth app library curation, medical device regulation constraints, and cross-platform differences in mobile phone sensor architectures may all contribute to the observed limited availability of mHealth apps using built-in phone sensors in curated mHealth app libraries. However, more efforts are needed to increase the number of such apps on curated lists, as they offer easily accessible low-cost options to assist people in managing clinical conditions.

(JMIR Mhealth Uhealth 2020;8(2):e16741) doi:10.2196/16741

KEYWORDS

telehealth; mHealth; smartphone; mobile apps; instrumentation; health care quality; health care access; and health care evaluation; medical informatics; consumer health informatics; physician-patient relations; prescriptions; patient participation; patient-generated health data; diagnostic self evaluation; self-care; self-management; medical device legislation

Introduction

Background

With origins in the early 1990s and the inception of devices such as the IBM *Simon* Personal Communicator, early smartphone devices offered *untethered* mobile telephony, augmented by a humble suite of modular apps to extend basic phone functionality, hence the *smart* moniker in *smartphone* [1,2]. Nearly 3 billion people worldwide now use smartphones [3]. The release of the Apple iPhone in 2007 and subsequent competing Android smartphone offerings from Google and other vendors saw the emergence of platform-specific app stores, offering downloadable apps for a myriad of purposes [4]. Of the estimated 4.5 million apps available in the Google and Apple app stores, a million collectively pertain to health, fitness, nutrition, and well-being in general [5,6]. A subset of 300,000 of these apps may be regarded as *bona fide* mobile health (mHealth) apps, some of which may be potentially prescribed to patients for the diagnosis or treatment of health conditions [7]. Acknowledged by the World Health Organization in 2011, mHealth is defined as medical and public health practices supported by mobile devices, such as mobile phones, patient-monitoring devices, personal digital assistants, and other devices such as wearables [8]. More than 500 million people worldwide are believed to have downloaded one or more mHealth apps to their mobile phone [9].

Digital Disruption, Prescription, and Self-Prescription of Apps

Innovation is a hallmark of developments in medical technology, with a rich pedigree that long precedes contemporary *digital disruption* such as that attributable to mobile telephones and related technologies [10]. In 1995, Christensen and Bower [11,12] coined the term *disruptive technology* (later termed *disruptive innovation*) to describe the creation of new markets in response to novel emergent technologies based on values that are different from that of existing markets. Ubiquity, accessibility, and familiarity with mobile phone technology, combined with increasing general interest in health and the rising cost of clinician-led health care, may all contribute to the emergence of one such new *disrupted* market, namely, in the context of mHealth [10]. Health consumers may now independently seek out mHealth apps to assist with the diagnosis or management of health conditions [13]. Mobile phone camera apps for wound care and microphone apps for sleep apnea management are examples of mHealth apps using built-in sensors where diagnostic or treatment procedures once restricted to the realms of formal medical consultation are now accessible to laypersons for download and *self-prescription*, constituting potential disruption, which circumvents traditional clinician-initiated care and supervision [14,15].

Self-management of health conditions without adequate medical guidance (colloquially termed the *Dr Google* effect) is viewed by some as a *disruption* to traditional doctor-patient relationships, with potential risks of delayed (or incorrect) diagnosis or inadequate treatment because of the selection of malfunctioning and ineffective or inappropriate mHealth apps [16,17]. On the contrary, others cite the emergence of the *Quantified Self* movement in the 1970s and ensuing developments in areas such as Precision Medicine as offering patients the opportunity to leverage mobile phone technology to improve health, heralding a *democratization of information control* in health care [18-21]. In contrast to self-initiated engagement with mHealth, some apps may be prescribed to patients under the guidance of health professionals [7,15]. *Badly behaving* mHealth apps pose regulatory challenges regarding the evidence of app quality, safety, and efficacy and present risks to human health by potential misdiagnosis and inadequate or ineffective treatments, or by delaying face-to-face medical consultations [7,15,22,23].

Taxonomies for Mobile Health App Sensors

Several taxonomies exist for describing mHealth apps; one simple method categorizes them as either passive or active [23]. Passive mHealth apps display static health information pages or acquire hand-keyed input of health information. In contrast, active mHealth apps generate some form of health data [13,23]. It is in this latter active realm that sensor-based mHealth apps reside. Built-in smartphone sensors are readily accessible in the devices owned by billions of mobile phone users worldwide. Smartphones have evolved to incorporate environment and position sensors to augment and enhance device functionality [24]. In addition to sound detection by the phone microphone, cameras document the visual world [25]. Touch screens facilitate flexible display presentation and command initiation [25]. Accelerometers sense device orientation and adjust screen display layout in either portrait or landscape modes accordingly, whereas GPS locates devices geographically [25].

Regulation and Compliance Issues

The utility of such a trove of sensors has not gone unnoticed by clinicians and app developers alike [24,26]. Pedometer apps have been coded to count steps based on accelerometer monitoring [27]. Photoplethysmography apps leverage mobile phone cameras to detect changes in skin color with blood flow, estimating respiratory rate, heart rate (and heart rate variability), blood pressure, and blood oxygen saturation [28-31]. Examples abound as to innovative uses of sensor information for gathering health data [26]. In contrast, examples also exist highlighting deficiencies in some sensor-based mHealth apps. For example, blood pressure values based on pulse estimates from a particular camera-based smartphone app were demonstrated to be erroneous, potentially exposing hypertensive persons to harm with spurious readings [32]. Oximetry readings from another camera-based app were found to be inaccurate, with the potential for incorrect blood oxygen saturation readings to put users at risk [33]. Regulatory authorities worldwide seek to mitigate

this risk by deeming any app that attempts diagnosis or treatment to be a medical device, requiring rigorous evaluation, testing, and regulatory control [4]. Given the impost this places on app developers, some have sought to circumvent regulation by defining some apps as for entertainment or recreation or by using sensor-generated data as an adjunct to an app's operation as opposed to its main purpose [23,34].

Searching for Apps Using Curated Libraries

App stores such as those offered by Apple and Google present literally millions of results in response to searches on health topics [4,35]. A 2016 review of clinical and health care–related apps in the Google and Apple app stores found 36 apps for clinical diagnosis and 44 patient health monitoring apps, with the mobile phone camera identified as the predominant built-in sensor used [35]. Mobile phone camera apps offered for image-based diagnosis of eye and skin conditions, or photoplethysmographic monitoring of pulse and estimated blood pressure, and sleep apnea diagnostic apps using mobile phone microphones are examples of sensor-based apps offered by major app stores [15,34,35]. Information regarding vetting procedures for the inclusion of apps in these vendor stores is not publicly available [36]. For example, Apple is reported to have introduced additional requirements for developers regarding the measurement accuracy of apps, but details of these requirements remain undisclosed [37]. The quality and safety of mHealth apps offered by these vast stores are questioned by some, as is the utility of listed app descriptions in facilitating informed use of apps in a prescription context [37,38]. App listing and availability are also tempered by emergent government medical device regulatory requirements in Europe, the United States, and elsewhere [4,36,39].

Distinct from app stores such as the Apple App Store and Google Play Store, a number of independent third-party mHealth app repositories have emerged, with the intent of providing curated *trusted* lists of health apps for users to review and to guide the selection of safe and effective mHealth apps [39]. Also known as health app clearinghouse websites, these libraries are Web-based portals that do not host apps per se but offer information and links to a range of vetted apps that have satisfied selection criteria required for inclusion in the respective repository [40-42]. Examples of such libraries include the government-funded National Health Service (NHS) Apps Library in the United Kingdom and two privately funded repositories, namely, AppScript in the United States and MyHealthApps in Europe and the United Kingdom [43]. Curation of apps submitted to these libraries consists of varying degrees of scrutiny [39]. Submissions to the NHS Apps Library and AppScript repositories require app developers to respond to questions regarding app quality and safety, which are evaluated by curators of these libraries using proprietary scoring methodologies, whereas the MyHealthApps site incorporates reviews from patients [13,22,44]. Intended audiences for such curated apps include clinicians (with the intent to prescribe an app for use by a patient) as well as laypersons seeking to self-manage their health. In contrast to reviews regarding the availability of mHealth apps in popular Google and Apple app stores (including those using built-in smartphone sensors), there is a paucity of information regarding sensor-based mHealth apps offered by third party–curated mHealth app libraries [4,16,35].

Objective

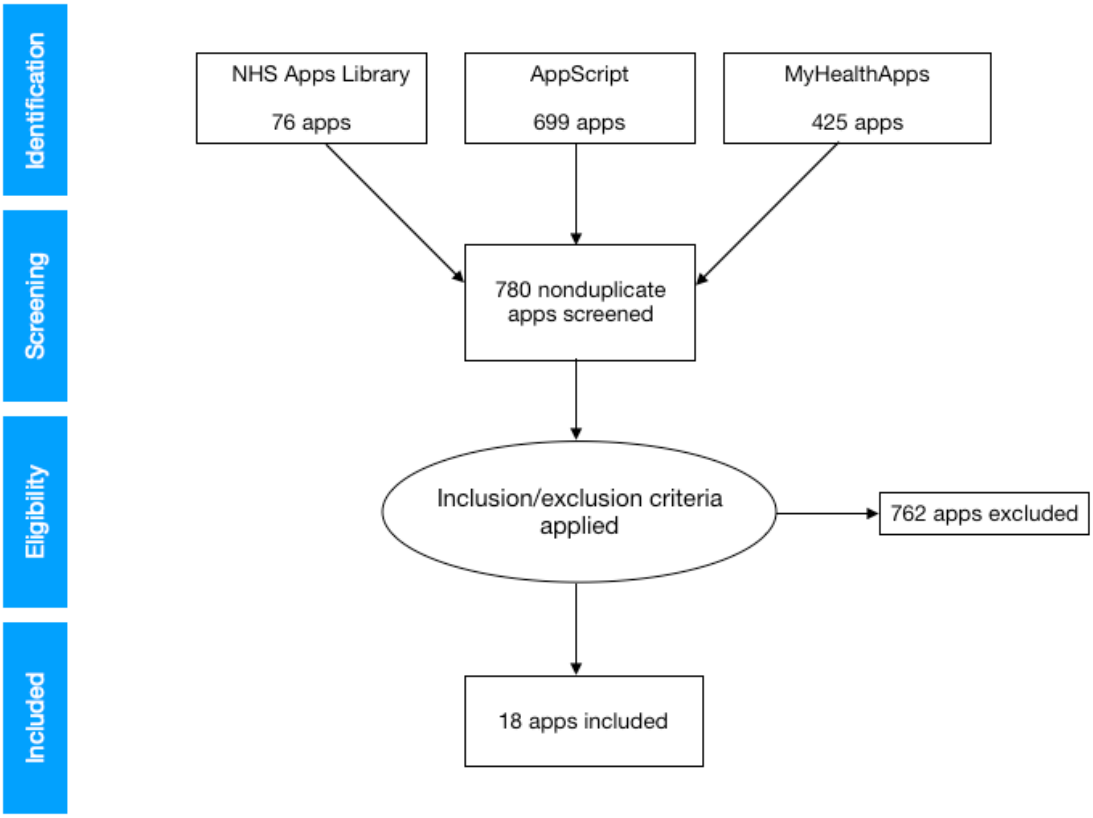
Given the potential for health improvement arising from the availability and utility of built-in sensors in billions of smartphones worldwide, the purpose of this systematic survey was to identify smartphone mHealth apps using built-in sensors, offered by three popular contemporary international curated mHealth app repositories, and to assess which health conditions these apps address and whether they are available across different platforms [39,43,45].

Methods

Libraries Selected for Survey

This survey, conducted in October 2019, considered all mHealth app listings in the NHS Apps Library, AppScript, and MyHealthApps–curated mHealth app repositories (Figure 1) [46-48]. These libraries were selected as examples of government-funded (NHS Apps Library) and privately funded curated mHealth app repositories (AppScript and MyHealthApps) [4,15,36,41]. The latter two privately funded libraries differ in that MyHealthApps incorporates patient reviews in the curation process, whereas AppScript uses a proprietary scoring process [22,41,44].

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram for survey.



Identification of Apps for Inclusion

All apps addressing health conditions using built-in mobile phone sensors to generate health data were identified using the publicly accessible search interfaces offered by each repository. As no search criteria were offered by these sites for filtering and identifying sensor-based apps, manual screening of the descriptions of all individual apps listed by each website was conducted by the lead researcher to screen for the use of built-in mobile phone sensors. Curated library descriptions for identified apps were inspected to categorize the purpose of the app as solely diagnostic, therapeutic, or a combination of both. Diagnostic apps were defined as those that identify the nature of a health condition, in contrast to treatment apps, which offered features for health condition management. Health conditions addressed by included apps were classified based on the description provided by each repository.

Exclusion Criteria

Apps using external or add-on sensors and nonsmartphone wearable device apps were excluded from this survey, as external components may impose additional cost, complexity, or excessive battery consumption, potentially reducing availability or accessibility to smartphone mHealth users [49]. *Propeller* is an example of an asthma therapy coaching app using an external Bluetooth sensor, which was excluded from this study [47]. Exercise, general activity, and accessibility apps were also excluded, as only apps used in diagnosis or treatment of specific health conditions were in scope of this survey. *Runkeeper* is an example of a GPS running tracker designed for monitoring exercise but excluded from this study, as no specific health condition was indicated for its use [47].

Availability of Apps

Mobile phone operating systems supported by included apps were noted, assessing the availability of these apps by users of the Apple iOS and Google Android phone types. The availability of included apps on advertised platforms was confirmed by following links advertised by each repository to inspect the Apple and Google app store app listings for apps. Apps were not downloaded or tested. App listings included as in scope by the lead researcher were then reviewed by the research team.

Low numbers across result groups precluded rigorous statistical analysis. Descriptive statistics were used where appropriate to illustrate results and to allow comparison between different libraries proportionate to respective library size.

Results

Overall Findings

A total of 1200 apps listed in the three selected curated mHealth app repositories were identified (Figure 1). Of 1200 apps, 780 nonduplicated apps were screened for eligibility. A total of 18 mHealth apps using built-in smartphone sensors were found in the three repositories surveyed. These represented 1.1% (8/699) to 3% (2/76) of the total app count across respective curated libraries (Table 1).

Table 1. Built-in sensor smartphone apps found in surveyed mobile health app libraries.

Curated mobile health app library	Total apps identified (n=1200), n	Built-in sensor apps included (n=18), n (%)
NHS[a] Apps Library	76	2 (3)
AppScript	699	8 (1.1)
MyHealthApps	425	8 (1.9)

[a]NHS: National Health Service.

Included Apps

Details of smartphone mHealth apps using built-in sensors included from each respective curated mHealth library in this survey are presented in Multimedia Appendix 1. Listings include app type (ie, diagnostic, therapeutic, or both), sensor type used, app name, description, mobile phone operating system, and health concern addressed by each app.

Cross-Platform Availability

Half (9/18, 50%) of all apps inspected were offered solely for use on the Apple iOS platform, with a further 11% (2/18) dedicated to the Android operating system (Table 2). Only about one-third (7/18, 39%) of the identified apps across all surveyed libraries were available for cross-platform use on Apple iOS and Android operating systems. The MyHealthApps repository offered the greatest cross-platform app availability, with 5 of the 8 (63%) identified apps in this library compatible with Apple iOS and Android operating systems. Most AppScript listings identified (6/8, 75%) were compatible only with Apple iOS.

Table 2. Operating systems for apps using built-in mobile phone sensors.

Operating system	Curated mobile health app library			Total, n (%)
	NHS[a] Apps Library	AppScript	MyHealthApps	
Apple iOS only	1	6	2	9 (50)
Android only	0	1	1	2 (11)
Both	1	1	5	7 (39)
Total	2	8	8	18 (100)

[a]NHS: National Health Service.

Purpose of the Apps

Almost one-fourth (4/18, 22%) of all included apps were dedicated entirely to the diagnosis of health conditions (predominantly available in MyHealthApps), whereas half were solely treatment oriented (Table 3). The AppScript and MyHealthApps libraries offered comparable numbers of combined diagnostic and therapeutic apps using built-in sensors, whereas more apps dedicated to treatment were available in AppScript compared with the other libraries.

Table 3. Purpose for mobile health apps identified using built-in mobile phone sensors.

Purpose	Curated mobile health app library			Total (n=18), n (%)
	NHS[a] Apps Library (n=2)	AppScript (n=8)	MyHealthApps (n=8)	
Diagnostic (Dx)	0	1	3	4 (22)
Therapeutic (Rx)	2	5	2	9 (50)
Both	0	2	3	5 (28)

[a]NHS: National Health Service.

Mobile Phone Sensors Used

Camera (7/18, 39%) and touch screens (6/18, 33%) were the most frequently identified smartphone sensors used (Table 4). Microphones and accelerometers (and mobile phone speakers) were found to be less frequently used sensors in the identified apps. No GPS-based mHealth apps were identified in this survey. MyHealthApps offered more camera-based apps than the other libraries combined, whereas AppScript listed more apps using touch screens and microphones.

Smartphone cameras assessed pulse rate using photoplethysmography in an anxiety treatment app (Beat Panic), a respiratory therapy app (HeartRate+ Coherence), and a cardiac app (Instant Heart Rate). Beat Panic and Heart Rate+ Coherence are examples where smartphone pulse rate sensing is a secondary function to support a main therapy, namely, anxiety management and breathing exercise, respectively. Camera images were also used for automated skin cancer diagnosis (SpotMole) and in capturing images for dermatological diagnosis (UMSkinCheck, iDoc24, and MyPso).

In addition to capturing responses to speaker-generated tones in audiology testing, touch screens were used in vision training (Vision training 1 and Visual Attention Therapy Lite), neurological tremor assessment (pdFIT and Dexteria), and anxiety management (Chill Panda and Antistress Chromotherapy). Microphone sensors were used in several respiratory therapy apps (Breathing Zone, SnoreLab, and SnoreMonitor SleepLab). The use of a mobile phone accelerometer sensor was identified in a single app for neurological tremor assessment (LiftPulse).

Table 4. Sensor types found in curated mobile health app libraries.

Sensor	Curated mobile health app library			Total (n=18), n (%)
	NHS[a] Apps Library (n=2)	AppScript (n=8)	MyHealthApps (n=8)	
Camera	1	2	4	7 (39)
Touch screen	1	3	2	6 (33)
Microphone	0	3	0	3 (17)
Accelerometer	0	0	1	1 (6)
Speaker	0	0	1	1 (6)

[a]NHS: National Health Service.

Health Conditions Addressed

Respiratory (4/18, 22%), dermatological (4/18, 22%), neurological (3/18, 17%), anxiety (3/18, 17%), and visual health (2/18, 11%) were the predominant health concerns addressed by the identified apps (Table 5). MyHealthApps and AppScript libraries listed more apps addressing a wider range of health conditions than the NHS Apps Library. The AppScript repository presented more apps for respiratory-related conditions, concerning snoring (n=2) and breathing exercises (n=2). Both the apps using built-in sensors in the NHS Apps Library addressed the management of anxiety.

Table 5. Summary of health conditions where built-in mobile phone sensors were used.

Health condition	Curated mobile health app library			Total (n=18), n (%)
	NHS[a] Apps Library (n=2)	AppScript (n=8)	MyHealthApps (n=8)	
Respiratory	0	4	0	4 (22)
Dermatology and skin cancer	0	1	3	4 (22)
Anxiety	2	0	1	3 (17)
Neurology	0	1	2	3 (17)
Visual acuity	0	2	0	2 (11)
Audiology	0	0	1	1 (6)
Cardiology	0	0	1	1 (6)

[a]NHS: National Health Service.

Sensor Types and Health Conditions

Mobile phone cameras are employed in addressing the broadest range of health issues (Table 6). For example, skin cancer assessment camera apps are available in MyHealthApps and AppScript repositories. Diagnostic pattern-matching algorithms analyze acquired camera images of skin lesions in one app in the MyHealthApps library, whereas another from AppScript captures photos for later analysis by a physician. General dermatology apps using smartphone cameras to capture images are listed in the MyHealthApps library. In addition, two apps for the assessment of tremor were identified in the AppScript and MyHealthApps libraries, using the touch screen to assess touch accuracy in Parkinson disease symptom assessment and accelerometer sensors to detect tremor-induced movements, respectively.

Table 6. Sensors, health conditions, and methodologies identified.

Sensor and health condition	Measure	Methodology used
Camera		
General anxiety disorder	Heart rate	Photoplethysmography
Cardiac	Heart rate	Photoplethysmography
Dermatology (n=2)	Photography	Clinician inspection
Respiratory (breathing exercise)	Heart rate variability	Photoplethysmography
Skin cancer	Photography	Steganographic pattern matching from photo
Skin cancer	Photography	Clinician inspection
Touch screen		
Panic attacks	Screen image display	Images displayed to reduce panic
Visual acuity (n=2)	Touch accuracy	Eye-hand coordination assessment and coaching
Parkinson disease	Touch accuracy	Fine motor skill assessment and coaching
Microphone		
Respiratory (sleep; n=2)	Snoring sound level and frequency	Snoring and apnea detection
Respiratory (breathing exercise)	Breath sound detection	Feedback to encourage slow purposeful breaths
Accelerometer		
Neurology	Tremor detection	Calculates tremor frequency
Speaker and touch screen		
Audiology	Calibrated sound generation	Self-administered hearing test

Discussion

Principal Findings

Curation activities offered by third-party mHealth libraries, which are underpinned by medical device regulation, contribute to informing and protecting mHealth consumers. In this study, we surveyed three popular curated libraries regarding a specific subset of mHealth apps, namely, those using built-in mobile phone sensors for diagnosis or treatment of health conditions. Key aims of this survey included determining app availability, mobile phone operating system compatibility, intended purpose (diagnosis or therapy), types of sensors employed, and the range of health conditions where built-in smartphone sensors are used. First, this survey yielded a relatively small number of apps across the libraries examined, with differences found in the number of apps available between libraries. Second, more apps were available for the users of Apple iOS smartphones than for those of Android devices; cross-platform availability differed between the libraries surveyed. Third, the majority of apps offered treatment and combined diagnosis and treatment, with a smaller proportion offering dedicated diagnostic functionality. Fourth, cameras, touch screens, and microphones were the most frequently used mobile phone sensors in these apps. Finally, the range of health conditions addressed by these apps included respiratory, dermatological, anxiety, and neurological conditions.

Finding Trusted Mobile Health Apps

Searching for apps related to particular health topics or medical concerns pose challenges for health professionals and consumers alike. Search engines, such as Google and Bing, which index available apps based on keyword search algorithms, often yield large volumes of uncurated search results for a given health topic [35,36,50,51]. Although the Apple and Google app stores categorize submitted apps for more focused searching (eg, *Health and well-being*), those searches can still return an overwhelming result list of indeterminate quality [4,35]. Search engines and app stores display star ratings and reviews to indicate the popularity of given apps, but these may not be reliable measures by which listed mHealth apps can be *trusted* [22,45]. In addition to high-level categorical grouping, third party–curated mHealth libraries offer more detailed subcategories and lists for specific health conditions and medical specialties.

No studies could be found that quantify the prevalence of mHealth apps using built-in sensors in curated mHealth app libraries. A 2016 review of health care–related apps available from the Google and Apple app stores identifies 80 clinical or health care–related mHealth apps for diagnosis or health monitoring [35]. Of the apps described in this review, mobile phone cameras are the most frequently employed sensor type, with camera images used by some apps for dermatological and ophthalmological diagnosis. Camera imaging is also employed in apps for blood flow monitoring by means of photoplethysmographic monitoring of pulse rate and estimation of blood pressure [35]. Emergent problems with blood pressure estimation received wide publicity when found to be unreliable in the case of at least one app [32]. In a number of health care contexts, app availability has been termed *volatile*, where apps may be removed from app stores in response to the revision of the underlying evidence base of an app or for medicolegal reasons [52].

Critics highlight a lack of transparency in standards applied to the screening of submitted apps before inclusion and hosting in popular app stores and search engines, resulting in mHealth app offerings, which may vary in quality or safety [7,45,51]. Measures of mHealth app quality have been developed (but not widely applied), including the (now defunct) Happtique Health App Certification, EU Kitemark certification, Intercontinental Medical Statistics (IMS) Score, and Mobile Application Rating Scale (MARS) [39,51]. For example, MARS evaluates mHealth app quality in five areas: aesthetics, functionality, engagement, information quality, and subjective quality [39,53]. Curated mHealth app libraries offer *trusted* sites for health consumers to select mHealth apps, constituting more detailed and specialized search portals than the aforementioned search engines and app stores [4,13]. Varying degrees of (proprietary) vetting are conducted to assert the safety and efficacy of curated apps, thereby imbuing search results with trust; detailed app scoring methodology and the incorporation of app quality measures, such as MARS, into the vetting process are not disclosed by these sites [40,54].

Primary and Supporting Roles for Sensors

In contrast to a million health and well-being apps on offer to mobile phone users from popular app stores, only 18 mHealth apps using built-in smartphone sensors are identified in this survey, representing 1.50% (18/1200) of all mHealth apps collectively offered by the three curated libraries examined here (Table 1). A key consideration in the curation process is that medical device regulatory requirements may preclude listing of some apps in these libraries to prevent harm to app users [50]. Active mHealth apps (ie, those using sensors to gather health data) may be at greater risk of causing negative health impacts because of potential harm from inaccurate or incorrect data, demanding more rigorous curation and potential exclusion from curated libraries [23]. Regulatory authorities may require the assessment and accreditation of mHealth apps that offer diagnostic or therapeutic recommendations or those that transform the functionality of the mobile phone into that of a medical device [23,54]. Some sensor-based mHealth apps may use sensors as a secondary or supporting measure and thus not be regarded as medical devices per se [23]. Overall, two such examples are identified in this survey: anxiety and breathing exercise apps that use camera sensors for pulse detection as a secondary or indirect health data measure.

Availability on Competing Mobile Phone Platforms

The respective smartphone market shares for Apple and Android devices are comparable [55,56]. In contrast, not all the apps identified in this survey are available across both popular mobile phone platforms, potentially disadvantaging some mHealth consumers. Half (9/18, 50%) of the apps identified in this survey are dedicated solely to Apple iOS, a further 11% (2/18) specific to Android, and only about one-third (7/18, 39%) available for both operating system platforms (Table 2). Apple iOS device manufacture is controlled solely by Apple, with relative homogeneity in hardware components such as sensors potentially offering app developers more stable or predictable target platforms for app development [56]. In contrast, Android devices may originate from multiple hardware vendors with disparate (sensor) hardware components, potentially adding complexity to the development of apps catering for a wider range of target device hardware and sensors [55,56].

Half of the identified mHealth apps (9/18, 50%) offer dedicated treatment features, with further about one-fourth (4/18, 22%) dedicated to diagnosis (Table 3). The imperative to seek (traditional doctor-patient) medical consultation regarding definitive diagnosis, potential risk of self-misdiagnosis, and regulatory restrictions may all contribute to the smaller proportion of purely diagnostic sensor-based apps offered by the libraries surveyed [57]. Dermatology and skin cancer diagnostic apps using the mobile phone camera constitute 4 of the 5 dedicated diagnostic apps identified.

Health Concerns and Sensor Types

Cameras and touch screens are the most frequently used sensors in the identified apps, followed by microphones and accelerometers. Apps using camera sensors are most prominent in the MyHealthApps library, whereas AppScript lists more microphone and touch screen apps (Table 4). Notwithstanding contemporary research studies regarding the use of GPS for activity tracking in mental health conditions such as bipolar disorder and general depression, no examples of translating this research into GPS-based sensor apps were found in any of the libraries surveyed [20,26]. Anxiety therapy was the sole focus of both apps identified in the NHS Apps Library. Respiratory concerns were the most frequently addressed health conditions in the AppScript library, whereas apps related to dermatology and neurological conditions were more prevalent in the MyHealthApps library (Table 5). Cameras are employed in a wider range of health conditions compared with other sensors (Table 6). Photoplethysmography is used to measure heart rate and heart rate variability in three camera apps, whereas photo capture for later inspection by a clinician is offered by two dermatology and skin cancer diagnostic apps. A single camera app performs steganography (pattern matching) for skin cancer diagnosis.

Conclusions

This survey found that mHealth apps using built-in sensors for diagnosis and treatment represented but a modicum of all apps found in the curated mHealth libraries examined. The nature and rigor of the curation process go some way to explain this observation, including the constraints of regulatory requirements for software deemed as medical devices. This may also help explain the smaller proportion of dedicated diagnostic apps observed in these libraries. Some health consumers may be disadvantaged by differences in the availability of apps on competing mobile phone platforms. Cameras, touch screens, and microphones were used most frequently in the surveyed apps. A limited range of health concerns were addressed by the surveyed apps.

Further efforts are needed to increase the availability of ubiquitous, low-cost mobile phone sensor technology in curated lists to assist with health conditions.

Authors' Contributions

CB conceptualized the survey, developed methodology, and collected data for the survey. He categorized and evaluated the results and prepared the draft manuscript. JC supervised the overall work. BK and CV contributed to discussing and revising the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Details of mobile health apps using built-in mobile phone sensors in surveyed curated libraries.
[PDF File (Adobe PDF File), 144 KB - mhealth_v8i2e16741_app1.pdf]

References

1. Ali EE, Chew L, Yap KY. Evolution and current status of mhealth research: a systematic review. BMJ Innov 2016;2(1):33-40 [FREE Full text] [doi: 10.1136/bmjinnov-2015-000096]
2. Reid AJ. A brief history of the smartphone. In: The Smartphone Paradox: Our Ruinous Dependency in the Device Age. Cham: Palgrave Macmillan; 2018:35-66.
3. Statista. 2019. Number of Smartphone Users Worldwide From 2016 to 2021 (in billions) URL: https://www.statista.com/statistics/330695/number-of-smartphone-users-worldwide [accessed 2019-12-03]
4. Paglialonga A, Lugo A, Santoro E. An overview on the emerging area of identification, characterization, and assessment of health apps. J Biomed Inform 2018 Jul;83:97-102 [FREE Full text] [doi: 10.1016/j.jbi.2018.05.017] [Medline: 29852318]
5. Statista. 2019. Number of Apps Available in Leading App Stores as of 3rd Quarter 2019 URL: https://www.statista.com/statistics/276623/number-of-apps-available-in-leading-app-stores/ [accessed 2019-12-03]
6. Glance D. The Conversation. 2013 Oct 2. Regulations to Ensure Phone Apps Don't Make You Ill URL: https://theconversation.com/regulations-to-ensure-phone-apps-dont-make-you-ill-18656 [accessed 2019-12-03]
7. Byambasuren O, Sanders S, Beller E, Glasziou P. Prescribable mHealth apps identified from an overview of systematic reviews. NPJ Digit Med 2018;1:12 [FREE Full text] [doi: 10.1038/s41746-018-0021-9] [Medline: 31304297]
8. World Health Organization. mHealth: New Horizons for Health through Mobile Technologies. Geneva: World Health Organization; 2011.
9. Khachatryan K. Medical device regulation in the information age: a mobile health perspective. Jurimetrics 2015;55(4):477-507 [FREE Full text]
10. Garge GK, Balakrishna C, Datta SK. Consumer health care: current trends in consumer health monitoring. IEEE Consumer Electron Mag 2018;7(1):38-46 [FREE Full text] [doi: 10.1109/mce.2017.2743238]
11. Bower JL, Christensen CM. Disruptive technologies: catching the wave. Harv Bus Rev 1995;73(1):43-53 [FREE Full text]
12. Christensen CM. The dilemmas of innovation: a summary. In: The Innovator's Dilemma: When New Technologies Cause Great Firms To Fail. Boston: Harvard Business Review Press; 1997:257-262.
13. IMS Institute for Healthcare Informatics. IQVIA. Parsippany: IMS Institute for Healthcare Informatics; 2015. Patient Adoption of mHealth URL: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/patient-adoption-of-mhealth.pdf [accessed 2019-12-03]
14. Wu W, Yong KY, Federico MA, Gan SK. The APD Skin Monitoring App for wound monitoring: image processing, area plot, and colour histogram. Scientific Phone Apps Mobile Device 2018;5:3 [FREE Full text] [doi: 10.30943/2019/28052019]
15. Kao CK, Liebovitz DM. Consumer mobile health apps: current state, barriers, and future directions. Phys Med Rehabil 2017 May;9(5S):S106-S115. [doi: 10.1016/j.pmrj.2017.02.018] [Medline: 28527495]
16. Millenson ML, Baldwin JL, Zipperer L, Singh H. Beyond Dr Google: the evidence on consumer-facing digital tools for diagnosis. Diagnosis (Berl) 2018 Sep 25;5(3):95-105. [doi: 10.1515/dx-2018-0009] [Medline: 30032130]
17. Morgan H. 'Pushed' self-tracking using digital technologies for chronic health condition management: a critical interpretive synthesis. Digit Health 2016;2:2055207616678498 [FREE Full text] [doi: 10.1177/2055207616678498] [Medline: 29942573]
18. Lupton D. Self-tracking, health and medicine. Health Sociol Rev 2017;26(1):1-5 [FREE Full text] [doi: 10.1080/14461242.2016.1228149]
19. Vegter M. Towards precision medicine; a new biomedical cosmology. Med Health Care Philos 2018 Dec;21(4):443-456 [FREE Full text] [doi: 10.1007/s11019-018-9828-z] [Medline: 29429062]
20. Cornet VP, Holden RJ. Systematic review of smartphone-based passive sensing for health and wellbeing. J Biomed Inform 2018 Jan;77:120-132 [FREE Full text] [doi: 10.1016/j.jbi.2017.12.008] [Medline: 29248628]
21. Bull S, Ezeanochie N. From Foucault to Freire through Facebook: toward an integrated theory of mHealth. Health Educ Behav 2016 Aug;43(4):399-411. [doi: 10.1177/1090198115605310] [Medline: 26384499]

22. Wicks P, Chiauzzi E. 'Trust but verify'--five approaches to ensure safe medical apps. BMC Med 2015 Sep 25;13:205 [FREE Full text] [doi: 10.1186/s12916-015-0451-z] [Medline: 26404791]
23. Herron J. Bad Apps: mHealth apps doubling as medical devices. J Electron Resour Med Librar 2016;13(4):177-181 [FREE Full text] [doi: 10.1080/15424065.2016.1256800]
24. Stankevich E, Timofeev I, Paramonov I. Mobile Phone Sensors in Health Applications. In: Proceedings of the 2012 12th Conference of Open Innovations Association. Oulu: Open Innovations Association (FRUCT); 2012 Presented at: FRUCT'12; Nov 5-9, 2012; Oulu, Finland p. 136-141 URL: https://doi.org/10.23919/FRUCT.2012.8122097 [doi: 10.23919/FRUCT.2012.8122097]
25. Frank R. Nature of sensors. In: Understanding Smart Sensors. Third Edition. Boston: Artech House, Incorporated; 2013:1-15.
26. Majumder S, Deen MJ. Smartphone sensors for health monitoring and diagnosis. Sensors (Basel) 2019 May 9;19(9):pii: E2164 [FREE Full text] [doi: 10.3390/s19092164] [Medline: 31075985]
27. Klasnja P, Pratt W. Healthcare in the pocket: mapping the space of mobile-phone health interventions. J Biomed Inform 2012 Feb;45(1):184-198 [FREE Full text] [doi: 10.1016/j.jbi.2011.08.017] [Medline: 21925288]
28. Parra L, Sendra S, Jiménez JM, Lloret J. Multimedia sensors embedded in smartphones for ambient assisted living and e-health. Multimed Tools Appl 2016;75(21):13271-13297 [FREE Full text] [doi: 10.1007/s11042-015-2745-8]
29. Agu E, Pedersen P, Strong D, Tulu B, He Q, Wang L, et al. The Smartphone as a Medical Device Assessing Enablers, Benefits and Challenges. In: Proceedings of the 2013 IEEE International Workshop of Internet-of-Things Networking and Control. Piscataway: IEEE; 2013 Presented at: IoT-NC'13; June 24, 2013; New Orleans p. 76-80 URL: https://web.cs.wpi.edu/~emmanuel/publications/PDFs/C37.pdf [doi: 10.1109/iot-nc.2013.6694053]
30. Lamonaca F, Polimeni G, Barbé K, Grimaldi D. Health parameters monitoring by smartphone for quality of life improvement. Measurement 2015;73:82-94 [FREE Full text] [doi: 10.1016/j.measurement.2015.04.017]
31. Thangada ND, Garg N, Pandey A, Kumar N. The emerging role of mobile-health applications in the management of hypertension. Curr Cardiol Rep 2018 Jul 26;20(9):78. [doi: 10.1007/s11886-018-1022-7] [Medline: 30046971]
32. Plante TB, Urrea B, MacFarlane ZT, Blumenthal RS, Miller ER, Appel LJ, et al. Validation of the instant blood pressure smartphone app. JAMA Intern Med 2016 May 1;176(5):700-702 [FREE Full text] [doi: 10.1001/jamainternmed.2016.0157] [Medline: 26938174]
33. Alexander J, Minhajuddin A, Joshi GP. Comparison of smartphone application-based vital sign monitors without external hardware versus those used in clinical practice: a prospective trial. J Clin Monit Comput 2017 Aug;31(4):825-831. [doi: 10.1007/s10877-016-9889-6] [Medline: 27170014]
34. Ko P, Kientz JA, Choe EK, Kay M, Landis CA, Watson NF. Consumer sleep technologies: a review of the landscape. J Clin Sleep Med 2015 Dec 15;11(12):1455-1461 [FREE Full text] [doi: 10.5664/jcsm.5288] [Medline: 26156958]
35. Gan S, Koshy C, Nguyen P, Haw Y. An overview of clinically and healthcare related apps in Google and Apple app stores: connecting patients, drugs, and clinicians. Scientific Phone App Mob Devices 2016;2:8 [FREE Full text] [doi: 10.1186/s41070-016-0012-7]
36. Parker L, Karliychuk T, Gillies D, Mintzes B, Raven M, Grundy Q. A health app developer's guide to law and policy: a multi-sector policy analysis. BMC Med Inform Decis Mak 2017 Oct 2;17(1):141 [FREE Full text] [doi: 10.1186/s12911-017-0535-0] [Medline: 28969704]
37. Wykes T, Schueller S. Why reviewing apps is not enough: Transparency for trust (T4T) principles of responsible health app marketplaces. J Med Internet Res 2019 May 2;21(5):e12390 [FREE Full text] [doi: 10.2196/12390] [Medline: 31045497]
38. Albrecht U, Malinka C, Long S, Raupach T, Hasenfuß G, von Jan U. Quality principles of app description texts and their significance in deciding to use health apps as assessed by medical students: Survey study. JMIR Mhealth Uhealth 2019 Feb 27;7(2):e13375 [FREE Full text] [doi: 10.2196/13375] [Medline: 30810534]
39. Jones M, Morris J, Deruyter F. Mobile healthcare and people with disabilities: current state and future needs. Int J Environ Res Public Health 2018 Mar 14;15(3):pii: E515 [FREE Full text] [doi: 10.3390/ijerph15030515] [Medline: 29538292]
40. Yetisen AK, Martinez-Hurtado JL, Vasconcellos FC, Simsekler MC, Akram MS, Lowe CR. The regulation of mobile medical applications. Lab Chip 2014 Mar 7;14(5):833-840. [doi: 10.1039/c3lc51235e] [Medline: 24425070]
41. Boudreaux ED, Waring ME, Hayes RB, Sadasivam RS, Mullen S, Pagoto S. Evaluating and selecting mobile health apps: strategies for healthcare providers and healthcare organizations. Transl Behav Med 2014 Dec;4(4):363-371 [FREE Full text] [doi: 10.1007/s13142-014-0293-9] [Medline: 25584085]
42. Rijcken C. The jungle of health apps. In: Pharmaceutical Care in Digital Revolution. Frisco: Elsevier Science & Technology; 2019:95-105.
43. Haute Autorité de Santé. Assessment and Improvement of Practice: Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth). Saint-Denis: Haute Autorité de Santé; Oct 2016.
44. Ashurst EJ, Jones RB. Is the Health App Challenge approach of patient-led application conception, development, and review worthwhile? Health Policy Technol 2017;6(1):83-92 [FREE Full text] [doi: 10.1016/j.hlpt.2016.12.001]
45. Torous J, Powell A, Knable MB. Quality assessment of self-directed software and mobile applications for the treatment of mental illness. Psychiatr Ann 2016;46(10):579-583 [FREE Full text] [doi: 10.3928/00485713-20160908-02]
46. National Health Service. London: NHS NHS Apps Library URL: https://www.nhs.uk/apps-library [accessed 2019-12-03]
47. AppScript. URL: https://www.appscript.net [accessed 2019-10-03]

48. MyHealthApps. URL: http://myhealthapps.net/ [accessed 2019-12-03]
49. Bastawrous A, Armstrong M. Mobile health use in low- and high-income countries: an overview of the peer-reviewed literature. J R Soc Med 2013 Apr;106(4):130-142 [FREE Full text] [doi: 10.1177/0141076812472620] [Medline: 23564897]
50. Mandl K, Mandel JC, Kohane IS. Driving innovation in health systems through an apps-based information economy. Cell Syst 2015 Jul;1(1):8-13 [FREE Full text] [doi: 10.1016/j.cels.2015.05.001] [Medline: 26339683]
51. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Mar 11;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]
52. Larsen ME, Nicholas J, Christensen H. Quantifying app store dynamics: longitudinal tracking of mental health apps. JMIR Mhealth Uhealth 2016 Aug 9;4(3):e96 [FREE Full text] [doi: 10.2196/mhealth.6020] [Medline: 27507641]
53. Anderson K, Emmerton LM. Contribution of mobile health applications to self-management by consumers: review of published evidence. Aust Health Rev 2016 Nov;40(5):591-597. [doi: 10.1071/AH15162] [Medline: 26681206]
54. Lechner NH, Strahonja V. Quality Factors for Mobile Medical Apps. In: Proceedings of the Central Eurpoean Conference on Information and Intelligent Systems. Zagreb: University of Zagreb; 2017 Presented at: CECIIS'17; September 27-29, 2017; Varaždin, Croatia p. 229-236 URL: http://archive.ceciis.foi.hr/app/public/conferences/2017/06/QSS-2.pdf
55. Daponte P, de Vito L, Picariello F, Riccio M. State of the art and future developments of measurement applications on smartphones. Measurement 2013;46(9):3291-3307 [FREE Full text] [doi: 10.1016/j.measurement.2013.05.006]
56. Boulos M, Wheeler S, Tavares C, Jones R. How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX. Biomed Eng Online 2011 Apr 5;10:24 [FREE Full text] [doi: 10.1186/1475-925X-10-24] [Medline: 21466669]
57. Lupton D, Jutel A. 'It's like having a physician in your pocket!' A critical analysis of self-diagnosis smartphone apps. Soc Sci Med 2015 May;133:128-135. [doi: 10.1016/j.socscimed.2015.04.004] [Medline: 25864149]

Abbreviations

MARS: Mobile Application Rating Scale
mHealth: mobile health
NHS: National Health Service

Edited by G Eysenbach; submitted 20.10.19; peer-reviewed by S Gan, C Reis, R Cruz Martínez; comments to author 08.11.19; revised version received 04.12.19; accepted 16.12.19; published 03.02.20.

Please cite as:
Baxter C, Carroll JA, Keogh B, Vandelanotte C
Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries
JMIR Mhealth Uhealth 2020;8(2):e16741
URL: https://mhealth.jmir.org/2020/2/e16741
doi:10.2196/16741
PMID:32012102

Original Paper

Content Analysis of Apps for Growth Monitoring and Growth Hormone Treatment: Systematic Search in the Android App Store

Luis Fernandez-Luque[1,2], PhD; José I Labarta[3], MD, PhD; Ella Palmer[4], PhD; Ekaterina Koledova[5], MD, PhD

[1]Qatar Computing Research Institute, Doha, Qatar

[2]Salumedia Labs, Sevilla, Spain

[3]Department of Pediatrics, Hospital Universitario Miguel Servet, Zaragoza, Spain

[4]inScience Communications, Springer Healthcare Ltd, London, United Kingdom

[5]Merck KGaA, Darmstadt, Germany

Corresponding Author:
Ekaterina Koledova, MD, PhD
Merck KGaA
Frankfurter Str. 250
Darmstadt, 64293
Germany
Phone: 49 6151 72 20915
Email: ekaterina.koledova@merckgroup.com

Abstract

Background: The use of mobile apps for health is growing. This rapid growth in the number of health apps can make it hard to assess their quality and features. The increased demand for and availability of mobile health apps highlights the importance of regular publication of reviews to identify potential areas of unmet needs and concern. The focus of this review is mobile apps for monitoring growth for health care professionals, caregivers, and patients. Monitoring growth as a part of healthy physical development is important across different periods of childhood and adolescence.

Objective: The goal of this content analysis is to map and understand the types of apps that currently exist that are related to growth monitoring and growth hormone treatment.

Methods: A semiautomated search was undertaken using the app search engine 42Matters, complemented by a manual search for growth apps using the web search tool of Google Play (Android App Store). Apps were rated on their relevance to growth monitoring and categorized by independent raters.

Results: In total, 76 apps were rated relevant to growth monitoring or growth hormone treatment. The level of agreement was measured for the semiautomated search and was very high (K=0.97). The target audience for 87% of the apps (66/76) was patients and relatives, followed by health care professionals (11%; 8/76) and both (3%; 2/76). Apps in the category “growth tracking tools for children and babies” were retrieved most often (46%; 35/76) followed by “general baby care apps” (32%; 24/76), “nonpharmacological solutions for growth” (12%; 9/76) and “growth hormone–related” (11%; 8/76). Overall, 19/76 apps (25%) tracked a precise location.

Conclusions: This study mapped the type of apps currently available for growth monitoring or growth hormone treatment that can be used as a foundation for more detailed evaluations of app quality. The popularity of care apps for children and growth monitoring apps should provide a great channel for potential intervention in childhood health in the future.

(JMIR Mhealth Uhealth 2020;8(2):e16208) doi:10.2196/16208

KEYWORDS

growth hormone; telemedicine; growth monitoring; mobile app; mobile health

Introduction

The use of mobile apps for health is growing, and between 2008-2015, the growth in the number of apps used was quadratic [1]. In November 2017, according to IQVIA (formerly Quintiles and IMS Health, Inc), 318,000 apps were available worldwide with more than 200 health apps being added to the Apple Store and the Google Play store each day [1,2]. This rapid growth in the number of health apps can make it hard to assess their quality

and features, although tools are being developed for this purpose [3], such as the Mobile App Rating Scale [4].

The increased demand for and availability of mobile health apps highlights the importance of regular publication of reviews to identify potential areas of unmet needs and concern. Consequently, methods for the systematic search for apps in app stores have been developed [5], and apps have been analyzed and characterized in disease areas where their use is widespread to identify their benefits and any shortcomings. For example, apps that focus on breast cancer have been shown to improve quality of life, and decrease stress [6]; however, it was found to be essential that medical personnel be involved in the creation of these apps to avoid the misuse of alternative therapies not supported by substantial evidence of efficacy [7]. Apps that focused on multiple sclerosis failed to meet patient needs and demands, and therefore, design collaboration between health professionals, researchers, and industry partners was suggested to increase patient adoption and engagement [8]. In a further analysis of multiple sclerosis physical activity apps, realistic goal setting and feedback were found to be critical for adoption [9]. In the field of diabetes, gaps between evidence-based recommendations and functionality of apps were revealed, potentially due to personalized education being underrepresented [10]. The conclusion of an evaluation of apps for endocrine-related disorders was that quality, content, data security, and privacy of apps were often low [11].

The privacy and data security of mobile health apps is an area of growing concern [12]. For example, there are some concerns that apps may be customized to retrieve extra personal information, such as GPS location, without the user's knowledge [13]. This has led to different approaches emerging to help ensure that mobile health apps are safe for users. This includes national efforts, such as the UK National Health Service Health Apps Library only including apps that comply with UK data protection principles concerning information privacy [12]. Scalable systems have also been developed for analyzing and predicting Android app compliance with privacy requirements [14].

Further development in mobile health apps has led to the concept of self-monitoring, which is becoming more widespread with the advent of devices such as Fitbits and Apple Watches. Fitbits can measure fitness levels and sleep patterns, and the Apple Watch can monitor Hemoglobin A_{1c} in diabetes patients [15] and heart rate/electrocardiogram in patients with cardiovascular diseases [16] to reveal anomalies, such as risk of arrhythmias. Other examples of self-monitoring include personal recording of blood pressure for potential hypertension [17] and the use of real-world glucose monitoring devices connected to the web by diabetes patients [18].

Monitoring growth as a part of healthy physical development is part of preventive child health programs, as growth restriction and short stature are regarded as relatively early signs of poor health. Height measurements in pediatric populations, generally referred to as growth monitoring, can theoretically identify treatable conditions in apparently healthy short children. Early diagnosis of growth disorders is essential for prognosis, and it should be the primary objective of pediatric endocrinologists as it can benefit the patient and avoid or diminish the complications of an unrecognized disorder [19,20]. Growth monitoring is also very important in children with growth hormone deficiency, children who are small for their gestational age, or for syndromes requiring treatment with growth hormone, as it can help to identify the condition early enough to improve the prognosis, predict growth outcomes [21], and evaluate adherence and response to treatment [22]. Health care professionals can monitor children's growth via adherence to growth hormone treatment through web-based platforms [23,24] and professional apps, which include official charts from organizations such as the World Health Organization [25]. Automated growth monitoring, where algorithms are integrated into electronic health records, is more efficient than standard growth monitoring, with a higher rate of referral to specialists and higher diagnostic yield of growth disorders. It has been shown that the prevalence of pathological short stature among referred children increased from 5.9% to 13.4% with this form of monitoring [26].

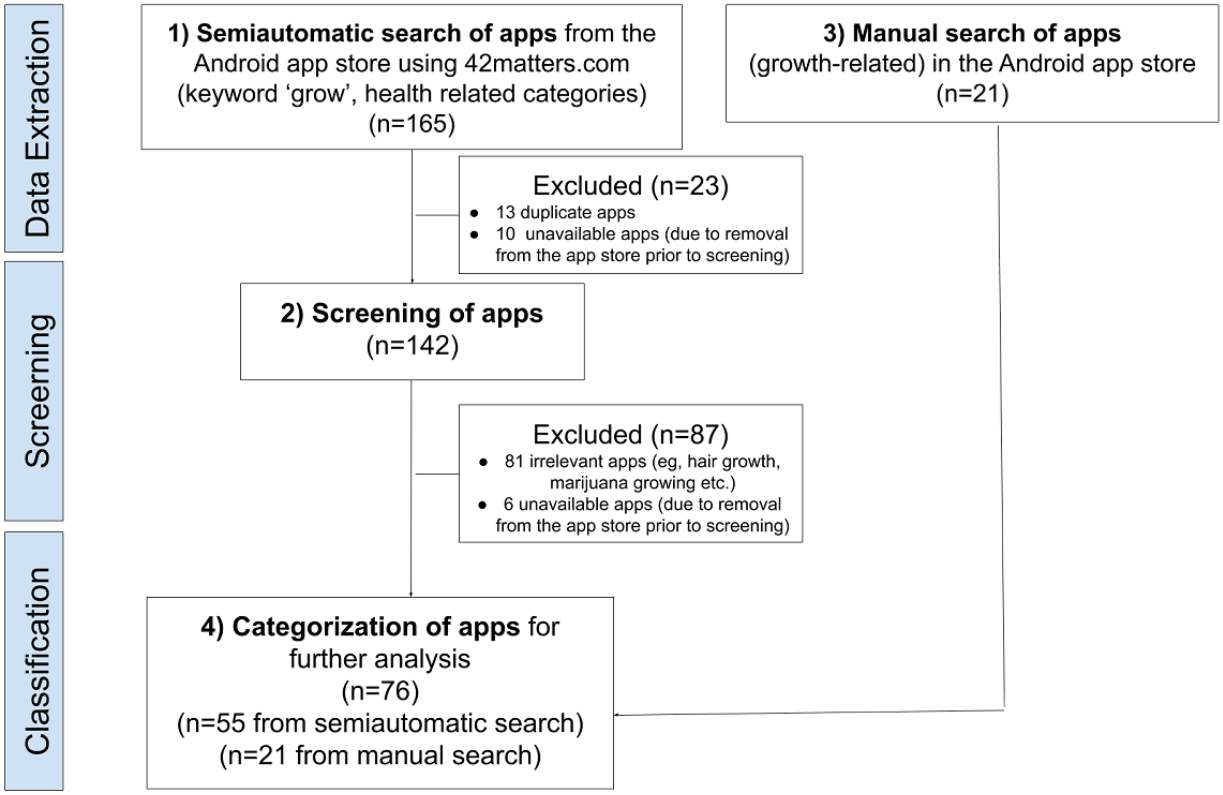
The focus of this review is mobile apps for monitoring growth for health care professionals, caregivers, and patients. Critical factors for the usability of growth apps are yet to be determined; therefore, this paper aims to provide a practical use and information overview for clinicians.

Methods

Extraction of Information About Health Apps Related to Growth

For the semiautomated search, as shown in Figure 1, searches were undertaken using the app search engine, 42Matters [27]. The use of 42Matters for obtaining information about health apps has previously been reported on in the literature [7,28,29]. Within 42Matters, we used the keyword "grow" to extract apps from the Android app store (Google Play) [30] in the Medical, Health, and Parenting categories. Data retrieved included the description, rating score, number of downloads, price, URL, and permission information.

Figure 1. Study flow.



The automated search using 42Matters was complemented with a manual search for growth apps using the web search tool of Google Play and using the terms "Growth hormone," "Growth," "Height," and "Short stature". The search was not limited by language. This manual search was undertaken to ensure all relevant apps were identified, since the availability of mobile apps can vary for technical reasons (eg, the temporal unavailability of apps, limitation to specific geographical regions).

The lists from the semiautomatic and manual searches were combined, and duplicate apps removed. Extended metadata (eg, permissions, downloads, screenshots) were extracted using a web-crawler and the 42Matters application programming interface. An updated version of the code used for retrieving the apps is available at GitHub under the creative commons license [31]. Standard and professional versions of apps were included.

Screening

The descriptions of the automatically extracted apps were read by two independent raters (LFL and EP) who gave the apps a "relevant" score (1) if the app was specific to growth monitoring or growth hormone treatment, or a "not relevant" score (0) if it was not. The level of agreement between the two raters was measured by an interrater score calculated using Cohen's kappa [32]. Cohen's kappa was calculated using the R Statistical Framework package IRR (R Foundation, Vienna, Austria). Ratings were: <0.20, poor; 0.21-0.40, fair; 0.41-0.60, moderate; 0.61-0.80, good; 0.81-1.00, very good.

Classification

The apps were classified further in a meeting between clinical and electronic health experts. Several growth-related applications were discussed, and a subset of categories was agreed upon and tested by three researchers (LFL, EK, and JC) using a random sample of growth-related apps. In a final consensus meeting, a complete set of categories were selected, and a categorization form was developed and tested for usability and relevance with a further random sample of growth-related apps. The final categorization form was hosted by Google Forms [33].

Three independent raters (LFL, EK and JC) then categorized the apps by reading the description of the app and filling in the categorization form as follows: (1) Target Audience (one choice from Patients/caregivers, Health care professionals, both, uncertain); (2) Type of app (one choice from growth tracking for children and babies, general baby care apps, growth hormone–related, nonpharmacological solutions for growth, unclear); (3) presence of medical/scientific references; and (4) additional aspects included in the app (multi-choice) (see Multimedia Appendix 1). If any of the classifications was not clear, a consensus was reached at a meeting with LFL and EP in January 2019. All analyses were reported descriptively.

Results

Overview

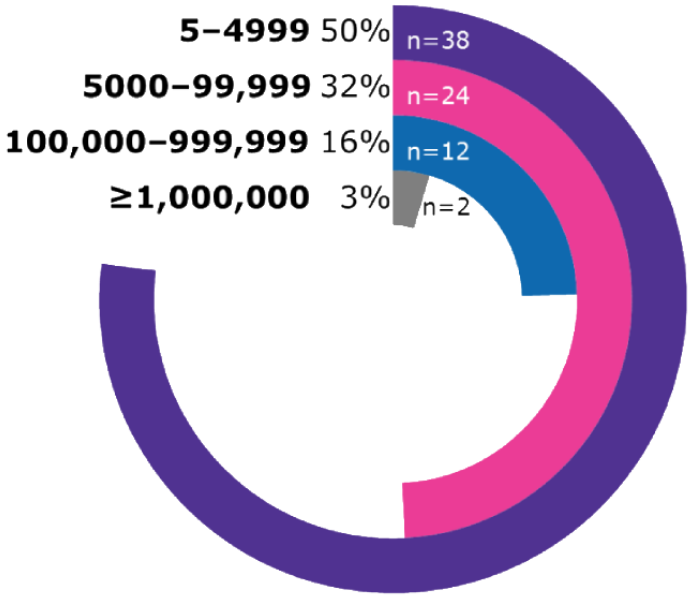
Information about health apps related to growth was extracted in a number of steps (Figure 1). Initially, the keyword "grow" was used to retrieve 142 apps from the app search engine of 42matters [27].

Screening

In total, 76 apps were rated "relevant" to growth monitoring or growth hormone treatment, with 55 from the semiautomated search and 21 from the manual search. The level of agreement between the two raters was measured for the semiautomated search and was very high (K=0.97), with just three discrepant results, which were resolved at a consensus meeting.

Cumulatively, there were at least 3.75 million downloads of the apps (Figure 2). The majority of apps (50%; 38/76) had between 5 and 4999 downloads, whereas just two apps (3%) had more than 1,000,000 downloads. It should be noted that while download numbers are a useful indicator of the popularity of apps, they should be used with caution. Some apps are not available in all countries, some may only be usable within a given hospital, and the number of downloads is greatly affected by the amount of time the app has been available.

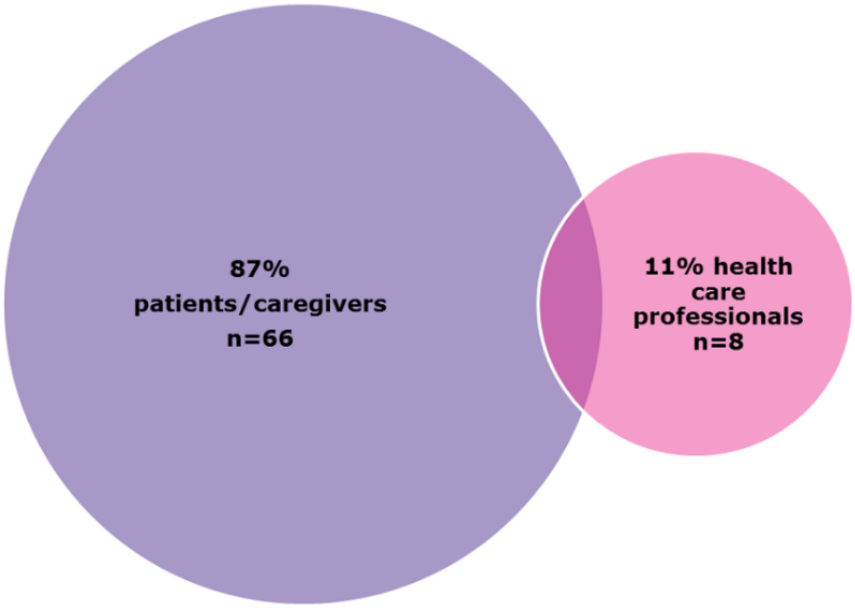
Figure 2. Percentage of apps in each download range.



Classification and Analysis

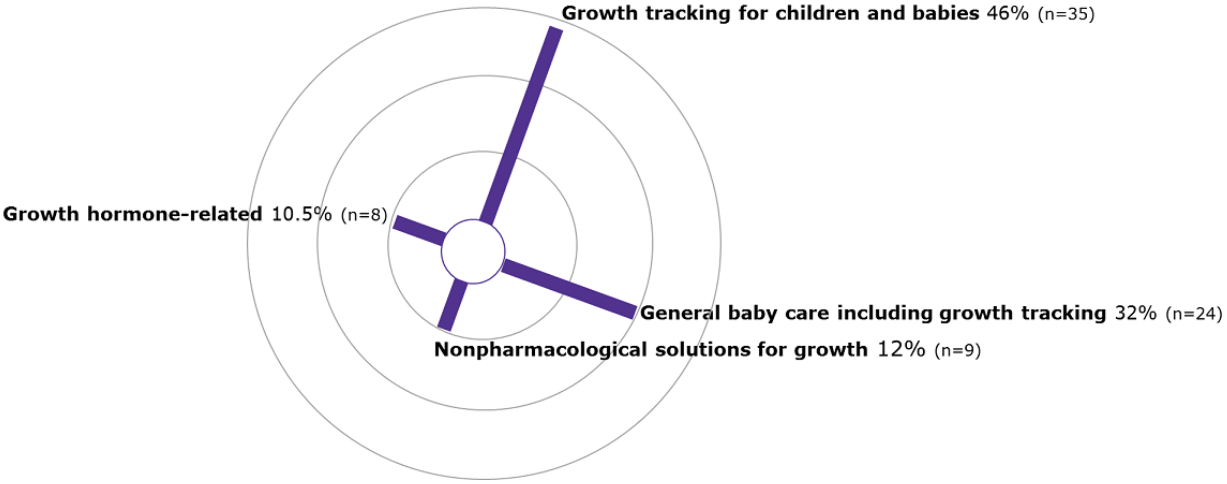
The target audience for 87% of the apps (66/76) was patients and relatives. Health care professionals were the target audience for 11% of the apps (8/76), and two apps were considered to fall into both patient/relative and health care professional categories (Figure 3).

Figure 3. Percentage of growth-related apps by target audience.



Apps in the category of growth tracking tools for children and babies were retrieved most often (46%; 35/76), followed by general baby care apps (32%; 24/76). These were apps which combined growth tracking with gamification and personalization features, such as inclusion of family photos and records of daily routines (eg, feeding). Nonpharmacological solutions for growth comprised 12% of the apps (9 /76), and 11% of the apps were growth hormone–related (8/76) (Figure 4 and Multimedia Appendix 2).

Figure 4. Percentage of apps in each growth tool category. Percentages have been rounded up/down, therefore do not total 100%.



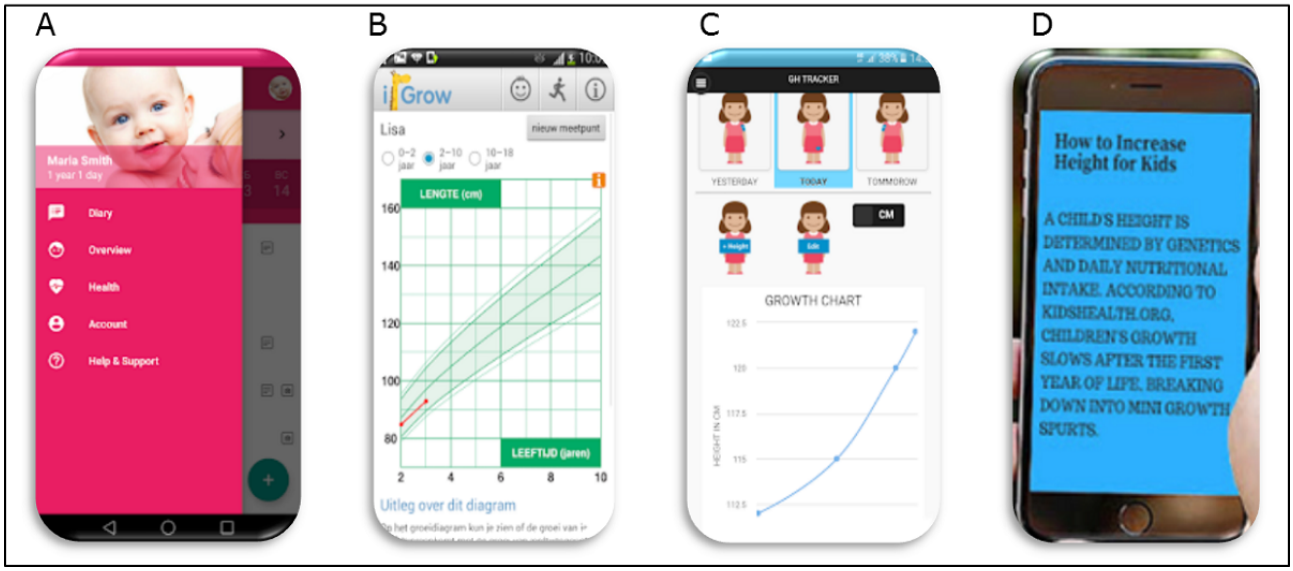
Overall, 31% (11/35) of apps in the growth tracking tools for children and babies category included references to growth charts, as did 46% (11/24) of apps in the general baby care category, and 13% (1/8) of apps in the growth hormone category. However, no apps in the nonpharmacological solutions for growth category included references to growth charts (see Multimedia Appendix 2).

The eight growth hormone–related apps were all targeted at patients/caregivers. They all included education about growth hormone deficiency and related diseases, and four apps also included education about growth tracking (eg, referral to correct growth references) or supporting and tracking adherence (Multimedia Appendix 3). Claims within the description of the growth hormone apps were aimed at improving quality of life; “these records can then be shown to a doctor who can in turn use them to improve the patients’ quality of life” and “receive reminders on when to inject, track adherence history, monitor growth and better connect with the care team.”

Apps describing nonpharmacological solutions for growth included “natural” growth treatments for adults, and included claims in the description such as “let this guide provide peace of mind that you can actually grow 1 to 4 inches through these techniques” and ”grow your height by using our app” (Multimedia Appendix 4).

The visual appearance of the apps varied considerably (Figure 5). The general baby care apps included visually appealing images such as a baby’s face, apps including growth tracking tools and growth hormone apps included images such as graphs, and the nonpharmacological apps were often mostly text with simple or no images.

Figure 5. Examples of app interface for each category. A. General baby care apps; B. Growth Tracking for children and babies; C. Growth hormone apps; and D. Nonpharmacological solutions for growth.



Permission data was extracted. A total of 19/76 apps (25%) tracked a precise location: 5/35 (14%) of the "growth tracking for children and babies" apps, 9/24 (38%) of the "general baby care" apps, which include growth tracking tools, 1/8 (13%) of the growth hormone apps, and 4/9 of the nonpharmacological treatment for growth apps (44%).

Discussion

This study is the first to map and understand the type of apps currently available that are related to growth monitoring. The majority of growth apps were general baby care apps, which include growth tracking tools. Growth tracking apps for children and babies were also popular, whereas there were fewer nonpharmacological and growth hormone apps. Patients and caregivers were the target audience for the vast majority of the apps, and the remainder were targeted at health care professionals or both. The quality of the apps was very heterogeneous, and in general, baby care apps were focused on monitoring and growth hormone apps were focused on education. Almost a quarter of the growth apps tracked precise location, which raises potential concerns in terms of privacy.

There is great interest in apps for monitoring growth and growth hormone treatment, as evidenced by the high download numbers in this evaluation. However, as observed in the first filtering of this analysis, two-thirds of apps were not relevant, indicating that navigating the range of available apps is not a trivial task. A high proportion of apps were aimed at growth in children and babies, aligning with the stage when growth is mostly dependent on nutrition (generally up to 4 years old) [34]. There were also nonpharmacological apps generally aimed at adults, which tended to prey on insecurities about short stature and offer advice not always backed up by scientific evidence.

Privacy is of particular concern, as noted in this evaluation. Some of the growth apps, such as 4/9 apps with nonpharmacological treatments for growth, requested location permissions without any apparent reason. One potential explanation is that location-based advertisements placed in mobile apps can be personalized and, therefore, apps made more profitable.

There is a need to educate users and health care professionals on digital health literacy and how to evaluate the trustworthiness of apps using tools that evaluate quality [3,4] and privacy settings [12,14]. Although there are frameworks for digital health literacy [35], our findings with regard to accessing private information, such as location, highlight the need to reinforce privacy and safety training to help clinicians and patients make safe decisions when choosing health apps. There is very little data on the assessment of apps in peer-reviewed publications, and there is a need for a list of useful and validated apps as well as an outlet for feedback on apps that include unrealistic expectations or inaccurate information.

More research is needed on how to facilitate the prescription of health apps [36], as it can be a time-consuming effort for health care professionals. Further, previous research [12] has shown that severe privacy risks have been found in a white list of apps recommended by health authorities. We should be aware that any assessment of the privacy and data security aspects of a mobile health app, like any other quality aspect, might vary when a new updated version is made public. A potential approach to overcome the dynamic nature of mobile health is to invest more in increasing digital literacy skills.

As shown in this analysis and other studies [7,10], there are currently few apps that include education and links between users and health care professionals. To allow users to detect abnormal growth and seek appropriate medical advice and care early on, an ideal app should combine educational and reference targets and be based on input from users such as parents and older children, as well as health care professionals. With growth disorders, similar to diabetes, optimizing health care delivery through apps is essential, as patients spend much time administering treatment by themselves without health care professional input. Apps for patients/caregivers should, therefore, support information exchange with health care professionals and patient support groups. All users of growth apps should receive educational information that includes the importance of attaining the objectives of growth hormone treatment during infancy, such as normalization of height as early as possible, maintaining normal height velocity, and attainment of normal adult height consistent with parental height.

Treatment adherence remains the most important factor influencing successful outcomes, as in most chronic therapies, including growth disorders [37,38]. Low adherence to growth hormone treatment is a significant factor determining reduced growth gain along with increased health costs. Several strategies have been proposed to improve patient adherence and education of parents and patients is essential [39]. Baby care apps often fail to provide adequate information on normal growth and development later in childhood and adolescence, or how to detect abnormal growth at an early stage and obtain medical advice, and, where necessary, care and treatment. There is also an unmet educational need for the prediction of growth outcomes to avoid unrealistic expectations. Apps developed by scientific and professional bodies, such as the "grow on the go" app, should be used by developers as a gold standard model, with validation by experts in auxology for accuracy and adequacy of growth charts.

Complementary to the methods for the systematic search of apps in app stores [5] that have been published, this review also explores a semiautomated approach to extract mobile app data, which can be used to facilitate part of the process of the analysis of health apps. Additionally, we observed a disparity in the availability of apps between the manual and semiautomated searches, which can be due to reasons such as versions of the mobile apps not being available in a given country and temporary removal of apps in the store. Commercial search engines for apps do not disclose their algorithms, and for that reason, we advocate complementing manual searches with automated approaches to minimize the risk of missing relevant apps. In our analysis of health apps, we only analyzed the description and screenshots of the health apps, not the ratings or the comments, as this would have been very time-consuming in a manual content analysis. However, new app-mining techniques are an emerging area which could help to automatize

apps for security [40], user reviews [41], features [42], gamification [43], and usability [44], among other aspects.

This initial analysis of growth-related apps was undertaken in the Android app store Google Play [30] as it currently has the highest number of apps available [45]. An analysis of iOS, Oppo, and Huawei apps was not undertaken due to difficulties extracting permission data, such as location tracking. Other limitations of this evaluation are that the number of downloads might not be correlated to usage and that some apps might have launched in only a few countries and, therefore, not visible in this screen. Apps were not downloaded for this review, which means some features and screenshots not visible in the description may have been missed. Additionally, usability [44] was not addressed, as it is extremely resource-intensive, especially in the context of growth since some apps are directed towards multiple groups (ie, children, patients, and clinicians). We also did not study elements related to user experiences, such as gamification and personalization. This is something of great importance that has been widely researched in other health areas [7,43].

Additionally, our report on privacy issues is very limited. For example, we did not analyze the privacy policy of the applications. However, clinicians should be aware of recent studies highlighting serious concerns on many health apps [46,47]. Further, clinicians and patients should be aware that available health apps might comply with the regulations in one country and not others.

This evaluation has shown that the vast majority of apps focused on the growth of babies and young children, with far fewer nonpharmacological apps and growth hormone apps available. Patients and caregivers were the target audience for most of the apps. The popularity of care apps for children and growth tracking apps should provide a great channel for potential intervention in childhood health in the future. Families can be empowered through mobile apps as they can monitor height against references [25] and, if taking growth hormone, can monitor their height and adherence in close cooperation with their health care team. Including education about the importance of growth potential and outcomes in childhood, apps could help combat misleading advice in growth apps aimed at adults. Further evaluations should include iOS apps, and a detailed study of the quality of existing health apps related to growth should be undertaken.

Acknowledgments

The authors would like to give a special acknowledgment to Jorge Cancela of Roche, Lausanne, Switzerland, for providing study concepts and classifying the apps. Data collection, data analysis, and editorial support were provided by Ella Palmer, inScience Communications, United Kingdom, and were sponsored by Merck KGaA, Darmstadt, Germany. This analysis was sponsored by Merck KGaA, Darmstadt, Germany. Merck KGaA, Darmstadt, Germany, provided financial support for the conduct of this research and preparation of the article. The sponsor participated in the study design, collection, analysis, and interpretation of the data; in the writing of the report and in the decision to submit the article for publication.

At the time of this study, LFL was an employee of the Qatar Computing Research Institute in Doha, Qatar. Presently, he is affiliated with Salumedia Labs in Sevilla, Spain.

Authors' Contributions

LFL designed the study, extracted, analyzed, and interpreted data, and provided feedback on all drafts. JILA was involved in conceptualizing the study and providing feedback on all drafts. EP analyzed and interpreted data and provided editorial support/feedback on all drafts. EK conceived of the study, analyzed, and interpreted data, and provided feedback on all drafts of the manuscript.

Conflicts of Interest

LFL is a shareholder of Salumedia, which consults with Merck and other pharmaceutical companies. Merck KGaA, Darmstadt, Germany, manufactures growth hormone products and develops and supplies growth hormone devices. EK is an employee of Merck KGaA, Darmstadt, Germany.

Multimedia Appendix 1
Categorization form.
[DOCX File , 47 KB - mhealth_v8i2e16208_app1.docx]

Multimedia Appendix 2
Table A. Apps targeted at a healthcare professional audience. Table B. Apps targeted at a patient/caregiver audience.
[DOCX File , 3904 KB - mhealth_v8i2e16208_app2.docx]

Multimedia Appendix 3
Growth tracking features of growth hormone apps.

[DOCX File , 625 KB - mhealth_v8i2e16208_app3.docx]

Multimedia Appendix 4
Apps with non-pharmacological solutions for growth.
[DOCX File , 417 KB - mhealth_v8i2e16208_app4.docx]

References

1. Xu W, Liu Y. mHealthApps: A Repository and Database of Mobile Health Apps. JMIR Mhealth Uhealth 2015 Mar 18;3(1):e28 [FREE Full text] [doi: 10.2196/mhealth.4026] [Medline: 25786060]
2. IQVIA. 2017 Nov 07. The Growing Value of Digital Health Evidence URL: https://www.iqvia.com/insights/the-iqvia-institute/reports/the-growing-value-of-digital-health [accessed 2020-01-28]
3. Paglialonga A, Lugo A, Santoro E. An overview on the emerging area of identification, characterization, and assessment of health apps. J Biomed Inform 2018 Jul;83:97-102 [FREE Full text] [doi: 10.1016/j.jbi.2018.05.017] [Medline: 29852318]
4. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Mar 11;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]
5. Grundy QH, Wang Z, Bero LA. Challenges in Assessing Mobile Health App Quality: A Systematic Review of Prevalent and Innovative Methods. Am J Prev Med 2016 Dec;51(6):1051-1059. [doi: 10.1016/j.amepre.2016.07.009] [Medline: 27659122]
6. Jongerius C, Russo S, Mazzocco K, Pravettoni G. Research-Tested Mobile Apps for Breast Cancer Care: Systematic Review. JMIR Mhealth Uhealth 2019 Feb 11;7(2):e10930 [FREE Full text] [doi: 10.2196/10930] [Medline: 30741644]
7. Giunti G, Giunta DH, Guisado-Fernandez E, Bender JL, Fernandez-Luque L. A biopsy of Breast Cancer mobile applications: state of the practice review. Int J Med Inform 2018 Feb;110:1-9 [FREE Full text] [doi: 10.1016/j.ijmedinf.2017.10.022] [Medline: 29331247]
8. Giunti G, Guisado Fernández E, Dorronzoro Zubiete E, Rivera Romero O. Supply and Demand in mHealth Apps for Persons With Multiple Sclerosis: Systematic Search in App Stores and Scoping Literature Review. JMIR Mhealth Uhealth 2018 May 23;6(5):e10512 [FREE Full text] [doi: 10.2196/10512] [Medline: 29792295]
9. Giunti G, Kool J, Rivera Romero O, Dorronzoro Zubiete E. Exploring the Specific Needs of Persons with Multiple Sclerosis for mHealth Solutions for Physical Activity: Mixed-Methods Study. JMIR Mhealth Uhealth 2018 Feb 09;6(2):e37 [FREE Full text] [doi: 10.2196/mhealth.8996] [Medline: 29426814]
10. Chomutare T, Fernandez-Luque L, Arsand E, Hartvigsen G. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. J Med Internet Res 2011 Sep 22;13(3):e65 [FREE Full text] [doi: 10.2196/jmir.1874] [Medline: 21979293]
11. Albrecht UV, von Jan U. Medical apps in endocrine diseases - hide and seek. Ther Adv Endocrinol Metab 2014 Apr;5(2):23-33 [FREE Full text] [doi: 10.1177/2042018814539375] [Medline: 25152809]
12. Huckvale K, Prieto JT, Tilney M, Benghozi P, Car J. Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment. BMC Med 2015 Sep 07;13:214 [FREE Full text] [doi: 10.1186/s12916-015-0444-y] [Medline: 26404673]
13. Quevedo Rodríguez A, Wägner AM. Mobile phone applications for diabetes management: A systematic review. Endocrinol Diabetes Nutr 2019 May;66(5):330-337. [doi: 10.1016/j.endinu.2018.11.005] [Medline: 30745121]
14. Zimmeck S, Wang Z, Zou L, Iyengar R, Liu B, Shaub F, et al. Automated Analysis of Privacy Requirements for Mobile Apps. 2017 Presented at: NDSS Symposium 2017; 26 Feb-1 Mar; San Diego, California, United States. [doi: 10.14722/ndss.2017.23034]
15. Osborn CY, van Ginkel JR, Marrero DG, Rodbard D, Huddleston B, Dachis J. One Drop | Mobile on iPhone and Apple Watch: An Evaluation of HbA1c Improvement Associated With Tracking Self-Care. JMIR Mhealth Uhealth 2017 Nov 29;5(11):e179 [FREE Full text] [doi: 10.2196/mhealth.8781] [Medline: 29187344]
16. Karmen CL, Reisfeld MA, McIntyre MK, Timmermans R, Frishman W. The Clinical Value of Heart Rate Monitoring Using an Apple Watch. Cardiology in Review 2019;27(2):60-62. [doi: 10.1097/crd.0000000000000243]
17. Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP, et al. Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. PLoS Med 2017 Sep 19;14(9):e1002389 [FREE Full text] [doi: 10.1371/journal.pmed.1002389] [Medline: 28926573]
18. Dunn TC, Xu Y, Hayter G, Ajjan RA. Real-world flash glucose monitoring patterns and associations between self-monitoring frequency and glycaemic measures: A European analysis of over 60 million glucose tests. Diabetes Res Clin Pract 2018 Mar;137:37-46 [FREE Full text] [doi: 10.1016/j.diabres.2017.12.015] [Medline: 29278709]
19. Savage MO, Backeljauw PF, Calzada R, Cianfarani S, Dunkel L, Koledova E, et al. Early Detection, Referral, Investigation, and Diagnosis of Children with Growth Disorders. Horm Res Paediatr 2016 Apr 8;85(5):325-332. [doi: 10.1159/000444525] [Medline: 27055026]

20. Scherdel P, Dunkel L, van Dommelen P, Goulet O, Salaün J, Brauner R, et al. Growth monitoring as an early detection tool: a systematic review. The Lancet Diabetes & Endocrinology 2016 May;4(5):447-456. [doi: 10.1016/s2213-8587(15)00392-7]
21. van Dommelen P, Koledova E, Wit JM. Effect of adherence to growth hormone treatment on 0-2 year catch-up growth in children with growth hormone deficiency. PLoS One 2018 Oct 24;13(10):e0206009 [FREE Full text] [doi: 10.1371/journal.pone.0206009] [Medline: 30356273]
22. Koledova E, Stoyanov G, Ovbude L, Davies PSW. Adherence and long-term growth outcomes: results from the easypod connect observational study (ECOS) in paediatric patients with growth disorders. Endocr Connect 2018 Aug;7(8):914-923 [FREE Full text] [doi: 10.1530/EC-18-0172] [Medline: 29976785]
23. Lion F. Electronic Recording of Growth Hormone Dosing History: The Easypod™ Auto-Injector. CDTH 2010 Nov 01;5(4):271-276. [doi: 10.2174/157488510792927474]
24. Loftus J, Lindberg A, Aydin F, Gomez R, Maghnie M, Rooman R, et al. Individualised growth response optimisation (iGRO) tool: an accessible and easy-to-use growth prediction system to enable treatment optimisation for children treated with growth hormone. J Pediatr Endocrinol Metab 2017 Oct 26;30(10):1019-1026. [doi: 10.1515/jpem-2017-0120] [Medline: 28902629]
25. WHO Multicentre Growth Reference Study Group. World Health Organization. 2006. WHO Child Growth Standards: Length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index-for-age: methods and development, (2006) URL: http://www.who.int/childgrowth/standards/technical_report/en/ [accessed 2020-01-28]
26. Sankilampi U, Saari A, Laine T, Miettinen PJ, Dunkel L. Use of electronic health records for automated screening of growth disorders in primary care. JAMA 2013 Sep 11;310(10):1071-1072. [doi: 10.1001/jama.2013.218793] [Medline: 24026604]
27. Rompikuntal PK, Vdovikova S, Duperthuy M, Johnson TL, Åhlund M, Lundmark R, et al. Outer Membrane Vesicle-Mediated Export of Processed PrtV Protease from Vibrio cholerae. PLoS One 2015 Jul 29;10(7):e0134098 [FREE Full text] [doi: 10.1371/journal.pone.0134098] [Medline: 26222047]
28. Mendiola MF, Kalnicki M, Lindenauer S. Valuable features in mobile health apps for patients and consumers: content analysis of apps and user ratings. JMIR Mhealth Uhealth 2015 May 13;3(2):e40 [FREE Full text] [doi: 10.2196/mhealth.4283] [Medline: 25972309]
29. Zhang M, Ying J, Song G, Fung DS, Smith H. Attention and Cognitive Bias Modification Apps: Review of the Literature and of Commercially Available Apps. JMIR Mhealth Uhealth 2018 May 24;6(5):e10034 [FREE Full text] [doi: 10.2196/10034] [Medline: 29793899]
30. Google Play. Browse our go to apps. URL: https://play.google.com/store/apps?hl=en [WebCite Cache ID 75La36uMI]
31. GitHub. 2019 Jul. 42Matters-webscraper URL: https://github.com/jose-javier-flors-sidro/42Matters-webscraper [accessed 2020-01-28]
32. Cohen J. Weighted kappa: nominal scale agreement with provision for scaled disagreement or partial credit. Psychol Bull 1968 Oct;70(4):213-220. [doi: 10.1037/h0026256] [Medline: 19673146]
33. Google Forms. URL: https://docs.google.com/forms/u/0/ [accessed 2020-01-28]
34. Lifshitz F. Nutrition and growth. J Clin Res Pediatr Endocrinol 2009 Jun 05;1(4):157-163 [FREE Full text] [doi: 10.4274/jcrpe.v1i4.39] [Medline: 21274290]
35. Paige SR, Stellefson M, Krieger JL, Anderson-Lewis C, Cheong J, Stopka C. Proposing a Transactional Model of eHealth Literacy: Concept Analysis. J Med Internet Res 2018 Oct 02;20(10):e10175 [FREE Full text] [doi: 10.2196/10175] [Medline: 30279155]
36. Lopez Segui F, Pratdepadua Bufill C, Abdon Gimenez N, Martinez Roldan J, Garcia Cuyas F. The Prescription of Mobile Apps by Primary Care Teams: A Pilot Project in Catalonia. JMIR Mhealth Uhealth 2018 Jun 21;6(6):e10701 [FREE Full text] [doi: 10.2196/10701] [Medline: 29929948]
37. Dawson LA. What factors affect adherence to medicines? Arch Dis Child Educ Pract Ed 2019 Feb 27;104(1):49-52. [doi: 10.1136/archdischild-2017-312820] [Medline: 29374624]
38. Graham S, Weinman J, Auyeung V. Identifying Potentially Modifiable Factors Associated with Treatment Non-Adherence in Paediatric Growth Hormone Deficiency: A Systematic Review. Horm Res Paediatr 2018 Dec 6;90(4):221-227 [FREE Full text] [doi: 10.1159/000493211] [Medline: 30522126]
39. Maggio MC, Vergara B, Porcelli P, Corsello G. Improvement of treatment adherence with growth hormone by easypod™ device: experience of an Italian centre. Ital J Pediatr 2018 Sep 27;44(1):113 [FREE Full text] [doi: 10.1186/s13052-018-0548-z] [Medline: 30261918]
40. Avdiienko V. Mining apps for abnormal usage of sensitive data. 2015 Presented at: 2015 IEEE/ACM 37th IEEE International Conference on Software Engineering; 16-24 May; Florence, Italy. [doi: 10.1109/icse.2015.285]
41. Vu PM, Nguyen TT, Pham HV, Nguyen TT. Mining User Opinions in Mobile App Reviews: A Keyword-Based Approach (T). In: IEEE. 2015 Presented at: 2015 30th IEEE/ACM International Conference on Automated Software Engineering (ASE); 9-13 Nov; Lincoln, Nevada, United States. [doi: 10.1109/ase.2015.85]
42. Gorla A, Tavecchia I, Gross F, Zeller A. Checking app behavior against app descriptions Share on. 2014 Presented at: ICSE 2014: Proceedings of the 36th International Conference on Software Engineering; May; Hyderabad, India.

43. Giunti G, Giunta DH, Hors-Fraile S, Isomursu M, Karoseviciute D. Detecting Gamification in Breast Cancer Apps: an automatic methodology for screening purposes. 2017 Presented at: 2017 IEEE 30th International Symposium on Computer-Based Medical Systems (CBMS); 22-24 Jun; Thessaloniki, Greece. [doi: 10.1109/cbms.2017.21]
44. Bakiu E, Guzman E. Which Feature is Unusable? Detecting Usability and User Experience Issues from User Reviews. 2017 Presented at: 2017 IEEE 25th International Requirements Engineering Conference Workshops (REW); 4-8 Sept; Lisbon, Portugal. [doi: 10.1109/rew.2017.76]
45. Statista. 2019. Number of apps available in leading app stores as of 4th quarter URL: https://www.statista.com/statistics/276623/number-of-apps-available-in-leading-app-stores/ [accessed 2020-01-28]
46. Dehling T, Gao F, Schneider S, Sunyaev A. Exploring the Far Side of Mobile Health: Information Security and Privacy of Mobile Health Apps on iOS and Android. JMIR Mhealth Uhealth 2015 Jan 19;3(1):e8 [FREE Full text] [doi: 10.2196/mhealth.3672] [Medline: 25599627]
47. Müthing J, Brüngel R, Friedrich CM. Server-Focused Security Assessment of Mobile Health Apps for Popular Mobile Platforms. J Med Internet Res 2019 Jan 23;21(1):e9818 [FREE Full text] [doi: 10.2196/jmir.9818] [Medline: 30672738]

Edited by G Eysenbach; submitted 10.09.19; peer-reviewed by JL Fernández-Alemán, A Martinez-Millana; comments to author 28.10.19; revised version received 11.12.19; accepted 16.12.19; published 18.02.20.

Please cite as:
Fernandez-Luque L, Labarta JI, Palmer E, Koledova E
Content Analysis of Apps for Growth Monitoring and Growth Hormone Treatment: Systematic Search in the Android App Store
JMIR Mhealth Uhealth 2020;8(2):e16208
URL: http://mhealth.jmir.org/2020/2/e16208/
doi:10.2196/16208
PMID:32130162

Original Paper

A Mobile App (mHeart) to Detect Medication Nonadherence in the Heart Transplant Population: Validation Study

Mar Gomis-Pastor[1,2], DPharm; Eulalia Roig[2,3*], MD, PhD; Sonia Mirabet[2*], MD, PhD; Jan T De Pourcq[4], DPharm; Irene Conejo[4], DPharm; Anna Feliu[4], PhD, DPharm; Vicens Brossa[2], MD; Laura Lopez[2], MD; Andreu Ferrero-Gregori[5], BSc; Anna Barata[6], DClinPsych; M Antonia Mangues[4], PhD, DPharm

[1]Pharmacy Department, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

[2]Heart Failure and Heart Transplant Unit, Cardiology Department, Hospital de la Santa Creu i Sant Pau, Barcelona, Catalonia, Spain

[3]Medicine Department, Autonomous University of Barcelona (UAB), Barcelona, Catalonia, Spain

[4]Pharmacy Department, Hospital de la Santa Creu i Sant Pau, Barcelona, Catalonia, Spain

[5]Institute of Biomedical Research IIB Sant Pau, Biomedical Research Networking Center on Cardiovascular Diseases (CIBERCV), Universitat Autonoma de Barcelona, Barcelona, Catalonia, Spain

[6]Moffitt Cancer Center, Florida, FL, United States

[*]these authors contributed equally

Corresponding Author:
Mar Gomis-Pastor, DPharm
Pharmacy Department
Hospital de la Santa Creu i Sant Pau
San Quintin nº89 PC 08041
Barcelona, 08026
Spain
Phone: 34 636060364
Email: mar@margomis.com

Abstract

Background: Medication nonadherence in heart transplant recipients (HTxR) is related to graft loss and death. mHeart is a mobile app that uses electronic patient-reported outcome measures (ePROMs) to identify and manage medication nonadherence in the outpatient heart transplant (HTx) population.

Objective: The study primarily aimed to validate mHeart to measure medication nonadherence in early stage HTxR by assessing the psychometric properties of ePROMs. The secondary aims were to (1) measure patient satisfaction with the mHeart tool and its usability and (2) explore the impact of a theory-based treatment on medication nonadherence rates to determine its scalability to larger research.

Methods: A prospective study was conducted in the outpatient clinic of a tertiary hospital. All consecutive early stage HTxR (<1.5 years from HTx) were included. The ePROM psychometric properties assessed were validity, reliability, responsiveness, interpretability, and burden. ePROMs comprised the 4-item Morisky-Green-Levine questionnaire and an adapted version of the Haynes-Sackett questionnaire. The Simplified Medication Adherence Questionnaire (SMAQ) was also applied on-site. Three consecutive medication nonadherence assessments were performed by a transplant pharmacist. To improve medication nonadherence, theory-based interventions were delivered in a 1-month period. Patient satisfaction was assessed by a semiquantitative Web-based survey at the end of the study.

Results: We included 31 early stage HTxR (age: mean 54 years, SD 12 years), and 71% (22/31) of them were men. The HTxR were taking a mean 13 (SD 4; range 7-18) drugs per day. A total of 42% (13/31) of patients were unaware of the consequences of medication nonadherence, and 39% (12/31) of patients were nonadherent to immunosuppressive treatment. The content validity measure showed excellent levels of expert panel agreement for the Haynes-Sacket (14/14, 100%) and Morisky-Green-Levine (13/14, 93%) questionnaires. SMAQ and Morisky-Green-Levine ePROMs showed similar measurement domains (convergent validity, phi=0.6, P<.001), which, as expected, differed from Haynes-Sackett ePROMs (divergent validity, phi=0.3, P=.12). Reliability assessment revealed a very strong association between ePROM and on-site PROMs (phi>0.7, P<.001). Reproducibility was moderate (Haynes-Sackett κ=0.6, P<.002) or poor (Morisky-Green-Levine κ=0.3, P=.11) because of unexpected improved medication adherence rates during the test-retest period. According to responsiveness, the theory-based multifaceted intervention

program improved medication nonadherence by 16% to 26% (P<.05). A burden analysis showed that ePROMs could potentially overcome traditional on-site limitations (eg, automatic recording of ePROM responses in the hospital information system). The mean score for overall patient satisfaction with the mHeart approach was 9 (SD 2; score range: 0-10). All 100% (29/29) of patients surveyed reported that they would recommend the mHeart platform to other HTxR.

Conclusions: ePROMs adhered to the quality standards and successfully identified medication nonadherence in the HTx population, supporting their widespread use. The theory-based intervention program showed a promising improvement in medication adherence rates and produced excellent patient satisfaction and usability scores in HTxR.

(JMIR Mhealth Uhealth 2020;8(2):e15957) doi:10.2196/15957

KEYWORDS

self-report; patient-reported outcome measures; behavioral sciences; treatment adherence and compliance; transplantation; early medical intervention; telemedicine; mobile health; validation studies; patient satisfaction

Introduction

Background

Heart transplant recipients (HTxR) require lifelong immunosuppressive therapy to prevent rejection episodes. The estimated percentage of medication nonadherence to immunosuppressive treatment after heart transplant (HTx) ranges from 15% to 30% [1]. These rates are worrisome as medication nonadherence impairs quality of life, increases health costs, and is a direct cause of graft loss and death after HTx [1-6].

Medication nonadherence in the HTx population is a dynamic behavior influenced by multilevel patient, provider, and health system factors [7]. To improve medication adherence, it is essential to frequently monitor medication nonadherence and identify modifiable risk factors for medication nonadherence, such as high therapeutic complexity, weak professional-patient relationship, and lack of patient motivation [4,5,7,8].

Subjective methods to evaluate medication adherence, such as self-reporting, are widely used [9] and well correlated with objective methods (eg, immunosuppressive drug level assay or electronic monitoring systems) [5,10]. Indeed, self-reporting is considered the best method to capture patient experiences and individual risk factors for medication nonadherence, such as patients' medication beliefs [11]. However, this method involves in-clinic facilities and requires patients to travel to the clinic [5].

Emerging research indicates that patient-reported adherence through mobile devices produces data of similar quality to those provided by traditional in-clinic methods [12]. Therefore, the use of electronic patient-reported measures (ePROMs) to detect nonadherent HTxR could help increase the feasibility of self-reporting and overcome current in-clinic limitations [13,14].

Medication adherence ePROMs could also provide valuable information to care providers to implement early and personalized interventions through mobile health technology. Indeed, internet interventions (ie, "treatments, typically behaviorally based, that are operationalized and transformed for delivery via the Internet") [13,15-17] show a promising impact on prompting changes in health behaviors such as medication adherence [15,16,18-20].

Behavior-based theories with demonstrated effectiveness in reducing medication nonadherence are recommended to be combined when a new intervention program is designed [21,22]. Moreover, motivational interviewing is a useful tool for professionals to deliver such theory-based interventions in the transplant population [23,24]. Although these behavior change techniques are increasingly used, there is a lack of studies applying them to internet interventions in the HTx population [2,25,26].

Previous Work

The mHeart medical device is a mobile app that is primarily intended to measure and manage medication adherence in outpatient HTxR. mHeart was designed to use ePROMs to identify medication nonadherence in the home setting and facilitate behavior change interventions to improve medication nonadherence rates. According to the directions for the International Society for Research on Internet Interventions (ISRII) [13], a prerequisite before recommending the widespread use of internet delivery is to demonstrate the accuracy of ePROM scores and their relationship with traditional in-clinic methods [27]. Moreover, the workflow of any new electronic behavior-based intervention designed to manage medication nonadherence should be tested before scaling it to larger research [28].

Study Objectives

The primary aim of this study was to validate mHeart to measure medication nonadherence in early stage HTxR in the home setting. To do this, we sought to identify the quality of the psychometric properties of the ePROMs reported as being critical in electronic health behavior change instruments [29,30], that is, validity, reliability, responsiveness, interpretability, and burden [31].

The secondary aims were (1) to measure patient satisfaction with mHeart and its usability and (2) to explore the impact of theory-based interventions on medication nonadherence rates among HTxR to determine the hypothetical scalability of the treatment within the context of a larger research study.

Methods

Study Design and Setting

This prospective research study was conducted in the ambulatory setting of a Heart Failure and Transplant Unit of a tertiary

university hospital from July 15, 2016, to December 1, 2016. The study was approved by the institutional review board of the hospital (IIBSP-MHE-2014-55). The participants were informed of the study purposes, the length of the follow-up, all the procedures, and the research team behind the study. Written informed consent was obtained from all participants.

Study Reporting Guidelines

The psychometric quality of the ePROMs was based on the Scientific Advisory Committee of the Medical Outcomes Trust (SAC-MOS) [31] and the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) consensus guideline [30]. The quality of the results obtained was compared with the International Society for Quality of Life Research (ISOQOL) standards [11].

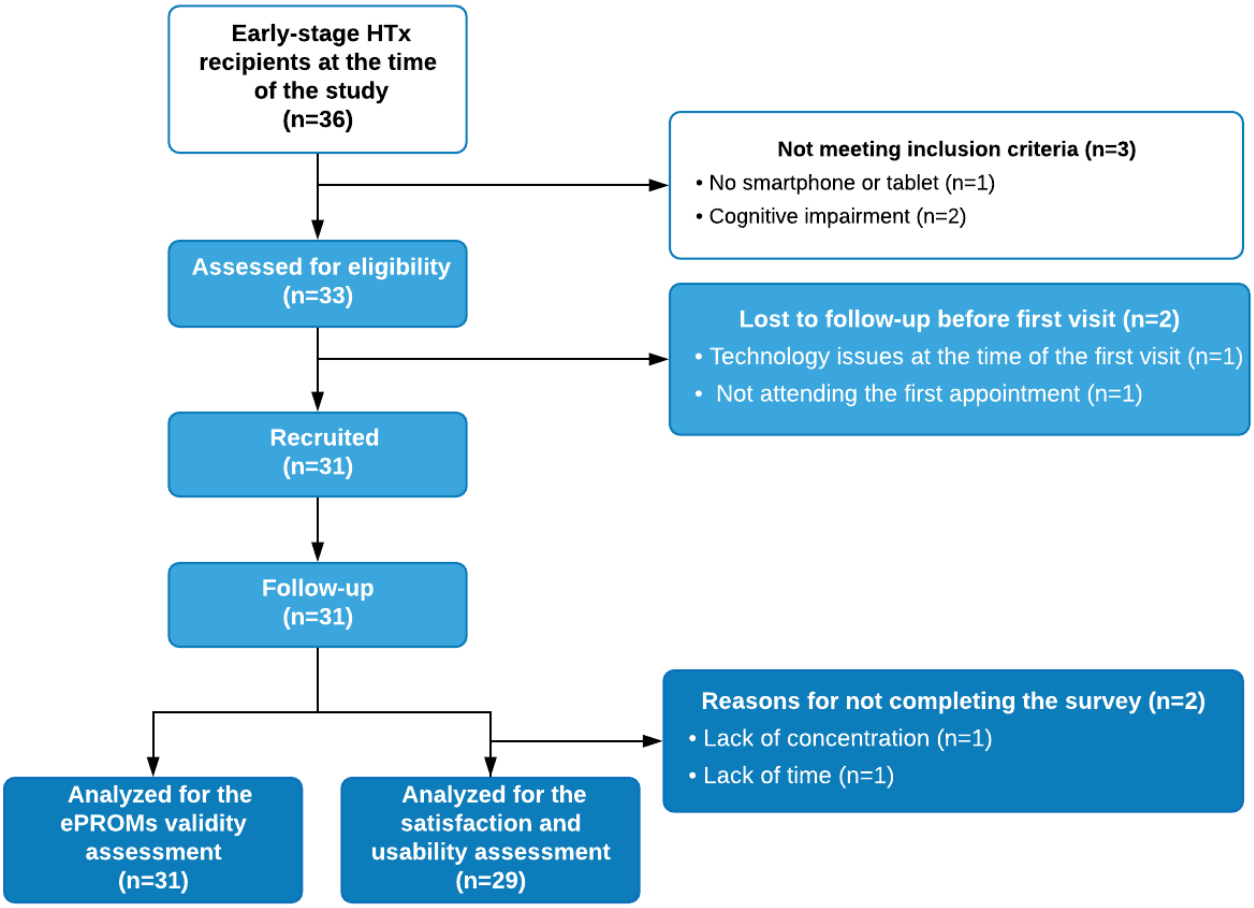
We followed the European Society for Patient Adherence, COMpliance, and Persistence Medication Adherence Reporting Guideline (EMERGE) [28] recommended criteria for transparent and accurate medication adherence reporting data. The directions for the ISRII [13] and the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and OnLine TeleHealth (CONSORT-EHEALTH) guidelines (section 5) [17] were followed to report the internet-based intervention program. The Theory Coding Scheme (TCS) [32] provided a reliable method to describe the theory underpinning the interventions.

In addition, the Checklist for Reporting Results of Internet E-Surveys [33] was applied to ensure the quality of reporting of the Web-based satisfaction survey.

Sample

Enrollment was conducted from July 21, 2016, to October 26, 2016, in the Cardiology Outpatient Clinic by transplant physicians during routine in-clinic appointments. All consecutive adult, early stage HTxR (less than 1.5 years from HTx) owning a smartphone and with no cognitive impairment were included. Cognitive impairment was defined as any condition limiting patients' ability, including memory and thinking skills, to use the mHeart system and complete the questionnaires. No previous computer or smartphone knowledge was required. HTxR did not receive any financial compensation, a phone, or wearables for their participation. The patient flowchart is shown in Figure 1.

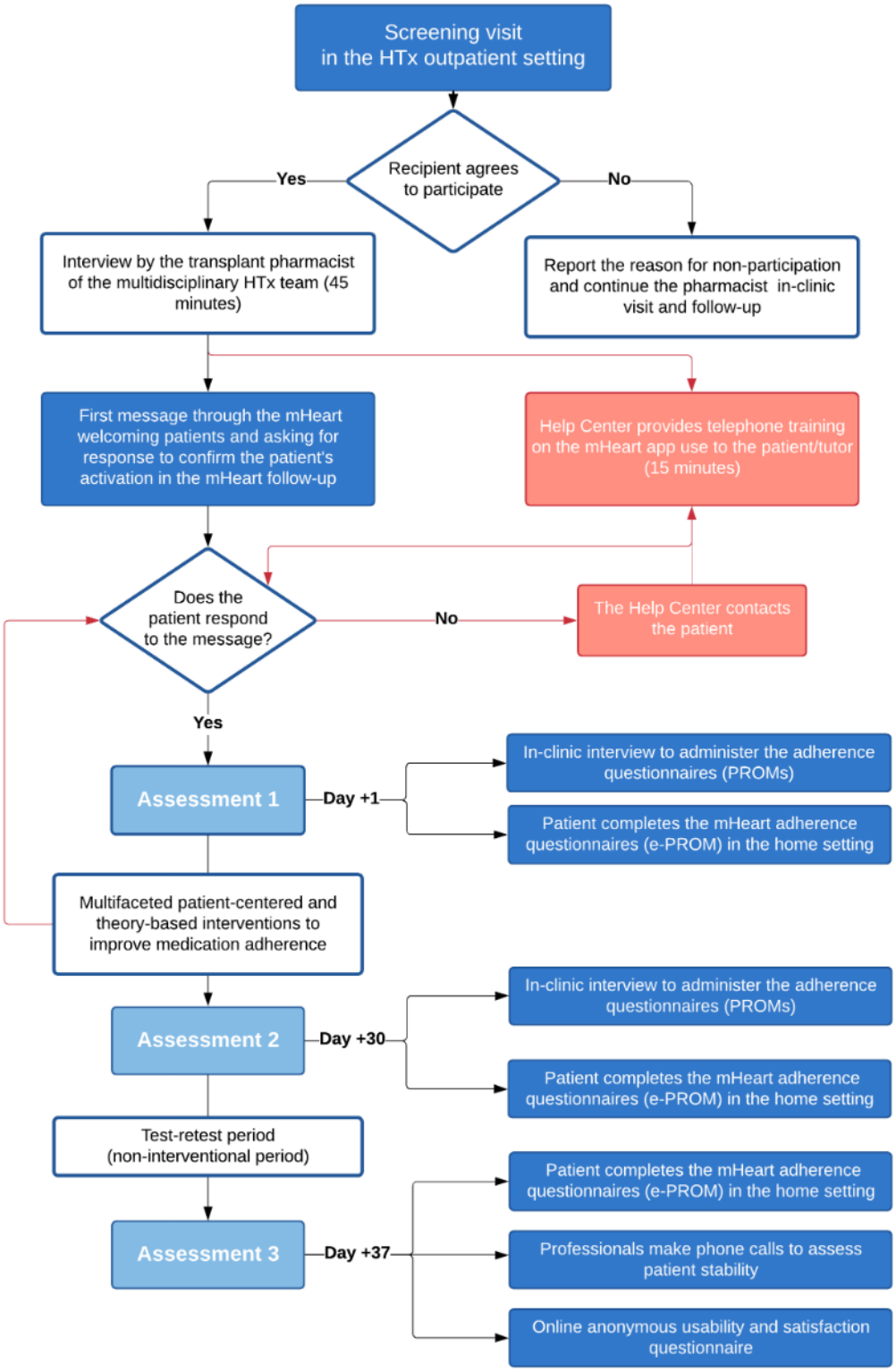
Figure 1. Val-mHeart study patient flowchart. Early-stage: <1.5 years from HTx; ePROMs: electronic patient-reported outcome measures; HTx: heart transplant.



Study Procedures

The algorithm summarizing the procedures is shown in Figure 2. After signing the informed consent form, all patients were assessed for eligibility (ie, the same day as enrollment by the physicians), and they completed a baseline face-to-face visit with the transplant pharmacist, followed by an initial mHeart training session.

Figure 2. Intervention algorithm summarizing the procedures performed throughout the study period. ePROM: electronic patient-reported outcome measure; HTx: heart transplant; PROMs: patient-reported outcome measures.



The interview with the pharmacist lasted approximately 45 min. Sociodemographic and clinical data were extracted from patients' electronic health records. The data were collected in a form provided in Multimedia Appendices 1 and 2. At the end of the visit, the pharmacist registered the new patient's profile in the mHeart system. Patient access was facilitated by an automated message sent to the patient's phone with a username and password.

Thereafter, a technical mHeart initial setup was provided by the mHeart Help Center of the private firm developing the technology. This session was conducted by telephone and lasted at least 15 min to enable at-home monitoring, that is, (1) downloading the app from the app store, (2) guiding the first access, and (3) providing training on the functionalities of the mHeart platform. This service was also responsible for query resolution and user assistance throughout the study.

As soon as the HTxR had received training, the transplant pharmacist sent them a welcome message through mHeart, requesting the patients' response to confirm their activation in the mHeart follow-up. Once the patients had responded to this message, three consecutive assessments were scheduled. The assessment procedures are described below, and these were conducted to measure the validity properties of the ePROMs.

Assessment 1

After the baseline visit (ie, on the same day), medication adherence was measured by the pharmacist using in-clinic patient-reported outcome measures (PROMs; Multimedia Appendix 2). No other interventions were performed to manage medication adherence during this in-clinic interview. On the same day, using the mHeart tool, patients were asked to complete the same ePROMs in the home setting.

During the 1-month period between assessments 1 and 2, multifaceted theory-based interventions were provided through mHeart to optimize adherence management [34]. The electronic interventions were interactive, with additional human support from the transplant pharmacist through the mHeart platform. The interventions were individually tailored, based on electronic patient-reported data. Several behavior change techniques [21,22] were used based on those with the strongest evidence base in medication adherence, such as social cognitive theory, the health belief model, transtheoretical model, and self-regulation model. Among others, less often reported but also used are the information-behavior-skill model, self-management theory, behavior modification theory, and problem-solving theory [22]. The techniques were based on Michie's taxonomy [35] and were delivered using motivational interviewing [23,24] as a common practice pattern to improve posttransplant medication adherence in HTx centers [9]. Interactive elements were also used as digital triggers to counter the law of attrition: alerts, prompts, reminders, notifications, messages, logs, reports, visualizations, and video calls [36,37]. The theoretical framework, the behavior change intervention techniques used, and the intervention workflow are fully described in Multimedia Appendix 3.

Assessment 2

Once the intervention program period finished, at least 30 days after assessment 1, the pharmacist conducted an in-clinic interview to perform the second medication adherence PROMs assessment. On the same day, the HTxR were also asked to complete the ePROMs in the home setting.

Thereafter, to allow the test-retest reliability analysis, the patients used mHeart for 7 days without any additional interventions by the pharmacist or contact with the HTx team. At the end of the reproducibility time interval, the patients were telephoned by the pharmacist to confirm clinical and therapeutic stability.

Assessment 3

After the test-retest reliability analysis, HTxR were asked to electronically complete the mHeart ePROMs and the satisfaction and usability survey.

mHeart Features Used During the Study

The mHeart medical device is a home-based mobile phone app complemented by a website [38]. From a technical point of view, access to the tool is multiplatform (ie, smartphone, tablet, or computer), and it can be downloaded for free from app stores [39,40]. mHeart is bidirectionally integrated with the hospital information system (HIS) using encrypted data. This integration between the two systems allows mHeart to directly obtain sociodemographic data from the HIS. In addition, mHeart uploads a weekly clinical report to the HIS, including all the data reported by the patients on the platform. The general layout is represented in Figure 3. An in-depth description of the technical specification of the system and the source code are provided in the online Mendely (Dataset) [41]. The version number of the app used was 3.0.2, and the content was frozen during the study.

From a clinical point of view, the mHeart tool was designed to primarily manage medication nonadherence using several features (Table 1). In addition, three of the subfunctionalities of the platform were to (1) resolve patients' queries about their treatment and health condition, (2) empower patients in terms of self-care, and (3) facilitate professionals' interventions based on patient-reported outcomes (ie, symptoms and adverse effects of drugs, heart rate, glycemia, weight, and blood pressure). A detailed demonstration of the clinical use of mHeart in HTxR can be found in a video format in Multimedia Appendix 4. More details about functionalities are also provided in the online Mendely (Dataset) [41].

Figure 3. The mHeart functional layer and cloud architecture. AWS: Amazon Web Services; BI: business intelligence; HIS: hospital information system; HL7: high level-7; LOPD: the Spanish Organic Data Protection Law; WS: Web server.

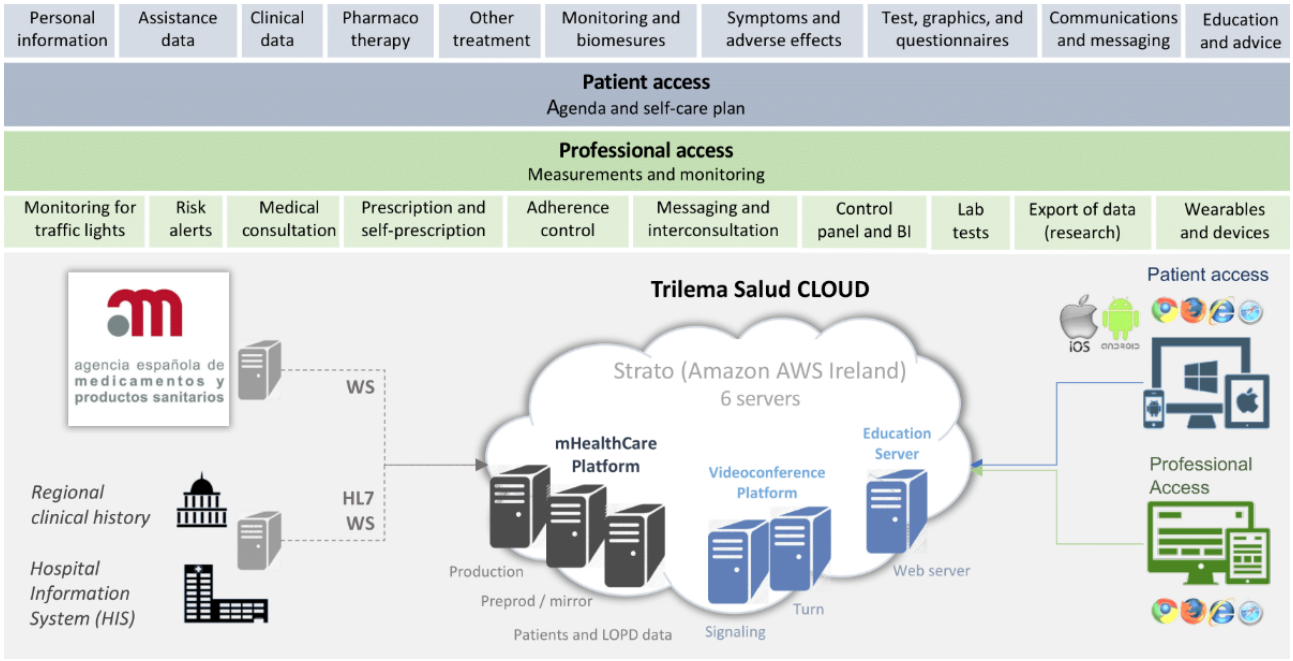


Table 1. mHeart platform features related to medication adherence management.

Features	Descriptions
Patient drug intakes	Push text reminds patients of medication intakes on their mobile phone. Patients can accept or reject the intakes scheduled. If a patient cancels a dose, they are asked to specify their reason for doing so on a checklist. Doses taken versus the total number of doses prescribed can be tracked. • A *traffic light* system warns the professional of a decrease in the patient's weekly adherence. • Detailed data are presented for patients and professionals in tables or graphs, including reasons for not taking medication.
Medication adherence ePROMs[a]	The ePROMs included to detect MNA[b] are the 1-item Haynes-Sackett questionnaire [42,43] adapted to the mHeart platform and the 4-item Morisky-Green-Levine questionnaire [44]. The professional sets up the frequency of the electronic questionnaire on the patient's diary. Push text alerts on the phone remind the patient to perform the programmed task. Test results are shown in tables and graphs to patients and professionals directly from the HIS[c] or the mHeart platform website.

[a]ePROM: electronic patient-reported outcome measure.

[b]MNA: medication nonadherence.

[c]HIS: hospital information system.

Measurement Variables

Medication Adherence Measures

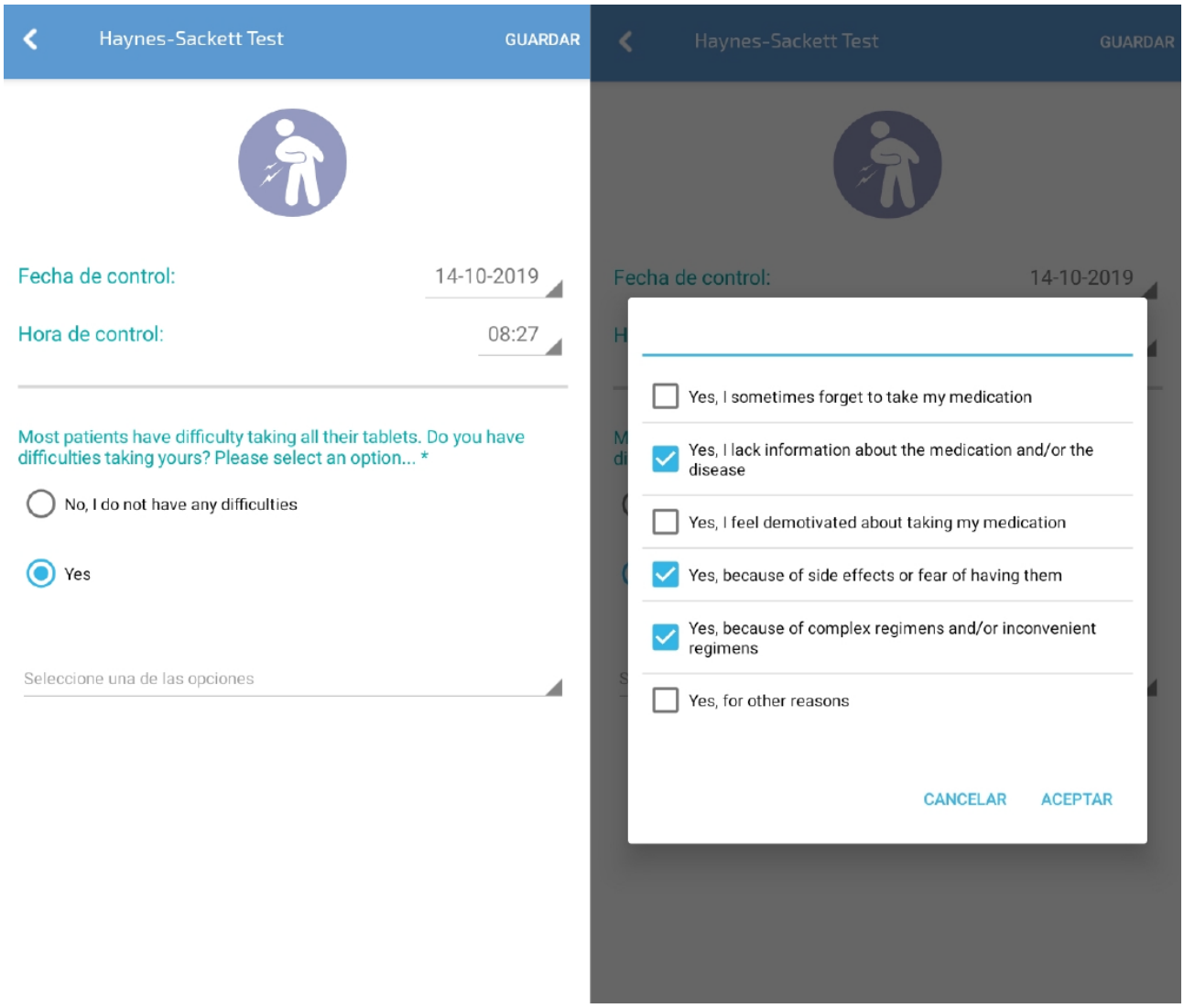
On the basis of the Ascertaining Barriers to Compliance taxonomy, medication adherence is divided into three phases: initiation, implementation, and persistence [34]. In this study, we focused on assessing the implementation phase of medication nonadherence by using self-reported instruments. Medication nonadherence implementation is defined as "the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen" (ie, omitting single or consecutive doses, delays in medication intakes, or self-initiated dose changes such as a reduction or increase in dosing). Poor regularity of intakes refers to delays up to 2 hours in the transplant population [45,46]. Medication nonadherence measured by the questionnaires below was defined as any response to items with an answer indicating nonadherence.

The ePROM validity study was based on two questionnaires implemented in the mHeart tool. First, the Morisky-Green-Levine questionnaire is a 4-item scale [44] assessing patients' medication-taking habits. In transferring the questionnaire to an electronic format, we implemented an exact copy of the Spanish validated version [47]. Second, the Haynes-Sackett questionnaire [42,43] is a 1-item scale asking patients whether they have any difficulty with their treatment. In transferring this questionnaire to an electronic format, we

implemented the Spanish version [48] and added six multiple-choice responses on patients' difficulties with medication [49] to improve providers' understanding of nonadherence (Figure 4 and Multimedia Appendix 5). In both mHeart questionnaires, the items can be answered using Yes or No checkboxes.

For the convergent and discriminant validity assessment, we used the Simplified Medication Adherence Questionnaire (SMAQ) Spanish version as the standard instrument. This questionnaire is a 6-item scale validated in the transplant population receiving immunosuppressive treatment [50]. To identify medication nonadherence risk factors [10], patients were also asked about (1) the knowledge of their regimen, (2) their opinion of the inconvenience of their medication regimens, (3) the importance of the immunosuppressive treatment, and (4) the adverse effects (Multimedia Appendix 3).

Figure 4. Electronic version of the Haynes-Sackett questionnaire, including 6 additional responses by patients to aid provider understanding of their difficulties with medication adapted for use with the mHeart platform. The score is based on the item 1 response: No (adherent) or Yes (nonadherent).



Patient Satisfaction and Usability

Patient satisfaction with the mHeart intervention program and the usability of the tool were assessed by a Web-based nonvalidated survey created for the study using the *Google Forms* tool. The survey items comprised 8 qualitative and 17 semiquantitative (score range: 0-10) questions (original version in Multimedia Appendix 6). No personal information was collected. Adaptive questioning was used to reduce the complexity of the survey. In addition, all items had a *no response* option, and no blank items were allowed. Respondents were able to review and change their answers before submitting their responses.

The survey was closed to the study participants. The participants were sent an mHeart message by a clinical pharmacist who was different from the transplant pharmacist in charge of the follow-up. The patients had no previous interaction with this provider. The message content comprised an invitation to complete the opinion survey to help the team and developers improve the usability and clinical use of the tool. The patients were assigned a random number from 1 to 31. The survey was voluntary, and no incentives were offered for participation. The patients had 1 week to complete the survey before it was closed to new responses. A reminder was sent to all the HTxR 3 days after the invitation was issued. HTxR accessed the survey through a link uploaded to their mHeart personal profile. Survey

completion was permitted by the *Google Form* tool when participants provided their identification number to avoid multiple entries.

The responses and the survey completion rate (ie, the ratio of users who finished the survey/users who agreed to participate) [33] were analyzed in depth. The completion time by participants was not determined.

Psychometric Variables to Assess Electronic Patient-Reported Outcome Measure Validity

The psychometric quality of the ePROMs was assessed in terms of validity, reliability, responsiveness, interpretability, and burden [30,31]. The validation measures and methodology are detailed in Multimedia Appendix 7 and briefly described in Table 2.

Table 2. Brief description of the validity properties assessed for the mHeart medication adherence electronic patient-reported outcome measures.

Validity properties	Description[a]
Content validity	The interrater agreement among an expert panel was performed to assess the following three content validity aspects. The expert panel comprised 14 health professionals, including 3 nurses, 7 cardiologists, and 4 clinical pharmacists. • The suitability of the questionnaires proposed for inclusion in the mHeart app. The discussion was verbal, and voting was by hand. • The suitability of the ePROMs[b] compared with the traditional in-clinic version. After written records were taken, a verbal discussion was held. • The suitability of the six medication difficulties added to the electronic version of the Haynes-Sacket questionnaire. After written records were taken, a verbal discussion was held.
Convergent and discriminant validity	Convergent and discriminant validity were assessed using the following aspects: • The correlation between the ePROM rates and a standard questionnaire was assessed. • The complementarity of the adherence to medication domains of the ePROMs included in the mHeart system was measured.
Reliability (reproducibility)	Reliability and reproducibility were assessed using two methods with different purposes: • The equivalent forms reliability method was used to assess the adequate association between the ePROMs scores and the in-clinic scores. With this aim, the PROMs were assessed in the same group of patients and on the same day. • The test-retest reliability method was used to assess the stability of the ePROM scores during a short time period (7 days) in clinically stable patients.
Responsiveness (sensitivity to change)	Change over time in medication adherence was measured by the difference in ePROM scores while a theory-based intervention program was performed. A 1-month interval was considered adequate to measure the validity of an indirect smartphone measure [51,52].
Interpretability	Three aspects of the interpretability property were analyzed and discussed: • The interpretation of the ePROM scores. • The meaningful change detected. • The scores obtained versus those published by other authors.
Respondent and administrative burden	Several criteria[a] were assessed regarding the time, effort, and other criteria of the ePROMs, depending on the respondents' and administrative points of view.

[a]Full details on validity properties assessed are provided in Multimedia Appendix 7.

[b]ePROM: electronic patient-reported outcome measure.

Statistical Analyses

Descriptive Analysis

Categorical variables are expressed as the number of cases and their percentages, whereas quantitative variables are expressed as mean and SD. Ordinal and quantitative variables not showing normal distribution are expressed as the median and quartiles. McNemar test was used on paired nominal data to determine whether the row and column marginal frequencies were equal. The level of significance was <5% (alpha<.05), bilateral approximation. All analyses were performed using the SPSS version 22.0 (IBM, Armonk, New York) and the R version 3.5.1 (R Project for Statistical Computing, Vienna, Austria).

Validity Analysis

The statistical methods used in the validation study are fully detailed in Multimedia Appendix 7. To estimate the interrater agreement measures, an agreement >75% of the expert panel was considered adequate [53]. The one-sample proportion test with continuity correction was applied. Association was measured by the *phi coefficient* (values range from 1 to +1). Phi values above 0.7 are interpreted as showing a very strong association, from 0.4 to 0.69 are interpreted as strong, from 0.3 to 0.39 are interpreted as moderate, from 0.2 to 0.29 are interpreted as weak, and from <0.19 to <0.001 are interpreted as showing no association [53,54]. Agreement was assessed by the *kappa coefficient* (values range from 1 to +1). Kappa values >0.75 are interpreted as strong agreement, from 0.4 to 0.75

indicate moderate agreement, and <0.40 indicate poor agreement [53,55]. In general, values of reliability coefficients >0.80 indicate excellent agreement [56].

Sample Size

In this finite population of early stage HTxR, we used a 5 subject-to-variable ratio rule [57]. Therefore, a sample size greater than or equal to 25 participants for a total of 5 items (1-item Haynes-Sackett and 4-item Morisky-Green-Levine questionnaire) was considered the minimum sample required.

To assess validity, reliability (equivalent forms method), responsiveness, interpretability, and burden, we included the entire sample in the analysis. For the test-retest reproducibility study, we included HTxR who remained stable for 7 days [31]. Stability was defined as the absence of need for medication changes or health center consultation and the absence of any symptoms different from those present at the last clinical evaluation.

Results

Participant Characteristics

A total of 31 early stage HTxR were included (age: mean 54 years, SD 12 years) and analyzed, and no attrition was observed (Figure 1). In all, 71% (22/31) of participants were men. The mean follow-up was 2.3 (SD 0.9) months. The mean time between HTx and the study was 1.2 years (SD 0.8 years). The patients' demographic and clinical characteristics are detailed in Multimedia Appendix 8.

At baseline, 71% (22/31) of patients used technologies frequently. Most of the patients reported that mHeart could be *useful* (22/31, 71%) or *very useful* (4/31, 13%). One-third of the patients (9/31, 29%) reported that they needed personal assistance to get started with using the mHeart platform.

Polypharmacy and Determinants of Medication Nonadherence

Polypharmacy was common; the mean total medication count was 13 (SD 4; range 7-18), exceeding 14 drugs per day in 36% (11/31) of patients. Patients reported a mean number of 6 (SD 4) adverse effects. As many as 61% (19/31) of them reported being self-reliant for medication management.

Medication-related inconvenience was moderate to high (>6 of 10) in 25% (8/31) of HTxR. As many as 74% (23/31) of them believed they were taking excessive medication. The danger of sometimes not taking immunosuppressive drugs was understood by 42% (13/31) of recipients. Furthermore, 32% (10/31) of recipients were unaware of the consequences of completely abandoning antirejection therapy. More details are provided in Multimedia Appendix 9.

Validity Measures

Content Validity

Regarding the adequate representability and relevance of the ePROMs to be included in the mHeart system, the Haynes-Sackett and the Morisky-Green-Levine questionnaires showed excellent agreement (>85%), whereas the SMAQ showed poor agreement (<75%; Table 3).

The suitability of the medication difficulties to support its addition to the Haynes-Sackett electronic version was excellent (>80%). Item agreement is detailed in Table 4.

The overall agreement between the ePROMs and the on-site PROMs was strong for the Haynes-Sackett (κ=0.826, P<.001) and for the Morisky-Green-Levine (κ=1, P<.001) questionnaires. Item agreement is detailed in Table 5.

Table 3. Expert panel interrater agreement on the most suitable questionnaires to measure medication adherence using the mHeart platform, measured by the group consensus method.

Round & adherence electronic patient-reported outcome measure	Agreement[a], n (%)	*P* value[b]	Inclusion in mHeart
Round 1			
Haynes-Sackett	13 (93)	.11	N/A[c]
Morisky-Green-Levine	12 (86)	.27	N/A
SMAQ[d]	10 (71)	.50	N/A
Round 2			
Haynes-Sackett	14 (100)	.03	Included
Morisky-Green-Levine	13 (93)	.11	Included
SMAQ	6 (43)	.99	Nonincluded

[a]Percentages of agreement. An agreement >75% of the expert panel was considered adequate.

[b]*P* value was one-sided to test whether *P* was greater than .75 (75%).

[c]N/A: not applicable.

[d]SMAQ: Simplified Medication Adherence Questionnaire validated in Spanish transplant population.

Table 4. Expert panel interrater agreement on several criteria for the six reasons for medication nonadherence Haynes-Sackett electronic patient-reported outcome measure, measured by the nominal group consensus method.

Reasons for medication nonadherence	Intuitive[a], n (%)	Easy[a], n (%)	Brief[a], n (%)	Useful[a], n (%)	Percentage of overall agreement[b], n (%)	*P* value[c]
I sometimes forget to take my medication	14 (100)	14 (100)	14 (100)	14 (100)	14 (100)	<.001
I lack information on medication and/or the disease	14 (100)	13 (93)	14 (100)	14 (100)	13.8 (98)	<.001
I feel demotivated about taking my medication	12 (86)	11 (79)	14 (100)	13 (93)	12.5 (89)	.01
Because of side effects or fear of having them	13 (93)	13 (93)	14 (100)	13 (93)	13.3 (95)	<.001
Because of complex regimens and/or inconvenient regimens	13 (93)	8 (57)	14 (100)	14 (100)	12.3 (88)	.02
Because of other reasons	12 (86)	14 (100)	13 (93)	12 (86)	12.8 (91)	.004

[a]Item criteria full description: true to the original in-clinic test, useful to evaluate medication adherence construct, intuitive, brief or fast to complete, and easy-to-understand language.

[b]Percentages of agreement. An agreement >75% of the expert panel was considered adequate.

[c]*P* value was one-sided to test whether *P* is greater than .75 (75%).

Table 5. Expert panel agreement on item characteristics of electronic patient-reported outcome measures compared with on-site patient-reported outcome measures, measured by the nominal group consensus method.

Patient-reported outcome measure item	True[a]		Useful[a]		Intuitive[a]		Brief[a]		Easy[a]	
	Kappa value	*P* value	Kappa value	*P* value	Kappa value	*P* value	Kappa value	*P* value	Kappa value	*P* value
Item 1 MGL[b]	1	<.001	1	<.001	1	<.001	1	<.001	1	<.001
Item 2 MGL	1	<.001	1	<.001	1	<.001	1	<.001	1	<.001
Item 3 MGL	1	<.001	1	<.001	1	<.001	1	<.001	1	<.001
Item 4 MGL	1	<.001	1	<.001	1	<.001	1	<.001	1	<.001
Item 1 HS[c]	1	<.001	0.6	<.01	0.4	.04	1	<.001	1	<.001

[a]Item characteristics' full description: true to the original in-clinic test, useful to evaluate medication adherence construct, intuitive, brief or fast to complete, and easy-to-understand language.

[b]MGL: Morisky-Green-Levine 4-item questionnaire.

[c]HS: Haynes-Sackett questionnaire.

Convergent and Discriminant Validity

The correlation of adherence to medication domains of the PROMs compared with the SMAQ is shown in Table 6.

Table 6. Convergent and discriminant validity assessed by the correlation of medication adherence patient-reported outcome measures with the Simplified Medication Adherence Questionnaire.

Validity property	Adherence to medication PROMs[a]	Electronic		In clinic		Interpretation
		Phi coefficient	*P* value	Phi coefficient	*P* value	
Convergent	Morisky-Green-Levine versus SMAQ[b]	0.6	<.001	0.9	<.001	Strong correlation; measures similar adherence domains
Divergent	Haynes-Sackett versus SMAQ	0.3	.12	0.4	.04	Weak correlation; measures different adherence domains

[a]PROMs: patient-reported outcome measures to assess medication adherence.

[b]SMAQ: Simplified Medication Adherence Questionnaire validated in Spanish transplant population.

Reproducibility

The equivalent forms reliability method showed a very strong association between the scores obtained using the ePROMs and on-site PROMs (phi>0.7, *P*<.001; Table 7).

For the test-retest reliability method, all participants remained stable between assessments. Low reproducibility was observed, whereas medication adherence improved during this interval according to both types of ePROM (Table 8).

Table 7. Reliability of medication adherence electronic patient-reported outcome measures compared with on-site patient-reported outcome measures using the equivalent forms reliability method.

Adherence to medication PROMs[a]	Phi coefficient	*P* value
HS[b] overall	0.8	<.001
MGL[c] overall	0.7	<.001
MGL item 1	0.7	<.001
MGL item 2	0.7	<.001
MGL item 3	0.6	<.001
MGL item 4	1	<.001

[a]PROMs: patient-reported outcome measures to assess medication adherence.

[b]HS: Haynes-Sackett questionnaire.

[c]MGL: Morisky-Green-Levine 4-item questionnaire.

Table 8. Test-retest reliability method to measure stability of medication adherence electronic patient-reported outcome measure scores over time.

ePROMs[a]	Assessment 2		Assessment 3		Kappa value	*P* value	Interpretation
	Adherent, n (%)	Nonadherent, n (%)	Adherent, n (%)	Nonadherent, n (%)			
HS[b]	29 (94)	2 (7)	31 (100)	0 (0)	0.6	.002	Moderate stability
MGL[c]	28 (90)	3 (10)	30 (97)	1 (3)	0.3	.11	Poor stability

[a]ePROMs: electronic patient-reported outcome measures to assess medication adherence.

[b]HS: Haynes-Sackett questionnaire.

[c]MGL: Morisky-Green-Levine 4-item questionnaire.

Responsiveness or Sensitivity to Change

According to the change in medication adherence over time, similar rates were obtained in assessment 2 between ePROMs and PROMs (Table 9). Details for each item are provided in Multimedia Appendix 10.

Interpretability

The ePROM scores showed a nonsignificant underestimation (*P*>.05) of medication nonadherence rates at assessment 1 but not at assessment 2. Almost all the patients were adherent according to the ePROMs at assessment 3. The baseline overall in-clinic medication nonadherence rate was 32% (10/31), as measured by the Morisky-Green-Levine PROMs. According to the SMAQ, 39% (12/31) of HTxR were nonadherent to immunosuppressive treatment. The theory-based multifaceted intervention program showed significant (*P*<.05) improvements in medication nonadherence, ranging from 16% to 26%, depending on the questionnaire used (Table 9).

Table 9. Medication adherence rates and improvement between study assessments.

Measure	Adherence to medication rates[a]						*P* value	
	Assessment 1[b]		Assessment 2[b]		Assessment 3[b]			
	Adherent, n (%)	Nonadherent, n (%)	Adherent, n (%)	Nonadherent, n (%)	Adherent, n (%)	Nonadherent, n (%)	A1 vs A2	A1 vs A3
ePROMs[c]								
HS[d]	25 (81)	6 (19)	29 (94)	2 (7)	31 (100)	0 (0)	.10	.01
MGL[e]	25 (81)	6 (19)	28 (90)	3 (10)	30 (97)	1 (3)	.26	.06
In-clinic PROMs								
HS	22 (71)	9 (29)	28 (90)	3 (10)	N/A[f]	N/A	.03	N/A
MGL	21 (68)	10 (32)	27 (87)	4 (13)	N/A	N/A	.06	N/A
SMAQ[g]	19 (61)	12 (39)	27 (87)	4 (13)	N/A	N/A	.005	N/A

[a]Medication adherence in the implementation phase is expressed as a binary variable: adherent or nonadherent. The Haynes-Sackett and Morisky-Green-Levine questionnaires measures adherence to overall medication. The Simplified Medication Adherence Questionnaire validated in the Spanish transplant population measures adherence to immunosuppression.

[b]The behavior-based interventional program established by the pharmacist was performed between assessments 1 and 2 (1 month at least). There was a 7-day gap between assessments 2 and 3 to allow the reproducibility test retest study without provider interactions. Only the electronic questionnaires were administered in Assessment 3.

[c]ePROM: electronic patient-reported outcome measures to assess medication adherence.

[d]HS: Haynes-Sackett.

[e]MGL: Morisky-Green-Levine.

[f]N/A: not applicable.

[g]SMAQ: Simplified Medication Adherence Questionnaire validated in the Spanish transplant population.

Burden

Regarding the criteria of respondent burden, 81% (25/31) of patients reported spending 1 to 2 min while completing the ePROMs, whereas the mean time for in-clinic PROMs was 6 min (SD 2 min; range 3-9). All patients were able to learn the basic digital competencies needed to complete the ePROMs. No missing values were found using the two methods.

Regarding administrative burden, the total mean time spent per day by the pharmacist on mHeart was 33 min (SD 6 min; range 21-44). This time allowed follow-up of all the patients. The on-site PROMs required an office to be available and an average of 45 min for each individual assessment. Both methods required the professional to be trained in motivational interviewing, medication management, and transplant basics.

Patient Satisfaction and Usability Survey

The completion rate was 93% (29/31 patients). The reasons for *no response* to the survey are detailed in Figure 1. HTxR reported no inconvenience because of the mHeart intervention approach employed. The mean ePROM appropriateness score was 8 (SD 2; score range: 0-10). The mean score for overall satisfaction with the mHeart approach was 9 (SD 2; score range: 0-10). All 100% (29/29) of the patients would recommend the mHeart platform to other recipients. Regarding patient suggestions for improving the platform, 24% (7/29) of HTxR made eight suggestions and 76% (22/29) of them responded, “No, I like it just as it is.”

Improvements were implemented based on patient feedback, for example, (1) to avoid patient recall bias, the order of the ePROM items was designed to automatically change whenever the test is completed; (2) patients could graphically consult any values they recorded in mHeart (eg, blood pressure); (3) pop-up alerts were established to let patients know that a new text message from the provider had arrived; and (4) diverse actions were implemented to decrease telephone use by patients to inquire about the compatibility of new therapies: the usability of the mHeart function to inquire about new therapies was improved, and text messages were sent to the patients, explaining how to use this function.

The details of each survey item score, patient suggestions, and the subsequent improvements are provided in Multimedia Appendix 11.

Discussion

Principal Findings

In this study, the first challenge was to validate mHeart ePROMs to detect early stage HTxR at risk for medication nonadherence in the home setting. With this aim in mind, the COSMIN [30] and SAC-MOS [31] standards provided a solid framework to support the quality of the assessed ePROM psychometric variables. As the mHeart ePROMs meet the minimum standards set by the ISOQOL [11], they can be used in clinical practice and comparative effectiveness research.

The excellent agreement observed between ePROMs and on-site PROMs confirmed that the mHeart electronic approach was as

effective as the traditional on-site method in identifying medication nonadherence. The ePROMs used in mHeart showed multiple advantages over on-site PROMS, such as eliminating potential professional interpretation of ambiguous responses that could affect medication adherence rates. Furthermore, the electronic approach required fewer in-clinic facilities than the traditional method of assessing medication nonadherence. The integration of the mHeart data with the HIS also reduced the time required to record ePROM responses in patients' medical records. These advantages reduced burden and enabled the pharmacists to focus on clinical tasks. This is clinically significant, as a pharmacist intervention is associated with better use of evidence-based therapies, reducing medication errors and emergency department visits while increasing patient satisfaction [58].

Regarding the baseline medication nonadherence values, the percentage of HTxR nonadherent to overall medication in this study was worrisome according to the Morisky-Green-Levine PROMs (32%) but similar to that observed in another series (33%) [59]. According to the SMAQ, the percentage (39%) of medication nonadherence to immunosuppressive treatment was slightly higher than the overall percentage reported in the HTx population (34%) [7] and considerably higher than that reported in a meta-analysis of the solid organ transplant population (25%) [4,25]. These results suggest that the ePROMs used in our study have a synergistic effect in identifying nonadherent recipients. However, they also highlight the need for intervention programs to improve medication nonadherence, as almost half of the HTxR were unaware of the consequences of medication nonadherence. Nevertheless, comparisons among medication nonadherence rates in the field of transplantation should be interpreted with caution as studies use different populations and methodologies [4].

The exploratory intervention program established to deal with this problem showed promising results. Immunosuppressive treatment adherence rates significantly improved in one-third of the recipients, according to the SMAQ. This figure is higher than that reported by most studies showing low or medium effect sizes of around 10% to 20% in medication adherence improvement [10,45]. In contrast to these studies, our program was designed to deliver personalized, internet-based multilevel interventions based on behavioral theories [7,21,22]. Indeed, human support and tailored interventions have been shown to be a requisite to improve medication nonadherence rates throughout eHealth [10,18]. Moreover, our exploratory study meets 72% of the TCS criteria (ie, items 1-11), indicating that the interventional study design complies with the theoretical basis of the intervention [32]. This is important as interventions meeting a minimum of 60% of the TCS criteria have been found to be highly effective [60].

Nonelectronic theory-based interventions have been considered highly effective when improvement was >20% [45]. Therefore, as the improvement in medication nonadherence in our exploratory study was higher (30%), the strategies applied proved to be synergistic and to enhance the effectiveness of the program [21,32]. Equally important, patients adhered well to the study protocol and provided excellent feedback. Among the benefits of the mHeart approach, patients highlighted personalized communication, support from professionals, and self-empowerment, which were the most relevant criteria used to design the mHeart intervention program.

Limitations

Our study includes a limited but representative sample comprising 86% of all early stage HTxR in our center. This characteristic is common in transplant population, as the prevalence is limited [61]. We did not enroll chronic-stage recipients for the following reasons: (1) early posttransplant medication nonadherence is a high-risk behavior with a huge impact on survival [1], (2) we wanted to avoid wide heterogeneity in chronic-stage providers and treatments, and (3) we wanted to avoid chronic-stage recipients having to travel to the clinic for the study. In addition, although early stage recipients are typically better adherers [3,62], this did not prevent us from observing an effect in the highest risk period after transplant.

The interval between medication nonadherence assessments may have led to recall bias. Although this bias could have influenced the electronic score, this limitation is intrinsically related to the validation methodology to ensure that the electronic and traditional methods are performed in similar conditions and in patients with similar psychological and functional status. Moreover, the short study periods used were methodologically grounded according to the main study aim of validating the ePROMs. In *sensitivity to change measures*, a 1-month interval is considered an adequate interval to measure the validity of an indirect smartphone health measure [51,52]. Moreover, fortnightly assessments are sufficient to identify additional medication nonadherence in the transplant population [46]. In *reproducibility measures*, intervals of 1 to 2 weeks are common [63]. Therefore, a 7-day interval was selected to minimize the effect of possible confounding variables [31] related to the multifaceted factors affecting posttransplant medication nonadherence [10,46].

Long-Term Workflow and Clinical Applications

Adherence monitoring is recognized as a standard quality practice in transplant centers [7]. In the past few decades, there has been a growing interest in improving the screening opportunities of medication nonadherence without increasing the in-clinic burden. The quality of the ePROM psychometric variables and the patient satisfaction reported in this study support the scalability of the mHeart ePROM for use in clinical practice and research [11]. The results obtained indicate that the electronic self-reporting approach provides a highly sensitive medication nonadherence measure in the transplant population to complement traditional and more time-consuming methods, such as blood tests or medication refills [25,46].

Furthermore, given that medication nonadherence behavior in the transplant population is influenced by several factors [7], optimal daily adherence is a real challenge for recipients [64]. Consequently, feasible holistic strategies are needed to help recipients reduce the negative impact of medication nonadherence on health outcomes [20]. The exploratory results of this behavioral theory–based intervention on medication nonadherence rates are encouraging. Future studies will

determine the intervention's effectiveness on clinical outcomes [13]. With this aim in mind, the EMERGE [28], TCS [32], and CONSORT-EHEALTH reporting criteria [17] standards were followed to support the scalability of the intervention methodology used in larger research. For now, the feasibility and effectiveness found in this study encourage following this path to curb the widespread problem of medication nonadherence.

Conclusions

The electronic method implemented in the mHeart medical device successfully identified medication nonadherence in the HTx population. ePROMs demonstrated their potential to overcome the limitations of traditional on-site methods. The ePROMs' quality properties supported their widespread use in research and clinical practice. The theory-based intervention program showed an encouraging improvement in medication adherence rates, with excellent patient satisfaction and usability scores. Therefore, the mHeart program resulted in significant benefits in estimating medication nonadherence in the HTx population and showed promise in guiding professionals' interventions with the potential to optimize HTx outcomes.

Acknowledgments

This study was supported by the General Pharmaceutical Council of Barcelona (a scientific research grant, 2016) and Astellas Pharma SL (a contribution with the institution). These contributions aimed to reinforce the study resources and were partly used to fund MG's time on the study and the technical development of the mHeart platform.

This study would not have been possible without the patients' contributions and willingness to participate in the study and use the mHeart platform. The authors wish to thank the following experts involved in the mHeart implementation: J Caparrus and N Alberich for help with data protection and confidentiality policy; V Robert and the Information Systems Department for conducting the platform interoperability; O Pozas and F Carbajo for their support from the Legal department; D Gallardo for expert advice on Intellectual Property; and M Ors, B Monsalve, and N Ichaso for their expertise on transference and innovation from the Hospital de la Santa Creu i Sant Pau, Barcelona, Spain (HSCSP) Research Institute. The authors would also like to thank the multidisciplinary team of the HSCSP Heart Failure and Heart Transplant Department for their contribution to the study (D Gil, E Galvez, S Ros, M Pirla, N Mesado, E Sole, J Alvarez, and M Ribas).

Authors' Contributions

All the authors made substantial contributions to specific areas, revised the work for important intellectual content, approved the final version to be published, and agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved.

Conflicts of Interest

The technological development of the mHeart platform lasted from March 15, 2015, to June 2, 2016, and was carried out by a private Spanish firm specializing in health care system apps (Trilema Salud). Most of the authors of this study participated as consultants, and MG, the transplant pharmacist, was assigned the role of the Project Coordinator. Neither the abovementioned funding entities nor the technical developers played any role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Multimedia Appendix 1
Questionnaire designed for completion in face-to-face interviews: sociodemographic, clinical, and technology acceptance among the heart transplant recipients included in the Val-mHeart study.
[PDF File (Adobe PDF File), 52 KB - mhealth_v8i2e15957_app1.pdf]

Multimedia Appendix 2
Questionnaire designed to be administered in face-to-face interviews: patient-reported outcomes related to the treatment regimen.
[PDF File (Adobe PDF File), 46 KB - mhealth_v8i2e15957_app2.pdf]

Multimedia Appendix 3
Behavior change techniques selected for use during the behavior-based intervention program and workflow adapted for delivery using the mHeart platform, and a description of the mHeart-based treatment designed to improve medication adherence in the Val-mHeart study.
[PDF File (Adobe PDF File), 93 KB - mhealth_v8i2e15957_app3.pdf]

Multimedia Appendix 4
Sample video of the mHeart mobile app.

[MP4 File (MP4 Video), 90609 KB - mhealth_v8i2e15957_app4.mp4]

Multimedia Appendix 5
Electronic version of the Haynes-Sackett questionnaire, including 6 additional responses by patients to improve provider understanding of their difficulties with medication adapted for use with the mHeart platform.
[PDF File (Adobe PDF File), 33 KB - mhealth_v8i2e15957_app5.pdf]

Multimedia Appendix 6
Patient Satisfaction and Usability Survey Original Spanish Version (the results and the items' translation to English language are provided in Multimedia Appendix 11).
[PDF File (Adobe PDF File), 270 KB - mhealth_v8i2e15957_app6.pdf]

Multimedia Appendix 7
Methodology used to measure validity properties of the electronic patient reported outcome measures to assess medication adherence in the at-home setting using the mHeart platform in heart transplant recipients (The Val-mHeart Study).
[PDF File (Adobe PDF File), 80 KB - mhealth_v8i2e15957_app7.pdf]

Multimedia Appendix 8
Demographic and clinical characteristics of the early-stage heart transplant recipients included in the Val-mHeart Study.
[PDF File (Adobe PDF File), 44 KB - mhealth_v8i2e15957_app8.pdf]

Multimedia Appendix 9
Heart transplant recipients' therapeutic characteristics and treatment-related patient-reported outcomes.
[PDF File (Adobe PDF File), 66 KB - mhealth_v8i2e15957_app9.pdf]

Multimedia Appendix 10
Nonadherence rates in early-stage heart transplant recipients listed by item in the study period.
[PDF File (Adobe PDF File), 38 KB - mhealth_v8i2e15957_app10.pdf]

Multimedia Appendix 11
Results of the Web-based survey on usability and satisfaction with the mHeart platform and intervention implemented during the study period in heart transplant recipients. Table 11A shows the categorical variables and Table 11B shows the quantitative variables.
[PDF File (Adobe PDF File), 96 KB - mhealth_v8i2e15957_app11.pdf]

References

1. Dobbels F, de Geest S, van Cleemput J, Droogne W, Vanhaecke J. Effect of late medication non-compliance on outcome after heart transplantation: a 5-year follow-up. J Heart Lung Transplant 2004 Nov;23(11):1245-1251. [doi: 10.1016/j.healun.2003.09.016] [Medline: 15539122]
2. Brocks Y, Zittermann A, Grisse D, Schmid-Ott G, Stock-Gießendanner S, Schulz U, et al. Adherence of heart transplant recipients to prescribed medication and recommended lifestyle habits. Prog Transplant 2017 Jun;27(2):160-166. [doi: 10.1177/1526924817699959] [Medline: 28617170]
3. Korb-Savoldelli V, Sabatier B, Gillaizeau F, Guillemain R, Prognon P, Bégué D, et al. Non-adherence with drug treatment after heart or lung transplantation in adults: a systematic review. Patient Educ Couns 2010 Nov;81(2):148-154. [doi: 10.1016/j.pec.2010.04.013] [Medline: 20627643]
4. Dew MA, DiMartini AF, Dabbs AV, Myaskovsky L, Steel J, Unruh M, et al. Rates and risk factors for nonadherence to the medical regimen after adult solid organ transplantation. Transplantation 2007 Apr 15;83(7):858-873. [doi: 10.1097/01.tp.0000258599.65257.a6] [Medline: 17460556]
5. Hansen R, Seifeldin R, Noe L. Medication adherence in chronic disease: issues in posttransplant immunosuppression. Transplant Proc 2007 Jun;39(5):1287-1300. [doi: 10.1016/j.transproceed.2007.02.074] [Medline: 17580126]
6. Hugon A, Roustit M, Lehmann A, Saint-Raymond C, Borrel E, Hilleret M, et al. Influence of intention to adhere, beliefs and satisfaction about medicines on adherence in solid organ transplant recipients. Transplantation 2014 Jul 27;98(2):222-228. [doi: 10.1097/TP.0000000000000221] [Medline: 24926826]
7. Denhaerynck K, Berben L, Dobbels F, Russell CL, Crespo-Leiro MG, Poncelet AJ, BRIGHT study team. Multilevel factors are associated with immunosuppressant nonadherence in heart transplant recipients: the international BRIGHT study. Am J Transplant 2018 Jun;18(6):1447-1460 [FREE Full text] [doi: 10.1111/ajt.14611] [Medline: 29205855]

8. Gomis-Pastor M, Mingell ER, Perez SM, Loidi VB, Lopez LL, Bassons AD, et al. Multimorbidity and medication complexity: new challenges in heart transplantation. Clin Transplant 2019 Oct;33(10):e13682. [doi: 10.1111/ctr.13682] [Medline: 31368585]
9. Senft Y, Kirsch M, Denhaerynck K, Dobbels F, Helmy R, Russell CL, BRIGHT study team. Practice patterns to improve pre and post-transplant medication adherence in heart transplant centres: a secondary data analysis of the international BRIGHT study. Eur J Cardiovasc Nurs 2017 Dec 1:1474515117747577. [doi: 10.1177/1474515117747577] [Medline: 29231747]
10. Kini V, Ho PM. Interventions to improve medication adherence: a review. J Am Med Assoc 2018 Dec 18;320(23):2461-2473. [doi: 10.1001/jama.2018.19271] [Medline: 30561486]
11. Reeve BB, Wyrwich KW, Wu AW, Velikova G, Terwee CB, Snyder CF, et al. ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research. Qual Life Res 2013 Oct;22(8):1889-1905. [doi: 10.1007/s11136-012-0344-y] [Medline: 23288613]
12. Sarzynski E, Decker B, Thul A, Weismantel D, Melaragni R, Cholakis E, et al. Beta testing a novel smartphone application to improve medication adherence. Telemed J E Health 2017 Apr;23(4):339-348. [doi: 10.1089/tmj.2016.0100] [Medline: 27564971]
13. Ritterband LM, Andersson G, Christensen HM, Carlbring P, Cuijpers P. Directions for the International Society for Research on Internet Interventions (ISRII). J Med Internet Res 2006 Sep 29;8(3):e23. [doi: 10.2196/jmir.8.3.e23] [Medline: 17032639]
14. Griffiths F, Lindenmeyer A, Powell J, Lowe P, Thorogood M. Why are health care interventions delivered over the internet? A systematic review of the published literature. J Med Internet Res 2006 Jun 23;8(2):e10. [doi: 10.2196/jmir.8.2.e10] [Medline: 16867965]
15. Heron KE, Smyth JM. Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments. Br J Health Psychol 2010 Feb;15(Pt 1):1-39 [FREE Full text] [doi: 10.1348/135910709X466063] [Medline: 19646331]
16. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med 2013;10(1):e1001362 [FREE Full text] [doi: 10.1371/journal.pmed.1001362] [Medline: 23349621]
17. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res 2011 Dec 31;13(4):e126 [FREE Full text] [doi: 10.2196/jmir.1923] [Medline: 22209829]
18. Lancaster K, Abuzour A, Khaira M, Mathers A, Chan A, Bui V, et al. The use and effects of electronic health tools for patient self-monitoring and reporting of outcomes following medication use: systematic review. J Med Internet Res 2018 Dec 18;20(12):e294 [FREE Full text] [doi: 10.2196/jmir.9284] [Medline: 30563822]
19. Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, et al. A Spanish pillbox app for elderly patients taking multiple medications: randomized controlled trial. J Med Internet Res 2014 Apr 4;16(4):e99 [FREE Full text] [doi: 10.2196/jmir.3269] [Medline: 24705022]
20. Fleming JN, Taber DJ, McElligott J, McGillicuddy JW, Treiber F. Mobile health in solid organ transplant: the time is now. Am J Transplant 2017 Sep;17(9):2263-2276 [FREE Full text] [doi: 10.1111/ajt.14225] [Medline: 28188681]
21. Davis R, Campbell R, Hildon Z, Hobbs L, Michie S. Theories of behaviour and behaviour change across the social and behavioural sciences: a scoping review. Health Psychol Rev 2015;9(3):323-344 [FREE Full text] [doi: 10.1080/17437199.2014.941722] [Medline: 25104107]
22. Conn VS, Enriquez M, Ruppar TM, Chan KC. Meta-analyses of theory use in medication adherence intervention research. Am J Health Behav 2016 Mar;40(2):155-171 [FREE Full text] [doi: 10.5993/AJHB.40.2.1] [Medline: 26931748]
23. Salvo MC, Cannon-Breland ML. Motivational interviewing for medication adherence. J Am Pharm Assoc (2003) 2015;55(4):e354-61; quiz e362. [doi: 10.1331/JAPhA.2015.15532] [Medline: 26161493]
24. Miller WR, Rose GS. Toward a theory of motivational interviewing. Am Psychol 2009 Sep;64(6):527-537 [FREE Full text] [doi: 10.1037/a0016830] [Medline: 19739882]
25. Fine RN, Becker Y, de Geest S, Eisen H, Ettenger R, Evans R, et al. Nonadherence consensus conference summary report. Am J Transplant 2009 Jan;9(1):35-41 [FREE Full text] [doi: 10.1111/j.1600-6143.2008.02495.x] [Medline: 19133930]
26. Vitinius F, Ziemke M, Albert W. Adherence with immunosuppression in heart transplant recipients. Curr Opin Organ Transplant 2015 Apr;20(2):193-197. [doi: 10.1097/MOT.0000000000000166] [Medline: 25856181]
27. Froud R, Fawkes C, Foss J, Underwood M, Carnes D. Responsiveness, reliability, and minimally important and minimal detectable changes of 3 electronic patient-reported outcome measures for low back pain: validation study. J Med Internet Res 2018 Oct 24;20(10):e272 [FREE Full text] [doi: 10.2196/jmir.9828] [Medline: 30355556]
28. de Geest S, Zullig LL, Dunbar-Jacob J, Helmy R, Hughes DA, Wilson IB, et al. ESPACOMP Medication Adherence Reporting Guideline (EMERGE). Ann Intern Med 2018 Jul 3;169(1):30-35. [doi: 10.7326/M18-0543] [Medline: 29946690]
29. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res 2010 May;19(4):539-549 [FREE Full text] [doi: 10.1007/s11136-010-9606-8] [Medline: 20169472]

30. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol 2010 Jul;63(7):737-745. [doi: 10.1016/j.jclinepi.2010.02.006] [Medline: 20494804]
31. Aaronson N, Alonso J, Burnam A, Lohr KN, Patrick DL, Perrin E, et al. Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res 2002 May;11(3):193-205. [doi: 10.1023/a:1015291021312] [Medline: 12074258]
32. Michie S, Prestwich A. Are interventions theory-based? Development of a theory coding scheme. Health Psychol 2010 Jan;29(1):1-8. [doi: 10.1037/a0016939] [Medline: 20063930]
33. Eysenbach G. Improving the quality of web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004 Sep 29;6(3):e34 [FREE Full text] [doi: 10.2196/jmir.6.3.e34] [Medline: 15471760]
34. Vrijens B, de Geest S, Hughes DA, Przemyslaw K, Demonceau J, Ruppar T, et al. A new taxonomy for describing and defining adherence to medications. Br J Clin Pharmacol 2012 May;73(5):691-705 [FREE Full text] [doi: 10.1111/j.1365-2125.2012.04167.x] [Medline: 22486599]
35. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol 2008 May;27(3):379-387. [doi: 10.1037/0278-6133.27.3.379] [Medline: 18624603]
36. Baumel A, Kane JM. Examining predictors of real-world user engagement with self-guided eHealth interventions: analysis of mobile apps and websites using a novel dataset. J Med Internet Res 2018 Dec 14;20(12):e11491 [FREE Full text] [doi: 10.2196/11491] [Medline: 30552077]
37. Muench F, Baumel A. More than a text message: dismantling digital triggers to curate behavior change in patient-centered health interventions. J Med Internet Res 2017 May 26;19(5):e147 [FREE Full text] [doi: 10.2196/jmir.7463] [Medline: 28550001]
38. Trilema Salud. mHeart Website URL: https://salud.trilema.es/ [accessed 2019-07-20]
39. Socioemprende SL. Google Play. mHeart URL: https://play.google.com/store/apps/details?id=nabelia.mheart&gl=ES [accessed 2019-07-20]
40. Socioemprende. App Store - Apple. mHeart URL: https://apps.apple.com/us/app/mheart/id1449696988 [accessed 2019-07-20]
41. Gomis-Pastor M, Mangues M, Pellicer V, Ors M. Mendeley Data. 2019. mHeart - mHealthCare Platform Adapted to the Heart Transplant Population - Technical Specifications and Software Source Code URL: https://data.mendeley.com/datasets/yf2dgcfmmh/4 [accessed 2020-01-10]
42. Sackett DL, Snow JC. The magnitude of compliance and non-compliance. In: Haynes RB, Taylor DW, Sackett DL, editors. Compliance in Health Care. Baltimore: Johns Hopkins University Press; 1979:11-22.
43. Sackett DL, Haynes RB, Guyat GH. Ayudar a los pacientes a cumplir los tratamientos. In: Haynes RB, Sackett DL, Guyatt GH, Tugwell P, editors. Epidemiol clínica, Cienc básica para la Med clínica 2a ed. Madrid, Spain: Editorial Médica Panamericana SA; 1994:249-278.
44. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care 1986 Jan;24(1):67-74. [doi: 10.1097/00005650-198601000-00007] [Medline: 3945130]
45. Dobbels F, de Bleser L, Berben L, Kristanto P, Dupont L, Nevens F, et al. Efficacy of a medication adherence enhancing intervention in transplantation: The MAESTRO-Tx trial. J Heart Lung Transplant 2017 May;36(5):499-508. [doi: 10.1016/j.healun.2017.01.007] [Medline: 28162931]
46. Gustavsen MT, Midtvedt K, Lønning K, Jacobsen T, Reisaeter AV, de Geest S, et al. Evaluation of tools for annual capture of adherence to immunosuppressive medications after renal transplantation - a single-centre open prospective trial. Transpl Int 2019 Jun;32(6):614-625. [doi: 10.1111/tri.13412] [Medline: 30770608]
47. Val JA, Amorós BG, Martínez PF. Estudio descriptivo del cumplimiento del tratamiento farmacológico antihipertensivo y validación del test de Morisky y Green. In: Estudio descriptivo del cumplimiento del tratamiento farmacológico antihipertensivo y validación del test de Morisky y Green. Spain: Atención primaria; 1992:767-770.
48. Orozco-Beltrán D, Carratalá-Munuera C, Gil-Guillén V. Improving treatment adherence: one of the most effective ways of increasing patient survival in secondary prevention. Rev Esp Cardiol Supl 2015;15(5):12-18. [doi: 10.1016/s1131-3587(16)30004-8]
49. Conthe P, Tejerina F. Heart failure treatment adherence and quality of life. Rev Esp Cardiol Supl 2007;7(6):57F-66F. [doi: 10.1016/s1131-3587(07)75256-1]
50. Suárez FJ, Plumed JS, Valentín MA, Palomo PP, Cepeda MA, Aguiar DL, Grupo de Estudio Vatren. Validation on the simplified medication adherence questionnaire (SMAQ) in renal transplant patients on tacrolimus. Nefrologia 2011;31(6):690-696 [FREE Full text] [doi: 10.3265/Nefrologia.pre2011.Aug.10973] [Medline: 22130285]
51. Conthe P, Contreras EM, Pérez AA, García BB, Martín MN, Jurado MG, et al. Treatment compliance in chronic illness: current situation and future perspectives. Rev Clin Esp 2014;214(6):336-344. [doi: 10.1016/j.rce.2014.03.008] [Medline: 24816042]
52. Pan YC, Lin HH, Chiu YC, Lin SH, Lin YH. Temporal stability of smartphone use data: determining fundamental time unit and independent cycle. JMIR Mhealth Uhealth 2019 Mar 26;7(3):e12171 [FREE Full text] [doi: 10.2196/12171] [Medline: 30912751]

53. Viladrich C, Doval E. Medición: Fiabilidad y Validez. Bellaterra, Barcelona: Laboratori d'estadística Aplicada i Modelització, Universitat Autónoma de Barcelona (UAB); 2011.
54. Akoglu H. User's guide to correlation coefficients. Turk J Emerg Med 2018 Sep;18(3):91-93 [FREE Full text] [doi: 10.1016/j.tjem.2018.08.001] [Medline: 30191186]
55. Fleiss JL, Levin B, Myunghee CP. Statistical Methods for Rates & Proportions. Third Edition. Hoboken: John Wiley Sons, Inc; 1981.
56. Hogan TP, Benjamin AM, Brezinski KL. Reliability methods: a note on the frequency of use of various types. Educ Psychol Meas 2000;60(4):523-531. [doi: 10.1177/00131640021970691]
57. Gorsuch RL. Factor Analysis. Second Edition. Hillsdale: NJ Lawrence Erlbaum Assoc; 1983.
58. Milfred-LaForest SK, Chow SL, DiDomenico RJ, Dracup K, Ensor CR, Gattis-Stough W, et al. Clinical pharmacy services in heart failure: an opinion paper from the Heart Failure Society of America and American College of Clinical Pharmacy Cardiology Practice and Research Network. Pharmacotherapy 2013 May;33(5):529-548. [doi: 10.1002/phar.1295] [Medline: 23649813]
59. Pérez AB, Suárez AL, Rodríguez JR, Márquez JM, Gallé EL. Medication adherence in patients who undergo cardiac transplantation. Transplant Proc 2013;45(10):3662-3664. [doi: 10.1016/j.transproceed.2013.11.006] [Medline: 24314989]
60. Lycett HJ, Raebel EM, Wildman EK, Guitart J, Kenny T, Sherlock J, et al. Theory-based digital interventions to improve asthma self-management outcomes: systematic review. J Med Internet Res 2018 Dec 12;20(12):e293 [FREE Full text] [doi: 10.2196/jmir.9666] [Medline: 30541741]
61. de Bleser L, Matteson M, Dobbels F, Russell C, de Geest S. Interventions to improve medication-adherence after transplantation: a systematic review. Transpl Int 2009 Aug;22(8):780-797 [FREE Full text] [doi: 10.1111/j.1432-2277.2009.00881.x] [Medline: 19386076]
62. de Geest S, Burkhalter H, Bogert L, Berben L, Glass TR, Denhaerynck K, Psychosocial Interest Group, Swiss Transplant Cohort Study. Describing the evolution of medication nonadherence from pretransplant until 3 years post-transplant and determining pretransplant medication nonadherence as risk factor for post-transplant nonadherence to immunosuppressives: the Swiss Transplant Cohort Study. Transpl Int 2014 Jul;27(7):657-666 [FREE Full text] [doi: 10.1111/tri.12312] [Medline: 24628915]
63. Polit DF. Getting serious about test-retest reliability: a critique of retest research and some recommendations. Qual Life Res 2014 Aug;23(6):1713-1720. [doi: 10.1007/s11136-014-0632-9] [Medline: 24504622]
64. Vanhoof JM, Vandenberghe B, Geerts D, Philippaerts P, de Mazière P, Dabbs AD, PICASSO-Tx consortium. Shedding light on an unknown reality in solid organ transplant patients' self-management: a contextual inquiry study. Clin Transplant 2018 Aug;32(8):e13314. [doi: 10.1111/ctr.13314] [Medline: 29897621]

Abbreviations

CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and OnLine TeleHealth
COSMIN: COnsensus-based Standards for the selection of health Measurement Instruments
EMERGE: European Society for Patient Adherence, COMpliance, and Persistence Medication Adherence Reporting Guideline
ePROM: electronic patient-reported outcome measure
HIS: hospital information system
HSCSP: Hospital de la Santa Creu i Sant Pau, Barcelona, Spain
HTx: heart transplant
HTxR: heart transplant recipients
ISOQOL: International Society for Quality of Life Research
ISRII: International Society for Research on Internet Interventions
MNA: medication nonadherence
SAC-MOS: Scientific Advisory Committee of the Medical Outcomes Trust
SMAQ: Simplified Medication Adherence Questionnaire
TCS: Theory Coding Scheme

Edited by G Eysenbach; submitted 21.08.19; peer-reviewed by H Mehdizadeh, S Weinland, T Gal, R Leek, S Hamel, JB Park; comments to author 18.09.19; revised version received 18.10.19; accepted 16.12.19; published 04.02.20.

Please cite as:
Gomis-Pastor M, Roig E, Mirabet S, T De Pourcq J, Conejo I, Feliu A, Brossa V, Lopez L, Ferrero-Gregori A, Barata A, Mangues MA
A Mobile App (mHeart) to Detect Medication Nonadherence in the Heart Transplant Population: Validation Study
JMIR Mhealth Uhealth 2020;8(2):e15957
URL: https://mhealth.jmir.org/2020/2/e15957
doi:10.2196/15957
PMID:32014839

Review

A Framework for Competencies for the Use of Mobile Technologies in Psychiatry and Medicine: Scoping Review

Donald Hilty[1], MBA, MD; Steven Chan[2], MBA, MD; John Torous[3], MD; John Luo[4], MD; Robert Boland[5], MD

[1]VA Northern California Health Care System, Mental Health & Department of Psychiatry and Behavioral Sciences, UC Davis School of Medicine, Mather, CA, United States

[2]Palo Alto VA Health Care System, Palo Alto, CA, United States

[3]Beth Israel Deaconess Medical Center, Psychiatry, Harvard School of Medicine, Boston, MA, United States

[4]Consultation-Liaison & Emergency Psychiatry, UC Irvine Department of Psychiatry, UCI Health, Irvine, CA, United States

[5]Harvard Longwood Psychiatry Residency Training Program, Brigham and Women's/Faulkner Hospitals, Harvard Medical School, Boston, MA, United States

Corresponding Author:
Donald Hilty, MBA, MD
VA Northern California Health Care System
Mental Health & Department of Psychiatry and Behavioral Sciences
UC Davis School of Medicine
10535 Hospital Way
Mather, CA, 95655
United States
Phone: 1 6263757857
Email: donh032612@gmail.com

Abstract

Background: To ensure quality care, clinicians need skills, knowledge, and attitudes related to technology that can be measured.

Objective: This paper sought out competencies for mobile technologies and/or an approach to define them.

Methods: A scoping review was conducted to answer the following research question, “What skills are needed for clinicians and trainees to provide quality care via mHealth, have they been published, and how can they be made measurable and reproducible to teach and assess them?” The review was conducted in accordance with the 6-stage scoping review process starting with a keyword search in PubMed/Medical Literature Analysis and Retrieval System Online, APA PsycNET, Cochrane, EMBASE, PsycINFO, Web of Science, and Scopus. The literature search focused on keywords in 4 concept areas: (1) competencies, (2) mobile technologies, (3) telemedicine mode, and (4) health. Moreover, 2 authors independently, in parallel, screened the search results for potentially relevant studies based on titles and abstracts. The authors reviewed the full-text articles for final inclusion based on inclusion/exclusion criteria. Inclusion criteria were keywords used from concept area 1 (competencies) and 2 (mobile technologies) and either 3 (telemedicine mode) or 4 (health). Exclusion criteria included, but were not limited to, keywords used from a concept area in isolation, discussion of skills abstractly, outline or listing of what clinicians need without detail, and listing immeasurable behaviors.

Results: From a total of 1232 results, the authors found 78 papers eligible for a full-text review and found 14 papers directly relevant to the 4 key concepts. Although few studies specifically discussed skills, the majority were clinical studies, and the literature included no lists of measurable behaviors or competency sets for mobile technology. Therefore, a framework for mobile technology competencies was built according to the review, expert consensus, and recommendations of the Institute of Medicine’s Health Professions Education Summit and Accreditation Council of Graduate Medical Education framework. This framework borrows from existing competency framework domains in telepsychiatry and social media (patient care, medical knowledge, practice-based learning and improvement, systems-based practice, professionalism, and interpersonal skills and communication) and added domains of mHealth clinical decision support, device/technology assessment/selection, and information flow management across an electronic health record platform. mHealth Asynchronous components require additional traditional learning, teaching, supervisory and evaluation practices. Interactive curricula with case-, problem-, and system-based teaching may help faculty focus on decision making and shape skills and attitudes to complement clinical exposure.

Conclusions: Research is needed on how to customize implementation and evaluation of mHealth competencies and to ensure skill development is linked to the quality of care. This will require the management of organizational change with technology and the creation of a positive electronic culture in a complex policy and regulatory environment.

(JMIR Mhealth Uhealth 2020;8(2):e12229) doi:10.2196/12229

KEYWORDS

apps; behavior; education; mobile; outcome; competency; technology; health; mobile phone; framework

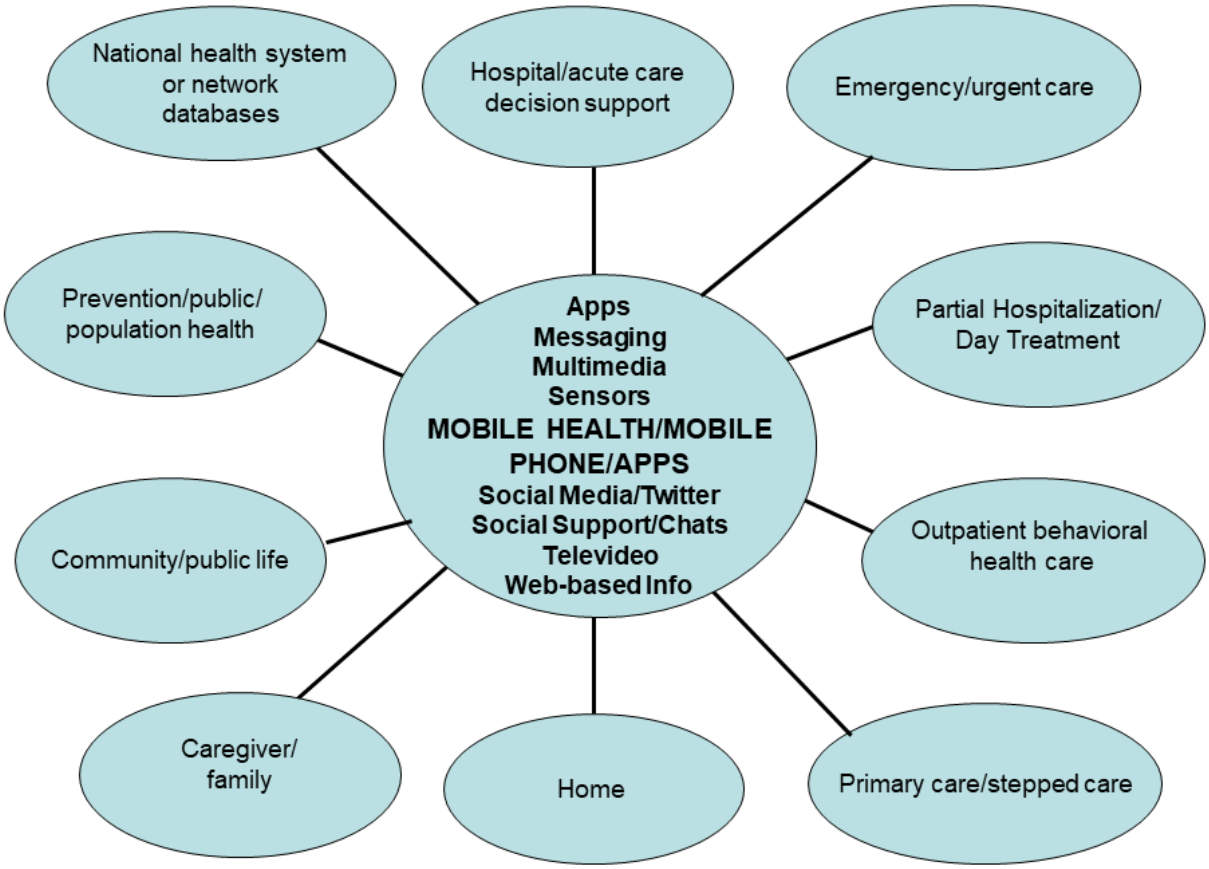
Introduction

Background

Mobile technologies such as mobile phones and other devices are supported by third generation and fourth generation mobile networks for data transport, computing, and integration. They have been a force in business, entertainment, and health communities and enable communication, monitoring, consulting, and other health care services across geographical, cost, and temporal barriers [1]. This movement is consistent with person- and patient-centered care, often spoken of as participatory medicine. It has moved patients from being mere passengers to responsible drivers of their health, and physicians value them as partners [2]. Accordingly, educational reform with technology is suggested by the World Health Organization [3] and the Institute of Medicine [4] to help physicians learn about technologies and educate patients.

In health care, mobile health (mHealth) components include monitoring, alerting, data collection, record maintenance, and detection and prevention systems [5]. mHealth was previously defined as "unwired e-med," [6] then as mobile communications and network technologies [7], and now as the application of mobile or wireless communication technologies to health and health care [8]. mHealth service architecture includes many settings, devices, and operational features (Figure 1). These afford accessibility, timeliness, and integration. Technology enables providers to do more with patients in a longitudinal, integrated way and is therefore called a *practice extender* [9].

Figure 1. How mobile health, mobile phone/device, and apps integrate information in the digital age.



mHealth recontextualizes health care communication via phones, tablet computers, and wearable devices (eg, smart watches and sensors) [10,11]. As such, mHealth intersects with the field of remote patient monitoring of patients outside of conventional clinical settings (eg, home-based chronic disease management). Persons, patients, caregivers, and family members report more

support if a problem arises and have fewer emergency department visits and hospitalizations [10,11]. Mobile apps offer (1) portability for access to data, systems, and other information, regardless of patient geography and transportation barriers; (2) an inexpensive option vs traditional desktop computers; and (3) additional features such as context-aware interventions and sensors [12] with real-time feedback. Although mobile technologies may feature live streaming of data, they are typically used like the 24-hour, 7-day per week Holter monitor in cardiology, which is read intermittently at the end of the data collection; therefore, it is usually functionally asynchronous.

The mHealth devices (Figure 1) have the following features [13]:

- Voice/video calling: convenient way for clinicians and patients to remotely communicate;
- SMS and multimedia message services: transmit text messages and video clips/sound files as a cost-effective way to deliver education;
- Multimedia functions: provide a range of learning opportunities;
- Inbuilt sensors: touch, motion, and GPS sensors that simplify clinical assessment and lifestyle and social activities;
- Device connectivity: practical and less error-prone data entry than manual processes.

mHealth also has clinical decision support (CDS) and information flow management features, which helps providers, patients, and others make decisions *in time*. These features improve outcomes, reduce unnecessary mistakes, and increase efficiency [14-16]. Health care has different types of information systems and domains, including the electronic health record (EHR), picture archiving and communication systems, laboratory information systems, and CDS systems. CDS provides clinicians, patients, and others with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. Research is investigating core components and processing features [13], including in child and adolescent psychiatry [15]. CDS arose within clinical informatics but is increasingly valued in medicine and behavioral health [16].

Competencies for Technology

Clinicians need a framework and skills/competencies for mHealth as a way to link skill and attitudinal change with quality of care [17]. The Institute of Medicine's core competencies for the health professions—now being applied to telepsychiatry and other technologies—include the ability to provide patient-centered care, work in interdisciplinary teams, employ evidence-based practice, apply quality improvement (QI), *and* use information technology [4]. Competency-based medical education movement focuses on clinical skill development and curricula to produce desired outcomes for learners in addition to knowledge acquisition [18]. Learner-centered educational outcomes are set, and then teaching and assessment methods are aligned [18,19]. Faculty assess learners during patient care in addition to seminars to ensure skill development [20,21].

A straightforward competency framework for some technologies is available for faculty, program directors, and administrators (eg, telepsychiatry and social media) [22-24]. It is based on the US Accreditation Council of Graduate Medical Education (ACGME) framework [25], which has domains related to patient care, medical knowledge, practice-based learning and improvement, systems-based practice, professionalism, and interpersonal skills and communication [25]. Another useful framework is the Royal College's Canadian Medical Education Directives for Specialists, which uses 7 roles that all physicians play: medical expert, communicator, collaborator, manager, health advocate, scholar, and professional [26].

The telepsychiatry competencies framework simplified the Dreyfus 5-level model of learners (level 1–novice; level 2–advanced; level 3–competent; level 4–proficient; and level 5–expert) [27] to 3 levels: novice/advanced beginner (eg, early clinicians or those unfamiliar with technology); competent/proficient (eg, able to translate in-person to technology-based care well); and expert (eg, advanced in clinical care and via technology). Others use a similar gradation nationally, such as the National Hospice and Palliative Care Organization [28].

The telepsychiatry *patient care* domain was divided into 2 parts: (1) clinical—the history, interviewing, assessment, and treatment and (2) administrative-based procedures/issues related to care such as documentation, EHR, medicolegal aspects, billing, and privacy/confidentiality. *Systems-based practice* included interprofessional education models of care and safety, whereas *professionalism* included integrity, ethics, culture, and diversity. As both telepsychiatry and in-person care are synchronous practices, the competencies are similar to a few significant and many minor adjustments in approach, execution, and evaluation (eg, inquiry about use of and comfort with technology and modification of a mental status examination at a distance). The competencies also added other important features such as detailed andragogy/pedagogy methods for teaching and assessment of learners, faculty development priorities, and institutional competencies for administration [22].

Social media and networking competencies apply as a preview of mHealth's asynchronous components [23]. Social media (1) is asynchronous not synchronous, so it cannot be *organized* or structured like traditional care; (2) may affect how participants engage within the therapeutic frame; (3) is conducted over public, private, and health system sites, making data integration and security difficult, if not impossible; (4) challenges users to maintain tight personal and professional boundaries, as email and texting may cause complications; and (5) requires clinicians to verify the identity of the patient for a social media account, as false identities are sometimes used [24]. A history about the use of social media needs to inquire about social media sites visited as well as for what purpose they are used [29].

For *patient care* related to social media, the competent/proficient clinician discusses technology during the consent process and screens for social media use. The clinician decides with the patient whether social media is *part of* the clinical service contract. This requires some reflection on its pros/cons, as much of it is outside the therapeutic hour [10]. At a minimum, if it is

part of the plan, it should be used as part of an established doctor-patient relationship. The clinician needs to systematically screen what is used and for what purpose(s) (eg, entertainment, health care, and behavioral health care). A plan may be needed to manage risks (eg, privacy, self-disclosure, and cyberbullying). As clinicians also have social media profiles, they have to be mindful of colleagues and patients–to portray a professional image–and to remember that one represents oneself, the institution, and the profession. Many of these challenges apply to mHealth, so additional screening and planning are needed with regard to patient care [17].

Lack of Existing Competencies for Mobile Health

mHealth is used clinician-to-clinician, clinician-to-patient, and person/people-to-others; the participants may be mobile or stationary. This poses significant challenges to clinical care, as mHealth alters communication, boundaries, and privacy/confidentiality; therefore, clinicians are encouraged to screen what technology is being used, how, and when [30]. mHealth may therefore affect the therapeutic relationship and it is important to use the *right* technology at the *right* time (eg, not using an app or text to express suicidal ideation [SI]) as part of a treatment plan. Although mHealth may empower patients via in-time learning and increased self-efficacy, all parties need to have time to acquire knowledge, gain skills, and adjust attitudes. This is greater than any single party seeking information, as knowledge does not necessarily translate into skill.

A conceptual approach may need to consider mHealth as both *inside* and *outside* of the clinical visit. Patients bring up apps, communications, and assignments from clinicians (eg, filling out a questionnaire). This is a new dimension of care typically without problems. An approach on competencies, however, encourages the clinician to use mHealth in the treatment plan more purposely (eg, using an app weekly for monitoring depression), rather than spontaneously. The clinician can help the patient use an app in a (structured) way that feeds into the EHR—instead of a half dozen apps that do not—which simplifies treatment and protects privacy. mHealth may also be used for communication outside the visit, and if a clinician uses her/his personal device for professional care, this may be disruptive, as texts and email create extra workload and irregular contact after hours (ie, a boundary problem).

There are things that mHealth, telemedicine/telepsychiatry (ie, video), social media, and other technologies have in common. mHealth like video connects participants synchronously (eg, live feed of data to a clinician for decisions) [31] or asynchronously [32]. Additional competencies are needed as mHealth includes CDS, mobile technology assessment/selection, and information flow management across an EHR platform. Unlike telepsychiatry, but like social media, mHealth may have asynchronous components (eg, texting) [33]. Not all patients may be suitable for mHealth and social media because of impulsivity (eg, disclosure of information, attempts at after-hours contact), and otherwise failing to understand the medium. On the other hand, some severely ill patients may benefit from mobile technologies. They may provide a *wraparound* approach, similar to case managers, for patients with schizophrenia who live in the community.

In addition to the clinical care adjustments, there are educational ramifications for mHealth competencies. The examples below show how supervision is on one hand similar (eg, mobile technologies are discussed like any other topic at a weekly supervisory meeting) but on the other hand, different (eg, additional supervisory contact to review online data about patient experiences over time). Accordingly, leaders need to organize a curriculum, perform program evaluation, train faculty, and administer change.

This paper will help with reference to mobile technologies' (ie, mHealth, mobile phones and other devices, and apps) competencies so the reader can:

1. develop competencies for mobile technologies using the ACGME framework, which is founded in the competency-based medical education movement,
2. model the mHealth competencies based on the competencies for telepsychiatry and social media, but shift them based on mHealth's components, concepts, operations, and processes,
3. model teaching and evaluation processes for clinicians, programs directors, and health care systems, which facilitate skill development based on those for telepsychiatry and social media but adjust them contextually based on mHealth's components, concepts, operations, and processes.

The section *Methods* outline the approach, strategy, validity assessment, and expert opinion processes. The *Results* are first organized into the findings, how the framework was built, and an overview of the competency movement in medicine. Existing competencies in telepsychiatry and social media are briefly described to provide historical background. Next, the *Results* outline unique elements of mHealth, with Figure 1 to provide clinical context, and a competency set, with examples to provide specifics. Some examples focus on clinical and supervisory themes, whereas others focus on teaching by faculty, with tables to outline both learning (Multimedia Appendix 1) and teaching (Multimedia Appendix 2) specifics. Figure 2 provides an overall picture on components of an e-learning culture and Figure 3 shows how the patient, clinician, and system need an interface.

Figure 2. Competency areas of an e-Culture for a training institution related to mobile health, mobile phone/device, and apps.

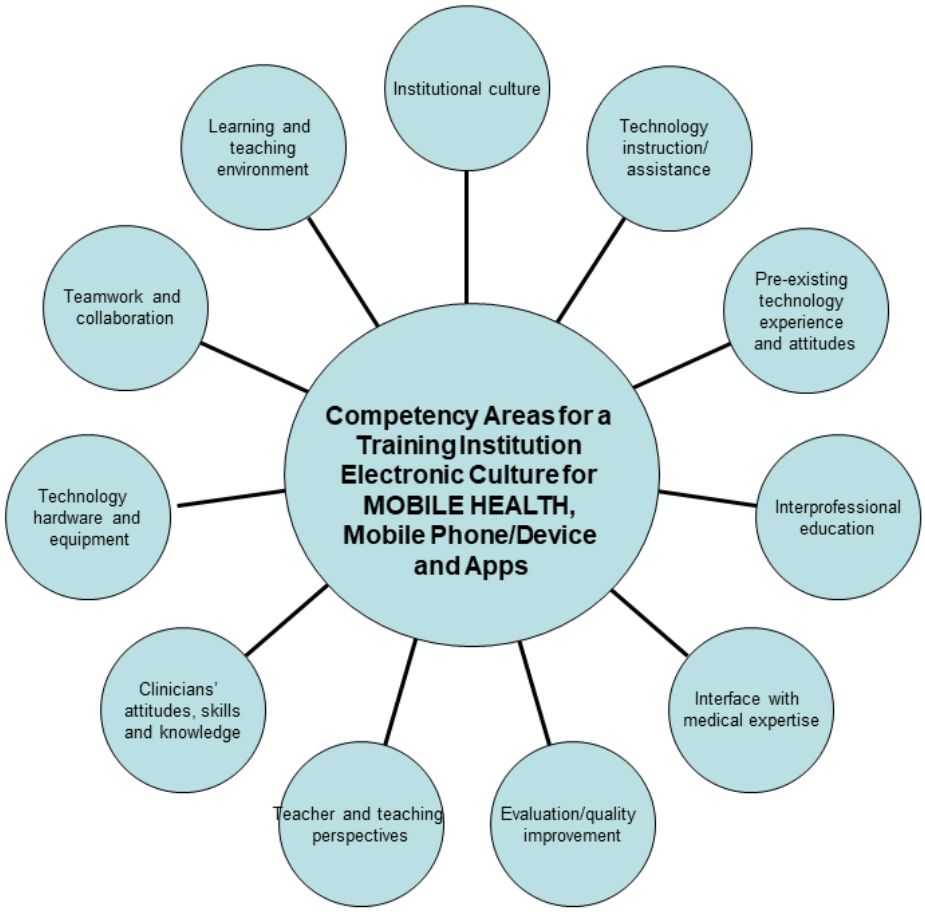
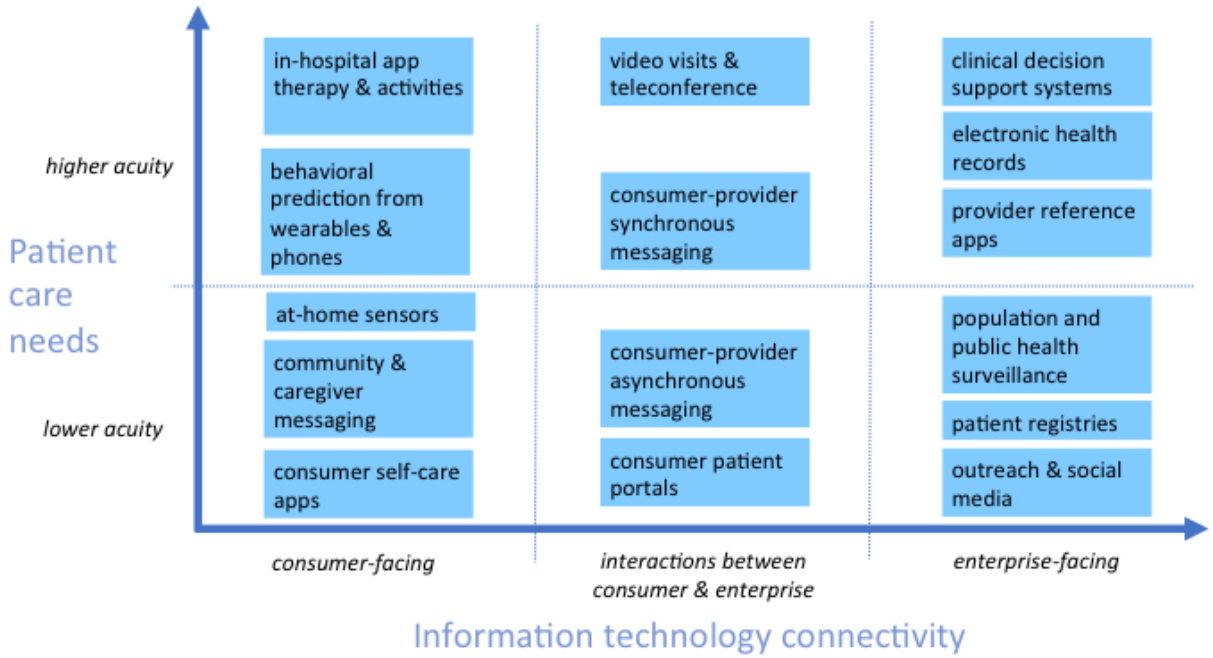


Figure 3. The relationship between patient care needs based on acuity and information technology connectivity.



Methods

Approach

The literature keyword search was conducted from July 2003 to February 2019. The philosophical approach to the search was used according to the original 6-stage process [34] and updated modifications [35] for scoping reviews. These reviews are typically undertaken to examine the extent, range, and nature of research in a topic area and identify gaps in knowledge rather than examine more specific, narrow topics based on study designs of systematic reviews. Both types of reviews use an approach based on concept, target population, and health outcomes.

The stages in this process have been described as (1) linking a clear purpose with a well-defined research question, with a rationale for completion; (2) identifying relevant studies based on the question and purpose, employing a suitable team; (3) selecting studies based on an iterative process involving searching the literature, refining the search strategy, and reviewing articles for study inclusion, along with reviewer discussion at the beginning, midpoint, and final stages; (4) charting the data and updating the form by having at least 2 reviewers extract information; (5) analysis, reporting, and considering the meaning of the findings (previously known as collating, summarizing, and reporting); and (6) using preliminary findings to obtain consultation from stakeholders toward an aim, using a plan for how data are collected, analyzed, reported, and integrated within the overall study outcome. Finally, clarifying terminology (eg, scoping reviews vs studies) and quality assessment are suggested [35].

The Research Question

The question that guided the review was, “What skills are needed for clinicians and trainees to provide quality care via mHealth, have they been published, and how can they be made measurable and reproducible to teach and assess them?” The goal was to identify behaviors (skills and competencies), make them measurable for implementation, and be able to assess learning outcomes, which are distinct from clinical treatment and service system outcomes. Implementation involves assessment of acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability [36]. As the search proceeded, additional terms were suggested by experts to potentially modify of the question, but new searches did not result in additional data, and the question did not change.

Identifying Relevant Studies: The Search Strategy

A literature keyword search from July 2003 to February 2019 (previously described) [30] placed keywords into concept areas [37]. The databases searched were PubMed/Medical Literature Analysis and Retrieval System Online, APA PsycNET, Cochrane, EMBASE, PsycINFO, Web of Science and Scopus, Science Citation Index, Social Sciences Citation Index, Telemedicine Information Exchange database, Centre for Reviews and Dissemination, and The Cochrane Library Controlled Trial Registry database. The initial literature search targeted 4 concept areas: (1) competency(ies) (skills, behavior, cognition, cognitive, pedagogy, framework, education, training, milestones, and curriculum); (2) mobile technologies (Web-based, apps, text, internet, mobile phone, wearable, and device); (3) telemedicine mode (video, synchronous, asynchronous, phone, and email); and (4) health (patient, clinician, care, services, medicine, psychiatry, mental, and behavioral).

Study Selection

An iterative process involving searching the literature, refining the search strategy, and reviewing articles for study inclusion was used. Two authors (DH and SC) independently, in parallel, screened the search results for potentially relevant studies based on titles and abstracts. Full-text articles were reviewed for final inclusion based on the keyword search. Inclusion criteria were keywords used from concept area 1 (competencies) and 2 (mobile technologies) and either 3 (telemedicine mode) or 4 (health). Exclusion criteria included keywords used from a concept area in isolation (eg, using the word competency but not mentioning a single skill); discussing skills abstractly (eg, as part of clinical skill development), outline or listing of what clinicians need (eg, knowledge, skills, and attitudes) without detail, listing behaviors that are not measurable (eg, good engagement), and terms in combination (eg, cognitive, milestones, and patient) without discussing competencies).

Findings of the searches were shared with others at the beginning of the process to decide study inclusion and exclusion, for the 2 reviewers to independently review abstracts and full papers; when disagreements on study inclusion occurred, a third reviewer determined the outcome. Reviewers met at the beginning, midpoint, and final stages of the abstract review process to discuss challenges and uncertainties related to study selection and to go back and to refine the search strategy. Study selection would have involved *posthoc* inclusion and exclusion criteria, based on the specifics of the research question, new familiarity with the subject matter, and expert input. However, none were added in this study.

Charting the Data

A data-charting form was not developed and used to extract data from each study, but notes were organized consistent with a narrative review or descriptive analytical methods by each reviewer to extract contextual or process-oriented information from each study, particularly the frameworks of telepsychiatric and social media competencies. The reviewers then compared and consolidated information regarding content. A qualitative content analysis approach would have been used if there was more content, to make sense of the wealth of extracted data. A descriptive analytical method was used to summarize the process and content information of discussions with experts, in an effort to chart and summarize complex concepts in a meaningful way.

Analysis, Reporting, and Considering the Meaning of the Findings

This phase was to organize meaningful results in a table, study by study, with skills outlined and parsed together incrementally. Then, the authors consolidated the data and followed up with the expert consensus step. There were few papers, so the findings were reported individually, as the depth of existing

research was less than expected. Indeed, there were virtually no experts outside of the authors with a command over the necessary different fields (eg, pedagogy, mHealth, and medical education administration). Therefore, the reporting of results and applying of meaning to the results was added to the authors' preliminary framework tables, and case examples were used to describe the findings. A descriptive numerical summary of results and a thematic analysis were not possible.

Consultation for Expert Opinion

Expert opinion was solicited in 4 ways: (1) a series of medical educator conference calls focused on teaching competencies [22,23], (2) discussion during several regional and national presentations (eg, American Association for Directors of Psychiatry Residency Training, (3) through individual discussions with educational experts [23], and (4) input from national behavioral health organizations–for example, psychiatry/medicine, psychology, social work, counseling, marriage/family, psychiatric nursing, and behavioral analysis) via 2 rounds of input for the consensus process [22,38]. That process was based on an already published review of interprofessional literature (ie, psychiatry/medicine, psychology, social work, counseling, marriage/family, psychiatric nursing, and behavioral analysis), which gained 2 rounds of input from national organizations as part of the consensus process [38].

The participants included educational leaders (eg, course/program directors, chairs, deans, a national society executive director), educational researchers, journal editors, and authors of educational textbooks. Participants had content expertise in medicine, psychiatry, education, health services, mobile technologies, and ethics. They represented viewpoints enriched by their leadership roles within their professional societies. Stakeholders were consulted with a purpose to validate preliminary findings, to integrate additional data related to the findings, and to revise the search to collect better data, if possible. Using a modified Delphi process, the conference participants reviewed an initial framework [22] based on qualitative analysis of identified themes that incorporated both ACGME competencies and the Royal College's Canadian Medical Education Directives for Specialists roles. The Delphi process is based on the principle that decisions from a structured group of individuals are more accurate than those from unstructured groups.

The conference calls series comprised 2 groups of 8 medical educators from the United States and Canada to discuss educational competency development. The preliminary findings were placed in the framework table, with both themes and individual suggestions (ie, findings). This allowed stakeholders to build on the evidence and offer a higher level of meaning, content expertise, and perspective to the preliminary findings. The references were also reviewed, and additional references were solicited. The Delphi process was modified in 3 ways: conferences were conducted by video/telephone, they occurred using groups of people from more than one organization, and part of the group feedback was provided by returning questionnaires.

Results

Overview

From a total of 1232 potential references, the authors found 78 eligible for a full-text review and 14 papers directly relevant to the concepts. From papers' references, another 10 papers were found, but they were mainly foundational sources about competencies from continuing and graduate education. There were a few papers on skill development, mainly in nurses and community health workers [39-41]. There were many references to patient education and the quality of a good app. There were also many references to informatics competencies, but none with competencies for mHealth; however, one used an ACGME framework [42].

Therefore, a framework was built according to the review, expert consensus, and recommendations of the Institute of Medicine's Health Professions Educational Summit [4] and ACGME framework [25]. It borrowed from existing frameworks in telepsychiatry, social media, and telebehavioral health. As mobile technologies have similarities to in-person and telepsychiatric care, mHealth competencies were placed in milestone domains of patient care, medical knowledge, practice-based learning and improvement, systems-based practice, professionalism, and interpersonal skills and communication.

Additional competencies were suggested as mHealth includes CDS, device/technology assessment/selection, and information flow management across an EHR platform. As care with mHealth may have asynchronous components—such as social media—competencies for trainees and clinicians may help them shift traditional learning, teaching, supervisory, and evaluation practices to achieve targeted outcomes. Asynchronous is defined in several ways but it includes sending information byte by byte, sequentially between parties (eg, texting), radiographs/pictures (eg, radiology and dermatology), and prerecorded information transfer [32].

Mobile Technologies Competencies

The experts agreed that the mHealth competency set be modeled after the ACGME framework of the telepsychiatric and social media competencies [22-24] and employ 3 levels named novice/beginner, competent/proficient, and expert [22,28]. The framework has been described in Multimedia Appendix 1.

Example 1: Description of Patient Care History Taking, Engagement, Assessment, and Treatment

The Patient Care section includes history taking, engagement and interpersonal skills, assessment, education and management, and treatment planning. It also includes administration, documentation, and medicolegal issues such as privacy, confidentiality, safety, data protection/integrity, and security. Clinicians should help patients reflect on the pros/cons of mobile technologies' use as part of ongoing treatment and document this (eg, as part of the consent form or in a progress note). This may include, but not be limited to, the competent/proficient clinician selecting the mobile technology option based on patient preference, skill and need (ie, purpose). To do that, it is helpful to know if the patient uses mobile technologies for personal

life, health care, and behavioral health care. The clinician should see if the patient is aware of risks (eg, privacy, self-disclosure, and potential for cyberbullying) and help them select options that are easy to use.

Technology in the form of mobile technologies can be useful for preparing for a treatment session or collecting information between sessions (eg, see the row titled "Management and treatment planning" in Multimedia Appendix 1). Ecological momentary assessment (EMA) involves repeated sampling of naturalistic behaviors and experiences [43-45] of day-to-day life such as habits (eg, smoking), mood changes (ie, depression), physical activity, and vital signs (eg, blood pressure). Paper-and-pencil diary methods (eg, medication calendars) are subject to memory lapses, recall bias, and bias related to social desirability. Now, mobile technologies may immediately capture information by alarms (ie, signal dependent) or key events (ie, event-dependent) that facilitate in-person trajectories and temporal sequences of behavior, particularly if wearable sensors are used.

In behavioral health, EMA measurement of changes in mood/affect correlate better with clinician-rated affective symptoms, may be used to detect subsequent risk of SI in bipolar patients [46], and may be preferable to patients (eg, Veterans prefer to complete psychometric measures such as the Patient Health Questionnaire or PHQ-9 using an iPhone [47,48]). If an urgent issue arises (eg, a patient reports SI via an app), an immediate telephone call or emergency response is almost always suggested, although a personalized email or text may be therapeutic and successful to prevent worsening [49-52].

Teaching, Assessment, and Evaluation of Mobile Technologies

Overview

The outcome (ie, competency skill or behavior) should predetermine its measurement as well as teaching, supervision, and organization of clinical services. This is particularly important as mobile technologies cause a shift, which may include events as part of a regular clinical visit or between visits. If clinicians who are supervisors pre-emptively decide that mobile technologies are not part of care or informally approach mHealth, trainees may not provide adequate supervision to develop necessary skills. Similarly, poor outcomes may occur if the discussion of mobile technologies is left to chance rather than a planned part of supervision.

The supervisor's approach requires many things, particularly a solid foundation in psychiatry (eg, the therapeutic frame and boundary issues) and experience with technology. She/he needs clear personal and professional boundaries and professional-personal wellness/balance to avoid other problems. She/he must plan how to monitor information flow and make decisions, if applicable, between visits. Patients and clinicians should have an initial discussion and monitor changes. Attention to longitudinal documentation is needed (eg, consent form and progress notes) for both supervisors and trainees. A patient's increasing number of requests for nonphone contact between visits (eg, apps, texts, and emails) may be a good sign or signal expectations that are not healthy.

Clinical Supervision of Mobile Technologies Competencies

An approach to teaching these competencies involves a wide range of methodologies, settings, and participants (Multimedia Appendix 2). Mobile technologies and social media have asynchronous functions, so an approach to *organize* the teaching plan is needed. A computer can be programmed to email, text, or otherwise contact a patient or a clinician may contact the patient throughout the week or vice versa. The flow of information has to be funneled *into* scheduled supervision as part of a caseload or quickly dealt with by a *curbside consultationin time*. Thus, clinical workflow and administrative policies may be required to provide a trainee time to reflect, consider options, and get advice before responding.

Traditional Teaching Approaches

Case-based learning (as seen in Multimedia Appendix 2) is a good teaching and learning method that uses real life examples or vignettes in seminars, site-based case conferences, and QI/grand round presentations. These also draw from trainees' experiences with patients about mobile technologies. Interactive methods such as role-plays can be used to flush out the issues, practice communication skills, identify options for decisions, and propose solutions for patients. Context for other settings and in-depth learning occurs through group input and feedback from peers and faculty. Furthermore, this provides an opportunity to build and solidify the resident *Role as an Educator* (Multimedia Appendix 2). She or he learns to work with an interprofessional team and adapt communication skills to multiple people. For a content area such as *Knowledge* (Multimedia Appendix 1), decision support tools may help clinicians evaluate apps to see if they are evidence based and develop an approach to use them in an evidence-based fashion.

Faculty cannot supervise mHealth care in real time like a scheduled visit. Reflection, peer advice, and faculty supervision may be required quickly, which may necessitate on-site *on-call* or *faculty of the day* supervision, but these other faculty may triage a situation differently than the trainee's ongoing supervisor. With regard to Example 1 given above related to SI, the trainee has to decide what to do and has several potential options: do nothing (if it is a chronic behavior for the patient); send a personalized, empathic text that is therapeutic [49]; telephone the patient; and trigger an emergency response. The personalized text may be part of an ongoing therapy for nonlethal impulsive harm (eg, self-mutilation). All parties should learn about clinic, department, and health system policies—if any are in place—or be prompted to develop them.

Example 2: Description of Supervision Clinical Care With Patients by Observing Faculty

CDS tools may also help with diagnosis and treatment [53] and this is learned in the flow of clinical care rather than by seminar, although case presentation and QI projects may help others learn and improve workflow. CDS is sometimes misunderstood as alert, notification, or explicit care suggestions, but CDS encompasses a variety of tools including, but not limited to computerized alerts and reminders for clinicians and patients, clinical guidelines, condition-specific order sets, focused patient

data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information [54].

CDS tools provide clinicians, patients, and others with knowledge and person-specific information, intelligently filtered and presented in a timely fashion. These help to enhance health and health care by enhancing decision making in the clinical workflow.

Examples are patient-report questionnaires and rating scales, which standardize evaluation and facilitate treatment tracking by automatically sending scores to a clinician in real time. One option (eg, Outcomes Questionnaires Analyst) utilizes electronic tracking of distress among patients and it has been used by some health systems with other disease-specific scales in order to within an online behavioral health EHR to inform decision making. Another uses the Brief Symptom Inventory for monitoring [52]. A Web-based CDS system for depression care management helps care managers and others implement the collaborative care model [55].

Discussion

Overview

Mobile technologies have similarities and differences to in-person and telepsychiatric care. The competencies for mobile technologies for trainees and faculty are based on graduate medical education, but they apply across health disciplines, professions, and behavioral health. Program directors, faculty, department leaders, and health system administrators must help trainees make decisions on how to best assess, triage, and treat patients and maintain the therapeutic relationship while using technology. Clinicians/faculty can model the importance of placing the patient's needs first and embracing technology for health care reform [3,4]. If and when they do not, students' digital professionalism has been shown to deteriorate during core clinical clerkships, according to behavior, privacy, and attitudinal measures [56].

Traditionally, clinicians depend on research and clinical measures as well as guidelines for care. The Healthcare Information and Management Systems Society (HIMSS) has created assessment guidelines for mobile technologies [57], and existing evidence-based guidelines for apps stratify purposeful use, content/process, measurement/assessment, and quality [30,58-61]. However, skills are needed to use the evidence base, and unfortunately, some *guidelines* on email, social media, and other technologies are not evidence- and consensus-based [17,39].

The Future State

Going forward with mHealth competencies, there are several suggestions. The findings need more detailed metrics and thorough evaluation to be measurable. For both cross-sectional and longitudinal trajectories, qualitative and quantitative evaluation of participants is suggested to iteratively improve the process. Research is also needed on to how to implement competencies in a customized way and evaluate them to ensure skill development improves quality of care. Organizational assessment and change are needed as this mHealth is a paradigm shift that recontextualizes digital health care. Trainees are a helpful *vehicle* for teaching faculty about mHealth, social media and other technologies—in clinical settings and particularly through QI, scholarship/research projects, and grants (eg, an Institute on Medicine as a profession and the Josiah Macy Jr Foundation 2-year grant on social media).

Technology significantly shapes people's lives, and they have expectations in health care as in the rest of the real world. Undergraduate universities, business, banking, and even dating services learned that to prosper and survive, they had to adjust to people's preferences for electronic and online modalities [62]. The business approach to new markets and to match products with user needs (Figure 3 [63]) could be useful for medicine related to technology. For patients' health care to improve, clinicians need to understand the person behind the patient, their motivations, and their behaviors [64]. To do this, new paradigms are needed to help organizations change [31,65-68], and institutional competencies for technology have been suggested for academic health centers [22]. At a minimum, a plan for technology infrastructure and policy/procedures are needed for clinical, education, and research missions. For mobile technologies, there are at least 5 paradigm shifts at hand—each driven by demand, outcomes, competencies, and evaluation:

1. Patients *and* trainees of the X, Millennial/Y, and Z generations want *and* expect a digital health care experience [23,24];
2. Technology-based health care is *at least as efficacious* (eg, telepsychiatry) as in-person care, and it leverages resources much more efficiently [32,56,69];
3. Health care systems must focus on skills/competencies *in addition to* knowledge to ensure quality, safety, and efficiency of care;
4. An EHR-platform informed by information systems should be a versatile, flexible foundation for *good* clinical care (eg, multiple entry portals via mHealth) [64];
5. The mHealth is an example of a new and strategically better way to *frame* or organize health care [8,13,23] *if* leaders and other participants embrace it and find a way to manage constraints (eg, reimbursement).

Shifts in Education and Practice

The path through training, lifelong practice, and accreditation has some disconnections despite common interests related to policy, regulatory, and other matters [30]. In behavioral health, coordination and collaboration may involve the Association of State and Provincial Psychology Board, the American Board of Psychiatry and Neurology, and the American Psychiatric Association. Legal and regulatory issues are complex as clinicians need to adhere to in-person and telehealth-relevant laws and requirements—and adapt those standards to mHealth—while attending to contextual and overarching jurisdictional issues of states and the government (and its agencies). Nongovernmental regulatory requirements and recommendations may also apply (eg, in the United States, Joint Commission, Council on Accreditation, Utilization Review Accreditation Commission, and HIMSS).

There are limitations to this set of mobile technologies competencies. First, study selection was based on guidance from a team (ie, only 2 reviewers), which was not

interdisciplinary, and without a transparent and replicable process. Second, a data-charting form was not developed and used to extract data from each study. Third, breaking the analysis phase into meaningful and systematic steps would have been more rigorous and would have provided a guide for future researchers [70]. Fourth, with regard to reporting and considering the meaning of the findings, only a thematic analysis was presented, rather than a numerical analysis of the extent and nature of studies. A summary of results would be in order, but when a scoping review is done when there is *insufficient evidence*, that is not always possible [71]. Fifth, broader input for consensus across organizations (eg, American/British/Canadian Medical Associations and American Telemedicine Association) could have been helpful. Sixth, although *posthoc* changes via experts were added to the table of competencies, there were few because of the authors' familiarity with the subject matter being far ahead of the literature and the experts obtained. A qualitative, small group interview approach with experts via a semistructured guide could have asked participants to identify models for care (regardless of whether they were published) and to specify key model components [71]. Finally, if calls had been recorded, summarized, and shared with the group, ideas could have been clarified and additional input gained.

Acknowledgments

The authors would like to thank the American Association of Medical Colleges, ACGME, American Psychiatric Association and the Board of Trustees Committee on Telepsychiatry, American Telemedicine Association and the Telemental Health Interest Group, Department of Psychiatry and Behavioral Sciences, University of California, Davis School of Medicine, and Veteran Affairs Northern California Health Care System and Mental Health Service.

Conflicts of Interest

None declared.

Multimedia Appendix 1
A Framework to Adapt Accreditation Council of Graduate Medical Education (ACGME) Core Competencies to Mobile Technologies Clinical Competencies.
[DOCX File , 26 KB - mhealth_v8i2e12229_app1.docx]

Multimedia Appendix 2
Teaching, Assessment, and Evaluation Methods for Mobile Technologies (Mobile Health, Mobile Phone, and Apps) Clinical Competencies.
[DOCX File , 20 KB - mhealth_v8i2e12229_app2.docx]

References

1. Tachakra S, Wang XH, Istepanian RS, Song YH. Mobile e-health: the unwired evolution of telemedicine. Telemed J E Health 2003;9(3):247-257. [doi: 10.1089/153056203322502632] [Medline: 14611692]
2. Miles A, Mezzich J. The care of the patient and the soul of the clinic: person-centered medicine as an emergent model of modern clinical practice. Int J Person Cent Med 2011 Jun 10;1(2):495-502. [doi: 10.5750/ijpcm.v1i2.61]
3. World Health Organization. 2010. Telemedicine Opportunities and Developments in Member States URL: http://www.who.int/goe/publications/goe_telemedicine_2010.pdf
4. Health Professions Education: A Bridge to Quality. Washington, DC, United States: National Academies Press; 2002.
5. Silva BM, Rodrigues JJ, de la Torre Díez I, López-Coronado M, Saleem K. Mobile-health: a review of current state in 2015. J Biomed Inform 2015 Aug;56:265-272 [FREE Full text] [doi: 10.1016/j.jbi.2015.06.003] [Medline: 26071682]
6. Laxminarayan S, Istepanian RS. UNWIRED E-MED: the next generation of wireless and internet telemedicine systems. IEEE Trans Inf Technol Biomed 2000 Sep;4(3):189-193. [doi: 10.1109/titb.2000.5956074] [Medline: 11026588]
7. Istepanian R, Lacal J. Emerging mobile communication technologies for health: some imperative notes on m-health. In: Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. 2003 Presented at: International Conference of the IEEE Engineering in Medicine and Biology Society; September 17-21, 2003; Cancun, Mexico p. 1414-1416. [doi: 10.1109/iembs.2003.1279581]
8. Steinhubl SR, Muse ED, Topol EJ. Can mobile health technologies transform health care? J Am Med Assoc 2013 Dec 11;310(22):2395-2396. [doi: 10.1001/jama.2013.281078] [Medline: 24158428]
9. Raney L, Bergman D, Torous J, Hasselberg M. Digitally driven integrated primary care and behavioral health: how technology can expand access to effective treatment. Curr Psychiatry Rep 2017 Sep 30;19(11):86. [doi: 10.1007/s11920-017-0838-y] [Medline: 28965319]
10. Hilty DM, Chan S, Torous J, Luo J, Boland RJ. A telehealth framework for mobile health, smartphones, and apps: competencies, training, and faculty development. J Technol Behav Sci 2019 Apr 15;4(2):106-123. [doi: 10.1007/s41347-019-00091-0]

11. Kumari P, Mathew L, Syal P. Increasing trend of wearables and multimodal interface for human activity monitoring: a review. Biosens Bioelectron 2017 Apr 15;90:298-307. [doi: 10.1016/j.bios.2016.12.001] [Medline: 27931004]
12. Torous J, Chan SR, Yee-Marie Tan S, Behrens J, Mathew I, Conrad EJ, et al. Patient smartphone ownership and interest in mobile apps to monitor symptoms of mental health conditions: a survey in four geographically distinct psychiatric clinics. JMIR Ment Health 2014;1(1):e5 [FREE Full text] [doi: 10.2196/mental.4004] [Medline: 26543905]
13. Honeyman E, Ding H, Varnfield M, Karunanithi M. Mobile health applications in cardiac care. Interv Cardiol 2014 Nov;6(2):- [FREE Full text]
14. Osheroff JA, Teich JM, Middleton B, Steen EB, Wright A, Detmer DE. A roadmap for national action on clinical decision support. J Am Med Inform Assoc 2007;14(2):141-145 [FREE Full text] [doi: 10.1197/jamia.M2334] [Medline: 17213487]
15. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. Br Med J 2005 Apr 02;330(7494):765 [FREE Full text] [doi: 10.1136/bmj.38398.500764.8F] [Medline: 15767266]
16. Torous J, Chan S, Luo J, Boland R, Hilty D. Clinical informatics in psychiatric training: preparing today's trainees for the already present future. Acad Psychiatry 2018 Oct;42(5):694-697 [FREE Full text] [doi: 10.1007/s40596-017-0811-4] [Medline: 29047074]
17. Hilty DM, Chan S, Hwang T, Wong A, Bauer AM. Advances in mobile mental health: opportunities and implications for the spectrum of e-mental health services. Mhealth 2017;3:34 [FREE Full text] [doi: 10.21037/mhealth.2017.06.02] [Medline: 28894744]
18. Frank JR, Mungroo R, Ahmad Y, Wang M, De Rossi S, Horsley T. Toward a definition of competency-based education in medicine: a systematic review of published definitions. Med Teach 2010;32(8):631-637. [doi: 10.3109/0142159X.2010.500898] [Medline: 20662573]
19. American Psychiatric Association Council on Medical EducationLifelong Learning. American Psychiatric Association. Arlington, VA; 2014. Training Psychiatrists for Integrated Behavioral Health Care URL: https://pdfs.semanticscholar.org/cff0/92a1753203e67bf645254664138b2a7070aa.pdf [accessed 2019-12-26]
20. Iobst WF, Sherbino J, Cate OT, Richardson DL, Dath D, Swing SR, et al. Competency-based medical education in postgraduate medical education. Med Teach 2010;32(8):651-656. [doi: 10.3109/0142159X.2010.500709] [Medline: 20662576]
21. Snell LS, Frank JR. Competencies, the tea bag model, and the end of time. Med Teach 2010;32(8):629-630. [doi: 10.3109/0142159X.2010.500707] [Medline: 20662572]
22. Hilty DM, Crawford A, Teshima J, Chan S, Sunderji N, Yellowlees PM, et al. A framework for telepsychiatric training and e-health: competency-based education, evaluation and implications. Int Rev Psychiatry 2015;27(6):569-592. [doi: 10.3109/09540261.2015.1091292] [Medline: 26540642]
23. Hilty DM, Zalpuri I, Stubbe D, Snowdy CE, Shoemaker EZ, Myint MT, et al. Social media/networking and psychiatric Education: competencies, teaching methods, and implications. J Technol Behav Sci 2018 Jul 9;3(4):268-293. [doi: 10.1007/s41347-018-0061-7]
24. Zalpuri I, Liu HY, Stubbe D, Wrzosek M, Sadhu J, Hilty D. Social Media and Networking Competencies for Psychiatric Education: Skills, Teaching Methods, and Implications. Acad Psychiatry 2018 Dec;42(6):808-817. [doi: 10.1007/s40596-018-0983-6] [Medline: 30284148]
25. Accreditation Council on Graduate Medical Education. 2013. Common Program Requirements URL: https://www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramRequirements/CPRs2013.pdf [accessed 2019-12-26]
26. Royal College of Physicians and Surgeons, CanMEDS Framework. 2005. The CanMEDS 2005 Physician Competency Framewor URL: http://www.ub.edu/medicina_unitateducaciomedica/documentos/CanMeds.pdf [accessed 2019-12-26]
27. Dreyfus S, Dreyfus H. University of California, Operations Research Center. 1980. A five-stage model of the mental activities involved in directed skill acquisition URL: http://www.dtic.mil/dtic/index.html
28. National Hospice and Palliative Care Organization. 2010. Interdisciplinary Team Competency Grid URL: https://www.nhpco.org/wp-content/uploads/2019/06/Competency_level_grid_final.pdf [accessed 2019-12-26]
29. Boyd DM, Ellison NB. Social network sites: definition, history, and scholarship. J Comp-Med Commun 2008;13:210-230. [doi: 10.1111/j.1083-6101.2007.00393.x]
30. Chan S, Torous J, Hinton L, Yellowlees P. Towards a framework for evaluating mobile mental health apps. Telemed J E Health 2015 Dec;21(12):1038-1041. [doi: 10.1089/tmj.2015.0002] [Medline: 26171663]
31. Hilty DM, Ferrer DC, Parish MB, Johnston B, Callahan EJ, Yellowlees PM. The effectiveness of telemental health: a 2013 review. Telemed J E Health 2013 Jun;19(6):444-454 [FREE Full text] [doi: 10.1089/tmj.2013.0075] [Medline: 23697504]
32. Yellowlees PM, Odor A, Iosif A, Parish MB, Nafiz N, Patrice K, et al. Transcultural psychiatry made simple--asynchronous telepsychiatry as an approach to providing culturally relevant care. Telemed J E Health 2013 Apr;19(4):259-264 [FREE Full text] [doi: 10.1089/tmj.2012.0077] [Medline: 23451812]
33. Srinivasan M, Li ST, Meyers FJ, Pratt DD, Collins JB, Braddock C, et al. "Teaching as a Competency": competencies for medical educators. Acad Med 2011 Oct;86(10):1211-1220. [doi: 10.1097/ACM.0b013e31822c5b9a] [Medline: 21869655]
34. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005 Feb;8(1):19-32. [doi: 10.1080/1364557032000119616]

35. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci 2010 Sep 20;5:69 [FREE Full text] [doi: 10.1186/1748-5908-5-69] [Medline: 20854677]
36. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011 Mar;38(2):65-76 [FREE Full text] [doi: 10.1007/s10488-010-0319-7] [Medline: 20957426]
37. Platt RE, Spencer AE, Burkey MD, Vidal C, Polk S, Bettencourt AF, et al. What's known about implementing co-located paediatric integrated care: a scoping review. Int Rev Psychiatry 2018 Dec;30(6):242-271. [doi: 10.1080/09540261.2018.1563530] [Medline: 30912463]
38. Maheu M, Drude K, Hertlein K. An interdisciplinary framework for telebehavioral health competencies. J Tech Behav Sci 2018 Mar 5;3:108-140. [doi: 10.1007/s41347-019-00113-]
39. Winters N, Langer L, Geniets A. Scoping review assessing the evidence used to support the adoption of mobile health (mHealth) technologies for the education and training of community health workers (CHWs) in low-income and middle-income countries. BMJ Open 2018 Jul 30;8(7):e019827 [FREE Full text] [doi: 10.1136/bmjopen-2017-019827] [Medline: 30061430]
40. Mofukeng DB, Roos SD. Clinical skills of nurses in mobile health services. Curationis 1999 Jun;22(2):4-9. [doi: 10.4102/curationis.v22i2.712] [Medline: 11040613]
41. Chuang Y, Lai F, Chang C, Wan H. Effects of a skill demonstration video delivered by smartphone on facilitating nursing students' skill competencies and self-confidence: A randomized controlled trial study. Nurse Educ Today 2018 Jul;66:63-68. [doi: 10.1016/j.nedt.2018.03.027] [Medline: 29677580]
42. Hersh WR, Gorman PN, Biagioli FE, Mohan V, Gold JA, Mejicano GC. Beyond information retrieval and electronic health record use: competencies in clinical informatics for medical education. Adv Med Educ Pract 2014;5:205-212 [FREE Full text] [doi: 10.2147/AMEP.S63903] [Medline: 25057246]
43. Carlson EB, Field NP, Ruzek JI, Bryant RA, Dalenberg CJ, Keane TM, et al. Advantages and psychometric validation of proximal intensive assessments of patient-reported outcomes collected in daily life. Qual Life Res 2016 Mar;25(3):507-516 [FREE Full text] [doi: 10.1007/s11136-015-1170-9] [Medline: 26567018]
44. van Os J, Delespaul P, Barge D, Bakker RP. Testing an mHealth momentary assessment Routine Outcome Monitoring application: a focus on restoration of daily life positive mood states. PLoS One 2014;9(12):e115254 [FREE Full text] [doi: 10.1371/journal.pone.0115254] [Medline: 25513813]
45. Depp CA, Kim DH, de Dios LV, Wang V, Ceglowski J. A pilot study of mood ratings captured by mobile phone versus paper-and-pencil mood charts in bipolar disorder. J Dual Diagn 2012 Jan 1;8(4):326-332 [FREE Full text] [doi: 10.1080/15504263.2012.723318] [Medline: 23646035]
46. Thompson WK, Gershon A, O'Hara R, Bernert RA, Depp CA. The prediction of study-emergent suicidal ideation in bipolar disorder: a pilot study using ecological momentary assessment data. Bipolar Disord 2014 Nov;16(7):669-677 [FREE Full text] [doi: 10.1111/bdi.12218] [Medline: 24903771]
47. Bush NE, Skopp N, Smolenski D, Crumpton R, Fairall J. Behavioral screening measures delivered with a smartphone app: psychometric properties and user preference. J Nerv Ment Dis 2013 Nov;201(11):991-995. [doi: 10.1097/NMD.0000000000000039] [Medline: 24177488]
48. Berrouiguet S, Baca-García E, Brandt S, Walter M, Courtet P. Fundamentals for future mobile-health (mHealth): a systematic review of mobile phone and web-based text messaging in mental health. J Med Internet Res 2016 Jun 10;18(6):e135 [FREE Full text] [doi: 10.2196/jmir.5066] [Medline: 27287668]
49. Odeny TA, Newman M, Bukusi EA, McClelland RS, Cohen CR, Camlin CS. Developing content for a mHealth intervention to promote postpartum retention in prevention of mother-to-child HIV transmission programs and early infant diagnosis of HIV: a qualitative study. PLoS One 2014;9(9):e106383 [FREE Full text] [doi: 10.1371/journal.pone.0106383] [Medline: 25181408]
50. Gonzalez J, Williams JW, Noël PH, Lee S. Adherence to mental health treatment in a primary care clinic. J Am Board Fam Pract 2005;18(2):87-96 [FREE Full text] [doi: 10.3122/jabfm.18.2.87] [Medline: 15798137]
51. Harrison V, Proudfoot J, Wee PP, Parker G, Pavlovic DH, Manicavasagar V. Mobile mental health: review of the emerging field and proof of concept study. J Ment Health 2011 Dec;20(6):509-524. [doi: 10.3109/09638237.2011.608746] [Medline: 21988230]
52. Luxton DD, McCann RA, Bush NE, Mishkind MC, Reger GM. mHealth for mental health: Integrating smartphone technology in behavioral healthcare. Prof Psychol Res Pract 2011;42(6):505-512. [doi: 10.1037/a0024485]
53. Center for MedicareMedicaid Services. Center for Medicare & Medicaid Services. 2019. Clinical Decision Support URL: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/ClinicalDecisionSupport_Tipsheet-.pdf [accessed 2019-12-26]
54. Fortney JC, Pyne JM, Steven CA, Williams JS, Hedrick RG, Lunsford AK, et al. A web-based clinical decision support system for depression care management. Am J Manag Care 2010 Nov;16(11):849-854 [FREE Full text] [Medline: 21348556]
55. Derogatis L, Fitzpatrick M. The SCL-90-R, the Brief Symptom Inventory (BSI),the BSI-18. In: Maruish ME, editor. The Use of Psychological Testing for Treatment Planning and Outcomes Assessment. New York: Routledge; 2004:1-41.

56. Mostaghimi A, Olszewski AE, Bell SK, Roberts DH, Crotty BH. Erosion of digital professionalism during medical students' core clinical clerkships. JMIR Med Educ 2017 May 03;3(1):e9 [FREE Full text] [doi: 10.2196/mededu.6879] [Medline: 28468745]
57. Arellano P, Bochinski J, Elias B. The Healthcare Information and Management Systems Society. 2012. Selecting a mobile appvaluating the usability of medical applications URL: https://www.mhimss.org/sites/default/files/resourcemedia/pdf/HIMSSguidetoappusabilityv1mHIMSS.pdf
58. Gonnermann A, von Jan U, Albrecht U. Draft guideline for the development of evidence based medicine-related apps. Stud Health Technol Inform 2015;210:637-641. [Medline: 25991226]
59. Agarwal S, LeFevre AE, Lee J, L'Engle K, Mehl G, Sinha C, WHO mHealth Technical Evidence Review Group. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. Br Med J 2016 Mar 17;352:i1174. [doi: 10.1136/bmj.i1174] [Medline: 26988021]
60. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. J Clin Epidemiol 2009 Oct;62(10):e1-34 [FREE Full text] [doi: 10.1016/j.jclinepi.2009.06.006] [Medline: 19631507]
61. Grundy QH, Wang Z, Bero LA. Challenges in assessing mobile health app quality: a systematic review of prevalent and innovative methods. Am J Prev Med 2016 Dec;51(6):1051-1059. [doi: 10.1016/j.amepre.2016.07.009] [Medline: 27659122]
62. Rogers EM. Diffusion Of Innovations. New York: Free Press; 2019.
63. Kotter J. Leading Change, With A New Preface By The Author. Boston: Harvard Business Review Press; 2019.
64. Yellowlees PM, Hogarth M, Hilty DM. The importance of distributed broadband networks to academic biomedical research and education programs. Acad Psychiatry 2006;30(6):451-455. [doi: 10.1176/appi.ap.30.6.451] [Medline: 17139015]
65. Armstrong EG, Mackey M, Spear SJ. Medical education as a process management problem. Acad Med 2004 Aug;79(8):721-728. [doi: 10.1097/00001888-200408000-00002] [Medline: 15277126]
66. Bowe CM, Lahey L, Kegan R, Armstrong E. Questioning the "big assumptions". Part II: recognizing organizational contradictions that impede institutional change. Med Educ 2003 Aug;37(8):723-733. [doi: 10.1046/j.1365-2923.2003.01580.x] [Medline: 12895253]
67. Frydman G. Patient-driven research: rich opportunities and real risks. J Participat Med 2009 [FREE Full text]
68. Christensen CM. Disruptive innovation: can health care learn from other industries? A conversation with Clayton M. Christensen. Interview by Mark D. Smith. Health Aff (Millwood) 2007;26(3):w288-w295. [doi: 10.1377/hlthaff.26.3.w288] [Medline: 17355981]
69. Sturmberg JP, O'Halloran D, Colagiuri R, Fernandez A, Lukersmith S, Torkfar G, et al. Health care frames - from Virchow to Obama and beyond: the changing frames in health care and their implications for patient care. J Eval Clin Pract 2014;20(6):1036-1044. [doi: 10.1111/jep.12266] [Medline: 25312686]
70. Korthuis PT, McCarty D, Weimer M, Bougatsos C, Blazina I, Zakher B, et al. Primary care-based models for the treatment of opioid use disorder: a scoping review. Ann Intern Med 2017 Mar 21;166(4):268-278 [FREE Full text] [doi: 10.7326/M16-2149] [Medline: 27919103]
71. Monash University. 2019. Clinical guideline for the diagnosis and management of work-related mental health conditions in general practice: GP summary URL: https://www.monash.edu/__data/assets/pdf_file/0010/1696681/GP-Summary-of-the-Work-Related-Mental-Health-Clinical-Guideline_Digital.pdf [accessed 2019-12-26]

Abbreviations

ACGME: Accreditation Council of Graduate Medical Education
CDS: clinical decision support
EHR: electronic health record
EMA: ecological momentary assessment
HIMSS: Healthcare Information and Management Systems Society
mHealth: mobile health
OQ: Outcomes Questionnaire
QI: quality improvement
SI: suicidal ideation

Edited by A Tsanas; submitted 16.09.18; peer-reviewed by S Acquilano, V Noel, K Long, J Farzi; comments to author 17.11.18; revised version received 26.03.19; accepted 29.05.19; published 21.02.20.

Please cite as:
Hilty D, Chan S, Torous J, Luo J, Boland R
A Framework for Competencies for the Use of Mobile Technologies in Psychiatry and Medicine: Scoping Review
JMIR Mhealth Uhealth 2020;8(2):e12229
URL: http://mhealth.jmir.org/2020/2/e12229/
doi:10.2196/12229
PMID:32130153

Original Paper

A Possible Mobile Health Solution in Orthopedics and Trauma Surgery: Development Protocol and User Evaluation of the Ankle Joint App

Florian Dittrich[1], Dr med; David Alexander Back[2], Priv-Doz; Anna Katharina Harren[3], Dr med; Marcus Jäger[4], Univ-Prof; Stefan Landgraeber[1], Univ-Prof; Felix Reinecke[5]; Sascha Beck[1,6], Dr med

[1]Department for Orthopaedics and Orthopaedic Surgery, Saarland University Medical Center and Saarland University Faculty of Medicine, Homburg, Germany

[2]Clinic of Traumatology and Orthopedics, Bundeswehr Hospital Berlin, Berlin, Germany

[3]Department of Plastic, Reconstructive & Aesthetic Surgery, Specialized Clinic Hornheide, Münster, Germany

[4]Department of Orthopaedics, Trauma and Recontructive Surgery, St. Marien Hospital Mülheim and Chair of Orthopaedics and Trauma Surgery, University of Duisburg-Essen, Essen, Germany

[5]Clinic of Trauma, Hand and Reconstructive Surgery, University Hospital Essen, Essen, Germany

[6]Sportsclinic Hellersen, Lüdenscheid, Germany

Corresponding Author:
Florian Dittrich, Dr med
Department for Orthopaedics and Orthopaedic Surgery
Saarland University Medical Center and Saarland University Faculty of Medicine
Kirrbergerstr. 100
Building 37-38
Homburg
Germany
Phone: 49 68411624520
Email: florian.dittrich@uks.eu

Abstract

Background: Ankle sprains are one of the most frequent sports injuries. With respect to the high prevalence of ankle ligament injuries and patients' young age, optimizing treatment and rehabilitation is mandatory to prevent future complications such as chronic ankle instability or osteoarthritis.

Objective: In modern times, an increasing amount of smartphone usage in patient care is evident. Studies investigating mobile health (mHealth)–based rehabilitation programs after ankle sprains are rare. The aim of this study was to expose any issues present in the development process of a medical app as well as associated risks and chances.

Methods: The development process of the Ankle Joint App was defined in chronological order using a protocol. The app's quality was evaluated using the (user) German Mobile App Rating Scale (MARS-G) by voluntary foot and ankle surgeons (n=20) and voluntary athletes (n=20).

Results: A multidisciplinary development team built a hybrid app with a corresponding backend structure. The app's content provides actual medical literature, training videos, and a log function. Excellent interrater reliability (interrater reliability=0.92; 95% CI 0.86-0.96) was obtained. The mean overall score for the Ankle Joint App was 4.4 (SD 0.5). The mean subjective quality scores were 3.6 (surgeons: SD 0.7) and 3.8 (athletes: SD 0.5). Behavioral change had mean scores of 4.1 (surgeons: SD 0.7) and 4.3 (athletes: SD 0.7). The medical gain value, rated by the surgeons only, was 3.9 (SD 0.6).

Conclusions: The data obtained demonstrate that mHealth-based rehabilitation programs might be a useful tool for patient education and collection of personal data. The achieved (user) MARS-G scores support a high quality of the tested app. Medical app development with an a priori defined target group and a precisely intended purpose, in a multidisciplinary team, is highly promising. Follow-up studies are required to obtain funded evidence for the ankle joints app's effects on economical and medical aspects in comparison with established nondigital therapy paths.

(JMIR Mhealth Uhealth 2020;8(2):e16403) doi:10.2196/16403

KEYWORDS

smartphone; ankle sprain; rehabilitation; self-care; mHealth; mobile phone

Introduction

Background

An ankle sprain is one of the most frequent injuries, with an incidence of 1:10,000 individuals per day in amateur and high-performance sports in the United States [1]. With respect to the high prevalence of ankle ligament injuries and patients' young age, optimizing aftercare and rehabilitation is mandatory [2]. Moreover, the economic burden of ankle sprains is enormous [3]. High medical, physiotherapeutic, and lost productivity costs burden health care systems and create the need for new, efficient diagnostic and therapeutic solutions [4].

To prevent long-term complications, complex ligament injuries and recurrent ankle sprains with progression to chronic ankle instability (CAI) have to be recognized. The development of ankle osteoarthritis (OA) as a long-term consequence of CAI was first shown by Harrington et al [5] in 1979. Following an ankle ligament injury, posttraumatic muscular insufficiency [6,7] and ankle OA were observed in 13% of the cases [8]. Therefore, the adequate and consequent treatment of an ankle sprain might prevent CAI and OA.

Nowadays, early functional treatment is considered the gold standard for the lateral ligament lesion of the ankle [2,9]. The latest national guideline published by the German Orthopedic Foot and Ankle Society (Deutsche Assoziation für Fuß und Sprunggelenk eV, DAF) also recommends a conservative approach to acute ligament tears of the lateral ankle joint [10].

In times of digitalization and emerging technologies, smartphones are regularly used to accomplish everyday tasks, such as Web-based banking and communication *via* messenger or email, and penetrate rapidly into more and more areas of life [11]. The portability and omnipresent accessibility of smartphones enable usage anywhere and anytime [12]. In general, the growing implementation of smartphones as a transfer media in medical context is evident [13].

It has already been shown that the patients' acceptance is given for collecting personalized health-relevant data *via* software apps, to share these with their peers or the medical staff [14]. Moreover, mobile short message service text messages and apps can have a positive impact on the posttraumatic outcome by showing increased adherence to medications and protocols, improved clinic attendance, and decreased readmission rates and emergency room visits [15].

However, the implementation and use of mobile health (mHealth) in medical care, especially in the fields of orthopedics and trauma surgery, can still be regarded to be in an early stage. So far, only 13 serious medical apps in orthopedics and trauma surgery have been identified for regular use in outpatient and inpatient medical care in German-speaking countries [16]. In a survey among German orthopedic and trauma surgeons, the *Ankle Joint App* (*Sprunggelenks-App*, Mediploy GmbH, Langenfeld, Germany) was shown to be frequently chosen, although the medical usage rate was still very low at 2.3% [17].

Studies investigating mHealth-based diagnostics [18] or rehabilitation programs after lateral ankle sprains already exist, for example, in the Netherlands (app: *Strengthen your Ankle*) [19], where a positive influence on medical and economic aspects could be demonstrated [20-22]. To date, the application of posttraumatic mHealth solutions after ankle sprains has not been investigated in Germany.

Objective

To address this gap, this work outlines the methodology to develop and design an app for patient education as well as prevention and identification of CAI after ankle sprains (*Ankle Joint App*). The publication of an app development process might be the basis for future mHealth solutions to improve patient care.

The app's content, usability, and styling were evaluated by German orthopedic or trauma surgeons and athletes who suffered from ankle sprain.

Methods

Development Protocol

Basic App Conception

A multidisciplinary team was involved in the development of the *ankle joint app*. The team members comprised 2 orthopedic and trauma surgeons (FD and SB), a physiotherapist, a lawyer, and a software and Web developer. Before programming the app, some general aspects regarding the software structure, design, and content had to be considered. At an early stage, the target group and the intended purpose needed to be defined precisely to clarify whether the app had to be defined as a medical device and therefore had to be regulated by medical products law [23].

Technical Specifications

The *ankle joint app* was developed using *React Native* (Facebook Inc) technology. *React Native* is a *Javascript*-based framework for software developers, building cross-platform mobile apps for Android or iOS devices. The framework features built-in components and application programming interfaces, which are essential for developing innovative and user-friendly mobile apps [24].

The backend server runs on a Web app based on the *Hypertext Preprocessor* framework *Symfony* and meets actual software security guidelines. Any data exchange between the backend server and the app runs via *Secure Sockets Layer* secured connection. All server structures are located in Germany. Patient-related data remain strictly on the mobile device.

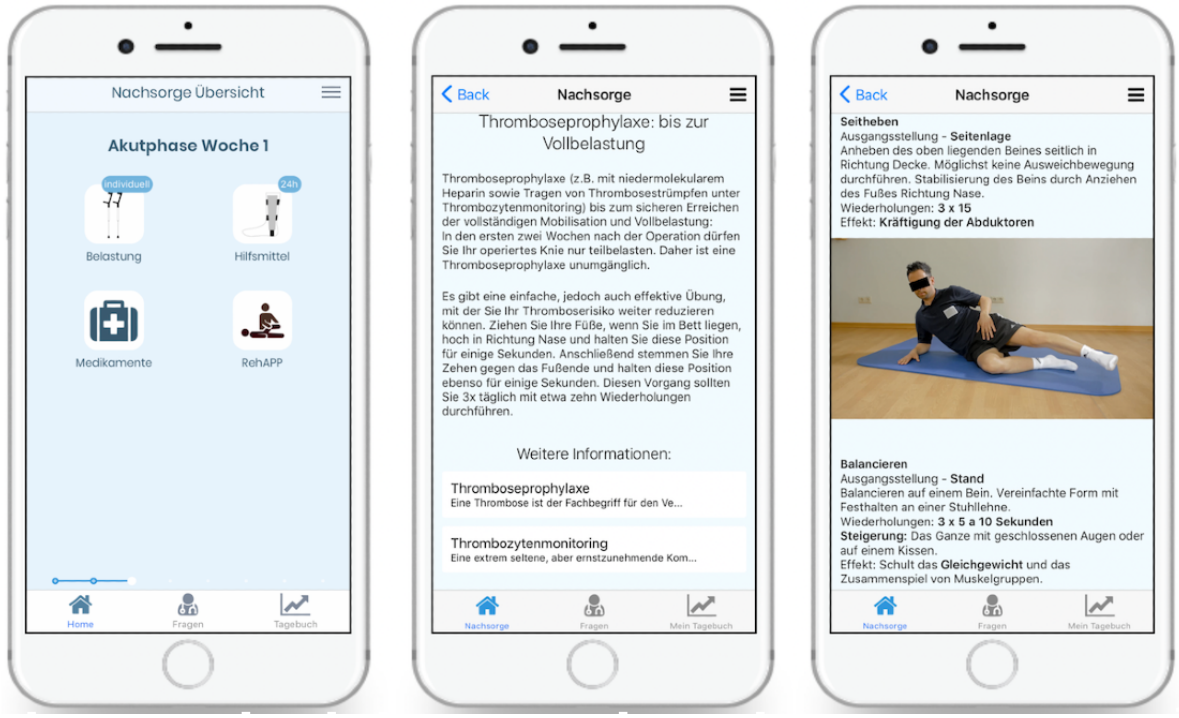
Texts and Videos

The *ankle joint app* is based on the latest national guidelines published by the German Orthopedic Foot and Ankle Society (DAF) and related medical literature. The content is written in German. All relevant references are stored in the app and are hyperlinked to the primary source to facilitate search for the

user. Special efforts have been made to ensure that the information communicated is short, clear, and easy to understand. To explain medical terms comprehensibly, a glossary function has been integrated to avoid overloaded main text pages. By answering frequently asked questions, personal data are collected and made available to the user at some key points. Thus, the content adapts to the individual healing process constantly.

With the cooperation of a physiotherapist and considering the current research data, a training program was created, which can be carried out without special equipment. In addition to giving some general information, for example, the PRICE-rule (P=protection, R=rest, I=ice, C=compression, and E=elevation) or the activation of the muscle-vein pump in the acute stage, patients are also provided with short video clips in the later stages (Figure 1). A total of 15 successive built-up exercises were made available to patients via the app. A special focus in this training circle was placed on early functional mobilization and proprioceptive training to prevent CAI.

Figure 1. App screen view: (a) timeline-based aftercare plan, (b) information, and (c) training videos.



Patient-Generated Data and Log Function

Initially, to start the timeline, the timepoint of the injury has to be defined. In addition, the user is asked to evaluate whether it was the first or the second event of an ankle sprain. Moreover, the kind of trauma and prescribed aids are requested. At regular intervals, patients are asked questions via push messages about their current level of pain, using the visual analog scale; feeling of instability; and load-bearing capacity. The collected patient-related data are presented to the patient in an understandable graphical form in the diary function (Figure 2).

German Cumberland Ankle

The Cumberland Ankle Instability Tool (CAIT) was developed for measuring the severity of functional ankle instability [25]. Using a well-established 9-item 30-point scale, the CAIT shows an adequate correlation to performance tests. It is a valid and reliable instrument for assessing CAI [26-28]. The minimal detectable change, as well as the minimal clinical important difference, lies at ≥3 points [29]. We assessed the status of CAI using the validated German CAIT in a digital form for the first time [30,31]. The CAIT was surveyed on day 56 after trauma. A score of <25 indicates CAI, and the app user is informed that additional diagnostics are recommended [32].

Figure 2. App screen view: (a) collection of patient-related data and (b) log function of patient-related data.

Styling, Design, and Testing

Special attention was paid to the development of an intuitive and user-friendly interface. To allow elderly patients to use the app, an onboarding feature was established to explain the main functions and interactions. Milestones in rehabilitation were presented graphically in a timeline to ensure clarity for patients about the progress of their rehabilitation. Information regarding the rehabilitation process was structured logically and linked to icons with a recognition factor.

After the app had been developed, an *alpha* test was carried out by the development team using the software *TestFlight* (Apple Inc). The following *beta* test was performed on persons who had already undergone an ankle distortion trauma. Some technical, content-related, and interactional improvements were made as a consequence to the test feedback under controlled conditions.

App Quality Testing

Study Design and Sample

The app was evaluated by 20 German orthopedic and trauma surgeons with a special interest in foot and ankle surgery as well as 20 athletes. All the physicians and athletes included were familiar with smartphone devices and used apps on a daily basis. The involved athletes already sustained an acute ankle sprain in their past sporting career. The study was conducted between June 2019 and August 2019. The link for the digital questionnaire on a *Google Docs* (Google LLC) platform was sent to the participants by email or Quick Response code scanning. The email addresses of the physicians were generated manually via the home pages of clinics or via established email distribution lists. The athletes were screened in local badminton or boxing clubs (FC Langenfeld, VFL Bochum, and Lanna martial arts Bochum).

German Mobile App Rating Scale

The MARS rating is a well-established assessment scale for medical app quality. It was developed for professionals, and it includes the sections classification, objective app quality, subjective app quality, and a modifiable app-specific section. MARS items are scored using a 5-point *Likert* scale (1=inadequate, 2=poor, 3=acceptable, 4=good, and 5=excellent). The objective app quality section includes 19 items divided into 4 subscales—*engagement*, *functionality*, *esthetics*, and *information quality*—and a separate *subjective app quality* section. The *subjective app quality* section contains four items evaluating the user's overall satisfaction.

Calculating the mean scores of the engagement, functionality, esthetics, and information quality objective subscales, as well as an overall mean app quality, total score is how the MARS is scored. Mean scores instead of total scores are used because items can be rated as *not applicable*. The subjective quality items can be scored separately as a mean subjective quality score [33].

The English MARS version's sections were extended in the MARS-G by an additional section focusing on the *medical gain* of an app. The 5 subscales and the overall score determine the app's quality [34]. All surgeons watched the associated MARS-G instructional video on how to use the MARS-G scale before rating in case of doubt [35].

Data Analysis

The analog (user) MARS-G was converted into a digital questionnaire on a *Google Docs* platform (Google LLC). Data

were saved and then transferred into an *Excel* table (Microsoft Corp). Descriptive statistics were calculated for all items. The intraclass correlation coefficient (ICC) was calculated among the reviewers. We selected an individual absolute agreement ICC (AA-ICC) for a two-way mixed model on the basis of ICC guidelines by Shrout and Fleiss [36]. All statistical analyses were conducted using SPSS (version 25, IBM Corp).

Results

Participants

A total of 20 foot and ankle surgeons as well as 20 athletes who suffered an ankle sprain took part in the app rating, which is equivalent to a response rate of 65% (20/31) for the surgeons and 44% (20/46) for the athletes. Excellent interrater reliabilities (two-way mixed model AA-ICC=0.92; 95% CI 0.86-0.96 for surgeons and athletes) were shown following the guidelines for ICC interpretation established by Koo et al [37]. The surgeons' group comprised 20% (4/20) Android and 80% (16/20) iOS users, and the athletes' group comprised 59% (10/17) Android and 41% (7/17) iOS users.

German Mobile App Rating Scale

The mean overall score for the *Ankle Joint App* was 4.4 (SD 0.5), rated by both surgeons and athletes. It was derived from the mean scores on app *functionality*, *engagement*, *esthetics*, and *information quality* (Figure 3). The mean subjective quality scores were 3.6 (surgeons: SD 0.7) and 3.8 (athletes: SD 0.5). The section *behavioral change*, which included an assessment of the perceived impacts on disease-related knowledge, attitude, awareness, and behavior, had mean scores of 4.1 (surgeons: SD 0.7) and 4.3 (athletes: SD 0.7). The *medical gain*, rated by the surgeons only, was 3.9 (SD 0.6; Table 1, Figure 3).

Figure 3. Mean scores of the (user) German Mobile App Rating Scale for the Ankle Joint App (surgeons: n=20 and athletes: n=20).

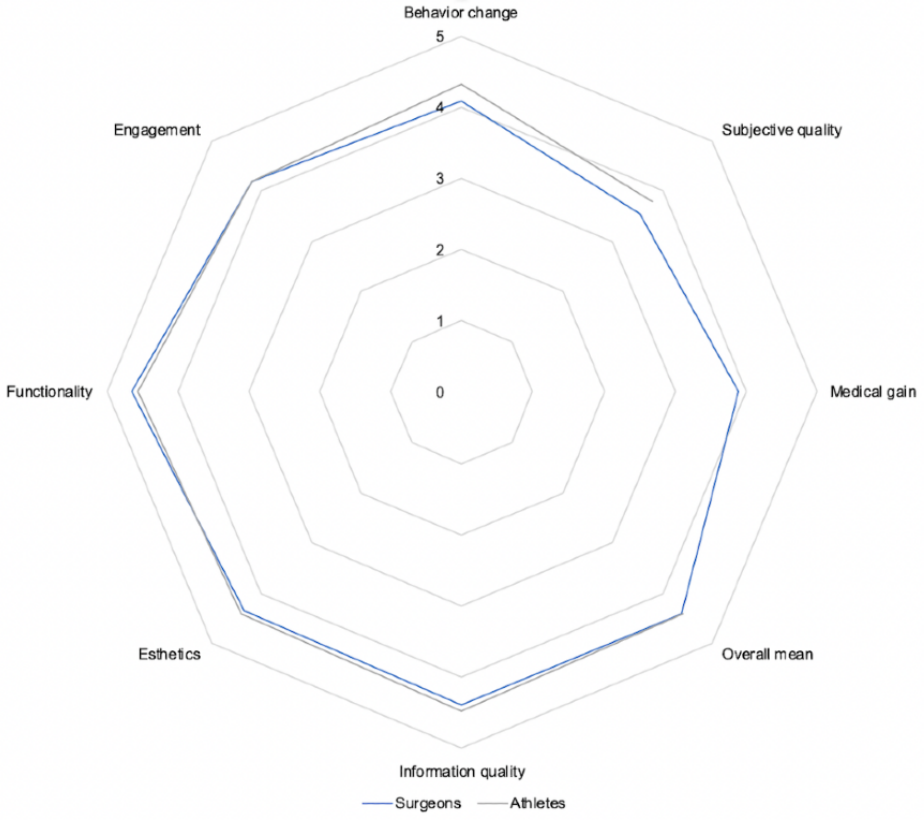


Table 1. Detailed results of the (user) German Mobile App Rating Scale.

Subscale	MARS-G[a] surgeons			uMARS-G[b] athletes		
	Minimum	Maximum	Mean (SD)	Minimum	Maximum	Mean (SD)
Engagement						
Entertainment	3	5	4.4 (0.9)	3	5	4.1 (0.7)
Interest	3	5	4.3 (0.9)	2	5	4.4 (0.9)
Customization	2	5	3.8 (0.8)	2	5	3.6 (0.9)
Interactivity	3	5	4.2 (0.7)	2	5	4.3 (0.9)
Target group	4	5	4.6 (0.5)	4	5	4.6 (0.5)
Functionality						
Performance	4	5	5.0 (0.2)	3	5	4.8 (0.6)
Usability	4	5	4.6 (0.5)	3	5	4.6 (0.6)
Navigation	4	5	4.6 (0.5)	3	5	4.5 (0.7)
Gestural design	4	5	4.5 (0.5)	4	5	4.5 (0.5)
Esthetics						
Layout	3	5	4.4 (0.8)	3	5	4.5 (0.6)
Graphics	4	5	4.6 (0.5)	3	5	4.5 (0.6)
Visual appeal	3	5	4.1 (0.7)	3	5	4.3 (0.7)
Information						
Accuracy of app description (in app store)	3	5	4.8 (0.5)	__[c]	—	—
Goals	3	5	4.3 (0.6)	—	—	—
Quality of information	3	5	4.5 (0.8)	4	5	4.7 (0.5)
Quantity of information	4	5	4.8 (0.4)	3	5	4.9 (0.5)
Visual information	4	5	4.3 (0.5)	3	5	4.5 (0.6)
Credibility	3	5	4.0 (0.9)	2	5	3.8 (1.0)
Evidence base	2	5	4.0 (1.1)	—	—	—
Medical gain						
Gain for patients	3	5	4.3 (0.8)	—	—	—
Gain for physicians	2	5	3.8 (0.9)	—	—	—
Risks, side and adverse effects	3	5	4.5 (0.6)	—	—	—
Transferability into routine care	2	5	3.3 (1.0)	—	—	—
Subjective quality						
Would you recommend this app to people who might benefit from it?	3	5	4.4 (0.9)	3	5	4.3 (0.7)
How many times do you think you would use this app in the next 12 months if it was relevant to you?	1	5	3.2 (1.2)	2	5	3.9 (0.7)
Would you pay for this app?	1	3	2.0 (0.7)	1	3	2.4 (0.8)
What is your overall star rating of the app?	4	5	4.6 (0.5)	3	5	4.6 (0.6)
Behavior						
Awareness	2	5	4.5 (0.8)	3	5	4.6 (0.6)
Knowledge	3	5	4.6 (0.6)	3	5	4.8 (0.6)
Attitudes	2	5	3.7 (0.9)	3	5	4.3 (0.7)
Intention to change	3	5	3.9 (0.8)	4	5	4.4 (0.5)
Help seeking	2	5	4.1 (1.0)	2	5	3.8 (1.0)

Subscale	MARS-G[a] surgeons			uMARS-G[b] athletes		
	Minimum	Maximum	Mean (SD)	Minimum	Maximum	Mean (SD)
Behavior change	2	5	4.0 (0.9)	3	5	4.3 (0.8)

[a]MARS-G: German Mobile App Rating Scale.

[b]uMARS-G: (user) German Mobile App Rating Scale.

[c]Not applicable.

Discussion

Principal Findings

Our research using the *Ankle Joint App* demonstrates that mHealth-based rehabilitation programs might be an adequate and innovative tool for patient education, prevention, and collection of personal data.

The achieved (user) MARS-G scores prove the app's quality from a professional and user point of view, demonstrating a comparatively high overall mean (user) MARS-G value [33]. The highest scores were reached in the functionality section for both surgeons and athletes. In accordance with a recent survey among orthopedic and trauma surgeons, intuitive usability was considered the most important factor for the regular use and quality of an app. The integration of complex functions in an intuitive lean and secure user interface poses a great challenge to the development team. Moreover, the development of an intuitive *frontend* is complex and involves high development costs and test phases [38]. Multifunctional apps, for example, in the field of diabetes mellitus type II therapy for patients over 50 years showed limited usability with negative effects on compliance and therapy outcomes. Apps with basic functions provide enhanced usability [39], but the limitation of software features affects the app's functionality. To address this divergence, trial runs with specific target groups and permanent reevaluation of the initial concept are mandatory during the app's development process.

As a first step, when developing an app, the target group and the intended purpose have to be defined precisely. The *Ankle Joint App* was especially designed for young and active patients to optimize conservative rehabilitation following an acute ankle sprain without osseous lesions. With respect to this, the differences in evaluating the medical gain for physicians and patients, with individual requirements in their rehabilitation episode [40], can be explained.

Customization seems to be important to the target group and might be improved in our app. We believe that medical apps have to be adaptable not only to the specific users' requirements but also to the varying hospital standards. The aspects to be considered in the development of medical apps are the limited areas of application in combination with varying standards of treatment, both national and international, and the legal and medical aspects of an app with regard to liability and data protection [21]. These aspects represent a challenge for financing the complex development and maintenance of an app, as the 10 most popular apps ranked by the number of users in Germany in 2018 were all available for free download [41].

Considering recent data scandals, which led to a fundamental distrust of apps that might be implemented in the context of *Big Data*, the secure and transparent collection of medical personal data can be challenging [42,43]. For this reason, we decided to store personal data exclusively on the mobile device to avoid cloud upload. In general, dichotomous scenarios about data exchange between patients and medical staff are possible. The recovery progress could be displayed analogously on the patient's smartphone in the event of a doctor's appointment (eg, CAIT). Alternatively, an upload of data into a secure cloud system can be taken into consideration [44]. In the event of deviations from the expected progression of the disease, patients could be informed about and provided with medical expertise more rapidly. Moreover, the collection of validated scores and surveys might be relevant for academic research.

In contrast to these positive effects, app users and providers (physicians and medical staff) should keep in mind that the collection and processing of personal data also represent cornerstones of app financing. This could lead to potential conflicts of interest as the collected data represent an immense value, for example, for the provision of personalized advertising [45]. Before downloading an app, the financing, development process, and data flow have to be completely and plausibly depicted by the publisher. Therefore, transparent and appropriate app store descriptions, data protection regulations, and terms and conditions of use are of utmost importance [46].

This study has some limitations. The evaluation of the app's quality was carried out within a theoretical framework; thus, it only reflects its use to a limited extent in daily clinical practice. It has to be mentioned that the app was only evaluated by a relatively small number of users (patients) for a short period of 3 months. Thus, data on compliance, demographics, and usage behavior are hardly representative. Moreover, the economic aspects of the development process and app costs per user were not taken into account. In addition, the response rate was moderate, which might lead to a bias toward users with high digital affinity. Comparative randomized control trial studies are required to gain funded evidence on the app's positive effects on patient education and treatment progress in comparison with established nondigital therapy paths to prevent CAI and reach a final scientific conclusion; this has to be addressed by future studies.

Nowadays, in many countries, an increasing number of patients visiting emergency units with minor complaints can be registered. Often, the treatment of these patients is time and staff consuming, compromising the medical attention of more severely injured individuals. This overcrowding may lead to negative consequences to the patients' safety and their outcome [47-49]. Given the increasing workload, physicians are

dissatisfied with highly time-consuming procedures, for example, electronic patient recording in the emergency department [50,51]. Apps might be used by the emergency staff to easily create and recommend digitally customized aftercare plans.

Moreover, the established discharge letter contains medical terminology, which offers very little benefit to a self-determined, competent patient. This practice does not meet the requirements of adequate patient involvement in the treatment process [52]. Improving patient education and optimizing the communication structures via apps on mobile devices have the potential to solve these issues. Individually designed and supervised aftercare treatments showed better outcomes [53]. The *Ankle Joint App* has a modular design and might be transferred to a wide range of aftercare treatments.

In contrast to the great potential of standardized medical app usage, there are also risks. However, medical resources and health care have to be distributed equally for everyone on the basis of moral and ethical obligations. This is why medical app usage also entails a particular risk of disadvantaging groups with low health competence and a high risk of disease [39]. In particular, the elderly patient might be disadvantaged by the use of medical apps, because in 2014, only about 17% of the individuals over 65 years regularly used a smartphone [54]. As degenerative diseases represent an important pillar of orthopedic and trauma surgery expertise, special attention has to be paid on the app development for these *newcomers* and their requirements in the future. Particularly in the area of app usability, the requirements of elder generations have to be addressed, for example, implementing an intuitive interface, a reading function, or a screen magnifier [55]. Self-endangerment because of incorrect app usage might occur, but the risk can be reduced by an *onboarding* function with an introduction of the app to new users and individual feedback mechanisms [56].

Conclusions

Working in a multidisciplinary team, using a backend structure to modify the app's content and using React Native, proved to be efficient in the development process of medical apps. The success was proven by reaching high overall mean MARS-G scores for the *Ankle Joint App* in surgeons and athletes. Data obtained suggest that an mHealth-based rehabilitation program might be a useful tool for patient education and collection of personal data. The achieved (user) MARS-G scores prove the tested app's high quality. Medical app development with an a priori defined target group and a precisely intended purpose, in a multidisciplinary team, is highly promising.

Acknowledgments

We acknowledge support by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) and Saarland University within the funding programme Open Access Publishing.

Conflicts of Interest

FD and SB are active in Mediploy GmbH and in the development process of the Ankle Joint App.

References

1. Waizy H, Harrasser N, Fehske K. [Lateral ligament injuries]. Unfallchirurg 2018 Sep;121(9):683-692. [doi: 10.1007/s00113-018-0535-2] [Medline: 30054645]
2. Vuurberg G, Hoorntje A, Wink LM, van der Doelen BF, van den Bekerom MP, Dekker R, et al. Diagnosis, treatment and prevention of ankle sprains: update of an evidence-based clinical guideline. Br J Sports Med 2018 Aug;52(15):956. [doi: 10.1136/bjsports-2017-098106] [Medline: 29514819]
3. Bielska IA, Wang X, Lee R, Johnson AP. The health economics of ankle and foot sprains and fractures: a systematic review of English-language published papers. Part 1: Overview and critical appraisal. Foot (Edinb) 2019 Jun;39:106-114. [doi: 10.1016/j.foot.2017.04.003] [Medline: 29108669]
4. Hupperets MD, Verhagen EA, Heymans MW, Bosmans JE, van Tulder MW, van Mechelen W. Potential savings of a program to prevent ankle sprain recurrence: economic evaluation of a randomized controlled trial. Am J Sports Med 2010 Nov;38(11):2194-2200. [doi: 10.1177/0363546510373470] [Medline: 20699429]
5. Harrington KD. Degenerative arthritis of the ankle secondary to long-standing lateral ligament instability. J Bone Joint Surg Am 1979 Apr;61(3):354-361. [Medline: 429402]
6. Kazemi K, Arab AM, Abdollahi I, López-López D, Calvo-Lobo C. Electromiography comparison of distal and proximal lower limb muscle activity patterns during external perturbation in subjects with and without functional ankle instability. Hum Mov Sci 2017 Oct;55:211-220. [doi: 10.1016/j.humov.2017.08.013] [Medline: 28843163]
7. Lobo CC, Morales CR, Sanz DR, Corbalán IS, Marín AG, López DL. Ultrasonography comparison of peroneus muscle cross-sectional area in subjects with or without lateral ankle sprains. J Manipulative Physiol Ther 2016;39(9):635-644. [doi: 10.1016/j.jmpt.2016.09.001] [Medline: 27793349]
8. Valderrabano V. Joint-preserving surgery of ankle osteoarthritis. Foot Ankle Clin 2013 Sep;18(3):xiii-xxiv. [doi: 10.1016/j.fcl.2013.06.013] [Medline: 24008221]
9. Kerkhoffs GM, Handoll HH, de Bie R, Rowe BH, Struijs PA. Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults. Cochrane Database Syst Rev 2007 Apr 18(2):CD000380. [doi: 10.1002/14651858.CD000380.pub2] [Medline: 17443501]

10. Rammelt S, Stürmer KM, Richter M. AWMF: AWMF aktuell. 2017 Aug 8. Fresh Outer Ligament Rupture on the Upper Ankle URL: https://www.awmf.org/uploads/tx_szleitlinien/012-022l_S1_Aussenbandruptur_oberes_Sprunggelenk_2017-08.pdf [accessed 2020-01-07]
11. Krebs P, Duncan DT. Health app use among US mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015 Nov 4;3(4):e101 [FREE Full text] [doi: 10.2196/mhealth.4924] [Medline: 26537656]
12. Cha S, Seo B. Smartphone use and smartphone addiction in middle school students in Korea: prevalence, social networking service, and game use. Health Psychol Open 2018;5(1):2055102918755046 [FREE Full text] [doi: 10.1177/2055102918755046] [Medline: 29435355]
13. Meskó B, Drobni Z, Bényei É, Gergely B, Győrffy Z. Digital health is a cultural transformation of traditional healthcare. Mhealth 2017;3:38 [FREE Full text] [doi: 10.21037/mhealth.2017.08.07] [Medline: 29184890]
14. Morris ME, Aguilera A. Mobile, social, and wearable computing and the evolution of psychological practice. Prof Psychol Res Pr 2012 Dec;43(6):622-626 [FREE Full text] [doi: 10.1037/a0029041] [Medline: 25587207]
15. Lu K, Marino NE, Russell D, Singareddy A, Zhang D, Hardi A, et al. Use of short message service and smartphone applications in the management of surgical patients: a systematic review. Telemed J E Health 2018 Jun;24(6):406-414. [doi: 10.1089/tmj.2017.0123] [Medline: 29111887]
16. Dittrich F, Beck S, Busch A, Dudda M, Harren A, Sander A, et al. [Is the discharge letter still relevant? : Chances and risks of 'Medical apps' in orthopedics and traumatology]. Orthopade 2018 Oct;47(10):842-848. [doi: 10.1007/s00132-018-3598-4] [Medline: 30039468]
17. Dittrich F, Busch A, Harren K, Jäger M, Landgraeber S, Reinecke F, et al. [Apps in clinical use in orthopedics and trauma surgery : The status quo in Germany]. Unfallchirurg 2019 Sep;122(9):690-696. [doi: 10.1007/s00113-019-0675-z] [Medline: 31127352]
18. Morales CR, Lobo CC, Sanz DR, Corbalán IS, Ruiz BR, López DL. The concurrent validity and reliability of the Leg Motion system for measuring ankle dorsiflexion range of motion in older adults. PeerJ 2017;5:e2820 [FREE Full text] [doi: 10.7717/peerj.2820] [Medline: 28070457]
19. VeiligheidNL2. Google Play Store. Versterk je Enkel URL: https://play.google.com/store/apps/details?id=nl.veiligheid.versterkjeenkel&hl=en_US [accessed 2020-01-07]
20. van Reijen M, Vriend II, Zuidema V, van Mechelen W, Verhagen EA. The implementation effectiveness of the 'Strengthen your ankle' smartphone application for the prevention of ankle sprains: design of a randomized controlled trial. BMC Musculoskelet Disord 2014 Jan 7;15:2 [FREE Full text] [doi: 10.1186/1471-2474-15-2] [Medline: 24393146]
21. van Reijen M, Vriend I, van Mechelen W, Verhagen EA. Preventing recurrent ankle sprains: is the use of an app more cost-effective than a printed booklet? Results of a RCT. Scand J Med Sci Sports 2018 Feb;28(2):641-648. [doi: 10.1111/sms.12915] [Medline: 28543566]
22. van Reijen M, Vriend I, Zuidema V, van Mechelen W, Verhagen EA. The 'Strengthen your ankle' program to prevent recurrent injuries: a randomized controlled trial aimed at long-term effectiveness. J Sci Med Sport 2017 Jun;20(6):549-554. [doi: 10.1016/j.jsams.2016.12.001] [Medline: 27988093]
23. Rämsch-Günther N, Stern S, Lauer W. [Qualification and classification of medical apps : what should be noted and what is BfArM's contribution?]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2018 Mar;61(3):304-313. [doi: 10.1007/s00103-017-2687-6] [Medline: 29349524]
24. Facebook. Facebook Open Source. 2019. React Native URL: https://facebook.github.io/react-native/ [accessed 2020-01-07]
25. Hiller CE, Refshauge KM, Bundy AC, Herbert RD, Kilbreath SL. The Cumberland ankle instability tool: a report of validity and reliability testing. Arch Phys Med Rehabil 2006 Sep;87(9):1235-1241. [doi: 10.1016/j.apmr.2006.05.022] [Medline: 16935061]
26. Kunugi S, Masunari A, Yoshida N, Miyakawa S. Association between Cumberland Ankle Instability Tool score and postural stability in collegiate soccer players with and without functional ankle instability. Phys Ther Sport 2018 Jul;32:29-33. [doi: 10.1016/j.ptsp.2018.03.002] [Medline: 29677566]
27. Sierra-Guzmán R, Jiménez F, Abián-Vicén J. Predictors of chronic ankle instability: analysis of peroneal reaction time, dynamic balance and isokinetic strength. Clin Biomech (Bristol, Avon) 2018 May;54:28-33. [doi: 10.1016/j.clinbiomech.2018.03.001] [Medline: 29544201]
28. Dressler P, Gehring D, Zdzieblik D, Oesser S, Gollhofer A, König D. Improvement of functional ankle properties following supplementation with specific collagen peptides in athletes with chronic ankle instability. J Sports Sci Med 2018 Jun;17(2):298-304 [FREE Full text] [Medline: 29769831]
29. Wright CJ, Linens SW, Cain MS. Establishing the minimal clinical important difference and minimal detectable change for the Cumberland ankle instability tool. Arch Phys Med Rehabil 2017 Sep;98(9):1806-1811. [doi: 10.1016/j.apmr.2017.01.003] [Medline: 28137476]
30. Gehring D, Faschian K, Lauber B, Lohrer H, Nauck T, Gollhofer A. Mechanical instability destabilises the ankle joint directly in the ankle-sprain mechanism. Br J Sports Med 2014 Mar;48(5):377-382. [doi: 10.1136/bjsports-2013-092626] [Medline: 24124039]

31. FOMT - Fortbildungen für Orthopädische Medizin und Manuelle Therapie. Cumberland Ankle Instability Tool (validierte deutsche Version (Gehring et al 2016)) URL: https://www.fomt.info/Downloads/Scores/Cumberland-Ankle-Instability-Tool.pdf?m=1574062714& [accessed 2020-01-07]
32. Wright CJ, Arnold BL, Ross SE, Linens SW. Recalibration and validation of the Cumberland Ankle Instability Tool cutoff score for individuals with chronic ankle instability. Arch Phys Med Rehabil 2014 Oct;95(10):1853-1859. [doi: 10.1016/j.apmr.2014.04.017] [Medline: 24814563]
33. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Mar 11;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]
34. Messner ET, Barke A, Baumeister H, Stoyanov S, Hides L, Kavanagh D, et al. Development and Validation of the German Version of the Mobile Application Rating Scale (MARS-G). JMIR mHealth and uHealth;JMIR Preprints 2019. [doi: 10.2196/14479]
35. MARS-Rating Universität Ulm. YouTube. 2017. MARS - Mobile Anwendungen Rating Skala URL: https://www.youtube.com/watch?v=5vwMiCWC0Sc&t=400s [accessed 2020-01-07]
36. Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. Psychol Bull 1979 Mar;86(2):420-428. [doi: 10.1037//0033-2909.86.2.420] [Medline: 18839484]
37. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. J Chiropr Med 2016 Jun;15(2):155-163 [FREE Full text] [doi: 10.1016/j.jcm.2016.02.012] [Medline: 27330520]
38. Mortensen D. Interaction Design Foundation. 2019. How to Create an Intuitive Design URL: https://www.interaction-design.org/literature/article/how-to-create-an-intuitive-design [accessed 2019-05-10] [WebCite Cache ID 78Gc3iT4J]
39. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. J Med Internet Res 2014 Apr 9;16(4):e104 [FREE Full text] [doi: 10.2196/jmir.2968] [Medline: 24718852]
40. Sanz DR, Lopez-Lopez D, Garcia DM, Medrano AS, Ponce AM, Lobo CC, et al. Effects of eccentric exercise in pressure pain threshold in subjects with functional ankle equinus condition. Rev Assoc Med Bras (1992) 2019 Mar;65(3):384-387 [FREE Full text] [doi: 10.1590/1806-9282.65.3.384] [Medline: 30994837]
41. Statista. Most Popular Mobile Apps by Number of Users in Germany in 2018 (in Millions) URL: https://de.statista.com/statistik/daten/studie/872047/umfrage/beliebteste-mobile-apps-nach-der-anzahl-der-nutzer-in-deutschland/ [accessed 2020-01-03]
42. Stroud C. Forbes. 2018 Apr 30. Cambridge Analytica: The Turning Point In The Crisis About Big Data URL: https://www.forbes.com/sites/courtstroud/2018/04/30/cambridge-analytica-the-turning-point-in-the-crisis-about-big-data/#2ae8f43b48ec [accessed 2020-01-07] [WebCite Cache ID 78Gc6v0IQ]
43. Ancker JS, Mauer E, Kalish RB, Vest JR, Gossey JT. Early adopters of patient-generated health data upload in an electronic patient portal. Appl Clin Inform 2019 Mar;10(2):254-260. [doi: 10.1055/s-0039-1683987] [Medline: 30970383]
44. Car J, Sheikh A, Wicks P, Williams MS. Beyond the hype of big data and artificial intelligence: building foundations for knowledge and wisdom. BMC Med 2019 Jul 17;17(1):143 [FREE Full text] [doi: 10.1186/s12916-019-1382-x] [Medline: 31311603]
45. Househ M, Aldosari B, Alanazi A, Kushniruk A, Borycki E. Big data, big problems: a healthcare perspective. Stud Health Technol Inform 2017;238:36-39. [Medline: 28679881]
46. Albrecht U, Malinka C, Long S, Raupach T, Hasenfuß G, von Jan U. Quality principles of app description texts and their significance in deciding to use health apps as assessed by medical students: survey study. JMIR Mhealth Uhealth 2019 Feb 27;7(2):e13375 [FREE Full text] [doi: 10.2196/13375] [Medline: 30810534]
47. Scherer M, Lühmann D, Kazek A, Hansen H, Schäfer I. Patients attending emergency departments. Dtsch Arztebl Int 2017 Sep 29;114(39):645-652 [FREE Full text] [doi: 10.3238/arztebl.2017.0645] [Medline: 29034865]
48. Carter EJ, Pouch SM, Larson EL. The relationship between emergency department crowding and patient outcomes: a systematic review. J Nurs Scholarsh 2014 Mar;46(2):106-115 [FREE Full text] [doi: 10.1111/jnu.12055] [Medline: 24354886]
49. Gonçalves-Bradley D, Khangura JK, Flodgren G, Perera R, Rowe BH, Shepperd S. Primary care professionals providing non-urgent care in hospital emergency departments. Cochrane Database Syst Rev 2018 Feb 13;2:CD002097 [FREE Full text] [doi: 10.1002/14651858.CD002097.pub4] [Medline: 29438575]
50. Perry JJ, Sutherland J, Symington C, Dorland K, Mansour M, Stiell IG. Assessment of the impact on time to complete medical record using an electronic medical record versus a paper record on emergency department patients: a study. Emerg Med J 2014 Dec;31(12):980-985. [doi: 10.1136/emermed-2013-202479] [Medline: 23975593]
51. Lorenzetti DL, Quan H, Lucyk K, Cunningham C, Hennessy D, Jiang J, et al. Strategies for improving physician documentation in the emergency department: a systematic review. BMC Emerg Med 2018 Oct 25;18(1):36 [FREE Full text] [doi: 10.1186/s12873-018-0188-z] [Medline: 30558573]
52. Lin R, Gallagher R, Spinaze M, Najoumian H, Dennis C, Clifton-Bligh R, et al. Effect of a patient-directed discharge letter on patient understanding of their hospitalisation. Intern Med J 2014 Sep;44(9):851-857. [doi: 10.1111/imj.12482] [Medline: 24863954]

53. Hayden JA, van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. Ann Intern Med 2005 May 3;142(9):776-785. [doi: 10.7326/0003-4819-142-9-200505030-00014] [Medline: 15867410]
54. Berauk VL, Murugiah MK, Soh YC, Sheng YC, Wong TW, Ming LC. Mobile health applications for caring of older people: review and comparison. Ther Innov Regul Sci 2018 May;52(3):374-382. [doi: 10.1177/2168479017725556] [Medline: 29714532]
55. Wildenbos GA, Jaspers MW, Schijven MP, Dusseljee-Peute LW. Mobile health for older adult patients: Using an aging barriers framework to classify usability problems. Int J Med Inform 2019 Apr;124:68-77. [doi: 10.1016/j.ijmedinf.2019.01.006] [Medline: 30784429]
56. Buus N, Juel A, Haskelberg H, Frandsen H, Larsen JL, River J, et al. User involvement in developing the MYPLAN mobile phone safety plan app for people in suicidal crisis: case study. JMIR Ment Health 2019 Apr 16;6(4):e11965 [FREE Full text] [doi: 10.2196/11965] [Medline: 30990456]

Abbreviations

AA-ICC: absolute agreement intraclass correlation coefficient
CAI: chronic ankle instability
CAIT: Cumberland Ankle Instability Tool
ICC: intraclass correlation coefficient
MARS-G: German Mobile App Rating Scale
mHealth: mobile health
OA: osteoarthritis

Edited by G Eysenbach; submitted 25.09.19; peer-reviewed by J Reponen, D López López, E Sadeghi-Demneh; comments to author 06.11.19; revised version received 29.11.19; accepted 16.12.19; published 26.02.20.

Please cite as:
Dittrich F, Back DA, Harren AK, Jäger M, Landgraeber S, Reinecke F, Beck S
A Possible Mobile Health Solution in Orthopedics and Trauma Surgery: Development Protocol and User Evaluation of the Ankle Joint App
JMIR Mhealth Uhealth 2020;8(2):e16403
URL: http://mhealth.jmir.org/2020/2/e16403/
doi:10.2196/16403
PMID:32130171

Original Paper

Automatic Work-Hours Recorder for Medical Staff (Staff Hours): Mobile App Development

Ting-Wei Chiang[1], BSE; Si-Yu Chen[1], MSc; Yuan-Chien Pan[2], MSc; Yu-Hsuan Lin[1,3,4,5], MD, PhD

[1]Institute of Population Health Sciences, National Health Research Institutes, Miaoli County, Taiwan

[2]Department of Psychology, National Taiwan University, Taipei, Taiwan

[3]Department of Psychiatry, National Taiwan University Hospital, Taipei, Taiwan

[4]Department of Psychiatry, College of Medicine, National Taiwan University, Taipei, Taiwan

[5]Institute of Health Behaviors and Community Sciences, College of Public Health, National Taiwan University, Taipei, Taiwan

Corresponding Author:
Yu-Hsuan Lin, MD, PhD
Institute of Population Health Sciences
National Health Research Institutes
Room A3234, No 35 Keyan Road, Zhunan Town
Miaoli County, 35053
Taiwan
Phone: 886 37206166 ext 36383
Email: yuhsuanlin@nhri.edu.tw

Abstract

Background: There are numerous mobile apps for tracking work hours, but only a few of them record work hours automatically instead of relying on manual logging. No apps have been customized for medical staff, whose work schedules are highly complicated as they have both regular hours and on-call duties.

Objective: The specific aims of this study were to (1) identify the *Staff Hours* app users' GPS-defined work hours, (2) examine the overtime work hours from the app-recorded total work hours and the participants' self-reported scheduled work hours, and (3) compare these app-recorded total work hours among different occupations.

Methods: We developed an app, *Staff Hours*, to automatically calculate a user's work hours via GPS background data. Users can enter their scheduled hours, including regular hours and on-call duties. The app automatically generates overtime reports by comparing the app-recorded total work hours with the user-defined scheduled hours. A total of 183 volunteers (60 females and 123 males; mean age 32.98 years, SD 6.74) were included in this study. Most of the participants (162/183, 88.5%) were medical staff, and their positions were resident physicians (n=89), visiting staff (n=38), medical students (n=10), registered nurses (n=25), and non–health care professionals (non-HCPs; n=21).

Results: The total work hours (mean 55.69 hours, SD 21.34) of the 183 participants were significantly higher than their scheduled work hours (mean 50.67 hours, SD 21.44; *P*=.01). Medical staff had significantly longer total work hours (mean 57.01 hours, SD 21.20) than non-HCPs (mean 45.48 hours, SD 20.08; *P*=.02). Residents (mean 60.38 hours, SD 18.67) had significantly longer work hours than visiting staff (mean 51.42 hours, SD 20.33; *P*=.03) and non-HCPs (mean 45.48 hours, SD 20.08; *P*=.004).

Conclusions: *Staff Hours* is the first automatic GPS location–based app designed for medical staff to track work hours and calculate overtime. For medical staff, this app could keep complete and accurate records of work hours in real time, reduce bias, and allow for better complying with labor regulations.

(JMIR Mhealth Uhealth 2020;8(2):e16063) doi:10.2196/16063

KEYWORDS

smartphone; mobile apps; medical staff; global positioning system; shift work schedule

Introduction

Background

Long work hours and shift work increase the risk of both physiological and psychological distress [1-6], including cardiovascular disease [7] and depressive symptoms [8]. Medical staff, especially trainee physicians, work for a large number of hours per week and have a heavy workload. Systematic reviews have reported that such long working shifts and erratic schedules result in numerous adverse consequences in patient care [9]. In 2003, the Accreditation Council for Graduate Medical Education implemented the first work-hour restriction policy for all physicians in training in the United States, limiting resident physicians' workweeks to 80 hours and shifts to 30 hours [10]. In Taiwan, similar policies by the Ministry of Health and Welfare limited workweeks to 88 hours in 2013 [11]. However, surveying medical interns' compliance with the 2003 work-hour limits in the United States using a traditional assessment took 2 years; the resulting national survey was published in 2006 [10]. In addition, these self-reports do not reflect the fluctuations of work hours in real time, especially for medical staff with frequent on-call duties.

Prior Work

Nowadays, smartphones offer us an objective and ecological source of measurement that continuously and passively collects data [12]. These reliable, quantitative data could facilitate real-time policy evaluation and target resources to those with the greatest need for them, even in remote and inaccessible regions. As of July 2019, the Google Play Store and iPhone Operating System (iOS) App Store had about 500 mobile apps dealing with the tracking of work hours [13]. However, most of those apps require manual entries or active clocking in and out. Fewer than 20 of those apps are capable of automatic timekeeping using various technologies such as GPS geofencing or Wi-Fi detections. Furthermore, medical personnel's work hours could not be identified solely by GPS geofencing technology. Physicians often have several on-call duties every month. During their on-call duty, physicians have to be physically present at the hospital or be on-call at home. In addition, some medical staff practice in more than 1 institution, and these patterns of work hours could not be identified by a simple GPS geofencing algorithm.

Goal of This Study

We herein report the design of the app *Staff Hours*, which automatically calculates users' work hours through GPS data. Automatic recording of exact working hours is highly beneficial for people with erratic work schedules. This GPS-based work-hours recorder would not need users to precisely log their work hours by manual input or clocking in and out. The specific aims of this study were to (1) identify the app users' GPS-defined work hours, (2) examine the overtime work hours from the app-recorded total work hours and the participants' self-reported scheduled work hours, and (3) compare these app-recorded total work hours among different occupations.

Methods

Participants

We collected data on 183 office workers from July 30, 2018, to August 25, 2019, using the *Staff Hours* database. All participants were volunteers interested in their work hours, and workers who lived within a 1-km radius from their workplaces were excluded from this study. Of these participants, 123 were males and 60 were females, and their mean age was 32.98 (SD 6.74) years. Most of the participants (162/183, 88.5%) were medical staff, and their positions were resident physicians (n=89), visiting staff (n=38), medical students (n=10), registered nurses (n=25), and non–health care professionals (non-HCPs; n=21). All clinical investigations were conducted according to the principles expressed in the Declaration of Helsinki.

Design of the Staff Hours App

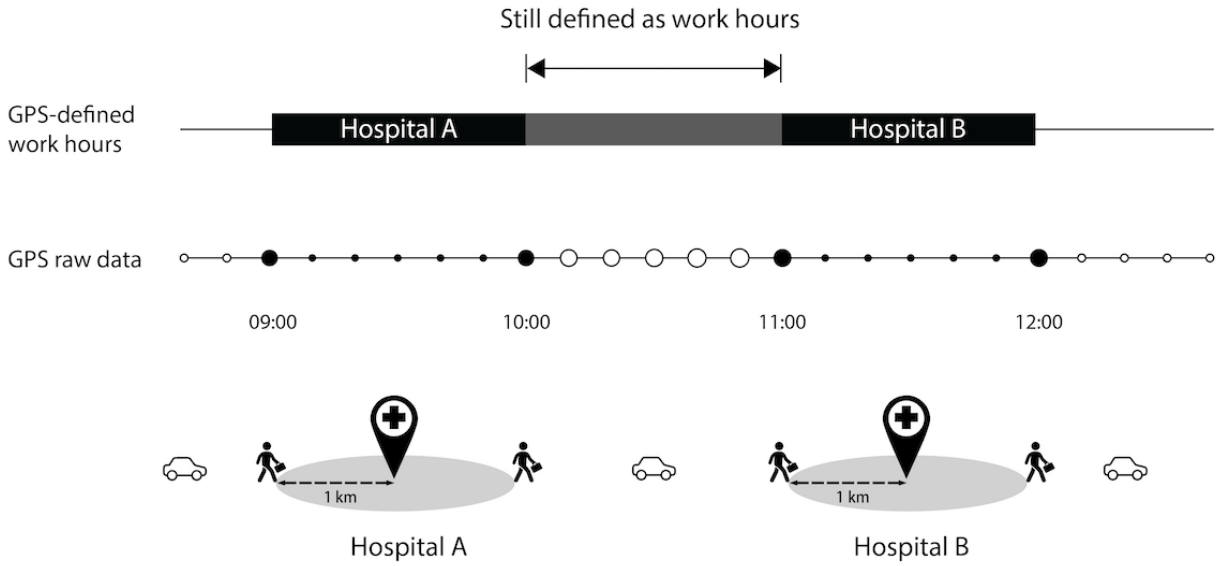
Staff Hours is a mobile app designed to record work hours automatically using the technology of geofencing. As medical staff, along with most office workers, work at fixed locations, geolocation data are valid indicators of whether one is at work. On the basis of this principle, we developed algorithms to log the exact work hours from GPS data; these hours are called *GPS-defined work hours*. Furthermore, this app can perform overtime calculations by comparing the regular work schedule defined by the user and the corresponding GPS results.

Staff Hours, which was designed and developed by our team, is now available exclusively in Taiwan through the iOS App Store and the Google Play Store. The app runs in the background and records GPS information every 10 min with low power consumption. For iOS users, the app should be kept *in use* to function correctly, either in the foreground or background.

Algorithm for GPS-Defined Work Hours

Upon installation, users would be asked to fill in the addresses of their workplaces; the app can track up to 5 locations simultaneously. Figure 1 illustrates how the app scans at 10-min intervals to detect whether the user's GPS coordinates are within a 1-km radius centered on either of the workplaces. When a user has been at the workplace for 30 min, the app automatically starts recording the work hours, counting from the time that the user's first location data within the range were received. Likewise, when a user leaves the neighborhood of the office for 30 min, the app considers the user to have gotten off work since the time that the first location data outside the range are collected.

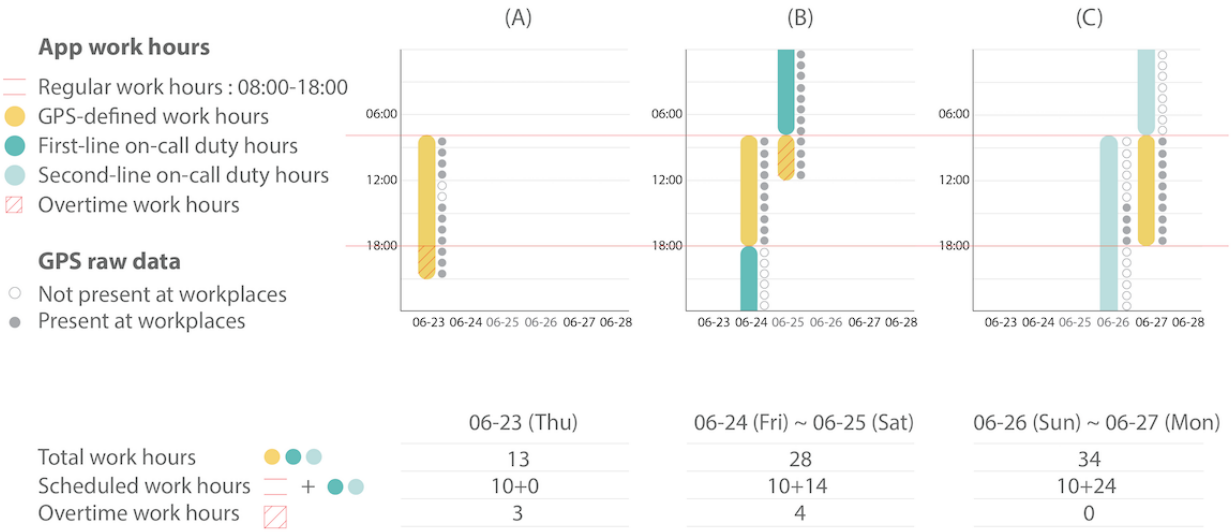
Figure 1. The recording process of GPS-defined work hours. For GPS raw data, the time interval between each dot is 10 min. If the coordinates captured are within the range, the dot is marked as solid; hollow if otherwise.



Integration of Work Periods

For any period in which a user is outside the GPS-detection range (considered not at work), if less than 8 hours, the app automatically integrates it with the former and the latter working periods, thus extending the GPS-defined work hours. In this context, when the user moves between the 5 or fewer recorded workplaces, or when the user leaves the current workplace but comes back later, the user is still considered *at work* for the whole time. The GPS-defined work hours would not be discontinued or interrupted in this case (Figures 1 and 2).

Figure 2. All types of work hours. (A) The regular work hours and overtime. (B) The on-call duty on a weekday and overtime. (C) The on-call duty on a weekend.



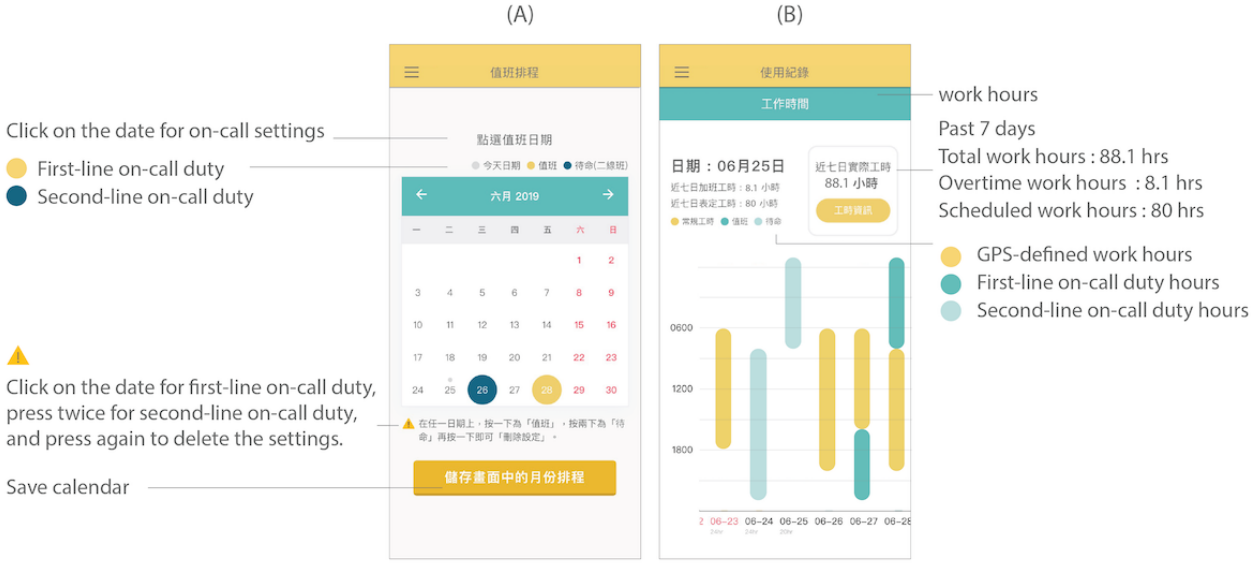
In the example in Figure 1, the user walks into and leaves the 1-km radius range of hospital A at 9 am and 10 am, respectively. First, 4 consecutive solid dots are collected at 9:30 am; so, the app records that the user has started working since 9 am. When 4 consecutive hollow dots are later collected at 10:30 am, the recording ends, resulting in a GPS-defined working period from 9 am to 10 am. Similar procedures are done as the user moves to work in hospital B; the generated GPS-defined working period in hospital B is from 11 am to 12 pm. Second, the app automatically integrates the detached GPS-defined working periods if the interval between them is less than 8 hours. As the gap between the working periods of hospitals A and B is only 1 hour (10:00-11:00), the app integrates them. Finally, the app logs the GPS-defined work hours as 3 hours (9:00-12:00).

Calculating Work Hours

Although the app counts GPS-defined work hours, users can also input their work schedules. The user-defined *scheduled work hours* include *regular work hours* and *on-call duty hours*

(Figure 2). For regular work hours, users should set a fixed starting and finishing time of work for weekdays upon installation; for on-call hours, users should input the dates in a month on which they have on-call duties (Figure 3). The app offers 2 selections for on-call duty hours, in line with the standard policies of the hospitals in Taiwan. Medical staff with *first-line on-call duty* are obligated to stay in the hospital overnight to care for patients and respond to any situations. Others with *second-line on-call duty* are on standby, that is, they are not required to be on site but should be prepared to take phone calls anytime and return to the hospital if needed. For weekdays, we define *on-call duty hours* as the time from getting off regular work to that of starting regular work on the next day. On weekends, the staff should be on-call for 24 hours, beginning from the time of starting regular work.

Figure 3. Screenshots of app user interface. (A) The on-call dates settings. (B) The work-hour statistics and charts.



The app automatically calculates the *total work hours* for users based on the following principles. During regular work time, the user's total work hours are equal to the GPS-defined work hours with the integration algorithm, regardless of the regular work schedule. This is because one's actual positioning data dominate the fixed work schedule. However, when it comes to on-call duties, the on-call hours have precedence over the GPS-defined hours because sometimes the staff is not obliged to be physically present within the range of the workplaces when working. In addition to the total work hours, this app also outputs the *overtime work hours* according to the following formula: *overtime work hours=total work hours−scheduled work hours.* The result can be a negative value, which would indicate that the exact working time was less than the scheduled working time (Figure 2).

The example in Figure 2 demonstrates how total and overtime work hours were calculated from the user's work schedule and the recorded GPS data. The user set 8 am to 6 pm to be regular work hours (10 hours) from Monday to Friday. Thus, on-call duty hours on the picked dates should be from 6 pm to 8 am (+1) for weekdays (14 hours) and from 8 am to 8 am (+1) for weekends (24 hours). On June 23, the user worked for a total of 13 hours according to the integrated GPS-defined work hours despite a short break at noon. The period from 6 pm to 9 pm was regarded as overtime as it was beyond the scheduled regular hours. On June 24, the user had first-line on-call duty. Although absent from workplace from 6 pm to 0 am (+1), the whole period of 14 hours was still included in *total work hours* as the on-call duty hours took precedence over the actual hours detected at workplaces. As for Saturday, June 25, the user did not have regular work; so, it was considered overtime from 8 am to 12 pm. On Sunday, June 26, the user had second-line on-call duty lasting 24 hours and then continued with Monday's regular work for another 10 hours. Hence, the total work hours were the sum of the 2 listed above, which equaled to 34 hours.

The users can check their total work hours, overtime work hours, and scheduled work hours for the past 7 days on the app. For higher accuracy and better flexibility, the app allows users to adjust their actual work hours within 7 days. In the example in Figure 3, the user had 8.1 hours of overtime in the past 7 days as it was the difference between the total work hours (88.1 hours) and scheduled work hours (80 hours). A visualization of a 28-day bar chart shows the staff's total work hours, with yellow and green representing GPS-defined work hours and on-call hours, respectively. They can also share visualized data of their weekly or monthly average work hours on their Facebook page.

Validation of App-Recorded Total Work Hours

We recruited 5 medical doctors and interviewed them regarding their work hours for the past 7 days to examine the accuracy of these (n=5×7=35) app-recorded total work hours by *Staff Hours*. This structural interview detailed the users' on-call duties, regular work hours, and overtime work hours for each day. These self-reported total work hours excluded the trainee physicians' educational activities. Therefore, we used these self-reported total work hours as the putative gold standard to validate the app-recorded total work hours. The sensitivity was

94.6% (242.7/256.6) and the specificity was 93.9% (547.6/583.4) for the app-recorded total work hours. There was a high correlation between the app-recorded total work hours and the self-reported counterparts (r=0.923; P<.001).

Statistical Analysis

A paired t test was used to compare the differences between the total work hours and the scheduled work hours. One-way analysis of variance was used to compare the differences in total work hours among all 5 categories of workers (ie, medical students, visiting staff, resident physicians, registered nurses, and non-HCPs). Fisher least significant difference (LSD) was used for further post hoc tests. In addition, we used independent t tests to examine the differences in the total work hours between the medical staff (ie, medical students, visiting staff, resident physicians, and registered nurses) and non-HCPs. All statistical analyses were 2-tailed, and P<.05 was considered to be statistically significant. Data arrangement and statistical analysis were performed using R software (version 3.5.3).

Results

Overview

The app-recorded total work hours (mean 55.69 hours, SD 21.34) of all the 183 participants were significantly higher than the self-reported scheduled work hours (mean 50.67 hours, SD 21.44; t_{182}=2.61; P=.01). All participants showed an average of 4.78 hours (SD 26.12) overtime work per week (ie, total work hours−scheduled work hours). Table 1 demonstrates that resident physicians had a significant positive overtime (mean 7.95 hours, SD 24.25), that is, the residents' total work hours were significantly higher than the scheduled work hours (t_{88}=3.14; P=.002).

Table 1. Total work hours and scheduled work hours among 5 occupations.

Occupation	Total work hours per week, mean (SD)	Scheduled work hours per week, mean (SD)
Resident physicians	60.38 (18.67)	52.31 (19.97)
Registered nurses	56.72 (28.80)	56.89 (30.88)
Visiting staff	51.42 (20.33)	44.46 (17.43)
Medical students	49.03 (20.06)	45.95 (13.79)
Non-HCPs	45.48 (20.08)	49.83 (22.17)

Table 1 also shows the comparisons of total work hours and scheduled work hours among the 5 categories. There were significant differences among the 5 categories on total work hours ($F_{4,183}$=3.047; P=.02). Post hoc comparisons using LSD tests further revealed that the resident physicians had significantly longer total work hours (mean 60.38 hours, SD 18.67) than the visiting staff (mean 51.42 hours, SD 20.33; P=.03) and non-HCPs (mean 45.48 hours, SD 20.08; P=.004). In addition, medical staff (ie, resident physicians, registered nurses, visiting staff, and medical students) had significantly longer total work hours (mean 57.01 hours, SD 21.20) than non-HCPs (mean 45.48 hours, SD 20.08; P=.02).

Discussion

Principal Findings

Our findings showed that medical staff had longer work hours than non-HCPs, and resident physicians worked for longer hours than visiting staff in hospitals. These findings are consistent with previous reports that showed that resident physicians typically work the greatest number of hours per week among all positions in hospitals [14]. Similarly, it is feasible to compare work hours among different hospitals, departments, or divisions using aggregate data collected from the Staff Hours' database. In this way, we can find out the *hot spots* where office workers have the longest total work hours or overtime. From September 2019, the Labor Standards Act in Taiwan will include regulations on the working hours for resident physicians. With the implementation of government policy, *Staff Hours* can serve as a real-time monitor for compliance with these work-hour limits. The app might also be useful in labor negotiations, balancing the unequal information between employers and employees. Although employers hold official records on work hours, the automatically recorded data in mobile apps provide evidence for employees when they claim overtime pay. In this study, each occupational group comprised greater than or equal to 10 people, which strengthens user privacy. Further analysis of the comparisons among different clusters should take individual privacy into account and make sure that there are not less than 10 people in each group.

The algorithms behind *Staff Hours* include not only the location-based work hours recording but also several critical designs for a better user experience. First, detached working periods are linked back together in the GPS-defined work hours because of the unique duty-based characteristics of health care work. Take a physician at an academic hospital as an example. She may have to leave the hospital for lectures on the university campus or walk a couple of blocks in the neighborhood to grab lunch in the middle of the scheduled working time. If the physician comes back to the hospital in less than 8 hours, the app still records the period that she is absent from the GPS range of the hospital as GPS-defined work hours. Second, the update interval of GPS location data in this app is set to be 10 min to improve battery performances; this is much longer than the geofencing responsiveness interval of approximately 2 min in the background location limits introduced in Android 8.0 (Application Program Interface level 26) to reduce undesired battery drain [15]. Third, users can adjust the work-hour logs manually only within 7 days. This restriction was established to avoid recall bias, increasing the accuracy of records [16]. Another associated advantage is that it may assure data integrity

and prevent future problems of data fraud, which would be crucial in labor inspections.

In addition, this app performs functions that specifically target medical staff, such as automatic calculations of overtime and on-call duty hours. Our findings demonstrated that all the participants on average worked 4.78 more hours per week than scheduled. The lengthy overtime may be from a selection bias in our participants, most of whom (89/183, 48.6%) were resident physicians whose total work hours were always higher than they should be. However, we observed that the scheduled ones were shorter than expected because few residents (58/89, 65%) logged their on-call dates in the system, which might result in an underestimation of the scheduled work hours. Moreover, this app could not differentiate the activities of working and learning in the institution for residents and medical students, which might result in an overestimation of total work hours. Together, they may lead to an overestimation of overtime and thus, we observed significant differences between the total and scheduled work hours in this study. Unsure of the validity of the scheduled and overtime work-hours data, we analyzed only the total work hours of the various occupations.

Limitations

Several methodological limitations should be noted when interpreting our findings. First, users who live within a 1-km geofencing radius from their workplaces are limited to using the algorithm of GPS-defined work hours. Furthermore, inaccuracies in GPS location tracking may occur when users work at smaller companies or clinics as the app transforms workplace addresses into latitudes and longitudes. Second, if only a few medical staff log their on-call duties in the app, the produced average overtime hours could be higher than the actual overtime hours. Third, the app could not identify breaks within the geofencing range, which might result in an overestimation of total work hours. Finally, there may be a selection bias in the participants as medical staff or other users with longer work hours may have a higher tendency to install *Staff Hours*.

Comparison With Prior Work

Staff Hours is the first app designed specifically for medical staff, with built-in functions for tracking on-call duties in hospitals. To the best of our knowledge, no prior study has enabled medical staff to use their personal smartphones, either Apple or Android models, to monitor their work hours automatically. The high accuracy of GPS-defined work-hours data without manual input and the integration between multiple work locations show the app's ease of use. Moreover, *Staff Hours* is the first app to perform comparisons on work hours among different categories of medical staff and also between medical staff and other occupations. For staff having excessive work hours, this app could serve as a *smoke alarm*, providing early signals of overwork or occupational burnout. We designed this app focusing on medical staff's work-hour patterns as they may have the most complicated work-hour patterns, including frequent on-call duties and multiple workplaces. The power-saving GPS data collection with optimal sampling rate and work periods integration in our algorithm overcame these challenges.

Conclusions

Staff Hours is the first automatic GPS location–based app designed for medical staff to track work hours and calculate overtime. For medical staff, this app could keep complete and accurate records of work hours in real time, reduce bias, and allow for better complying with labor regulations.

Acknowledgments

This study was supported by grants from the National Health Research Institutes of Taiwan (07A1-PHPP27-014) and the Ministry of Science and Technology of Taiwan (MOST 107-2314-B-400-038-MY3). The authors thank Mr Chang-En Hsieh and Ms Hsiao-Han Lin for their excellent technical assistance.

Conflicts of Interest

None declared.

References

1. Lin YH, Kuo TB, Ho YC, Lin SH, Liu CY, Yang CC. Physiological and psychological impacts on male medical interns during on-call duty. Stress 2012 Jan;15(1):21-30. [doi: 10.3109/10253890.2011.572208] [Medline: 21682655]
2. Lin YH, Chen CY, Li P, Lin SH. A dimensional approach to the phantom vibration and ringing syndrome during medical internship. J Psychiatr Res 2013 Sep;47(9):1254-1258. [doi: 10.1016/j.jpsychires.2013.05.023] [Medline: 23786911]
3. Lin YH, Chen CY, Lin SH, Liu CH, Weng WH, Kuo TB, et al. Gender differences in cardiac autonomic modulation during medical internship. Psychophysiology 2013 Jun;50(6):521-527. [doi: 10.1111/psyp.12038] [Medline: 23517383]
4. Lin YH, Lin SH, Li P, Huang WL, Chen CY. Prevalent hallucinations during medical internships: phantom vibration and ringing syndromes. PLoS One 2013;8(6):e65152 [FREE Full text] [doi: 10.1371/journal.pone.0065152] [Medline: 23762302]
5. Chen CY, Lin SH, Li P, Huang WL, Lin YH. The role of the harm avoidance personality in depression and anxiety during the medical internship. Medicine (Baltimore) 2015 Jan;94(2):e389 [FREE Full text] [doi: 10.1097/MD.0000000000000389] [Medline: 25590843]
6. Lin YH, Ho YC, Lin SH, Yeh YH, Liu CY, Kuo TB, et al. On-call duty effects on sleep-state physiological stability in male medical interns. PLoS One 2013;8(6):e65072 [FREE Full text] [doi: 10.1371/journal.pone.0065072] [Medline: 23750232]

7. Kivimäki M, Jokela M, Nyberg ST, Singh-Manoux A, Fransson EI, Alfredsson L, IPD-Work Consortium. Long working hours and risk of coronary heart disease and stroke: a systematic review and meta-analysis of published and unpublished data for 603,838 individuals. Lancet 2015 Oct 31;386(10005):1739-1746 [FREE Full text] [doi: 10.1016/S0140-6736(15)60295-1] [Medline: 26298822]
8. Virtanen M, Stansfeld SA, Fuhrer R, Ferrie JE, Kivimäki M. Overtime work as a predictor of major depressive episode: a 5-year follow-up of the Whitehall II study. PLoS One 2012;7(1):e30719 [FREE Full text] [doi: 10.1371/journal.pone.0030719] [Medline: 22295106]
9. Mansukhani MP, Kolla BP, Surani S, Varon J, Ramar K. Sleep deprivation in resident physicians, work hour limitations, and related outcomes: a systematic review of the literature. Postgrad Med 2012 Jul;124(4):241-249. [doi: 10.3810/pgm.2012.07.2583] [Medline: 22913912]
10. Landrigan CP, Barger LK, Cade BE, Ayas NT, Czeisler CA. Interns' compliance with accreditation council for graduate medical education work-hour limits. J Am Med Assoc 2006 Sep 6;296(9):1063-1070. [doi: 10.1001/jama.296.9.1063] [Medline: 16954485]
11. Ministry of Health and Welfare. 2013. Medical Residents? Labor Rights Protection Guideline. URL: https://www.health.taichung.gov.tw/media/302252/481916431154.pdf [accessed 2019-12-31]
12. Pan YC, Lin HH, Chiu YC, Lin SH, Lin YH. Temporal stability of smartphone use data: determining fundamental time unit and independent cycle. JMIR Mhealth Uhealth 2019 Mar 26;7(3):e12171 [FREE Full text] [doi: 10.2196/12171] [Medline: 30912751]
13. App Annie - The App Analytics and App Data Industry Standard. URL: https://www.appannie.com/cn/ [accessed 2019-07-31]
14. Baldwin DC, Daugherty SR. Sleep deprivation and fatigue in residency training: results of a national survey of first- and second-year residents. Sleep 2004 Mar 15;27(2):217-223. [doi: 10.1093/sleep/27.2.217] [Medline: 15124713]
15. Android Developers. Developer Guides URL: https://developer.android.com/guide/ [accessed 2019-07-31]
16. Coughlin SS. Recall bias in epidemiologic studies. J Clin Epidemiol 1990;43(1):87-91. [doi: 10.1016/0895-4356(90)90060-3] [Medline: 2319285]

Abbreviations

iOS: iPhone Operating System
LSD: least significant difference
non-HCP: non–health care professional

Edited by G Eysenbach; submitted 30.08.19; peer-reviewed by B Lognos, LA Lee; comments to author 29.10.19; revised version received 07.11.19; accepted 15.12.19; published 25.02.20.

Please cite as:
Chiang TW, Chen SY, Pan YC, Lin YH
Automatic Work-Hours Recorder for Medical Staff (Staff Hours): Mobile App Development
JMIR Mhealth Uhealth 2020;8(2):e16063
URL: http://mhealth.jmir.org/2020/2/e16063/
doi:10.2196/16063
PMID:32130165

Original Paper

The Swedish Version of the Electronic Health Literacy Scale: Prospective Psychometric Evaluation Study Including Thresholds Levels

Josefin Wångdahl[1,2], PhD; Maria Jaensson[3], PhD; Karuna Dahlberg[3], PhD; Ulrica Nilsson[2,4], PhD

[1]Department of Public Health and Caring Sciences, Uppsala University, Uppsala, Sweden

[2]Department of Neurobiology, Care Sciences and Society, Karolinska Institute, Huddinge, Sweden

[3]School of Health Sciences, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

[4]Department of Perioperative Medicine and Intensive Care, Karolinska University Hospital, Stockholm, Sweden

Corresponding Author:
Ulrica Nilsson, PhD
Department of Neurobiology, Care Sciences and Society
Karolinska Institute
Alfred Nobels Allé 23
Huddinge
Sweden
Phone: 46 8 524 838 22
Email: ulrica.nilsson@ki.se

Abstract

Background: To enhance the efficacy of information and communication, health care has increasingly turned to digitalization. Electronic health (eHealth) is an important factor that influences the use and receipt of benefits from Web-based health resources. Consequently, the concept of eHealth literacy has emerged, and in 2006 Norman and Skinner developed an 8-item self-report instrument to measure these skills: the eHealth Literacy Scale (eHEALS). However, the eHEALS has not been tested for reliability and validity in the general Swedish population and no threshold values have been established.

Objective: The aim of this study was to translate and adapt eHEALS into a Swedish version; evaluate convergent validity and psychometric properties; and determine threshold levels for inadequate, problematic, and sufficient eHealth literacy.

Methods: Prospective psychometric evaluation study included 323 participants equally distributed between sexes with a mean age of 49 years recruited from 12 different arenas.

Results: There were some difficulties translating the English concept *health resources*. This resulted in this concept being translated as *health information* (ie, *Hälsoinformation* in Swedish). The eHEALS total score was 29.3 (SD 6.2), Cronbach alpha .94, Spearman-Brown coefficient .96, and response rate 94.6%. All a priori hypotheses were confirmed, supporting convergent validity. The test-retest reliability indicated an almost perfect agreement, .86 (P<.001). An exploratory factor analysis found one component explaining 64% of the total variance. No floor or ceiling effect was noted. Thresholds levels were set at 8 to 20 = inadequate, 21 to 26 = problematic, and 27 to 40 = sufficient, and there were no significant differences in distribution of the three levels between the Swedish version of eHEALS and the HLS-EU-Q16.

Conclusions: The Swedish version of eHEALS was assessed as being unidimensional with high internal consistency of the instrument, making the reliability adequate. Adapted threshold levels for inadequate, problematic, and sufficient levels of eHealth literacy seem to be relevant. However, there are some linguistic issues relating to the concept of *health resources*.

(JMIR Mhealth Uhealth 2020;8(2):e16316) doi:10.2196/16316

KEYWORDS

eHealth; literacy; internet; psychometrics

Introduction

Globally, the internet is an important resource for health-related information and health services, which requires a range of digital skills among users and also new ways of describing and evaluating users' digital capabilities and experience in this rapidly changing health context [1]. The use of the internet in Sweden has steadily increased in recent years, and currently about 95% of all households have internet access. Internet access has increased the most in the elderly population, and in people aged 76 years and older, 87% have internet access at home. Of those, 49% use the internet to seek health-related information, compared with 96% of persons aged 26 to 45 years, 90% to 95% of persons aged 46 to 65 years, and 76% of persons aged 66 to 75 years [2]. In the present health care system, people are expected to participate and be engaged in their own care; they must be able to understand health instructions regarding how to manage their care (ie, health literacy) [3-5]. Traditional health literacy refers to an individual's ability to use printed information. However, with the increasing digitalization of information and services, the modern health care system must be aware of the health literacy levels of its patients in cyber space in order to maximize the benefits of electronic health (eHealth) technologies, challenging for both patients and health care staff [6].

The internet is significantly impacting health and health care, and it has the potential to advance health care delivery and support decision-making [1,7]. Thus, internet-enabled health care is a strategic priority globally. EHealth is an important factor that influences the use and receipt of benefits from Web-based health resources [1,8]. Consequently, the concept of eHealth literacy has emerged [1,9,10] and has been described as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" [10].

Because eHealth literacy is a more recent construct than health literacy, it is hard to find studies that have been published regarding its association with health outcomes [11]. However, limited health literacy has been found to affect a person's quality of care, resulting in lower satisfaction with care and a lower understanding of their medical situation [12,13]. This increases, for example, the probability of an adverse medication reaction because of misunderstanding the instructions [12,14]. Health literacy is also associated with the extent to which people benefit from health examinations [15], the quality of their postoperative recovery [16], and even mortality [11].

In a systematic review of questionnaires measuring eHealth literacy, 8 questionnaires were identified. It is noteworthy that the eHealth Literacy Scale (eHEALS) questionnaire was used in 45 of the 53 included articles [17]. eHEALS was developed in 2006 by Norman and Skinner [10] and aims to measure a broad range of literacy skills, which could make it useful in assessing the effects of strategies for delivering online information and applications. eHEALS is an 8-item instrument with each item scored on a 5-point Likert scale with response options ranging from strongly agree to strongly disagree. Total scores on the eHEALS range from 8 to 40, with higher scores representing higher self-perceived eHealth literacy [10].

The eHEALS is available in a range of languages [9,10,18-23], and the English version has been successfully administered via telephone [24]. Psychometric testing of eHEALS indicates that it is a reliable and valid instrument [10,23,25-27] but also that its validity requires further investigation [9]. However, there are no threshold levels for eHEALS, and eHEALS has not been tested for validity in the general Swedish population. Thus, the aim of our research was to translate and adapt the eHEALS into a Swedish version; evaluate convergent validity and psychometric properties; and determine threshold levels for inadequate, problematic, and sufficient eHealth literacy.

Methods

Study Design and Participants

This prospective psychometric evaluation study was conducted in three phases: translation, content validity testing, and psychometric evaluation. Data collection for phases 1 and 2 was completed from September 2018 to January 2019 and for phase 3 from February 2019 to May 2019 [28]. The project was approved by the Regional Ethical Review Board in Stockholm, Sweden, (no 2019/5:1) and follows the principles outlined in the 1964 Helsinki Declaration and its subsequent amendments. Participants received written and verbal information about the study, including its purpose and procedures, the voluntary nature of participation, and their option to withdraw at any time. By answering the questionnaire, participants consented to taking part in the study. Participants were also guaranteed confidentiality and secure data storage.

Phase 1: Translation

Permission to translate and use the eHEALS [10] was obtained from the creator of the instrument, Cameron D Norman, PhD. After permission was granted, one professional translator with Swedish as a native language translated the original English version of eHEALS into Swedish (ie, the Swedish version of eHEALS [Sw-eHEALS]). The translator was instructed to use plain language and that the translation should be comprehensible to a 12-year-old child. This means that items should be short and simple and should not contain difficult words or jargon [29]. Two of the researchers (JW and UN) compared Sw-eHEALS with the original English version by examining how well it fit into the Swedish context and checking it for plain language. The researchers found that the Swedish version required some minor contextual changes and changes into simpler language in order to make it easier to understand the content. The translator stated that translating the English concept of *health resources* into Swedish was problematic because the Swedish concept of *Hälsoresurser* does not have the same meaning and the word is not commonly used in Swedish. The creator was contacted to discuss this, and he stated that there have been similar problems with the concept when translating it into other languages. Based on discussions with Dr Norman and also with four bilingual native English and Swedish speakers, it was decided to translate *health resources* as *Hälsoinformation* (ie, *health information*).

An expert panel including seven Swedish speakers was recruited to examine the quality of the translation [30]. The panel included two teachers of Swedish for people with a different mother tongue, two development managers with expertise in communication in health care, and three researchers in medicine, caring sciences, and health literacy. The experts were asked to comment on spelling, grammar, and whether they thought the translation had been written in plain language. After reviewing the experts' feedback, the two researchers made some linguistic modifications and the Sw-eHEALS was then backtranslated by another native English-speaking translator who was blinded to the original eHEALS version. The backtranslated version and the original English eHEALS version were then compared by the translators and the two researchers. The two versions were found to match in terms of purpose and content.

Phase 2: Face Validity

In order to evaluate the face validity [29,31] of the Sw-eHEALS, interviews were conducted with six participants recruited purposively and through snowball sampling [32] by two of the researchers (JW and UN) and one research assistant. A mix of ages, sexes, and educational levels was sought (see demographic characteristics of the participants in Table 1). Participants received verbal and written information about the face validity test and the main study and were instructed to think aloud during completion of the Sw-eHEAL and highlight any problematic points. They were also asked to reflect on why they selected specific responses.

Participants found the items easy to understand and answer and their verbal answers agreed with their marked answers in the Sw-eHEALS. There were no signs of misunderstandings. However, the concept of health information was interpreted slightly differently, even though the concept is broad. Some participants reported that the questions were quite similar and that they could be placed in a different order. They also reported that the Likert scale could include fewer or different alternatives. The face validity testing resulted in some minor changes in wording and confirmed the clarity and comprehensibility of Sw-eHEALS.

Table 1. Demographics of the content validity test group (n=6).

Variable	Value
Gender	
Male	3
Female	3
Age in years	
Mean	50
Range	28-78
Educational level	
7-9 years	1
10-12 years	2
More than 12 years	3
Country of birth, Sweden	6

Phase 3: Psychometric Evaluation

Participants and Settings

A study population comprising 300 participants was considered to be appropriate given that the general rule of thumb for factor analysis is 300 cases [33]. The inclusion criteria for participation was being an adult (aged 18 years and older), having Swedish as a native language, and being available on the day of the data collection. Participants were recruited from university courses, craft training, larger workplaces with academic and nonacademic staff, nongovernmental organizations serving elderly people, athletic clubs, and two choirs. A total of 12 arenas selected for diversity in age, sex, and level of education were visited by one of the researchers (JW).

Study Questionnaires and Additional Questions

The Sw-eHEALS, an additional questionniare, and general and demographics questions (age, biological sex, education level) were used. The HLS-EU-Q16 (Health Literacy Survey European Questionnaire, 16-item) aims to measure comprehensive health literacy (ie, perceived personal skills in finding, understanding, judging, and applying health information in order to maintain and improve health) [34]. The HLS-EU-Q16 was used to assess construct validity. HLS-EU-Q16 items were answered on a 4-point Likert scale ranging from very difficult to very easy. The total score of the index is summed to range from 0 to 16, with higher scores representing higher self-perceived comprehensive levels of health literacy. Score points between 0 to 8 represents inadequate health literacy, 9 to 12 score points represents problematic comprehensive health literacy, and 13 to 16 score points represents sufficient comprehensive health literacy [34,35].

One question was asked about general self-perceived health: "How do you assess your overall health status?" Response options were very poor, poor, fair, good, and very good [15,36,37].

Two questions were asked about interest in using the internet. "How useful is the internet in helping you make decisions about your health?" Response options to this *usability of the internet*

question were not useful at all, not useful, unsure, useful, and very useful. “How important is it for you to be able to access health resources on the internet?” Response options to this *importance of the internet* question were not important at all, not important, unsure, important, and very important [10].

One question was asked about the frequency of internet use: “How often do you use the internet?” Response options were almost every day, several days a week, around one day a week, less than one day a week, and almost never [9].

Data Collection

On the day of the data collection, one of the researchers (JW) visited the arenas and informed participants verbally and in writing about the project and the meaning of informed consent. Those participants who agreed to participate answered the questionnaire directly. In one of the arenas, however, the organization manager distributed the written information and questionnaire instead of the researcher because it was difficult for all the staff to attend a meeting.

For analysis test-retest reliability, some of the participants were invited to answer the questionnaire twice within one week. A sample size in the retest of 25 participants was considered appropriate [38]. However, in order to include participants of different ages, sex, and education levels, 35 persons were asked to participate in the test-retest. In order to compare answers from the test and retest on an individual level and to ensure anonymity, participants marked their questionnaires with a code comprising the first three letters of their mother’s name and the year she was born.

Psychometric Testing

Psychometric testing was guided by the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) [29,31,39].

Feasibility

Feasibility of the instrument was assessed by successful response rate and missing data from the questionnaires [39].

Construct Validity

Construct validity focuses on evaluating tests of the hypotheses and can be described as the degree to which scores of an instrument are consistent with a hypothesis [31]. Based on previous studies on health literacy showing positive associations between limited health literacy and high age [3,13,40,41], poor health [15,16,40,42,43], and low education level [41,44,45], hypotheses regarding correlations between Sw-eHEALS and age, level of education, and self-perceived general health were used. Hypotheses regarding positive correlations between Sw-eHEALS and interest in and level of internet use [9] were also used. Furthermore, positive correlations were seen between Sw-eHEALS and the HLS-EU-Q16 total score and the four HLS-EU-Q16 items measuring aspects of health literacy in relation to the internet [28].

Reliability

Internal Consistency

Internal consistency describes the degree of interrelatedness among items [31]:

- Exploratory factor analysis with principal axis factoring was used to identify the underlying relationships between the items in Sw-eHEALS [29].
- Cronbach alpha was calculated for the sum score and each item to assess the average correlation of items within each scale.
- Split-half reliability was used to measure the correlation between random split segments and determine how much error in a test score is due to poor test construction [46].

Test-Retest Reliability

Test-retest reliability can be described as the extent to which scores for the same participants are the same in measurements repeated over time [31].

Floor and Ceiling Effects

Floor and ceiling effects (ie, number of respondents who achieved the lowest or highest possible scores [29]) were examined. Floor or ceiling effects were considered a problem if more than 15% of a study population achieved the lowest or highest possible score [29].

Thresholds

The Sw-eHEALS scores were categorized according to the threshold values for health literacy assessed by the HLS-EU-Q16 [34,47]: inadequate = 0 to 8 (represents 50% of the sum score for HLS-EU-Q16), problematic = 9 to 12 (represents 25% of the sum score for HLS-EU-Q16), and sufficient = 13 to 16 (represents 25% of the sum score for HLS-EU-Q16). Adapted to Sw-eHEALS scores, the thresholds for eHealth literacy are inadequate = 8 to 20 (represents 50% of the sum score for Sw-eHEALS), problematic = 21 to 26 (represents 25% of the sum score for Sw-eHEALS), and sufficient = 27 to 40 (represents 25% of the sum score for Sw-eHEALS).

Statistical Analysis

Data are presented as mean, standard deviation, number, percentage, or range. Spearman rank was used to analyze the correlation between the total mean scores on Sw-eHEALS and HLS-EU-Q16. Self-perceived health, level of education, and age were also used. A coefficient magnitude of >.40 was considered evidence of construct validity (ie, moderate to strong correlations) [39]. Internal consistency was measured using a Spearman-Brown coefficient with values between .70 to .90 considered acceptable [48,49] and Cronbach alpha with a range of .70 to .95 considered acceptable [29,46]. Test-retest reliability was measured using the weighted kappa coefficient, with an accepted value of ≥.70 [29,50]. The Friedman test was used to analyze differences between Sw-eHEALS and HLS-EU-Q16 in terms of numbers of patients with inadequate, problematic, and sufficient health literacy. The chi-square test was used to analyze differences in sex, Student *t* test was used to analyze differences in age, and the Wilcoxon signed-rank test was used to analyze differences in age, educational levels, general self-perceived health, and Sw-eHEALS levels between

participants with the same levels of health literacy on both the Sw-eHEALS and HLS-EU-Q16 compared with those with different levels. All data were analyzed using SPSS Statistics version 24.0 for Windows (IBM Corp). Two-tailed *P* values less than .05 were considered significant.

Results

Feasibility

A total of 368 persons were invited to participate, and 348 answered the study questionnaires, giving a response rate of 94.6%; 24 questionnaires were incomplete and were excluded, resulting in a total of 323 valid questionnaires included in the analysis (Figure 1). There were no statistically significant differences regarding sex, age, or highest education level between the included participants versus those who declined to participate. Also, no pattern of structural problems in terms of difficulties in responding to certain items was found.

Sex was equally distributed, and the mean age was 49.2 (SD 21.5) years ranging from 19 to 94 years. Of the total, 90.4% (292/323) had at least 10 years' education, and 85.8% (277/323) perceived their own general health as being good or very good. The majority (231/323, 71.5%) had sufficient comprehensive health literacy (HLS-EU-Q16), and the mean sum score of Sw-eHEALS was 29.3. Most participants reported that they used the internet almost every day (284/323, 87.9%), that they thought the internet was useful or very useful (243/323, 75.2%), and that the internet was important or very important (250/323, 77.4%; Table 2).

Figure 1. Flowchart of the data collection.

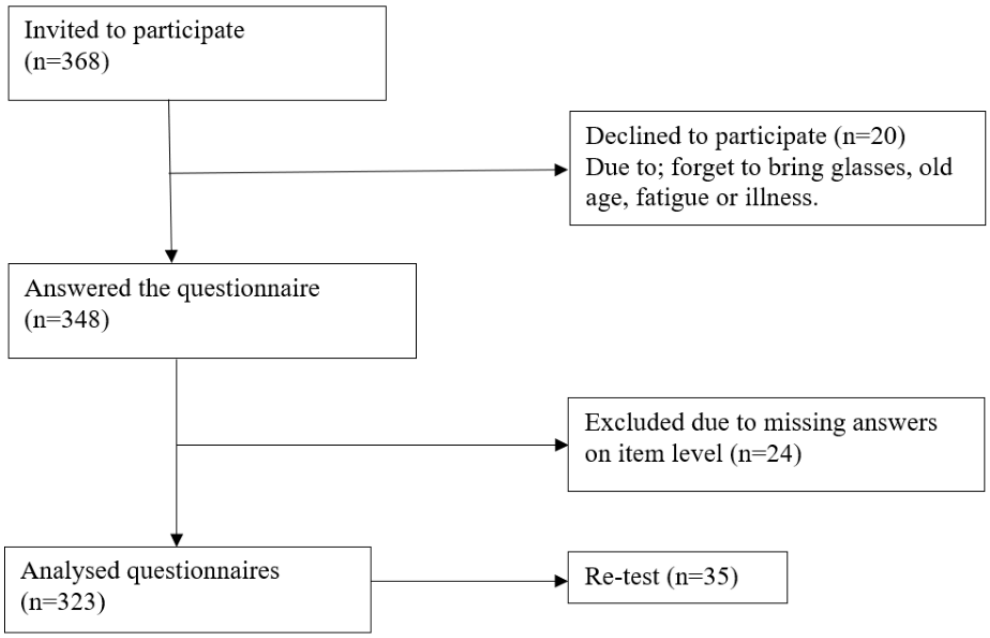


Table 2. Demographics of the respondents with a valid eHEALS sum score (n=323) and the test-retest group (n=35).

Characteristics	All	Test-retest group
Biological sex, n (%)[a]		
Man	160 (50)	21 (60)
Woman	160 (50)	14 (40)
Age in years		
Mean (SD)	49.2 (21.5)	44.4 (12.2)
Range	19-94	26-89
Highest education level, n (%)		
1-6 years	4 (1)	1 (3)
7-9 years	24 (8)	2 (6)
10-12 years	149 (47)	4 (11)
Graduated from university	143 (45)	28 (80)
General self-perceived health, n (%)		
Very poor	0 (0)	0 (0)
Poor	8 (3)	1 (3)
Fair	38 (12)	1 (1)
Good	197 (61)	25 (71)
Very good	80 (25)	8 (23)
HLS-EU-Q16[b], n (%)		
Inadequate	20 (6)	2 (6)
Problematic	72 (22)	4 (12)
Sufficient	231 (72)	27 (82)
Sw-eHEALS[c]		
Mean (SD)	29.3 (6.2)	31.2 (33.0)
Range	8-40	12-40
Frequency of internet use, n (%)		
Almost never	8 (3)	1 (3)
Less than 1 day a week	1 (0)	0 (0)
Around 1 day a week	8 (3)	1 (3)
Several days a week	22 (7)	2 (6)
Almost every day	284 (88)	31 (89)
Usability of the internet, n (%)		
Not useful at all	12 (4)	1 (3)
Not useful	12 (4)	2 (6)
Unsure	52 (16)	1 (3)
Useful	171 (54)	17 (49)
More useful	72 (23)	14 (40)
Importance of the internet, n (%)		
Not important at all	11 (3)	1 (3)
Not important	16 (5)	3 (9)
Unsure	43 (13)	2 (6)
Important	137 (43)	15 (43)

Characteristics	All	Test-retest group
Very important	113 (35)	14 (40)

[a]Missing n=3.

[b]HLS-EU-Q16: Health Literacy Survey European Questionnaire, 16-item.

[c]Sw-eHEALS: eHealth Literacy Scale.

Construct Validity

The Sw-eHEALS sum score was weak and negatively correlated with age and weak and positively correlated with education level, self-perceived health, frequency of using the internet, and two items in the HLS-EU-Q16. Moderate positive correlations were found with perceptions of the internet as being useful and important, the HLS-EU-Q16 sum score, and two items on the HLS-EU-Q16 (Table 3).

Table 3. Spearman rho correlations between the Sw-eHEALS sum score and demographic characteristics, questions, and questionnaires.

Variable	Value	*P* value
Age	–0.30	<.01
Education level	0.23	<.05
Self-perceived health	0.19	<.01
Usability of the internet	0.57	<.05
Importance of the internet	0.47	<.05
Frequency of internet use	0.36	<.05
HLS-EU-Q16[a] sum score	0.47	<.05
HLS-EU-Q16 item: Finding information about the treatment of illnesses that concern you	0.51	<.05
HLS-EU-Q16 item: Assessing whether information on health risks in the media is reliable	0.49	<.05
HLS-EU-Q16 item: Deciding on how you can protect yourself from illness based on information in the media	0.37	<.05
HLS-EU-Q16 item: Understanding information in the media about how to get healthier	0.38	<.05

[a]HLS-EU-Q16: Health Literacy Survey European Questionnaire, 16-item.

Reliability

Factor analysis showed that the Kayser-Meyer-Olkin measure of sampling adequacy for the analysis was good (92, *P*<.001). The eigenvalue was 5.5 and explained 69% of the total variance, also reflected in the scree plot, which supported a unidimensional scale. All items loaded high ranging from .73 to .86. Cronbach alpha for the sum score of Sw-eHEALS was .94 and ranged from .92 to .93 for the individual items. The Spearman-Brown coefficient for the sum score of Sw-eHEALS was .96. Weighted Cohen kappa coefficient was acceptable for the sum score (.86, *P*<.001) and ranged from .64 to .79 (*P*<.001) for the individual items (Table 4).

Table 4. Reliability testing: exploratory factor analysis, Cronbach alpha, Spearman-Brown coefficient, and weighted quadratic Cohen kappa for the Swedish version of the eHealth Literacy Scale sum score or individual items.

Variable	Exploratory factor analysis	Cronbach alpha	Spearman-Brown coefficient	Weighted quadratic Cohen kappa
Sw-eHEALS[a] total score	—	.94	.96	.86
Item 1: I know what health resources are available on the internet	.73	.93	—	.64
Item 2: I know where to find helpful health information on the internet	.83	.93	—	.71
Item 3: I know what health information is available on the internet	.86	.92	—	.70
Item 4: I know how to find helpful health information[b] on the internet	.85	.92	—	.79
Item 5: I know how to use the health information[b] I find on the internet to help me	.82	.93	—	.72
Item 6: I have the necessary skills to evaluate the health resources I find on the internet	.74	.93	—	.75
Item 7: I can distinguish between high- and low-quality health information on the internet	.78	.93	—	.68
Item 8: I feel confident in using information from the internet to make health decisions	.79	.93	—	.72

[a]Sw-eHEALS: Swedish version of the eHealth Literacy Scale.

[b]Health information=health resources in the original version by Norman and Skinner [10]

Test-Retest Reliability

A total of 35 participants were included in the test-retest. The mean age was 44 years with a range of 26 to 89 years, 60% (21/35) were male, 91% (32/35) had at least 10 years' education and 94% (33/35) perceived their own general health as being good or very good. The majority (82%, 27/35) had sufficient comprehensive health literacy (HLS-EU-Q16), and the mean sum score of the Sw-eHEALS was 32.1. Most participants reported that they used the internet almost every day (89%, 31/35), that they thought the internet was useful or very useful (89%, 31/35), and that the internet was important or very important (83%, 29/35; Table 2). The weighted quadratic Cohen kappa for the Sw-eHEALS total score was .86 (P<.001) and ranged from .70 to .79 (P<.001) for 6 items and .64 to .68 (P<.001) for 2 items (Table 4).

Floor and Ceiling Effects

A total of 2% (7/323) of the participants had the lowest possible sum score and 4% (15/323) the highest possible sum score on the Sw-eHEALS.

Thresholds

The thresholds adapted for Sw-eHEALS resulted in 7.1% (23/323) of participants with inadequate, 18.8% (61/323) with problematic, and 74.0% (239/323) with sufficient eHealth literacy. When comparing numbers of participants with inadequate, problematic, and sufficient health literacy between Sw-eHEALS and HLS-EU-Q16, there were no statistical differences (P=.10), indicating that the thresholds determined for Sw-eHEALS seem to be relevant. Distribution between the three levels of eHealth literacy was similar for the HLS-EU-Q16, with 6.2% (20/323) of participants with inadequate, 22.3% (72/323) with problematic, and 71.5% (231/323) with sufficient eHealth literacy (Table 2). When dichotomized into insufficient (inadequate + problematic) and sufficient eHealth literacy, there was a significantly greater proportion of participants who scored the same levels of health literacy on both questionnaires (46+208=254/323, 78.6%) compared with participants who had different scores (42+27=69/323, 21.4%; P<.001; Table 5). There were no significant differences in age, sex, educational level, or general self-perceived health between these two groups.

Table 5. Distribution of participants scoring insufficient and sufficient health literacy and eHealth literacy.

	Insufficient health literacy, n (%)	Sufficient health literacy, n (%)
Insufficient electronic health literacy, n (%)	46 (14.3)	27 (8.3)
Sufficient electronic health literacy, n (%)	42 (13.1)	208 (64.3)

Discussion

Principal Findings

The results of this study support the intended use of Sw-eHEALS for measuring the self-reported eHealth literacy of Swedish persons. This paper shows that the process of translating an instrument from English into Swedish is not simple and quick. Capturing the culture and meaning of the words can be a challenge. Finding a suitable term for *health resources* in Swedish was problematic. Thus, several steps were taken that involved contacting the creator of the original instrument and also discussing the issue with experts and laymen. It is important that the content of the items remains the same as in the original. This is why we have described the translation process thoroughly. Although it is important that the content of the items remains the same as in the original version and reflects the true meaning of the construct, the wording or word order in the translated versions must be suitable for the target language and understandable by speakers with different levels of education and health literacy [30,51].

It has also been emphasized that translated items can assume different meanings and can affect the meanings perceived by the respondents. A lot of problems stem from the fact that the questions in the questionnaire or the wording of items in the instrument are culturally embedded. In other cases, structural differences mean that the exact equivalent objects or entities do not exist or that terms used to describe something in one country describe something else in another [52]. In this study, Sw-eHEALS was perceived as being easy to understand and answer, and no structural problems with specific items were found.

Our study found 1-factor structure (ie, unidimensionality) of the Sw-eHEALS, which is in line with previous studies, irrespective of using classical or modern test theory, as well as in different languages and populations [9,18,20,22,53-56]. The unidimensionality indicates that all the items measure a single underlying construct that is in line with what was originally proposed by the authors of the instrument [10]. However, a 2-factor structure has been reported [26,57,58], divided into the constructs of knowledge about resources and evaluation of resources. A 3-factor structure has also been reported including the construct: awareness, skills, and evaluation [8,59]. The 1-factor structure is important to Sw-eHEALS because this indicates it is appropriate to sum the item scores into a total score.

Internal consistency was assessed using Cronbach alpha and split-half reliability; both these coefficients were high, and the published recommendations for Cronbach alpha (ie, .70 to .95) were satisfied [29]. Other language versions of eHEALS have also reported high reliability with Cronbach alpha ≥.88 [18,20,22,53-55]. A high Cronbach alpha is usually found for questionnaires that contain a large number of items because Cronbach alpha is dependent on the number of items in a questionnaire [29]. The Sw-eHEALS includes 8 items.

The construct validity of the Sw-eHEALS was acceptable. Moderate positive correlations were found with the HLS-EU-Q16, which is in line with Neter et al [58]. Moderate positive correlations were also found with perceptions of the internet as being useful and important for finding information about the treatment of illnesses that cause concern and assessing whether information about health risks in the media is reliable. Previous studies support the relationship between eHealth literacy, use of the internet [9,18,20,53,60], mobile phone use [20], computer knowledge [53], and the amount of time spent online [20,54]. The findings have suggested that frequent internet users use the internet for health reasons and that this could result in a great level of self-reported eHealth literacy and that frequent internet users perceive that their ability to engage with and evaluate general internet resources is transferable to health-related content [8]. Furthermore, low eHealth literacy levels appear to be associated with poor skills using a personal computer, downloading files, and finding health information online and difficulties in receiving help from online sources [20].

The adapted threshold levels for inadequate, problematic, and sufficient levels of eHealth literacy were based on the levels for the HLS-EU-Q16 [35,47]. The threshold levels for Sw-eHEALS seem to be relevant, and it is important to establish these levels in order to identify those individuals and groups who suffer from inadequate and problematic eHealth literacy and are in need of support. To use a questionnaire without any thresholds or cutoff levels in research or in clinical practice is problematic because it is hard to evaluate what the values reflect (ie, insufficient or sufficient eHealth literacy). However, these suggested threshold levels for eHEALS have to be further evaluated in other populations and in other languages.

The test-retest reliability for the Sw-eHEALS sum score was .86, indicating an almost perfect agreement [50], to be compared with the creators of eHEALS, r=.68 [10], and the Persian version, r=.85 [55], analyzed using Pearson correlation. In our study, the time period between repeated measurements was one week, compared with the Persian version, which had a 2-week time period [55], and the original version, which had a 6-month follow-up [10]. If the time between the two tests is too long, respondents could have been exposed to things that changed their opinions, feelings, or attitudes about their behavior [51]. Terwee et al [29] believe that the time period between repeated administrations should be long enough to prevent recall but short enough to ensure that clinical changes have not occurred. Often, one or two weeks will be sufficient.

Floor and ceiling effects were acceptable; 2% of the participants scored the worst possible score (8), and 4% scored the best possible score (40). An acceptable floor and ceiling effect of eHEALS has been reported for the Italian version [18] and the Dutch version [9] in persons suffering from chronic disease [22] and in persons with moderate to high cardiovascular risk [26]. In an ideal situation, a questionnaire should be able to measure the entire spectrum of a phenomenon. If floor or ceiling effects are present, it is likely that extreme items will be missing at the lower or upper end of the scale. As a consequence, people with the lowest or highest possible score cannot be distinguished from each other, reducing reliability [29]. However, it has been reported that eHEALS does not seem to be able to detect small but clinically important changes in participants with mid to

higher levels of eHealth literacy in a population suffering from moderate to high cardiovascular risk [26].

Limitations

This study has a number of limitations. One limitation is that the sample included may not be representative of the majority of Swedish speakers. However, the included participants were recruited from different arenas, including groups of different ages, sex, and levels of education. Second, eHEALS measures self-reported eHealth literacy, which is not the same as measuring the person's knowledge of eHealth. Self-reported eHealth literacy might be over- or underestimated depending on things like the person's level of self-efficacy. Therefore, further studies are needed to study the association between subjective and objective eHealth literacy. Another limitation was the use of a nonvalidated question to assess general self-perceived health. However, it has been claimed that self-perceived health is one of the internationally leading health indicators reflecting a person's subjective general perception of health [36]. It has also been argued that self-rated health is inclusive and dynamic in judging the trajectory of health and that it influences behaviors that subsequently affect health status and reflects resources that affect the ability to cope with health threats [37].

Conclusion

This study confirmed that Sw-eHEALS is a reliable and valid tool for assessing the perceived comfort and skills of Swedish speakers in using information technology for health (ie, eHealth literacy). However, there are some linguistic issues relating to the concept of *health resources*. The adapted threshold levels for inadequate, problematic, and sufficient levels of eHealth literacy seem to be relevant and important when conducting further studies, especially intervention studies.

Acknowledgments

This study is supported by Vetenskapsrådet (Swedish Research Council), grant number 2015-02273. A special thank you to the experts in the panel in phase 1 for their valuable input. We would also like to thank Anahita Amipour for helping with data collection in phase 2. Last, thank you to the participants of the study for their participation and help.

Conflicts of Interest

None declared.

References

1. Norgaard O, Furstrand D, Klokker L, Karnoe A, Batterham R, Kayser L. The e-health literacy framework: a conceptual framework for characterizing e-health users and their interaction with e-health systems. Knowl Manag Elearning Int J 2015 Jul;7(4):533-540. [doi: 10.34105/j.kmel.2015.07.035]
2. Davidsson P, Palm M, Mandre Å. [The Swedes and the Internet 2018]. URL: https://svenskarnaochinternet.se/rapporter/svenskarna-och-internet-2018/the-swedes-and-the-internet-2018-summary/ [accessed 2020-01-15]
3. Sørensen K, Pelikan JM, Röthlin F, Ganahl K, Slonska Z, Doyle G, et al. Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). Eur J Public Health 2015 Dec;25(6):1053-1058 [FREE Full text] [doi: 10.1093/eurpub/ckv043] [Medline: 25843827]
4. Koster ES, Schmidt A, Philbert D, van de Garde EMW, Bouvy ML. Health literacy of patients admitted for elective surgery. Z Gesundh Wiss 2017;25(2):181-186 [FREE Full text] [doi: 10.1007/s10389-016-0774-z] [Medline: 28357196]
5. Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: a systematic review and integration of definitions and models. BMC Public Health 2012;12:80 [FREE Full text] [doi: 10.1186/1471-2458-12-80] [Medline: 22276600]
6. Tan SS, Goonawardene N. Internet health information seeking and the patient-physician relationship: a systematic review. J Med Internet Res 2017 Jan 19;19(1):e9 [FREE Full text] [doi: 10.2196/jmir.5729] [Medline: 28104579]
7. Kantor D, Bright JR, Burtchell J. Perspectives from the patient and the healthcare professional in multiple sclerosis: social media and patient education. Neurol Ther 2018 Jun;7(1):23-36 [FREE Full text] [doi: 10.1007/s40120-017-0087-3] [Medline: 29243028]
8. Hyde LL, Boyes AW, Mackenzie LJ, Leigh L, Oldmeadow C, Riveros C, et al. Electronic health literacy among magnetic resonance imaging and computed tomography medical imaging outpatients: cluster analysis. J Med Internet Res 2019 Aug 28;21(8):e13423 [FREE Full text] [doi: 10.2196/13423] [Medline: 31464188]
9. van der Vaart R, van Deursen AJ, Drossaert CH, Taal E, van Dijk JA, van de Laar MA. Does the eHealth Literacy Scale (eHEALS) measure what it intends to measure? Validation of a Dutch version of the eHEALS in two adult populations. J Med Internet Res 2011;13(4):e86 [FREE Full text] [doi: 10.2196/jmir.1840] [Medline: 22071338]
10. Norman CD, Skinner HA. eHEALS: the eHealth Literacy Scale. J Med Internet Res 2006 Nov;8(4):e27 [FREE Full text] [doi: 10.2196/jmir.8.4.e27] [Medline: 17213046]
11. Neter E, Brainin E. Association between health literacy, ehealth literacy, and health outcomes among patients with long-term conditions. Eur Psychol 2019 Jan 21;24(1):68-81 [FREE Full text] [doi: 10.1027/1016-9040/a000350]

12. Kirmayer LJ, Narasiah L, Munoz M, Rashid M, Ryder AG, Guzder J, Canadian Collaboration for Immigrant and Refugee Health (CCIRH). Common mental health problems in immigrants and refugees: general approach in primary care. CMAJ 2011 Sep 06;183(12):E959-E967 [FREE Full text] [doi: 10.1503/cmaj.090292] [Medline: 20603342]
13. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: an updated systematic review. Ann Intern Med 2011 Jul 19;155(2):97-107. [doi: 10.7326/0003-4819-155-2-201107190-00005] [Medline: 21768583]
14. Sundquist J. Migration, equality and access to health care services. J Epidemiol Community Health 2001 Oct;55(10):691-692 [FREE Full text] [doi: 10.1136/jech.55.10.691] [Medline: 11553650]
15. Wångdahl J, Lytsy P, Mårtensson L, Westerling R. Health literacy and refugees' experiences of the health examination for asylum seekers: a Swedish cross-sectional study. BMC Public Health 2015 Nov 23;15:1162 [FREE Full text] [doi: 10.1186/s12889-015-2513-8] [Medline: 26596793]
16. Hälleberg Nyman M, Nilsson U, Dahlberg K, Jaensson M. Association between functional health literacy and postoperative recovery, health care contacts, and health-related quality of life among patients undergoing day surgery: secondary analysis of a randomized clinical trial. JAMA Surg 2018 Aug 01;153(8):738-745 [FREE Full text] [doi: 10.1001/jamasurg.2018.0672] [Medline: 29710226]
17. Karnoe A, Kayser L. How is eHealth literacy measured and what do the measurements tell us? A systematic review. Knowl Manag ELearn Int J 2015;7(4):576-600. [doi: 10.34105/j.kmel.2015.07.038]
18. Diviani N, Dima AL, Schulz PJ. A psychometric analysis of the Italian version of the ehealth literacy scale using item response and classical test theory methods. J Med Internet Res 2017 Apr 11;19(4):e114 [FREE Full text] [doi: 10.2196/jmir.6749] [Medline: 28400356]
19. Tomás C, Queirós P, Ferreira T. [Analysis of the psychometric properties of the Portuguese version of an eHealth literacy assessment tool]. Rev Enf Ref 2014 Jun 30;4(2):19-28. [doi: 10.12707/RIV14004]
20. Chang A, Schulz PJ. The measurements and an elaborated understanding of Chinese eHealth literacy (C-eHEALS) in chronic patients in China. Int J Environ Res Public Health 2018 Dec 23;15(7):1553. [doi: 10.3390/ijerph15071553] [Medline: 30041420]
21. Mitsutake S, Shibata A, Ishii K, Okazaki K, Oka K. [Developing Japanese version of the eHealth Literacy Scale (eHEALS)]. Nihon Koshu Eisei Zasshi 2011 May;58(5):361-371. [Medline: 21905612]
22. Paige SR, Krieger JL, Stellefson M, Alber JM. eHealth literacy in chronic disease patients: an item response theory analysis of the eHealth literacy scale (eHEALS). Patient Educ Couns 2017 Feb;100(2):320-326. [doi: 10.1016/j.pec.2016.09.008] [Medline: 27658660]
23. Paramio PG, Almagro BJ, Hernando G, Aguaded GJI. [Validation of the eHealth Literacy Scale (eHEALS) in Spanish University Students]. Rev Esp Salud Publica 2015;89(3):329-338 [FREE Full text] [doi: 10.4321/S1135-57272015000300010] [Medline: 26388346]
24. Stellefson M, Paige SR, Tennant B, Alber JM, Chaney BH, Chaney D, et al. Reliability and validity of the telephone-based ehealth literacy scale among older adults: cross-sectional survey. J Med Internet Res 2017 Oct 26;19(10):e362 [FREE Full text] [doi: 10.2196/jmir.8481] [Medline: 29074471]
25. Nguyen G, Gambashidze N, Ilyas SA, Pascu D. Validation of the safety attitudes questionnaire (short form 2006) in Italian in hospitals in the northeast of Italy. BMC Health Serv Res 2015 Jul 24;15:284 [FREE Full text] [doi: 10.1186/s12913-015-0951-8] [Medline: 26204957]
26. Richtering S, Morris R, Soh S, Barker A, Bampi F, Neubeck L, et al. Examination of an eHealth literacy scale and a health literacy scale in a population with moderate to high cardiovascular risk: Rasch analyses. PLoS One 2017;12(4):e0175372 [FREE Full text] [doi: 10.1371/journal.pone.0175372] [Medline: 28448497]
27. Koo M, Norman CD, Hsiao-Mei C. Psychometric evaluation of a Chinese version of the eHealth literacy scale (eHEALS) in school age children. Global J Health Educ 2012;15(1).
28. Wangdahl JM, Dahlberg K, Jaensson M, Nilsson U. Psychometric validation of Swedish and Arabic versions of two health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in a Swedish context: a study protocol. BMJ Open 2019 Sep 17;9(9):e029668 [FREE Full text] [doi: 10.1136/bmjopen-2019-029668] [Medline: 31530602]
29. Terwee CB, Bot SDM, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 2007 Jan;60(1):34-42. [doi: 10.1016/j.jclinepi.2006.03.012] [Medline: 17161752]
30. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol 1993 Dec;46(12):1417-1432. [Medline: 8263569]
31. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol 2010 Jul;63(7):737-745. [doi: 10.1016/j.jclinepi.2010.02.006] [Medline: 20494804]
32. Valerio MA, Rodriguez N, Winkler P, Lopez J, Dennison M, Liang Y, et al. Comparing two sampling methods to engage hard-to-reach communities in research priority setting. BMC Med Res Methodol 2016 Oct 28;16(1):146 [FREE Full text] [doi: 10.1186/s12874-016-0242-z] [Medline: 27793191]

33. Wilson Van Voorhis CR, Morgan BL. Understanding power and rules of thumb for determining sample sizes. TQMP 2007 Sep 01;3(2):43-50. [doi: 10.20982/tqmp.03.2.p043]
34. Sørensen K, Van den Broucke S, Pelikan JM, Fullam J, Doyle G, Slonska Z, et al. Measuring health literacy in populations: illuminating the design and development process of the European Health Literacy Survey Questionnaire (HLS-EU-Q). BMC Public Health 2013 Oct 10;13:948 [FREE Full text] [doi: 10.1186/1471-2458-13-948] [Medline: 24112855]
35. Wångdahl J, Mårtensson LJSM. Göteborg University. 2013. HLS-EU-Q16 Svensk version 2 URL: https://medicine.gu.se/digitalAssets/1459/1459843_hls-eu-q16-svensk-version-2.pdf [accessed 2020-01-15]
36. Nielsen SS, Krasnik A. Poorer self-perceived health among migrants and ethnic minorities versus the majority population in Europe: a systematic review. Int J Public Health 2010 Oct;55(5):357-371. [doi: 10.1007/s00038-010-0145-4] [Medline: 20437193]
37. Benyamini Y. Why does self-rated health predict mortality? An update on current knowledge and a research agenda for psychologists. Psychol Health 2011 Nov;26(11):1407-1413. [doi: 10.1080/08870446.2011.621703] [Medline: 22111660]
38. Bujang M, Baharum N. A simplified guide to determination of sample size requirements for estimating the value of intraclass correlation coefficient: a review. Arch Orofacial Sci 2017;12(1). [doi: 10.1007/springerreference_205392]
39. De Vet H, Terwee C, Mokkink L. Measurement in Medicine: A Practical Guide. Cambridge: Cambridge University Press; 2011.
40. Palumbo R, Annarumma C, Adinolfi P, Musella M, Piscopo G. The Italian Health Literacy Project: insights from the assessment of health literacy skills in Italy. Health Pol 2016 Sep;120(9):1087-1094. [doi: 10.1016/j.healthpol.2016.08.007] [Medline: 27593949]
41. Paasche-Orlow MK, Parker RM, Gazmararian JA, Nielsen-Bohlman LT, Rudd RR. The prevalence of limited health literacy. J Gen Intern Med 2005 Feb;20(2):175-184 [FREE Full text] [doi: 10.1111/j.1525-1497.2005.40245.x] [Medline: 15836552]
42. Easton P, Entwistle VA, Williams B. Health in the 'hidden population' of people with low literacy. A systematic review of the literature. BMC Public Health 2010 Aug 05;10:459 [FREE Full text] [doi: 10.1186/1471-2458-10-459] [Medline: 20687946]
43. Levin-Zamir D, Baron-Epel OB, Cohen V, Elhayany A. The association of health literacy with health behavior, socioeconomic indicators, and self-assessed health from a national adult survey in israel. J Health Commun 2016;21(sup2):61-68. [doi: 10.1080/10810730.2016.1207115] [Medline: 27669363]
44. Almaleh R, Helmy Y, Farhat E, Hasan H, Abdelhafez A. Assessment of health literacy among outpatient clinics attendees at Ain Shams University Hospitals, Egypt: a cross-sectional study. Public Health 2017 Oct;151:137-145. [doi: 10.1016/j.puhe.2017.06.024] [Medline: 28800559]
45. Omariba DWR, Ng E. Health literacy and disability: differences between generations of Canadian immigrants. Int J Public Health 2015 Mar;60(3):389-397. [doi: 10.1007/s00038-014-0640-0] [Medline: 25549612]
46. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16(3):297-334. [doi: 10.1007/bf02310555]
47. Pelikan J, Röthlin F, Ganahl K, Peer S. Measuring comprehensive health literacy in general populations—le HLS-EU instruments. 2014 Presented at: Second International Conference of Health Literacy and Health Promotion; 2014; Taipei.
48. McDowell I. Measuring Health: A Guide to Rating Scales and Questionnaires. NY: Oxford University Press; 2006.
49. de Vet HCW, Mokkink LB, Mosmuller DG, Terwee CB. Spearman-Brown prophecy formula and Cronbach's alpha: different faces of reliability and opportunities for new applications. J Clin Epidemiol 2017 May;85:45-49. [doi: 10.1016/j.jclinepi.2017.01.013] [Medline: 28342902]
50. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1977 Mar;33(1):159-174. [Medline: 843571]
51. Drost EA. Validity and reliability in social science research. Educ Res Perspect 2011;38(1):105.
52. Rode N. Translation of measurement instruments and their reliability: an example of job-related affective well-being scale. Metodoloski Zvezki 2005;2(1):15. [doi: 10.1037/t01753-000]
53. Chung S, Nahm E. Testing reliability and validity of the eHealth Literacy Scale (eHEALS) for older adults recruited online. Comput Inform Nurs 2015 Apr;33(4):150-156. [doi: 10.1097/CIN.0000000000000146] [Medline: 25783223]
54. Chung S, Park BK, Nahm E. The Korean eHealth Literacy Scale (K-eHEALS): reliability and validity testing in younger adults recruited online. J Med Internet Res 2018 Apr 20;20(4):e138 [FREE Full text] [doi: 10.2196/jmir.8759] [Medline: 29678800]
55. Lin C, Broström A, Griffiths MD, Pakpour AH. Psychometric evaluation of the Persian eHealth Literacy Scale (eHEALS) among elder iranians with heart failure. Eval Health Prof 2019 Feb 11:163278719827997. [doi: 10.1177/0163278719827997] [Medline: 30744419]
56. Mitsutake S, Shibata A, Ishii K, Okazaki K, Oka K. [Developing Japanese version of the eHealth Literacy Scale (eHEALS)]. Nihon Koshu Eisei Zasshi 2011 May;58(5):361-371. [Medline: 21905612]
57. Gazibara T, Cakic J, Cakic M, Pekmezovic T, Grgurevic A. eHealth and adolescents in Serbia: psychometric properties of eHeals questionnaire and contributing factors to better online health literacy. Health Promot Int 2018 May 25;34(4):770-778. [doi: 10.1093/heapro/day028] [Medline: 29800141]

58. Neter E, Brainin E, Baron-Opel O. The dimensionality of health literacy and eHealth literacy. Eur Health Psychol 2015;17(6):275-280.
59. Sudbury-Riley L, FitzPatrick M, Schulz PJ. Exploring the measurement properties of the eHealth Literacy Scale (eHEALS) among baby boomers: a multinational test of measurement invariance. J Med Internet Res 2017 Feb 27;19(2):e53 [FREE Full text] [doi: 10.2196/jmir.5998] [Medline: 28242590]
60. Del Giudice P, Bravo G, Poletto M, De Odorico A, Conte A, Brunelli L, et al. Correlation between ehealth literacy and health literacy using the ehealth literacy scale and real-life experiences in the health sector as a proxy measure of functional health literacy: cross-sectional web-based survey. J Med Internet Res 2018 Oct 31;20(10):e281 [FREE Full text] [doi: 10.2196/jmir.9401] [Medline: 30381283]

Abbreviations

COSMIN: Consensus-Based Standards for the Selection of Health Measurement Instruments
eHealth: electronic health
eHEALS: eHealth Literacy Scale
HLS-EU-Q16: Health Literacy Survey European Questionnaire, 16-item
Sw-eHEALS: Swedish version of eHEALS

Edited by E Borycki, G Eysenbach; submitted 18.09.19; peer-reviewed by T Vreugdenhil, G Pravettoni, E Neter; comments to author 13.11.19; revised version received 03.12.19; accepted 10.12.19; published 24.02.20.

Please cite as:
Wångdahl J, Jaensson M, Dahlberg K, Nilsson U
The Swedish Version of the Electronic Health Literacy Scale: Prospective Psychometric Evaluation Study Including Thresholds Levels
JMIR Mhealth Uhealth 2020;8(2):e16316
URL: https://mhealth.jmir.org/2020/2/e16316
doi:10.2196/16316
PMID:32130168

Original Paper

Accuracy of Vital Signs Measurements by a Smartwatch and a Portable Health Device: Validation Study

Christina Hahnen[1], MSc; Cecilia G Freeman[2], BSc; Nilanjan Haldar[2], BSc; Jacquelyn N Hamati[2], BSc; Dylan M Bard[2], BSc; Vignesh Murali[2], BSc; Geno J Merli[3], MD; Jeffrey I Joseph[4], DO; Noud van Helmond[5], MD

[1]College of Medicine, Radboud University Medical Center, Nijmegen, Netherlands

[2]Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, United States

[3]Department of Surgery and Medicine, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, United States

[4]Department of Anesthesiology, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, United States

[5]Department of Anesthesiology, Cooper Medical School of Rowan University, Cooper University Health Care, Camden, NJ, United States

Corresponding Author:
Noud van Helmond, MD
Department of Anesthesiology
Cooper Medical School of Rowan University
Cooper University Health Care
One Cooper Plaza, 2nd Floor Dorrance, Suite# D206
Camden, NJ, 08103
United States
Phone: 1 8563422000
Email: vanhelmond-noud@cooperhealth.edu

Abstract

Background: New consumer health devices are being developed to easily monitor multiple physiological parameters on a regular basis. Many of these vital sign measurement devices have yet to be formally studied in a clinical setting but have already spread widely throughout the consumer market.

Objective: The aim of this study was to investigate the accuracy and precision of heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and oxygen saturation (SpO_2) measurements of 2 novel all-in-one monitoring devices, the BodiMetrics Performance Monitor and the Everlast smartwatch.

Methods: We enrolled 127 patients (>18 years) from the Thomas Jefferson University Hospital Preadmission Testing Center. SBP and HR were measured by both investigational devices. In addition, the Everlast watch was utilized to measure DBP, and the BodiMetrics Performance Monitor was utilized to measure SpO_2. After 5 min of quiet sitting, four hospital-grade standard and three investigational vital sign measurements were taken, with 60 seconds in between each measurement. The reference vital sign measurements were calculated by determining the average of the two standard measurements that bounded each investigational measurement. Using this method, we determined three comparison pairs for each investigational device in each subject. After excluding data from 42 individuals because of excessive variation in sequential standard measurements per prespecified dropping rules, data from 85 subjects were used for final analysis.

Results: Of 85 participants, 36 (42%) were women, and the mean age was 53 (SD 21) years. The accuracy guidelines were only met for the HR measurements in both devices. SBP measurements deviated 16.9 (SD 13.5) mm Hg and 5.3 (SD 4.7) mm Hg from the reference values for the Everlast and BodiMetrics devices, respectively. The mean absolute difference in DBP measurements for the Everlast smartwatch was 8.3 (SD 6.1) mm Hg. The mean absolute difference between BodiMetrics and reference SpO_2 measurements was 3.02%.

Conclusions: Both devices we investigated met accuracy guidelines for HR measurements, but they failed to meet the predefined accuracy guidelines for other vital sign measurements. Continued sale of consumer physiological monitors without prior validation and approval procedures is a public health concern.

(JMIR Mhealth Uhealth 2020;8(2):e16811) doi:10.2196/16811

KEYWORDS

medical devices; mHealth; vital signs; measurements validity

Introduction

Background

In recent years, advances in technology and the availability of ample venture capital have been combining to produce a growing array of new medical diagnostic devices. New consumer devices are being developed to easily monitor multiple physiological parameters at home or on the go—often connecting with mobile devices to provide user-friendly updates of health status (mobile health). The vision behind these devices is that they will transform conventional medicine into *digital medicine*, facilitating a transition from treating disease to promoting health, from being reactive to being proactive, from being general to being individualized, from offering office-based health care to bringing health care to patients, and from interrupting daily life to being incorporated into it [1].

This vision is appealing, but presently, some of the publicized work in the field of consumer physiological monitoring appears to be characterized by excessive hype [2]. Many of these new technologies have yet to be formally studied in a clinical setting, and there are more than a few examples of digital *snake oil* [2] with substantial societal uptake of devices before their eventual discrediting [3]. This practice appears to be a barrier to truly advancing the field of consumer physiological monitoring.

Smartwatches are one type of consumer device to easily monitor physiological parameters on a regular basis, and more recently, *medical tricorders* have been introduced. A medical tricorder [4] is an all-in-one handheld portable device to be used by consumers to quickly obtain several vital sign measurements to monitor medical conditions.

Objectives

The aim of this study was to assess the accuracy of vital signs measurements by 2 novel all-in-one physiological monitoring devices, a smartwatch, and a medical tricorder.

Methods

Ethical Approval

This study was approved by the Institutional Review Board of Thomas Jefferson University (IRB-nr: 18D.358), and subjects were enrolled between June 27, 2018 and November 9, 2018. Before participation, all subjects provided written informed consent after all procedures and study risks were fully explained.

BodiMetrics Performance Monitor

The BodiMetrics Performance Monitor (BodiMetrics, Manhattan Beach) is a commercially available tricorder that is sold by several major US-based retailers such as Walmart, Amazon, and Costco. Due to its pocket-size (88×56×13 mm), it can easily be carried around for frequent measurement of vital signs. To create a user profile, it requires the input of sex, date of birth, height and weight, and an initial calibration for systolic blood pressure (SBP) obtained with a conventional upper-arm sphygmomanometer. The tricorder provides measurements of SBP, oxygen saturation (SpO_2), and heart rate (HR) via different sensors, and the measurements are displayed on a touch screen. The device uses audio and visual instructions to guide users through a measurement; the right index finger needs to be placed beneath the cap on top, the right thumb on the electrode on the front, and the right middle finger on the electrode on the back of the device (Figure 1). Then, the electrode on the left lateral side needs to be placed in the left palm. To ensure a successful measurement, contact needs to be maintained with all electrodes, while the index finger is inserted under the cap. A measurement takes about 30 seconds to complete. HR is measured through contact with the electrodes, whereas SpO_2 is measured using a plethysmography sensor under the top flap. SBP is measured through the determination of pulse transit time from the electrocardiogram (ECG) and photoplethysmography signals [5]. According to the manufacturer specifications, HR can be measured between 30 to 210 bpm and SpO_2 can be measured between 70% and 100% [6]. The manufacturer does not provide information about the SBP measurement range.

Figure 1. BodiMetrics Performance Monitor tricorder. Vital sign measurements are performed by placing the right index finger on the plethysmography sensor in the right upper corner under the flap. In addition, contact has to be made with the electrocardiogram electrodes at the front, left lateral side, and back using both hands.

Everlast TR10 Smartwatch

The Everlast TR10 smartwatch (Figure 2; Everlast) is a smartwatch that is for sale through several US-based retailers such as Walmart and Amazon. Unlike the BodiMetrics tricorder, the Everlast smartwatch does not require any user specific information or a calibration before use. It provides measurements of SBP, diastolic blood pressure (DBP), and HR. Results are shown on a display, and a button on the side is used to navigate through the different measurements. We were unable to verify the underlying measurement methods with the manufacturer. The back plate of the watch contains contact electrodes and a photoplethysmography sensor, which we presume are utilized for the different physiological measurements.

Figure 2. Everlast smartwatch. To enable a physiological measurement, the watch must be worn on the bare wrist making contact with the skin. Measurements are initiated by pressing the button on the right side of the watch.

Standard Device

We used the validated Cardiocap/5 (Datex-Ohmeda) hospital-grade vital signs monitor for reference measurements [7]. The Cardiocap/5 has a mean blood pressure (BP) measurement range of 25 to 260 mm Hg in adults. It uses a plethysmography sensor to measure SpO_2. HR can be measured using ECG or can be derived from the SpO_2 measurement. The measurement range for peripheral SpO_2 is 40% to 100% and 30 to 250 bpm for HR. The measurement accuracy for SpO_2 between 80% and 100% is ±2% and between 50% and 80% is ±3%. The accuracy for HR is ±5% or ±5 bpm depending on which of the two is greater [8]. The manufacturer does not provide any information about the BP accuracy, but the device does fulfill the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization (ISO) guidelines. This means that its measurements are accurate within 5 mm Hg with a SD of ≤8 mm Hg [9,10]. To confirm the Cardiocap's accuracy in BP measurements, we compared Cardiocap noninvasive BP measurements with intra-arterial BP measurements from a previously published dataset [11]. The average absolute difference between the two methods from six paired BP measurements in 100 subjects (582 total pairs) was 4.3 (SD 6.8) mm Hg for SBP and 4.8 (SD 7.2) mm Hg for DBP measurements. This difference is within the recommended limits for accuracy when comparing the obtained measurements from a noninvasive monitor with intra-arterial measurements [9,10].

For BP measurements, the participant's arm circumference was measured, and the appropriate cuff size was chosen accordingly. The standard adult-size cuff (REF572428) and the large adult-size cuff (REF 572429, both Datex-Ohmeda, Inc) were used for arm circumferences of 25 to 35 cm and 33 to 47 cm, respectively.

Subjects

We recruited study participants, aged more than 18 years, from patients visiting the Thomas Jefferson University Hospital Preadmission Testing Center. Exclusion criteria were as follows: (1) contraindication for automated BP measurement on both arms for reasons including but not limited to a history of breast cancer surgery with radiation therapy or axillary lymph node dissection, arteriovenous fistula for hemodialysis, or an open wound; (2) irregular heart rhythms such as atrial fibrillation and atrial flutter; (3) missing upper extremity, hand, or finger; (4) inability to wear a watch because of wrist circumference or edema of the arm, wrist, or hand; (5) lack of appropriate-sized BP cuff; and (6) pacemaker or other implanted medical device [6].

Testing Procedure

Research staff were trained to measure BP, SpO_2, and HR with the Everlast smartwatch, BodiMetrics tricorder, and Cardiocap/5 according to their manufacturers' guidelines. The investigational devices used in the study were new devices and were acquired through Amazon shortly before the study commenced. We followed a validation protocol derived from the ANSI/AAMI/ISO 2013 standards for evaluating noninvasive automated sphygmomanometers [3,9,10]. Study procedures were explained, and participants were seated in a chair with back support and armrests, with both feet on the floor; subjects were instructed not to cross their legs or speak during the study. After 5 min of rest, the measurement protocol began with an initial standard measurement and a calibration measurement for the BodiMetrics tricorder (Figure 3). After this calibration, sequential measurements were taken, alternating between the reference and the investigational devices, with 60 seconds in between each measurement. This yielded a pattern where two standard measurements bounded each investigational device measurement [9,10]. In total, four standard and three investigational device measurements were obtained per participant. If a measurement with one of the investigational

devices failed, up to two additional attempts were made. Participants were blinded to the standard measurements but not to the investigational measurements as these required the participants' interaction with the devices.

Data and Statistical Analysis

The reference SBP, DBP, HR, and SpO_2 values were all calculated by determining the average of the two standard vital sign measurements that bounded the investigational measurements (Figure 3). This yielded three reference-investigational comparison pairs for the different vital signs for each device. As our protocol was derived from a BP validation protocol, we excluded data from subjects with a variation in standard measurements greater than 12 mm Hg for SBP and 8 mm Hg for DBP, in accordance with validation guidelines [9,10].

For BP measurement validation, the main outcome was the mean (SD) of the absolute difference between the respective investigational devices and the reference values for SBP and DBP [9,10]. The BP measurement results have been presented elsewhere previously [12] and are reported again with permission. BP measurements by the investigational devices were considered accurate if the mean absolute difference was ≤5 mm Hg with a SD of ≤8 mm Hg [9,10]. Accuracy of the BP measurements by the investigational devices was also graded according to the classification from the British Society of Hypertension [13,14].

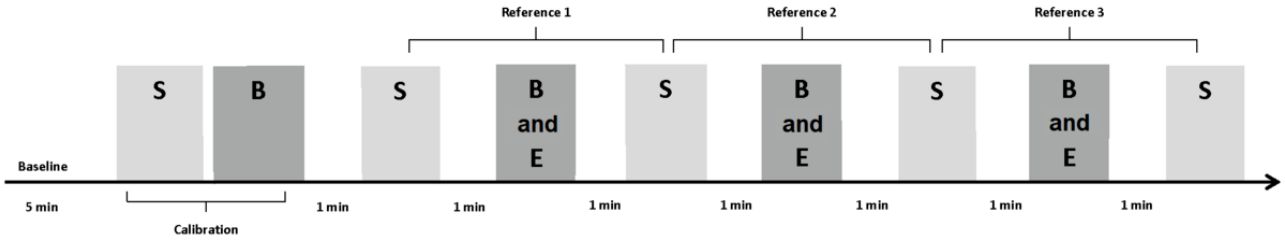
For HR measurement validation, the main outcomes were the mean of the absolute difference between the respective investigational devices and the reference values, and the percent absolute difference between the respective investigational devices and the reference values. HR measurements were considered accurate if the mean absolute difference was within either ±10% or ±5 bpm, depending on which of the two was greater [15].

For SpO_2, the main outcome was the root mean square error (RMSE) between the respective investigational devices and the reference values. SpO_2 measurements were considered accurate if the mean RMSE was ≤3.0% [16].

The main outcome data were visualized using Bland-Altman plots (Sigmaplot, version 14, Systat Software Inc). The dotted line in the Bland-Altman plot represents the mean relative difference (investigational minus reference), and the dashed lines represent ±1.96 SDs for the absolute difference. In addition, correlation analyses and scatterplots were utilized to assess the relation between the respective investigational devices and the reference values. To aid in the interpretation of clinical applicability of these devices, we also assessed the rates at which they successfully detected values for vital signs that were measured outside the normal range by reference values (≥140 mm Hg SBP, ≥90 mm Hg DBP, <60 bpm HR, or <90% for SpO_2). The solid line in the scatterplots represents the line of identity. The dashed lines in the scatterplots for BP, HR, and SpO_2 represent the cutoff for stage 2 hypertension, bradycardia, and hypoxemia, respectively. Normality of values was assessed using the Shapiro-Wilk test. In the case of normally distributed residuals, Pearson correlation analysis was performed, and in the case of non-normally distributed residuals, Spearman correlation analysis was performed. Means are reported with SD for all variables. Nominal variables are reported as n with relative proportion in percentage.

All data files are available from the Data Archiving and Networked Services database [17].

Figure 3. Study timeline. B: BodiMetrics Performance Monitor measurement; E: Everlast smartwatch measurement; S: Standard measurement (light grey color). The dark grey color indicates the investigational devices.



Results

Principal Results

We enrolled a total of 127 subjects, and data from 41 participants were discarded because of excessive variation in sequential standard BP measurements, as specified by the ANSI/AAMI/ISO 2013 standards for evaluating noninvasive automated sphygmomanometers [3,9,10], and from 1 participant because of repeated failure of BodiMetrics calibration; 85 subjects were included in the final analysis. Demographics and characteristics of the study population are displayed in Table 1. These data have previously been presented by Van Helmond et al [12] and are reproduced with permission.

Table 1. Validation study: participant characteristics (n=85).

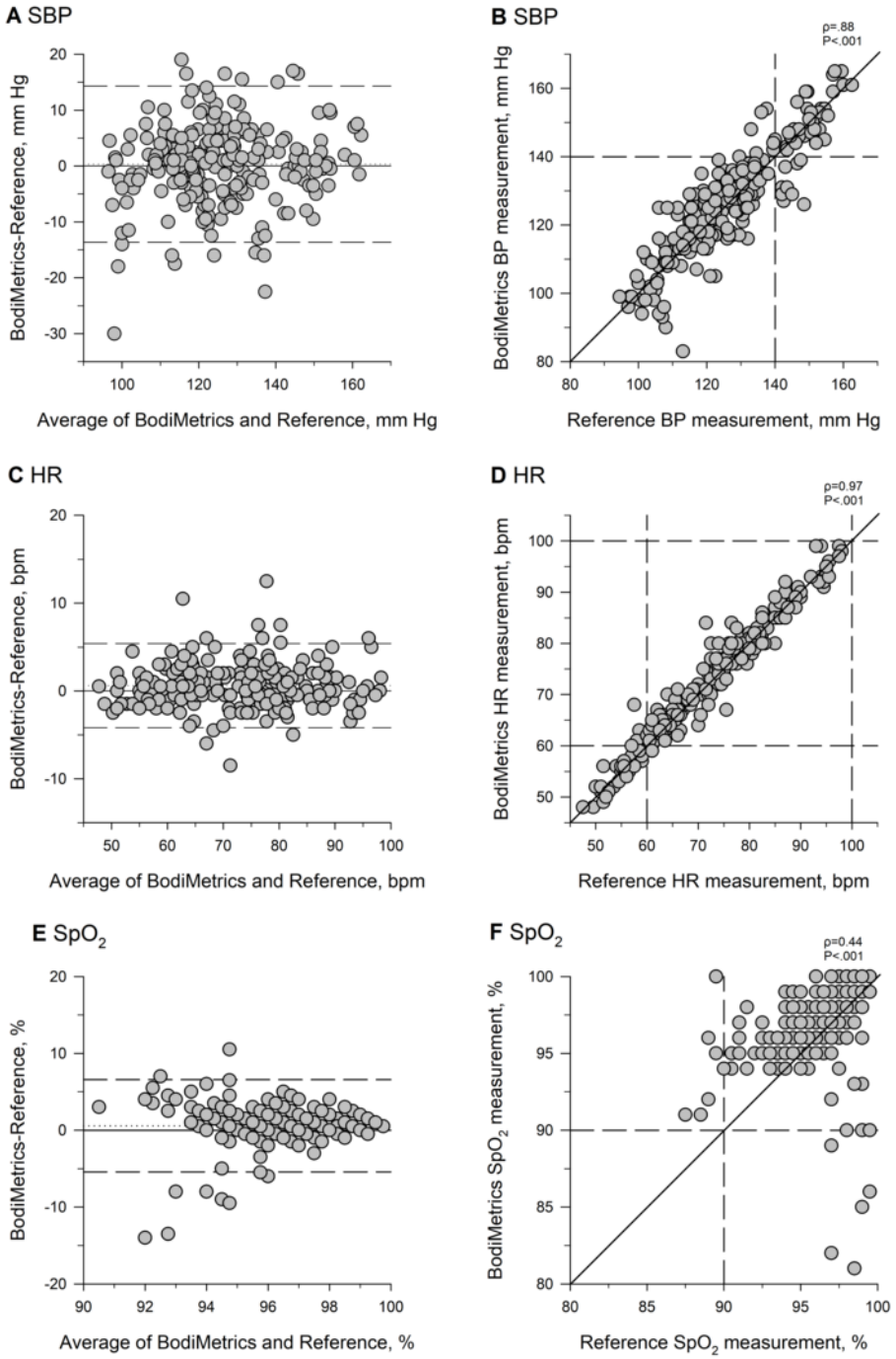
Participant characteristics	Values
Systolic blood pressure at baseline (mm Hg), mean (SD)	125 (15)
Diastolic blood pressure at baseline (mm Hg), mean (SD)	76 (9)
Heart rate at baseline (bpm), mean (SD)	72 (12)
Oxygen saturation at baseline (%), mean (SD)	96 (2)
Age (years), mean (SD)	53 (21)
Body mass index (kg/m^2), mean (SD)	28 (7)
Gender, n (%)	
Male	49 (58)
Female	36 (42)
Ethnicity, n (%)	
White	61 (72)
Black	12 (14)
Asian	6 (7)
Education, n (%)	
High school or General Educational Diploma	28 (33)
College or university degree	38 (45)
Master's degree	6 (7)
Doctorate	5 (6)
Self-reported medical history, n (%)	
Hypertension	32 (38)
Taking medication for hypertension	31 (36)
Diabetes	13 (15)
Taking medication for diabetes	12 (14)
Heart attack	3 (4)
Taking medication for heart attack	3 (4)
Heart failure	2 (2)
Taking medication for heart failure	1 (1)
Peripheral vascular disease	2 (2)
Taking medication for peripheral vascular disease	2 (2)
Stroke	1 (1)
Taking medication for stroke	0 (0)
Smoking	8 (9)

BodiMetrics Performance Monitor

Blood Pressure

The BodiMetrics tricorder failed in 6 (7%) participants for a total of 13 (5%) of the maximum 255 BP measurements that could have been obtained in the 85 participants. The average absolute difference between the BodiMetrics tricorder and the reference was 5.3 (SD 4.7) mm Hg for SBP (Figure 4). The performance monitor, thus, failed to meet the predefined accuracy target for SBP measurements [9,10]. According to the British Society of Hypertension guidelines, the BodiMetrics is a grade-B BP monitor [13,14]. BodiMetrics tricorder measurements correlated well with reference measurements (ρ=0.88; P<.001); the BodiMetrics tricorder measured a hypertensive B*P* value (≥140 mm Hg) for 80% of the hypertensive reference SB*P* values (Figure 4).

Figure 4. Systolic blood pressure (A and B), heart rate (C and D), and oxygen saturation (E and F) measurements by BodiMetrics tricorder and reference values. SBP: systolic blood pressure, HR: heart rate, SpO_2: oxygen saturation.



Heart Rate

The BodiMetrics tricorder failed in 3% (3/85) participants for a total of 3.1% (8/251) HR measurements. The average absolute difference between the BodiMetrics tricorder and the reference values was 1.8 (SD 1.8) bpm (Figure 4). The mean absolute percentage difference was 2.5 (SD 2.5) %. The BodiMetrics tricorder, therefore, met the predefined accuracy cutoff for HR measurements [15]. Correlation analysis revealed a statistically significant, strong correlation (ρ=0.97; *P*<.001; Figure 4) between the BodiMetrics tricorder HR measurements and the reference values. The BodiMetrics tricorder measured a bradycardic HR value (<60 bpm) for 90% of the bradycardic reference HR measurements (Figure 4).

Oxygen Saturation

The BodiMetrics tricorder failed in 4% (4/85) participants for a total of 3.5% (9/257) SpO_2 measurements. The RMSE for SpO_2 between BodiMetrics Performance Monitor measurements and reference values was 3.1% (Figure 4). The BodiMetrics Performance Monitor measurements, thus, failed to meet the predefined accuracy standard [16]. BodiMetrics Performance Monitor SpO_2 measurements were moderately correlated with reference values (ρ=0.44; *P*<.001; Figure 4). The BodiMetrics tricorder measured no hypoxic SpO_2 values (<90%) for any of the hypoxic reference SpO_2 measurements (Figure 4).

Everlast TR10 Smartwatch

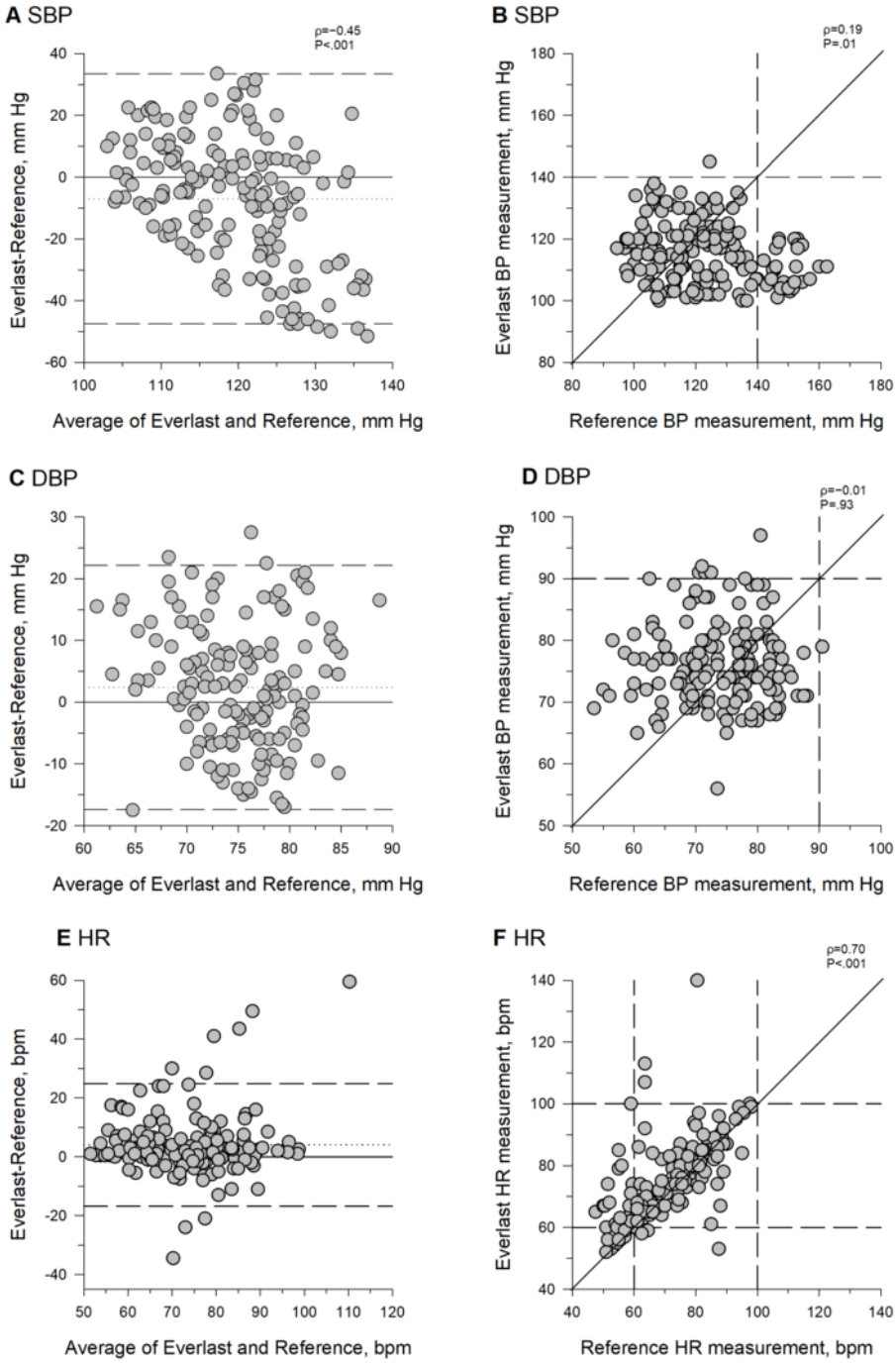
Blood Pressure

The Everlast watch failed in 38% (33/85) participants for a total of 34.1% (87/255) BP measurements. The average absolute differences between the Everlast watch and reference were 16.9 (SD 13.5) mm Hg for SBP and 8.3 (SD 6.1) mm Hg for DBP (Figure 5). The watch's performance, thus, failed to meet the predefined accuracy guideline for SBP and DBP measurements and is considered a grade-D monitor for SBP and DBP measurements according to the British Society of Hypertension guidelines [9,13,14]. The difference between the Everlast watch and reference measurement was dependent on the SB*P* value, such that lower SBPs were estimated higher and higher SBPs were estimated lower (ρ=−0.45; *P*<.001; Figure 5). Everlast BP measurements were not correlated with reference BP measurements, and the Everlast watch failed to measure any hypertensive B*P* values for any of the hypertensive reference SBP or DBP measurements (Figure 5).

Heart Rate

The Everlast watch failed in 36% (31/85) participants for a total of 31.8% (81/255) HR measurements. The average absolute difference between the Everlast watch and the reference was 6.5 (SD 9.2) bpm (Figure 5). The mean absolute percentage difference was 9.9 (SD 14.3) %. The Everlast watch, therefore, met the predefined accuracy guidelines [15]. Correlation analysis revealed a significant moderate correlation (ρ=0.7; *P*<.001) between the Everlast watch HR measurements and the reference values (Figure 5). The Everlast smartwatch measured a bradycardic HR value (<60 bpm) for 33% of the bradycardic reference HR measurements (Figure 5).

Figure 5. Systolic blood pressure (A and B), diastolic blood pressure (C and D), and heart rate (E and F) measurements by Everlast smartwatch and reference values. BP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate.



Discussion

Principal Findings

The aim of this study was to assess the accuracy of vital sign measurements by 2 novel, all-in-one physiological monitoring devices, a smartwatch, and a medical tricorder. We found that the accuracy guidelines for HR measurements were met by both investigational devices. However, neither device met the accuracy guidelines for BP measurements. The SpO_2 measurements by the BodiMetrics also did not meet the accuracy guidelines for transmissive pulse oximetry. The absolute or relative differences from the reference measurements were very large for the Everlast watch, whereas the BodiMetrics' measurements were closer to meeting the predefined standards.

The results of our study indicate that the Everlast smartwatch is not accurate enough to be used to monitor vital signs. For the

BP measurements, the Everlast smartwatch did not correctly measure any (0%) of the hypertensive values for the values that were hypertensive when measured with the standard cuff. Although the watch met our predefined accuracy standard for HR, it detected only 33% of the bradycardic HR values that were measured by the standard monitor. In addition to the accuracy problems, the watch failed to obtain any measurement at all for 32% of HR and 34% of SBP and DBP measurements.

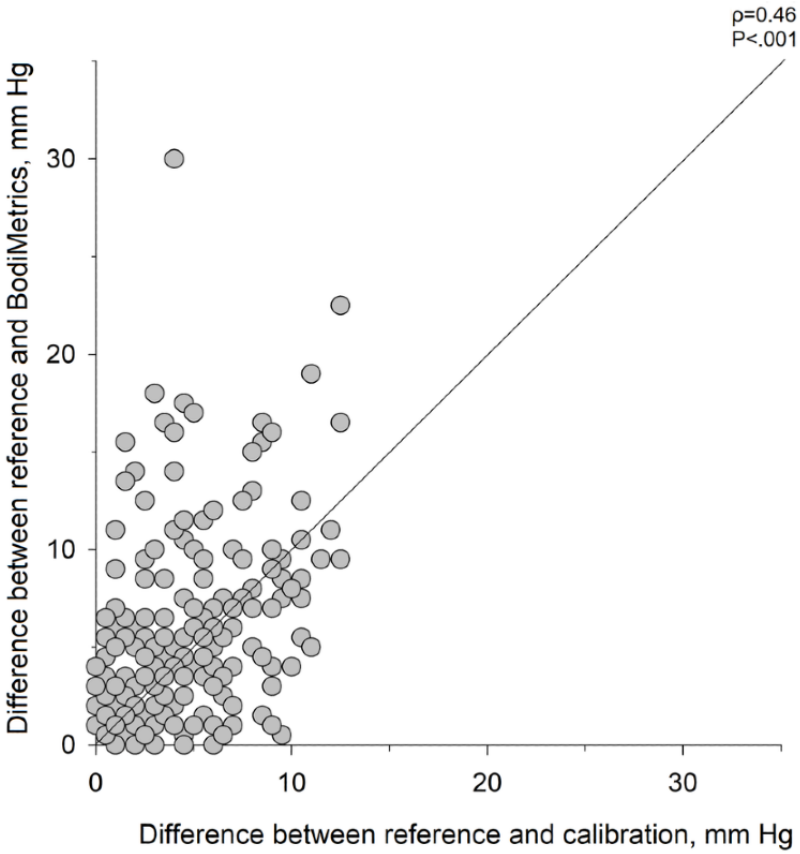
We are not aware of any prior studies on the Everlast smartwatch to compare the findings of this study with, but we found 3 studies by a Dutch research group on the BodiMetrics Performance Monitor, which is marketed in Europe under the name Checkme [5,18,19]. A study by Schoot et al [5] compared the SBP measurements obtained with the BodiMetrics Performance Monitor with the SBP measurements obtained by a reference automated cuff in 37 outpatients in supine position and sitting position and found average absolute differences of approximately 6.7 (SD 5.4) mm Hg in supine position and approximately 10.1 (SD 7.0) mm Hg in sitting position. The average absolute difference they found is somewhat larger than the difference we found in this study (5.3 [SD 4.7] mm Hg). An underlying reason for this difference may be that the bias calculation in their study did not average the two standard measurements that bounded each investigational measurement, and that naturally occurring drift in BP, thus, may have exaggerated the detected difference [9]. They also did not exclude any subjects based on drift in standard measurements, as we did per the ANSI/AAMI/ISO BP monitor validation protocol [9]. In a subsequent study by Weenk et al [18], the same group compared all vital signs measured by the BodiMetrics with a standard hospital-grade monitor in 41 Internal Medicine inpatients. They found an average absolute difference of 10.7 (SD 11.0) mm Hg between BodiMetrics SBP measurements and the reference. For HR, the average absolute difference was 2.9 (SD 2.9) bpm, and for SpO_2, the RMSE was 4.2% [18]. These BodiMetrics-to-reference differences are substantially greater than the difference we encountered and are potentially because of a smaller dataset of 69 data pairs per vital sign compared with our 242 BP, 246 SpO_2, and 247 HR data pairs. There were also differences in the measurement protocol between the Weenk et al's study [18] and this study. They obtained data from inpatients in supine position, whereas our subjects were seated outpatients. Moreover, we averaged bounding standard measurements to reduce the influence of drift, whereas Weenk et al [18] did not. Another difference is that they performed calibration of the BodiMetrics once in the morning and then collected data on three different time points during the day, whereas our measurements were taken in the approximately 20 to 30 min following calibration [18]. The subject's BP may have changed significantly from the value at which the BodiMetrics was calibrated in their study, which might have affected the accuracy of the measurements. In contrast, the BP during our protocol was likely similar to the calibration value [20]. In a third study from the same group, Ogink et al [19] compared BodiMetrics SBP measurements with SBP measurements obtained at home by 11 patients with hypertension using various home automated BP monitors over 3 weeks. BodiMetrics SBP measurements were found to be weakly correlated to cuff SBP measurements, and there was a large absolute difference between the two measurements (eg, 44% of measurements differed by >10 mm Hg). Although the accuracy of the BodiMetrics is difficult to assess from this study, considering there was no standardized monitor or measurement protocol, the reported low accuracy appears to indicate that the BodiMetrics SBP measurement becomes significantly more inaccurate when some time passes since calibration.

To address concerns related to BP calibration dependency, an alternative validation protocol specific to cuff-less monitors has been suggested by the Institute of Electrical and Electronics Engineers (IEEE). This validation protocol requires the same accuracy as the ANSI/AAMI/ISO standard for cuff-based devices, but it differs from the ANSI/AAMI/ISO protocol, in that it includes validation measurements after artificial changes in BP are induced after initial calibration to ensure accuracy over a wide range of B*P* values. In addition, the IEEE protocol includes validation measurements obtained after a significant period (weeks to months) since the initial calibration to investigate time-dependent calibration integrity [20]. We did not induce different BPs or investigate time-dependent changes in accuracy in this study.

To assess whether the BodiMetrics accuracy may be affected by changes in BP from the calibration value, we performed a posthoc analysis on the difference between the reference values and the BodiMetrics SBP measurements versus the difference in the reference values and the calibration value (Figure 6). We found a significant moderate correlation between these two absolute differences, indicating that the accuracy of the BodiMetrics tricorder incrementally decreases when it is used at incrementally different pressures from the calibration value. These findings would need to be confirmed in a prospective manner while consciously changing BP in study subjects to warrant any definitive conclusions. On the basis of our findings, we conclude that the current calibration process demonstrates a limitation of the BodiMetrics tricorder that should be further examined.

With regard to the initial calibration of the BodiMetrics, Weenk et al [18] reported that in 18% of the participants the calibration procedure failed and that the main reasons for failed calibration were shivering and cold hands. In the study conducted by Schoot et al [5], 12 of the 52 (23%) volunteers were excluded because of repeated calibration failure. We started our study during the hot summer months and only recognized a correlation between calibration issues and cold hands in 1 participant who was tested in late October. Overall, our calibration failure rate was lower than that reported by Weenk et al [18] who conducted their study between March and May [18]. As reported in the BodiMetrics' users guide, dry and cold hands can influence the connectivity between hands and electrodes [5]. The conductivity is also affected by a thick stratum corneum [21]. The study by Weenk et al [18] found no correlation between patient gender, age, or weight and failure of calibration. As we only observed a failure in calibration at first or second attempt in 4.7% of attempts, we were not able to study any of these relationships.

Figure 6. Difference between BodiMetrics tricorder systolic blood pressure measurements and calibration measurement versus difference between reference systolic blood pressure measurements and calibration measurement. The solid line in the scatterplot represents the line of identity. Data shown were not normally distributed (Shapiro-Wilk test).



Practical Implications and Future Directions

Use of devices such as the Everlast smartwatch may result in individuals incorrectly assuming that they are, for example, normotensive or hypertensive. This might delay diagnosis or result in incorrect medication self-adjustments. The BodiMetrics tricorder's accuracy for SBP and HR was considerably better than the accuracy of the Everlast smartwatch in this study. However, the BodiMetrics tricorder did not meet the predefined accuracy standards for SBP and SpO_2 measurements. The BodiMetrics tricorder has approval for measurements of SpO_2 and HR from the US Food and Drug Administration, but not for measurement of SBP [22]. The results of this study suggest that it is doubtful that the tricorder should be used for SBP or SpO_2 measurements. Proper validation of consumer vital sign monitors before commercial release would aid in avoiding the potential serious repercussions of inaccurate vital sign measurements.

Limitations

A limitation that pertains to this study is that we modified the BP monitor validation protocol that our study was based on by using an automated hospital vital signs monitor instead of a mercury sphygmomanometer [14] and auscultation. We made this adjustment to accommodate the assessment of different vital signs in one protocol and this adjustment is based on the precedent that other groups have set by following a similar approach [3,5,18,19]. In the near feature, we aim to conduct a study on cuff-less BP monitors using a mercury sphygmomanometer as a reference.

Another area of interest for future studies is the accuracy and precision of consumer vital sign monitors in real-world settings by individuals in their home environment, as that is where these devices are ultimately being used [19]. Such studies could also address whether issues related to maintenance, servicing, and wear and tear of devices adversely affect performance.

Conclusions

The Everlast TR10 smartwatch is not accurate enough to be used as a vital sign's measurement device. The BodiMetrics device was substantially more accurate, but it still failed to meet predefined accuracy guidelines for SBP and SpO_2. The continued sale of consumer physiological monitor devices without the required prior validation and market approval procedures is a significant public health concern.

Acknowledgments

The authors received no specific funding for this work.

Authors' Contributions

NVH, JJ, and GM were responsible for the conceptualization of this manuscript. CF, NVH, JH, DB, VM, CH, and NH were responsible for data curation of this project. CH and NVH were responsible for formal data analysis for this manuscript. NVH, JJ, CF, NH, JH, DB, VM, CH, and GM were responsible for study execution and data collection. NVH, JJ, and GM were responsible for project administration. GM and JJ were responsible for the resources. NVH, JJ, and GM supervised the project. CH and NvH were responsible for the visualization of data. CH, NvH, and CF were responsible for writing the original draft. CH, NVH, CF, NH, JH, DB, VM, GM, and JJ were responsible for writing, review, and editing of this document

Conflicts of Interest

JIJ is a founder and equity owner and has received research support from RTM Vital Signs LLC, a company developing a noninvasive and long-term implantable vital sign monitoring system with real-time diagnostic algorithms and that can transfer data via cell phone to a central monitoring system. JIJ and NVH have pending patent applications related to vital sign measurement. The other authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript.

References

1. Torkamani A, Andersen KG, Steinhubl SR, Topol EJ. High-definition medicine. Cell 2017 Aug 24;170(5):828-843 [FREE Full text] [doi: 10.1016/j.cell.2017.08.007] [Medline: 28841416]
2. Klasko SK, Chen AF. Digital 'Snake Oil' or the future of healthcare? Healthc Transform 2016;1(4):234-239. [doi: 10.1089/heat.2016.29032.dso]
3. Plante TB, Urrea B, MacFarlane ZT, Blumenthal RS, Miller ER, Appel LJ, et al. Validation of the instant blood pressure smartphone app. JAMA Intern Med 2016 May 1;176(5):700-702 [FREE Full text] [doi: 10.1001/jamainternmed.2016.0157] [Medline: 26938174]
4. Roddenbery G. Goodreads. Star Trek: The Original Series URL: https://www.goodreads.com/series/40416-star-trek-the-original-series [accessed 2020-01-13]
5. Datex-Ohmeda, Inc. Biomedical Manuals. Madison, WI, USA: General Electric Company; 2007 May 09. Datex-Ohmeda Cardiocap™/5: Technical Reference Manual URL: https://biomedicalmanuals.com/wp-content/uploads/2019/03/CardioCap-5.pdf
6. BodiMetrics. 2016. Products - BodiMetrics Performance Monitor URL: https://bodimetrics.com/product/bodimetrics-performance-monitor/ [accessed 2020-01-08]
7. US Food & Drug Administration. Food and Drug Administration. 2001. Premarket notification 510(k) Datex Ohmeda Cardiocap 5 (Rev B) and accessories URL: https://onlinelibrary.wiley.com/doi/pdf/10.1002/9780471462422.eoct546
8. Pacagnella RC, Souza JP, Durocher J, Perel P, Blum J, Winikoff B, et al. A systematic review of the relationship between blood loss and clinical signs. PLoS One 2013;8(3):e57594 [FREE Full text] [doi: 10.1371/journal.pone.0057594] [Medline: 23483915]
9. Graves J, Quinn D. Non-Invasive Sphygmomanometers — Part 2: Clinical Investigation of Automated Measurement Type. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013.
10. Stergiou GS, Alpert BS, Mieke S, Wang J, O'Brien E. Validation protocols for blood pressure measuring devices in the 21st century. J Clin Hypertens (Greenwich) 2018 Jul;20(7):1096-1099 [FREE Full text] [doi: 10.1111/jch.13294] [Medline: 30003697]
11. Sheshadri V, Tiwari AK, Nagappa M, Venkatraghavan L. Accuracy in blood pressure monitoring: the effect of noninvasive blood pressure cuff inflation on intra-arterial blood pressure values. Anesth Essays Res 2017;11(1):169-173 [FREE Full text] [doi: 10.4103/0259-1162.181430] [Medline: 28298779]
12. van Helmond N, Freeman CG, Hahnen C, Haldar N, Hamati JN, Bard DM, et al. The accuracy of blood pressure measurement by a smartwatch and a portable health device. Hosp Pract (1995) 2019 Oct;47(4):211-215. [doi: 10.1080/21548331.2019.1656991] [Medline: 31423912]
13. O'Brien E, Waeber B, Parati G, Staessen J, Myers MG. Blood pressure measuring devices: recommendations of the European Society of Hypertension. BMJ 2001 Mar 03;322(7285):531-536 [FREE Full text] [doi: 10.1136/bmj.322.7285.531] [Medline: 11230071]
14. O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, Altman DG, et al. An outline of the revised British Hypertension Society protocol for the evaluation of blood pressure measuring devices. J Hypertens 1993 Jun;11(6):677-679. [doi: 10.1097/00004872-199306000-00013] [Medline: 8397248]
15. ANSI/AAMI. Cardiac Monitors, Heart Rate Meters, and Alarms. Arlington: American National Standards Institute Inc; 2002.

16. Center for Devices and Radiological Health. Food and Drug Administration. 2013. Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff URL: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug [accessed 2020-01-13]
17. van Helmond N. DANS easy - KNAW (Data Archiving and Networked Services). 2019. Validation study of two new commercial vital sign measurement devices URL: https://easy.dans.knaw.nl/ui/datasets/id/easy-dataset:133082 [accessed 2020-01-13]
18. Weenk M, van Goor H, van Acht M, Engelen LJ, van de Belt TH, Bredie SJ. A smart all-in-one device to measure vital signs in admitted patients. PLoS One 2018;13(2):e0190138 [FREE Full text] [doi: 10.1371/journal.pone.0190138] [Medline: 29432461]
19. Ogink PA, de Jong JM, Koeneman M, Weenk M, Engelen LJ, van Goor H, et al. Feasibility of a new cuffless device for ambulatory blood pressure measurement in patients with hypertension: mixed methods study. J Med Internet Res 2019 Jun 19;21(6):e11164 [FREE Full text] [doi: 10.2196/11164] [Medline: 31219050]
20. IEEE. Engineering in Medicine and Biology Society - IEEE Standard for Wearable, Cuffless, Blood Pressure Measuring Devices. New York: The Institue of Electrical and Electronis Engineers Inc; 2014.
21. BodiMetrics. 2016. Support & FAQ URL: http://bodimetrics.com/contact/support [accessed 2020-01-08]
22. US Food & Drug Administration. 2015. Premarket Notification 510(k) Summary Checkme Pro Health Monitor URL: https://www.accessdata.fda.gov/cdrh_docs/pdf15/K150869.pdf [accessed 2020-01-13]

Abbreviations

AAMI: Association for the Advancement of Medical Instrumentation
ANSI: American National Standards Institute
BP: blood pressure
DBP: diastolic blood pressure
ECG: electrocardiogram
HR: heart rate
IEEE: Institute of Electrical and Electronics Engineers
ISO: International Organization for Standardization
RMSE: root mean square error
SBP: systolic blood pressure
SpO_2: oxygen saturation

Edited by G Eysenbach; submitted 27.10.19; peer-reviewed by J Carter, A Ramachandran; comments to author 16.11.19; revised version received 18.11.19; accepted 15.12.19; published 12.02.20.

Please cite as:
Hahnen C, Freeman CG, Haldar N, Hamati JN, Bard DM, Murali V, Merli GJ, Joseph JI, van Helmond N
Accuracy of Vital Signs Measurements by a Smartwatch and a Portable Health Device: Validation Study
JMIR Mhealth Uhealth 2020;8(2):e16811
URL: https://mhealth.jmir.org/2020/2/e16811
doi:10.2196/16811
PMID:32049066

Original Paper

A Mobile Phone–Based Support Intervention to Increase Use of Postabortion Family Planning in Cambodia: Cost-Effectiveness Evaluation

Jeremy Hill[1], BA, MSc, MBBS; Jourdan McGinn[2], MSc; John Cairns[2], MPhil; Caroline Free[3], PhD; Chris Smith[4,5], PhD

[1]Department of Global Health and Development, London School of Hygiene and Tropical Medicine, London, United Kingdom
[2]Department of Health Services Research and Policy, London School of Hygiene and Tropical Medicine, London, United Kingdom
[3]Department of Population Health, London School of Hygiene and Tropical Medicine, London, United Kingdom
[4]Graduate School of Tropical Medicine and Global Health, Nagasaki University, Nagasaki-shi, Japan
[5]Department of Clinical Research, London School of Tropical Medicine, London, United Kingdom

Corresponding Author:
Chris Smith, PhD
Graduate School of Tropical Medicine and Global Health
Nagasaki University
1-12-4, Sakamoto
Nagasaki-shi, 852-8523
Japan
Phone: 81 8087105309
Email: christopher.smith@lshtm.ac.uk

Abstract

Background: Despite progress over the last decade, there is a continuing unmet need for contraception in Cambodia. Interventions delivered by mobile phone could help increase uptake and continuation of contraception, particularly among hard-to-reach populations, by providing interactive personalized support inexpensively wherever the person is located and whenever needed.

Objective: The objective of this study was to evaluate the cost-effectiveness of mobile phone–based support added to standard postabortion family planning care in Cambodia, according to the results of the MOTIF (MObile Technology for Improved Family planning) trial.

Methods: A model was created to estimate the costs and effects of the intervention versus standard care. We adopted a societal perspective when estimating costs, including direct and indirect costs for users. The incremental cost-effectiveness ratio was calculated for the base case, as well as a deterministic and probabilistic sensitivity analysis, which we compared against a range of likely cost-effectiveness thresholds.

Results: The incremental cost of mobile phone–based support was estimated to be an additional US $8160.49 per 1000 clients, leading to an estimated 518 couple-years of protection (CYPs) gained per 1000 clients and 99 disability-adjusted life-years (DALYs) averted. The incremental cost-effectiveness ratio was US $15.75 per additional CYP and US $82.57 per DALY averted. The model was most sensitive to personnel and mobile service costs. Assuming a range of cost-effectiveness thresholds from US $58 to US $176 for Cambodia, the probability of the intervention being cost-effective ranged from 11% to 95%.

Conclusions: This study demonstrates that the cost-effectiveness of the intervention delivered by mobile phone assessed in the MOTIF trial lies within the estimated range of the cost-effectiveness threshold for Cambodia. When assessing value in interventions to improve the uptake and adherence of family planning services, the use of interactive mobile phone messaging and counselling for women who have had an abortion should be considered as an option by policy makers.

Trial Registration: ClinicalTrials.gov NCT01823861; https://clinicaltrials.gov/ct2/show/NCT01823861

(JMIR Mhealth Uhealth 2020;8(2):e16276) doi:10.2196/16276

KEYWORDS

mHealth; digital health; cost-effectiveness; contraception; postabortion contraception; postabortion family planning; Cambodia

Introduction

Contraception provides significant benefits for the health of women and children, as well as substantial social and economic benefits [1]. An estimated 225 million women in developing countries had an unmet need for contraception in 2014, and if the need were met, it could avert 52 million unintended pregnancies, 24 million abortions (of which around half are unsafe), 70,000 maternal deaths, and 500,000 newborn deaths per year [2].

In Cambodia, over the last decade, progress has been made in reducing an unmet need for contraception. This has coincided with a reduction in maternal, infant, and under-5 mortality [3]. Nonetheless, there is a continued unmet need for contraception in Cambodia. The 2014 Cambodia Demographic and Health Survey reported that among married women aged 15-49 years who wanted to delay a pregnancy by more than 2 years or have no further children, only 56% were using contraception [3]. There has been a rise in the rate of induced abortions from 21 per 1000 women in 2005 to 28 in 2010, with 26% of women having more than one abortion [4].

Interventions delivered by mobile phone could help increase uptake and continuation of contraception, particularly among hard-to-reach populations [5-9]. Compared with face-to-face interventions, mobile phone–based interventions have the advantage that they can provide interactive personalized support inexpensively wherever the person is located and whenever needed [10]. The use of this technology could be of value to women who have had an abortion, as they may face stigma when seeking services or may find it difficult to make informed decisions about family planning at the time of their abortion.

The MOTIF (MObile Technology for Improved Family planning) trial evaluated an intervention delivered by mobile phone to provide postabortion family planning support to women who received safe abortion at Marie Stopes International Cambodia (MSIC) clinics [11]. This trial compared usage of different family planning services during a period of 12 months after abortion among women who were provided with family planning advice via their mobile phones (six automated interactive voice messages over 3 months with a facilitated link to counsellor phone support via a call center and appointment booking if requested) in addition to standard postabortion family planning care provided in accordance with national guidelines, with usage of family planning services among women receiving standard care alone.

The MOTIF intervention was effective at increasing uptake of long-acting reversible contraceptive methods (subdermal implant and intrauterine device [IUD]), which are associated with lower discontinuation rates compared with those of short-acting hormonal methods [12-14]. Long-acting methods are more cost-effective in comparison with short-term methods [15,16], but little evidence exists on the cost-effectiveness of behavior change interventions aimed at improving the uptake of these methods. We aimed to conduct a cost-effectiveness analysis of the MOTIF trial intervention to address this evidence gap.

Methods

Rationale and assumptions

We conducted a cost-effectiveness evaluation comparing a mobile phone–based intervention in addition to standard postabortion family planning care with standard care alone, using the results of the MOTIF trial. The methods and results of this trial have been previously published [11,14]. In short, standard care included counselling at the clinic, offer of follow-up appointment, and provision of the contact details of an MSIC counselling hotline. Those allocated to the intervention also received six automated interactive voice messages and were provided with phone support from a counsellor depending on their responses to the messages, and optional additional reminder messages were provided to those women who chose to receive oral or injectable contraceptives (a detailed description is provided in Multimedia Appendix 1). The conceptual framework for the cost-effectiveness evaluation is shown in Figure 1. Because postabortion family planning care is delivered over a limited period of time after induced abortion for each individual but the effects of long-acting contraceptive methods may be accrued over the lifespan of the product without further costs being incurred, we chose to model the activities required to deliver postabortion family planning care to a cohort of women along with overhead costs for 1 year only. The time horizon for effects was 10 years, according to the parameters of the Impact2 model as described below.

Figure 1. Conceptual framework for the service provision model based on the MOTIF trial. Inputs from the MOTIF trial are shown in green. Models used to derive costs and effects are shown in yellow. IUD: intrauterine device; MOTIF: MObile Technology for Improved Family planning; OCP: oral contraceptive pill.

Service Provision Model

We constructed a model to simulate total contraceptive and abortion services obtained for a single cohort of 1000 women after abortion in the intervention and control arms, using Excel 2016 (Microsoft Corp, Redmond, Washington). This design was chosen to link the empirical service usage data from the MOTIF trial (monthly services per user) to the Impact2 model (annual services per 1000 users). No discounting was applied to costs, because these were modelled to occur during 1 year.

Monthly service provision parameters were taken from 66% (328/500) of participants remaining in the study at the end of the 12-month follow-up period. Previously published MOTIF findings showed that missing data had a negligible effect on the contraceptive method mix at 12 months [17]. Moreover, some participants in the MOTIF trial used more than one type of contraceptive service (owing to discontinuation or switching). The use of 12-month follow-up parameters allowed us to more accurately reflect this in the overall service provision rates for the simulated cohort of 1000 women in each arm. Model parameters are presented in Table 1. Effects were calculated using contraceptive service parameters only, whereas costs were calculated using both contraceptive service and abortion service parameters. Contraceptive service provision rates and confidence intervals were derived from monthly MOTIF trial data.

Table 1. Service provision model parameters.

	Base	Deterministic range (95% CI)	Probabilistic distribution
Intervention arm and parameters			
Contraception services[a]			
Oral contraceptive pill	2172	2013-2330	Lognormal
Injectable	558	512-604	Lognormal
Implant	172	123-220	Lognormal
IUD[b]	112	72-153	Lognormal
Abortion services[a]			
Repeat abortion	47	21-91	Beta
Control arm parameters			
Contraception services[a]			
Oral contraceptive pill	3308	3112-3499	Lognormal
Injectable	325	291-358	Lognormal
Implant	75	42-109	Lognormal
IUD	63	32-93	Lognormal
Abortion services[a]			
Repeat abortion	69	35-120	Beta

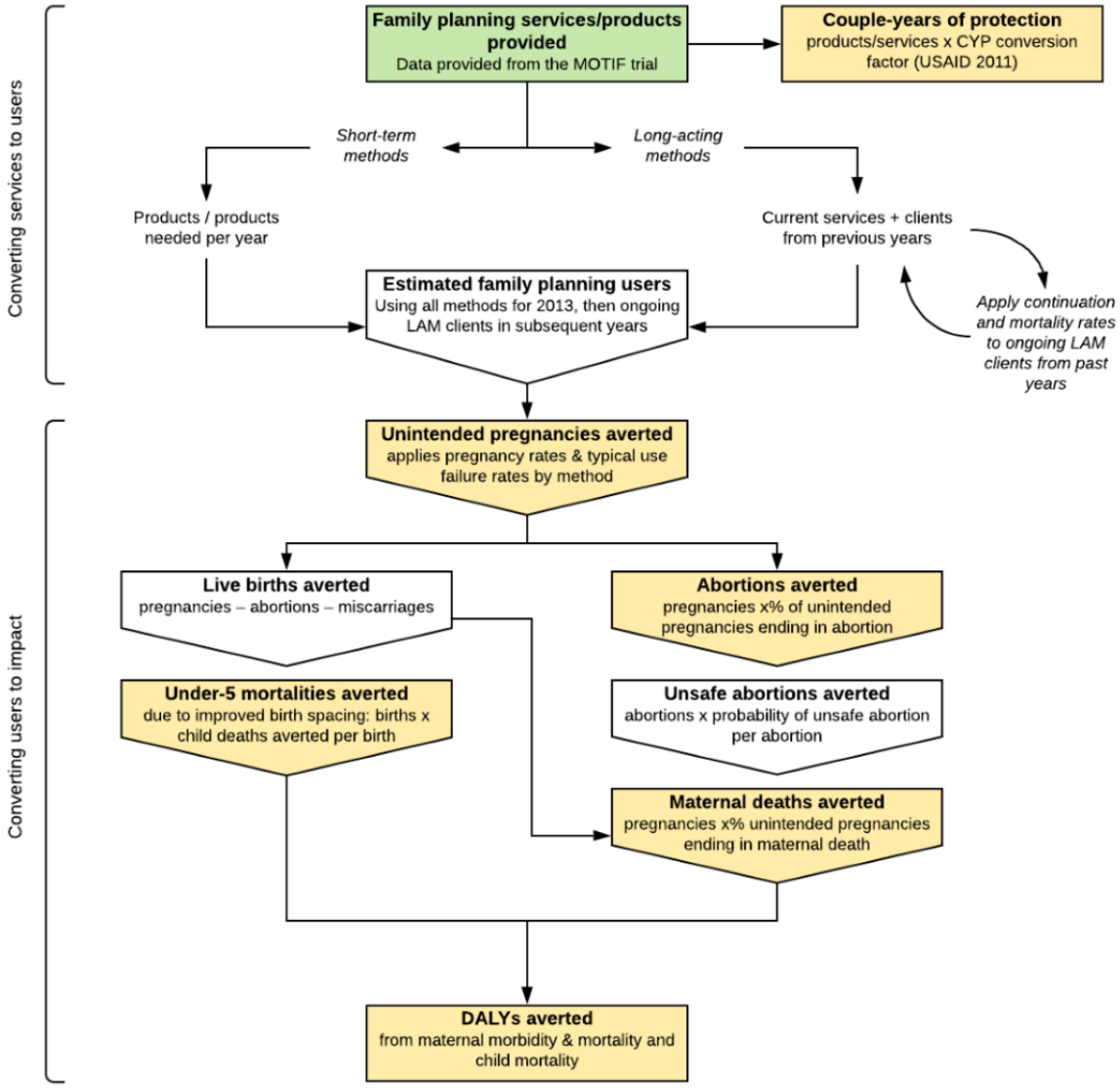
[a]Per 1000 participants per year.

[b]IUD: intrauterine device.

Effects

Effects were estimated using the Marie Stopes Impact2 (version 4) modelling tool (illustrated in Figure 2) using the default settings in "organization" mode for Cambodia in 2013. This tool uses user-provided rates of contraceptive use, which we derived from the service provision model, to estimate effects such as disability-adjusted life-years (DALYs, calculated using 2010 Global Burden of Disease estimates [18]) averted and couple-years of protection (CYPs), taking account of effective usage, discontinuation, and failure rates and wastage for each contraceptive method, as well as country-specific rates for unintended pregnancies, induced abortions, maternal mortality, and under-5 mortality. Consistent with the Global Burden of Disease Methodology [18], no discounting of effects was applied and age weighting was uniform. Hutterite fertility rates account for the age structure of the population, which we adjusted in the model to reflect the MOTIF sample population. Discounting of fertility over the time horizon was also applied according to Hutterite rates. Effects were calculated to include the service lifespan of each contraceptive method (in the Impact2 model, we selected 10 years for IUDs and four years for implants). The Impact2 model includes assumptions based on published research. Of relevance to this study, 31% of pregnancies worldwide are unintended, and in Asia, 57% of unintended pregnancies end in abortion [2,19]. The full methodology and assumptions of the Impact2 model are described elsewhere [20,21].

Figure 2. Marie Stopes International Impact2 model framework. Inputs, outputs, and processes used in the Impact2 model are illustrated, as they apply to this study. Green: inputs to the model from the MOTIF trial. Yellow: effects reported in this study. Adapted from Weinberger et al [21]. CYPs: couple-years of protection; DALYs: disability-adjusted life-years; LAM: long-acting method; MOTIF: MObile Technology for Improved Family planning.



Costs

The base case analysis was performed from a societal perspective. Costs were collected in 2014 in US dollars (commonly used in Cambodia) and were expressed in constant 2011 purchasing power parity-adjusted US dollars.

For MSIC clinics, provider costs included medical consumables, personnel, and estimates of the time taken to provide each service. To account for overheads, 20% was added to personnel costs. For non-MSIC clinics, costs for personnel and overheads were not available, and commodity costs were assumed to be the same as those at MSIC clinics. Costs attributable to the intervention included airtime to deliver the mobile phone–based intervention and a proportion of fixed costs (computers and phones). MSIC personnel costs for training and delivery of the intervention were estimated from hourly wages and time spent on the intervention.

User costs included direct medical costs (service fees), direct nonmedical costs, and indirect costs of attending postabortion family planning services for the proportion of women who attended a separate appointment after their initial abortion. The average home-clinic round trip distance was multiplied by the per kilometer average price of motorcycle transport to obtain transport costs. If the client visited a different clinic, the estimated distance was reduced by one-third. Indirect costs to users were attributed to all women irrespective of formal employment status [22]. The time required for users to access each service was the sum of clinical time (reported by MSIC staff) and estimated travel time. Indirect costs attributable to repeat abortions were also included. In Cambodia, injectable and oral contraceptives are widely available at pharmacies, and therefore, costs were assumed to be negligible for clients obtaining these products from non-MSIC clinics. Unit costs and their sources are reported in Table 2 [22-24].

Table 2. Unit costs.

	Base	Deterministic range[a]	Probabilistic distribution	Comment/source
Provider costs[b]				
MOTIF[c] intervention costs (per participant)				
Airtime: voice messages	0.79	0.39-1.18	Gamma	Actual costs from the MOTIF study
Airtime: outgoing phone calls	2.16	1.08-3.25	Gamma	Actual costs from the MOTIF study
Computer	1.34	0.67-2.01	Gamma	Actual costs from the MOTIF study
Phone	0.2	0.1-0.3	Gamma	Actual costs from the MOTIF study
Family planning service commodities				
Oral contraceptive pill (one cycle)	0.29	0.15-0.44	Gamma	Direct cost reported by an MSIC[e] clinic
IUD[d]	0.4	0.2-0.6	Gamma	Direct cost reported by an MSIC clinic
Medical abortion (Mariprist)	0.7	0.35-1.05	Gamma	Direct cost reported by an MSIC clinic
Surgical abortion	5	2.5-7.5	Gamma	Personal communication with MOTIF trial authors
Injectable contraceptive (one dose)	0.5	0.25-0.75	Gamma	Direct cost reported by an MSIC clinic
Implanted subdermal contraceptive (Femplant)	8	4-12	Gamma	Direct cost reported by an MSIC clinic
Long-acting contraceptive device removal	3	1.5-4.5	Gamma	Personal communication with MOTIF trial authors
Personnel (hourly)				
Midwife/health care service provider	2.36	1.18-3.54	Gamma	Direct cost reported by an MSIC clinic
Counsellor	2.52	1.26-3.78	Gamma	Direct cost reported by an MSIC clinic
User costs[a]				
Direct costs				
IUD[d] insertion	5	2.5-7.5	Gamma	Direct price to users reported by an MSIC clinic
Implant insertion	25	12.5-37.5	Gamma	Direct price to users reported by an MSIC clinic
Injectable (MSIC clinic)	1	0.5-1.5	Gamma	Direct price to users reported by an MSIC clinic
Injectable (pharmacy)	0.73	0.37-1.1	Gamma	Direct price to users reported by a local pharmacy
Oral contraceptive pill (MSIC clinic)	0.4	0.2-0.6	Gamma	Direct price to users reported by an MSIC clinic
Oral contraceptive pill (pharmacy)	0.37	0.19-0.56	Gamma	Direct price to users reported by a local pharmacy
IUD removal	2	1-3	Gamma	Direct price to users reported by an MSIC clinic
Implant removal	3.75	1.8-5.63	Gamma	Direct price to users reported by an MSIC clinic
Repeat abortion (surgical)	25	12.5-37.5	Gamma	Direct price to users reported by an MSIC clinic
Repeat abortion (medical)	20	10-30	Gamma	Direct price to users reported by an MSIC clinic
Mobile phone				
Airtime to call a clinic/hotline (per min)	0.07	0.04-0.11	Gamma	Advertised cross-network charge in Cambodia
Transport				
Motorbike travel (per km)	0.22	0.11-0.33	Gamma	Data from Rozemuller et al [23]
Average distance from clinic to home (km)	38.2	30.1-46.3[f]	Gamma	Data from the MOTIF study
Indirect costs				
Gross national income per capita	2534	2280.6-2787.4[g]	Gamma	World Bank development data [22]

	Base	Deterministic range[a]	Probabilistic distribution	Comment/source
Gross daily income per capita	6.9	6.2-7.6[g]	Gamma	World Bank development data [22]
Repeat abortion (total household indirect cost)	5.07	2.54-7.61	Gamma	Data from Potdar et al [24]

[a]The range used for deterministic analysis was 50% above and below the base case estimate unless otherwise indicated. This range was then assumed to represent the 95% confidence interval of the distribution indicated for probabilistic sensitivity analysis.

[b]Unit costs were combined to calculate the service level costs used in the model.

[c]MOTIF: MObile Technology for Improved Family planning.

[d]IUD: intrauterine device.

[e]MSIC: Marie Stopes International Cambodia.

[f]Range used is the 95% confidence interval from MOTIF data.

[g]Range used is 10% above and below the base case estimate.

Cost-Effectiveness

Incremental cost and utility per 1000 participants were calculated by subtracting the estimated cost and each of the measures of effect (CYPs, pregnancies averted, abortions averted, under-5 mortality, maternal mortality, and DALYs) in the MOTIF intervention arm from those in the standard care arm. The incremental cost-effectiveness ratio (ICER) for each measure of effect was calculated by dividing incremental cost by incremental effect.

Sensitivity Analysis

To estimate the effect of uncertainty, the model was subjected to deterministic and probabilistic sensitivity analyses [25]. Upper and lower range values were determined for each input parameter. Where possible, 95% CIs were derived from MOTIF trial data. Else, range values were calculated as 50% above and below the base case estimate to allow a wide range of uncertainty. The appropriate prior distribution for each parameter was chosen according to 2012 International Society for Pharmacoeconomics and Outcomes Research-Society for Medical Decision Making recommendations, and upper and lower range values were taken as the 95% CI of that distribution [26,27]. We assumed that changes in fees charged to users to access health services would not affect demand for those health services (ie, the price elasticity of demand for the services involved in the MOTIF intervention was zero).

The probabilistic sensitivity analysis consisted of a Monte-Carlo simulation with 1000 iterations randomized according to the probability distribution of each parameter. Contraceptive use outcomes for each iteration were inputted to the Impact2 model to produce the joint probability distribution for effects. Uncertainty introduced through the Impact2 model itself was not included, because information about parameters used in the Impact2 model was not available. Simulation results for ICERs assessed using CYPs and DALYs were plotted on the cost-effectiveness plane, and the cumulative probability for cost-effectiveness across a range of cost-effectiveness thresholds was visualized as a cost-effectiveness acceptability curve (CEAC) [28].

To understand the relevance of the cost-effectiveness analysis to decision makers, the results of the base case and sensitivity analyses were compared with the likely range of cost-effectiveness thresholds. Ochalek et al have described a method for empirically deriving cost-effectiveness thresholds in low- and middle-income countries, along with their estimate for a list of countries. The estimated cost-effectiveness threshold for Cambodia using this method ranged from US $58 to US $176 or 12%–35% of the gross domestic product per capita [29].

Scenario Analysis

To understand the health financing implications of reducing or removing user fees, two scenario analyses were conducted to model the effect on costs from user and provider perspectives. Because user fees represent a transfer from users to providers, from a societal perspective, the net direct effect on costs is zero. For users, we calculated the average estimated cost per client in each scenario. For providers interested in the effect of user fees on cost-effectiveness, we calculated the estimated ICER from the provider perspective.

Results

The incremental cost of mobile phone–based support from a societal perspective over a 12-month period was an additional US $8160.49 per 1000 clients, and it is reported along with costs to providers and users in Table 3. We estimate that an additional 518 CYPs are gained per 1000 clients receiving the MOTIF intervention and that this would avert 180 pregnancies, 103 abortions, and 99 DALYs. The ICER was US $82.57 per DALY averted and US $15.75 per additional CYP (Table 4). The ICER for DALYs averted fell within the cost-effectiveness threshold range.

Table 3. Base case cost and effect results for the MOTIF (MObile Technology for Improved Family planning) intervention versus standard of care.

	Intervention	Standard care	Incremental value
Costs[a] (US $)			
Provider	4079.74	−1625.20	5704.94
User	15,906.83	13,451.28	2455.55
Total	19,986.56	11,826.07	8160.49
Effects[a]			
Couple-years of protection	1350.6	832.6	518.0
Pregnancies averted[b]	441	260	180
Abortions averted[b]	251	148	103
U5[c] mortalities averted[b]	3	2	1
Maternal mortalities averted[b]	0	0	0
DALYs[d] averted	241.6	142.8	98.8

[a]Costs and effects are calculated per 1000 users.

[b]Rounded to the nearest whole.

[c]U5: under five.

[d]DALYs: disability-adjusted life-years.

Table 4. Base case incremental cost-effectiveness ratio (ICER) results for the MOTIF (MObile Technology for Improved Family planning) intervention.

Effect	ICER (US $ per unit of effect)
Couple-years of protection	15.75
Pregnancies averted	45.22
Abortions averted	79.33
U5[a] mortalities averted	7659.96
Maternal mortalities averted	—[b]
DALYs[c] averted	82.57

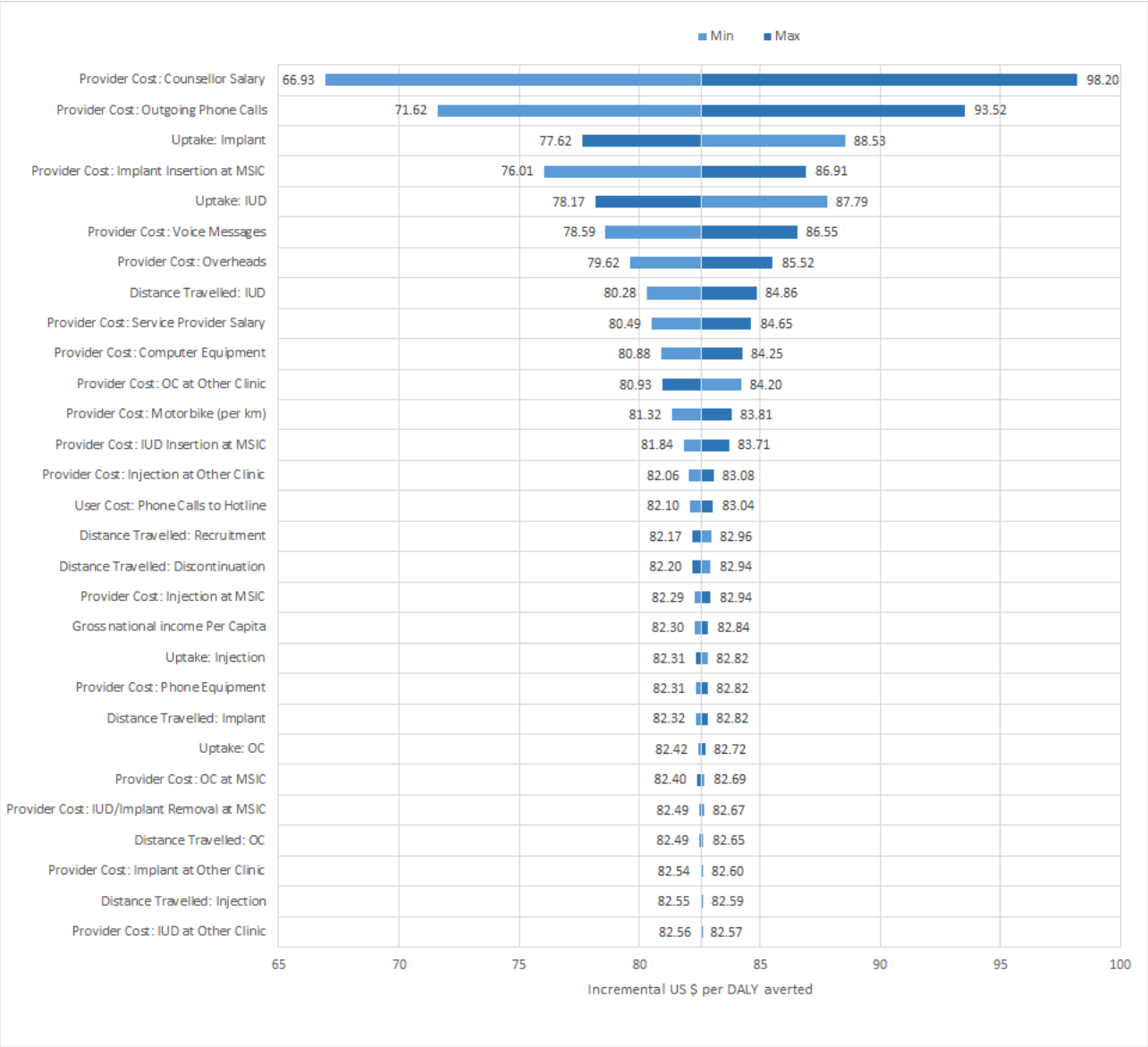
[a]U5: under five.

[b]No maternal mortalities were estimated to have been averted in either arm; therefore, no ICER calculation is possible.

[c]DALYs: disability-adjusted life-years.

Results of the deterministic sensitivity analysis are presented as a tornado plot in Figure 3. The base case model was most sensitive to personnel costs, costs for phone calls and voice messages, the uptake and delivery of long-acting contraceptive methods (IUD or implant), and the percentage added to reflect overhead costs. For all parameters, the ICER estimated using upper and lower range values fell within the cost-effectiveness threshold range.

Figure 3. Tornado plot of deterministic sensitivity analysis using MOTIF intervention model parameters. For each parameter, the ICER was recalculated taking the upper and then lower deterministic range value. ICER ranges are centered on the ICER point estimate of US $82.57 per DALY averted. DALYs: disability-adjusted life-years; ICER: incremental cost-effectiveness ratio; IUD: intrauterine device; MOTIF: MObile Technology for Improved Family planning; MSIC: Marie Stopes International Cambodia; OC: oral contraceptive.



Simulations recorded for probabilistic sensitivity analysis are presented on the cost-effectiveness plane for DALYs averted and CYPs in Figures 4 and 5. Results for the two measures of effect appear very similar, albeit on a different horizontal scale, because the Impact2 modelling tool estimates approximately five times the number of CYPs achieved as DALYs averted, for any set of randomized inputs. On the plane for DALYs, most simulations lie within the cost-effectiveness threshold range. CEACs for the two measures of effect are shown in Figures 6 and 7. The CEAC measured per DALY averted shows that the intervention has an 11% probability of being cost-effective at the lower end of the cost-effectiveness range (US $58) and a 95% probability at the upper end of the range (US $176). A 50% probability of being cost-effective would be achieved at a cost-effectiveness threshold of US $83 per DALY averted and about US $16 per CYP.

Figure 4. Monte-Carlo simulation results plotted on the cost-effectiveness plane, with effects measured in DALYs averted. Linear demarcations of the upper and lower bounds for the cost-effectiveness threshold for DALYs averted are included for comparison. DALYs: disability-adjusted life-years; MOTIF: MObile Technology for Improved Family planning.

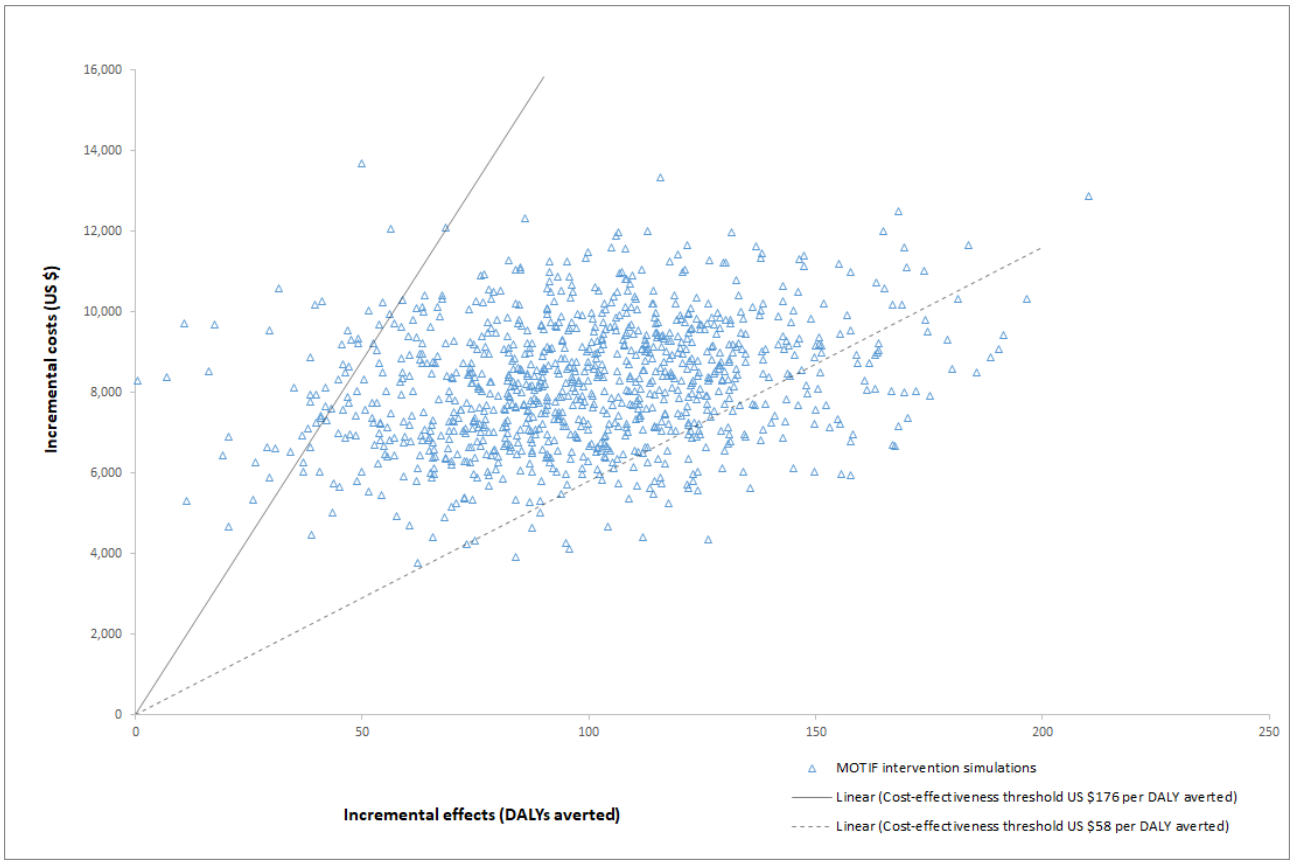


Figure 5. Monte-Carlo simulation results plotted on the cost-effectiveness plane, with effects measured in CYPs. CYPs: couple-years of protection.

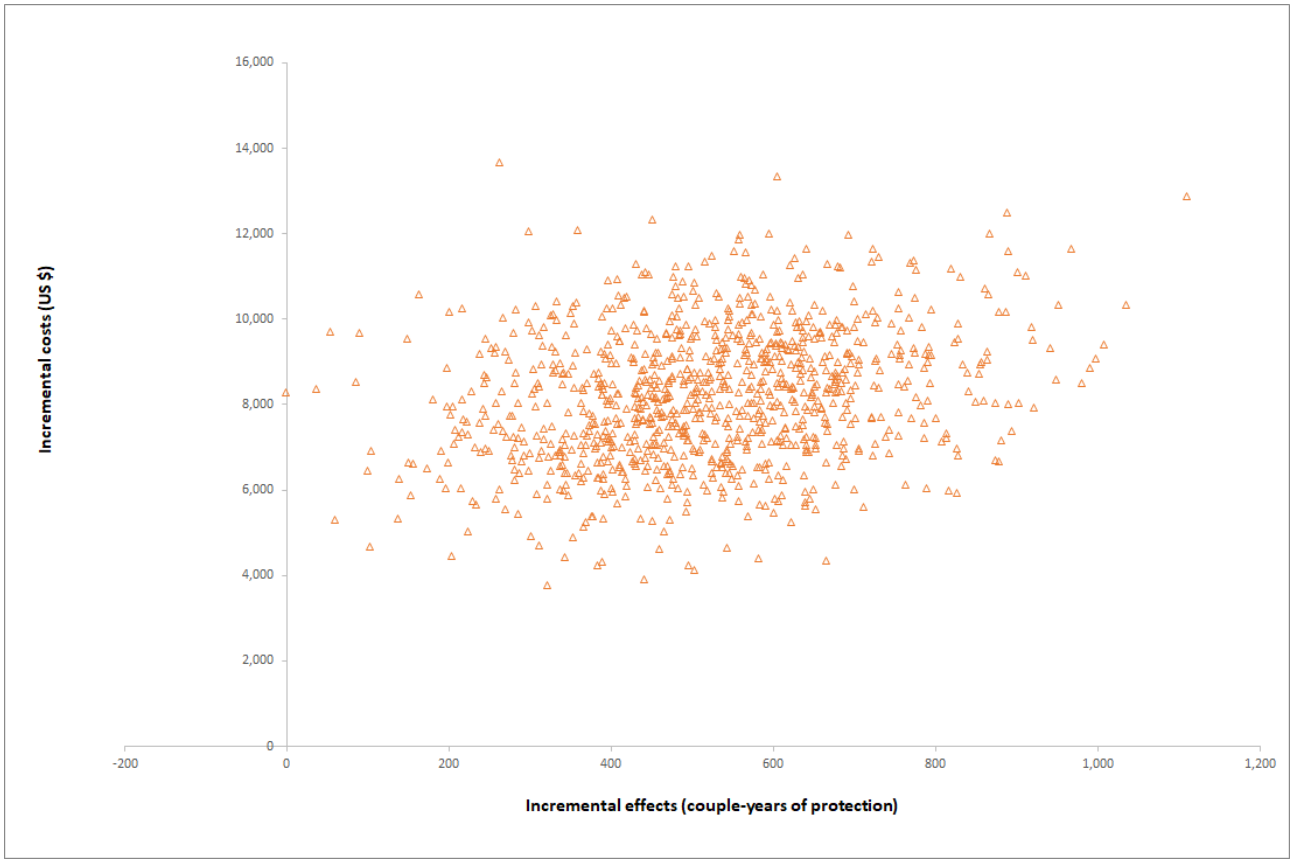


Figure 6. Cost-effectiveness acceptability curve derived from Monte-Carlo simulations of MOTIF intervention results, with effects measured in DALYs averted. DALYs: disability-adjusted life-years; MOTIF: MObile Technology for Improved Family planning.

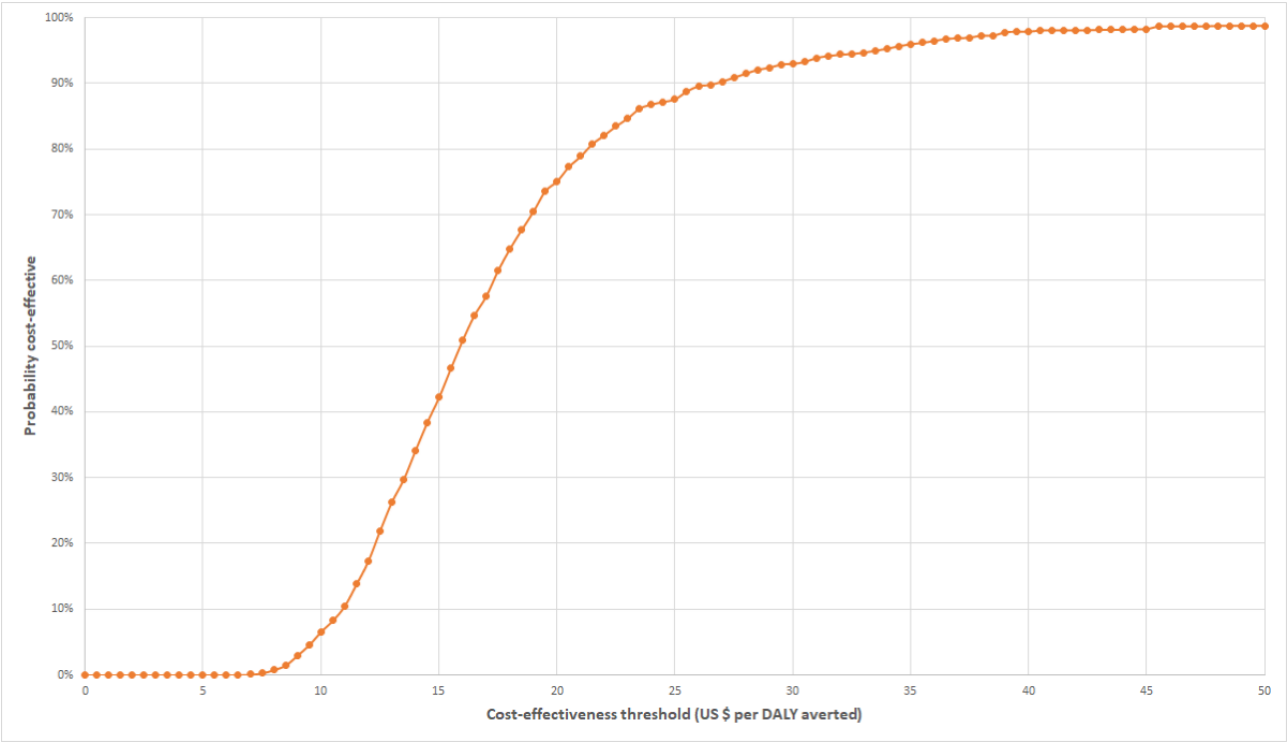
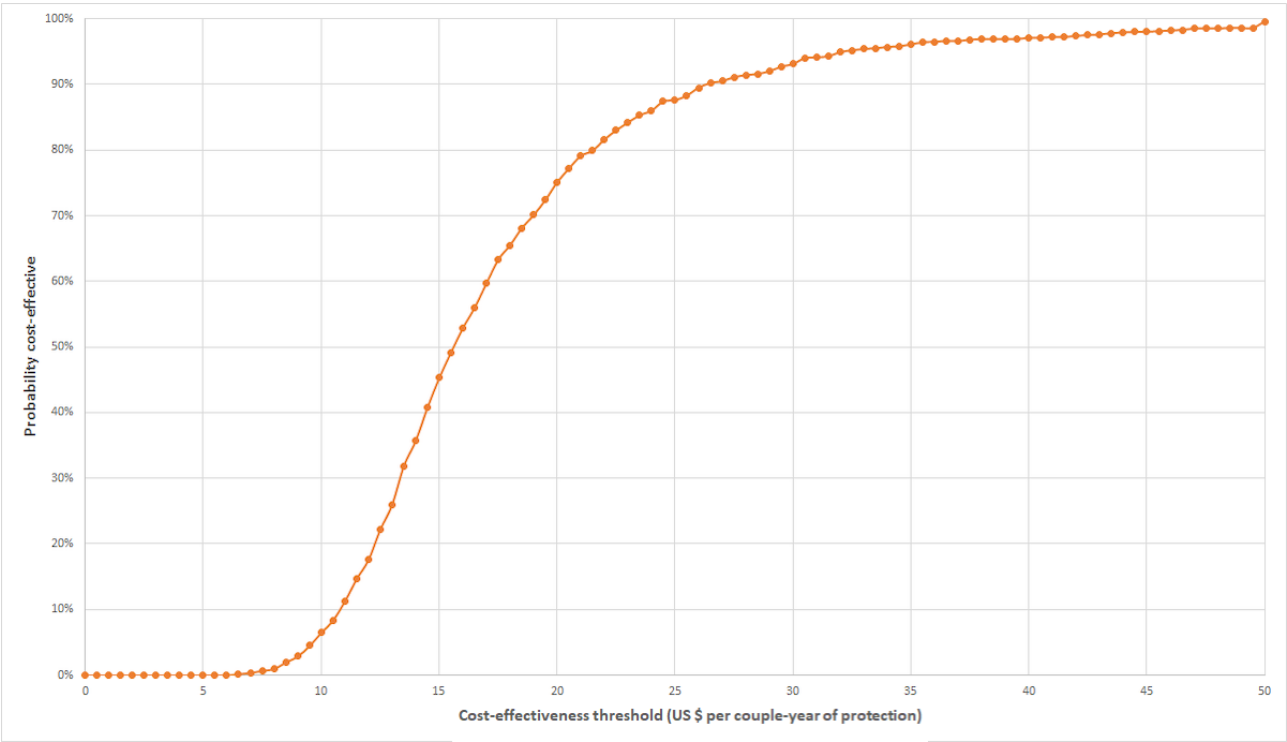


Figure 7. Cost-effectiveness acceptability curve derived from Monte-Carlo simulations of MOTIF intervention results, with effects measured in CYPs averted. CYPs: couple-years of protection; MOTIF: MObile Technology for Improved Family planning.



Average costs from a user perspective and cost-effectiveness from a provider perspective, with either 50% or no user fees, are compared with costs and cost-effectiveness from a societal perspective in Table 5. With decreasing user fees, the average cost to users participating in the MOTIF intervention decreased from US $15,906.83 to US $8772.00 per 1000 participants (from 80% to 44% of the cost of the program from a societal perspective). The ICER from the provider's perspective increased from US $57.72 to US $77.58 per DALY averted. With the removal of user fees and by considering the provider perspective, the MOTIF intervention remained within the range of cost-effectiveness thresholds for Cambodia.

Table 5. Costs for users and providers in scenarios involving variable user fees.

	Base case	Scenario 1 (50% user fees)	Scenario 2 (no user fees)	Societal perspective[a]
Total cost per 1000 participants, user perspective (US $)[b]				
Intervention	15,906.83	12,339.41	8772.00	19,986.56
Standard care	13,451.28[c]	10,864.97	8278.66	11,826.07
Incremental	2455.55	1474.44	493.34	8160.49
ICER[d], provider perspective (US $ per unit of effect)[b]				
Couple-years of protection	11.01	12.91	14.80	15.75
Pregnancies averted	31.61	37.05	42.49	45.22
Abortions averted	55.46	65.00	74.54	79.33
U5[e] mortalities averted	5355.02	6275.95	7196.88	7659.96
Maternal mortalities averted	—[f]	—	—	—
DALYs[g] averted	57.72	67.65	77.58	82.57

[a]Costs and ICERs from a societal perspective are included for reference. These results remain constant in each scenario, as the user fee represents a transfer from users to providers, but a net zero change from a societal perspective.

[b]Results are presented as total cost (direct and indirect) from a user perspective and ICER from a provider perspective to reflect the outcome of interest for the respective groups. Changes in demand resultant from the imposition of user fees have not been modelled as part of the scenario analysis.

[c]Under standard care with 100% user fees, the program provides income to providers.

[d]ICER: incremental cost-effectiveness ratio.

[e]U5: under five.

[f]No maternal mortalities were estimated to have been averted in either arm; therefore, no ICER calculation is possible.

[g]DALYs: disability-adjusted life-years.

Discussion

Principal Findings

This study demonstrates that the cost-effectiveness of the intervention delivered by mobile phone assessed in the MOTIF trial lies within the estimated range of the cost-effectiveness threshold for Cambodia. When assessing value in interventions to improve the uptake and adherence of family planning services, the use of interactive mobile phone messaging and counselling for women who have had an abortion should be considered as an option by policy makers. The MOTIF trial demonstrated that women randomized to an intervention delivered by a mobile phone were more likely to use long-acting contraceptive methods. Although these methods are known to be more cost-effective, the results of this study extend the evidence to show that an intervention delivered by a mobile phone favoring these methods is itself cost-effective.

Strengths of the Study

This study has several strengths. Many of the cost and effect parameters are derived from trial and intervention delivery data rather than estimates from the literature, therefore improving the external validity of cost-effectiveness estimates within the Cambodian context. The use of the Impact2 model allows for replicable measurements of effects and comparison across studies. The cost-effectiveness estimates of the base case, the deterministic sensitivity analysis, and 96% of the probabilistic simulations fell within the chosen range of cost-effectiveness thresholds, and the threshold range was drawn from empirically derived cost-effectiveness threshold ranges, which are intended to realistically reflect what health systems are willing to pay [29,30]. We also included scenario analyses relating to the application of user fees for family planning services. Together, the design and results of this analysis might provide useful information when adapting the findings of the study to implementation, where affordability for public sector providers is likely to be an important factor.

Another strength of the study lies in the timely and important contribution to the literature linking innovations in mobile phone–based delivery with the delivery of family planning services. With the proliferation of mobile technology in the most rural and remote areas of the globe, there is great opportunity for harnessing mobile technology to reach women with life-saving health information. This study adds to the emerging body of knowledge about how to most effectively and efficiently achieve this aspect.

Limitations of the Study

Deterministic testing indicated that estimated ICERs were particularly sensitive to counsellor personnel costs, estimated as a product of salary and time. However, these time estimates were not collected systematically, and they do not account for a run-in period of lower efficiency. Our estimates are therefore most relevant to a scaled-up intervention or a scenario where support by mobile phone is added to existing activities, for example, an established call center, where run-in time is reduced to a minimum. Process evaluations (unpublished) of the MOTIF trial intervention suggested that the link to a counsellor who

could make an appointment if requested was a key to the success of the intervention, so programmatic implementation of a similar intervention should include these components. Although a component of training time was included in costs to deliver the intervention, the cost of ongoing technical support and training was not included. Sensitivity testing also indicated that the proportion of overheads attached to personnel costs produced a large change in ICER in comparison with other parameters. Overheads were not estimated as individual unit costs as part of the study, and thus, the approximation of overheads as a proportion of personnel costs could be improved.

Many of the cost parameters were estimated by personal communication with MOTIF study authors and staff, limiting the external validity of our results in other regions of Cambodia. Further, a range of 50% above and below the point estimate was used for sensitivity analyses. This was intended to capture a broad range of uncertainty in estimated costs, although it still may not accurately represent the cost of family planning services elsewhere in the country.

In the MOTIF trial, contraceptive use outcomes were self-reported by participants. Although this is the standard in family planning research, self-reported measures have been shown to overestimate contraceptive use and are susceptible to recall bias [31]. These outcomes were used as inputs for the Impact2 model, so the effects estimated using this model would be affected in a similar way to contraceptive use outcomes in the MOTIF trial.

The Impact2 modelling tool is based on a number of assumptions linking contraceptive service provision to health outcomes. Although these assumptions are founded in a strong evidence base, the evidence is drawn from the survey data of all women of reproductive age, and it is possible that patterns of contraceptive use and decision-making behavior might differ in a postabortion population. Although the model settings for Cambodia were used and the modelled population was adjusted to match the age distribution of participants in the MOTIF trial, it is possible that differences between the trial population and the population used to inform the Impact2 model, for example, the socioeconomic distribution, might result in errors. The authors of the Impact2 methodology note that estimates of under-5 mortality may be particularly unreliable owing to limited data on linkages among contraception use, birth spacing, and child mortality [20]. Despite these limitations, CYPs and DALYs are well-known measures of effect, and a focus on these outcomes increases the interpretability of this study in comparison with other interventions.

Comparison With Existing Research

There is extensive related literature in the areas of mobile health (mHealth) and economic evaluation [32,33], of which, a number of studies relate specifically to family planning interventions. In a 2016 study by Mangone et al, a modelling approach was used to estimate the costs of a scaled-up mHealth intervention for reproductive health in Tanzania. This did not include a component of effectiveness; however, it did propose models for cost recovery based on mobile phone charges, in which costs were consistent with the findings of this analysis [34]. Zakiyah et al conducted a systematic review of economic evaluations of family planning interventions in low- and middle-income countries, identifying nine eligible studies, and in all of these, family planning interventions were found to be highly cost-effective [35]. There have been two systematic reviews of mobile phone–based interventions for family planning services; one focused on adults and the other focused on adolescents [9,10]. Both these reviews identified limited but promising evidence that mHealth interventions are effective for improving uptake and adherence to contraception, noting that there was sparse data from low- and middle-income countries. Our study is consistent with these findings and adds an important piece of economic evidence supporting the implementation of interventions delivered by mobile phone for family planning in these settings.

Implications for Future Research and Health Policy

With the proliferation of cheap and accessible mobile phones and network access, even in rural and remote locations, there is substantial interest in taking advantage of mobile innovations to aid the delivery of family planning programs. The MOTIF trial intervention, which was recently included as a digital high-impact practice in family planning behavior change, is an example of a scalable mobile innovation [36]. However, it is difficult to make a case for scaled-up digital health interventions without an assessment of cost-effectiveness. This study demonstrates that the cost-effectiveness of the intervention in the MOTIF trial lies within the range of the cost-effectiveness threshold for Cambodia, thus supporting decision makers to include mHealth interventions in future family planning policies in Cambodia.

The sensitivity and scenario analyses included in this study provide useful details for health policy makers. Personnel costs and mobile phone costs have the greatest effects on the cost-effectiveness of the intervention and provide a useful focus for the business case that would accompany a scaled-up mHealth intervention. The cost and effect parameters used in this analysis were collected in a trial environment, whereas modest economies of scale could be achieved with wider implementation, for example, through automation of some call center tasks and bulk pricing agreements with network operators. From a user perspective, removal of user fees for services almost halved the average cost per participant in the intervention group. The effect of user fees on participation in family planning services was assumed to be zero in this study. Although there is likely to be some effect in practice, evidence from low- and middle-income countries suggests that contraceptive services are inelastic with respect to price [37]. These areas of uncertainty and opportunity are all fruitful areas for further economic and operational research.

Although this study provides useful evidence to support the cost-effectiveness of the MOTIF intervention, research to test and compare the cost-effectiveness of other interventions for improving the uptake of postabortion family planning services would improve the generalizability of this study to other settings.

Conclusion

This study demonstrates that the use of an intervention delivered by a mobile phone to provide postabortion family planning

counselling was cost-effective for increasing CYPs and for preventing pregnancy and abortion. It also provides a basis for further research on how this emerging technology can improve access to family planning services.

Acknowledgments

We thank all clients and clinic staff who participated in the study. We thank Ly Sokhey, Uk Vannak, Kathryn Church, Anisa Berdellima, and Aisha Dasgupta at Marie Stopes International and Ties Hoomans at LSHTM for comments on previous versions and collecting cost data during the trial.

Authors' Contributions

CS, JM, and JC conceptualized the study; JM and JH performed formal analysis; CS, JM, JH, and JC were responsible for the methodology; JC, CF, and CS supervised the study; JM, JH, and CS prepared the original draft; and JM, JH, JC, CF, and CS reviewed and edited the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed description of the MOTIF intervention.
[DOCX File , 13 KB - mhealth_v8i2e16276_app1.docx]

References

1. Cleland J, Conde-Agudelo A, Peterson H, Ross J, Tsui A. Contraception and health. Lancet 2012 Jul 14;380(9837):149-156. [doi: 10.1016/S0140-6736(12)60609-6] [Medline: 22784533]
2. Singh S, Darroch JE, Ashford LS. Guttmacher Institute. New York: Guttmacher Institute; 2014. Adding It Up 2014: The Costs and Benefits of Investing in Sexual and Reproductive Health URL: https://www.guttmacher.org/report/adding-it-costs-and-benefits-investing-sexual-and-reproductive-health-2014 [accessed 2020-01-26]
3. National Institute of Statistics/Cambodia, Directorate General for Health/Cambodia, ICF International. The DHS Program. Phnom Penh, Cambodia: National Institute of Statistics/Cambodia, Directorate General for Health/Cambodia, and ICF International; 2015. Cambodia Demographic and Health Survey 2014 URL: http://dhsprogram.com/publications/publication-FR312-DHS-Final-Reports.cfm [accessed 2020-01-26]
4. Fetters T, Samandari G. Abortion incidence in Cambodia, 2005 and 2010. Glob Public Health 2015;10(4):532-544. [doi: 10.1080/17441692.2014.992453] [Medline: 25649162]
5. Källander K, Tibenderana JK, Akpogheneta OJ, Strachan DL, Hill Z, Asbroek AA, et al. Mobile health (mHealth) approaches and lessons for increased performance and retention of community health workers in low- and middle-income countries: a review. J Med Internet Res 2013;15(1):e17 [FREE Full text] [doi: 10.2196/jmir.2130] [Medline: 23353680]
6. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med 2013;10(1):e1001362 [FREE Full text] [doi: 10.1371/journal.pmed.1001362] [Medline: 23349621]
7. Castaño PM, Bynum JY, Andrés R, Lara M, Westhoff C. Effect of daily text messages on oral contraceptive continuation: a randomized controlled trial. Obstet Gynecol 2012 Jan;119(1):14-20. [doi: 10.1097/AOG.0b013e31823d4167] [Medline: 22143257]
8. Hou MY, Hurwitz S, Kavanagh E, Fortin J, Goldberg AB. Using daily text-message reminders to improve adherence with oral contraceptives: a randomized controlled trial. Obstet Gynecol 2010 Sep;116(3):633-640. [doi: 10.1097/AOG.0b013e3181eb6b0f] [Medline: 20733446]
9. L'Engle KL, Mangone ER, Parcesepe AM, Agarwal S, Ippoliti NB. Mobile Phone Interventions for Adolescent Sexual and Reproductive Health: A Systematic Review. Pediatrics 2016 Sep;138(3). [doi: 10.1542/peds.2016-0884] [Medline: 27553221]
10. Smith C, Gold J, Ngo TD, Sumpter C, Free C. Mobile phone-based interventions for improving contraception use. Cochrane Database Syst Rev 2015;6:CD011159. [doi: 10.1002/14651858.CD011159.pub2] [Medline: 26115146]
11. Smith C, Vannak U, Sokhey L, Ngo TD, Gold J, Khut K, et al. MObile Technology for Improved Family Planning Services (MOTIF): study protocol for a randomised controlled trial. Trials 2013 Dec 12;14:427 [FREE Full text] [doi: 10.1186/1745-6215-14-427] [Medline: 24330763]
12. Ali MM, Cleland J. Contraceptive switching after method-related discontinuation: levels and differentials. Stud Fam Plann 2010 Jun;41(2):129-133. [Medline: 21466113]
13. Ali MM, Park MH, Ngo TD. Levels and determinants of switching following intrauterine device discontinuation in 14 developing countries. Contraception 2014 Jul;90(1):47-53 [FREE Full text] [doi: 10.1016/j.contraception.2014.03.008] [Medline: 24792145]

14. Smith C, Ngo TD, Gold J, Edwards P, Vannak U, Sokhey L, et al. Effect of a mobile phone-based intervention on post-abortion contraception: a randomized controlled trial in Cambodia. Bull World Health Organ 2015 Dec 01;93(12):842-50A [FREE Full text] [doi: 10.2471/BLT.15.160267] [Medline: 26668436]
15. Chiou CF, Trussell J, Reyes E, Knight K, Wallace J, Udani J, et al. Economic analysis of contraceptives for women. Contraception 2003 Jul;68(1):3-10. [doi: 10.1016/s0010-7824(03)00078-7] [Medline: 12878280]
16. Henry N, Schlueter M, Lowin J, Lekander I, Filonenko A, Trussell J, et al. Cost of unintended pregnancy in Norway: a role for long-acting reversible contraception. J Fam Plann Reprod Health Care 2014 Dec 23;41(2):109-115. [doi: 10.1136/jfprhc-2014-100878]
17. Smith C, Jarvis C, Free C. Assessing loss to follow-up in the MObile Technology for Improved Family Planning (MOTIF) randomised controlled trial. Trials 2017 Dec 01;18(1):577 [FREE Full text] [doi: 10.1186/s13063-017-2316-6] [Medline: 29191231]
18. Murray CJ, Vos T, Lozano R, Naghavi M, Flaxman AD, Michaud C, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012 Dec 15;380(9859):2197-2223. [doi: 10.1016/S0140-6736(12)61689-4] [Medline: 23245608]
19. Sedgh G, Singh S, Hussain R. Intended and unintended pregnancies worldwide in 2012 and recent trends. Stud Fam Plann 2014 Sep;45(3):301-314 [FREE Full text] [doi: 10.1111/j.1728-4465.2014.00393.x] [Medline: 25207494]
20. Weinberger MB, Fry K, Boler T, Hopkins K. Estimating the contribution of a service delivery organisation to the national modern contraceptive prevalence rate: Marie Stopes International's Impact 2 model. BMC Public Health 2013;13 Suppl 2:S5 [FREE Full text] [doi: 10.1186/1471-2458-13-S2-S5] [Medline: 23902699]
21. Weinberger M, Fry K, Hopkins K. Marie Stopes International. London: Marie Stopes International; 2015. Impact 2 v3: An innovative tool for estimating the impact of reproductive health programmes-methodology paper URL: https://mariestopes.org/resources/impact-2-methodology-paper/ [accessed 2020-01-26]
22. The World Bank. World Development Indicators: Cambodia URL: https://data.worldbank.org/country/cambodia [accessed 2018-02-08]
23. Rozemuller B, Thou P, Yan S. International Labour Organization. Phnom Penh, Cambodia: International Labour Organisation, Ministry of Rural Development Cambodia; 2002. Rural Transporters: A Survey of Transport Businesses in Rural Cambodia URL: http://www.ilo.org/emppolicy/pubs/WCMS_ASIST_8399/lang--en/index.htm [accessed 2020-01-26]
24. Potdar R, Fetters T, Phirun L. Initial loss of productive days and income among women seeking induced abortion in Cambodia. J Midwifery Womens Health 2008;53(2):123-129. [doi: 10.1016/j.jmwh.2007.06.010] [Medline: 18308261]
25. Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. Methods For The Economic Evaluation Of Health Care Programmes. Oxford, UK: Oxford University Press; 2005.
26. Briggs AH, Claxton K, Sculpher MJ. Decision Modelling For Health Economic Evaluation. Oxford, UK: Oxford University Press; 2006.
27. Caro JJ, Briggs AH, Siebert U, Kuntz KM, ISPOR-SMDM Modeling Good Research Practices Task Force. Modeling good research practices--overview: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force--1. Value Health 2012;15(6):796-803 [FREE Full text] [doi: 10.1016/j.jval.2012.06.012] [Medline: 22999128]
28. Barton GR, Briggs AH, Fenwick EA. Optimal cost-effectiveness decisions: the role of the cost-effectiveness acceptability curve (CEAC), the cost-effectiveness acceptability frontier (CEAF), and the expected value of perfection information (EVPI). Value Health 2008;11(5):886-897 [FREE Full text] [doi: 10.1111/j.1524-4733.2008.00358.x] [Medline: 18489513]
29. Ochalek J, Claxton K, Lomas J. CHE Research Paper. York, UK: Centre for Health Economics, University of York; 2015. Cost Per DALY Averted Thresholds for Low- and Middle-Income Countries: Evidence From Cross Country Data URL: http://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP122_cost_DALY_LMIC_threshold.pdf [accessed 2020-01-26]
30. Woods B, Revill P, Sculpher M, Claxton K. Country-Level Cost-Effectiveness Thresholds: Initial Estimates and the Need for Further Research. Value Health 2016 Dec;19(8):929-935 [FREE Full text] [doi: 10.1016/j.jval.2016.02.017] [Medline: 27987642]
31. Stuart GS, Grimes DA. Social desirability bias in family planning studies: a neglected problem. Contraception 2009 Aug;80(2):108-112. [doi: 10.1016/j.contraception.2009.02.009] [Medline: 19631784]
32. Guerriero C, Cairns J, Roberts I, Rodgers A, Whittaker R, Free C. The cost-effectiveness of smoking cessation support delivered by mobile phone text messaging: Txt2stop. Eur J Health Econ 2013 Oct;14(5):789-797 [FREE Full text] [doi: 10.1007/s10198-012-0424-5] [Medline: 22961230]
33. Iribarren SJ, Cato K, Falzon L, Stone PW. What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. PLoS One 2017;12(2):e0170581 [FREE Full text] [doi: 10.1371/journal.pone.0170581] [Medline: 28152012]
34. Mangone ER, Agarwal S, L'Engle K, Lasway C, Zan T, van Beijma H, et al. Sustainable Cost Models for mHealth at Scale: Modeling Program Data from m4RH Tanzania. PLoS One 2016;11(1):e0148011 [FREE Full text] [doi: 10.1371/journal.pone.0148011] [Medline: 26824747]

35. Zakiyah N, van Asselt AD, Roijmans F, Postma MJ. Economic Evaluation of Family Planning Interventions in Low and Middle Income Countries; A Systematic Review. PLoS One 2016;11(12):e0168447 [FREE Full text] [doi: 10.1371/journal.pone.0168447] [Medline: 27992552]
36. High-Impact Practices in Family Planning. Washington, DC: USAID; 2018. Digital Health for Social and Behavior Change: New technologies, new ways to reach people URL: http://www.fphighimpactpractices.org/briefs/digital-health-sbc/ [accessed 2020-01-26]
37. Korachais C, Macouillard E, Meessen B. How User Fees Influence Contraception in Low and Middle Income Countries: A Systematic Review. Stud Fam Plann 2016 Dec 17;47(4):341-356 [FREE Full text] [doi: 10.1111/sifp.12005] [Medline: 27859370]

Abbreviations

CEAC: cost-effectiveness acceptability curve
CYPs: couple-years of protection
DALYs: disability-adjusted life-years
ICER: incremental cost-effectiveness ratio
IUD: intrauterine device
MOTIF: MObile Technology for Improved Family planning
MSIC: Marie Stopes International Cambodia

Edited by G Eysenbach; submitted 16.09.19; peer-reviewed by N Alshaiban, M Lozano-Lozano, L Zhang, I Contreras, W Zhang; comments to author 08.10.19; revised version received 29.10.19; accepted 16.12.19; published 25.02.20.

Please cite as:
Hill J, McGinn J, Cairns J, Free C, Smith C
A Mobile Phone–Based Support Intervention to Increase Use of Postabortion Family Planning in Cambodia: Cost-Effectiveness Evaluation
JMIR Mhealth Uhealth 2020;8(2):e16276
URL: http://mhealth.jmir.org/2020/2/e16276/
doi:10.2196/16276
PMID:32130166

Original Paper

Circadian Rhythms in the Telephone Calls of Older Adults: Observational Descriptive Study

Timothée Aubourg[1,2,3], MSc; Jacques Demongeot[2,3,4], MD, PhD; Hervé Provost[1,3], MSc; Nicolas Vuillerme[2,3,4], PhD

[1]Orange Labs, Chemin du Vieux Chêne, Meylan, France

[2]University Grenoble Alpes, AGEIS, Grenoble, France

[3]LabCom Telecom4Health, University Grenoble Apes & Orange Labs, Grenoble, France

[4]Institut Universitaire de France, Paris, France

Corresponding Author:
Timothée Aubourg, MSc
Orange Labs
Chemin du Vieux Chêne
Meylan
France
Phone: 33 0438429192
Email: timothee.aubourg@gmail.com

Abstract

Background: Recent studies have thoughtfully and convincingly demonstrated the possibility of estimating the circadian rhythms of young adults' social activity by analyzing their telephone call-detail records (CDRs). In the field of health monitoring, this development may offer new opportunities for supervising a patient's health status by collecting objective, unobtrusive data about their daily social interactions. However, before considering this future perspective, whether and how similar results could be observed in other populations, including older ones, should be established.

Objective: This study was designed specifically to address the circadian rhythms in the telephone calls of older adults.

Methods: A longitudinal, 12-month dataset combining CDRs and questionnaire data from 26 volunteers aged 65 years or older was used to examine individual differences in the daily rhythms of telephone call activity. The study used outgoing CDRs only and worked with three specific telecommunication parameters: (1) call recipient (alter), (2) time of day, and (3) call duration. As did the studies involving young adults, we analyzed three issues: (1) the existence of circadian rhythms in the telephone call activity of older adults, (2) their persistence over time, and (3) the alter-specificity of calls by calculating relative entropy.

Results: We discovered that older adults had their own specific circadian rhythms of outgoing telephone call activity whose salient features and preferences varied across individuals, from morning until night. We demonstrated that rhythms were consistent, as reflected by their persistence over time. Finally, results suggested that the circadian rhythms of outgoing telephone call activity were partly structured by how older adults allocated their communication time across their social network.

Conclusions: Overall, these results are the first to have demonstrated the existence, persistence, and alter-specificity of the circadian rhythms of the outgoing telephone call activity of older adults. These findings suggest an opportunity to consider modern telephone technologies as potential sensors of daily activity. From a health care perspective, these sensors could be harnessed for unobtrusive monitoring purposes.

(JMIR Mhealth Uhealth 2020;8(2):e12452) doi:10.2196/12452

KEYWORDS

outgoing telephone call; circadian rhythm; older adults; call-detail records; digital phenotyping; digital biomarkers; digital health; mhealth

Introduction

Background

Circadian rhythms of activity—biological processes working on 24-hour cycles—can be used to represent relevant temporal markers in an individual's life. They have two broad characteristics: (1) at the endogenous level, they are regulated by the brain's suprachiasmatic nucleus (SCN), which can be considered, at least partly, as the individual's biological master clock [1], and (2) at the exogenous level, regulation of the SCN

is influenced by the *entraining power* of external *time givers*, known as zeitgebers [2]. Zeitgebers can be social, such as meal schedules [3] or work schedules [4], but they can also have a physical origin, as evidenced by the effect of light, exposure to which has a direct impact on an individual's resting time [5].

In the field of health monitoring for older populations, the analysis of circadian rhythms of activity represents an increasingly important issue, one that may permit health care professionals to more adequately address their patients' needs, treatments, and care [6]. Notably, by understanding their patients' lifestyle habits, health care professionals may be better able to detect the possible occurrence of risky situations, such as a sedentary lifestyle [7], fall accidents [8], or sleep disturbances [9,10], that can have severe impacts on their health status. In practice, this monitoring is often challenging because the medical expert must be able to detect patients' circadian rhythms of activity in a precise way. In the field of health care research, such promising approaches as actigraphy [11] have been proposed recently to tackle this issue. Interestingly, actigraphy has shown that it is possible to model older individuals' gross motor activities by means of wearable sensors. Two recent reviews [8,12] on this subject notably described how this approach offers unprecedented opportunities to enhance traditional health care systems by using objective, inexpensive, and easy-to-use sensors [8]. These record individuals' daily physical activities in a precise, real-time manner to help detect risky behaviors [7], signs of cognitive dysfunction [13], or severe events such as personal injury accidents [14], whose occurrence may increase with age.

At a clinical level, however, current opportunities for using actigraphy are limited. In older adults, although analysis of the circadian rhythms of their physical activities is well served by this approach, social activities have yet to be investigated. This issue is all the more important in aging populations because life—especially social life—is not purely physical, but is also subject to particular social events, such as a relative's death [15] or the transition to retirement [16]; these events can be associated with the occurrence of severe health issues in older individuals, particularly illustrated by the phenomena of social isolation and depression [17]. It is also important to stress that social issues are not always reflected in an individual's physical activity, but they remain significantly important to health, insofar as they can alter both the biological and social rhythms of life [18]. Thus, complementary methods are required to include the social aspects of older adults' circadian rhythms of activity if we wish to monitor their health adequately.

Prior Work

In today's digital society, active and passive information collection methods, such as digital questionnaires or call-detail records (CDRs), generate vast amounts of data at high velocity from our telephones. This offers an unprecedented opportunity to capture and better understand the mechanisms of circadian rhythms in social activities [19]. Because the telephone has become such an integral part of our hyperconnected digital lives, as well as our children's lives, telephone data may contain relevant information about the social interactions occurring throughout the day between individuals and their social networks.

In the field of health monitoring, exploiting these data could provide opportunities to enrich existing approaches that rely on monitoring physical activity by using objective, noninvasive data on social activity. This could also open up new research perspectives for innovation within traditional health care systems [20,21]. Interestingly, a recent literature review published in JMIR mHealth and uHealth [21] focused specifically on the use of CDRs provided by network communication operators. Notably, following their qualitative analysis of 46 full-text articles, the authors concluded on page 1 of the review that CDRs' "potential to be used as a means of improving health care is increasingly promising" [21]. They further stressed several advantages of using CDRs in health research, including the ability to model individuals' social behaviors by routinely and passively collecting data, thereby bringing robustness and effectiveness to surveys of individual telephone users. Moreover, because of the telephone's ubiquity [19], the authors of the review stated on page 5 that using CDRs "does not preclude those from low socioeconomic groups" [21].

Other studies specifically examining the circadian rhythms of social activity have pointed to the possibility of estimating the expression of those rhythms by analyzing the CDRs of individuals' telephone use [22-25]. A recent study from Aalto University in Finland provided a relevant methodology for estimating the circadian rhythms of social activity from the telephone communications of high school students [22]. Its authors analyzed an 18-month dataset for 24 adolescents, combining mobile telephone calls and questionnaire data to assess individual differences in the daily rhythms of mobile phone call activity. The results and their consistency demonstrated the existence of circadian rhythms in the outgoing telephone call activity in this young population, as did their alter-specificity (ie, in the way that callers, also named *egos*, place their calls with their recipients, also named *alters*, over the day). We should highlight that the studies mentioned above, which provided their participants' ages, targeted groups consisting typically of students or young working adults [22-25]. Furthermore, as the authors themselves acknowledged [21] on page 5 of their review, one limitation of CDR analysis involves "the validity of study findings focusing on particular demographics, since the extent of group representation is not known" [21]. In other words, whether and how similar results to those reported for healthy young adults [22] could also be observed among other populations, including older adults, has yet to be established.

Study Goals

This study was specifically designed to address the existence of circadian rhythms in the telephone calls of older adults at an individual level. In order to be able to compare this work with the existing literature [22], we focused on three specific issues in the following ways: (1) the existence of circadian rhythms, by computing the hourly ratio of outgoing telephone calls made by older individuals, (2) the consistency of such patterns, by evaluating their persistence over time, and (3) their alter-specificity, by using measures of relative entropy at a given

time to analyze how callers allocated their communication time across their social network throughout the day (ie, the variety of alters communicating with their corresponding egos).

Methods

Data Collection and Volunteer Recruitment

Our dataset included 12 months of outgoing CDRs from 26 older volunteers in France: 20 women (77%) and 6 men (23%); median age 84 years (range 71-91). CDRs provided by the local network communication operator were collected from their personal telephones. Each telephone CDR contains the date; hour; source ID used (ego); destination user's ID (alter); direction, which is established here as outgoing; and call duration in seconds. Individuals with several telephones registered with their network communication operator (ie, one or more landline telephones and/or one or more mobile phones) provided outgoing CDRs for all of them. Note that although CDRs contain both calls and text messages, this paper only selected telephone calls, so as to facilitate comparison with existing studies [22] in the literature. Also, once during the study, participants also completed a questionnaire about the contacts in their telephone social network. They classified each of their telephone contacts into one of five distinct social categories: family, friends, associations, health care professionals, and others.

This study and its corresponding experimental protocol were submitted to the French Data Protection Authority (Commission Nationale de l'Informatique et des Libertés [CNIL] registered data protection officer, France Telecom 2011 No. 44). All experimental methods were carried out in accordance with its regulations, written informed consent was obtained from all participants before data collection, and participant data were anonymized to ensure privacy.

Data Preprocessing

As participants did not all enroll in the survey at the same time—thus, their dates of inclusion varied—the CDR dataset was filtered to select the time interval when the greatest number of older adults were actively participating. The CDR dataset was then preprocessed, following the method described by Saramäki et al [26], by selecting only the participants who used their telephones throughout the entire 12-month observation period. Therefore, the results cover a set of 21 individuals; see Table 1 for details.

Table 1. Structure of the call-detail records (CDRs) dataset before and after preprocessing.

Participant characteristics	Before preprocessing	After preprocessing
Number of participants, n (%)		
Total	26 (100)	21 (100)
Female	20 (77)	16 (76)
Male	6 (23)	5 (24)
Age in years		
Range	71-91	71-91
Mean (SD)	84 (4)	83 (4)
Total number of outgoing calls	19,198	18,338
Average number of calls per individual		
1st quartile	285	481
Median	590	710
3rd quartile	944	1096

Data Analysis Procedures

Measuring the Circadian Rhythms of Outgoing Telephone Call Activity

We followed the descriptive approach designed by Aledavood et al [22], which consisted of calculating the circadian patterns of the outgoing telephone call activity of our older adult participants across the study's entire 12-month dataset. This two-step process consisted of the following: (1) coarse-graining the time dimension into a unique day divided into 24 1-hour time slots and (2) calculating the average frequency of telephone calls for each time slot. We followed this approach at two distinct population levels: (1) the aggregate level, to obtain a concise overview of the dataset's structure and trends and (2) the individual level, to obtain the circadian patterns of outgoing telephone call activity for each individual. Distinguishing the aggregate level from the individual level allowed us to avoid an ecological fallacy [27] when interpreting the results.

Assessing the Consistency of Circadian Rhythms in Outgoing Telephone Call Activity

Overview

For assessing the consistency of circadian rhythms in outgoing telephone call activity, we followed an analytical approach based on the notion of persistence, which was first introduced for social signature analysis by Saramäki et al [26]. This notion was subsequently applied to studies estimating circadian rhythms [22-24]; the approach consists of comparing the stability of estimated patterns at distinct, successive time points by following three steps.

Step 1: Temporal Discretization

Data were coarse-grained as previously done by other authors [22]. Since the dataset contained 12 months of observations, they were split into three successive 4-month periods named T1, T2, and T3. Aggregating data into intervals of several months enhanced the robustness of persistence analysis by limiting the effects of short-term variations in call patterns [28]. This also reduced the probability of dealing with empty datasets.

Step 2: Circadian Rhythm Calculation

The circadian rhythm of each ego's outgoing telephone call activity was calculated for periods T1, T2, and T3, as described in the previous section.

Step 3: Persistence Analysis

The persistence of each ego's circadian rhythm was analyzed. This consisted of, first, calculating the stability of each ego's call patterns between successive periods (T1, T2, and T3) and, second, comparing this stability with a reference scale measured by the square root of the Jensen-Shannon divergence (JSD) dissimilarity measure [27] (see Statistical Tools in the Methods section).

First, we note D_{self} as a dissimilarity measure of the individual's circadian rhythms between two successive periods (see Figure 1, equation 1). We note that $<D_{self}>$ is the average of D_{self}, (see Figure 1, equation 2).

Second, a reference scale for further comparison was built for each ego, calculating the JSD between each ego and all the other egos in each period, T1, T2, and T3. We note D_{ref} as a dissimilarity measure between two circadian rhythms of two distinct individuals in the same period (see Figure 1, equation 3). We note that $<D_{ref}>$ is the average of D_{ref} (see Figure 1, equation 4).

Finally, the persistence of a given ego's circadian rhythm was assessed by comparing his or her average call pattern over time with his or her average reference scale. Formally, an individual's circadian rhythm can only be found to be persistent if, and only if, $<D_{self}>/<D_{ref}><1$.

Figure 1. Equations used in the manuscript.

Equation 1. $D_{self}(i,T,T+1) = \sqrt{JSD\left(P_i^T, P_i^{T+1}\right)}$

where P_i^T is the discrete probability distribution of ego *i*'s call ratio in period *T*.

Equation 2. $< D_{self} > = \left(\frac{1}{N_T - 1}\right) \cdot \sum_{T=1}^{N_T-1} D_{self}(i,T,T+1)$

where N_T is the number of time periods (here, three).

Equation 3. $D_{ref}(i,j,T) = \sqrt{JSD\left(P_i^T, P_j^T\right)}$

where P_i^T is the discrete probability distribution of ego *i*'s call ratio in period *T*,
and P_j^T is the discrete probability distribution of ego *j*'s call ratio in the same period *T*, with $i \neq j$.

Equation 4. $< D_{ref} > = \left(\frac{1}{n-1}\right) \cdot \sum_{i=1}^{n-1} D_{ref}(i,j,T)$

where *n* is the number of individuals (here, 21).

Equation 5. $p_{i,normalised}(t) = \frac{p_i(t) - \min(p_i)}{\max(p_i) - \min(p_i)}$

With $(p_i(t))_{i=1,k}$ being the vector for the daily ratio of calls during a period of length *k* for individual *i*, k=23 and *i* in {1...*n*}.
Thus, $p_i(t)$ is the ratio of calls made by individual *i* during hour *t*, with *t* in {0...23}.

Equation 6. $JSD(p1,p2) = H\left(\pi_2 \cdot \sum_{i=1}^{2} p_i\right) - \pi_2 \cdot \sum_{i=1}^{2} H(p_i)$

where *p1* and *p2* are two discrete probability distributions, π_2=1/2,
and *H*(.) is the Shannon entropy.

Equation 7. Formally, let $A_i = \{a_{i1} \ldots a_{im}\}$, ego *i*'s set of alters, where *m* represents the size of his or her telephone social network. We define origin entropy at a given 6-hour interval *t* as :

$$H_{origin}(i,t) = -\sum_{k=1}^{m} p_{i,k}(t).\, log\left(p_{i,k}(t)\right)$$

Where $p_{i,k}(t)$ is the fraction of calls from ego *i* to alter a_{ik} at interval *t*.

Measuring Alter-Specificity in Circadian Rhythms

The alter-specificity in the circadian rhythms of outgoing telephone call activity was investigated jointly using individuals' CDRs and questionnaire data, as previously done by Aledavood et al [22]. Concretely, the three following points were analyzed according to the time of day: (1) the existence of specific hours used for communicating with a specific alter, (2) the ratio of outgoing telephone calls directed to each individual's top 2 alters, and (3) the variation in telephone call durations between individuals and their social networks.

Assessing the Existence of Specific Hours for Communicating With Specific Alters

For assessing the existence of alter-specificity in the circadian rhythms of outgoing telephone call activity, we made a two-step analysis of how each ego communicated with their alters throughout the day.

Step 1: Temporal Discretization

We began by coarse-graining the time dimension into four bins of equal duration—night (12 am-6 am), morning (6 am-12 pm), afternoon (12 pm-6 pm), and evening (6 pm-12 am)—for each ego and for periods T1, T2, and T3.

Step 2: Alter-Specificity Calculation

For each ego, we analyzed the alter-specificity of outgoing telephone call patterns over 24 hours during periods T1, T2, and T3, comparing the alter-structure of the estimated circadian rhythms with the alter-structure of a null model simulating total randomness in alter-specificity. To do this, we estimated the diversity of alters in each 6-hour bin for each ego and calculated the associated relative entropies (see Statistical Tools in the Methods section) during periods T1, T2, and T3. This calculation involved two steps: Step 2a and Step 2b.

Step 2a: Origin Entropy Calculation

First, we calculated each ego's origin entropy H_{orig} in each 6-hour bin for periods T1, T2, and T3.

Step 2b: Relative Entropy Calculation

Second, we obtained the relative entropy H_{rel} by normalizing with H_{orig} the average reference entropy $<H_{ref}>$, which resulted from the null model. This null model works under the hypothesis that no specific times are associated with telephone calls to specific alters. Thus, a low relative entropy value, tending to 0, indicates that there is significant alter-specificity in the call pattern.

Measuring the Specificity of Outgoing Telephone Calls to the Top Two Alters

To investigate the rhythm of outgoing telephone calls from egos to their 2 favorite alters, we analyzed how the 2 favorite alters affected the circadian rhythm of the ego's outgoing telephone call activity. To do this, we selected each ego's 2 most frequently called alters for periods T1, T2, and T3 and for each of the four time bins. Next, we calculated the corresponding fraction of calls over each ego's entire, 12-month, outgoing telephone call activity.

Statistical Tools

Normalization

To visualize the peaks and troughs of each individual's telephone call activity, we normalized the daily ratio of their calls to be contained between 0 and 1, which enables us to avoid any excessive influence of extreme values on the graph's colors. To this end, we used a unity-based normalization formula [29]. Formally, let n be the number of participants included in the study. Let $(p_i(t))_{i=1,k}$ be the vector for the daily ratio of calls during a period of length k for individual i, with k=23 and the i range being $\{1...n\}$.

Thus, $p_i(t)$ is the ratio of calls made by individual i during hour t, with the t range being $\{0...23\}$.

Then, for each element $p_i(t)$ of p_i, we note $p_{normalised,i}(t)$, its normalized value (see Figure 1, equation 5).

Jensen-Shannon Divergence

The JSD is a measure of dissimilarity that compares two probability distributions; it is a symmetrical, finite-value version of the Kullback-Leibler divergence. Its square root can be used as a metric for measuring the distance between two probability distributions (see Figure 1, equation 6, for its definition in a discrete context).

Entropy Measures

Overview

The entropy construct consists of three successive steps: (1) the origin entropy calculation measuring alter-specificity in the original dataset, (2) the reference entropy calculation measuring alter-specificity in a random dataset configuration [22], and (3) the relative entropy calculation standardizing the original entropy value in step 1 divided by the reference entropy value in step 2 [22]. The steps are discussed more precisely as follows:

1. The first step is the origin entropy calculation. This measures the diversity of the alters called by each ego in each of the four 6-hour intervals or bins during the day. The frequency of outgoing calls from each older adult to each of their alters is calculated separately for each 6-hour interval. Then, an entropy value—the origin entropy [22]—is calculated for each of these periods. This calculation enables us to quantify the proportion of distinct alters called by each older adult during corresponding periods.
2. The second step is the reference entropy calculation. This measures the diversity of alters called by each older adult during the day using a random configuration, named the null model, where there is no alter-specificity [22]. In the null model, the original call frequency patterns and the number of calls made to each alter are the same as in the original dataset, but associations between alters and the hour of calls are randomly shuffled so as to have no particular alter-specificity.
3. The third step is the relative entropy calculation. This compares the alter-specificity measurements obtained in step 1 with the alter-specificity measurements of their corresponding null models obtained in step 2.

In detail, this occurs for a given ego i, where i is between 1 and n, and n=21 is the number of participants.

Step 1: Origin Entropy

Formally, let $A_i=\{a_{i1}...a_{im}\}$, ego i's set of alters, where m represents the size of his or her telephone social network. We define origin entropy at a given 6-hour interval t, as in equation 7 in Figure 1.

Step 2: Reference Entropy

We next define a null model, which simulates a system without a specific alter-structure. The number of calls from ego i to each alter is maintained, but the times of calls to their alters are shuffled in order to simulate randomness in each 2-week period, as done by Aledavood et al [22]. Next, for each 6-hour interval t of the shuffled dataset, we calculate the corresponding $H_{origin}(i,t)$ as defined in step 1. The reference entropy is obtained by iterating this process n=1000 times, as previously described, and calculating the corresponding average H_{origin} for each time interval.

Step 3: Relative Entropy

To estimate the alter-specificity of the original system, we normalized the origin entropy of ego *i* at each time interval *t* by their previously calculated reference entropy:

$$H_{relative}(i,t)=H_{origin}(i,t)/H_{reference}(i,t)$$

Results

There Are Circadian Rhythms in the Outgoing Telephone Call Activity of Older Adults

This study's results suggest the existence of circadian rhythms in the outgoing telephone call activity of older adults at both the aggregate and individual levels. At the aggregate level, Figure 2 shows that the population's average circadian pattern of outgoing telephone call activity was marked by two distinct peaks: one in midmorning, around 10 am, and one toward the end of the day, around 6 pm. These twin peaks were separated by a period of low activity in the afternoon, beginning at around 2 pm. The first activity peak, in midmorning, was higher than a second peak that occurred at the end of the afternoon. Interestingly, there was a small nocturnal activity peak at around 2 am, which was unusual with regard to the dataset's marked diurnal pattern.

First observations were subsequently refined by zooming into the individual level. The results also highlighted the circadian rhythms of outgoing telephone call activity for each participant separately. Figure 3, A illustrates the different outgoing communication patterns of a sample of 6 distinct egos from night to evening. Individuals A and E showed a preference for calling in the morning, whereas individuals B, C, and F preferred the afternoons or evenings. In particular, we noted a potential atypical pattern illustrated in Figure 3, A. Individual D displayed a prominent and atypical nocturnal calling activity at around 2 am and, interestingly, it was directed to one specific alter.

To put these examples back into their context, we normalized each ego's hourly call frequencies between 0 and 1, where 1 was assigned to the maximums reached and 0 to the minimums reached (see Statistical Tools in the Methods section). This standardization enables us to avoid the visual distraction and influence of extreme values, such as any particularly high peaks in telephone call activity, when mapping frequencies on a graph. Thus, the results are displayed on the comparative heat map of Figure 3, B, synthetically illustrating the existence of the older adults' various circadian rhythms, from night to evening. It seems that individual D was the only one leading a nocturnal lifestyle, but this observation explains the small, atypical nocturnal activity peak occurring at around 2 am at the aggregate level (see Figure 2).

Figure 2. Aggregate-level circadian pattern of the outgoing telephone call activity of older adults. Bars represent the average hourly frequency of outgoing telephone calls. Error bars represent the hourly standard deviations. The wide range of the 5% error bars indicates that average outgoing telephone call activity differed significantly between individuals, especially at 2 am.

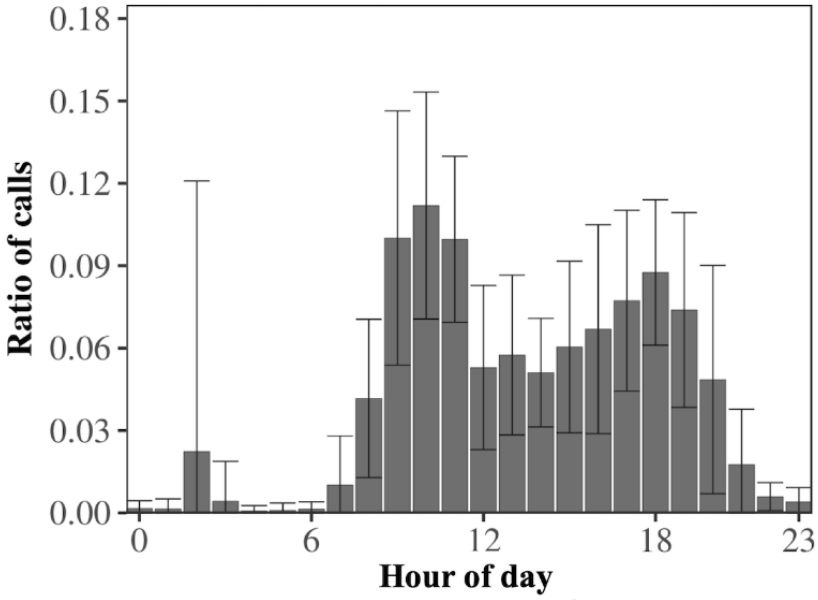
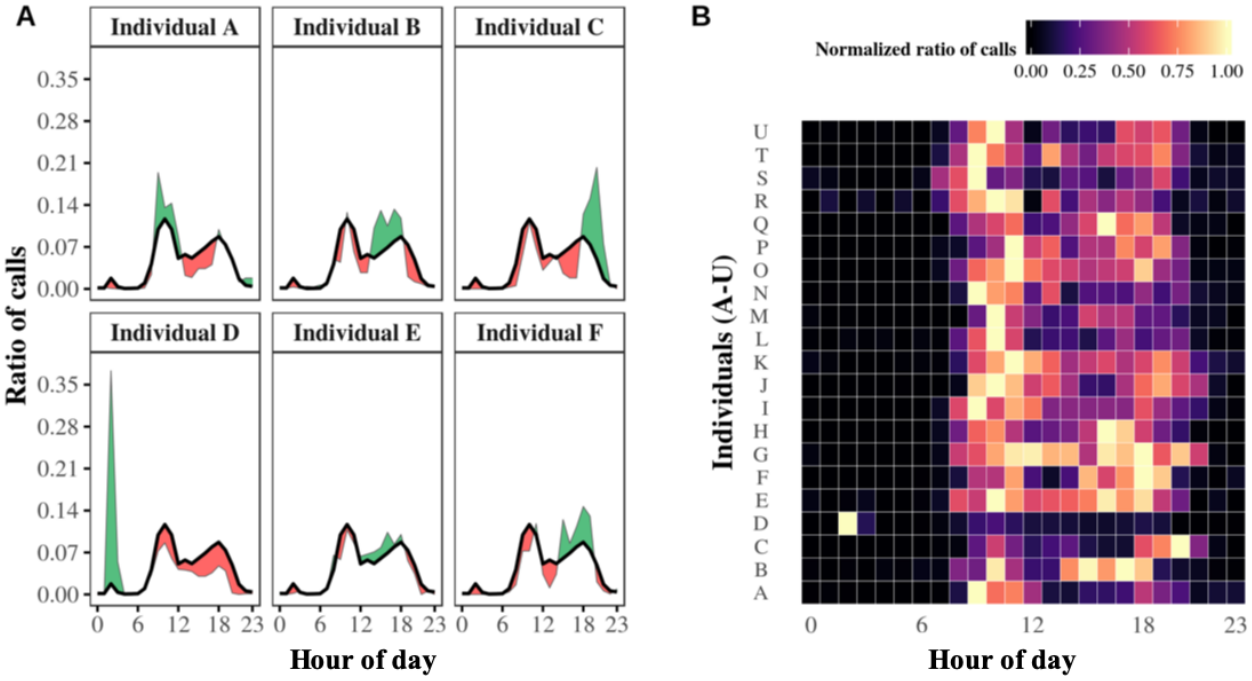


Figure 3. Circadian patterns of outgoing telephone call activities at the individual level. Panel A. Individual circadian patterns of the outgoing telephone call activity profiles of 6 distinct egos. Each small graph shows a specific ego. The black line represents the average circadian pattern of outgoing telephone calls for the population, whereas the individual's circadian pattern of calling is represented by a green or red area indicating higher or lower outgoing telephone calls than the average. Panel B. Heat map showing 21 individual outgoing telephone call patterns. The entire population's normalized individual circadian patterns are shown aggregated onto one heat map. Each horizontal strip summarizes the circadian pattern of one ego, associating each hour of the day with the corresponding ratio of outgoing telephone calls in appropriately colored boxes. The greater the ratio of outgoing telephone calls, the brighter the corresponding box.



Circadian Rhythms of Outgoing Telephone Call Activity May Be Consistent Among Older Adults

The consistency of the circadian rhythms calculated above was confirmed by our persistence analysis (see Methods section for details). Figure 4 displays the results of this analysis for all the egos. The average self-distance D_{self} of all the egos is clearly lower than their average reference distance D_{ref}. More precisely, on average, $<D_{self}>$=0.24 (SD 0.06), whereas $<D_{ref}>$=0.38 (SD 0.07). Indeed, all the egos' self-distances were lower than their reference distances, which implies that their circadian patterns tended to retain their shape over time. These results were also confirmed using Aledavood et al's more statistical approach [22]. We compared each ego's successive circadian rhythms of outgoing telephone call activity by using a Kolmogorov-Smirnov comparison test. We obtained P values greater than .05 in all 42 cases (21 participants; D_{self} and D_{ref}), implying that the case for suggesting similarity between successive egos' patterns cannot be rejected. We also repeated the analysis by changing the JSD measure for a classic Euclidean distance (L2), as proposed by Aledavood et al [22], and drew a similar conclusion. See Table 2 for details.

Figure 4. Averaged persistence histogram. Red bars represent average reference distances and blue bars represent average self-distances for all the egos. Blue and red dashed lines represent the average self-distance and reference distance for the entire population, respectively.

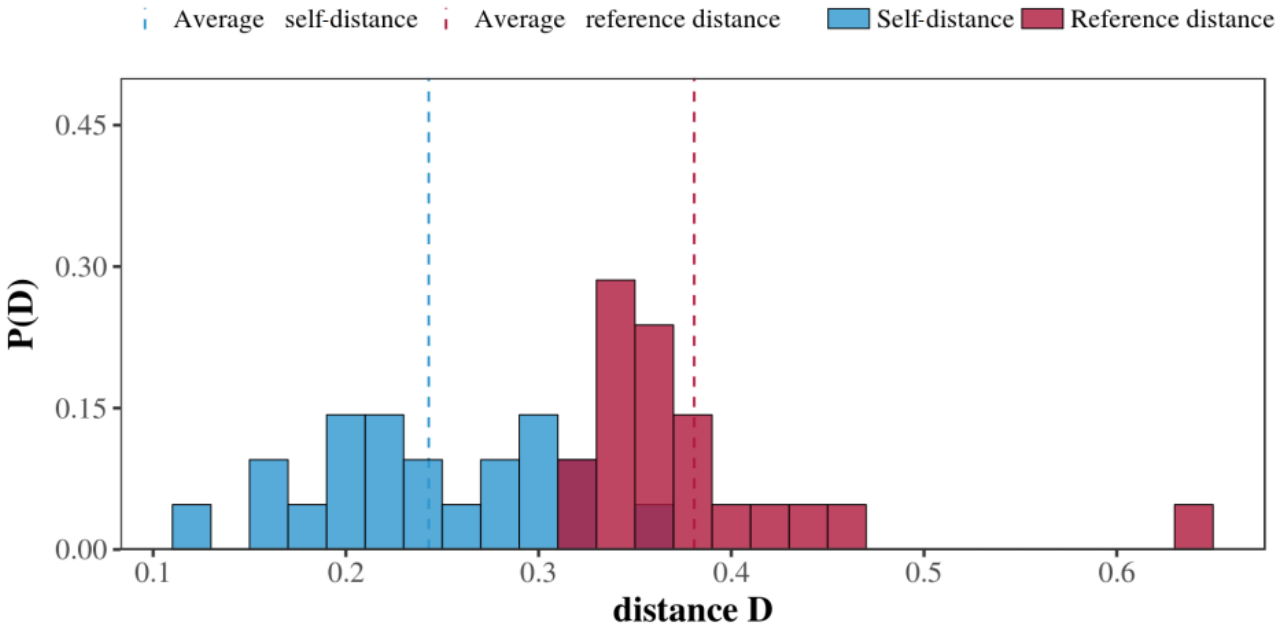


Table 2. Summary of the averaged √JSD[a] and Euclidian distance (L2) metrics for the entire population's references and self-distances.

Measures	√JSD distance	L2 distance
Self-distance, mean (SD)	0.24 (0.06)	0.14 (0.04)
Reference distance, mean (SD)	0.38 (0.07)	0.23 (0.07)

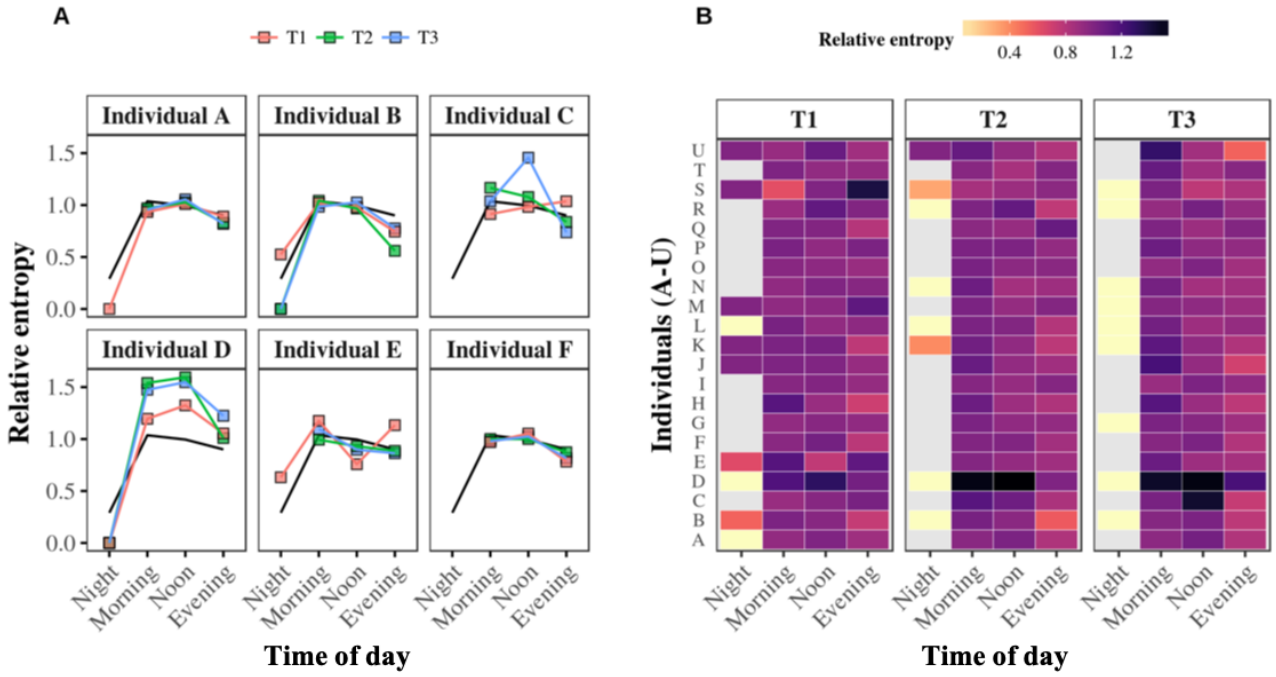
[a]JSD: Jensen-Shannon divergence.

Alter-Specificity Is Indeed Evidenced in the Circadian Rhythms of Older Adults' Outgoing Telephone Call Activity

Overall, these results suggest the existence of alter-specificity in the circadian rhythms of older adults' outgoing telephone call activity. This alter-specificity is reflected by the relative entropy calculation, which indicates whether communication with specific alters takes place at specific times of day. Figure 5, A illustrates the relative entropy results calculated for the 6 egos in Figure 3. In general, in this figure, the average entropy of the population (black line) reveals that egos tend to have low entropy values in the evening and at night but higher entropies in the morning and afternoon. The results also imply that older adults' communications tend to be more focused on specific alters in the evening. The figure nevertheless shows that this trend does not hold for every participant, for instance, ego E.

These examples are put into context in Figure 5, B, which puts all the individuals' entropy values for periods T1, T2, and T3 onto one heat map. Although some egos clearly only made outgoing telephone calls to a narrow range of alters, this observation cannot be generalized over our entire population of older adults. Moreover, although a relative entropy value tending to 1 indicates a broad diversity of alters, as per Aledavood et al [22], there are specific contexts in which a high relative entropy value does not necessarily reflect the diversity of alters in the egocentric networks of our older individuals. The appearance of such a context depends on the null model's ability for generating significant randomness (see Statistical Tools in Methods section for details). If we consider an older individual whose entire nocturnal outgoing telephone call activity consists of a single call, this context should be evidenced by a low origin entropy value tending to 0. Consequently, a null model with a random structure should also logically provide a low reference entropy value tending to 0. There is no way to break down such detail because, by definition, the null model affects individuals' time associations but preserves the number and time frequencies of calls. Thus, normalizing such a small origin entropy value by such a small reference entropy value, even when averaged, automatically makes the resulting relative entropy value skyrocket toward 1. A similar mathematical risk is attenuated by just a few more calls, but it will still exist if the ego's overall outgoing telephone call activity is predominantly aimed at a few distinct alters. Thus, this paper's notion of relative entropy must be considered accurate for making decisions about alter-specificity in a specific time interval. This means a high relative entropy tending to 1 does not necessarily imply the existence of a high diversity of alters in the ego's network. Instead, it does not let us conclude that there is a high degree of alter-specificity. Additionally, Aledavood et al's description of relative entropy results [22] also points out other originalities concerning this notion, such as its ability to exceed 1 in particular contexts.

Figure 5. Relative entropy values at the individual level. Panel A. The relative entropy values of the same 6 individuals described in Figure 2 for the night, morning, afternoon, and evening are calculated for the first, second, and third 4-month periods: T1 (red curve), T2 (green curve), and T3 (blue curve), respectively. The black curve represents the whole population's average relative entropy value over the three periods. Panel B. The heat map summarizes all the relative entropy values of all 21 egos. The lower or higher the relative entropy, the brighter or darker the color assigned to it, respectively. Missing values are assigned a grey color.



The results also suggest that the alter-specificity evidenced above by the relative entropy may be associated with the older adult's 2 most frequently called alters. For example, Figure 6, A shows the fraction of calls to the top 2 alters averaged at the population level for the whole year (black line) against those of the same 6 egos in Figures 2 and 4, averaged for periods T1, T2, and T3. The population pattern in this figure reveals that the fraction of calls to the top 2 alters reaches a maximum in the evening and at night, and it decreases in the morning and afternoon. It also seems proportionally inversed with the relative entropy variation (see Figure 5, A). Interestingly, the aggregation of the results of each individual's top 2 alters in Figure 6, B's heat map seems to confirm this trend. We further evaluated this trend by calculating the correlation between relative entropy and the fraction of calls to each ego's top 2 alters during each 6-hour bin. Of 21 egos, 11 (52%) showed a significant negative correlation between entropy and the fraction of calls to their top 2 alters (P<.05); the 21-ego population average was close to -0.87. These results confirmed that for 11 of the 21 egos, a low entropy value correlated with a high fraction of their calls to their top 2 alters. No conclusions could be drawn for the other 10 egos.

Interestingly, by using questionnaire data, as did Aledavood et al [22], we recorded additional information about the kinds of telephone communications occurring between egos and alters throughout the day, according to their social relationship and the telephone call duration parameter. Two insights from these results clearly stand out in Figure 7: (1) the duration of outgoing telephone calls tended to be at a minimum at night and then increased throughout the day to the evening and (2) on average, egos communicated for longer with their restricted social network (ie, family and friends) than with their wider social network (ie, associations and health professionals). The longest telephone calls between older individuals and their friends and family occurred in the evenings. On the contrary, the duration of telephone calls to health care professionals and associations decreased throughout the day. This difference was not surprising. Indeed, in France, associations and health care professionals are not typically available by telephone after 5 pm.

Figure 6. Fraction of outgoing telephone calls to top 2 alters at the individual level. Panel A. Each graph displays one participant's fraction of calls to their top 2 alters during the night, morning, afternoon, and evening, calculated for periods T1 (red curve), T2 (green curve), and T3 (blue curve). The black curve represents the average fraction of calls to the top 2 alters of the entire population over the three periods. Panel B. These heat maps summarize the fractions of outgoing telephone calls going to the top 2 alters of each of the 21 egos. High fractions are assigned brighter colors, whereas low fractions of calls are assigned darker colora. Missing values are assigned the color grey.

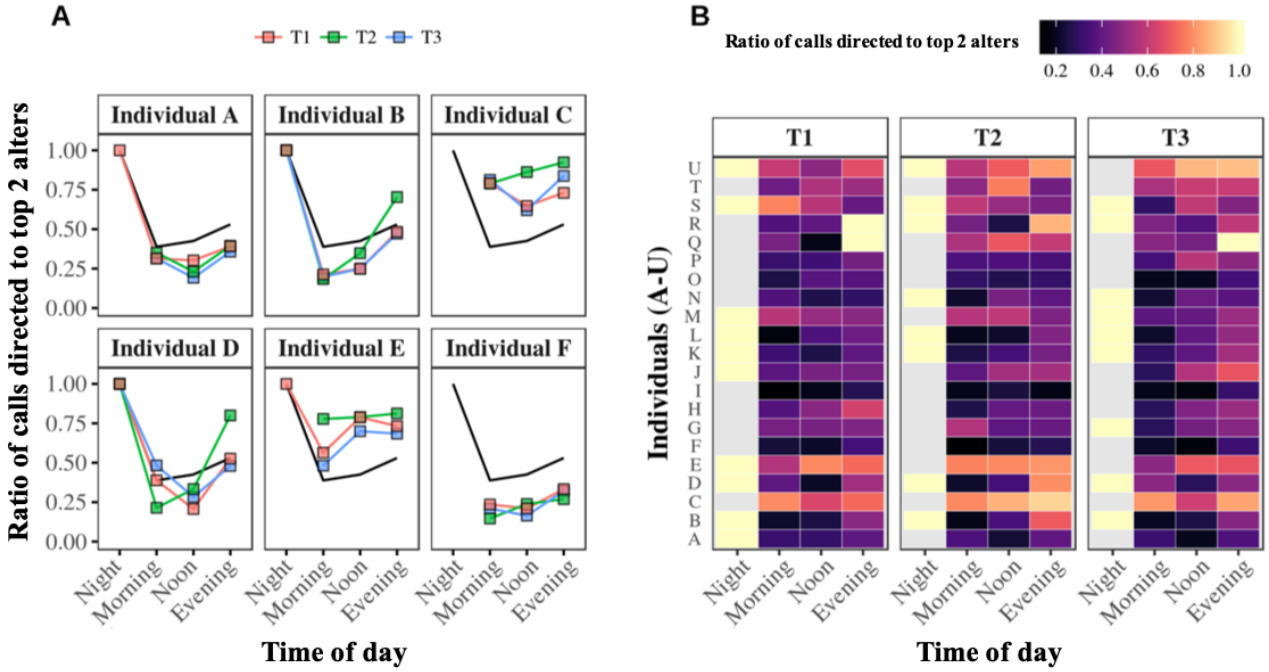
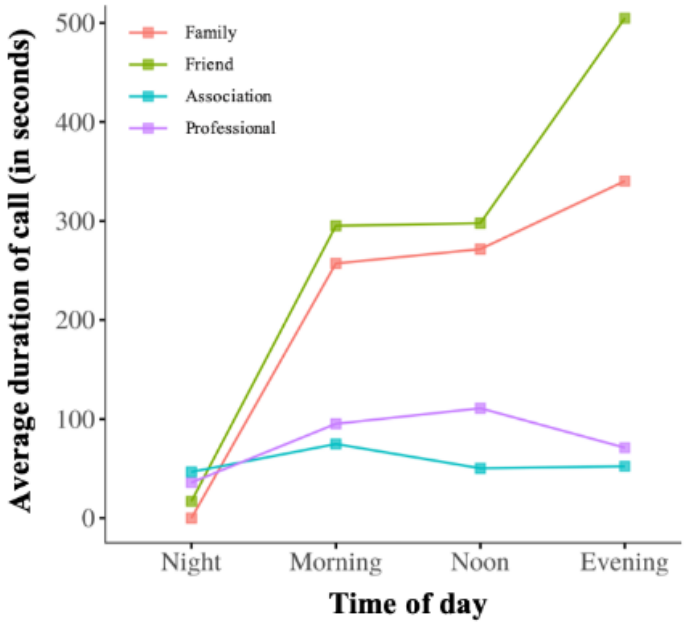


Figure 7. Aggregate-level average call duration throughout the day. Curves represent average call durations from egos to their families (red curve), friends (green curve), health care professionals (purple curve), and clubs or associations (blue curve).



Discussion

Principal Findings

Because studies to date on the circadian rhythms of telephone telecommunications at the individual level have focused especially on young individuals [22-25], we investigated whether similar results could be observed among older adults. We focused on a combination of CDRs and questionnaire data to examine a small sample of participants aged 65 years or older (n=21). Our analysis was based on CDRs of their outgoing calls over 12 consecutive months and was restricted to three specific telecommunication parameters: (1) the telephone call recipient (alter), (2) the moment in time, and (3) telephone call duration. Additionally, we evaluated questionnaire data collected from participants on their level of closeness with their alters, classified into the four broad categories of (1) friend, (2) family, (3) association, and (4) health care professional. To be able to

compare our results with those in the existing literature, we used the methodology proposed by Aalto University [22] and focused on three specific issues: (1) the existence, (2) the consistency, and (3) the alter-specificity of the circadian rhythms of outgoing telephone call activity among older adults.

Overall, results showed that older adults had their own specific circadian rhythms of outgoing telephone call activity; salient features varied between individuals, with different preferences involving calling from morning to night and throughout the day (see Figure 2). It was subsequently demonstrated that these circadian rhythms of outgoing telephone call activity were also consistent, as reflected by their persistence over time (see Figure 3). Our investigation of the alter-specificity of these rhythms showed that they seemed partly structured by how older adults allocated their communication time among their social network. Indeed, on average, the relative entropy calculations and the older adults' ratios of calls to their top 2 alters (see Figures 4 and 5) suggested that, although the evening and night were mostly reserved for a few specific alters, the morning and afternoon were more likely to be used for calling their wider social network. In addition to this temporal factor, the nature of telephone communications also seemed to be influenced by the social relationships between egos and their alters. Indeed, the average call duration in this older adult population was much higher for conversations with friends or family than with contacts in associations or health care. Call duration also varied throughout the day, with shorter calls in the morning and afternoon and longer telephone conversations occurring in the evening and at night.

Taken together, these findings provide the first support for the hypothesis that telephone CDRs can provide fine-grained data whose analysis can help to estimate older individual's circadian rhythms of telephone call activity. These circadian rhythms notably influenced the way individuals interacted with their social network over 24 hours, which may have been a demonstration of appropriate social sensibility [30]. Sensibility is linked to the concept of intentionality [30] and may rely, in this paper, on the older adult's ability to efficiently organize and prioritize their communication time throughout the day. This efficient organization may be reflected by at least two evident observations: (1) telephone calls to medical professionals generally took place early in the day, when they were most readily available, instead of in the evening, an unfavorable time for business interactions, and (2) calls to friends and family generally occurred in the evening, when they were more likely to be available and responsive. For retired people, this second point could reflect the fact that family and friends have social constraints of their own, such as work schedules, household tasks, or childcare duties, making them unwilling to accept being disturbed as their days begin. Thus, based on social sensibility, particular changes in the circadian rhythms of telephone call activity, such as persistent attempts to call friends and family in the morning and health care professionals in the evening, may be representative of a behavioral drift. This drift may be a valuable indication of a disruption to their ability to organize or prioritize social calls throughout the day. Three points thus stand out:

1. At the social level, these findings suggest that the results of recent studies on young populations could be extended to older ones [22]. A relevant perspective for future studies surely lies in increasing the sample sizes of the populations studied to compare these results against findings with greater statistical power.
2. At the health monitoring level, telephones have the potential to become sensors of older adults' daily social activities. The valuable data they generate about older adults' social lives, such as how they communicate with relatives and health care professionals over time, promises future innovative monitoring methods. Information collected objectively and noninvasively could provide health care professionals with behavioral insights about their patients in the form of alerts. Direct reflections of an individual's telephone call activity [31] may help those professionals to better prevent the occurrence or worsening of certain severe health issues, such as social isolation or depression [17]. Clinicians might also use older individuals' circadian rhythms of social activity or social sensibility timing to determine the best time of day to send health care prompts and information or set up individual telephone consultations by targeting hours when patients are more inclined to respond [32]. Enhancing the synergies between health care professionals, patients, and new monitoring technologies [33] could help to reinforce preventive, participative, pluri-expert, predictive, and personalized (5P) medicine [34].
3. At the clinical level, the information on social activity provided by CDRs could be harnessed to complement existing innovative approaches to monitoring physical activity, such as actigraphy [11,35], to provide a complete picture of older adults' daily activities. They could also enrich traditional methods of clinical practice, such as health questionnaires requiring the patient's active participation at a given time, by means of passive daily data collection that requires no supplementary effort from the patient.

It is also important to mention that in the field of health research, the methods designed by Aledavood et al [22] and used in this paper could provide a methodology for measuring the quality of CDRs. This is a challenging point given that the numerous studies investigating correlations between specific health issues, such as depressive symptoms [30], and daily behaviors measured using telephone data have (1) shown significant but contradictory results [36] and (2) not yet had their discrepancies explained. Hence, by assessing the consistency of the observed phenomena in such studies, persistence analysis could be an interesting means of addressing these two points together.

Telephones and the methodology used in this paper may provide an innovative, relevant future direction for the field of health monitoring of older adults. However, before classifying the telephone as a valid clinical sensor of social activity in older populations, a number of caveats and limitations should be considered.

Limitations

First, any rapid, straightforward generalization of our results should be avoided because of the small sample size of 21 older

adults remaining after the data preprocessing step. This small sample means that our results could suffer from an as yet unquantified selection bias. Our interest in working with a small sample of individuals lies in the opportunity to collect, monitor, and analyze individual datasets of significant richness, mixing behavioral observations with social information over a long period of time. The added value of a study with such a dataset configuration is not the generalization of results but rather the acquisition of significant insights for future studies of big data [22].

Because we followed our preprocessing step precisely [26]—also used for circadian rhythm estimation methodology in telephone calls [22]—our data may have been open to another selection bias. Of our 26 initial participants, only those who had been active throughout the observation period were selected, as in previous studies [26]. Individuals whose telephone call activity ceased for any given reason were excluded from this study. On the one hand, filtering was justified because it separated viable participants from those who had encountered specific problems, such as changing telephones, changing telecommunications operators, or a desire to withdraw from the study for personal reasons. On the other hand, the preprocessing step could prove problematic in some cases because a lack of information could be a source of information in itself [37]. This is the case when missing values result from a change in individual behavior caused by a given event or a set of events, such as an accident, a disease, anxiety, depression, or social isolation. Consequently, excluding individuals from the study because of an absence of telephone call activity automatically introduced a clear selection bias into our analysis. Thus, we have to mention that our results only stand for older individuals who showed telephone call activity throughout the entire duration of the study.

Finally, our results did not indicate that the circadian pattern of outgoing telephone call activity of any individual was a manifestation of their complete inherent circadian rhythm. Telephone call patterns should only be interpreted as an insight into an individual's overall behavior, one that allows us to draw a first draft of their true inherent circadian rhythm. In today's hyperconnected society, individuals can have social interactions through multiple communication media: telephone calls, text messages, or virtual social networks. A relevant way to enhance the robustness of circadian estimation could be to combine outgoing telephone call patterns with other sources of data (eg, incoming calls, text messages, and location data) and, more generally, to attempt a multidimensional analysis based on active and passive temporal data from telephones [38]. In the last few years, combining such data at the individual level has led to the birth of totally new domains of research [39]. For instance, in health, the digital phenotyping concept [40] attempts to surpass the expectations of classic individual actigraphy by mixing active and passive data generated by everyday tools like mobile phones [41]. Actigraphy typically presents such obvious disadvantages as the perceptions that it is both too invasive for patients with regard to medical protocols and too vague with regard to their social situation. Using a mobile phone as a multi-sensor can eliminate the costs of multiple external actigraphy devices, and this everyday object eases patients' concerns about health care monitoring. A recent study [42] even reported that patients were more likely to share their suicidal thoughts with a mobile phone app than with their own psychiatrist.

Perspectives for the Future

As other authors have mentioned [22], it would be interesting for future studies to compare individuals' incoming and outgoing communications with their social network. This could be all the more important in health care contexts given that disruptions to an individual's social interactions may be the sign of such severe health issues as depression [17]. With this in mind, we have immediate plans for a follow-up study comparing incoming and outgoing telephone calls in the hope of revealing any synchronous or asynchronous phenomena at the individual level.

Acknowledgments

We thank the reviewers for critically reading the manuscript and suggesting substantial improvements. We also thank Félix Renard for providing us his feedback on earlier drafts of the manuscript.

Authors' Contributions

This work is part of the PhD thesis of the first author TA, co-supervised by NV and HP, within the Telecom4Health program. TA, HP and NV contributed to conception and design of the study. HP and NV performed data collection. TA organized the database and performed the statistical analysis. TA, JD, HP and NV interpreted the data. TA wrote the first draft of the manuscript. TA, JD, HP and NV contributed to manuscript revision.

Conflicts of Interest

None declared.

References

1. Czeisler CA, Duffy JF, Shanahan TL, Brown EN, Mitchell JF, Rimmer DW, et al. Stability, precision, and near-24-hour period of the human circadian pacemaker. Science 1999 Jun 25;284(5423):2177-2181 [FREE Full text] [doi: 10.1126/science.284.5423.2177] [Medline: 10381883]

2. Quante M, Mariani S, Weng J, Marinac CR, Kaplan ER, Rueschman M, et al. Zeitgebers and their association with rest-activity patterns. Chronobiol Int 2019 Feb;36(2):203-213. [doi: 10.1080/07420528.2018.1527347] [Medline: 30365354]
3. Wehrens SMT, Christou S, Isherwood C, Middleton B, Gibbs MA, Archer SN, et al. Meal timing regulates the human circadian system. Curr Biol 2017 Jun 19;27(12):1768-1775.e3 [FREE Full text] [doi: 10.1016/j.cub.2017.04.059] [Medline: 28578930]
4. James SM, Honn KA, Gaddameedhi S, Van Dongen HPA. Shift work: Disrupted circadian rhythms and sleep-implications for health and well-being. Curr Sleep Med Rep 2017 Jun;3(2):104-112 [FREE Full text] [doi: 10.1007/s40675-017-0071-6] [Medline: 29057204]
5. Kawasaki A, Wisniewski S, Healey B, Pattyn N, Kunz D, Basner M, et al. Impact of long-term daylight deprivation on retinal light sensitivity, circadian rhythms and sleep during the Antarctic winter. Sci Rep 2018 Nov 01;8(1):16185 [FREE Full text] [doi: 10.1038/s41598-018-33450-7] [Medline: 30385850]
6. Virone G, Alwan M, Dalal S, Kell S, Turner B, Stankovic J, et al. Behavioral patterns of older-adults in assisted living. IEEE Trans Inf Technol Biomed 2008 May;12(3):387-398. [doi: 10.1109/titb.2007.904157] [Medline: 18693506]
7. Van Cauwenberg J, Van Holle V, De Bourdeaudhuij I, Owen N, Deforche B. Diurnal patterns and correlates of older adults' sedentary behavior. PLoS One 2015;10(8):e0133175 [FREE Full text] [doi: 10.1371/journal.pone.0133175] [Medline: 26244676]
8. Sun R, Sosnoff JJ. Novel sensing technology in fall risk assessment in older adults: A systematic review. BMC Geriatr 2018 Jan 16;18(1):14 [FREE Full text] [doi: 10.1186/s12877-018-0706-6] [Medline: 29338695]
9. Mattis J, Sehgal A. Circadian rhythms, sleep, and disorders of aging. Trends Endocrinol Metab 2016 Apr;27(4):192-203 [FREE Full text] [doi: 10.1016/j.tem.2016.02.003] [Medline: 26947521]
10. Abbott SM, Knutson KL, Zee PC. Health implications of sleep and circadian rhythm research in 2017. Lancet Neurol 2018 Jan;17(1):17-18. [doi: 10.1016/S1474-4422(17)30410-6] [Medline: 29262995]
11. Ancoli-Israel S, Cole R, Alessi C, Chambers M, Moorcroft W, Pollak C. The role of actigraphy in the study of sleep and circadian rhythms. Sleep 2003 May 01;26(3):342-392. [doi: 10.1093/sleep/26.3.342] [Medline: 12749557]
12. Straiton N, Alharbi M, Bauman A, Neubeck L, Gullick J, Bhindi R, et al. The validity and reliability of consumer-grade activity trackers in older, community-dwelling adults: A systematic review. Maturitas 2018 Jun;112:85-93. [doi: 10.1016/j.maturitas.2018.03.016] [Medline: 29704922]
13. Wu JQ, Li P, Stavitsky Gilbert K, Hu K, Cronin-Golomb A. Circadian rest-activity rhythms predict cognitive function in early Parkinson's disease independently of sleep. Mov Disord Clin Pract 2018;5(6):614-619 [FREE Full text] [doi: 10.1002/mdc3.12692] [Medline: 30637282]
14. Rogers TS, Blackwell TL, Lane NE, Tranah G, Orwoll ES, Cauley JA, et al. Rest-activity patterns and falls and fractures in older men. Osteoporos Int 2017 Apr;28(4):1313-1322 [FREE Full text] [doi: 10.1007/s00198-016-3874-2] [Medline: 28013364]
15. Götze H, Brähler E, Gansera L, Schnabel A, Gottschalk-Fleischer A, Köhler N. Anxiety, depression and quality of life in family caregivers of palliative cancer patients during home care and after the patient's death. Eur J Cancer Care (Engl) 2018 Mar;27(2):e12606. [doi: 10.1111/ecc.12606] [Medline: 27859889]
16. Hamm JM, Heckhausen J, Shane J, Infurna FJ, Lachman ME. Engagement with six major life domains during the transition to retirement: Stability and change for better or worse. Psychol Aging 2019 May;34(3):441-456. [doi: 10.1037/pag0000343] [Medline: 30973238]
17. Domènech-Abella J, Lara E, Rubio-Valera M, Olaya B, Moneta MV, Rico-Uribe LA, et al. Loneliness and depression in the elderly: The role of social network. Soc Psychiatry Psychiatr Epidemiol 2017 Apr;52(4):381-390. [doi: 10.1007/s00127-017-1339-3] [Medline: 28154893]
18. Grandin LD, Alloy LB, Abramson LY. The social zeitgeber theory, circadian rhythms, and mood disorders: Review and evaluation. Clin Psychol Rev 2006 Oct;26(6):679-694. [doi: 10.1016/j.cpr.2006.07.001] [Medline: 16904251]
19. Blondel V, Decuyper A, Krings G. A survey of results on mobile phone datasets analysis. EPJ Data Sci 2015 Aug 5;4(1):10. [doi: 10.1140/epjds/s13688-015-0046-0]
20. Russ TC, Woelbert E, Davis KAS, Hafferty JD, Ibrahim Z, Inkster B, MQ Data Science Group. How data science can advance mental health research. Nat Hum Behav 2019 Jan;3(1):24-32. [doi: 10.1038/s41562-018-0470-9] [Medline: 30932051]
21. Jones KH, Daniels H, Heys S, Ford DV. Challenges and potential opportunities of mobile phone call detail records in health research: Review. JMIR Mhealth Uhealth 2018 Jul 19;6(7):e161 [FREE Full text] [doi: 10.2196/mhealth.9974] [Medline: 30026176]
22. Aledavood T, López E, Roberts SG, Reed-Tsochas F, Moro E, Dunbar RI, et al. Daily rhythms in mobile telephone communication. PLoS One 2015;10(9):e0138098 [FREE Full text] [doi: 10.1371/journal.pone.0138098] [Medline: 26390215]
23. Aledavood T, Lehmann S, Saramäki J. Digital daily cycles of individuals. Front Physiol 2015 Oct 07;3:7. [doi: 10.3389/fphy.2015.00073]
24. Aledavood T, Lopez E, Roberts SGB, Reed-Tsochas F, Moro E, Dunbar RIM, et al. Channel-specific daily patterns in mobile communication. In: Proceedings of European Conference on Complex Systems 2014. Cham, Switzerland: Springer

International Publishing; 2016 May Presented at: European Conference on Complex Systems 2014; September 22-26, 2014; Lucca, Italy p. 209-218 URL: https://chesterrep.openrepository.com/handle/10034/611411
25. Aledavood T, Lehmann S, Saramäki J. Social network differences of chronotypes identified from mobile phone data. EPJ Data Sci 2018 Oct 24;7(1):1-13. [doi: 10.1140/epjds/s13688-018-0174-4]
26. Saramäki J, Leicht EA, López E, Roberts SG, Reed-Tsochas F, Dunbar RI. Persistence of social signatures in human communication. Proc Natl Acad Sci U S A 2014 Jan 21;111(3):942-947 [FREE Full text] [doi: 10.1073/pnas.1308540110] [Medline: 24395777]
27. Lin J. Divergence measures based on the Shannon entropy. IEEE Trans Inf Theory 1991;37(1):145-151. [doi: 10.1109/18.61115]
28. Saramäki J, Moro E. From seconds to months: An overview of multi-scale dynamics of mobile telephone calls. Eur Phys J B 2015 Jun 24;88(6):1. [doi: 10.1140/epjb/e2015-60106-6]
29. Dodge Y, editor. The Oxford Dictionary of Statistical Terms. 6th edition. Oxford, UK: Oxford University Press; 2006.
30. Schulkin J. Roots of Social Sensibility and Neural Function. Cambridge, MA: MIT Press; 2000.
31. Aubourg T, Demongeot J, Renard F, Provost H, Vuillerme N. Association between social asymmetry and depression in older adults: A phone Call Detail Records analysis. Sci Rep 2019 Sep 18;9(1):13524 [FREE Full text] [doi: 10.1038/s41598-019-49723-8] [Medline: 31534178]
32. Garm A, Park GH, Song X. Using an electronic comprehensive geriatric assessment and health coaching to prevent frailty in primary care: The CARES Model. Med Clin Rev 2017;3(S1):9 [FREE Full text] [doi: 10.21767/2471-299X.1000051]
33. Orth M, Averina M, Chatzipanagiotou S, Faure G, Haushofer A, Kusec V, et al. Opinion: Redefining the role of the physician in laboratory medicine in the context of emerging technologies, personalised medicine and patient autonomy ('4P medicine'). J Clin Pathol 2019 Mar;72(3):191-197 [FREE Full text] [doi: 10.1136/jclinpath-2017-204734] [Medline: 29273576]
34. Demongeot J, Jelassi M, Taramasco C. Big data approach for managing the information from genomics, proteomics, and wireless sensing in e-health. In: Dey N, Bhatt C, Ashour A, editors. Big Data for Remote Sensing: Visualization, Analysis and Interpretation. Cham, Switzerland: Springer International Publishing; 2019.
35. Ho S, Mohtadi A, Daud K, Leonards U, Handy TC. Using smartphone accelerometry to assess the relationship between cognitive load and gait dynamics during outdoor walking. Sci Rep 2019 Feb 28;9(1):3119 [FREE Full text] [doi: 10.1038/s41598-019-39718-w] [Medline: 30816292]
36. Rohani DA, Faurholt-Jepsen M, Kessing LV, Bardram JE. Correlations between objective behavioral features collected from mobile and wearable devices and depressive mood symptoms in patients with affective disorders: Systematic review. JMIR Mhealth Uhealth 2018 Aug 13;6(8):e165 [FREE Full text] [doi: 10.2196/mhealth.9691] [Medline: 30104184]
37. Torous J, Staples P, Barnett I, Sandoval L, Keshavan M, Onnela JP. Characterizing the clinical relevance of digital phenotyping data quality with applications to a cohort with schizophrenia. NPJ Digit Med 2018;1:15 [FREE Full text] [doi: 10.1038/s41746-018-0022-8] [Medline: 31304300]
38. Quadri C, Zignani M, Capra L, Gaito S, Rossi GP. Multidimensional human dynamics in mobile phone communications. PLoS One 2014;9(7):e103183 [FREE Full text] [doi: 10.1371/journal.pone.0103183] [Medline: 25068479]
39. Jain SH, Powers BW, Hawkins JB, Brownstein JS. The digital phenotype. Nat Biotechnol 2015 May;33(5):462-463. [doi: 10.1038/nbt.3223] [Medline: 25965751]
40. Onnela J, Rauch SL. Harnessing smartphone-based digital phenotyping to enhance behavioral and mental health. Neuropsychopharmacology 2016 Jun;41(7):1691-1696 [FREE Full text] [doi: 10.1038/npp.2016.7] [Medline: 26818126]
41. Torous J, Onnela J, Keshavan M. New dimensions and new tools to realize the potential of RDoC: Digital phenotyping via smartphones and connected devices. Transl Psychiatry 2017 Mar 07;7(3):e1053 [FREE Full text] [doi: 10.1038/tp.2017.25] [Medline: 28267146]
42. Torous J, Staples P, Shanahan M, Lin C, Peck P, Keshavan M, et al. Utilizing a personal smartphone custom app to assess the Patient Health Questionnaire-9 (PHQ-9) depressive symptoms in patients with major depressive disorder. JMIR Ment Health 2015;2(1):e8 [FREE Full text] [doi: 10.2196/mental.3889] [Medline: 26543914]

Abbreviations

5P: preventive, participative, pluri-expert, predictive, and personalized
CDR: call-detail record
CNIL: Commission Nationale de l'Informatique et des Libertés
JSD: Jensen-Shannon divergence
L2: Euclidean distance
SCN: suprachiasmatic nucleus
T1: first 4-month period
T2: second 4-month period
T3: third 4-month period

Edited by G Eysenbach; submitted 09.10.18; peer-reviewed by M Jordan-Marsh, P Santana-Mancilla, M Ghajarzadeh; comments to author 31.03.19; revised version received 24.05.19; accepted 28.06.19; published 25.02.20.

Please cite as:
Aubourg T, Demongeot J, Provost H, Vuillerme N
Circadian Rhythms in the Telephone Calls of Older Adults: Observational Descriptive Study
JMIR Mhealth Uhealth 2020;8(2):e12452
URL: http://mhealth.jmir.org/2020/2/e12452/
doi:10.2196/12452
PMID:32130156

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org