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Original Paper

Capturing Rest-Activity Profiles in Schizophrenia Using Wearable and Mobile Technologies: Development, Implementation, Feasibility, and Acceptability of a Remote Monitoring Platform

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Abstract

Background: There is growing interest in the potential for wearable and mobile devices to deliver clinically relevant information in real-world contexts. However, there is limited information on their acceptability and barriers to long-term use in people living with psychosis.

Objective: This study aimed to describe the development, implementation, feasibility, acceptability, and user experiences of the *Sleepsight* platform, which harnesses consumer wearable devices and smartphones for the passive and unobtrusive capture of sleep and rest-activity profiles in people with schizophrenia living in their homes.

Methods: A total of 15 outpatients with a diagnosis of schizophrenia used a consumer wrist-worn device and smartphone to continuously and remotely gather rest-activity profiles over 2 months. Once-daily sleep and self-rated symptom diaries were also collected via a smartphone app. Adherence with the devices and smartphone app, end-of-study user experiences, and agreement between subjective and objective sleep measures were analyzed. Thresholds for acceptability were set at a wear time or diary response rate of 70% or greater.

Results: Overall, 14 out of 15 participants completed the study. In individuals with a mild to moderate symptom severity at baseline (mean total Positive and Negative Syndrome Scale score 58.4 [SD 14.4]), we demonstrated high rates of engagement with the wearable device (all participants meeting acceptability criteria), sleep diary, and symptom diary (93% and 86% meeting criteria, respectively), with negative symptoms being associated with lower diary completion rate. The end-of-study usability and acceptability questionnaire and qualitative analysis identified facilitators and barriers to long-term use, and paranoia with study devices was not a significant barrier to engagement. Comparison between sleep diary and wearable estimated sleep times showed good correspondence (ρ=0.50, P<.001).

Conclusions: Extended use of wearable and mobile technologies are acceptable to people with schizophrenia living in a community setting. In the future, these technologies may allow predictive, objective markers of clinical status, including early markers of impending relapse.

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KEYWORDS

sleep; circadian rhythm; mHealth; smartphone; relapse; psychosis

Introduction

Background

Approximately 80% of those treated for the first episode of psychosis experience at least 1 further episode within 5 years [1]. Relapse often goes undetected until the individual is severely unwell, by which time the episode is disabling, distressing, and compromises illness trajectory [2]. Developing systems for detecting the early signs of deterioration [3] and prompting preventative interventions that avert relapse and hospital admission is, therefore, a priority.

Disturbances in rest-activity patterns are frequently reported in the early stages of relapse in schizophrenia. Sleep disturbance is the most common relapse indicator to be identified by family members [4], and it is reported by 68% [5] to 79% [6] of patients. They commonly precede relapse by over a week [5], suggesting they occur in the early stages of deterioration. Insomnia, sleep fragmentation, and reduced total sleep time have been associated with severity of psychotic experiences [7-9], and recent evidence suggests that sleep disruption may play a causal role in the genesis of psychotic symptoms [10,11]. Similarly, the organization of motor activity has been shown to vary with the severity of psychotic symptoms [12,13]. Sleep and rest-activity disturbance, therefore, appear to be an important, objective early sign of deterioration in clinical status.

Rest-activity profiles across phases of illness are poorly characterized, in part due to the challenges of sampling these rhythms over long periods in individuals with psychosis. To date, objective estimation of sleep under free-living conditions has been derived from wrist actigraphy [14,15], which estimates sleep parameters from patterns of rest-activity [16]. Actigraphy typically lacks wireless capability, thereby necessitating home or clinic visits for the manual download of data and precluding the real-time data upload necessary for triggering preventative interventions. Actigraphs are recognizable as clinical devices, which can be stigmatizing and aesthetically unacceptable to the user [17] and limits their suitability for apps where long-term use in naturalistic settings is required.

The Case for Wearable and Mobile Technologies

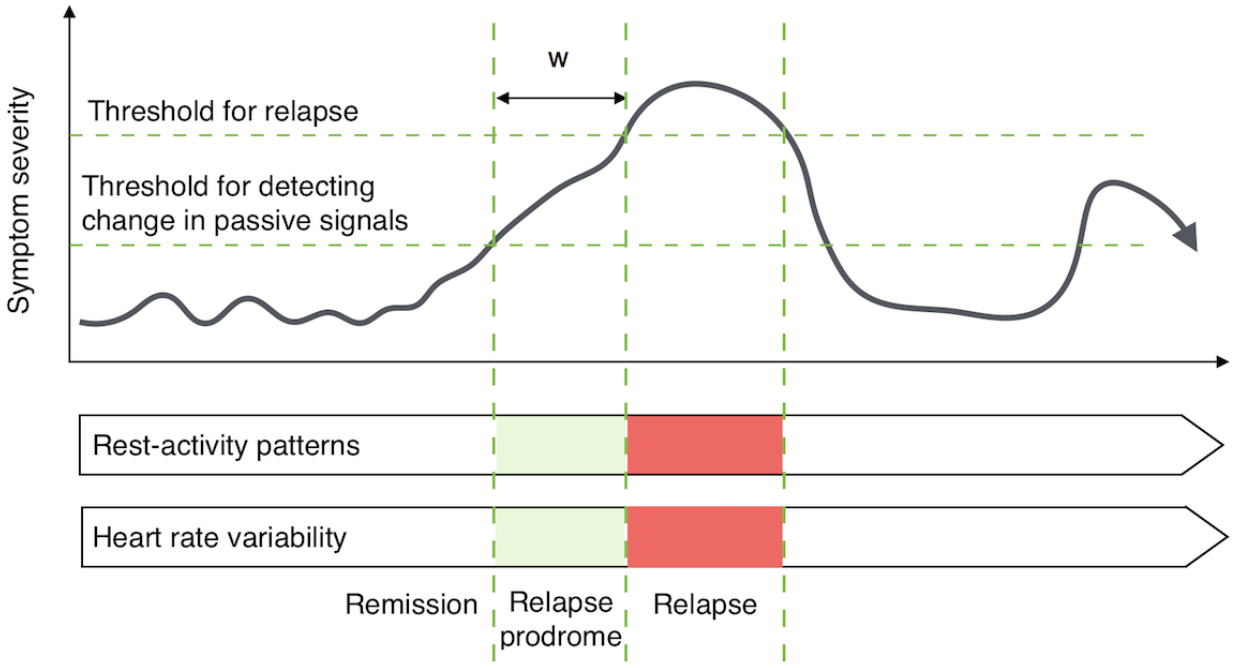
Recent advances in consumer wearable technology offer several advantages over actigraphy for the remote, continuous, and unobtrusive sampling of rest-activity patterns across phases of illness, in ecologically valid settings. Marketed as lifestyle devices for improving health and well-being, they are designed to be aesthetically and functionally appealing for everyday use, and might, therefore, be more compatible with extended use than currently available actigraphy. Worn on the wrist, such devices measure motor activity via accelerometry and some sample mean heart rate using photoplethysmography. Heart rate may provide an additional predictive signal as cardiovascular regulation also expresses a circadian oscillation [18], and increased mean heart rate [19] and reduced variability [20,21] have been associated with increasing severity of psychotic symptoms.

Crucially, most devices now communicate automatically and wirelessly with smartphones, thereby reducing the burden of data collection by allowing information to be uploaded over the mobile network and delivered to a researcher, clinician, or patient in near real-time. Some manufacturers provide an application programming interface (API), allowing researchers and software developers to access data directly from the company's servers. The average cost of consumer wearable devices is a quarter to a third of that of currently available research actigraphs.

Accelerometers, gyroscopes, ambient light, and other sensors within smartphones can also be harnessed to infer rest-activity patterns through the *passive* sensing of motor activity, geographical location, and phone usage, among other variables [22,23]. Touchscreen technology facilitates the *active* capture of self-rated measures of symptomatology [24] as well as the delivery of psychological interventions [25] and information for promoting self-management [26]. Smartphone ownership and mobile data coverage continue to expand in developing and advanced economies [27], and mobile phone ownership has increased among people living with mental illness [28,29]. mHealth approaches that employ wearable and smartphone technologies, therefore, show promise as innovative, cost-effective, and scalable "4P interventions" [30]—predictive, pre-emptive, personalized, and participatory—in the management of mental disorders in real-world settings.

Although several studies have explored the feasibility and acceptability of smartphone interventions in schizophrenia [24,26,28,31], wearable devices have received less attention. Studies using traditional actigraphy in schizophrenia have generally lasted in the order of several hours to days [15] to at most 28 days [7]. With regard to consumer devices, 1 study found good levels of adherence with a clip-on activity tracking device over a 6-month period in individuals with a range of psychiatric diagnoses, 8 of whom had schizophrenia-spectrum diagnoses [32]. However, these findings were in the context of promoting weight loss and physical activity and did not examine 24-hour adherence. Whether the longer-term, continuous use of wearable devices is acceptable to individuals with schizophrenia has not been studied. Schizophrenia is associated with paranoid beliefs and impairments in motivation and cognition, which may interfere with engagement with mobile and wearable technologies. Considerable challenges surrounding device validation and the regulatory and ethical frameworks for employing consumer devices in clinical contexts also exist [33].

Figure 1. A theoretical overview of the approach, where continuous passive variables that have been shown to co-vary with severity of psychopathology, including rest-activity profiles and heart rate variability, are captured using digital technologies (bottom). Disturbances in these variables may be detectable in the early stages of relapse (top), thus providing a window for preventative intervention (w).



The *Sleepsight* Study

This pilot study represents the first stage in an ongoing program of research for applying wearable and smartphone technologies for the identification of early signs of deterioration in schizophrenia, with a particular emphasis on passive sensing of rest-activity rhythms (Figure 1). The purpose of this paper is (1) to describe the user-centered development and implementation of a platform for sampling rest-activity profiles in schizophrenia; (2) to evaluate the feasibility, acceptability, and user experience of the system in outpatients with schizophrenia over an 8-week period; and (3) to provide preliminary evidence demonstrating that meaningful passive behavioral parameters and self-rated subjective data can be captured using the platform. The mHealth Evidence and Assessment checklist [34,35] developed through World Health Organization expert consensus for improving the generalizability and replicability of mHealth research was used as a framework for synthesizing and reporting this work.

Methods

Principles of Platform Development

The *Sleepsight* platform was developed through collaboration between patients, clinicians, bioinformaticians, and software developers, and it was guided by the following core principles:

1. User-centered design: People living with psychosis were involved throughout the development and testing cycle. Consultation groups consisted of patients who advised on the selection of wearable and mobile devices, the design of the software app, and aspects of the study design including recruitment strategy, feedback of data, and incentivization. The subsequent acceptability-feasibility study comprised a separate group of patients living in the community.
2. Integration with everyday life: Initial user-group testing with a range of currently available research wearables (GENEActiv, Activinsights, Cambridge, UK; ActiGraph GT9X Link, Actigraph corp, Pensacola, USA; Empatica E4, Milan, Italy) suggested that they would not be acceptable for extended use due to their design and limited functionality. To enhance acceptability and minimize user burden and stigma, widely available consumer-oriented technologies were therefore considered. The user groups favored the wrist-worn Fitbit Charge HR (Fitbit Inc, San Francisco) due to its appearance as a lifestyle device that is acceptable to both younger and older users and the ability to view metrics relating to sleep and activity via the Fitbit app.
3. Wireless functionality: The Fitbit provided wireless data transfer to a smartphone and allowed access to minute-level activity, sleep, and heart rate data via API calls to the Fitbit server [36]. As with all consumer devices, data are preprocessed on the device to minimize the volume of data transfer and maximize battery life, which precludes access to raw sensor data. The Fitbit required charging approximately every 5 days, taking around 2 hours, and was splashproof but not waterproof. An Android-based Motorola Moto G second-generation smartphone was selected due to its robust build quality, long battery life, relatively low cost, and easy-to-read 5-inch screen.
4. Remote and real-time: Each participant was provided with a 4G mobile data plan, which allowed data to be continuously uploaded to the research server and adherence with the wearable device, sleep, and symptom diary to be

monitored in real-time. Participants with a home wireless network could also upload data via this route.

5. Secure: Safeguarding privacy and data security was a cornerstone of the platform. Usernames were obfuscated using an MD5 hash algorithm [37], and data were encrypted and transmitted to the secure end point via the mobile network or participants' home wireless network. Data were cached on the phone until connectivity was available and cleared from the device following transmission. All participants received a unique identifier, and no personally identifiable digital information was stored or transmitted.
6. Open source software: Code for the platform architecture is publicly available to promote replicability, refinement of the software, and assessment of external validity through studies in other centers.

The *Sleepsight* Platform

Sleepsight was developed around the Purple Robot [38-40] mobile app (Centre for Behavioral Intervention Technologies, Northwestern University, Chicago, United States), which allows real-time data acquisition from a range of Android smartphone sensors and integrates with wearable devices (Figure 2). Purple Robot operates in the background, with no intervention from the user, and it was configured to sample the smartphone accelerometer and light sensors and access information about device battery level and the frequency of screen-unlock events (Table 1). Global Positioning System (GPS) location, call, or text message content were not captured in response to advice from the user group that this would be perceived as intrusive for many users. Purple Robot consolidated data from 2 further sources: the wearable device—via API calls to the Fitbit server multiple times a day—and the *Sleepsight* app. Data are uploaded to the researcher-facing dashboard, where circadian patterns in rest-activity variables can be visualized in real-time (Figure 3), and interruptions in the data stream are identified and acted upon.

The *Sleepsight* app [41] prompted the user, once a day at a time that was previously agreed with the study team, to complete a 30-second sleep diary (time to bed, time out of bed, and sleep quality) followed by a self-report symptom diary taking 2-3 min to complete. The purpose of the symptom diary was to provide an outcome measure of clinical status against which associations with passive sensor variables could be examined. Each complete submission was followed by a short motivational message (eg, "good job - see you tomorrow!"). The app also provided a help section with instructions on how to use the devices and contact information in case of difficulties.

Interoperability with existing local electronic patient clinical record systems was not supported at this stage, though future integration is planned.

Figure 2. Sleepsight platform architecture.

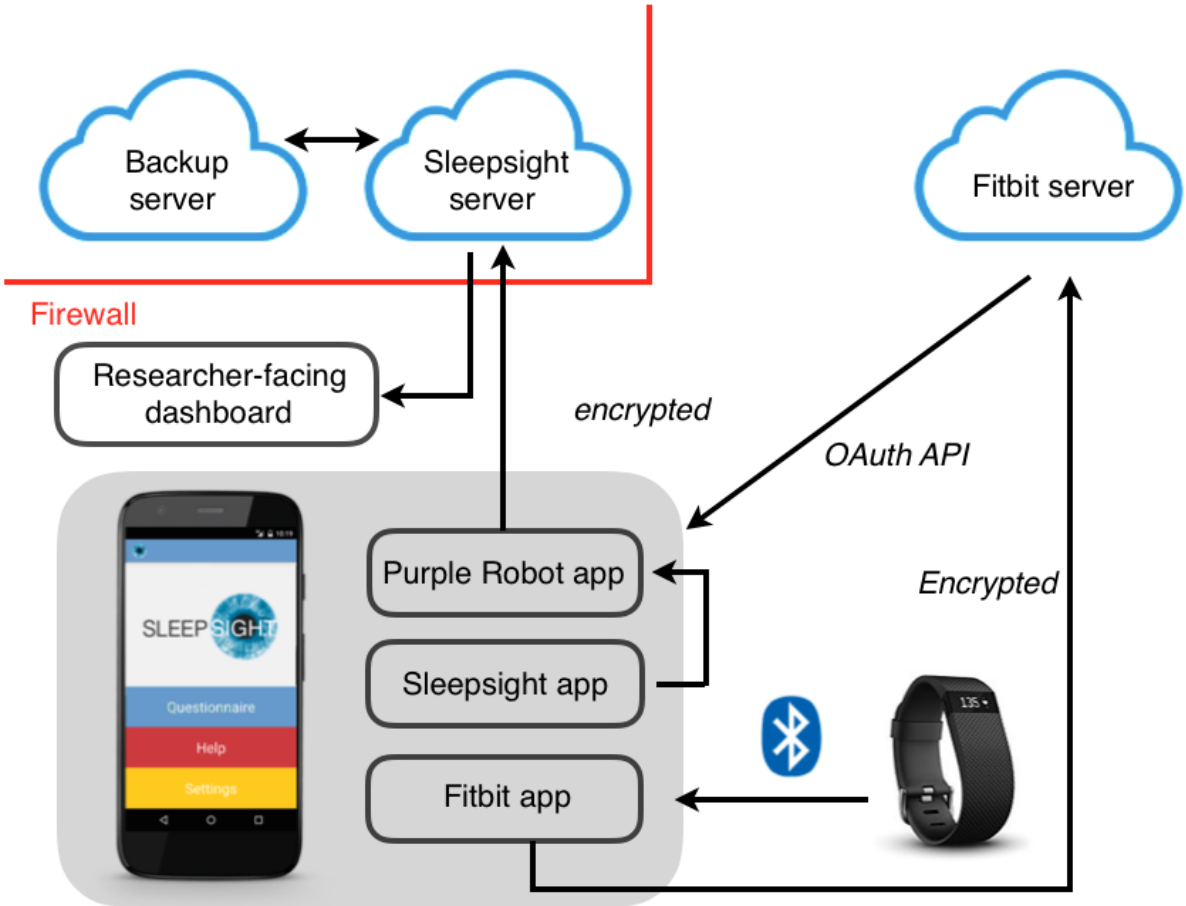
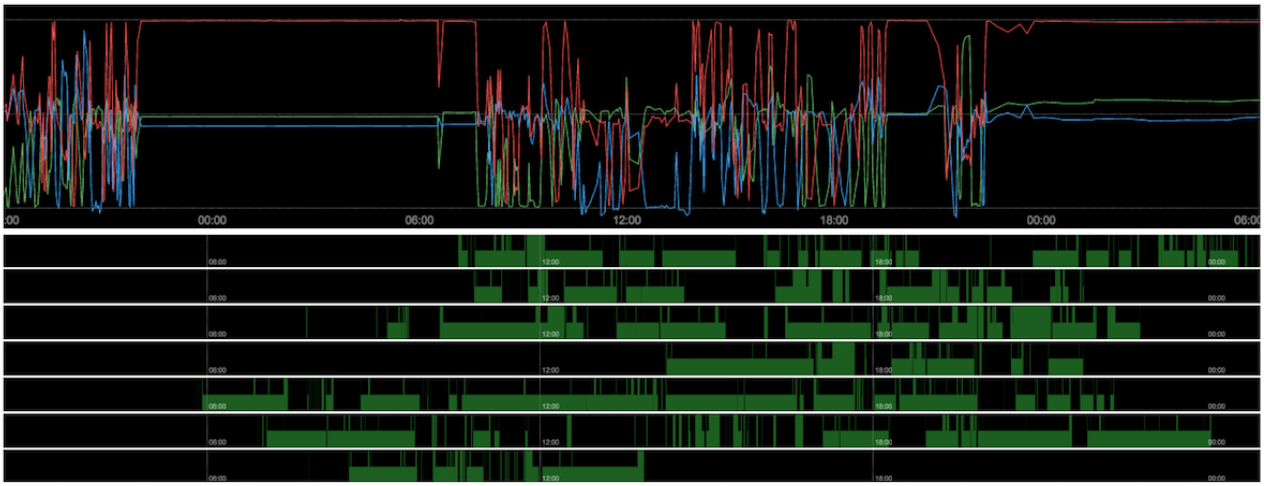


Table 1. Passive variables provided by the *Sleepsight* system.

Device and sensor(s)	Output from sensor(s)
Wearable device	
Tri-axial accelerometer	Raw data not available[a]
Photoplethysmogram (optical sensor)	Mean heart rate/minute
Smartphone	
Tri-axial accelerometer	Acceleration/g sampled at 10 Hz
Light sensor	Ambient light intensity/lux
Battery probe	Battery level and charging events
Screen event probe	Whether or not the screen was active

[a]Instead, several derived variables computed by Fitbit available: steps per minute; lightly, moderately, and very active minutes; sleep onset, offset, number of awakenings, and total sleep time.

Figure 3. Two sample variables from the researcher-facing dashboard for a single participant. Upper panel: accelerometer output from smartphone showing periods of rest-activity over a continuous 36-hour period; lower panel: smartphone screen state showing screen doze state (lower bars) and active screen state (upper bars) over 7 days.



Participants

A total of 15 adults with a diagnosis of schizophrenia were recruited through clinical teams from community psychiatric services in South London (Table 2). Inclusion criteria were ICD-10 criteria for schizophrenia, aged between 18 and 65 years, and capacity to consent to research; the criteria for exclusion were gross cognitive, sensory, or motor impairments that precluded the use of study devices. Participants were not selected on the basis of clinical status. Most had low-mild symptom intensity at baseline, as reflected in the total Positive and Negative Syndrome Scale (PANSS) scores; however, 2 participants were experiencing significant ongoing psychotic symptoms, with a PANSS positive subscale score above 20 (moderate intensity or greater on at least 5 of the 7 items). Overall, 8 participants had negative symptoms subscale scores of at least 20 (moderate intensity or greater on 5 of the 7 items) and 2 greater than 25 (severe intensity or greater on at least 5 items). All were receiving antipsychotic treatment, and 7 of the participants were prescribed clozapine, as indicated in the United Kingdom for psychosis that is resistant to other antipsychotics. A total of 8 participants lived alone and 7 lived with a spouse, children, or wider family. None of the participants were in regular paid employment. All participants owned a mobile device of their own, and just over half of the participants had a touchscreen device.

Study Procedures

Screening for eligibility and all clinical assessments were undertaken by an experienced psychiatrist (NM). Participants were asked to use the system continuously for 8 weeks, during this period, passive sensing and symptom rating variables were collected remotely.

On enrollment, informed consent and psychiatric, medical, and sleep histories were obtained. The PANSS, Pittsburgh Sleep Quality Index [42], Insomnia Severity Index [43], and Morningness-Eveningness Questionnaire [44] measures were completed. Participants were provided with the study devices and cables and adapters for charging, and a 4G mobile contract with 5 GB data allowance per month was also provided. Participants received an individual 45-min face-to-face training session, where the use of the smartphone, *Sleepsight* app, wearable device, and its synchronization were explained.

Table 2. Clinical characteristics of participants at baseline.

Clinical characteristics	Statistics
Sex, n (%)	
Male	9 (60)
Female	6 (40)
Age, mean (range)	44.1 (30-54)
Duration of illness in years, mean (range)	16.6 (5-33)
Mean Positive and Negative Syndrome Scale, (range, SD)	
Positive subscale	13.5 (7-23; 4.3)
Negative subscale	19.7 (8-36; 7.5)
General subscale	25.1 (16-40, 6.4)
Total score	58.4 (32-81; 14.4)
Medication, n (%)	
Clozapine	7 (47)
Oral antipsychotic	5 (33)
Depot antipsychotic	3 (20)
Mobile device ownership, n (%)	
Nontouchscreen mobile phone	7 (47)
Touchscreen smartphone	8 (53)

They were asked to wear the Fitbit on the nondominant wrist at all times, except for when bathing or swimming, and they were advised to charge the smartphone once a day when going to bed and to charge the device every 4 to 5 days. It was explained that the purpose of the study was to assess feasibility and acceptability; therefore, putative markers of relapse would not be monitored or responded to during the study.

In addition to the provision of a mobile data plan, it was explained to participants on enrollment that they would be given the option of keeping the wearable device and smartphone on study completion to provide an incentive for engagement and completion and compensation for their time. However, the equipment would remain the property of the research team for the duration of the study, and they would be asked to return them if they withdrew before study completion. This strategy was formulated with user groups, and it was thought to be a fair and appropriate approach.

The 8-week data collection period then began, and participants were free to use the smartphone for making calls, messages, and Web browsing. Participants were asked to use the study smartphone as their primary device, and where necessary, their pre-existing telephone number and personal information were transferred to the new device. Participants received a personalized encouragement text message once weekly, with the aim of promoting motivation and engagement with the research team, and participants were instructed not to perform any updates to the Fitbit firmware during the course of their participation. Data from each user were monitored on a daily basis. Where there was evidence of continued nonadherence for 2 or more days—for example, no signal from the wearable device—a text message prompt was sent to the participant, followed by telephone contact if necessary.

Outcome Measures

Feasibility was defined as the proportion of participants using each element of the system (wearable device, sleep log, and symptom log) for at least 70% of the 8-week study period. “Definitely feasible” was defined as ≥70% participants meeting the criteria; “possibly feasible” as 50% to 69% participants; and “not feasible” as <50% of participants. Removal of the wearable device was detected by the absence of the heart rate signal. In a test conducted separately (see Multimedia Appendix 1), absence of heart rate signal was found to be a highly valid proxy for nonwear.

The symptom diary items were developed and validated in schizophrenia in the Clintouch study [24] against the PANSS [45], and it consisted of items relating to mood, anxiety, hallucinations, grandiosity, and paranoia.

Acceptability and usability were assessed at the end of the study using a questionnaire conducted in person, adapted from previous studies [26] (Multimedia Appendix 1). Subsequent discussion of user experiences arising from the questionnaire was transcribed verbatim during the interview to further explore attitudes and individual experiences toward the technology.

Data Analysis

Quantitative analyses were undertaken using R software [46]. Associations between clinical parameters at baseline (PANSS positive score, PANSS negative score, and age) and adherence to wearable device, sleep, and symptom diaries were calculated using Spearman correlation coefficients for nonparametric data.

End-of-study questionnaires are reported descriptively. Interview transcripts were cross-checked for accuracy by a second researcher. Analysis of qualitative end-of-study user experiences

followed a grounded theory approach [45], using a coding frame based on major and minor categories emerging from the data, which were refined through discussion between 2 research clinicians.

Ethical approval was obtained from the Dulwich Research and Ethics Committee, London, United Kingdom. As a research study that did not alter routine clinical care and had no intention of commercialization, national regulatory approval from the Medicines and Healthcare Regulatory Agency was not required at this stage.

Results

Adherence and Feasibility

Of the 15 participants, 14 completed the study, with varying levels of adherence to each element of the system. One participant withdrew from the study at the end of week 1 due to finding the wearable device uncomfortable, particularly in bed, and returned the study devices. That participant did not report suspicion toward the devices as a cause of discontinuation and had a low total PANSS score of 47. Rather than adopting the study phone, 1 participant wished to continue to use her own smartphone, and it was therefore agreed that she would use this in parallel with the study device. The mean monthly data volume generated by the system per participant was approximately 1.1 GB, not including personal data use. One participant used the monthly data allocation within the first 3 weeks and was provided with an unlimited data plan for the remainder of the study. There was no loss or damage to devices.

For the wearable device, all the participants exceeded the 70% threshold for feasibility, with a mean wear time of 21.8 hours/day or 91% of the total study duration.

For the *Sleepsight* app, 93% (13/14) of participants met the feasibility criteria for completion of the daily sleep diary, with a mean average of 91% (51/56) of all possible questionnaires being completed. Moreover, 86% (12/14) of participants met the feasibility criteria for completion of the symptom diary, with a mean average of 88% (49/56) of all possible questionnaires being filled (Figure 4). Participants 4 and 14, whose sleep and symptom diary completion rates were at or below the feasibility threshold, scored 29 and 36, respectively, on the negative symptoms scale of the PANSS, consistent with negative symptoms in the severe range, and both had a history of treatment-resistant illness. Participant 4 received 4 further weekly top-up training sessions after reporting difficulties in completing the diaries and using the smartphone for making calls and sending text messages.

Spearman correlation demonstrated a significant negative relationship between PANSS positive score and sleep diary completion ($\rho=-.49$, $P<.05$) and symptom diary completion ($\rho=-.40$, $P<.01$). PANSS negative score was negatively correlated with wearable adherence ($\rho=-.49$, $P<.05$), sleep diary completion ($\rho=-.75$, $P=.001$), and symptom diary completion ($\rho=-.53$, $P<.05$). Associations between age and adherence with diaries and wearable device were nonsignificant.

Although adherence to the wearable device remained relatively stable throughout the 8-week study period, sleep and symptom log completion dropped off toward the latter quarter of the study, though remaining mostly above 70% (Figure 5).

Figure 4. Overall adherence to wearable device, sleep, and symptom diaries for each participant.

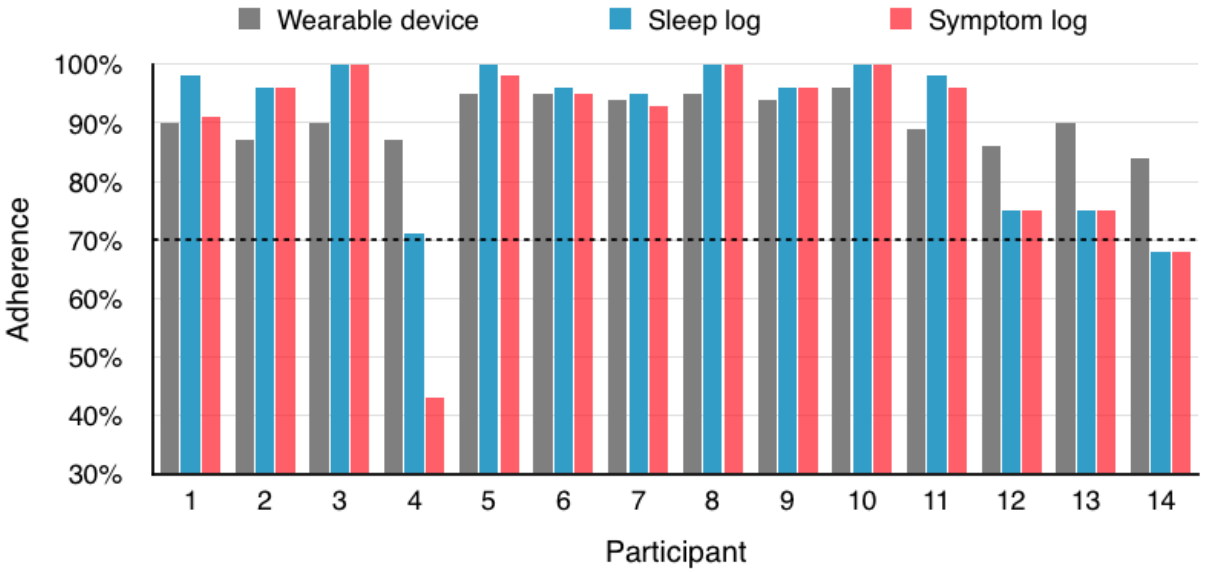
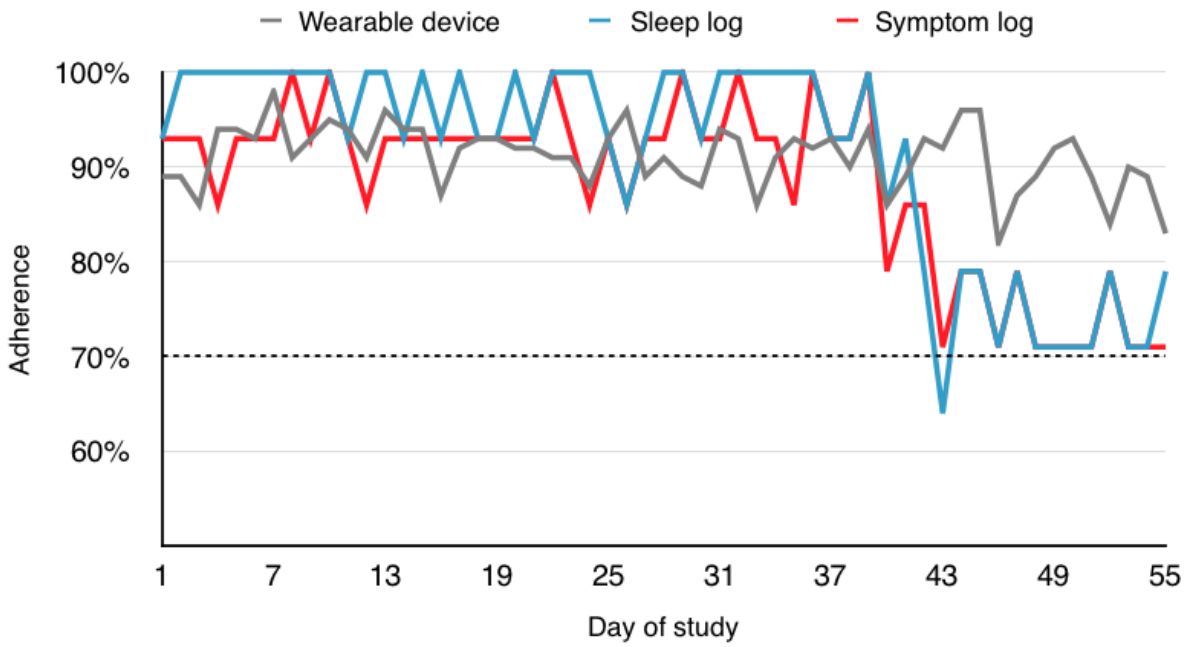


Figure 5. Mean longitudinal adherence to wearable device, sleep, and symptom diaries for all participants over the 8-week study period.



End-of-Study Acceptability and Usability Findings

Overall, responses to the end-of-study questionnaire relating to the *Sleepsight* system and each of its elements were positive (Multimedia Appendix 1). A total of 14 participants completed the end-of-study interview; the majority found the system to be easy to grasp and use, though 1 participant found it complicated. Moreover, 9 participants expressed a wish to continue using the system in its current state and 11 felt that sleep monitoring could be a successful strategy for the early detection of relapse.

All participants found the personalized encouragement text messages to be helpful in improving motivation. In addition, 10 users were motivated by the prospect of receiving devices at the end of the study, and a similar proportion of participants reported frequently using the Fitbit app to view their sleep and physical activity patterns. All participants expressed a wish to keep the study devices after the study had ended. Moreover, 3 participants reported feeling occasionally suspicious toward the technology and worried that their personal information was at times being monitored. However, this did not lead to discontinuation.

Of the 14 participants, 13 reported an inverse association between their sleep and mental well-being, and 12 of the 14 participants reported significant sleep disturbance around the time of their first episode of psychosis or subsequent relapse.

Further themes extracted from the end-of-study interview clustered around 3 major themes: attitudes and beliefs toward the concept of remote sensing for predicting relapse, factors relating to the technology, and factors relating to the users' illness in interacting with digital technologies.

Attitudes and Beliefs Relating to Remote Sensing and Relapse Prediction

All but 1 participant reported experiences of sleep disturbance as an important problem, either during periods of stability or around episodes of acute illness, and welcomed the emphasis on sleep as a possible predictor of deterioration. Many felt that measuring sleep patterns would be an important element of self-management and could imagine how psychological or pharmacological interventions delivered in the early stages of relapse could be therapeutic. Overall, 5 participants commented on how they would have concerns over false alarms—for example, whether sleeping poorly in the absence of deterioration in symptoms would trigger a response. One preferred the terms sleep "tracking" or "logging" rather than "monitoring," which held connotations of surveillance. Moreover, 4 participants felt that their engagement in the study was influenced by the knowledge that their data were not being analyzed and responded to in real time, and if this were to have been the case, they would have greater levels of engagement.

Technology-Related Factors

Half of the users commented that the wearable was at times uncomfortable: the strap would feel tight, which was particularly bothersome in bed. However, most of the users reported initial discomfort, which improved as the study progressed. One participant reported intermittent concern over radiation emerging from the optical heart rate monitor. There were no reports that the sleep metrics were inaccurate; however, 3 participants felt that the Fitbit overestimated step count. A third of participants found value in using the Fitbit for setting and attaining physical activity goals. Charging of the Fitbit or smartphone did not raise any concerns. Two-thirds of participants found that completing the daily symptom diary helped them reflect on mental state and gain greater insight into the links between their symptoms and behaviors, especially sleep. A sense of being

"acknowledged" as a specific consequence of using the symptom diary was reported by 3 individuals. Moreover, 2 mentioned how it encouraged family to be involved and became a focus for education. In addition, 6 participants stated that the symptom diary became repetitive and tedious, particularly when the users felt their symptom burden was low, and that if there were no incentive, they would be unlikely to answer the questionnaire on a daily basis. Two users found some questions difficult to understand. A wish to have greater flexibility in the timing of diary completion was raised by 2 users.

Illness-Related Factors

A quarter of participants expressed concern that adherence would diminish during relapse. First, users' cognitive function and therefore the ability to interact with the technology might decrease as symptoms escalate. Second, users may develop suspicion toward the devices, leading to discontinuation. Generally, users felt that the wearable device would be better tolerated in this scenario than the smartphone diaries.

Comparison of Subjective and Objective Estimates of Rest-Activity

Correspondence between self-reported (sleep diary) and objectively (Fitbit) determined daily time in bed for all participants showed good overall correlation (ρ=.50, *P*<.001 [2-tailed]). At an individual level, 10 out of 14 patients showed good agreement between subjective and objective measures, reaching the level of statistical significance (Figure 6). Participants 2, 4, 7, and 11 showed poorer agreement between measures, which for participants 4, 7, and 11 are likely to be due to the clustering of sleep diary estimates around the same value, suggesting that these participants gave stereotyped responses that varied little from day to day.

More detailed visualization of these data in 2 participants suggests that the Fitbit captured both within and interindividual variability in rest-activity profiles. Figure 7 shows circadian variation in heart rate signal in a middle-aged participant treated with clozapine who led an active social life, with a regular circadian rhythm entrained to the light-dark cycle, and a younger participant, treated with aripiprazole, who spent considerable time in the bedroom playing online computer games. This second case demonstrates a striking free-running non-24-hour circadian rhythm, with no correspondence to the light-dark cycle and progressive delay in sleep-onset—an observation that has been previously reported in a single case report [47]. Subjective sleep times collected via the sleep diary, shown in green, suggest a close correspondence between subjective sleep times and objective rest-activity profiles in these participants.

Figure 6. Comparisons of subjectively (sleep diary) and objectively (Fitbit) determined daily time in bed for each participant, fitted with robust bisquare regression to account for outliers. *, ** Significance at the .05, <.01 levels, respectively, for the 2-tailed test.

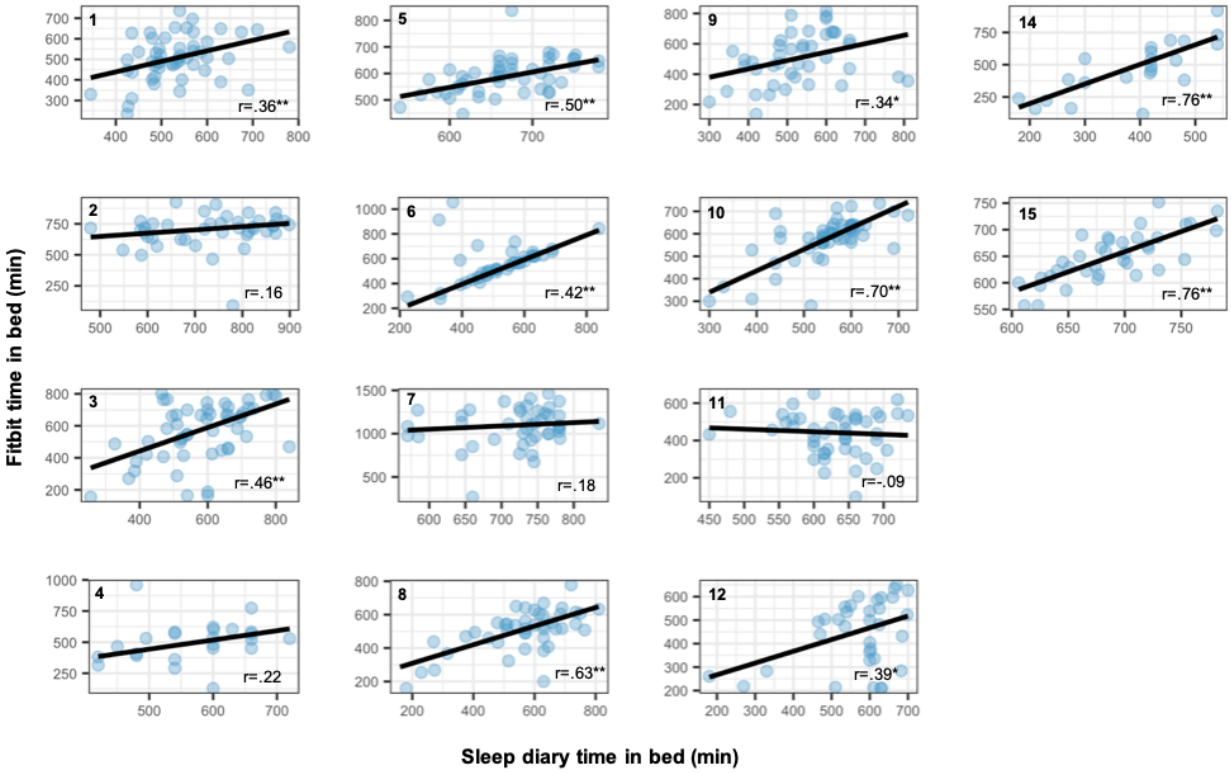
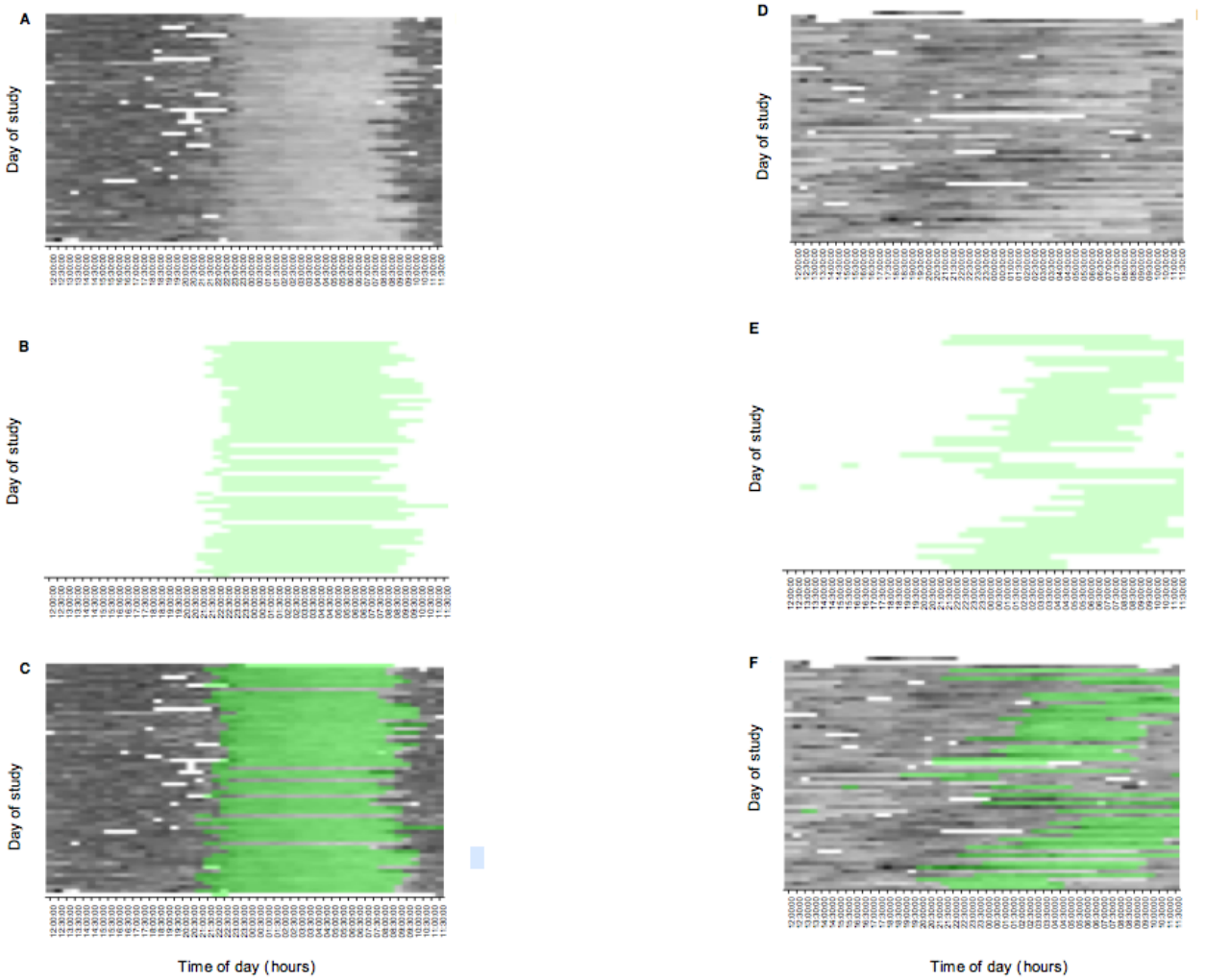


Figure 7. Rest-activity profiles from 2 participants—one with a regular rest-activity profile (A-C) and another with a highly variable, free-running circadian rhythm, not entrained to the day-night cycle (D-F). A and D: heart rate data from the wearable device, with darker shading indicating higher mean heart rate. B and E: subjective sleep times from sleep diary. C and F: subjective sleep times superimposed upon heart rate data (see main text for further details).



Discussion

Principal Findings

However sophisticated the engineering and analytic solutions, the success of digital interventions in improving clinical outcomes will depend crucially on whether they are adopted by patients for long-term use. We collaborated with patients in the design and deployment stages and asked participants with severe mental illness, under the care of secondary level psychiatric services with a range of positive and negative symptom severity, to use wearable and smartphone devices over 2 months in a naturalistic, ecologically valid setting. Our findings suggest that people with schizophrenia are enthusiastic about the concept of sleep disturbance as an indicator of relapse, and they are willing to adapt existing consumer technologies in managing their condition. Consistent with previous research examining smartphone interventions [26,28,31], we observed good levels of adherence with passive monitoring using wearable technologies over the study duration, across a range of ages and symptom severity. Adherence with active monitoring using smartphone diaries tended, however, to drop off toward the latter quarter of the study, suggesting that passive monitoring was more acceptable to users. This raises questions about striking the correct balance when integrating passive and active approaches, each of which have their strengths, and it also raises questions about how motivation with active monitoring can be maintained over time. In particular, users with significant negative symptoms experienced difficulties with completing the sleep and symptom diaries. Although some participants reported mild and intermittent suspicion, paranoia was not a cause of discontinuation. Similarly, there were very few concerns over data security and privacy, which may reflect the efforts that were made to build a trusting, collaborative relationship with participants.

Motivation and Incentives

The relatively high rates of adherence in this study may be attributable to the incentives that were offered. Though all participants reported this as a motivating factor, the majority also reported intrinsic interest in the system and wished to continue using it after the study ended. Nonetheless, enhancing engagement and motivation by providing users with information that they value is a key challenge for the field. Each user is

unique in which elements of the system they find engaging. Some participants may value feedback on physical activity, others on sleep duration, and others on their self-rated symptoms. Adaptable systems that can be tailored to each user may be a solution. Given that this was an observational study, we opted against providing explicit feedback of passive sensor or diary data, due to its liability to influence the underlying behavior we aim to examine; however, this may have reduced levels of adherence. Alternative approaches such as "gamification" [48] are attracting increasing interest.

Furthermore, promoting motivation by providing relatively low-cost mobile communication technologies, which many patients may otherwise be unable to afford, may have the added benefit of enhancing social interaction, communication with the care team, and functioning. In a clinical scenario, should mobile technologies be shown to be effective in reducing relapse, provision of equipment and a mobile data contract would represent a relatively insignificant financial outlay in comparison with the personal, social, and economic costs of relapse [49].

Cost is also an important factor in considering the scalability and reach of digital interventions. The cost of the Fitbit Charge HR was £100, the Moto G smartphone £140, and the mobile data plan £14 per month. The overall cost for consumables per user for the study was, therefore, £270, which equates to approximately just over half the cost of a day on an acute psychiatric ward [50] or the average cost of a monthly dose of paliperidone long-acting injectable antipsychotic medication [51]. As affordability and ownership of digital technologies grows in populations with serious mental illness [28,29,52], this approach has the potential to address the disparities in health care provision in underserved populations with serious mental illness globally [53].

Consumer Devices in Clinical Research

The use of consumer wearable devices in clinical contexts raises several important considerations. These devices are marketed as products that claim to enhance fitness and well-being, often supported by bold but unsubstantiated claims. Although some validation data are published from healthy populations showing acceptable agreement between consumer devices to actigraphy for some physical activity measures [54] and sleep [55] and with ECG for heart rate [56,57], no such data are available for populations with psychosis. Do these devices, therefore, have a role as tools for clinical prediction?

We suggest that they do, depending on the question being asked [58]. Our goal is not to draw conclusions about sleep parameters (eg, total sleep time, sleep efficiency) per se, for which the use of unvalidated devices would be inappropriate. Rather, our objective is to ask whether changes in longitudinal rest-activity patterns at the within-person level, captured using wearable device and smartphone sensors, predict deterioration in clinical status. The measurement error of these devices in healthy populations is comparable with that of actigraphy [54,55], and given the high level of noise inherent in free-living conditions, we hypothesize that should a signal exist, both consumer and research devices should be able to capture it. Comparison of subjective and objective estimates (Figure 6) and visualization of wearable data (Figure 7) suggest that consumer devices capture both inter- and within-individual variability in rest-activity patterns, and our subsequent work will primarily use within-person analyses to evaluate the association between these predictors and mental state, making calibration and interdevice reliability less of an issue.

Though we welcome further validation studies of consumer against gold standard devices, consumer devices follow a rapid product cycle, meaning they are rapidly superseded by newer models. Deciding on which device to study, and in which clinical groups, is therefore challenging. Another issue is the closed nature of these devices, due to reasons of intellectual property, manufacturers do not publish the algorithms through which activity and sleep outputs are calculated, and the researcher generally lacks control over the implementation of algorithm updates during the course of a study. In addition, preprocessing of data on the consumer device limits their granularity to minute-level data, at best. In turn, this might constrain the choice of subsequent analysis, for example, it is uncertain whether nonlinear patterns of motor activity [59,60] can be extracted from these data.

In navigating these challenges, greater collaboration between medical and consumer device manufacturers (each of whom operate a fundamentally different business model), researchers, and consumers will be necessary for driving innovation in this area. It is worth reiterating that research grade, wearable accelerometers that are acceptable for long-term use do not currently exist, and further research is urgently needed to evaluate the reliability and validity of consumer wearable and mobile devices as clinical tools [61]. Regardless of its accuracy, the clinical utility of a device will be limited if adherence is poor.

Limitations

This small pilot study was designed primarily to evaluate feasibility and acceptability in patients in remission, and at this stage, we are unable to draw any conclusions about its potential for identifying early markers of relapse or offer evidence of the validity of the signal from the wearable device. Our supplementary trial suggested that the absence of HR signal is highly correlated to nonwear; however, movement of the device may activate the HR sensor, and there remains the possibility that spurious readings were produced while the device is removed from the wrist. Participants were in a relatively stable phase of illness, and the influence of worsening psychopathology on adherence was not examined directly. Future studies should aim to test adherence over longer periods, in more unstable populations such as in the period following hospitalization [62]. Although a user group involving young people was consulted in the development phase, the field study did not include younger adults under the care of early intervention services. This group is particularly likely to benefit from early intervention strategies and also engage well with digital interventions. The name of the study, which emphasized sleep in psychosis, may have led to a bias toward the recruitment of participants who experienced difficulties with sleep, which may have improved acceptability. However, this also illustrates the importance of designing interventions that address clinical

problems, which patients perceive to be important, and framing them as such. We did not test the acceptability of collecting GPS location data, which recent studies suggest may be a useful feature in predicting clinical status in a bipolar disorder [63]. As rates of smartphone ownership among people with mental illness grow, the incentive value of providing patients with smartphones may diminish.

Conclusions and Future Directions

We found enthusiasm and high levels of engagement with passive monitoring in people with schizophrenia, which exceeded our acceptability thresholds, across a range of ages, symptom dimensions, and severity. However, mHealth technologies are unlikely to be acceptable to all patients, and it will, therefore, be important to further understand which groups are most likely to engage with and benefit from these interventions, while maximizing their reach by developing adaptable, tailored tools. An inherent property of participatory interventions is that they are likely to improve participants' outcomes and relapse risk, for example, by encouraging the user to reflect on their symptoms and monitor variables such as their sleep [64]. This has important implications in the design of future mHealth research and argues for studies that detect the improvement in outcomes in a randomized controlled design rather than a purely observational design.

A further under-researched area is how the adoption of digital interventions by health care professionals can be facilitated [65] such that clinical decision making is enhanced, rather than being perceived as an additional burden to an already busy schedule. Listening to the needs of clinicians in the co-design of technologies will be integral to their success, as will secure integration with existing medical record systems.

Extracting clinically meaningful information in real time from high-volume, multidimensional data represents another major challenge [66]. Although our interest focuses on circadian rest-activity profiles, combining additional sensor variables such as the ultradian organization of motor activity [12,59] and speech analysis [67] is likely to improve precision. The signature and optimal thresholds for relapse are likely to be different for each patient, and the inputs, sensitivity, and specificity of algorithms will, therefore, need to be tuned to each individual.

A long-term ambition of this approach is to enhance clinical care by identifying early signs of deterioration and thereby facilitate self-management and preventative psychological or pharmacological intervention. As research in this area continues to advance, future efforts should focus upon how clinicians, patients, technologists, and the industry can work together effectively to maximize the clinical utility, validity, and implementation of these novel tools.

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Authors' Contributions

NM wrote the manuscript and collected and analyzed the data; MK and DWJ analyzed the data; and MK, AF, RJ, and CK developed the smartphone app and data handling infrastructure. RD and JM provided study oversight. All authors read, contributed to, and approved the final manuscript.

Conflicts of Interest

RJ is an employee of AstraZeneca.

Multimedia Appendix 1
Responses to end-of-study questionnaire; validity of heart rate signal for adherence.
[PDF File (Adobe PDF File), 298 KB - mhealth_v6i10e188_app1.pdf]

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Abbreviations

API: application programming interface
GPS: Global Positioning System
PANSS: Positive and Negative Syndrome Scale

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Original Paper

Assessing the Attitudes and Perceptions Regarding the Use of Mobile Health Technologies for Living Kidney Donor Follow-Up: Survey Study

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Abstract

Background: In 2013, the Organ Procurement and Transplantation Network began requiring transplant centers in the United States to collect and report postdonation living kidney donor follow-up data at 6 months, 1 year, and 2 years. Despite this requirement, <50% of transplant centers have been able to collect and report the required data. Previous work identified a number of barriers to living kidney donor follow-up, including logistical and administrative barriers for transplant centers and cost and functional barriers for donors. Novel smartphone-based mobile health (mHealth) technologies might reduce the burden of living kidney donor follow-up for centers and donors. However, the attitudes and perceptions toward the incorporation of mHealth into postdonation care among living kidney donors are unknown. Understanding donor attitudes and perceptions will be vital to the creation of a patient-oriented mHealth system to improve living donor follow-up in the United States.

Objective: The goal of this study was to assess living kidney donor attitudes and perceptions associated with the use of mHealth for follow-up.

Methods: We developed and administered a cross-sectional 14-question survey to 100 living kidney donors at our transplant center. All participants were part of an ongoing longitudinal study of long-term outcomes in living kidney donors. The survey included questions on smartphone use, current health maintenance behaviors, accessibility to health information, and attitudes toward using mHealth for living kidney donor follow-up.

Results: Of the 100 participants surveyed, 94 owned a smartphone (35 Android, 58 iPhone, 1 Blackberry), 37 had accessed their electronic medical record on their smartphone, and 38 had tracked their exercise and physical activity on their smartphone. While 77% (72/93) of participants who owned a smartphone and had asked a medical question in the last year placed the most trust with their doctors, nurses, or other health care professionals regarding answering a health-related question, 52% (48/93) most often accessed health information elsewhere. Overall, 79% (74/94) of smartphone-owning participants perceived accessing living kidney donor information and resources on their smartphone as useful. Additionally, 80% (75/94) perceived completing

some living kidney donor follow-up via mHealth as useful. There were no significant differences in median age (60 vs 59 years; *P*=.65), median years since donation (10 vs 12 years; *P*=.45), gender (36/75, 36%, vs 37/75, 37%, male; *P*=.57), or race (70/75, 93%, vs 18/19, 95%, white; *P*=.34) between those who perceived mHealth as useful for living kidney donor follow-up and those who did not, respectively.

Conclusions: Overall, smartphone ownership was high (94/100, 94.0%), and 79% (74/94) of surveyed smartphone-owning donors felt that it would be useful to complete their required follow-up with an mHealth tool, with no significant differences by age, sex, or race. These results suggest that patients would benefit from an mHealth tool to perform living donor follow-up.

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KEYWORDS

follow-up; kidney transplantation; living kidney donor; mobile phone, mHealth

Introduction

Living donation accounted for over a quarter of all kidney transplants performed in the United States in 2016, with over 5500 people serving as living kidney donors [1]. Living donor nephrectomy, while generally safe for properly screened donors, is associated with long-term risks including increased rates of hypertension and end-stage renal disease in specific donor subgroups when compared to similarly healthy nondonors [2-6]. Donor follow-up and engagement are imperative to understand these donation-related risks and improve donor care management and counseling [7,8]. In 2013, the Organ Procurement and Transplantation Network (OPTN) began requiring all US transplant centers to perform living kidney donor follow-up for at least 2 years following live donor nephrectomy. Living kidney donor must complete both a clinical and laboratory component at 6 months, 1 year, and 2 years postnephrectomy. The clinical components include filling out a questionnaire that asks about vital status, working for income, readmission since the last visit, kidney complications, maintenance dialysis, developed hypertension, developed diabetes requiring medication, and cause of death if applicable. Laboratory components include urine protein and serum creatinine [9]. Despite this requirement, living kidney donor follow-up data continues to be missing and incomplete, as reported currently [2,10]. Documented challenges to collecting follow-up information include costs, donor inconvenience, and data collection burden [7,11-13]. The burdens of living kidney donor follow-up might be reduced for both transplant centers and donors by the use of mobile health (mHealth), which is the delivery of health services and resources through mobile devices such as smartphones [14]. As we advance and explore mHealth in solid organ transplantation [15], it is important to understand living kidney donor attitudes, perceptions, and willingness to use mHealth as part of postdonation care management.

Smartphone ownership in the United States increased from 35% in 2011 to 77% in 2016 [16], {, 2017 #9}and smartphones have changed the way patients and providers interact with the health system [17]. Outside of transplantation, mHealth has improved health care access, reduced costs, and increased self-management of chronic diseases in both observational studies and clinical trials [18-25]. Within the transplant community, single-center studies have examined the acceptability and effects of mHealth technologies among organ transplant recipients [26-30]. However, little is known about mHealth attitudes and perceptions among living donors, a distinct population that is generally healthier than the average US adult, without chronic conditions or regular interaction with the health system. After recovering from the donation, living donors may not view follow-up and further engagement with the transplant center as necessary [7].

To understand living kidney donor attitudes and perceptions about using mHealth for follow-up and engagement postdonation, we administered a telephone survey to donors who underwent living donor nephrectomy at our center. The survey included questions on smartphone use, current health maintenance behaviors, accessibility to health information, and attitudes toward using mHealth for postdonation care management.

Methods

Survey Design

The survey instrument was developed based on a review of the mHealth literature and pilot tested among clinical transplant providers, living donors, and researchers at our center. The final cross-sectional survey consisted of 14 questions: 4 on smartphone usage, 5 on health maintenance behavior, 3 on accessibility to health information, and 2 on attitudes toward using mHealth for living kidney donor follow-up (Multimedia Appendix 1). The study was reviewed and approved by the Johns Hopkins Medicine Institutional Review Board (NA_00044282).

Study Population

The study population consisted of 100 living kidney donors who underwent living donor nephrectomy at a large urban transplant center, The Johns Hopkins Hospital in Baltimore, Maryland, and agreed to participate in our study. These donors were part of a 25% (63/252) random sample of living kidney donors at our center (N=252) who had participated in a prospective longitudinal follow-up study, the Wellness and Health Outcomes of LivE Donors (WHOLE-Donor) study, and consented to be contacted for future research (WHOLE study N=1008) [31,32]. We aimed for a sample size of 98 participants based on power calculations to detect a 25% difference between 2 populations (alpha=.05, beta=.80, p1=0.60, minimum sample size N=98). We attempted to contact each individual in our random sample at most 3 times between March and April 2017 and surveyed a convenience sample of the first 100 living kidney

donors to agree to the study. The first 100 living kidney donors to agree to participate in the study and provide informed consent took the survey and were classified as participants, leaving the remaining 152 to be classified as nonparticipants.

Survey Administration

All contact and demographic information for participants was obtained from the WHOLE-Donor study, which is a longitudinal multicenter cohort of living kidney donors. Participants were read an oral consent form, and once consent was obtained, the survey was administered over the phone. Participants were first asked if they owned a smartphone; if they responded no (n=6), the survey was concluded, and no further questions were asked.

Statistical Analysis

To compare participants who perceived using mHealth for living kidney donor follow-up as useful to those who did not, we separated Likert scale questions into 2 categories. Participants who responded to these survey questions as "slightly useful," "moderately useful," or "extremely useful" were categorized as perceiving mHealth technologies as useful. Participants who responded to these questions as "not useful or useless", "slightly useless", "moderately useless", or "extremely useless" were categorized as perceiving mHealth technologies for living kidney donor follow-up as not useful.

We examined associations between participant characteristics and smartphone use and attitudes toward mHealth for living kidney donor follow-up using rank sum for continuous variables and Fisher's exact tests for categorical variables. All analyses were performed using Stata MP 14.2 for Linux (College Station, Texas, USA).

Results

Study Population

From a total of 252 living kidney donors contacted, 39.7% (100/252) participated in the survey, 5.9% (15/252) declined to participate, 7.1% (18/252) had incorrect or no contact information, and the remaining 47.2% (119/252) either did not answer the phone or asked to be called back at another time but were not recontacted before we reached our target sample size.

Of the 100 participants surveyed, 60 were female and 93 were white. The year of kidney donation ranged from 1988 to 2014, with a median (interquartile range [IQR]) of 10 (8-14) years from donation to the time of survey participation. The median (IQR) age of participants was 60 (51-66) years (Table 1). Participants in our study were more likely to be white than potential participants not included in our convenience sample (93/100, 93.0%, vs 126/152, 82.9%; *P*=.03), but there were no significant differences in age, years since donation, or gender of participants and nonparticipants (Table 1).

Smartphone Usage

Of the 100 participants surveyed, 94 owned a smartphone. All 6 participants who did not own a smartphone were male, 5 were white, and 1 identified as other race. The median (IQR) age of smartphone owners was 59 (range, 50-66) years, compared with the median (IQR) age of 63 (57-68) years for nonsmartphone owners (Table 2). Of the 94 participants who owned a smartphone, 35 owned an Android, 58 owned an iPhone, and 1 owned a Blackberry. Android owners were similar in age and gender but were more likely to be African American individuals (3/35, 9%, vs 1/58, 2%; *P*=.03) compared with iPhone owners, and there were no statistically significant differences in age or gender between Android and iPhone owners (Table 3).

All participants who owned smartphones used them for phone calls, 97% (91/94) for short message service text messaging, 95% (89/94) for internet browsing and accessing apps, 92% (86/94) for email, 67% (63/94) for social media, and 59% (55/94) for video calls. In addition, 32% (30/94) spent <1 hour per day on their smartphone, 51% (48/94) spent 1-3 hours, 13% (12/94) spent 4-6 hours, 3% (3/94) spent 7-10 hours, and 1% (1/94) spent more than 11 hours.

Table 1. Study participants' and nonparticipants' characteristics.

Characteristics	Participants (n=100)	Nonparticipants (n=152)	*P* value
Age (years), median (interquartile range)	60 (51-66)	58 (50-66)	.37
Years since donation, median (interquartile range)	10 (8-14)	11 (7-15)	.54
Gender, n (%)			.52
Male	40 (40.0)	59 (38.8)	[a]—
Female	60 (60.0)	93 (61.2)	—
Race, n (%)			.03
White	93 (93.0)	126 (82.8)	—
Asian or Pacific Islander	2 (2.0)	6 (3.9)	—
Black	4 (4.0)	17 (11.1)	—
Other	1 (1.0)	3 (2.0)	—

[a]Not applicable.

Table 2. Participant characteristics by smartphone ownership.

Characteristics	Not a smartphone owner (n=6)	Smartphone owner (n=94)
Age (years), median (interquartile range)	63 (57-68)	59 (50-66)
Years since donation, median (interquartile range)	13 (11-20)	10 (8-14)
Gender, n (%)		
Male	6 (100)	34 (36.2)
Female	0 (0)	60 (64)
Race, n (%)		
White	5 (83)	88 (94)
Asian or Pacific Islander	0 (0)	2 (2)
Black	0 (0)	4 (4)
Other	1 (17)	0 (0)

Table 3. Participant characteristics by smartphone type.

Characteristics	Android owner (n=35)	iPhone owner (n=58)	*P* value
Age (years), median (interquartile range)	62 (49-67)	59 (51-63)	.83
Gender, n (%)			.65
Male	11 (31)	22 (38)	—[a]
Female	24 (69)	37 (62)	—
Race, n (%)			.03
White	30 (86)	57 (98)	—
Asian or Pacific Islander	2 (6)	0 (0)	—
Black	3 (9)	1 (2)	—

[a]Not applicable.

Health Maintenance Behaviors

Of the 94 participants with smartphones, 90 had contacted a health care provider using their smartphone in the past year. All participants who had contacted a health care provider used phone calls. In addition to phone calls, 68% (61/90) used email, 37% (33/90) used short message service text messages, 24% (22/90) used some other medium, and 2% (2/90) used video calls. Of those who used some other medium, 96% (21/22) reported using the internet or apps to connect with a health care provider.

Overall, 85% (80/94) of participants who owned a smartphone were confident that they could maintain a healthy lifestyle, 13% (12/94) were somewhat confident, 1% (1/94) were not confident, and 1% (1/94) reported feeling unsure. In the prior year, 37 participants had accessed their electronic medical record on their smartphone, 38 participants had tracked their exercise and physical activity on their smartphone, and 24 participants had tracked their nutrition, or what they ate or drank, on their smartphone.

Accessibility to Health Information

In the year prior to study participation, 93 participants had asked a health-related question. Of those, 97% (90/93) had used their doctors, nurses, or other health care professionals to answer their question, 90% (84/93) had used the internet, 74% (69/93) had used friends or word of mouth, 50% (46/93) had used traditional news sources (defined as television, radio, and newspaper), 44% (41/93) had used social media or digital news, 31% (29/93) had used academic or medical journals, and 13% (12/93) had used other sources.

Overall, of participants who owned a smartphone and who had asked a medical question in the prior year, 47% (44/93) most often used their doctors or other health care professionals to answer the question, 38% (35/93) most often used the internet, 9% (8/93) most often used some other resource, 2% (2/93) most often used social media, 2% (2/93) most often used traditional news sources, 1% (1/93) most often used academic or medical journals, and 1% (1/93) most often used friends or word of mouth. When asked to choose the most trusted source of health information, 77% (72/93) reported their doctors, nurses, and other health care professionals; 10% (9/93) reported the internet; 5% (5/93) reported academic or medical journals, 4% (4/93) reported other, 2% (2/93) reported traditional news sources, 1% (1/93) reported friends or word of mouth, and 0% reported social media.

Table 4. Participant characteristics by perceived usefulness of smartphone living kidney donor follow-up.

Characteristics	Useful (n=75)	Not useful (n=19)	*P* value
Age, median (interquartile range)	60 (50-65)	59 (50-72)	.65
Years since donation, median (interquartile range)	10 (8-14)	12 (8-12)	.45
Gender, n (%)			.57
Male	27 (36)	7 (37)	—[a]
Female	48 (64)	12 (63)	—
Race, n (%)			.34
White	70 (93)	18 (95)	—
Asian or Pacific Islander	1 (1)	1 (5)	—
Black	4 (5)	0.0	—

[a]Not applicable.

Table 5.

Characteristics	Useful (n=74)	Not useful (n=20)	*P* value
Age (years), median (interquartile range)	58 (50-64)	63 (53-72)	.03
Years since donation, median (interquartile range)	10 (8-12)	12 (9-17)	.10
Gender, n (%)			.43
Male	26 (35)	8 (40)	—[a]
Female	48 (65)	12 (60)	—
Race, n (%)			.73
White	68 (92)	20 (100)	—
Asian or Pacific Islander	2 (3)	0 (0)	—
Black	4 (5)	0 (0)	—

[a]Not applicable.

Attitudes Toward Mobile-based Follow-up

When asked how useful it would be to complete some of their kidney donor follow-up on their smartphone, 33% (31/94) reported extremely useful, 31% (29/94) reported moderately useful, 16% (15/94) reported slightly useful, 10% (9/94) reported neither useful nor useless, 4% (4/94) reported slightly useless, 2% (2/94) reported moderately useless, and 4% (4/94) reported extremely useless. Those who perceived completing some of their living kidney donor follow-up on their smartphone as extremely, moderately, or slightly useful (75/94, 80%) were similar in age (median 60 vs 59 years, *P*=.65), sex (36/75, 36%, vs 37/75, 37%, male; *P*=.57), race (70/75, 93%, vs 18/19, 95%, white; *P*=.34) and number of years from donation (median 10 vs 12 years; *P*=.45) compared with those who did not find it useful (Table 4).

When asked how useful it would be to access living kidney donor follow-up information and resources on their smartphone, 35% (33/94) reported extremely useful, 31% (29/94) reported moderately useful, 13% (12/94) reported slightly useful, 11% (10/94) reported neither useful nor useless, 5% (5/94) reported slightly useless, 1% (1/94) reported moderately useless, and 4% (4/94) reported extremely useless. Those who perceived accessing living kidney donor follow-up information and resources on their smartphone as extremely, moderately, or slightly useful (79%, 74/94) were younger (median 58 years) than those who did not (median 63 years; *P*=.03) but were similar in sex (26/74, 35%, vs 8/20, 40%, male; *P*=.43), race (68/74, 92%, vs 20/20, 100%, white; *P*=.73), and number of years from donation (median 10 vs 12 years; *P*=.10; Table 5).

Discussion

Principal Findings

In this study of living kidney donor perceptions and attitudes toward the use of mHealth for postdonation care management, 79% (74/94) reported that it would be useful to complete some living kidney donor follow-up on their smartphone. This attitude was consistent across age, gender, race, and years since donation. Smartphone ownership was high (94/100, 94.0%), with the majority (58/94, 62%) of participants owning an iPhone. While 77% (72/93) of participants trusted their doctors, nurses, or other health care professionals the most to answer a health-related question, over half (48/93, 51.6%) most often accessed health information elsewhere. These results suggest that an mHealth system for postdonation care management might be welcomed by living kidney donors and also improve donor engagement by facilitating communication between living kidney donors and their transplant center.

Our findings of high interest in mHealth technology among living donors are consistent with prior single-center studies of transplant recipients and candidates. McGillicuddy et al found that 79% of kidney transplant recipients at a single center had a positive attitude toward mHealth for monitoring and managing their medical regimen, and 95% of dialysis patients surveyed at a single center on the kidney transplant waitlist reported interest in using mHealth to increase physical activity [26,27]. Our findings are promising for future engagement of living kidney donors with mHealth technology, despite generally not having prior chronic conditions and being less engaged with the health system.

Additionally, mHealth for living kidney donor follow-up not only has the potential to be useful for donors but also could aid transplant centers in meeting federal data collection and reporting requirements. Currently, more than half of US transplant centers are not able to meet the mandated OPTN policy for living kidney donor follow-up data collection and reporting [10]. Therefore, an mHealth platform that aims to both increase donor engagement and reduce transplant center burden may help with improved follow-up. Moreover, this mHealth system could be reasonably extended to capture survey and other follow-up data beyond 2-years postdonation and provide long-term data on donation-related sequelae.

Limitations

One limitation of this study is that all participants were from a single center, which may not provide the ability to detect more subtle relationships between attitudes toward mHealth technologies for living kidney donor follow-up and participant demographics. Additionally, our sampling method might have introduced selection bias. However, since this survey was administered as part of a larger ongoing cohort study, we were able to directly compare characteristics between participants and nonparticipants and found that participants in this study were similar to nonparticipants. While our sample size had a low number of African American and other minority individuals, which may have affected our findings, this does reflect national trends of living kidney donation. Finally, the median time since donation of our study participants was 10 years. The majority of these participants donated prior to 2013 when 2-year postdonation follow-up was mandated by the OPTN. Living kidney donors who donated their kidney before the current era of postdonation follow-up data collection and reporting requirements may be less inclined to perceive mHealth for living kidney donor follow-up as necessary; this might have underestimated our already high reported perceived usefulness of mHealth for living kidney donor follow-up in the broader donor population.

Conclusions

Overall, smartphone ownership in our study was high (94/100, 94.0%), and 79% (74/94) of participants perceived completing some living kidney donor follow-up on their smartphone as useful. These results suggest that patients would be willing to engage with an mHealth system for living kidney donor follow-up and benefit from the implementation of this technology. This work motivates future research to examine the feasibility of implementing such a system in US transplant centers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey questions and possible responses.

[PDF File (Adobe PDF File), 251KB - mhealth_v6i10e11192_app1.pdf]

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Abbreviations

IQR: interquartile range
mHealth: mobile health
OPTN: Organ Procurement and Transplantation Network
WHOLE: Wellness and Health Outcomes of LivE Donors

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Original Paper

Teleconsultation Using Mobile Phones for Diagnosis and Acute Care of Burn Injuries Among Emergency Physicians: Mixed-Methods Study

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Abstract

Background: The referral process in acute care remains challenging in many areas including burn care. Mobile phone apps designed explicitly for medical referrals and consultations could streamline the referral process by using structured templates and integrating features specific to different specialties. However, as these apps are competing with commercial chat services, usability becomes a crucial factor for successful uptake.

Objective: The aim of this study was to assess the usability of a mobile phone app for remote consultations and referrals of burn injuries.

Methods: A total of 24 emergency doctors and 4 burns consultants were recruited for the study. A mixed-methods approach was used including a usability questionnaire and a think-aloud interview. Think-aloud sessions were video-recorded, and content analysis was undertaken with predefined codes relating to the following 3 themes: ease of use, usefulness of content, and technology-induced errors.

Results: The users perceived the app to be easy to use and useful, but some problems were identified. Issues relating to usability were associated with navigation, such as scrolling and zooming. Users also had problems in understanding the meaning of some icons and terminologies. Sometimes, some users felt limited by predefined options, and they wanted to be able to freely express their clinical findings.

Conclusions: We found that users faced problems mainly with navigation when the app did not work in the same way as the other apps that were frequently used. Our study also resonates with previous findings that when using standardized templates, the systems should also allow the user to express their clinical findings in their own words.

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KEYWORDS

mobile phone; referral and consultation; emergency medicine; mHealth; teleconsultations; burns; usability evaluation; think-aloud; video analysis; South Africa

Introduction

The referral process between primary health care and specialized services remains challenging for several reasons, particularly in resource-constrained settings where specialists are in short supply. Inappropriate or delayed referrals result in inefficient use of resources, both financial and human, but more importantly, it may result in suboptimal care for patients [1].

Electronic referral and consultation systems have been suggested as a promising replacement for paper-based referrals [2,3]. Better medical decisions can be made as all relevant patient and clinical information is available to both the referring clinician and the specialist. Moreover, with electronic systems, the speed of communication and referrals is faster, and the quality of the information exchange is improved by using standardized templates compared with referral letters with illegible handwriting [3].

One area where over- and under-referrals are common is within burn injury care [4-9]. Two core components in the referral process of burn injuries are accurate diagnosis by the initial provider and the ability to effectively communicate these findings to a specialist for referral and management advice. Due to the visual nature of burn wounds, burn care has a tradition of utilizing image- and video-based telemedicine to enhance clinical practice and improve outcomes in patients [10-17]. In the past, telemedicine systems have relied on expensive and bulky infrastructure, which makes implementation difficult in resource-limited settings [18]. Furthermore, burn injuries are still a significant problem, especially in low- and middle-income countries [19]. For best possible outcomes in this group of patients, the decision on management and facility destination (whether to transfer or not) must be made in a timely manner. As burns are often difficult to assess by inexperienced doctors [20-25], remote assistance can be crucial for further management and final disposition. Inaccurate estimation of the size and depth of the burn can lead to over or under fluid resuscitation with adverse effects [26]. Therefore, effective consultation is paramount.

In recent years, as an ad hoc solution to the shortcomings in the referral and consultation process, communication via instant messaging using mobile phones has increased among health care workers. This is exemplified by the increasing reports on the use of chat services such as WhatsApp (WhatsApp Inc) for clinical consultations both within and between hospitals [27-32]. The use of such chat services has often evolved spontaneously from a need for more straightforward and faster channels of communication [33]. Benefits reported include shorter response time [34], flattening of hierarchies, and the ability to break down geographical barriers [35]. Areas in which the use of these chat services are particularly appealing are those with a prominent visual component [31,35], including diagnosis and management of acute burns [32,36]. However, there are some issues using services such as WhatsApp in medical practice. One drawback is that the information that is sent is less structured and often without patient identifiers, making it hard to keep track of which patient is being discussed [37]. In addition, the information including images will not be documented within the hospital information system [37]. Furthermore, despite some authors emphasizing the security of WhatsApp due to its end-to-end encryption [31,32,35,36], patient-related information including images is nonetheless stored on users' phones, and it is ultimately up to the user to delete messages when no longer needed. Another problem is that by default, WhatsApp saves images and videos to the users' photo gallery, and depending on the settings, images may be uploaded to other third-party cloud services. On the other hand, deleting messages makes it impossible for information to be audited in the future. There have been attempts to resolve these issues by developing apps intended explicitly for medical consultations [38-42]. Apps such as these can be tailored to contain a premade form to add demographic and clinical information, a chat function, and other features. This approach could allow for smoother consultations as the referring clinician will be prompted to provide the information that the consultant is requesting [3].

Regardless of the app being used, besides proper implementation, it is essential to assess user needs and their perceptions [43]. The most important aspect of technology acceptance and uptake among users is perceived usefulness—"the degree to which a person believes that using a particular system would enhance his/her job performance" [44]. Another critical factor, especially for continuous use, is ease of use—"the degree to which a person believes that using a particular system would be free from effort" [44]. The International Standards Organization (ISO 9241-11) defines usability as the "extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [45].

From our experience in implementing a mobile phone-based referral and consultation system for acute burn injuries in South Africa, uptake has been rather slow, where physicians still choose to call the burns consultant or send them a message via other general text messaging apps (primarily WhatsApp) [32,36]. For example, in a recent report from Cape Town, South Africa, WhatsApp was the preferred method for communicating clinical findings for pediatric burn care [36]. Although there are several reasons for the low uptake of new systems, usability is one important aspect to consider. Therefore, the aim of this study was to assess the usability of a mobile phone app for remote consultations and referrals of burn injuries.

Methods

The Vula App

Vula mobile is a mobile phone app for remote consultation and referrals between emergency doctors at point of care and specialists, which was developed by Vula Mobile, Mafami Pty Ltd. The app runs on both iPhone and Android operating systems, and it can be downloaded free of charge. The app was introduced to the Western Cape, South Africa, in 2014 and now allows for referrals to 15 specialties such as ophthalmology, orthopedics, dermatology, and burns. The app currently handles over 5000 referrals per month, with 62 specialist teams actively taking referrals on Vula. The ability to refer patients with burns was introduced in April 2016, and it handled around 250

referrals during 2017. The app provides a template for each specialty, including patient and clinical data (see Figure 1, screenshot 1). There are specific features related to each specialty, the ability to take photographs, and a chat function. The burns section of the app includes a feature to draw the burn on a depiction of a body, which will calculate burn size and fluid requirements (see Figure 1, screenshots 2, 3, and 4). This feature also allows the burns consultant to see the location, size, and depth of the burn. All the documented information including photos are only saved within the app and not saved elsewhere on the phone. The form and the features were established in collaboration with burns experts and emergency specialists before the development of the burns section of the app. When a referring clinician has completed the form, the information is uploaded to a secure server and shared with the burns specialist on call who will be notified. The specialist reviews the information on their mobile phone or computer and sends back treatment and referral advice either via predefined medical advice options or an instant messaging function. After the consultation is complete, the specialist can archive the referral, which will remove it from both the referring doctor's and the specialist's devices. Users are mandated to take the necessary precautions in accordance with the "South African Protection of Personal Information Act, 2013" and to act in accordance with national and local legislation. The user is prompted by the app to make sure that the patient has consented to data being stored electronically. As with any consultation, whether it is face-to-face or telephonic, both the referring doctor and the specialist have to make the appropriate medical documentation as mandated by the health care organization where they operate. In this study, participants assessed the app on their own device.

Participants and Setting

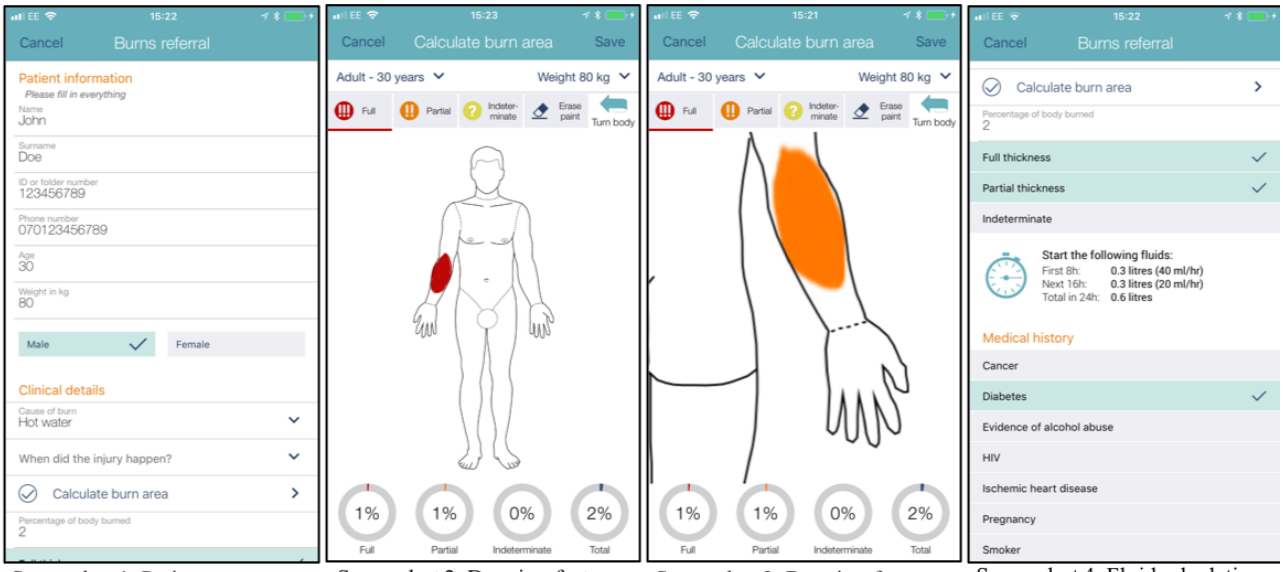
Cape Town has experienced rapid urbanization with a large part of its population living in suboptimal housing that is characterized by crowded living situations, lack of running water, lack of electricity, and houses built out of flammable materials [46]. It has a high burden of burn injuries, with an estimated mortality rate of 7.9 per 100.000 person-years [47]. In Cape Town, there are 2 hospitals with specialized burns units serving the Western Cape province. Depending on the burn severity and day-to-day capacity, patients can be treated at local clinics or referring hospitals. Furthermore, to improve referral of patients in the region, referral criteria have been implemented [48]. However, studies indicate that inappropriate or delayed referrals are still commonplace in this region [6].

This study was conducted in the emergency centers at 2 health facilities, 1 district hospital, and 1 health clinic in Cape Town. Participants were doctors sampled at the emergency center at Khayelitsha Hospital and Gugulethu Community Health Centre by convenience sampling. The primary focus of this study is on emergency doctors; however, an additional 4 of the burns consultants who were registered with the app were selected by convenience sampling and interviewed for the study to explore their view of the app. Although training is available upon request, no training is required to use the app. All participants had used the app for other specialties, and some participants used the app for burns consultations. Among the participants, 6 had never used the app for burns, 14 had used it less than 5 times, and 4 had used it more than 5 times. The burns consultants had all used the app for consultations at least 10 times before the interview.

Evaluation Methods

This study was a mixed-methods study including a qualitative approach using the think-aloud method and a questionnaire measuring different usability metrics. As the app is already in use, the goal of this usability study was to identify usability problems related to the Vula app to improve the existing app.

Figure 1. Screenshots of the user interface of the Vula app for burn injury consultations and referrals.



Screenshot 1: Patient information and clinical details.

Screenshot 2: Drawing feature (anterior side).

Screenshot 3: Drawing feature (posterior side).

Screenshot 4: Fluid calculation and medical history.

Think-Aloud Protocol

A think-aloud test was conducted with each participant to assess the usability of the app. The purpose of think-aloud protocols is to have users *think aloud* while performing a set of tasks. The users are asked to verbalize whatever they are looking at, thinking, doing, and feeling [49]. The think-aloud method is suitable to generate data on the cognitive processes when performing a set of tasks [49]. Participants were given a case description of a patient with 2 burn injuries on the right forearm, 1 on the back (posterior side), and 1 on the front (anterior side) (see Textbox 1). Each burn was equal in size and covered about 3% of the body surface, 1 full thickness and 1 partial thickness. The interviewer who acted as the patient had drawn on the arm with a marker to indicate location, size, and depth to facilitate an examination. The participants were asked to use the app as they would in a real situation. Descriptions of tasks for emergency doctors are shown in Table 1 and for burns specialist in Table 2. A camera (GoPro Hero4, GoPro, Inc, San Mateo, California) was mounted to each participant's chest to record their hands holding the mobile phone (see Figure 2). The interviews took place during their working hours in either an empty examination room or a break room. Interviews lasted for 10 to 20 min. Data collection took place during December 2016 and August 2017. During the second period of data collection, we extended the interview by going through the app once again where the interviewer asked about their thoughts on the different parts and asked further questions about specific problems encountered.

Questionnaire

At the end of the interview, the participants completed the previously validated Health Information Technology Usability Evaluation Scale (Health-ITUES) [50]. The Health-ITUES is a customizable questionnaire that subjectively measures the usability of eHealth tools. Each question can be customized to address the specific type of eHealth tool, the type of user, and the specific tasks that users are expected to perform using the system in a specified context. In this study, user=*emergency staff*, *tool*=app, *task*=management of burns, and *context*=emergency care services. The questionnaire covers 4 different domains: quality of work life, perceived usefulness, perceived ease of use, and user control. In total, the questionnaire contains 20 questions measured on a 5-point Likert-scale, ranging from strongly disagree (1) to strongly agree (5), as well as a *non-applicable* option.

Textbox 1. Case description of patient.

Weight: 80 kg

Sex: Male

Cause of burn: Spilled hot coffee (3% of the body surface, 1 full thickness and 1 partial thickness)

When did the injury happen: 3 hours ago

Medical history: Diabetes; Tuberculosis

Table 1. Tasks associated with the Vula app for referral doctors.

Task identification	Tasks associated with the Vula app for referring doctors
Task 1	Launch app from home screen
Task 2	Choose new referral
Task 3	Choose "Burns" in the list of specialties
Task 4a	Choose doctor on call at the referral facility
Task 4b	For first time users: Press the button saying "Yes, I am allowed to refer"
Task 5	Fill out patient information
Task 6	Choose cause of burn from list
Task 7	Select how long ago the burn injury happened
Task 8	Click on "Calculate burn area"
Task 9	On the "Calculate burn area" page, draw the burn on the picture and click save
Task 10	A box will appear with the fluid calculation, and percentage of the burn area will be displayed as well as burn depth.
Task 11	If applicable, select any of the conditions in the list under medical history
Task 12	Take one or more photos of the burn injury
Task 13	Add comments
Task 14	"Click refer" or "Save and refer later"

Table 2. Tasks associated with the Vula app for burns specialists.

Task identification	Tasks associated with the Vula app for the specialists
Task 1	Launch app from home screen
Task 2	Select the new referral from the list of referrals
Task 3	Review the information about the referral
Task 4	Go into “Send advice” page
Task 5	Select where the patient should be treated from the drop-down list
Task 6	Choose fluid resuscitation protocol
Task 7	Choose drugs to be given
Task 8	Choose recommended dressings
Task 9	Write further instructions if any
Task 10	Write your assessment of the total burn surface area
Task 11	Write your assessment of the burn depth
Task 12	Click “send advice” button (the user will be taken to the chat window where the selected information has been compiled into a message.)
Task 13	If necessary, chat with the referring doctor

Figure 2. User taking a photo of burn injury (left picture), and camera mounted to user’s chest (right picture).

Table 3. Usability themes and definitions.

Usability themes	Definition
Usability-related aspects	These codes are used to describe usability problems and issues identified when analyzing video usability data. The codes focus on aspects of the user interface and the user system
Usefulness of content codes	These codes are used to describe issues regarding the usefulness of the user interface or system being evaluated from analyzing the data
Safety- and technology-induced error codes	These codes are used to identify and tag errors made by users when analyzing data

Data Analysis

Video recordings were analyzed with MAXQDA (Version 12, VERBI Software, Berlin, Germany), a software for analysis of qualitative data. The program allows for analysis of both video and text. First, the audio recordings from the video were transcribed verbatim. In MAXQDA, this can be done using timestamps to have easy access to each audio and video segment that correlates with the text segment in the transcript. The videos can be analyzed by coding directly into the timeline when viewing the video. Content analysis with predefined codes developed by Kushniruk and Borycki was used for coding the data [51]. The codes cover 3 themes: usability, usefulness, and safety- and technology-induced errors (see Table 3). The coding scheme was adapted to suit this study, and codes were also added if findings did not fit the predefined codes. Conversely, some codes were omitted if they did not apply to the material. AK and SCF independently coded all interviews and discussed the labeling of each coded event. PYY worked in the final stage with AK to ensure the codes were accurately assigned to each scenario. The data from the questionnaire were analyzed using

descriptive statistics with SPSS (Version 23, IBM Corp, Armonk, NY).

Ethical Considerations

All participants were presented with both verbal and written information about the study before the interview, and written consent was obtained. Consent forms with participant identifiers were separated from the collected data. Data are presented on an aggregated level. The study was approved by the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee.

Results

Characteristics of Study Participants

Overall, 24 emergency doctors were included in the study, and all of them were working in the emergency department at the 2 different health facilities. Demographics of the study participants are presented in Table 4. Most participants were rotating, that is, they were on a short-term allocation to the emergency center. Experience in emergency care varied from 3 months to 7 years with a median time of 1 year. Participants rated their experience with burn care as either minimal (n=11), moderate (n=10), extensive (n=1), or none (n=2). The participants all used mobile phones for private and work purposes. The purpose of use was sending images, apps, or browsing the internet for reference on medical conditions, criteria, and drug dosage calculations. The mobile phones were also used to discuss cases with seniors using either instant messaging or voice calls.

Findings From Think-Aloud Sessions

All participants were able to complete all tasks with no major difficulties. However, several usability issues were identified. Usability issues were classified as either *usability problems*, *usefulness of content*, or *safety- or technology-induced errors*, as described in the Methods section (Table 3). Codes and frequency of problems encountered related to each domain in this analysis are presented in Table 5.

Usability-Related Aspects

The video analysis revealed 149 problems related to the usability of the app. Most of these problems were related to navigation, consistency, meaning of icons and terminology, and a lack of user instructions. The majority of the problems occurred in the section where the user is prompted to draw the burn on a depiction of a body (Table 1, Task 9). In this part of the app, the most prevalent problems were related to navigation, specifically to zooming and moving the picture.

Table 4. Demographics of study participants (N=24).

Characteristics	Participants
Gender, n (%)	
Male	12 (50)
Female	12 (50)
Age (in years)	
Median	27
Mean	27.63
Range	25-34
Experience in emergency care (in months)	
Median (SD)	12 (18)
Range	3-84
Experience in burn care, n (%)	
None	2 (8)
Minimal	10 (41)
Moderate	11 (45)
Extensive	1 (4)
Operating system	
iOS	15
Android	9

Table 5. Usability codes, definitions, frequency of problems, and number of users experiencing problems.

Code	Definition of code	Times usability problem occurred, n	Users experiencing problems (N=24), n (%)
Usability codes			
Consistency	Relates to aspects of consistency in the user interface	23	10 (42)
Font	Relates to aspects of font size or text readability	1	1 (4)
Graphics	Relates to aspects of graphics of the system	4	3 (13)
Lack of user instructions[a]	Relates to aspects of lack of user instructions	17	10 (42)
Layout	Relates to aspects of the layout of screens or information on those screens	6	5 (21)
Meaning of icons/terminology	Relates to aspects of understanding language or labels used in the interface	20	12 (50)
Navigation	Relates to aspects of moving through a system or user interface	30	14 (58)
Overall ease of use	Coded when the user makes comments of the overall ease of use of the system	27	9 (38)
Speed/response time	Relates to aspects of system speed or response time	1	1 (4)
Understanding instructions	Relates to aspects of understanding user instructions	5	5 (21)
Visibility of system status	Relates to aspects of understanding what the system is doing	15	11 (46)
Usefulness of content codes			
Accuracy/correctness	Relates to aspects of the accuracy or correctness of information or advice provided by the system	19	14 (58)
Overall usefulness[a]	Coded when a user makes comments on the overall usefulness of the system	5	3 (13)
Relevance	Relates to aspects of the relevance of information and features to the user carrying out their task.	30	13 (54)
Safety- and technology-induced error codes			
Mistake	Coded when a review of the data indicates the user has made a mistake that is not corrected	7	4 (17)
Slip	Coded when a review of the video data indicates the user has made a mistake but corrects the mistake	34	20 (83)
Work-around	Coded when the user is not using the approach to carrying out work that is recommended by the health care organization or computer system	8	8 (33)

[a]New code added to the original coding scheme.

The users often tried to move the picture using one finger instead of two, which resulted in accidental marks which had to be erased (Figure 3, point 6). The users expressed varying degrees of frustration when this happened. A few users mentioned that they did not see the textbox saying “Pinch to zoom, use two fingers to scroll” (Figure 3, point 2), which is related to the codes *lack of user instructions* and *understanding of user instructions*. This textbox is only visible when entering the page and disappears when the user starts drawing. Even if they said they saw it and knew they had to use two fingers to scroll, they would still use one finger out of habit:

> *So initially it took me a while. Just navigating was a bit hard, because I want to go there, want to move up, and then I kind of you know want to move. I know that you need to put two fingers I’m just not used to it.* [User 17]

Other problems in this section were related to the layout and meaning of icons and terminology. Some users did not see the erase button and as a work-around, they canceled and re-entered (Figure 3, point 4). A few users also did not see the button for turning the body around to display the back of the patient, resulting in the user drawing both burns on the same side (Figure 3, point 5):

> *And then also didn’t initially see that there is a turn body to do the other side.* [User 17]

Similarly, a few users did not know that it was possible to change the color to indicate different burn depths, indicating a lack of user instructions. There was also a problem with the system visibility in this part illustrated by the fact that users tried to press the buttons for burn depth even though they were already selected, which is indicated by a line right beneath the

button (Figure 3, point 1). Some users also thought the percentage indicators at the bottom of the screen were buttons to select burn depth (Figure 3, point 3):

> *I didn't see that you could change the color of the paint, I just used to write it in the description.* [User 22]

Some users were also confused about the calculation of the burn surface, and some users did not agree with the calculated percentage in relation to their perception of how big the burn was:

> *It's quite difficult to mark with like a finger, because I think with what I've drawn and what you have [on your arm] it's quite a difference, in that it looks like you have a bigger burn on the diagram than what you have.* [User 22]

Overall, most users found the drawing function to be a useful way to convey the information about burn surface and depth. However, a few users did not find it easy to use and suggested other ways of conveying the burn surface area:

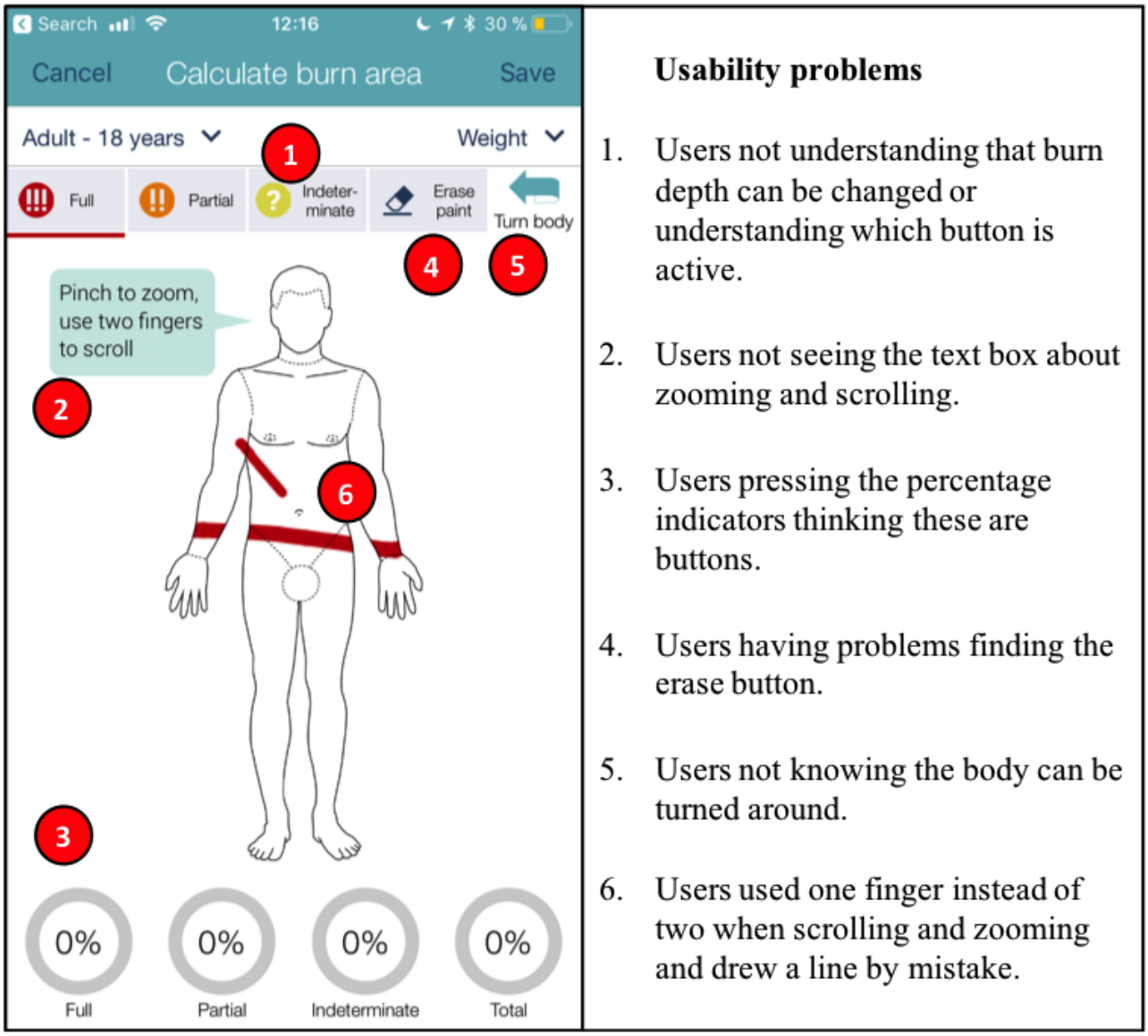
> *This is too difficult in my opinion because when you try to zoom and then suddenly it draws I'm not a big fan of this I'm not going to lie, I rather just work it out by myself [laughing] than use this.* [User 21]

Usefulness of Content

Many users had comments or experienced issues that related to the content of the app. These were either related to the relevance or accuracy or correctness. One re-occurring theme was that they often could not provide information that was asked for in the app, such as patient's phone number, weight, or time of injury:

> *...time of injury is obviously very very important, which I think also gets guesstimated quite a bit here in this area.* [User 13]

Figure 3. Usability problems identified in the drawing section.



The users did not indicate that any information asked for in the app was redundant. Instead, they suggested more fields or options to provide information in some areas that they thought would be relevant. For example, a section to provide the overall condition of the patient, such as other trauma, or a section where they could describe what management had already been undertaken:

> *I would rather like this part again to rather to be, type in because this is like limited choice.* [User 16]
>
> *I don't think there was a section that says what your management has been so far. I think that is quite helpful just to kind of let the other doctor know what you have done.* [User 17]

Some issues were related to the accuracy and correctness of some of the information. For example, some users had problems selecting the cause of the burn and were debating whether hot coffee should be classified as a hot liquid or as hot water. Although most users did not seem to struggle when choosing the cause, some discrepancy remains; while 8 users chose *hot water*, 16 chose *hot liquid*:

> *...ok cause of burn, I would choose hot water burn, coffee is basically hot water, but I find that a bit ambiguous* [User 2]

In addition, some users thought that the list of comorbidities was too limited. Many users suggested that there should be a free text field below each of these sections where they could provide more information.

After the user has finished and saved the drawing of the burn, a box with the fluid calculation is displayed. The users thought this was a useful feature, but some users noted that this was not relevant information, as they would not give intravenous fluid to a patient with a small burn like in the test scenario:

> *So, the one thing it doesn't speak about is whether you can use, so a minor burn like that I wouldn't necessarily go with IV-fluids.* [User 12]

Many users also talked about how the ability to send pictures was one of the most relevant parts of the app. Most users did not encounter any problems when taking the photos. However, one user thought that the app would automatically save photos to the phone library and was confused when he could not find them. Another user chose to take photos before starting the app and then import the pictures:

> *I'm going to add the photos from the gallery, because I have the photos already, ehm, so that's the, where is the picture now? Ok, seems I lost the images.* [User 1]

At the bottom of the form, there is a field for additional comments, which many users used to write a message to the consultant with information they thought would be relevant. These messages often included information that was already filled in, such as age and gender of the patient or the size of the burn. Many users also used this field to specify that the burn was the result of hot coffee.

Safety- and Technology-Induced Error Codes

This theme included slips, mistakes, and work-arounds. One of the most common issues was that users made a slip while using the drawing section. Although this did not cause any significant problems, the users found it frustrating. Only a few users made mistakes that they seemed unaware of making. One user selected an expert from the list that was not on call; during a real scenario, this could have resulted in no response. When using the drawing tool, one user only circled the burn without coloring it in, which resulted in a 0% calculation. The user manually typed in the percentage that the user estimated to be 9%. As some users did not know the body could be flipped around, these users drew both burns on the same side of the body, also resulting in a smaller burn area calculation. Slips, mistakes, and work-arounds were most of the time the result of an underlying usability problem such as understanding user instructions, meaning of icons or terminology, or visibility of system status.

Other Insights

During the think-aloud sessions, some users made comments about the app that was not specifically related to the design or functions of the app itself. For example, some users said they would not use the app on a small burn such as the one in the test scenario, that is, they did not find the app useful for smaller burns:

> *Since it's not a circumferential burn, I would consider admitting this patient to our surgical team and for them to debride the patient rather than referring the patient. So, I wouldn't refer the patient via the app.* [User 24]

Furthermore, when talking about their previous experience using the app, some users said that the specialists were slow to respond, and sometimes they would call them if they had not heard back from them in a while.

User Satisfaction

Questions and scores relating to each construct in the Health-ITUES questionnaire are presented in Table 6. In general, the app scored high on most of the constructs, with the construct "ease of use" scoring the highest. Usefulness also scored high; however, the questions relating to the ability to receive management advice in a timely manner tended to be lower (items 5, 10, and 12). The construct "user control" scored the lowest, especially the items relating to error prevention (item 18 and 19).

Interviews With Burns Consultants

A total of 4 interviews were also conducted with burns consultants who used the app to give diagnostic support to emergency doctors. The first screen the consultants see displays all information about the patient sent by the referring doctor. From this page, they can either go into "Send advice," "Chat," or review photos. Some consultants did not use the app in the way it was intended to be used; mostly they found it easier to initiate a chat with the referring doctor. In one case, the consultant was unaware of the send advice function. One of the participants said, in general, it is good with predefined options, but in this app, the options were not very useful:

> *It irritates me that I need to tell them the dose. So, if I choose morphine, I have to write the dose. That's standard protocol, the nurse or doctor should know this, or use another app, or it should be in this app.* [Consultant 1]

They all found the pictures to be very beneficial as they could then more accurately assess the burn depth and size. However, 1 consultant expressed that many doctors will not clean the burns or remove blisters before taking the pictures, which then made it harder for the consultant to be able to assess the burn. The consultant suggested there should be instructions in the app about this before the user takes a picture. One consultant seemed unaware that the referring doctor could take pictures within the app and would usually ask them to send pictures through WhatsApp instead.

Table 6. Health-Information Technology Usability Evaluation Scale (Health-ITUES).

Item	Concept	Score (1-5)	Cronbach alpha
Quality of work life		4.42	.76
1. I think the app has improved the emergency staff's ability to care for burns	System impact – career mission	4.67	__[a]
2. I think the app has been a positive addition to burn care at the hospital	System impact – organizational level	4.46	—
3. The app is an important part in the acute management of burns	System impact – personal level	4.13	—
Perceived usefulness		4.14	.92
4. Using the app makes it easier to receive expert advice on management of burns	Productiveness	4.5	—
5. Using the app enables me to receive burn management advice more quickly	Productiveness	3.70	—
6. Using the app makes it more likely that I have sufficient knowledge on how to manage acute burns	Productiveness	4.00	—
7. Using the app is useful for receiving information about burn management	General usefulness	4.13	—
8. I think that the app presents a more equitable process for burn management	General usefulness	4.38	—
9. I am satisfied with the app for receiving information on burn management	General satisfaction	4.13	—
10. I can receive information on burn management in a timely manner because of the app	Performance speed	3.88	—
11. Using the app increases receiving information about burn management	Productiveness	4.33	—
12. I am able to receive advice on burn management whenever I use the app	Information needs	3.88	—
Perceived ease of use		4.64	.74
13. I am comfortable with my ability to use the app	Competency	4.71	—
14. Learning to operate the app is easy for me	Learnability	4.63	—
15. It is easy for me to become skillful at using the app	Competency	4.67	—
16. I find the app easy to use	Ease of use	4.54	—
17. I can always remember how to log on and use the app	Memorability	4.67	—
User control		3.73	.55
18. The app gives me error messages that clearly tell me how to fix problems	Error prevention	2.67	—
19. Whenever I make a mistake using the app, I recover easily and quickly	Error prevention	3.87	—
20. The information (such as on-screen messages and other documentation) provided with the app is clear.	Information needs	4.33	—

[a]Not applicable.

Discussion

Principal Findings

Although the Health-ITUES questionnaire showed the usability to be satisfactory, the think-aloud evaluation revealed several important usability problems that should be considered for improvements for this particular app and for others planning to design apps for remote consultations.

Usability

Most issues occurred in the drawing feature, which is a central feature of the app that allows the users to describe the size, depth, and location of the burn. For the burns consultant, this information is of great importance when assessing a burn. Some users expressed frustration, and a few even said they thought this feature was too difficult to use. Conversely, many users said that this was one of the strengths of the app, suggesting it may be a central feature that is not present in other communication apps. The consultants also mentioned that being able to see the location of the burn visually is very important for them to do their assessment. This resonates with the findings by Blom et al in their study on expectations of burn specialists about image-based teleconsultation [52].

Given that the drawing function is one of the central features but at the same time where most users struggled, it calls for some reflection. Any extra added feature needs to be well justified, that is, increase the usefulness of the app, but at the same time, it needs to be easy to use, that is, free of effort. Rust et al argue that adding extra features may be attractive but could lead to a product that is overly complex with decreased usability, resulting in *feature fatigue* [53]. Considering these problems that the users encountered, we suggest that any extra feature be well justified (add value to the user) and be designed to be easy to use.

Other usability problems were related to the meaning of icons and their functionalities. Although design changes can improve these, it also demonstrates the importance of user testing with the intended users. Ehrler et al, who found similar issues assessing a mobile app to support nurses, suggest both design changes and also training to mitigate some of these problems [54].

Another finding related to the drawing feature was that some users did not agree with the calculation of the burn surface and said that they would have assessed the burn to be larger had they not used the app. It is well documented in the literature that nonburns specialists tend to overestimate burn surface area when visually assessing the burn [23,24]. One way to at least make it more apparent in the app would be to have the percentage indicated on each body part as a reminder of the burn surface area.

One critical part of usability testing of medical apps is to identify problems that could result in harm to the patient; for example, the fact that some users made mistakes that led to either a smaller or larger calculation of the percentage, which in turn could lead to adverse effects if this discrepancy is significant. This is one of the reasons why supplementing with photos is important so that the burns consultant can make their assessment of the burn.

Usefulness of Content

Although it is important that new technologies are easy to use, the usefulness of the content of a system is equally or even more important to end users [55]. Although the participants found the content to be useful in the app, many users thought that the app lacked some information or options. First, many users felt limited by the predefined choices and often wanted to describe more about the injury. For example, the medical conditions that are asked for in the app are limited to a few that are of interest to the burn specialist. However, some users thought this list could have been extended. In a similar vein, many users were also not sure whether hot coffee should be classified as *hot liquid, not water* or *hot water*. Both these options are meant to indicate that the burn was a scald. *Hot liquids, not water* is meant to represent what can be referred to as a dense liquid burn that is caused by liquids such as milk and oil [56]. In contrary to less dense liquids such as water, dense liquids will retain more heat and will adhere to the skin longer because of their higher viscosity. Therefore, such burn injuries may result in deeper burns. Although coffee or tea, for example, is not just water, it still has the same properties, which many users also mentioned. However, as one participant pointed out, if milk is added, this will change. In terms of the usability of the app, this relates to the meaning of icons/terminology, as well as information needs. At best, this may only cause confusion and irritation, but there could be instances where misunderstandings might have implications for the patient.

Despite a field for additional comments at the bottom of the form, some users suggested that there should be a possibility to specify with free text under each subsection when the options were too limiting. We did not further explore why some participants felt like this, but one explanation could be that at this point in the user test, they were unaware of the comment box that is located at the end of the form. A study by Hysong et al of e-referral systems reported similar findings where the primary health practitioners felt constrained by the use of templates and that they were not able to communicate findings clearly [57]. Similarly, in the tests with the burn consultants, some of them said they did not like the predefined options in their present form and would rather use the chat function instead. Hysong et al, on the other hand, found that specialists thought that more rigid templates with mandatory fields would enhance the quality of the referrals [57]. Other studies have found that feedback from consultants is more consistent and timely when referral templates are used [58,59]. One interesting finding regarding the comment box was that many participants used this to write a message to the specialist repeating much of the information already filled out. These messages would often be of a friendly nature including phrases such as “dear Dr” or “kind regards.” This highlights the fact that a consultation is not merely an exchange of information but also a collaboration that requires personal communication [60].

Our findings indicate that both emergency doctors and consultants wanted more flexibility within the system. Flexible systems can make it easier to transfer information about special

cases, reducing the need for additional phone and text communication. However, when designing a system, the need for flexibility must be balanced with the need for its usability. Although it might be tempting to design a system for every scenario to maximize flexibility, one needs to take into account that when the flexibility of a system increases, so does its complexity and consequently its usability. This is often termed the flexibility-usability trade-off [61], and when doing this trade-off, it is important to understand the users' needs, both present and future. This is, however, not always possible, especially with newer technologies. In addition, as acute burn injuries can manifest in different ways, it is difficult to design a template that will fit the clinical presentation of every single patient. Esquivel et al outlined 10 recommendations for improving the effectiveness of electronic referrals [3]. One recommendation that our findings support is to *design and use standardized electronic referral templates that include both structured and free text fields*. They argue that when designing electronic referral templates, there must be both structured fields to capture required information and free text fields for providers to freely expand on their clinical findings.

The usability tests with the consultants revealed that the 2 more experienced users found the "Send advice" function cumbersome and would rather just chat with the referring doctor. The 2 less experienced consultants seemed to be unaware of some of the functionalities in the app, such as the "Send advice" function or how to access the photos, suggesting that the user interface may not be clear for new users.

Significance of Findings

Although the participants in our study perceived the burns section of the app to be useful and easy to use, it is still not used on a regular basis. However, there are other reasons for low uptake that are not related to the usability of the app. These include, but are not limited to, awareness of the app, resistance to new technologies and attitudes among colleagues [43]. Even though traditional means of discussing and referring patients with burns by telephonic consultations and paper-based referrals are still prevalent, recent reports from South Africa have described the use of WhatsApp as a mode of communication for clinical decision support [32,36]. The fact that WhatsApp is very prevalent may be a reason why a specific app for medical referrals is not widely adopted. For the referring doctor seeking advice, the most important aspect will inevitably be to receive advice back from the consultant in a timely manner. Therefore, the consultants have an important role to play as pioneers for apps such as the Vula app. Nikolic et al note in their recent study that the widespread use of WhatsApp may impede the introduction of other communication apps designed for medical consultations [62]. Future research should focus on identifying the barriers to using mobile phone-based referral and consultation systems.

Methodological Considerations

The methods and equipment for data collection used in this study were simple, low cost, and allowed for quick data collection. None of the participants objected or showed any signs of being uncomfortable wearing the recording equipment. The video coding scheme was useful and covered most aspects. However, we changed the original definitions to cover both positive and negative aspects of the events and not only focus on problems. By doing this, the data generated more findings concerning things that the users liked about the app. We also added some codes that we thought were not covered in the original coding scheme. For example, *Lack of user instructions* was added as an extension to the code *Not understanding user instructions*.

During the think-aloud session, the interviewer tried not to interfere, except for encouraging the interviewee to keep talking. However, we found that the participants would mostly verbalize what they were doing but not what they were thinking and feeling. Consequently, during the second period of data collection, we extended the interview by going through the app once again where the interviewer asked about their thoughts on the different parts of the app.

Although the users rated the app to be easy to use, the think-aloud interviews found several problems related to the ease of use. This is not surprising as the purpose of a usability questionnaire is to assess the users' overall perception of the app and not identify specific problems. It is, however, useful for comparing different user groups, different designs of the app, or how user perceptions change over time.

As this was a mixed-methods study spanning both emergency burn care and health informatics, we think it was a strength that the authors come from different disciplines, including public health, political science, sociology, emergency medicine, nursing, and health informatics. Another strength of the study was the large number of participants in the user tests. A limitation was the relatively homogenous sample, where all users were young junior doctors. Sonderegger et al found that age affects several usability measures such as speed and accuracy [63]. Cillessen et al studied the user satisfaction of a clinical notes app and only differences by medical specialty but no differences by sex, age, professional experience, or training hours [64]. Nevertheless, our sample does represent the typical user from our study population.

Conclusions

Mobile referral and communication systems are a relatively new concept that could simplify the consultation and referral process within burn care and other specialties. However, when a new system is competing with other technologies such as instant messaging apps or traditional phone calls, usefulness and ease of use become highly important. Although the Health-ITUES questionnaire showed high satisfaction with the system, the think-aloud interviews provided additional insights for further improvements. The users liked the ability to describe the burns through both the built-in drawing function as well as with photographs. For the burn consultants, the drawings and the photos were considered the most valuable information for their assessment. We also found that users had problems with navigation in the drawing section when the app did not act in the same way as other apps that were frequently used. There was also some confusion regarding terminology and the meaning of buttons and icons. Our study also resonates with previous findings that when using standardized electronic consultation

and referral templates, the system should also allow the users to freely express their clinical findings in their own words.

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Authors' Contributions

AK, MH, PYY, and LAW contributed to the design of the study; AK, MH, PYY, and SCF contributed to the development of measurement tools; AK collected data and LAW assisted with logistics in the field. AK and SCF contributed to data analysis, and PYY assisted with unresolved codes. AK, SCF, and MH contributed to interpretation of the results. AK drafted the manuscript. All authors read, commented on, and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

Health-ITUES: Health-Information Technology Usability Evaluation Scale

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Review

Current Status and Future Directions of mHealth Interventions for Health System Strengthening in India: Systematic Review

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Abstract

Background: With the exponential increase in mobile phone users in India, a large number of public health initiatives are leveraging information technology and mobile devices for health care delivery. Given the considerable financial and human resources being invested in these initiatives, it is important to ascertain their role in strengthening health care systems.

Objective: We undertook this review to identify the published mobile health (mHealth) or telemedicine initiatives in India in terms of their current role in health systems strengthening. The review classifies these initiatives based on the disease areas, geographical distribution, and target users and assesses the quality of the available literature.

Methods: A search of the literature was done to identify mHealth or telemedicine articles published between January 1997 and June 2017 from India. The electronic bibliographic databases and registries searched included MEDLINE, EMBASE, Joanna Briggs Institute Database, and Clinical Trial Registry of India. The World Health Organization health system building block framework was used to categorize the published initiatives as per their role in the health system. Quality assessment of the selected articles was done using the Cochrane risk of bias assessment and National Institutes of Health, US tools.

Results: The combined search strategies yielded 2150 citations out of which 318 articles were included (primary research articles=125; reviews and system architectural, case studies, and opinion articles=193). A sharp increase was seen after 2012, driven primarily by noncommunicable disease–focused articles. Majority of the primary studies had their sites in the south Indian states, with no published articles from Jammu and Kashmir and north-eastern parts of India. Service delivery was the primary focus of 57.6% (72/125) of the selected articles. A majority of these articles had their focus on 1 (36.0%, 45/125) or 2 (45.6%, 57/125) domains of health system, most frequently service delivery and health workforce. Initiatives commonly used client education as a tool for improving the health system. More than 91.2% (114/125) of the studies, which lacked a sample size justification, had used convenience sampling. Methodological rigor of the selected trials (n=11) was assessed to be poor as majority of the studies had a high risk for bias in at least 2 categories.

Conclusions: In conclusion, mHealth initiatives are being increasingly tested to improve health care delivery in India. Our review highlights the poor quality of the current evidence base and an urgent need for focused research aimed at generating high-quality evidence on the efficacy, user acceptability, and cost-effectiveness of mHealth interventions aimed toward health systems strengthening. A pragmatic approach would be to include an implementation research component into the existing and proposed digital health initiatives to support the generation of evidence for health systems strengthening on strategically important outcomes.

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KEYWORDS

mHealth; telemedicine; health care system; India

Introduction

Background

Progress in the management of communicable diseases and reproductive maternal and child health conditions, combined with demographic transition, have caused a shift in the burden of mortality and morbidity to noncommunicable diseases (NCDs) [1]. In India, the contribution of NCDs to deaths increased from 37.9% in 1990 to 61.8% in 2016 [2]. The pauci-symptomatic nature and the long-term management and medication availability requirements force a change in the approach to NCD care delivery from facility-based service to domiciliary care, in which the consumer is not in constant contact with the health care system. Integrated care delivery is required using a risk factor–based rather than a disease-specific approach, with the need for periodic reassessment and treatment modification. Rural areas are at particular disadvantage due to the inadequacy and maldistribution of workforce and services.

Technological innovations present the possibility of turning a mobile device into a key component of health care delivery. Reduction in cost of handsets and increase in network coverage has led to a rapid expansion of mobile phone ownership in India. The number of mobile connections in India has grown to over 1 billion with 42% of the subscribers living in rural areas [3]. Out of 650 million active mobile users in 2017, nearly 300 million had a smartphone [4].

Mobile health or mHealth, defined by the global observatory for eHealth as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” is increasingly being used to support NCD care delivery [5]. Potential advantages include reducing response time by using trained nonphysician health workers, providing decision support, minimizing variability in the quality of delivered care, and optimizing monitoring and patient engagement, eventually reducing the cost of care and improving outcomes [6].

A number of initiatives that use mobile devices for delivering health care are currently being developed and implemented in India [6-9]. Given the considerable financial and human resources being invested in planning, development, and implementation of these initiatives, it is critical to ascertain their role in strengthening health care systems.

Objectives

We undertook this review to identify the published mHealth or telemedicine (provision of health care services using telecommunication technology) initiatives in India in the context of the health system building blocks and their potential for health systems strengthening. The review also presents the disease area, type of telecommunication device used, geographical distribution of the study sites, and target users of the innovation for these published mHealth initiatives in India. Finally, we highlight actions required for ensuring an effective role of mHealth interventions in strengthening the Indian health system.

Methods

Search Strategy

A search of the literature was done to identify mHealth or telemedicine articles published from India between January 1997 and June 2017. The electronic bibliographic databases and registries searched included MEDLINE, EMBASE, Joanna Briggs Institute EBP Database, World Health Organization’s (WHO) International Clinical Trials Registry Platform, ClinicalTrial.gov, IndMED, and Clinical Trial Registry of India. The key search terms used included device (smartphones, cell phone, mobile phone, tablet, personal digital assistant, laptop, personal computer); service (Interactive Voice Response, text message, global positioning system, videoconferencing); intervention (primary care, secondary care, tertiary care, disease prevention, disease control, disease management, risk factor control, telemedicine, and mHealth); diseases (NCDs, communicable diseases, maternal, and child health); and India. The list of subheadings (MeSH) and text-words used along with the detailed strategy used for searching the databases is provided as Multimedia Appendix 1. The information technology (IT) devices included computers, fixed-line phones, personal digital assistants, feature phones, smartphones, and wearables. Articles related to the health effects of IT devices were excluded from this review.

We included primary research articles (trials, quasi-experimental, pre- and postintervention, cohort studies, descriptive and analytical cross-sectional studies, exploratory studies, and protocols for trials or quasi-experimental studies); review articles (systematic and narrative reviews); system description studies (describing system architecture); case studies; and opinion papers. A database was developed using Microsoft Office Access interface, and information was abstracted in 2 stages.

Stage 1

Year of publication and disease focus were abstracted for all the selected articles. The disease focus was classified under (1) communicable, maternal, perinatal, and nutritional conditions and (2) NCDs, using the WHO global health estimates classification [10].

Stage 2

Research articles containing primary data were carried forward to the second stage. Data related to geographical location, devices used, intended target users, target health system domain, and type of mHealth app or tool used were extracted. Review articles, system description studies, case studies, and opinion papers that did not have specific information on the above-mentioned indicators were excluded at this stage.

The WHO health system building block framework was used to arrange the abstracted information under the following heads: (1) service delivery, (2) health workforce, (3) health information systems, (4) access to essential medicines, (5) financing, and (6) leadership or governance [11]. A framework developed by Labrique et al was used to classify the identified mHealth app or tool as per their types and uses [12]. We grouped all consumer-centric interventions by adding medical consultations offered through mobile technologies to the *client education and behavior change communication*. Health workers' awareness and perception of mHealth were included under *provider training and education*.

The Cochrane risk of bias assessment tool was used to assess the risk of selection bias, reporting bias, performance bias, detection bias, and attrition bias in randomized controlled trials (RCTs). Agency for Healthcare Research and Quality standards score was used to arrive at a composite indicator of quality (good, fair, and poor) for RCTs. Study quality was considered (1) "good" if it met all criteria (low for each domain, as per Cochrane risk of bias tool); (2) "fair" if the risk of bias was high for 1 domain or unclear for 2 and unlikely to have biased the outcomes; and (3) "poor" if 2 or more criteria had high or unclear risk of bias likely to have affected the outcomes. The quality assessment for observational cohort, pre-post and cross-sectional studies was done using the National Institutes of Health, US Department of Health and Human Services quality assessment tool [13]. Two reviewers (AB and OJ) independently assessed the quality of the selected evidence. Any discordance in the selection, categorization, or quality assessment was resolved by discussion. The quality of the systematic reviews was assessed using the AMSTAR 2 checklist. AMSTAR 2 is a measurement tool created to assess the methodological quality of systematic reviews.

Results

Search Results

The combined search strategies yielded 2187 citations. After removing duplicates, a total of 1303 articles were screened for their relevance. Following the title and abstracts screening, a total of 886 articles were filtered out for criteria related to country, language, and nonrelevance. A total of 417 articles were selected for full-text evaluation. Exclusion of 99 articles not having mHealth or IT as the primary intervention resulted in the final selection of 318 articles (Figure 1).

Figure 2 shows the distribution of the articles and disease focus. Approximately 44.6% (142/318) of the selected articles had an NCD focus; 14.8% (47/318) were directed toward the domain of communicable, maternal, perinatal, and nutritional conditions; and the remaining 40.6% (129/318) addressed cross-cutting topics. The first 10 years (1997-2006) saw only a small number of articles with a focus on the role of telemedicine in improving the health services through medical consultations and communication between the health care providers. A sharp increase was seen after 2012, driven primarily by NCD-focused articles.

Table 1 presents distribution of the type of studies published between 1997 and 2017, divided into 5-year periods. Out of the 318 articles, more than 25.8% (82/318) were opinion-based articles, followed by 21.7% (69/318) descriptive and analytical cross-sectional studies. Less than 3.5% (11/318) followed an experimental design that allowed evaluation of the impact of interventions on the health outcomes. Most studies published between 1997 and 2006 were case studies or opinion articles.

A majority of studies had been conducted in the south Indian states, with Tamil Nadu (27) and Karnataka (24) leading the list. Delhi (17) and Maharashtra (13) had the highest number of sites from the rest of the country. No articles were published from Jammu and Kashmir and north-east Indian states. Moreover, 7 published articles reported findings from multicentric studies. A map of India with the distribution of the study sites is available (Figure 3) [14].

Figure 4 shows the devices used in the studies. Personal computers (desktops, notebooks) and fixed-line phones were the most commonly used tools until 2011. Articles using feature phones and smartphones as a technology device emerged after 2012.

A total of 125 articles provided information about the end users of the tool. Physicians were the most frequent end users 44.0% (55/125), followed by patients 26.4% (33/125) and general community 10.4% (13/125). Only 6.4% (8/125) of the initiatives aimed at engaging community health workers.

Risk of Bias and Quality Assessment

Table 2 presents the risk of bias assessment for the selected RCTs. Overall, the methodological rigor of the included studies was poor. One study [15] had low risk of bias in all categories, whereas others had a high risk of bias in 2 or more categories. Moreover, 4 studies failed to provide enough information to allow assessment of risk of selection, performance, or detection bias (ie, unclear risk of bias).

Multimedia Appendices 2-4 provide details of quality assessment of the studies. More than 40% (44.8%, 56/125) of the cross-sectional studies had stated their research objectives or questions (Multimedia Appendix 2). Criterion related to description of the study population, demographics, clinical profile, and recruitment location was satisfied in 70% (48/69) of the studies. Sample size justification was not provided in more than 90% (62/69) of studies, with convenience sampling being the commonest approach. Only 15% (10/69) of the cross-sectional studies reported adjusting for potential confounders. Definition of the exposure (independent variables) and outcome measures (dependent variables) was present in approximately 60% (40/69) of the studies.

All the 4 cohort studies had stated their objectives and defined study populations (Multimedia Appendix 3). However, none of the studies had provided justification for the chosen sample size. All 4 studies used clearly defined, accepted methods for assessment of both exposure and control groups. Only 2 studies reported loss to follow-up.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

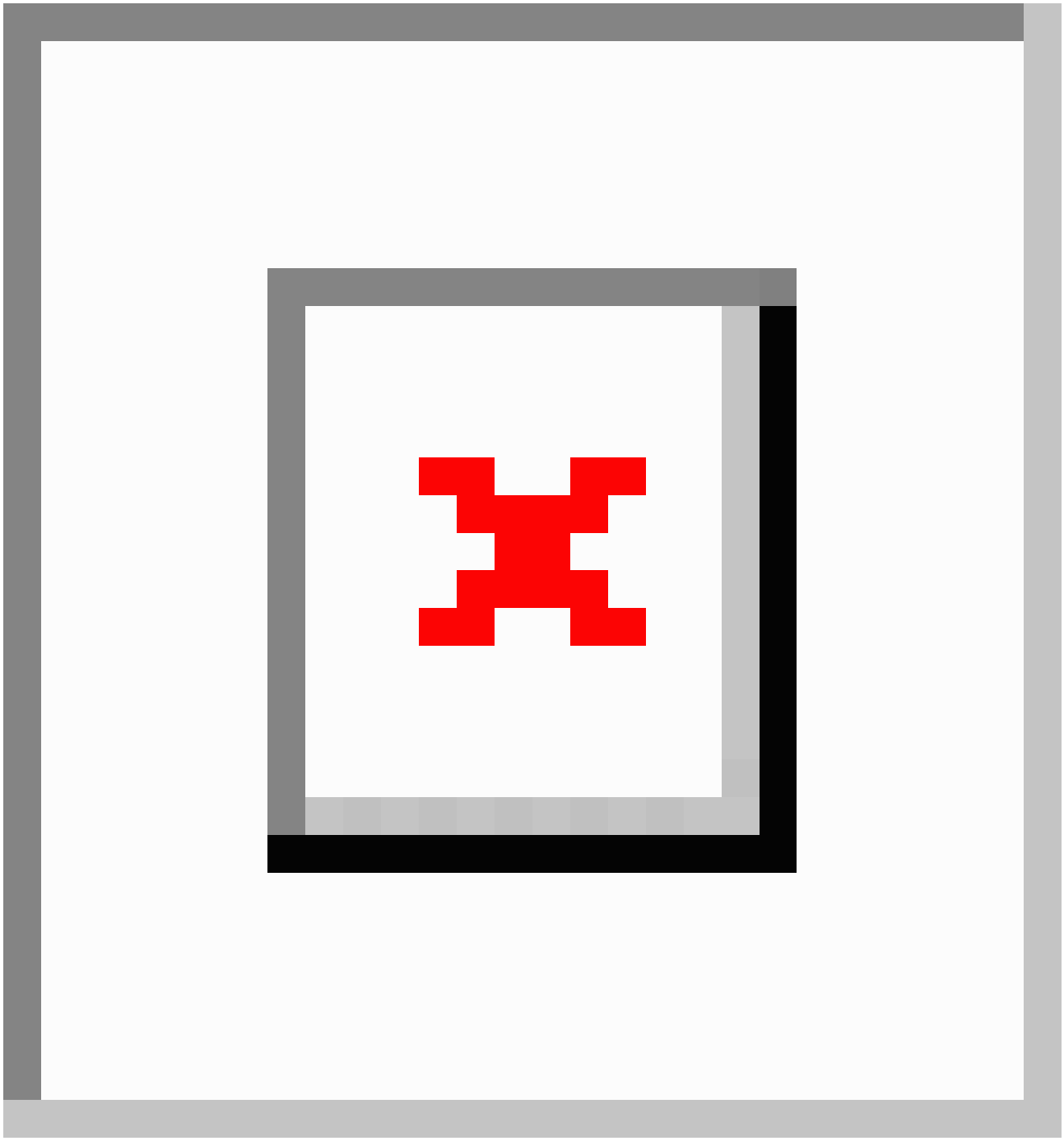

Figure 2. Year-wise distribution of the published articles and disease area.

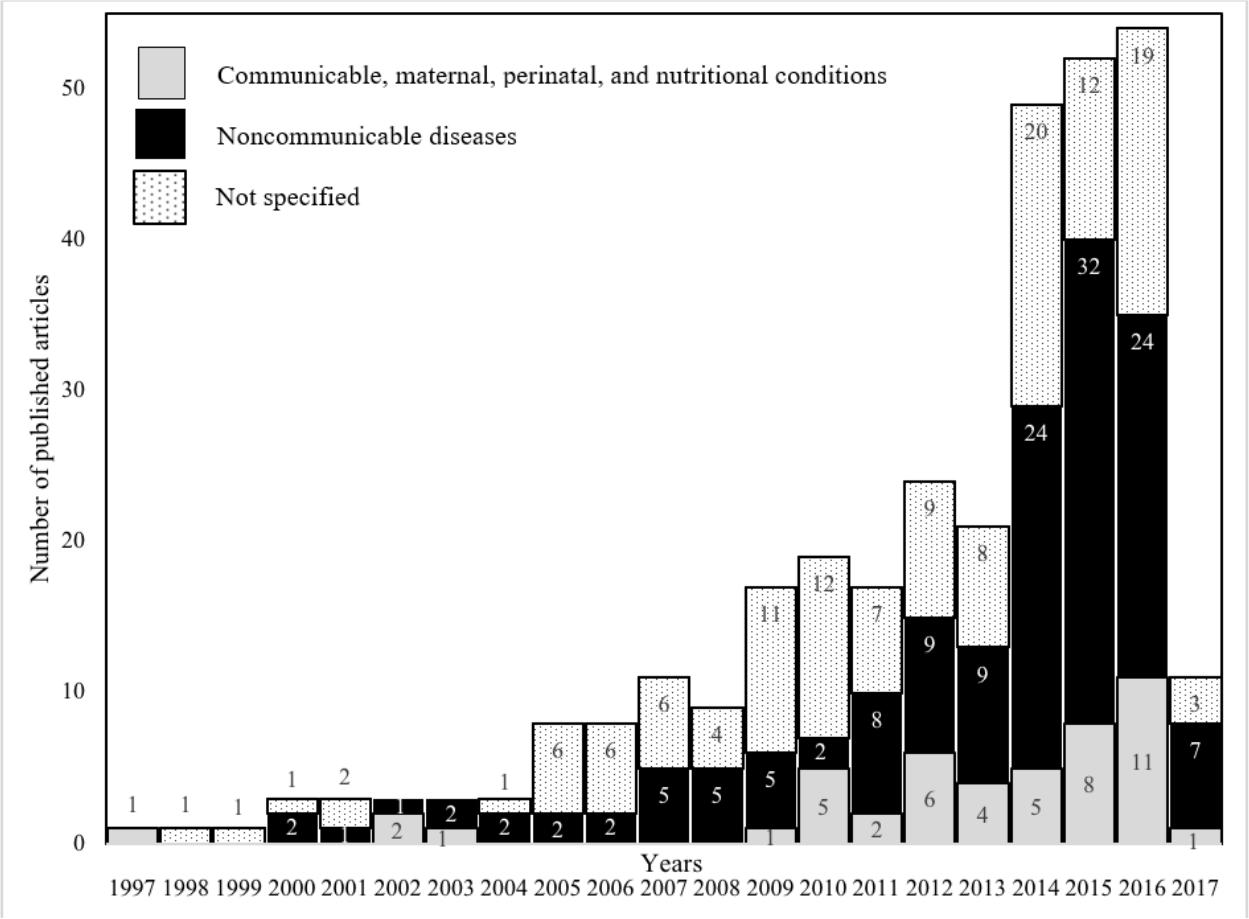

Table 1. Year-wise distribution of the type of published articles.

Serial number	Study type	Period in years				Articles, n (%)
		1997-2001	2002-2006	2007-2011	2012-2017	
1	Trials	—[a]	—	2	9	11 (3.4)
2	Quasi-experimental and pre-post intervention	—	—	1	8	9 (2.8)
3	Cohort study	—	—	—	4	4 (1.3)
4	Descriptive and analytical cross-sectional studies	—	4	12	53	69 (21.7)
5	Exploratory	—	—	5	21	26 (8.2)
6	Protocols (trials and quasi-experimental)	—	—	1	5	6 (1.9)
7	Systematic and narrative reviews	—	—	3	13	16 (5)
8	System architectural	—	—	7	39	46 (14.5)
9	Case study	2	8	19	20	49 (15.4)
10	Opinion article	7	13	23	39	82 (25.8)

[a]Not applicable.

Figure 3. Geographical distribution of the study sites (n=125). Map source: Ministry of External Affairs, Government of India.

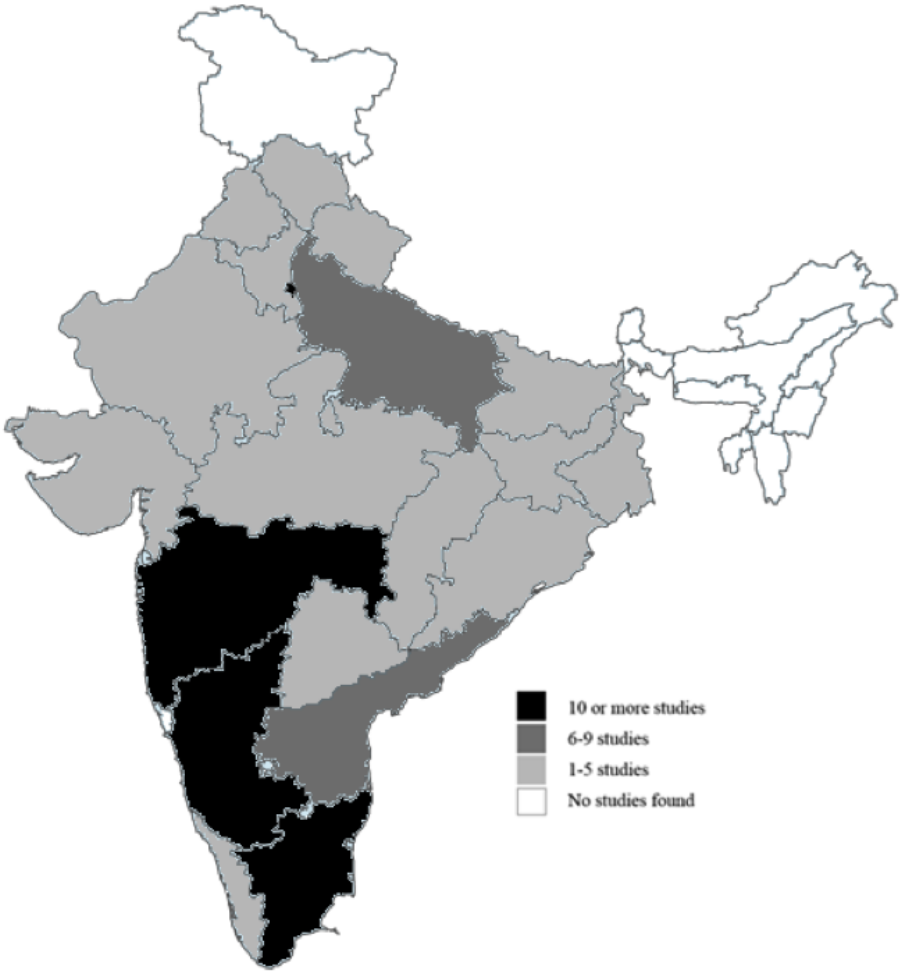

Figure 4. Changing preference of device used over time (n=125).

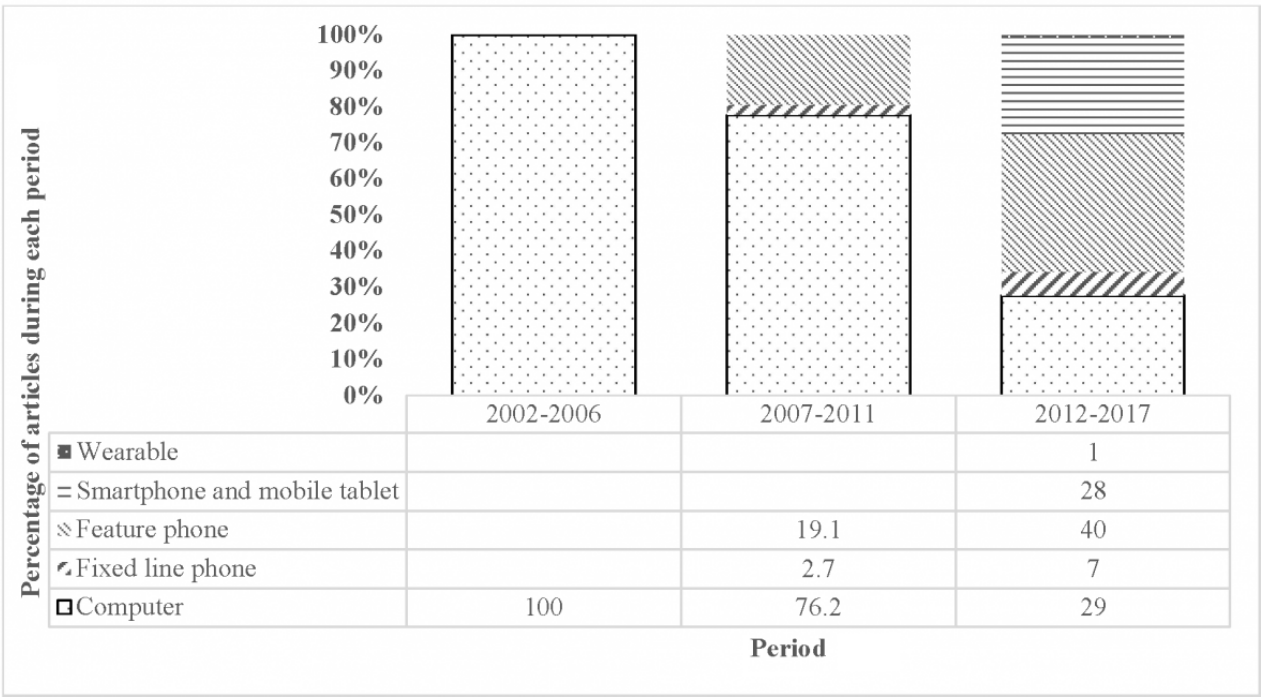

Table 2. Risk of bias assessment for randomized control trials.

Author	Random sequence generation	Allocation concealment	Blinding (participants and personnel)	Blinding (outcome assessment)	Selective reporting	Incomplete outcome data	Other sources of bias	AHRQ[a] score
Arora et al, 2017 [15]	Low	Low	Low	Low	Low	Low	Low	Good
Jain et al, 2010 [16]	Low	Low	High	Low	Low	Low	Low	Fair
Sharma et al, 2011 [17]	High	High	High	Unclear	Low	Low	High[b]	Poor
Prasad et al, 2012 [18]	High	High	High	Unclear	Low	Low	Low	Poor
Ramachandran et al, 2013 [19]	Low	Low	High	Low	Low	Low	Low	Fair
Radhakrishnan et al, 2014 [20]	Low	Unclear	High	High	Unclear	Low	Low	Poor
Shet et al, 2014 [21]	Unclear	Low	Low	Low	Low	Low	Low	Fair
Kaur et al, 2015 [22]	Low	High	High	High	Low	Low	Low	Poor
Kumar et al, 2015 [23]	Low	High	High	Low	Low	Low	Low	Poor
Patnaik et al, 2015 [24]	High	High	High	High	High	High	High[c]	Poor
Limaye et al, 2017 [25]	Low	High	High	Low	Low	Low	Low	Poor

[a]AHRQ: Agency for Healthcare Research and Quality.

[b]Contamination and source of recruitment of the study subjects are not mentioned.

[c]High and unequal attrition rates noted between the 2 study arms.

Table 3. Classification of the mHealth initiatives based on different health systems' building blocks and mHealth tools.

mHealth tools	World Health Organization health system building block classification					
	Service delivery	Health workforce	Medical products, vaccines, and technologies	Health information system	Leadership and governance	Total
Client education and behavior change communication	61	—[a]	—	1	1	63
Sensors and point-of-care diagnostics	2	—	11	—	—	13
Provider training and education	—	11	—	—	1	12
Provider-to-provider communication	5	5	—	—	—	10
Electronic decision support	3	5	1	—	—	9
Data collection and reporting	—	—	1	3	1	5
Registries or vital event tracking	1	—	—	4	—	5
Provider work planning and scheduling	—	4	—	—	—	4
Electronic health records	—	—	—	3	—	3
Supply chain management	—	—	1	—	—	1

[a]Not applicable.

Only 2 of the pre-post single group studies had a sufficient sample size, whereas others were feasibility studies with no sample size justification (Multimedia Appendix 4). Outcomes measures were defined in all, and 1 study had used a nonvalidated tool for outcomes measurement. Outcome assessor blinding was not reported in any of the pre-post studies. Quality assessment of the 2 systematic reviews revealed methodological flaws including a lack of risk of bias assessment (Multimedia Appendix 5 [26,27]).

Health Systems Building Blocks

The classification in Table 3 is based on the primarily targeted health system building block and mHealth tool. Multimedia Appendix 6 provides details of the multiple health system building blocks targeted by each article. A majority of these articles had their focus on 1 (36.0%, 45/125) or 2 (45.6%, 57/125) blocks, most frequently service delivery and health workforce. Approximately 16.8% (21/125) of the articles targeted 3 building blocks, and only 2.4% (3/125) of the articles had initiatives that had bearings on 4 building blocks of the health system.

Health Service Delivery

Nearly 57.6% (72/125) of the primary research articles had service delivery strengthening as a primary focus. Key activities covered included patient consultations, remote diagnosis, and follow-up through videoconferencing. Mobile phones were primarily used for treatment adherence reminders (text and Interactive Voice Response), appointment reminders, and behavior change messaging (n=8) [18,21,28-33]. Development process was described in 21 articles, 32 articles reported utility [16-25,30,31,34-57], and 20 articles reported user acceptability of the initiative [28,32,33,58-74]. Other aspects explored were technology-related perception of the end users (n=13) [29,75-85], patient satisfaction (n=2) [86,87], assessment of health care professional needs, and challenges related to health service delivery using IT (n=2) [88,89].

Health Workforce

Nearly 20.0% (25/125) of the articles had health workforce as the primarily targeted health system domain. Establishment of a provider-to-provider communication through teleconsultations, remote trainings, and capacity building was the most common health workforce strengthening activity. Objectives included reporting changes in the knowledge scores of the health care workers following tele-education interventions (n=11) [90-100] or a survey of mHealth or telemedicine-related knowledge, attitude, and practice among the health care professionals without any intervention (n=8) [16,101-108]. Articled describing use of mobile apps for screening, referral, guideline-based care, and provider work planning appeared only after 2013. Development and utility of community health worker-centric interventions that facilitated task shifting for disease screening, referral, and health information dissemination were discussed in 5 articles [109-113].

Essential Medical Products, Vaccines, and Technologies

Medical products and technology were the focus of 11.2% (14/125) of the selected articles, with nearly half relating to eye care [114-121], specifically using remotely operated technological tools for disease diagnosis (n=6) [115,118,122-125]. One study evaluated patient experience for health monitoring [126] and another evaluated a mobile-based vaccine management tool [127].

Health Information

In total, 8.8% (11/125) of the articles evaluated strengthening of the health information system, with focus on vital event tracking, disease surveillance, and case notification in rural areas [128-137]. Articles were mostly related to communicable diseases, maternal, perinatal, and nutritional conditions. One study evaluated mobile- and tablet-based systems for collection of data related to behavior research [138].

Leadership, Governance, and Financing

A total of 3 studies addressed leadership-, governance-, and financing-related issues. Finding the challenges related to the financing of the existing mHealth programs and the legal issues related to teleconsultations in India were the key objectives of these studies [139-141].

Discussion

Principal Findings

We describe, for the first time, the landscape of mHealth initiatives from a health system perspective from the second most populous country in the world that faces major challenges in health care delivery. The emerging evidence base around mHealth in India shows a progress from anecdotal telemedicine user stories to primary research articles, providing evidence on effectiveness in achieving the health objectives. The shift of focus of the mHealth initiatives over time toward NCDs is similar to the finding from China [142].

A notable finding was the concentration of mHealth solutions in a few states, with almost complete exclusion of the others, including some of the most underserved areas such as the north-eastern regions and Jammu and Kashmir, where mHealth might introduce great efficiency. A recent report by the Global Burden of Disease Study group pointed out at the heterogeneity of diseases and risk factors between Indian states [143]. Interstate variations in the structure and performance of health care delivery systems add to the challenge of last mile health care delivery. Therefore, it is important to test solutions in different states, especially the disadvantaged states that have the potential of experiencing the most transformative change.

The evolution in device choice may indicate changing consumer preferences in the contemporary mobile technology. However, the scientific basis for selecting these devices was not clearly articulated. Choice should take into account the technological know-how of end users, local health systems, nature of intervention, and availability of resources required to support the technology. The relevance of this knowledge becomes more important as these solutions are targeted to community health workers and patients to promote self-management and health promotion in communities.

Analysis in terms of the WHO health system building blocks revealed focus on service delivery and workforce strengthening, with relative neglect of health governance and health financing domains. Most of the reported mHealth interventions were being implemented as standalone solutions often with no health systems integration strategy. To reap maximal benefits, mHealth innovations should function as integrable tools that yield positive outcomes related to access, equity, quality, and responsiveness.

Client education, which increases access to health information, was the most widely used mHealth service delivery tool.

However, contextual background to the health information that was being provided to the clients was not provided in the articles we reviewed. Similar findings in terms of the mHealth tools used emerged from China [142].

While assessing the studies for the methodological rigor, we found the use of nonvalidated instruments (survey and questionnaire) to be common. Sample size justification was provided only in a minority of reports. Use of convenience sampling has been a cause of prevalent skepticism related to mHealth interventions [144]. Another major flaw was the lack of a proper experimental design that allows generation of high-quality evidence. This combination of use of narrowly focused interventions in relatively small populations using loose experimental designs raises serious questions about internal as well as external validity of these studies, and this led to the use of a derisive term "pilotitis" to describe these mHealth studies.

Limitations

Any review is only as good as the quality of the studies that are included. Studies published in biomedical literature only represent a subset of mHealth interventions as a fair number of studies are never submitted to academic journals. The mHealth apps that are available through the app stores were outside the scope of this review. Moreover, conducting a meta-analysis to provide estimates of clinical or cost-effectiveness was not possible due to the large differences in the methodologies used and outcome variables. Finally, while reporting the focus of the interventions, we used WHO's health system building blocks and selected the primarily targeted health system domain. Caveat for interpreting these findings is that a number of interventions would have a synergistic effect on other health system domains. For instance, any intervention that is focused on capacity building of the health workforce would not only have an impact on the "health workforce" building block but would also improve the quality of care, thus strengthening the "service delivery."

Conclusions

In conclusion, mHealth initiatives are being increasingly tested to improve health care delivery in India. Despite the widespread perception that health care delivery capacity could be rapidly scaled up for achieving universal health coverage by leveraging the expanding mobile communications networks and high ownership of mobile devices, the quality of evidence remains suboptimal. Robust scientific evaluation of effectiveness through appropriately designed and sampled studies powered on clinical end points is critical for establishing the on-field appropriateness of mHealth initiatives. Our review highlights an urgent need for focused research aimed at generating high-quality evidence on efficacy and user acceptability of mHealth interventions aimed toward health systems strengthening considering contextual factors and size and specifics of the problems being addressed. We need well-designed, cost-effective studies to help policy makers use the finite health budgets to ensure maximum health benefits. A pragmatic approach would be to include an implementation research component into the existing and proposed digital health initiatives to support generation of evidence for health system strengthening on strategically important outcomes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy for databases.

[PDF File (Adobe PDF File), 231KB - mhealth_v6i10e11440_app1.pdf]

Multimedia Appendix 2

Quality assessment for cross-sectional studies.

[PDF File (Adobe PDF File), 75KB - mhealth_v6i10e11440_app2.pdf]

Multimedia Appendix 3

Quality assessment for observational cohort.

[PDF File (Adobe PDF File), 30KB - mhealth_v6i10e11440_app3.pdf]

Multimedia Appendix 4

Quality assessment for pre-post studies.

[PDF File (Adobe PDF File), 30KB - mhealth_v6i10e11440_app4.pdf]

Multimedia Appendix 5

Quality assessment of systematic reviews (AMSTAR 2).

[PDF File (Adobe PDF File), 29KB - mhealth_v6i10e11440_app5.pdf]

Multimedia Appendix 6

Study objectives, mHealth tool used, and health system framework classification of the selected articles.

[PDF File (Adobe PDF File), 135KB - mhealth_v6i10e11440_app6.pdf]

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Abbreviations

IT: information technology
mHealth: mobile health
NCD: noncommunicable disease
RCT: randomized controlled trial
WHO: World Health Organization

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Original Paper

Patient Perceptions of Their Own Data in mHealth Technology–Enabled N-of-1 Trials for Chronic Pain: Qualitative Study

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Abstract

Background: N-of-1 (individual comparison) trials are a promising approach for comparing the effectiveness of 2 or more treatments for individual patients; yet, few studies have qualitatively examined how patients use and make sense of their own patient-generated health data (PGHD) in the context of N-of-1 trials.

Objective: The objective of our study was to explore chronic pain patients' perceptions about the PGHD they compiled while comparing 2 chronic pain treatments and tracking their symptoms using a smartphone N-of-1 app in collaboration with their clinicians.

Methods: Semistructured interviews were recorded with 33 patients, a consecutive subset of the intervention group in a primary study testing the feasibility and effectiveness of the Trialist N-of-1 app. Interviews were transcribed verbatim, and a descriptive thematic analysis was completed.

Results: Patients were enthusiastic about recording and accessing their own data. They valued sharing data with clinicians but also used their data independently.

Conclusions: N-of-1 trials remain a promising approach to evidence-based decision making. Patients appear to value their roles as trial participants but place as much or more importance on the independent use of trial data as on comparative effectiveness results. Future efforts to design patient-centered N-of-1 trials might consider adaptable designs that maximize patient flexibility and autonomy while preserving a collaborative role with clinicians and researchers.

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KEYWORDS

mHealth; patient-generated health data; self-management; chronic pain; qualitative research; N-of-1 trials; mobile phones

Introduction

Evidence-based medicine, as described by Sackett et al (1996), is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" [1]. At the top of the evidence hierarchy are randomized controlled trials (RCTs) and meta-analyses of RCTs [2]. However, even when such evidence is available, applying it to an individual patient in clinical practice is not always straightforward [3].

Even the highest quality RCTs and meta-analyses can only estimate the average effect of a treatment from a group of trial participants [4]. Because there is inherent heterogeneity in the effects of any treatment (ie, individuals within a population experience differences in the magnitude and direction of treatment and side effects), the average effect estimated in an RCT is not always applicable to an individual patient [4,5]. The uncertainty around applying such evidence may be particularly salient when patients have attributes (eg, complex medical or social circumstances) that differentiate them from an average RCT participant. Several studies have convincingly demonstrated that typical patients in many RCTs (ie, those at the 50th percentile for risk of poor outcomes) differ greatly from and often receive much less benefit than the average patients [3]. Therefore, investigators have sought methods that bring evidence-based practice closer to Sackett's ideal [1,5].

N-of-1 trials are individualized crossover trials that may help to address this dilemma by comparing the effectiveness of 2 (or more) treatments for an individual patient [6]. N-of-1 trials have the potential to improve clinical decision making in several ways; for example, they can be conducted in a "real world" environment—with clinically complex patients who would likely not meet the stringent inclusion criteria of a traditional RCT—and adapted with individualized protocols that consider the needs and preferences of patients and clinicians [5-7].

Despite many potential advantages, N-of-1 trials are infrequently used in health care [5], partly because of inherent limitations of the method. They are as follows. N-of-1 trials are only applicable to chronic, nonfatal conditions and to treatments with rapid onset and washout. In addition, the appeal of N-of-1 trials has been limited by several external factors including cost, lack of external funding opportunities, and the substantial time investment required from both clinician and patient [5].

Some of these logistical barriers may be overcome with the usage of mHealth technology to collect and synthesize patient-generated health data (PGHD). PGHD is defined as "health-related data created, recorded, or gathered from and by patients (or family members or other caregivers) to help address a health concern" [8]. The explosion of wearables and mHealth technology apps designed to collect and manage PGHD may provide an approach to N-of-1 trial data collection that eases participant burden while providing valuable information that informs decision making and improves patients' understanding of their own symptoms and treatments.

Patients appear to value and use PGHD obtained from mHealth and wearable technologies. However, few studies have examined patients' experience with PGHD in the N-of-1 trial setting [7,9,10]. In a study that examined theoretical barriers and facilitators to N-of-1 trial adoption, patients with chronic conditions expressed enthusiasm for the N-of-1 trial concept [7]. In particular, patients appeared to value the idea of having individualized results and felt that participation would have other likely benefits such as more rigorous self-monitoring of symptoms and side effects [7]. However, patients also expressed concerns about potential safety issues and skepticism around feasibility, given the already busy schedules of clinicians and lives of patients [7]. Two previous studies that qualitatively examined perspectives of N-of-1 trial participants reported that patients were largely satisfied with their N-of-1 trial experience and that participation increased self-awareness of their medical condition [9,10]. However, both studies were based in the United Kingdom and neither reported on N-of-1 trials that included an mHealth component.

In this study, we extend prior knowledge by exploring patients' experiences in monitoring their own symptoms and collaborating with primary care providers to use PGHD resulting from mHealth supported N-of-1 trials for chronic pain management. Our findings shed light on ways in which patients make sense of and use their health data in partnership with clinicians to inform treatment decisions in the N-of-1 trial context. Results of our work may inform targeted patient education, shared decision making, and self-management interventions to improve chronic pain. In addition, our findings have important implications for patient-centered design and implementation of mHealth technology–enabled N-of-1 trials.

Methods

Design and Setting

This qualitative study was embedded within a randomized controlled trial, Personalized Research for Monitoring Pain Treatment (PREEMPT), which examined the effectiveness of using a mobile pain software app for conducting single-patient crossover ("N-of-1") trials among patients with chronic musculoskeletal pain. Members of our team collaborated with the nonprofit mHealth developer Open mHealth to create the app, called Trialist, to promote tracking and summarizing of chronic pain symptoms using a smartphone. The Trialist app allows tracking of chronic pain symptoms over time while also providing graphical summaries of results of N-of-1 comparative trials.

The Personalized Research for Monitoring Pain Treatment Study

Details of the PREEMPT study design are reported elsewhere [11]. Briefly, a sample of primary care clinicians and their chronic pain patients were recruited. Patients were randomized to the Trialist app intervention or usual care. Both Trialist app intervention and usual care groups had multiple variables measured at baseline and at 3, 6, and 12 months through self-administered questionnaires. Questions assessed pain intensity, pain interference, medication adherence, medication-related shared decision making, pain treatment satisfaction, and general health-related quality of life.

Figure 1. Example of patients' view within the app.

Intervention patients were provided free access to the app for use on their mobile device (iOS or android). These patients collaborated with their clinicians to create single-patient crossover (N-of-1) trials. In setting up the N-of-1 trial, the patient and clinician would jointly determine treatments to compare length of time for each treatment (1 or 2 weeks) and the number of times the patient would switch between treatment A and B (2, 3, or 4); for example, a patient might use treatment A for 2 weeks and then switch to treatment B for 2 weeks, then A again for 2 weeks, and then B again. For comparison, the following 8 treatment categories were available: acetaminophen; any nonsteroidal anti-inflammatory drug; opioid combination product with codeine; opioid combination product with hydrocodone; opioid combination product with oxycodone; tramadol; complimentary or alternative treatments such as massage, meditation, or physical exercise; and current ongoing therapy (or no therapy). The following 2 types of PGHD were produced during the trial: tracking data and summary data (ie, comparative results).

Tracking Data

Intervention patients were queried weekly on their adherence to their assigned treatment over the previous 7 days. They were prompted to use the app to provide daily symptom reports on 3 dimensions of pain—pain on average, pain interference with enjoyment of life, and pain interference with daily activities of living. Participants also received daily prompts to report on the following 5 potential side effects of treatment: drowsiness, fatigue, constipation, sleep problems, and cognitive impairment. Patients could enter text as part of their regular reporting. They could view these symptom and side effect reports as simple time line graphs, as seen in Figure 1, anytime during and after their N-of-1 trial. These daily and weekly reports from intervention patients constituted their own tracking data. The example graph in Figure 1 shows trends in patient-reported pain and sleep problems.

Summary Data

Treatment comparison data were made available at the end of a trial. At that time, results comparing the 2 treatments could be viewed by both patient and clinician during a results review visit. Results were presented in 6 different graphical displays; 3 graphs focused on changes in pain intensity over the N-of-1 trial (Figures 2, 3, and 4), 1 bar graph compared Treatments A and B for pain intensity and side effects (Figure 5), and the final 2 graphs provided estimates of changes in the effect and the probability that one treatment was better than another (Figure 6 and 7). These graphs displaying participants' summary data were the basis on which patients and clinicians evaluated their N-of-1 trial results, as seen in Figure 2.

For this study, a sample of patients was interviewed after the results review visit about their use of the Trialist app and their experiences with their own PGHD including the tracking data compiled from participants' daily and weekly reports and summary data displayed at the end of an N-of 1 trial. We report on those patient interviews.

Figure 2. Pain intensity chronology (zero is no pain).

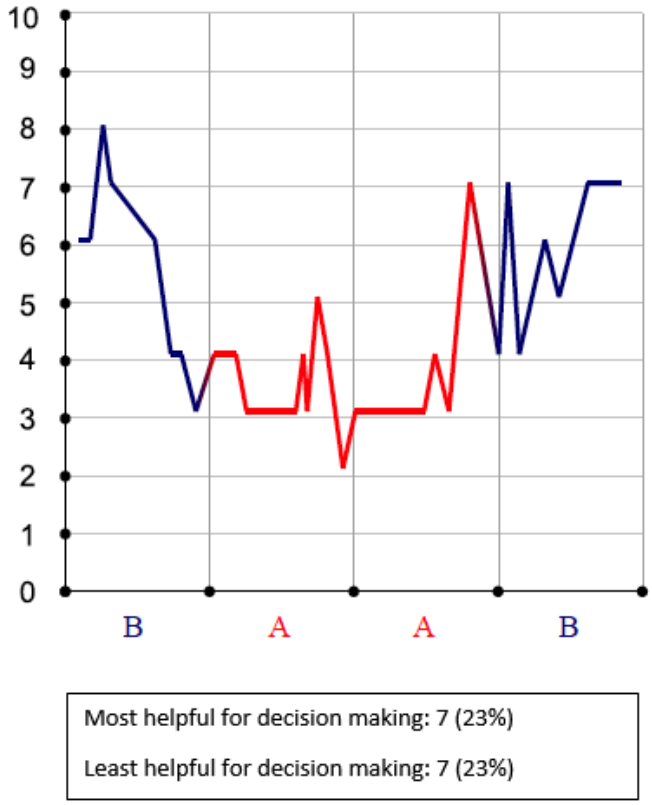


Figure 3. Pain intensity by treatment (zero is no pain).

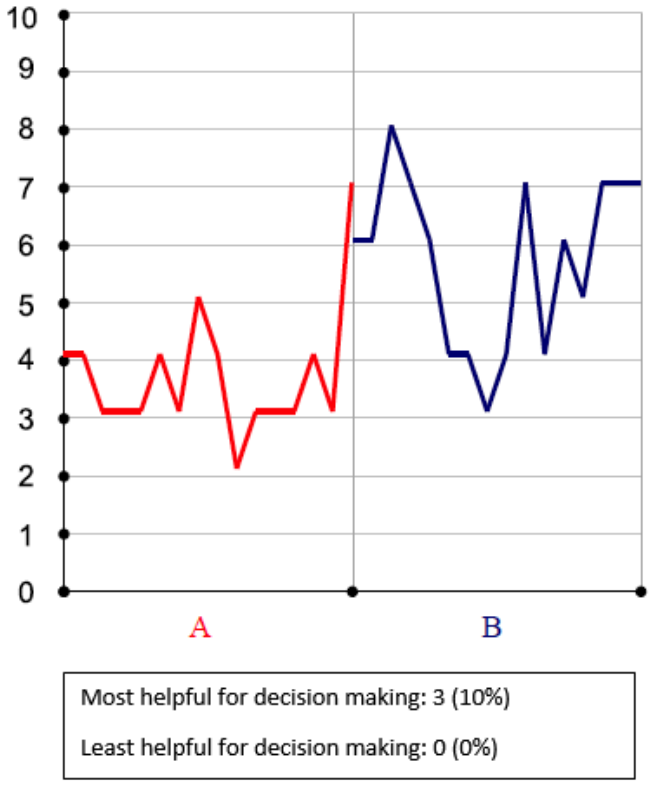


Figure 4. Pain intensity average (zero is no pain).

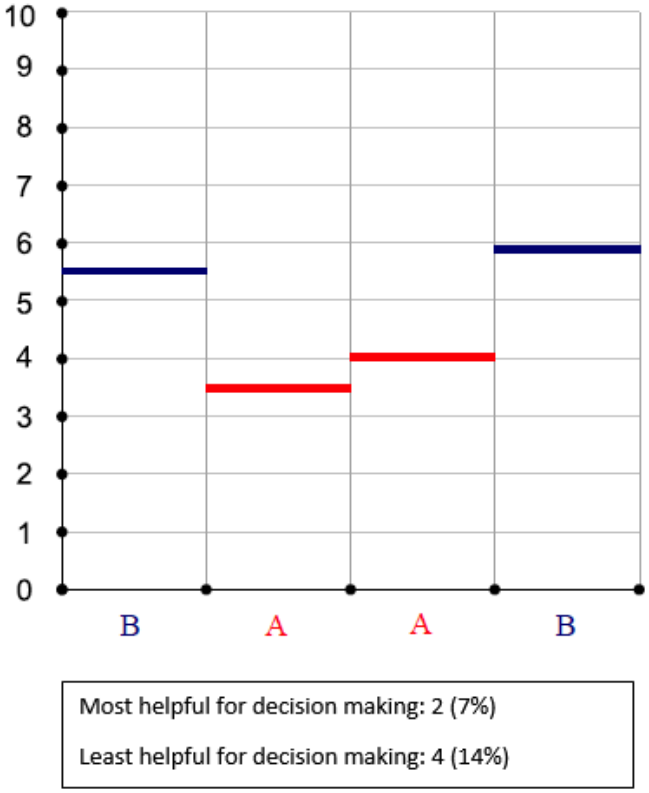


Figure 5. Averaged secondary outcomes (shorter bar is better outcome).

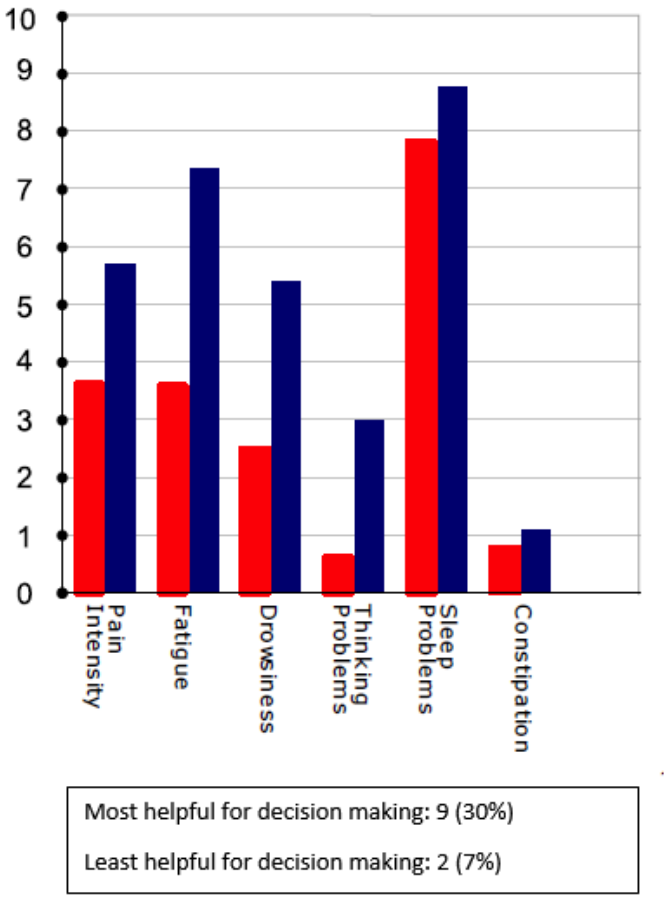


Figure 6. Estimated difference between treatments (bars represent margins of error).

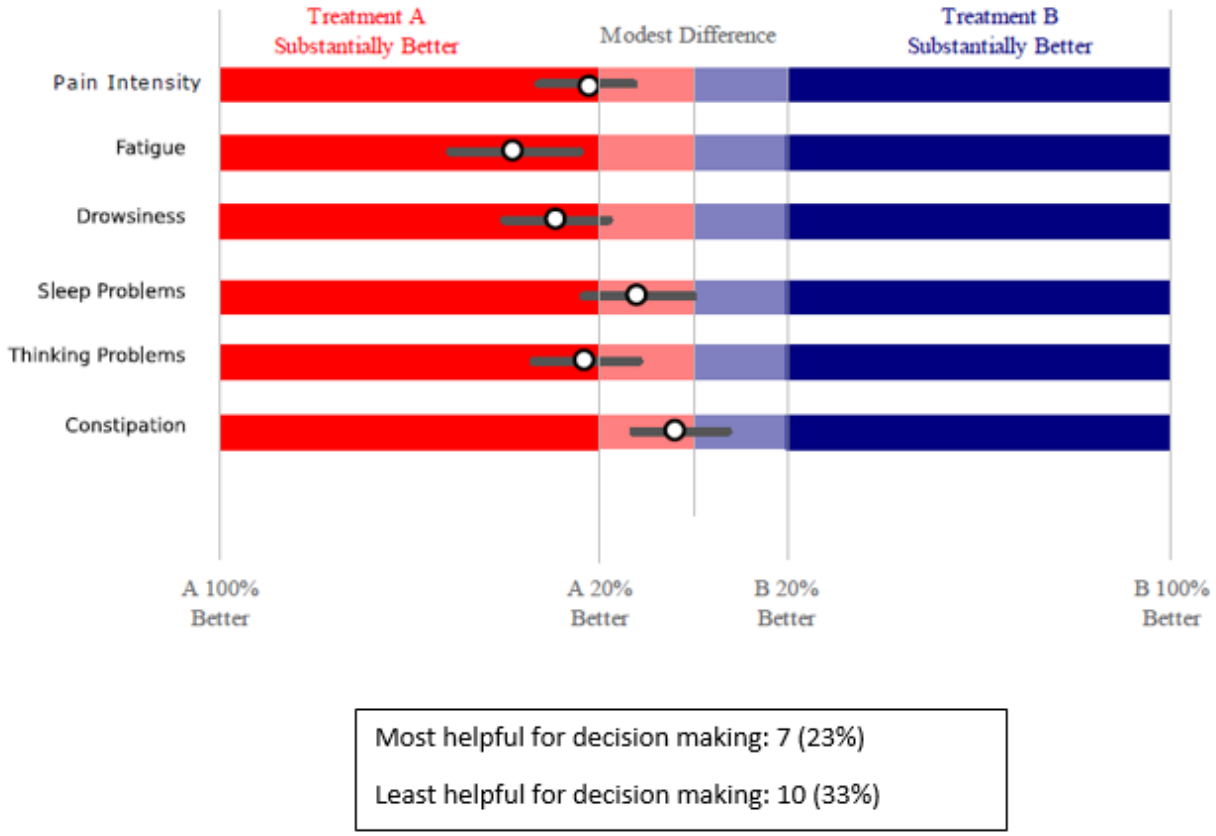
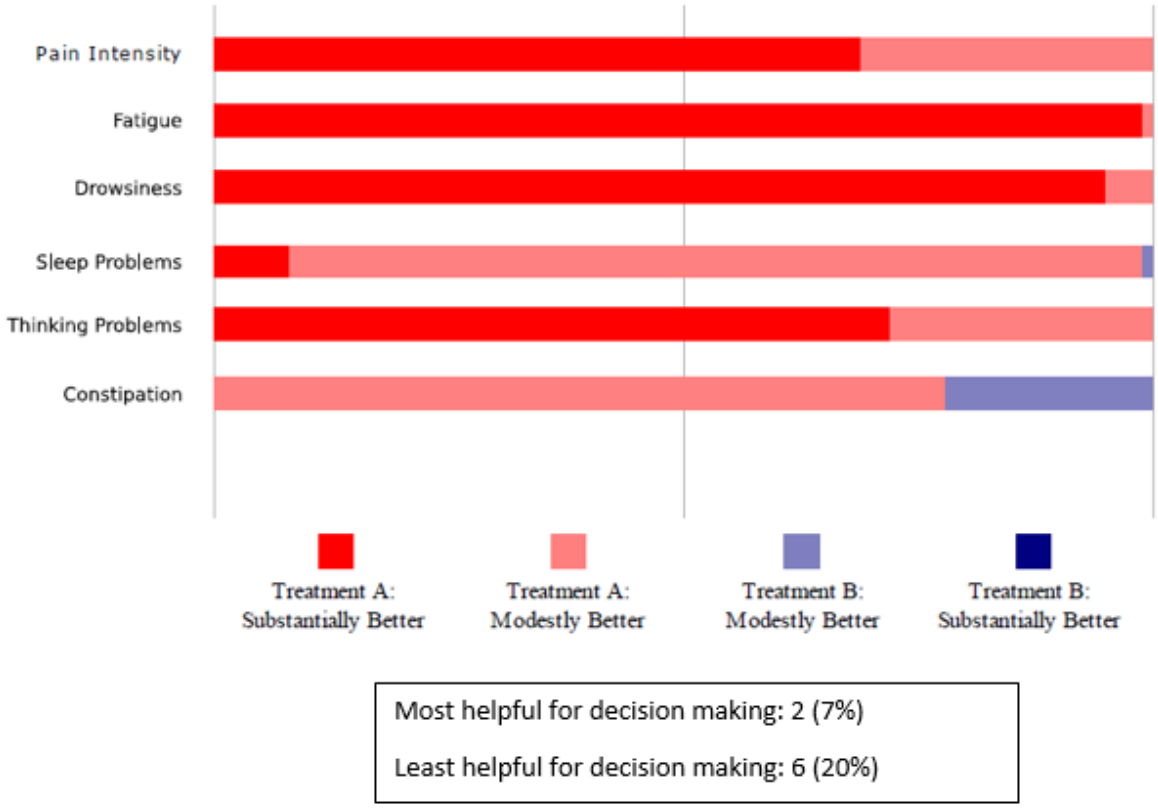


Figure 7. Likelihood that one treatment is better than the other.



Data Collection and Analysis

The research team designed this qualitative study once the larger study was underway. A patient interview guide was developed. The semistructured interview consisted of questions and open-ended prompts, which were designed to assess the usability and acceptance of the Trialist app, understanding of individualized (N-of-1) study results, preferences for presentation of summary data, and perceptions about PGHD and the process of compiling it.

A consecutive sample of patients from the intervention group was invited to participate in qualitative interviews from February 2016 to September 2016, an 8-month period within the parent study, which lasted from May 2014 to April 2017. Patients were invited at randomization, and those who had completed the N-of-1 trial and were scheduled for a results review visit were interviewed separately from their collaborating clinician. Interviews were completed immediately following the results review visits, which took place an average of 31 days after completing the N-of-1 trial. Because qualitative interviews were designed when the study was already underway, not all potentially eligible patients completed N-of-1 trials and results review visits during the interview period.

Institutional Review Board approval was obtained from University of California, Davis (#496804) and Veterans Affairs, Northern California Health Care System (#13-12-00717) for all aspects of the study, including a modification for these patient interviews that had not been part of the original study design.

Interview data were organized using Dedoose Version 7.1.3 (Los Angeles, CA: SocioCultural Research Consultants, LLC). A descriptive thematic analysis was conducted to identify themes related to patient experiences and perceptions. Repeated reading and analyst triangulation were employed to enhance the quality and validity of themes [12,13]. Sociodemographic characteristics of the interviewed patients were obtained from data collected for the main PREEMPT trial. During their interviews, patients were asked to self-report any background in mathematics, statistics, engineering, science, or health care (yes or no). The research team explored whether there were apparent differences in patient experiences or preferences related to this background.

Results

Patient Characteristics

Overall, 215 patients with chronic musculoskeletal pain were randomized into the RCT. Altogether, 107 control group patients received usual care and 108 intervention patients were supplied with the Trialist app; 10 patients in the intervention group did not start a trial, and 3 patients stopped the trial too early to have any results. The remaining 95 patients completed their planned N-of-1 trials. Of these, 80 completed an in-person results review visit, 2 patients used an electronic patient portal for the discussion with the clinician, and 13 patients received N-of-1 trial results by mail.

Table 1. Sociodemographic characteristics of Personalized Research for Monitoring Pain Treatment participants who participated in qualitative interviews (N=33).

Characteristic	Participants
Age (years), mean (SD)	55 (10)
Sex, n (%)	
Female	15 (45)
Male	18 (55)
Race or ethnicity, n (%)	
White, non-Hispanic	22 (66)
Black, non-Hispanic	3 (9)
Asian, non-Hispanic	1 (3)
Hispanic or Latino	5 (15)
Other	2 (6)
Highest completed education, n (%)	
High school diploma or equivalent (general educational development)	1 (3)
Some college (associate's degree or vocational training)	16 (48)
College degree (bachelor of arts and bachelor of science)	8 (24)
Graduate degree	8 (24)
Self-reported background in math, statistics, engineering, science or health care, n (%)	19 (58)
Married, n (%)	20 (61)
Employed (full or part time), n (%)	16 (48)

During the qualitative interview period, 46 patients were randomized to the intervention group. Of these, 33 patients were interviewed after their results review visit, 5 potentially eligible intervention patients did not start a trial, 6 did not consent to the interview, and 2 consented but did not complete the interview. The demographics of the 33 interviewed patients are displayed in Table 1.

From our analysis, 3 major themes emerged with subthemes for each. The themes are summarized along with illustrative quotations in Textbox 1.

1. Patients were enthusiastic about *accessing* their PGHD.
2. Patients found value in *sharing* data with their clinicians.
3. Patients engaged energetically in *using* their own data for a wide range of purposes, some apart from those anticipated by investigators.

Textbox 1. Summary of themes and subthemes with illustrative quotations in italics.

1. Accessing Data
   a. Value of tracking data
      - *I think that documenting it was the most helpful.*
      - *The most important factor for me was the diary.*
   b. Simplicity of presentation
      - *These are too confusing for me...I want simple.*
      - *It's like homework...I don't think so.*
   c. Alternatives to data presentation
      - *I would like to see a little person—maybe some more pictures...I mean I understand the bars, but I get excited when I see a little girl riding a bike or somebody going up an [in]cline [to represent changes in pain].*
2. Sharing Data
   a. Patient-clinician relationship
      - *We [patient and clinician] had a nice interchange about elaborating on why the results were the way they were. You can only do that sitting side by side together.*
      - *She [the clinician] gets to know how my feet are truly feeling.*
   b. Confusion about data analysis
      - *She [the clinician] had no idea what the graphs meant.*
3. Using Data
   a. Noticing: increasing self-awareness
      - *I think documenting it was most helpful because then I could see how many days I'd been a space cadet.*
   b. Deciding: drawing conclusions and correlations
      - *[The app] helped me draw my own conclusions.*
      - *I guess it just made you pause...think about your day. What you did. How it felt. Those things, on a daily basis, I think it is a useful exercise in pain management.*
      - *Well, I was confused until he [the clinician] explained it...The clinician [was the most influential factor in making a treatment decision].*
   c. Acting: self-management
      - *I was also accountable when I wrote notes when I could say I didn't do this or I didn't do that or if that increased my fatigue...it made me think about what could be causing some other things and if I needed to address it.*
      - *It let me play around with do I need one [medication dose], do I need to take two, do I need to take 'em six hours apart, do I need to take 'em eight hours apart.*
      - *Door number three, that I came up with, worked better...the last half of the trial I was on Plan C [his own plan].*

Accessing Data

Value of Tracking Data

Nearly all interviewed patients expressed enthusiasm about having access to their tracking data. They valued having recorded data as well as its presence in a format to which they could refer. "[T]he most important factor for me was the diary," said one respondent (female, 50s), whereas another said, "I think that documenting it was the most helpful..." (female, 70s). A patient (male, 40s) who stated he had "a little TBI (traumatic brain injury)" credited the tracking as a memory aide.

Simple Presentations of Summary Data

Critically for the N-of-1 context in which treatment comparisons were to be made, a majority of respondents preferred simple presentations of summary data. A variety of graphical presentations of data summarizing trial results were provided to patients and clinicians at the results review visit. As part of the patient interview, respondents were asked which graphs they preferred. Of 33 patients in this subsample, 42% (14/33) did not identify themselves as having a background in mathematics, engineering, science, or the health professions (Table 1), but even those who did (19/33, 58%) expressed preference for simple data presentations of N-of-1 trial results. In choosing which graph was the most helpful to them in making a treatment decision, just over half of patients (16/30, 53%) found either Figure 6 or 7—the two summary graphs that included information about effect size and statistical uncertainty—least helpful for decision making, as seen in Figures 2-7. A footnote to each graph in Figures 2-7 displays the number of interviewees (of 30 who responded to this question) who endorsed that graph as either the most or least helpful in making a treatment decision.

One patient requested that clinicians "spare the patient" the work of complex interpretation of graphs. Another suggested that patients would lose interest in an array of data: "Keep it to the point" (male, 50s). Another interviewee said the following in reference to the more statistically oriented graphs, as seen in Figures 6 and 7: "These are too confusing to me...I want simple" [male, 40s].

Referring to one of the graphs (Figure 6), a respondent said "It's like homework. I don't think so" [female, 70s].

Alternative App Designs

Many patients proposed a number of innovative suggestions for alternative ways to design the app and showed a range of preferences for data presentation; for example, one respondent (female, 50s) wanted to be able to track more than one pain source, whereas another (female, 50s) suggested creating a link to pain management tips when pain scores were high. Patients suggested changes in the app's design to increase their own motivation to input their data—one respondent (female, 40s) suggested adding graphics, specifically a bicycle going up a hill, to illustrate effort and progress. Another (male, 60s) suggested varying questions' order to prevent rote and unthinking responses to repeated queries about pain-related symptoms such as fatigue:

> *When the questions are repetitive, people tend to know exactly what to hit every single day and it's done. They shoulda come up with different questions that meant the same, but would make the person read 'em, instead of knowing what to put, if I'm being honest.*

Some respondents wanted compression of data, whereas others sought more detail.

Sharing Data

Value to Patient-Clinician Relationship

Patients were questioned about the format for results of review visits with clinicians and asked if email or phone visits to review the N-of-1 trial results summary data would have been as satisfactory as an in-person visit. Most respondents preferred to meet in person with clinicians to discuss results. One patient with a high level of statistical knowledge stated,

> *We [patient and clinician] had a nice interchange about elaborating on why the results were the way they were. You can only do that looking at it side-by-side together.* [male, 70s]

Another, without statistical expertise, explained a preference for face-to-face contact saying, "It's easier to have a discussion and ask questions if someone's right in front of you" [female, 50s].

Some patients specifically reported that they engaged their clinicians more effectively when they could back up symptom reporting with summary data. A patient (male, 40s) engaged in an appeal for disability services was enthusiastic about graphed data that would provide "...proof that–for my appeal–to have proof of a graph." Another (male, 50s) suggested that the tracking data generated in real time added credibility to communication with the clinician: "She [the clinician] gets to know how my feet are truly feeling."

Another (female, 50s) was able to collect data on the symptom that troubled her the most (constipation) and bring it to the clinician's attention as they studied trial results together. Others reported improved relationships with their clinicians from engaging in the N-of-1 trials using PGHD.

Understanding Data Analysis

A few patients admitted their lack of understanding about data analysis. In the portion of the interview reviewing data analysis for the N-of-1 trial, 2 patients relied on the staff interviewer to clarify N-of-1 data. One (female, 70s) exclaimed, upon viewing graphs not previously viewed with the clinician, "Oh, these are cool...I never read this. " After the interviewer briefly explained the data, another respondent (male, 50s) said that the data had been "confusing, but once it's explained..."

Some respondents perceived that their clinicians were also uncertain about data analysis. Several patients reported that their clinicians did not look at the graphical summary data during the results review visit. Some patients reported that their clinicians had limited interest in PGHD, and a few suggested that clinicians, like themselves, might not have understood the data summaries. While reporting that his clinician did not refer to summary graphs, a patient (male, 60s) stated that the clinician

had admitted that she did not understand them: She [the clinician] had no idea what the graphs meant.

Several respondents suggested that adding text explanations to summary graphs would have facilitated interpretation, presumably for both patients and clinicians.

Using the Data

Noticing

Overwhelmingly, patients reported noticing what they had not noticed before from daily reporting of their symptoms. One patient said "I think that documenting it was the most helpful...[because] then I could see how many days I'd been a space cadet" [female, 70s].

One respondent (female, 50s) found that the app clarified some specifics about her condition, for example, the role constipation played in her well-being. Patients remarked on their enhanced awareness of symptoms, for example, noting that the trial identified issues with sleep, activity, medication use, and others.

Deciding: Drawing Conclusions and Correlations

Most patients described interacting with their tracking data such that it moved them beyond noticing, toward drawing conclusions and correlations from their data. One respondent (male, 50s) said about the app, "It helps you understand the interaction between your sleep and your pain, between your activity and your pain." Another patient (female, 50s) praised the app's tracking function, saying it made her "sit and think about it. I guess just make you pause...think about your day. What you did. How it felt. Those things, on a daily basis, I think is a useful exercise in pain management."

Similarly, another patient (female, 50s) described enhanced self-awareness leading to better pain management:

> *It definitely helped me pay attention to what was helping alleviate my pain. It felt like I was more mindful.*

One patient (male, 60s) said, "It [tracking] just triggered me to start looking at my overall health." Several patients spoke of the conclusions and correlations they drew from their data: "[The app] helped me draw my own conclusions [male, 30s].

Patients had varied reactions to different pieces of their data. One respondent (male, 50s), on being asked what was most influential in coming to a treatment decision, suggested that the trial results were less important "It was more the fact that I was actually entering and writing down." Another respondent (male, 50s) was also enthusiastic about the graphs of daily symptom reports within the app, stating the following:

> *Cool thing about the app and these graphs is it helps you understand the interaction between your sleep and your pain, your activity and your pain. Between your pain and your social life and your work life and your home life.*

About the collected data, another (female, 40s) said "It validated what I kind of already knew inside." However, several patients, particularly those who felt more confusion about what graphs meant, reported that the clinician's input was the main factor in deciding which treatment was better:

> *Well, I was confused until he [the clinician] explained it...The clinician [was the most influential factor in making a treatment decision].* [female, 50s]

Acting: Self-Management

Most patients used the tracking data to guide self-management. One (male, 40s) reported that he would not have tried an alternative treatment without the app. Another (male, 50s) suggested a higher level of accountability for health behavior from documenting:

> *I was also accountable when I wrote notes when I would say I didn't do this or I didn't do that or if that increased my fatigue...it made me think about what could be causing some other things and if I needed to address it.*

Another respondent (male, 50s) stated that symptom report graphs were valuable and reinforced a changed approach,

> *I [used to] let it [pain] peak too much. Now I've gotten it down, and I can really tell by the graph.*

Some patients described further steps in self-management. Patients used data to identify triggers they subsequently worked to avoid or data that motivated improved attention to activity or socializing. Patients made alterations in the dose, frequency, and other aspects of treatment regimens. One patient said:

> *"It [data from the app] let me play around with do I need one [medication dose], do I need to take two, do I need to take 'em six hours apart, do I need to take 'em eight hours apart."* [female, 50s]

Another (male, 50s) echoed this, having tracked his dose response:

> *In terms of dosage and the frequency, it allowed me to experiment with how much I was taking and how often I was taking it in terms of dealing with that pain.*

A few patients revealed highly independent decisions about their treatment approaches. When asked if he had a sense from summary data that one treatment in the N-of-1 trial was better than another, one patient (male, 70s) answered:

> *Yeah, mine...I mean, I don't know if they would accept that for an answer, but door number three, that I came up with, worked better...The last half of the trial, I was on Plan C [his own plan].*

Another (male, 50s) said "It [viewing the summary data via the app] helped me decide going forward my next strategy."

Many patients reported on their own analyses of their data. One respondent (male, 40s) commented on using the app to "not give me the answer but give it [data] to me so I can say 'ok, mmm...'."

Another patient (male, 30s) spoke at length about using data independently:

> *It was good for me to be able to correlate things even before there was some sort of analysis presented to me.*

However, this same patient also said of the summary analyses

> *[E]ven though it's my own information and I'm putting it into it [the app], having it presented that way [in summary graphs] back to me was helpful.*

This patient suggested an increased level of patient use of data:

> *I think making that app available to–or I mean, could you make that app available to people just to use on their own–I don't know–to present that monthly analysis of something like that to where they could do their own?...[D]raw my own conclusions about what was going on with my health.*

Discussion

Principal Findings

As is true in qualitative research, these results are not representative, but rather illustrate issues for discovery and discussion. Our findings from a consecutive sample of the intervention group in a randomized controlled trial examining smartphone-enabled N-of-1 trials for chronic pain (The PREEMPT Study) reinforced previous findings about patient enthusiasm for access to their own PGHD and benefits to N-of-1 trial participation that included increased awareness of symptoms [9,10,14-16].

Participants demonstrated clear preference for simple presentations of summary data. Although few studies have reported on patient preferences for data presentation in the N-of-1 trial context, previous studies examining patient preferences for the presentation of risk-benefit information have similarly found that patients often prefer more simplistic data presentations [17,18]. However, there is a variability in what patients consider "simple" or "understandable." Respondents in our study were eager to personalize the content and display of their PGHD within the app in the way that made the most sense to them. Tait et al (2012) found that patients who were given risk-benefit information that matched their preferred data visualization format (eg, if their preferred format was a pictograph, the information was presented to them as a pictograph) not only reported greater satisfaction with information but also interpreted it with significantly greater accuracy [19]. As clinicians and health systems work toward shared health decision making and improved chronic condition management, they may find it important to assess patients' preferred styles of data presentation. In future use of their own PGHD, patients might use their preferred method of tracking symptoms and receiving comparative treatment trial results. With appropriate cautions about overinterpreting data, patients could be provided with presentations of data most useful and motivating to them.

Although our research group was concerned about the tradeoff between accuracy and simplicity of statistical results, no patients expressed similar concerns. We might assume that our respondents did not fully understand statistical uncertainty, but we did not test our patients' knowledge nor did we teach a primer on statistical interpretation. Future N-of-1 studies might incorporate these additions. Some patients expressed confusion about the meaning of statistical summary data, and almost all expressed a preference for simplicity of results. In the primary study, 23% of N-of-1 trials completed (22/95) did result in significant statistical differences in treatment regimens (ie, a 95% credible interval that excluded the null value) [20]. The research team was concerned that patients would confuse statistical and clinical significance, perceiving greater clinical meaning from lesser statistical difference, especially in trials in which the difference was not significant. Those concerns were borne out during interviews when patients reported that summary graphs with the most information about effect size and statistical uncertainty were the least helpful for decision making. Instead, patients appeared primarily concerned with finding any differences between treatment regimens and in being able to use data to confirm their qualitative perceptions. The growth of patient-centered research approaches may allow for a sophisticated development of consumer friendly data analyses that also meet the bar for understandability and accuracy, in particular, accurately conveying the amount of uncertainty.

We found that although patients used their data autonomously for self-management, they also wanted to partner with their clinicians to review the results and make decisions. A previous study that examined clinicians' perspectives on N-of-1 trials revealed concerns about the potentially negative impact on the clinician-patient relationship [7]. However, no patients in our study reported such concerns. On the contrary, most felt that discussing trial results with their clinicians was valuable and important. The optimum way for clinicians and patients to share N-of-1 trial data remains to be determined; our study only hints at patients' perceptions from sharing their data as well as at a caution that clinicians too will need education about interpreting these data.

Our study suggested that patients evaluated the tracking data and summary data distinctively. Patients were enthusiastic about the tracking data and somewhat less so about summaries to which they had only brief exposure. The main study was designed to collect daily symptom reports for the primary purpose of comparing the effectiveness of two alternative treatment regimens. However, qualitative analysis reported here reveals that patients did not see the comparison function as the only, or possibly even the main, value of their PGHD. Instead, they appreciated the ability to track their symptoms over time with perhaps greater motivation because an eventual comparison was in store. This may be a case of the process having as much or more value than the outcome alone. These findings are consistent with those of another qualitative study, which found that patients were primarily motivated to participate in N-of-1 trials to increase accountability for self-management and promote behavior change rather than to compare treatments [21].

Importantly, our study focused on chronic pain and relied on patient self-report for the primary outcome. Because patients were experiencing and reporting any changes in pain throughout the trial, the final comparative effectiveness result may have been less meaningful. Future work might explore whether patients report more benefit from comparative effectiveness

results in situations where the main outcome is important to patients, but not as easily perceived by them (ie, cholesterol and A1C).

Some patients expressed confusion about the summary data's meaning, and almost all expressed preference for simple presentations of trial results. This suggests that to engage patients deeply in their own N-of-1 trials could mean designing analysis strategies more transparent to patients, in addition to being easily understood. Could patients choose analyses they want with simple explanations of tradeoffs between comprehensiveness and comprehensibility? One might program different interpretations for different types of patients (eg, one for the math phobic and another for the data enthusiast). In addition, what ways are there to bring data analyses to patients? Are clinical visits the optimum setting, or are there other forums in which comparative data analysis could be viewed and discussed? Notably, participants in our study were a fairly educated group with about half reporting a college or graduate degree and 58% (19/33) reporting a background in mathematics, statistics, engineering, science, or health care. Future work might explore whether enthusiasm for and engagement with PGHD is similarly high in populations with less education and more limited prior experience with mathematics, statistics, engineering, science, or health care fields.

Although not the focus of these interviews, participants revealed a well known, but sometimes unacknowledged, aspect of clinical practice that patients modify and enact their own treatment regimens. Our interviews showed a wide range of therapeutic actions by patients, at times independently of their clinicians and N-of-1 protocols. Like clinicians, N-of-1 trial researchers should be aware of this and may consider adaptive designs that would enable patients and clinicians to partner in modifying initial trial protocols.

Conclusion

Notes and numeric data tracked and analyzed by the Trialist app in N-of-1 trials make possible new conclusions and decisions about both collaborative treatment and self-management. Structured records in the app may be shared with clinicians who weigh in with their professional input, a conversation that might not take place without the app's facilitation. Patients in our study valued sharing PGHD with clinicians, even as they also made their autonomous uses of data. Future N-of-1 studies might consider individualized, adaptable protocols and emphasize clarity of data presentation to optimize shared decision making.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

PGHD: patient-generated health data
PREEMPT: Personalized Research for Monitoring Pain Treatment
RCT: randomized controlled trial

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Original Paper

An mHealth Diabetes Intervention for Glucose Control: Health Care Utilization Analysis

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Abstract

Background: Type 2 diabetes (T2D) is a major chronic condition requiring management through lifestyle changes and recommended health service visits. Mobile health (mHealth) is a promising tool to encourage self-management, but few studies have investigated the impact of mHealth on health care utilization.

Objective: The objective of this analysis was to determine the change in 2-year health service utilization and whether utilization explained a 1.9% absolute decrease in glycated hemoglobin (HbA_{1c}) over 1-year in the Mobile Diabetes Intervention Study (MDIS).

Methods: We used commercial claims data from 2006 to 2010 linked to enrolled patients' medical chart data in 26 primary care practices in Maryland, USA. Secondary claims data analyses were available for 56% (92/163) of participants. In the primary MDIS study, physician practices were recruited and randomized to usual care and 1 of 3 increasingly complex interventions. Patients followed physician randomization assignment. The main variables in the analysis included health service utilization by type of service and change in HbA_{1c}. The claims data was aggregated into 12 categories of utilization to assess change in 2-year health service usage, comparing rates of usage pre- and posttrial. We also examined whether utilization explained the 1.9% decrease in HbA_{1c} over 1 year in the MDIS cluster randomized clinical trial.

Results: A significant group by time effect was observed in physician office visits, general practitioner visits, other outpatient services, prescription medications, and podiatrist visits. Physician office visits (P=.01) and general practitioner visits (P=.02) both decreased for all intervention groups during the study period, whereas prescription claims (P<.001) increased. The frequency of other outpatient services (P=.001) and podiatrist visits (P=.04) decreased for the control group and least complex intervention group but increased for the 2 most complex intervention groups. No significant effects of utilization were observed to explain the clinically significant change in HbA_{1c}.

Conclusions: Claims data analyses identified patterns of utilization relevant to mHealth interventions. Findings may encourage patients and health providers to discuss the utilization of treatment-recommended services, lab tests, and prescribed medications.

Trial Registration: ClinicalTrials.gov NCT01107015; https://clinicaltrials.gov/ct2/show/NCT01107015 (Archived by Webcite at http://www.webcitation.org/72XgTaxIj)

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KEYWORDS

cluster randomized clinical trial; health care; health service utilization; mHealth; type 2 diabetes

Introduction

Type 2 diabetes (T2D) is a major chronic health problem affecting 30.3 million Americans [1]. Persons with uncontrolled diabetes are at increased risk of serious health complications including hypertension, premature death, vision loss, heart disease, stroke, kidney failure, and amputation of toes, feet, or legs [1]. Diabetes is also costly to the US health care system. In the most recent available national study (2012), the total cost of patients diagnosed with diabetes in the United States was US $245 billion, with Medicare paying US $74.3 billion [2]. After adjusting for population sex and age differences, the average medical expenditures of people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes [2].

Once diagnosed, lifestyle management is the first line of defense for blood glucose (BG) control in diabetes and is continued regardless of prescription medications [3]. Self-management gained through diabetes self-management education and communication with providers is recommended by professional guidelines although studies demonstrate moderate effects on diabetes outcomes. Professional treatment guidelines also recommend BG control through quarterly or annual physician visits with glycated hemoglobin (HbA_{1c}) and glucose tests, cardiology and neurology visits, and annual eye and foot exams, as well as multiple health care service utilization to monitor medications, adequacy of individual self-management, and disease progression.

mHealth is a promising tool for delivering interventions designed to promote lifestyle management, but it is neither well understood nor are there well-designed studies of its efficacy and effectiveness. Studies investigating Web-based interventions to promote T2D self-management are inconclusive or demonstrate only moderate effects [4]. Few studies demonstrate even moderate effects that are randomized, include interventions maintaining behavior >6 months, or include older adults or minorities. Although administrative claims data has been used in previous studies to identify the determinants of adherence to diabetes medications and the economic burden of diabetes [5,6], few studies have used administrative claims data to determine changes in health service utilization before and after a mobile phone intervention for adults with T2D. A limited set of studies have demonstrated mixed results of mHealth interventions on health service utilization or costs [7-9].

The analysis reported here, the Mobile Diabetes Intervention Study (MDIS), was a cluster randomized clinical trial (c-RCT) evaluation of a 1-year mobile phone intervention previously described in detail [10,11]. In the c-RCT, mobile phone software allowed patients to securely enter diabetes self-care data on a mobile phone and receive automated real-time educational, behavioral, and motivational messages specific to the patient-entered data. Providers had access to analyzed patient data linked to standards of care and evidence-based guidelines. The 1-year c-RCT reported a 1.9% clinically significant improvement (P=.001) in HbA_{1c}, the gold standard measure for improved diabetes management [11]. This improvement is important because a reduction of 0.5%-1.0% in HbA_{1c} is considered clinically significant to reduce the risk of comorbid conditions; the FDA recognizes a 0.4% improvement as clinically significant for the prescription antihyperglycemic medications [12-14]. In addition, 5 related substudies evaluating the MDIS impact on physician prescribing behavior, differences by participant age, depression, diabetes distress, and a mixed methods analysis of patient engagement reported modest benefits [15-18]. The purpose of this *a priori*-identified secondary data analysis [10] was to determine whether a mobile phone intervention impacted the utilization of health services identified in commercial insurance administrative claims data and whether changes in health service utilization explained HbA_{1c} change over time. In the current analysis, we hypothesized that the mobile phone personalized behavioral intervention would include more monitoring in-between health service visits and therefore impact utilization and improve HbA_{1c} over a 1-year treatment period.

Methods

Design

This study was an administrative claims exploratory data analysis of the previously described c-RCT (NCT01107015) [10,11], where changes in health care utilization during the trial were compared with rates of usage before the trial. Subsequently, the observed changes in health care usage were compared with changes in HbA_{1c}. In addition to analyzing claims data, BG data were obtained by abstraction from patients' medical charts [11]. We planned *a priori* to evaluate utilization but not costs, as cost data would be sparse or skewed in a study of 92 participants [10].

Participants

The c-RCT was conducted in 26 primary care practices in 4 distinct geographic areas in Maryland, USA [11]. The c-RCT randomly assigned 26 primary care practices to 1 of 3 stepped treatment groups described below (groups 2-4) or a control usual care (UC) group (group 1) [10,11]. Enrolled patients (n=163) followed their physician randomization assignment. The study population included adult patients aged 18-64 years having a physician diagnosis of T2D at least 6 months prior to study enrollment and HbA_{1c}≥7.5%. Patients were only eligible for the parent study if their health services were covered by a commercial insurer [10,11]. The primary outcome of the parent study was an absolute change in HbA_{1c} (percentage point of total hemoglobin) comparing the UC (control) group and the maximal treatment group at baseline and 12 months [10,11].

Intervention

Group 1 received usual care (UC), group 2 received coaching only (CO), group 3 received coaching and patient care provider portal (CPP), and group 4 received coaching and patient care provider portal with decision support (CPDS) [10,11]. The maximal treatment was a mobile phone–based and Web-based self-management patient CPDS [11]. Providers in the CPDS group had access to analyzed patient data linked to the standard of care and evidence-based guidelines, while providers in the CO group received data from their patients if patients chose to

share it. Providers in the coaching and patient care provider portal group received unanalyzed patient data [11].

Measures

For the current secondary data analysis, we analyzed all-cause and diabetes-related adjudicated (paid) claims data for 56% (92/163 participants in the parent study) participants in each study group, (UC, n=28; CO, n=17; CPP, n=13; and CPDS, n=34). All-cause utilization was defined as any claims-based health care utilization inclusive of diabetes and any other diagnosis on the claim. We had access to commercial insurance claims data from 2006 through 2010 for study participants covered by the state's largest commercial insurer. Other participants were covered by multiple commercial insurers and not included in this analysis. Claims data were aggregated into 12 categories: physician office visits, general practitioner, cardiologists, outpatient services, lab claims, prescription claims, endocrinologists, ophthalmologists, podiatrists, emergency department visits, inpatient visits, and total inpatient hospital days. The physician office visits category was defined as available outpatient records for an office visit validated by the commercial insurance company. General practitioners were defined as any medical visits listed as family practice, general practice, or internal medicine. Category classifications (ie, lab vs prescription claims) were confirmed by the insurer.

Four utilization categories were excluded from the analysis because data were sparse: endocrinologist visits, emergency department visits, inpatient hospital visits, and total inpatient hospital days. Ophthalmologist and podiatrist visits were also infrequent. However, due to their importance in standard diabetes care, we included them in revised models. Data were organized by date and grouped into the 12 months prior to randomization (prerandomization period) and 12 months after randomization (postrandomization period). Patient medical charts were used to collect HbA_{1c} values at baseline and at 3, 6, 9, and 12 months [11].

Study Oversight

The Institutional Review Board of the University of Maryland, Baltimore, approved this study. A data and safety monitoring board was designated to review the study procedures and adverse events. After enrollment was closed, errors in consent were found and all participants, both physicians and patients, were asked to sign consent forms again, as recommended by the Institutional Review Board. All patients in the final analysis were reconsented.

Statistical Analysis

Administrative claims data for the participants' study year were compared with the previous year using generalized linear mixed-effects models to examine the effects of treatment group differences overall, over time, and grouped by time interaction. Specifically, the prerandomization year was the reference year. The treatment effect thus analyzes whether health service visit frequencies were different by group, comparing the year before to the study intervention period. The time by treatment group effect represents the group differential changes from the prerandomization period to the postrandomization period. To address the clustering of physician practices in the parent study, random effects were used to account for within-practice clustering and within-patient correlation.

Due to infrequent ophthalmologist and podiatrist visits (which caused nonconvergence models), these claims' data were analyzed using repeated measures analysis of variance. Considering the skewed frequency of claims, a Poisson distribution was selected for the outcome.

To examine the impact of utilization on HbA_{1c}, general linear models were used. Two tests were conducted for each type of visit: 1 model included only a baseline HbA_{1c} and visit count effect (postrandomization period only) and the other included both of these effects as well as a study group effect. The study group effect examined whether the number of visits, baseline HbA_{1c}, and group membership (physician office and general practitioner) predicted 12-month HbA_{1c}. The tests without group-effect modeling examined whether the number of visits and baseline HbA_{1c} predicted 12-month HbA_{1c}. The statistical software SAS version 9.3 (SAS Institute, Cary, NC) was used for all analyses. The level of significance was set at ≤.05.

Results

The baseline characteristics for the study population are described in greater detail in the parent study [11]. However, for the purposes of understanding utilization, we report descriptive participant characteristics relevant to utilization outcomes. At study enrollment, the mean age of study participants was 52 years, 54% (50/92) were female and 40% (37/92) were African American individuals (Table 1). A total of 55% (51/92) of patients entered the study with an HbA_{1c} between 7.5% and 8.9 %, although a substantial portion of participants had a baseline HbA_{1c} of >9% (an indication for treatment by an endocrinologist rather than a primary care provider). In the CPDS group, more than half of participants had an HbA_{1c} value of >9%. Most participants had been diagnosed with diabetes for ≥8 years, were nonsmokers, and had at least some college education.

In general, patients were not depressed or distressed by their diabetes, with 79% (73/92) reporting minimal to mild depression and an average diabetes distress scale score of 2.6: <2: little distress and ≥3: high distress [18]. Participants' total cholesterol levels were desirable, low-density lipoprotein levels were near ideal: UC group: 105.1 (SD 31.8) mg/dl; CO group: 102.3 (SD 25.9) mg/dl; CPP group: 94.6 (SD 30.6) mg/dl; and CPDS group: 112.4 (SD 30.4) mg/dl). Their high-density lipoprotein (HDL) levels were satisfactory: UC group: 44.8 (SD 10.7) mg/dl; CO group: 43.2 (SD 12.5) mg/dl; CPP group: 42.2 (SD 13.0) mg/dl; and CPDS group: 45.9 (SD 11.6) mg/dl.

The baseline characteristics of those not included in our analysis (covered by multiple insurers) were compared with participants insured by the single insurer for whom we had administrative claims data. There were no differences among the 2 groups except for the duration of diabetes. Participants in the administrative claims data group had diabetes longer (mean, 9.2 years) than participants who were not covered by the insurer (mean, 6.9 years, P=.02; data not shown).

Table 1. Baseline characteristics for participants with commercial insurance coverage (n=92).

Baseline characteristics[a]	UC[b] (n=28)	CO[c] (n=17)	CPP[d] (n=13)	CPDS[e] (n=34)	*P* value
Glycated hemoglobin (%), mean (SD)	9.2 (1.8)	9.5 (2.0)	8.8 (1.6)	9.5 (1.6)	.63
7.5-8.9	18 (64.3)	9 (52.9)	8 (61.5)	16 (47.1)	.55
≥9.0	10 (35.7)	8 (47.1)	5 (38.5)	18 (52.9)	
Age (years), mean (SD)	52.8 (8.6)	52.4 (9.0)	55.2 (6.4)	52.5 (6.7)	.40
Sex, n (%)					.44
Male	10 (36)	10 (59)	7 (54)	15 (44)	
Female	18 (64)	7 (41)	6 (46)	19 (56)	
Race, n (%)					
Black (non-Hispanic)	15 (54)	6 (35)	6 (46)	10 (29)	
White (non-Hispanic)	12 (43)	10 (59)	6 (46)	21 (62)	*<.001* [f]
Duration of diabetes (years), mean (SD)	10.8 (8.0)	8.4 (5.8)	7.6 (5.3)	9.0 (5.5)	*<.001*
Smoking status, n (%)					*<.001*
Nonsmoker	23 (82)	12 (70)	11 (85)	25 (74)	
Current	4 (14)	4 (24)	2 (15)	3 (9)	
Former	1 (4)	1 (6)	0 (0)	6 (18)	
Education, n (%)					.20
High school or trade school	7 (25)	4 (24)	5 (39)	8 (24)	
Some college or associate's degree	9 (32)	8 (47)	6 (46)	15 (44)	
Bachelor's degree or higher	12 (43)	5 (29)	2 (15)	11 (32)	
Body mass index (kg/m^2)[g], n (%)					*<.001*
Normal	0 (0)	0 (0)	1 (8)	0 (0)	
Preobese	4 (14)	3 (18)	5 (39)	7 (21)	
Obese class 1	11 (39)	5 (29)	0 (0)	7 (21)	
Obese class 2	6 (21)	4 (24)	1 (8)	9 (27)	
Obese class 3	7 (25)	5 (30)	6 (46)	11 (32)	
Comorbidities, n (%)					
Hypertension					.004
No	13 (46)	4 (24)	6 (46)	9 (27)	
Yes	15 (54)	13 (77)	7 (54)	25 (74)	
Hypercholesterolemia					.21
No	12 (43)	9 (53)	4 (31)	15 (44)	
Yes	16 (57)	8 (47)	9 (69)	19 (56)	
Coronary artery disease					*<.001*
No	26 (93)	15 (88)	13 (100)	30 (88)	
Yes	2 (7)	2 (12)	0 (0)	4 (12)	
Microvascular complications					*<.001*
No	24 (86)	16 (94)	12 (92)	30 (88)	
Yes	4 (14)	1 (6)	1 (8)	4 (12)	

Baseline characteristics[a]	UC[b] (n=28)	CO[c] (n=17)	CPP[d] (n=13)	CPDS[e] (n=34)	*P* value
Depression (PHQ-9[h]) score					
Minimal to mild (0-9)	22 (30)	15 (21)	10 (14)	26 (35)	
Moderate (10-14)	2 (20)	0 (0)	2 (20)	6 (60)	
Moderately severe (15-19)	4 (57)	2 (29)	1 (14)	0 (0)	
Severe depression (20-27)	0 (0)	0 (0)	0 (0)	2 (100.0)	.21
Patient-reported outcomes, mean (SD)					
Diabetes Distress Scale[i]	2.4 (0.8)	2.6 (0.9)	2.7 (0.7)	2.8 (1.0)	.41
Diabetes symptom inventory[j]	20.7 (15.0)	18.1 (13.8)	23.3 (17.1)	23.8 (16.8)	.65
Laboratory outcomes, mean (SD)					
Systolic blood pressure (mmHg)	133.3 (25.1)	130.9 (17.7)	134.8 (14.4)	130.2 (12.2)	.84
Diastolic blood pressure (mmHg)	78.9 (13.1)	79.7 (11.5)	81.2 (7.0)	78.3 (8.1)	.85
Low-density lipoprotein (mg/dL)	105.1 (31.8)	102.3 (25.9)	94.6 (30.6)	112.4 (30.4)	.32
High-density lipoprotein (mg/dL)	44.8 (10.7)	43.2 (12.5)	42.2 (13.0)	45.9 (11.6)	.76
Triglycerides (mg/dL)	191.6 (193.0)	161.7 (101.4)	168.9 (116.8)	173.9 (120.8)	.91
Total cholesterol (mg/dL)	188.3 (56.7)	179.2 (23.8)	167.4 (43.3)	191.0 (31.6)	.35

[a]Data Source: claims data, primary care provider office patient medical records, and research surveys.

[b]UC: usual care.

[c]CO: coaching only.

[d]CPP: coaching and patient care provider portal.

[e]CPDS: coaching and patient care provider portal with decision support.

[f]All italicized values indicate statistical significance, $P<.05$

[g]BMI: normal, 18.5-24.9 kg/m^2; preobese, 25-29.9 kg/m^2; obese class 1, 30-34.9 kg/m^2; obese class 2, 35-39.9 kg/m^2; obese class 3, ≥40.0 kg/m^2.

[h]PHQ-9: Patient Health Questionnaire-9.

[i]17-item measure, a mean across 17 items; each item scored from 1 (little distress) to 6 (serious distress).

[j]9-item measure, mean scores range from 0 (no dysfunction) to 100 (worst possible health status).

Table 2 compares changes in utilization from the previous year to the study year by service type. Physician office visits ($P=.01$), general practitioner visits ($P=.02$), other outpatient services ($P=.001$), prescription claims ($P<.001$), and podiatrist visits ($P=.04$) showed significant changes in utilization. Physician office visits and general practitioner visits both decreased over time while prescription claims increased. Interestingly, UC and CO groups experienced decreases in the utilization of other outpatient services and for podiatrist visits, whereas groups CPP and CPDS increased their utilization of these services.

A significant group by time effect was observed in physician office visits, general practitioner visits, other outpatient services, and prescription claims. The CPDS group, which had the most intense intervention, had the smallest decline of all treatment groups for physician office visits (−2.68), while the UC group had the largest decline in physician office visits (−5.09; $P=.01$). Both groups had similar physician office visit counts for the year prior to the study, but the CPDS group maintained higher utilization during the study period. For general practitioner visits, the CPDS group showed the smallest decrease in visits (−1.38), while the CPP group showed the largest decrease in visits (−3.39; $P=.02$). The groups had similar visit counts for the year prior to the study, but the CPDS group maintained a higher utilization during the study period than the other groups. In other outpatient services, the CPDS group had a significant increase in the number of claims in the study year (+0.35), while the UC group had a significant decline (−3.38; $P=.001$). This may be partially due to the unequal visit counts of the prior year, as the UC group had the highest prior year other outpatient services visit count. The CPDS group also had a significant increase in prescription claims from the prior year to the study year (+43.95) compared with the CPP group, which showed the only decline in prescription claims (−2.19; $P<.001$). Repeated measures analysis of variance revealed that podiatrist claim changes from the prior year to the study year were different across the groups. The CPDS group showed the greatest gain in podiatry visits (+0.48), while the CO group showed the greatest decline (−0.88; $P=.04$). Group by time effects for ophthalmologists, cardiologists, or lab claims were not significant.

Changes in service utilization over the study period had no significant effect on HbA_{1c} (Table 3). No significant effects of the various study year utilization visit counts were observed on changes in 12-month HbA_{1c} to explain the clinically significant results obtained in the parent study [11].

Table 2. Changes in service utilization by type of service, by time (1 year) and group difference (n=92).

Claim type[a] and visits	UC[b] (n=28), mean (SD)	CO[c] (n=17), mean (SD)	CPP[d] (n=13), mean (SD)	CPDS[e] (n=34), mean (SD)	Group time, *P* value
Physician office visits					
Previous year	10.00 (6.74)	10.00 (7.81)	7.79 (7.83)	10.45 (7.06)	—
Study year	4.91 (4.43)	6.20 (5.36)	4.08 (4.98)	7.76 (5.35)	—
Increment	−5.09 (5.77)	−3.75 (6.64)	−4.11 (4.22)	−2.68 (5.91)	*.01* [f]
General practitioner visits					
Previous year	5.29 (3.63)	4.75 (3.21)	5.36 (5.18)	5.72 (4.09)	—
Study year	2.44 (2.62)	2.60 (2.40)	2.33 (2.61)	4.34 (3.62)	—
Increment	−2.84 (3.95)	−2.19 (2.37)	−3.39 (3.95)	−1.38 (2.74)	*.02*
Cardiologist visits					
Previous year	0.40 (1.09)	0.69 (2.27)	0.31 (1.11)	0.44 (1.05)	—
Study year	0.14 (0.59)	0.53 (1.12)	0.17 (0.39)	0.41 (1.02)	—
Increment	−0.26 (0.62)	−0.13 (2.22)	−0.17 (0.94)	−0.03 (1.29)	.54
Other outpatient services					
Previous year	6.99 (12.71)	2.00 (3.18)	2.49 (7.17)	3.93 (7.47)	—
Study year	3.61 (5.28)	1.00 (1.54)	2.92 (4.17)	4.27 (8.32)	—
Increment	−3.38 (10.34)	−0.94 (3.17)	+0.22 (2.64)	+0.35 (7.58)	*.001*
Lab claims					
Previous year	4.17 (3.71)	3.31 (2.18)	2.77 (2.23)	4.61 (2.96)	—
Study year	2.15 (2.00)	2.30 (2.66)	1.67 (1.61)	4.20 (3.27)	—
Increment	−2.02 (3.70)	−0.94 (3.28)	−1.17 (1.98)	−0.41 (2.96)	.09
Prescription claims					
Previous year	11.88 (32.80)	3.19 (8.01)	25.95 (76.71)	7.97 (19.93)	—
Study year	19.28 (48.14)	29.03 (51.10)	25.92 (60.94)	50.93 (102.04)	—
Increment	+7.39 (20.90)	+15.25 (25.80)	−2.19 (38.51)	+42.95 (84.66)	*<.001*
Ophthalmologist visit					
Previous year	0.11 (0.42)	0 (0)	0.08 (0.28)	0.12 (0.33)	—
Study year	0.18 (0.77)	0 (0)	0 (0)	0.15 (0.50)	—
Increment	+0.07 (0.47)	0 (0)	−0.08 (0.29)	+0.03 (0.39)	.67
Podiatrist visit					
Previous year	0.57 (1.43)	1.50 (2.88)	0 (0)	0.37 (1.2)	—
Study year	0.46 (1.23)	0.59 (1.58)	0.08 (0.29)	0.85 (1.44)	—
Increment	−0.11 (1.20)	−0.88 (2.13)	+0.08 (0.29)	+0.48 (1.67)	*.04*

[a]Data source: claims data.

[b]UC: usual care.

[c]CO: coaching only.

[d]CPP: coaching and patient care provider portal.

[e]CPDS: coaching and patient care provider portal with decision support.

[f]All italicized values indicate statistical significance, $P<.05$

Table 3. Mobile Diabetes Intervention Study: Changes in utilization by service type and effect on HbA_{1c} over a 1-year period.

Claim type[a]	Claims during study, mean (SD)	HbA_{1c}[b] change per visit			
		Model without group effect		Model with group effect	
		Estimate	*P* value	Estimate	*P* value
Physician office visits	6.1 (5.2)	−0.016	.61	−0.01	.75
General practitioner visits	3.2 (3.1)	0.002	.97	0.009	.86
Cardiologist visits	0.3 (0.9)	−0.026	.87	0.024	.88
Ophthalmologist visits	0.1 (0.5)	0.083	.76	−0.012	.96
Podiatrist visits	0.6 (1.3)	−0.185	.09	−0.188	.08
Outpatient services	3.3 (6.1)	0.002	.96	−0.009	.75
Lab claims	2.9 (2.8)	−0.009	.87	0.001	.99
Prescription claims	33.8 (75.0)	−0.001	.51	−0.001	.61

[a]Data Source: Commercial Insurer, November 2006-January 2010.

[b]HbA_{1c}: glycated hemoglobin.

Discussion

Principal Findings

To our knowledge, this administrative claims analysis is the first study assessing a c-RCT mobile phone diabetes intervention's impact on health service utilization. This study expands on the study by Quinn et al [11] by assessing the intervention's effect on changes in health service utilization and whether those changes explain the clinically significant change in HbA_{1c} reported in the primary study. We found that mobile phone-based treatment and behavioral coaching intervention decreased physician office visits, general practitioner visits, and lab claims over time while prescription claims increased. The issue of whether an increase or decrease in claims as a result of the intervention is desirable or undesirable is unclear. Increases in medication prescriptions may be a good outcome, suggesting that appropriate physician intensification occurred and participants were more appropriately taking their medications [17]. Decreases in physician visits and labs saves money but could either indicate less need for care, or if too infrequent, may suggest mHealth participants are inappropriately substituting the in-person care with attention from the intervention.

Our finding of no significant effects of utilization visits to explain the change in 12-month HbA_{1c} obtained in the parent study [11] may be due to the intervention's multiple behavior change strategies. In a follow-up mixed methods analysis of patient engagement in the parent study, we learned that some patient behaviors (glucose monitoring, healthy eating, and taking medication) contributed to greater changes in HbA_{1c} [15]. It may also be that our sample of claims data was too small or too short in follow-up to evaluate the impact of utilization on changes in HbA_{1c} over a 1-year period.

The generally positive findings reported here need to be put into context with the mixed economic results from diabetes management interventions reported in other studies. Nundy examined the impact of a 6-month mHealth demonstration project among adults (n=74) with type 1 and type 2 diabetes who were members of an academic medical center's employee health plan. Although those authors observed pre-post improvements in glycemic control (*P*=.01) and a significant decrease in per person outpatient visits, only 20% of the eligible population participated in the study [19]. Another study found improvements in clinical measures but no impact on health care utilization or cost [20]. None of these studies are directly analogous to this study, which highlights the difficulty in determining successful integration of mobile phone diabetes interventions in clinical settings as a reimbursable service.

Payers

The results of our study will inform payers attempting to understand the potential of mobile phone diabetes management technology. Payers have been reluctant to reimburse for mHealth visits, partly due to lack of evidence that mHealth interventions make a difference in utilization and related costs. Payers' views are short term, not long term, because members may not be enrolled in their plan for the next insured year. The prevention or delay of complications require years. Therefore, a short-term outcome, such as change in HbA_{1c} as demonstrated in our primary study, as an indicator of prevention may be more appealing to payers than specific utilization effectiveness of an mHealth intervention.

Payers are "experimenting" with health and wellness apps, but current reimbursement payments for mHealth care are largely limited to remote rural areas. Payers have a financial interest in minimizing their risk by actively promoting the health of their policyholders. However, most health care technologies are used in the current fee-for-service (FFS) model, including our evaluation [21]. In a FFS system in which there are only codes for medical devices and human to clinician visits, "there are few, if any, reimbursement codes that exist for frequent high-value patient touchpoints driven by technology rather than humans." [22]. The potential benefits of mobile phone diabetes care from the perspective of payers may be driven by the transformation of the incentives from pay for service to pay-for-value or performance. Mobile phone diabetes management, such as our intervention focusing on behavioral

change based on digital contacts between patients and providers that improves clinical outcomes and utilization metrics, is well-placed in a bundled payment model. The bundled payment model could include a per-patient amount for a bundle of services to be provided, preferably with payment based on agreed-upon clinical outcomes achieved by the mobile phone digital contacts, instead of an FFS payment system based solely on the number of office contacts.

Limitations

We advise caution in generalizing our findings. Participants in the study were insured by a single commercial insurer and may have experience with and access to resources including individual group practice guidelines, access to specialists, and variations in insurance plan coverage and coinsurance different from the rest of the population with T2D. We attempted to address these differences by enrolling multiple community physicians to participate in the study and randomization at the practice level with patient enrollment following physician randomization assignment. Administrative claims data may not adequately capture service utilization by persons with T2D. For example, diabetes is infrequently the primary diagnosis for emergency department visits or hospitalizations but is often an underlying condition (eg, to myocardial infarction). The analysis was unlikely to see more severe conditions requiring hospitalizations because of exclusion criteria and therefore unlikely to observe high utilizers where diabetes is severe and uncontrolled, (eg, gangrene or kidney failure), although 45% (41/92) of participants had HbA_{1c}>9% at enrollment. Improvements in utilization, both increases and decreases depending on the health service, may have occurred after the utilization analytic year. Some utilization was required of the study treatment (ie, visiting primary care provider and receiving prescription for HbA_{1c} tests).

Conclusion

Our program of studies [11,15,17,18,23], including the analysis reported here, demonstrates that a mobile phone diabetes technology achieved a clinically significant change in BG control and that important service utilization increased (pharmacy) or decreased (physician office visits). These findings may help persons with T2D diabetes engage with health service providers and participate in decisions to receive services, lab tests, and prescribed medications recommended by treatment guidelines.

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The funders of this study did not play a role in the design and conduct of the study; collection, management, analysis, and interpretation of the data, or in the preparation of the manuscript. WellDoc did not have veto power over or have say about changing any manuscript text other than the description of the software coaching system they provided. Dr. Ram Miller served as the Data and Safety Monitoring Board (DSMB).

Authors' Contributions

CCQ was the principal investigator for these studies. CCQ, KKS, JMT, MDS, MLT, and ALG-B were responsible for the design, data analyses, writing, and review of the manuscript. EAB was responsible for the data analyses and manuscript review. KKS contributed to the writing and review of the manuscript.

Conflicts of Interest

In March 2018, after completion of this analysis, CCQ was included as a Scientific Advisor to WellDoc.

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Abbreviations

BG: blood glucose
CO: coaching only

CPDS: coaching and patient care provider portal with decision support
CPP: coaching and patient care provider portal group
c-RCT: cluster randomized clinical trial
FFS: fee-for-service
BG: blood glucose
HbA_{1c}: glycated hemoglobin
MDIS: Mobile Phone Diabetes Intervention Study
T2D: type 2 diabetes
UC: usual care

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Review

Benefits of Mobile Apps in Pain Management: Systematic Review

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Abstract

Background: Pain is a common condition with a significant physical, psychosocial, and economic impact. Due to enormous progress in mobile device technology as well as the increase in smartphone ownership in the general population, mobile apps can be used to monitor patients with pain and support them in pain management.

Objective: The aim of this review was to assess the efficacy of smartphone or computer tablet apps in the management of patients with pain.

Methods: In December 2017, a literature search was performed in the following databases: MEDLINE, EMBASE, CINAHL, Cochrane, and PsycINFO. In addition, a bibliography search was conducted. We included studies with at least 20 participants per arm that evaluated the effects of apps on smartphones or computer tablets on improvement in pain.

Results: A total of 15 studies with 1962 patients met the inclusion criteria. Of these, 4 studies examined the effect of mobile apps on pain management in an in-clinic setting and 11 in an out-clinic setting. The majority of the original studies reported beneficial effects of the use of a pain app. Severity of pain decreased in most studies where patients were using an app compared with patients not using an app. Other outcomes, such as worst pain or quality of life showed improvements in patients using an app. Due to heterogeneity between the original studies—patient characteristics, app content, and study setting—a synthesis of the results by statistical methods was not performed.

Conclusions: Apps for pain management may be beneficial for patients, particularly in an out-clinic setting. Studies have shown that pain apps are workable and well liked by patients and health care professionals. There is no doubt that in the near future, mobile technologies will develop further. Medicine could profit from this development as indicated by our results, but there is a need for more scientific inputs. It is desirable to know which elements of apps or additional devices and tools may improve usability and help patients in pain management.

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KEYWORDS

mobile application; pain; pain management; smartphone; cell phone; telemedicine; review

Introduction

Mobile device technology has improved enormously in the past years. With higher screen resolution or better processor performance, not only has the hardware improved but also many software programs known as mobile apps have been developed, thereby setting up a technological revolution. Use of internet on smartphones and the proportion of total internet use have increased within the past few years [1-3] and are part of the daily life worldwide. The number of health-related mobile apps increased rapidly within the past 10 years; in 2017, about 40% of the more than 300,000 apps available on the market were related to health issues, including monitoring and management of illnesses [4]. Chronic illnesses seem to be a particular target for the use of these apps. The result of a review showed that the use of apps helps to improve asthma control and even lung

function. Patients' symptoms and medication usage are recorded, and recommendations to adapt treatment, for example, to increase the dose of inhaled drugs, are provided [5]. Patients with type 1 diabetes appreciate an app as a supplement for disease management (eg, communication with health care professionals) [6]. The use of a smartphone app shortens times for medical personnel to review glucose-level diaries from patients [7] and has the potential for improving glucose control in type 1 and 2 diabetes [7,8].

Pain, acute and chronic, is a substantial burden on individuals, health care systems, and employers [9]. Patients with acute pain need to be treated carefully to prevent abuse of pain medication, in particular the abuse of opioids, and to prevent the development of chronic pain. Apps assist to monitor patients with acute or chronic pain and can inform and support them in the management of pain, for example, changes in the dosage of analgesics, early detection of adverse effects of analgesics, or providing coping strategies to manage pain. Published (systematic) reviews appraised the usability of smartphone or computer tablet app use in patients with pain. The reviews show that many of the commercially available apps lack usability and have other limitations, such as absence of rigorous scientific evaluation of the provided content and the recommendations given to patients [10-17]. None of the published reviews assessed the efficacy of apps in the management of patients with acute or chronic pain. The objective of this review is to assess the efficacy of smartphone or computer tablet apps in the management of patients with pain.

Methods

Data Reporting

This systematic review is based on the preferred reporting items for systematic reviews and meta-analyses (PRISMA) [18].

Literature Search

At the end of December 2017, a systematic literature search was commissioned to the Careum Bibliothek of the University of Zurich. The following electronic databases were searched by an experienced librarian: MEDLINE, EMBASE, CINAHL, Cochrane, and PsycINFO. We used, among others, the following search terms as medical subject headings and other subject headings: "Pain+," "Pain Management," "Pain Measurement," "Cellular Phone+," "Mobile Devices," "Mobile Applications," "Telehealth," and "Telemedicine+." Detailed description of one search strategy is provided in Multimedia Appendix 1. Only articles written in English or German were considered. No restriction regarding publication date was applied.

Eligibility Criteria

Studies included in this review evaluated the effects of mobile apps (which we refer to as apps and are defined as a type of application software designed to run on a mobile device [19]) on smartphones or computer tablets on improvement in pain. Studies with at least 20 participants per arm were included and could have an in-clinic or an out-clinic setting. In-clinic setting describes the situation when the intervention with an app was made in a hospital, clinic, or another institution only, regardless of whether patients were in ambulatory or stationary treatment (being cared for at least 24 hours in a hospital). Out-clinic describes the setting when the intervention with an app was performed by the patients themselves in an ambulatory treatment, meaning patients could use the app wherever they were.

Studies were excluded if devices other than a smartphone or computer tablet (eg, smartwatches, palmtops, handheld computers, or similar devices) or if an app not defined as above was used for data collection (eg, internet website and short message service [SMS]). Furthermore, exclusion criteria were the use of apps designed for diagnosis of a medical condition or not explicitly designed for pain-level recording, management, or treatment (eg, usual music players, video conference programs, and video games). These exclusion criteria did not apply if there was another app that was designed to take part in the study, for example, pain diary. In addition, studies were excluded if they included patients with a cognitive handicap, did not provide sufficient baseline data, described the development process of an app without measuring the effects of app use on pain, were conducted in the field of veterinary health, or were not available for purchase.

Study Selection and Data Extraction

All references were initially screened by title and abstract by 2 reviewers (SET and JMB) for relevance. Finally, full-text analysis for eligibility was performed by SET and JMB independently. Disagreements were discussed and resolved by consensus or third-party arbitration (JS).

Outcomes

The primary outcome of interest of this systematic review was improvement of pain. Other outcomes of interest assessed in the studies, such as worst pain (the worst pain intensity during a certain defined observational period) or improvement in mobility were also included in analysis.

Quality of Studies

The checklist of the Scottish Intercollegiate Guidelines Network (SIGN) [20] for randomized controlled trials (RCTs) was used to review the quality of included RCTs. Overall assessment of each study focused on bias minimization was rated in categories; RCT categories are high quality (++), acceptable (+), low quality (−), and reject (0). High ratings mean the majority of criteria are met and further research is unlikely to change results; acceptable quality is provided by studies in which most criteria are met with few flaws, but conclusions may change after future studies. Low quality is given if either most criteria are not met or significant flaws in key aspects of the study design are present, and therefore, further studies may change conclusions. If a study did not meet the SIGN quality criteria and was considered to be in the category unacceptable, it was rejected.

For before-after studies (often called pre-post studies where variables are measured before and after an intervention and all participants are assigned to 1 intervention group), no checklist is required [20].

Statistics

The primary objective of this study was to assess the mean pain difference between intervention and control groups or before

and after intervention. If data for several time points were available, the last one was considered to be the most relevant to our analysis. Heterogeneity of studies did not allow meta-analysis; so, only descriptive and comparative analysis was used to summarize findings across all studies.

A secondary objective was to summarize other outcomes as well as applicability and feasibility of the apps in a qualitative way. Most of the additional outcomes reviewed were too heterogeneous to compare statistically. Qualitative descriptive exploration was performed, and the most important results were summarized in a table.

For the primary comparative analysis, studies were included if sufficient data were available and measurement scales were comparable. Only study results with very similar pain rating scales were included (eg, Visual Analog Scale, VAS, on a scale of 0-10; numeric rating scale, NRS, 0-10; and VAS on a scale of 0-100), and where necessary, different pain score scales were rescaled to a 0- to 10-point scale. We graphically show the mean pain scores over time separately for each study arm where available. The effects of treatment in the multiple-arm studies with sufficient data for comparison are shown in a forest plot. Studies that did not have an observational period—all of which have an in-clinic study setting—are shown in a separate graph. If data were missing and could not be calculated from the other available data, corresponding authors were contacted twice via email. If authors did not respond, data were considered missing.

Results

Study Selection

As shown in Figure 1, systematic literature search retrieved 2232 studies, which were reduced to 1258 after deduplication. After further manual deduplication, 1230 studies remained. After an additional bibliography screening of the relevant studies, 8 additional scientific studies were included, leading to 1238 studies. After title and abstract screening, 1193 articles were excluded. Finally, 45 full texts were reviewed closely using inclusion and exclusion criteria as well as criteria for the methodological quality, resulting in 15 eligible studies. The main reasons for exclusion are displayed in Figure 1.

Study Overview

Characteristics of included studies are shown in Table 1 and in Multimedia Appendix 2. A total of 7 RCTs [21-27], 6 before-after studies [28-33], 1 controlled before-after study [34], and one retrospective data analysis [35] with a total of 1962 patients were reviewed. Of these, 11 studies were conducted in an out-clinic setting and 4 studies in an in-clinic setting. In addition, 8 of the studies were controlled (7 RCTs and 1 controlled before-after study); 1 was a 3-armed RCT. Moreover, 7 studies were single arm, 6 of which compared baseline to follow-up parameters (before and after), and 1 was a retrospective analysis of collected data [35]. Studies were published between 2015 and early 2018. Publication date of Blödt et al [21] differs from literature search because citation recommendation is dated for 2018, whereas the article was available online in 2017. The mean age of participants ranged between 12 and 68 years, and the follow-up period ranged between 0 and 28 days for in-clinic setting and 14 and 180 days for out-clinic setting. A total of 15 studies were conducted using a smartphone, 3 gave the possibility to use an app designed for multiple devices (smartphone, computer tablet, and computer [23,33,35]), and 2 studies were conducted solely with computer tablets [26,34]. A total of 12 apps were used for treatment of chronic pain; 2 interventions were used for management of singular acute pain [26,28] and 1 for recurrent (menstrual) pain [21]. Detailed information about each app used in the included studies can be found in Multimedia Appendix 3.

Missing Data

One study did not report mean pain values but only mean change in pain values. Therefore, description of results but no graphic representation was possible [26]. Schatz et al [24] did not compare baseline to follow-up mean pain values, and consequently, the study could also not be included in the graphical representation. Authors of studies with missing data were contacted through email (corresponding email address on publication), but none of them responded. Huber et al [35] did not report the last day of use of the app in their intention-to-treat (ITT) analysis. Therefore, graphical representation was not possible for ITT analysis (missing x-axis value) but only for patients who completed the full observational time of this retrospective analysis.

Effects of Apps on Pain

Figure 2 shows improvement in pain over time, and Figure 3 illustrates the effect size of the intervention in 6 controlled studies [21-23,25,27,34]. One study did not provide information about the standard deviation, and therefore, only mean pain values are shown in the graph [22]. In addition, 4 studies reported a significant improvement in pain in the group using the app [21,23,25,27]. In another study [21], patients showed no significant improvement at follow-up after 29 and 58 days. Skrepnik et al [25] reported only mean percentage change in walking pain; therefore, significance of mean change in pain was not possible to calculate. One study showed nonsignificant tendency toward improvement [22]; 1 study did not report improved pain in the intervention group [34].

Figure 4 shows a mean decrease in pain over time in 5 single-arm studies [30-33,35]. All studies showed a significant decrease over time. Huber et al's [35] ITT comparison of baseline pain to mean pain at the end of the observational time showed statistically significant decrease. Figure 5 shows a decrease in pain in 2 single-arm studies, with immediate postintervention measurements. One study showed a statistically significant decrease in chronic pain; the other showed no decrease in patients with acute pain [28,29]. Schatz et al [24] did not report about the severity of pain at baseline and follow-up. Therefore, we were not able to depict the results graphically. However, analysis based on daily pain diary data showed lower next-day pain in the intervention group compared with control group. Stinley et al [26] did not provide mean pain measurements; therefore, graphic depiction was also not possible. They reported that pain scores between groups did not differ.

Figure 1. Study flow.

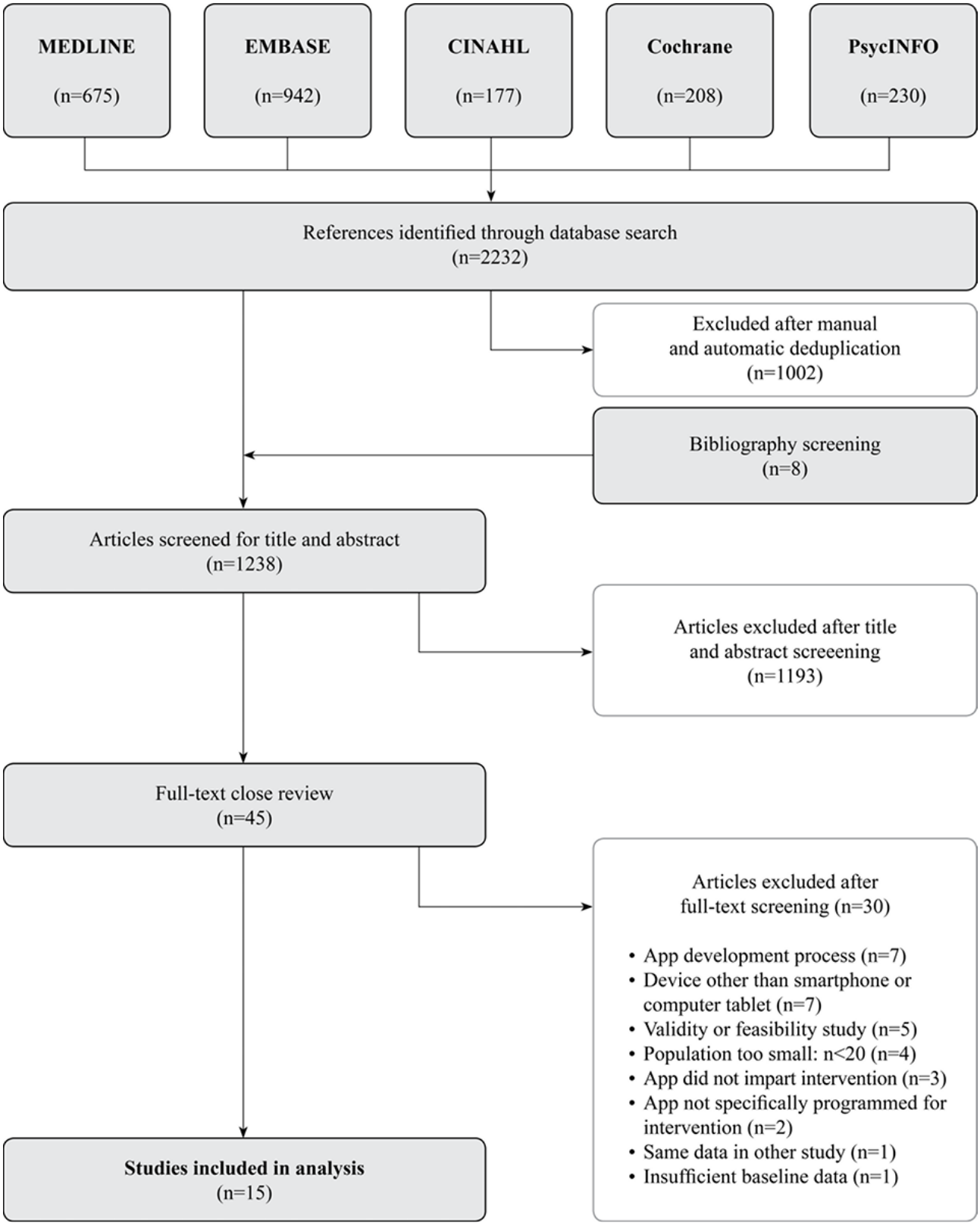


Table 1. Baseline characteristics of all included studies.

Author, year	Study design	Device	Patients, N	Female, n (%)	Age, mean (SD)	Follow up (days)	Type of pain
Blödt et al, 2018 [21]	RCT[a]	S[b]	221	221 (100)	24 (3.6)	174[c]	Recurrent menstrual pain
Sun et al, 2017 [27]	RCT	S	46	14 (30.4)	67.5 (N/A[d])	14	Chronic cancer
Skrepnik et al, 2017 [25]	RCT	S	211	106 (50.2)	62.6 (9.4)	90	Chronic walking pain
Raj et al, 2017 [34]	cBAS[e]	T[f]	214	103 (48.1)	60.1 (12.7)	21	Chronic cancer
Oldenmenger et al, 2017 [33]	BAS[g]	S/T/C[h]	84	44 (52.4)	59 (11)	42	Chronic cancer
Lee et al, 2017 [32]	BAS	S	23	10 (43.5)	28.1 (3)	56	Chronic neck pain
Jibb et al, 2017 [31]	BAS	S	40	17 (42.5)	14.2 (1.7)	28	Chronic cancer
Huber et al, 2017 [35]	RDA[i]	S/T/C	180	105 (58.3)	33.9 (10.9)	84	Chronic low back pain
Jamison et al, 2016 [30]	BAS	S	90	58 (64.4)	46.7 (12.9)	180	Chronic pain
Guétin, de Diego et al, 2016 [29]	BAS	S	53	42 (79.3)	47.4 (16.5)	—[j]	Chronic pain
Guétin, Brun et al, 2016 [28]	BAS	S	35	17 (48.6)	61.3 (11.6)	—	Acute pain before coronarography
Stinley et al, 2015 [26]	RCT	T	40	20 (50)	12.3 (2.9)	—	Acute needle stick pain
Schatz et al, 2015 [24]	RCT	S	46	27 (58.7)	13 (2.5)	112	Chronic pain in sickle cell disease
Irvine et al, 2015 [23]	RCT	S/T/C	597	358 (60)	N/A (N/A)	112	Chronic low back pain
Guillory et al, 2015 [22]	RCT	S	82	51 (75)	48.6 (11.6)	28	Chronic non cancer pain

[a]RCT: randomized controlled trial.

[b]S: smartphone.

[c]Duration of six menstruation cycles with a mean of 29 days.

[d]N/A: not available.

[e]cBAS: controlled before-after study.

[f]T: computer tablet

[g]BAS: before-after study.

[h]C: computer.

[i]RDA: retrospective data analysis.

[j]Not applicable.

Effects of Apps on Other Outcomes and Information About Feasibility

Blödt et al [21] reported that patients using the app had pain for fewer days and needed less pain medication compared with the control group. In 2 studies [21,33], worst pain improved using the app but did not in another study [34]. Furthermore, statistically significant decreases were found in momentary pain, total pain interference (eg, general activity or mood), and pain catastrophizing in 1 study [30]. Anxiety decreased in patients using the app in 2 studies [28,29], whereas there was no reduction in another study [30]. Stinley et al [26] reported only a decrease in anxiety in the subgroup of patients with high anxiety levels. Guillory et al [22] reported statistically significant improvements in pain interference with general activities, pain interference with sleep, pain interference in relation with others, and positive affect for app users compared with the control group during the intervention period. However, 1 week after the intervention period, sleep pain and positive affect were not significant any more. In another study, statistically significant improvements in functionality, well-being, productivity, and presenteeism at work were reported for the treatment group compared with the control group [23]. One study found that age, ethnicity, and gender did not influence compliance or satisfaction with the app [30].

All studies evaluating changes in quality of life revealed a statistically significant improvement in the groups using an app [23,27,31,32]. In addition, 8 studies reported high satisfaction with the ease of use of the app [21,23,25,27-29,33,36], and 3 studies stated good feasibility of app use with high diary completion rates [22,27,31]. Further details about the additional outcomes can be found in Multimedia Appendix 4.

Figure 2. Improvement in pain over time in multiple armed studies. Pain scale (Numeric Rating Scale): 0-10.

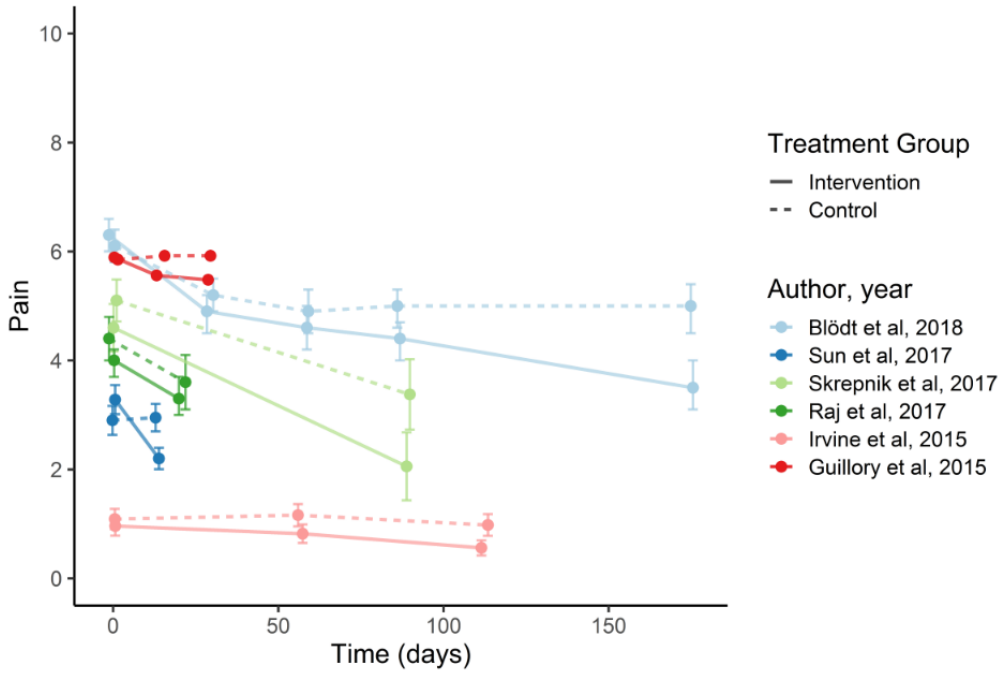


Figure 3. Forest plot of intervention effect on pain in multiple armed studies. Pain scale (Numeric Rating Scale): 0-10.

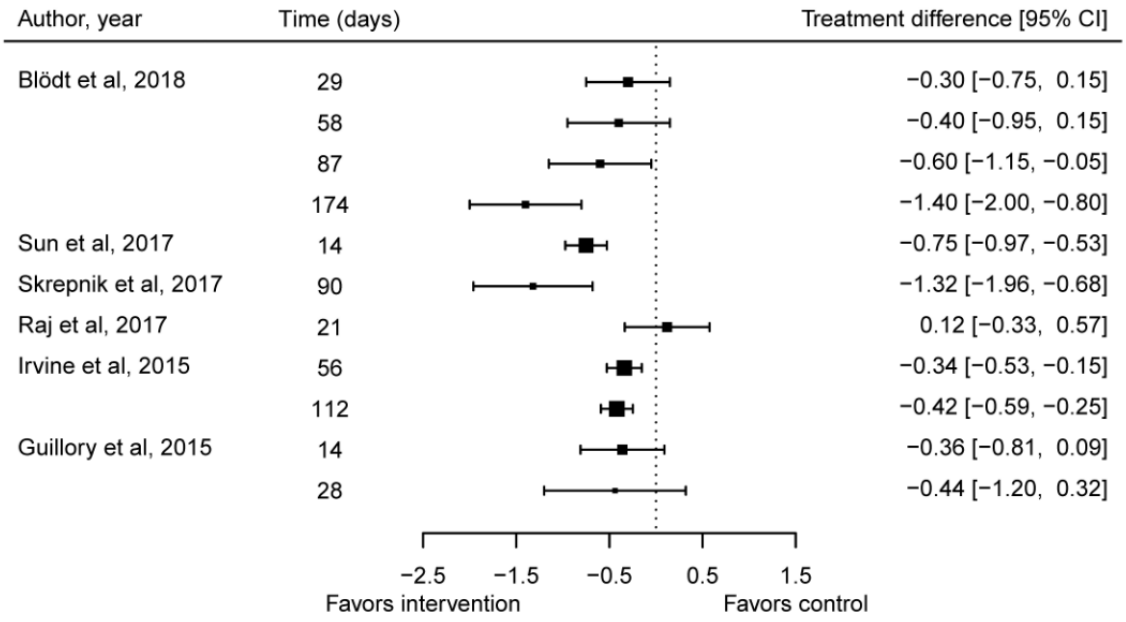


Figure 4. Decrease in pain in out-clinic before-after studies and in the retrospective data analysis. Pain scale (Numeric Rating Scale): 0-10.

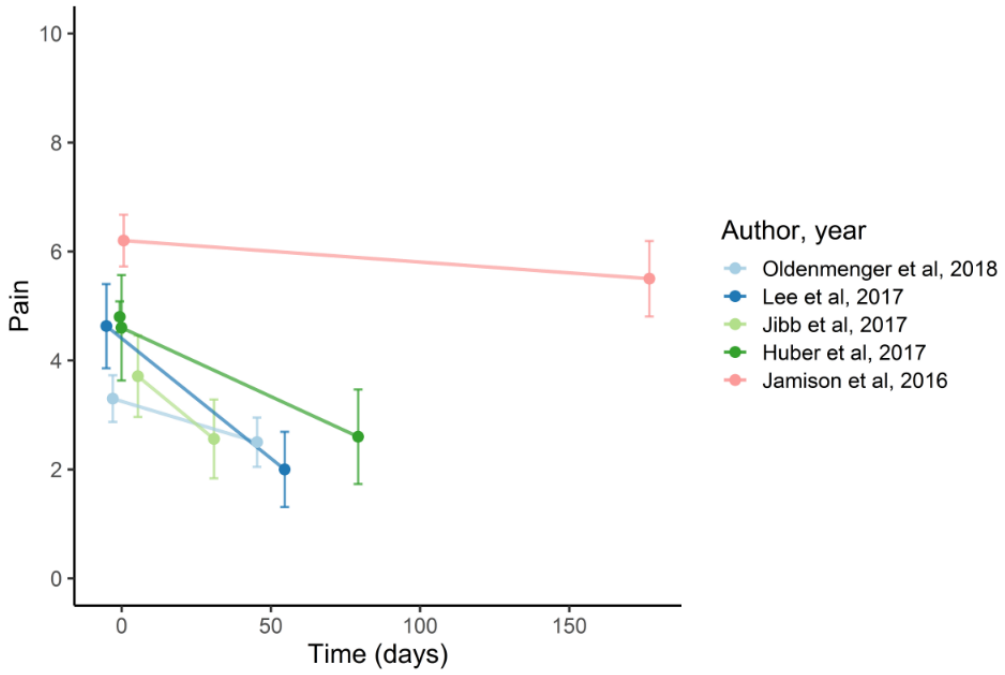
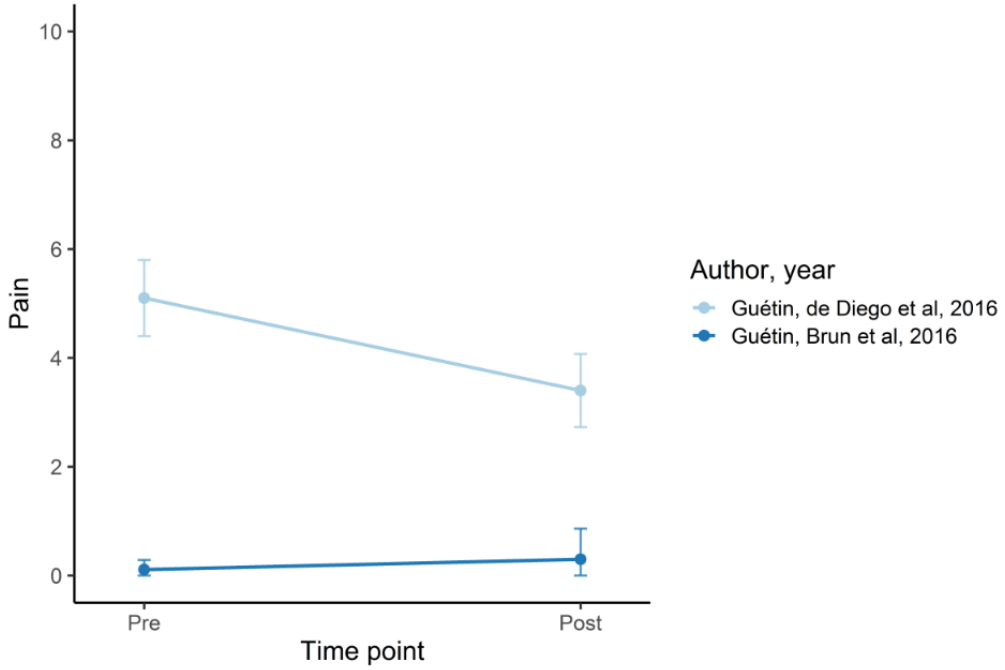


Figure 5. Decrease in pain in in-clinic before-after studies. Pain scale (Numeric Rating Scale): 0-10.



Methodological Quality of the Randomized Controlled Trials

Multimedia Appendix 5 shows the risks of biases of all included RCTs using the corresponding SIGN checklist [20]. Furthermore, 1 RCT was of high quality [24], and 6 RCTs [21-23,25-27] were of acceptable quality. The studies of acceptable quality had a deficiency in at least one of the following areas: description of random allocation (checklist item 1.2), concealment (1.3), comparability at baseline (1.5), missing ITT analysis (1.9), or missing multisite comparisons (1.10).

Discussion

Principal Findings

The main objective of this review was to evaluate the efficacy of apps on smartphones or tablets for the management of patients with pain. The results of 7 RCTs, 6 before-after studies, 1 controlled before-after study, and 1 retrospective data analysis were included in this review. The majority of the original studies reported beneficial effects of the use of a pain app. Severity of pain decreased in most studies in patients using an app compared with those not using an app. Other outcomes, such as *worst pain* or *quality of life*, showed improvements in patients using an

app. Due to heterogeneity between the original studies—patient characteristics, app content, and study setting—a synthesis of the results by statistical methods was not performed.

Comparison With Existing Literature

To the best of our knowledge, this is the first systematic review about the efficacy of smartphone or computer tablet apps for the management of patients with pain. There are published systematic reviews that study the quality of the content (eg, evidence-based interventions or inclusion of health care professionals in the development process) and ease of use of commercially available apps for pain management [10-15,17]. None of the reviews that were reported assessed the overall effectiveness of apps as tools for managing pain in patients.

Authors of 3 reviews [10-12] criticized that the apps were not comprehensive in terms of pain self-management and that health care professionals and patients were scarcely involved in the development of the app. Furthermore, they reported a lack of scientific evidence in app content. Machado et al [13] examined the quality of apps for low back pain. Although 58 out of 61 apps included some type of intervention (eg, information for strengthening and/or stretching exercises and yoga, which was listed in the National Institute for Health and Care Excellence guidelines for low back pain [37]), most of the assessed apps lacked evidence and were of poor quality. Bhattarai et al [14] evaluated smartphone apps for self-management in patients with arthritic pain in their systematic review. Out of 373 assessed apps, only 4 met the authors' inclusion criteria, and 3 of them did not fulfill the minimal usability criteria. Portelli and Eldred [15] reviewed the degree to which apps adhere to evidence-based practices in psychological research for pain management. Integrated theoretical reference to cognitive behavioral therapy (CBT) principles was only present in 6 out of 195 apps investigated.

Other studies not meeting our inclusion criteria (eg, use of other devices or use of apps not specifically made for intervention) showed results similar to the studies included in our analysis. In the study of Kristjánsdóttir et al [38], patients used early smartphone models to fill in pain diaries on the internet and to communicate with the therapist through SMS in a 4-week intervention trial. As a result, catastrophizing of pain was reduced in the intervention compared with the control group after 4 weeks and 5 months, but benefits were no longer evident after an 11-month follow-up assessment [39]. Somers et al [40] demonstrated that remote pain-coping skills training delivered via videoconferencing on a computer tablet is feasible and effective in decreasing pain, reducing psychological distress, and pain catastrophizing. Basch et al [41] demonstrated that access to a Web-based collection of information about symptoms at home during chemotherapy with alerts to treating staff is beneficial for patients. The intervention group had better quality of life, less emergency room admissions, and longer chemotherapy than the control group.

Reviews about the effects of apps in other medical fields showed reduction in anxiety [42] and depressive symptoms [43] as well as improvement in asthma control and lung function [5]. Another study reported the use of a medication app, which improved medication adherence and lowered the rate or number of missed medications [44]. In patients with diabetes, apps shortened times for clinical personnel to review glucose diaries compared with the traditional personal glucose diaries [7] and have the potential of improving glucose control in type 1 and 2 diabetes [7,8], as well as increasing adherence to treatment in patients older than 60 years [45]. Another app was effective in promoting physical activity measured as steps per day after 8 weeks [46].

One study reported no improvement in systolic blood pressure with app use, although there was a small improvement in medication adherence [47]. Hurkmans et al [48] showed that addition of an app in a weight loss program did not improve dietary patterns or physical activity.

Comment on Results

For the sake of overview, we depicted acute and chronic pain outcome studies in the same figures. However, acute pain and chronic pain are two different entities; therefore, direct comparison is difficult, and this should be considered when interpreting the results. Furthermore, part of our results showing no effect of app use on pain management can be explained. The app examined by Raj et al [34] was a clinical decision support tool for physicians treating patients with cancer pain to evaluate improvement in pain control and to suggest treatment changes in opioid prescription (developed by mathematical algorithms). However, physicians were free to use or ignore the treatment suggestions provided by the app. Effectively, there was no statistically significant difference in either new prescription of or change in opioid medication in the intervention group compared with the control group. Guétin et al [28] did not report a decrease in pain during coronarography, which is not surprising because of the absence of pain in most patients before the procedure. Stinley et al [26] investigated pain and anxiety during venepuncture in children. The intervention group generated a mandala (defined by the authors as a drawing in which artists create a design using a circular outline [26]) on a computer tablet, and the control group received standard care treatment. The absolute pain levels were not reported; therefore, understanding why the intervention did not improve pain is difficult.

Limitations and Strengths

The main limitation of our review is the heterogeneity of the included studies for the synthesis of study results. On the other hand, this enables existing data to be represented in general without selection bias. Furthermore, apps are a new element in telehealth and their development is still progressing. Indeed, apps were only made available for a wide population in 2008 and 2009, when the Apple's App store and Google Play for Android, respectively, were introduced. Our strength is that this review is based on the PRISMA guidelines [18] and that the SIGN checklists [20] were used to critically appraise the included studies. The heterogeneity between the studies regarding the eligibility criteria, interventions, apps, and outcome selection prevented a meta-analysis. We attempted to compensate for this limitation by supplying a well-balanced, detailed, and qualitative review of the studies included.

Implications

In the management of patients with pain, apps can provide patients a wide range of features such as pain diary, educational features, reminders, treatment recommendation aspects, and direct communication with health care personnel in a single mobile app. Furthermore, intelligent systems such as chatbots or virtual assistants are already part of daily life for many people. These new technologies should be introduced into telehealth in the near future, and their testing for validity and usability is crucial. Correspondingly, there is a need for more high-quality studies for the evaluation of the efficacy of these new instruments.

Furthermore, our review showed that a standardized assessment of pain is lacking in the included studies, and therefore, it would be desirable that the scientific community agrees on a standardized protocol for pain assessment. In addition, there is a need for detailed reporting of the structure, data assessment, and functions of the apps and studies to investigate the elements of the apps or additional devices or tools that may improve usability and help patients in pain management. This information would strengthen future studies and allow researchers to synthesize the results of different studies.

Conclusions

Apps for pain management may be beneficial for patients, particularly in an out-clinic setting. Studies have shown that pain apps are workable and well liked by patients and health care professionals. There is no doubt that in the near future, mobile technologies will develop further. Medicine could profit from this development as our results indicate, but there is a need for more scientific inputs. It is desirable to know which elements of apps or additional devices or tools may improve usability and help patients in pain management.

Acknowledgments

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Authors' Contributions

SET was involved in the study conception, selection of trials, data extraction, data analysis, interpretation of results, and drafting of the manuscript and its revision. IG was involved in the data extraction, data analysis, and graphical presentation. GP was involved in graphical presentation and drafting of the manuscript. JS was involved in the study conception, data analysis, interpretation of results, and drafting of the manuscript and revision. JMB was involved in the study conception, selection of trials, data extraction, data analysis, interpretation of results, and drafting of the manuscript and its revision.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy for Ovid MEDLINE(R).

[PDF File (Adobe PDF File), 71KB - mhealth_v6i10e11231_app1.pdf]

Multimedia Appendix 2

Baseline characteristics of all included studies.

[PDF File (Adobe PDF File), 32KB - mhealth_v6i10e11231_app2.pdf]

Multimedia Appendix 3

Detailed information of apps used in the included studies.

[PDF File (Adobe PDF File), 115KB - mhealth_v6i10e11231_app3.pdf]

Multimedia Appendix 4

Additional outcomes of interest.

[PDF File (Adobe PDF File), 117KB - mhealth_v6i10e11231_app4.pdf]

Multimedia Appendix 5

Scottish Intercollegiate Guidelines Network (SIGN) checklist for randomized controlled trials.

[PDF File (Adobe PDF File), 22KB - mhealth_v6i10e11231_app5.pdf]

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Abbreviations

ITT: intention-to-treat
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
NRS: Numeric Rating Scale
RCT: randomized controlled trial
SIGN: Scottish Intercollegiate Guidelines Network
SMS: short message service
VAS: Visual Analog Scale

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Original Paper

The QardioArm Blood Pressure App for Self-Measurement in an Obese Population: Validation Study Using the European Society of Hypertension International Protocol Revision 2010

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Abstract

Background: Obesity and high blood pressure (HBP) pose high cardiovascular risks, and they are frequent causes of cardiovascular disease.

Objective: The aim of this study was to validate the mobile app QardioArm for high blood pressure monitoring in obese subjects (body mass index ≥30 kg/m^2) according to guidelines in the European Society of Hypertension-International Protocol 2 (ESH-IP2).

Methods: We recruited 33 obese subjects and measured their blood pressure using QardioArm (test device) and Omron M3 Intellisense (Omron Healthcare, Kyoto, Japan; standard device). We compared systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) according to the ESH-IP2.

Results: A total of 95 of 99 differences for SBP and 91 of 99 for DBP displayed absolute differences within 10 mm Hg. A total of 98 of 99 differences for SBP and 98 of 99 for DBP exhibited absolute differences within 15 mm Hg. This result satisfied requirements for part 1 of the ESH-IP2. A total of 27 out of 33 individuals for SBP and 30 out of 33 individuals for DBP had a minimum of 2 of 3 comparisons within 5 mm Hg difference. None of the subjects had 3 differences outside 5 mm Hg for SBP and DBP, satisfying part 2 of the ESH-IP2. For HR measurements, a total of 90 of 99 differences had absolute differences within 3 beats per minute (bpm), and a total of 94 or 99 differences had absolute differences within 5 bpm. A total of 98 of 99 differences had absolute differences within 8 bpm. Therefore, the test device satisfied part 1 of ESH-IP2 criteria for HR. For part 2 of ESH-IP2, 31 of 33 individuals had a minimum of 2 of 3 comparisons within 3 bpm difference for HR. Only 1 of 33 subjects had 3 differences outside 3 bpm.

Conclusions: To the best of our knowledge, this was the first study to show that an app that measures blood pressure and HR meets the requirements of the ESH-IP2 in an obese population. We believe the ESH-IP2 should publish explicit criteria for validation of blood pressure devices in specific populations.

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KEYWORDS

obesity; blood pressure determination

Introduction

Obesity and high blood pressure (HBP) pose high cardiovascular risks, and they are frequent causes of cardiovascular disease [1]. They often influence the primary causes of morbidity and mortality worldwide [2-5]. In adults, obesity is defined as body mass index (BMI) greater than 30 kg/m^2, with overweight defined as BMI of 25 to 30 kg/m^2, normal weight as BMI of 18.5 to 25 kg/m^2, and underweight as BMI under 18.5 kg/m^2[6,7]. HBP is defined as blood pressure (BP) of 140/90 mm Hg or more in adults 18 years of age or older who are not taking medication for hypertension [8-15].

The prevalence of this disease in the world is around 20% to 30%, which may increase adverse cardiovascular events in the obese population. These events are recognized by the physicians and health policy makers as significant health problems because of the several secondary impacts on the morbidity, mortality, medical, and economic cost [16,17].

Obesity and HBP are closely related, as increases in weight and BMI favor increases in BP. Conversely, weight loss reduces obesity and hypertension [9,12,18]. Causal mechanisms for obesity-associated hypertension include increased sympathetic nervous system activity, increased renal sodium retention secondary to insulin resistance or hyperinsulinemia, and obesity-mediated inflammation [19-24]. Therefore, strict BP control is necessary in obese individuals, as is weight reduction with changes in diet, lifestyle, and physical activity [24,25]. Active involvement of patients in their own treatment is a crucial factor in the successful management of hypertension. Home blood pressure monitoring (HBPM) increases patient compliance and has a great potential to improve hypertension control rates [8-12,15,24-28].

Currently, HBPM is performed with new technologies, including mobile apps, to obtain even greater benefits than can be obtained with conventional devices [29-31]. In all cases, self-measurement of BP at home requires a precise BP measurement technique and an accurate sphygmomanometer [25]. However, the primary disadvantage of automated home sphygmomanometers is their inaccuracy [32]. The majority of commercially available devices have not been evaluated independently for accuracy [13,29-31,33-37]. To evaluate the accuracy of devices in clinical practice, the Association for the Advancement of Medical Instrumentation published a validation protocol for electronic and aneroid sphygmomanometers in 1987. This was followed in 1990 by the protocol of the British Hypertension Society; both protocols were revised in 1993 [38,39]. On the basis of these experiences, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) published a simplified protocol (international protocol) to facilitate the evaluation process in 2002 that revised, unified, and simplified the previous guidelines [40]. This most recent protocol of the ESH, revised in 2010 (ESH-IP2) was more demanding than the previous protocol [32]. These protocols were meant for the general adult population, and it should not be assumed that a device that has been validated in the general population will be accurate in specific populations such as obese patients [41].

A few studies [42-44] demonstrated the accuracy of automatic BP monitors in specific populations such as obese patients, and none validated a mobile app that measures BP following the ESH protocol in this population. In 2017, QardioArm was validated in the general [45,46] and diabetic populations [46].

We hypothesized that the QardioArm mobile app for HBPM will show validated measures of BP and HR and will meet the requirements of ESH-IP2 in an obese population. Moreover, the purpose of this study was to validate the mobile app QardioArm for HBPM, according to the ESH-IP2 in obese subjects (BMI≥30 kg/m^2) [6,7].

Methods

Ethics Approval

The Clinical Research Ethics Committee of Hospital Clínico San Carlos in Madrid, Spain, approved this study (number 18/135-O_P_Tesis).

This study complied with the ethical principles of the Declaration of Helsinki [47], including amendments from 2000 to 2013. Participants were informed regarding the study. All participants gave written informed consent to participate.

The Devices

Omron M3 Intellisense

The Omron M3 Intellisense (Omron Healthcare, Kyoto, Japan) was the standard device used as the benchmark. The device was recently validated for the general population according to the international protocol [48]. The Omron M3 Intellisense is an automated oscillometric upper arm device for HBPM. The standard cuff of the device is for arms with circumferences of 22 to 32 cm, and a large cuff is also available for arm circumferences of 32 to 42 cm.

QardioArm

The QardioArm app (Qardioarm, Atten Electronic Co, Dongguan, China) was the test device. QardioArm is a fully automatic, noninvasive, and wireless BP monitor. This BP measurement system is intended to measure SBP and DBP as well as pulse rates in adults [49]. The unit uses an inflatable cuff that wraps around the upper arm. The cuff circumference is limited from 22 cm to 37 cm. To operate the device, a specific free Qardio app can be downloaded from the Apple App Store or Google Play (or getqardio website). It requires a device with Bluetooth 4.0, iOS 7.0 (or later), Android 4.4 *KitKat* (or later), and is compatible with iPhone, iPod, iPad, and Apple Watch, as well as with Android phones and tablets.

The QardioArm has an automatic screen with graphics and visuals to facilitate interpretation of data. The app can be configured to issue reminders and warnings, and the measurements and progress can be shared in real time with other users.

Patients and Recruitment

A consecutive sampling method was used to recruit the study subjects in Ciudad Real (Spain) from family, as well as friendly and known environments to the investigator.

According to the ESH-IP2 [32], a total of 33 participants who satisfied inclusion and exclusion criteria were included. The inclusion criteria were men and women aged at least 25 years. Of the total participants, at least 10 must be men and 10 must be women, with a BMI≥30 kg/m^2. Exclusion criteria were sustained arrhythmias, circulatory problems for which use of the cuff was contraindicated, or pregnancy.

Study Protocol

The validation team consisted of 2 nurses with adequate experience (more than 6 years) in BP measurement. The measurement room was properly conditioned with an adequate temperature and without any factor that could influence the measurements, including noise and distractions [32,40]. Each participant reported his or her gender and date of birth, and weight, height, and BMI (calculated by the Quetelet´s equation as BMI=weight in kilograms/height in meters squared) were registered, and circumference of the arm was measured to ensure that the cuff size was adequate. Subsequently, the subject relaxed for 10 min and 9 consecutive BP measurements were performed on the same arm, with the left arm at heart level, according to the ESH-IP2 protocol [32,40]. Measurements were taken alternating the Omron M3 Intellisense and the QardioArm app, as follows:

- BPA: entry BP, with the standard device
- BPB: device detection BP with the test instrument
- BP1: with standard device
- BP2: with the test instrument
- BP3: with standard device
- BP4: with the test instrument
- BP5: with the standard device
- BP6: with the test instrument
- BP7: with the standard device

During measurement, the individual remained calm, quiet, sitting, and not moving, with the back straight, keeping the feet on the floor in a parallel position, without crossing the legs. They rested the arm on a flat surface, with the palm of the hand upwards and the elbow slightly flexed so that their arm was at the height of the heart. The interval between BP measurements was 30 to 60 seconds [32]. All measurements were made in the same room.

Data Analysis

Statistical analyses were performed using IBM SPSS Statistics, version 19 (SPSS Inc, Chicago, Illinois) [50]. The results were expressed as mean (SD). The accuracy of a device according to the ESH-IP2 was based on comparisons between the test device (QardioArm) and the reference device (Omron M3) measurements. For each subject, the device measurements BP2, BP4, and BP6 were first compared with BP1, BP3, and BP5, respectively, and then to the measurements BP3, BP5, and BP7, respectively. Comparisons more favorable to the device were used. Differences were classified separately for both SBP and DBP according to whether the values were within 5, 10, or 15 mm Hg [32] and for the HR, according to whether the values were within 3, 5, or 8 bpm. Results were analyzed and expressed according to the ESH-IP2 requirements to determine whether the device passed or failed the validation protocol. Parts 1 and 2 of the validation process concerned the number of differences in the requested ranges for individual measurements (99 measurements) and for individual subjects (33 subjects) [32].

Bland-Altman graphs were used to represent the relationship between the difference between SBP (device to reference) and mean SBP (device and reference), DBP difference (device to reference) and mean DBP (device and reference), or HR difference (device to reference), and average HR (device and reference).

Results

Participants

A total of 36 subjects were screened: 14 males and 19 females. Age, weight, height, BMI, arm circumference, and their mean recruitment BP are displayed in Table 1.

Blood Pressure Measurements

The validation results for the QardioArm BP device according to the ESH-IP2 are shown in Tables 2 and 3. The numbers of measurements differing from the standard device Omron M3 by 5, 10, and 15 mm Hg or less are displayed in Tables 2 and 3, for SBP and DBP according to the ESH-IP2 [32]. The mean differences between the standard and the tested device were 3.94 (SD 3.65) mm Hg for SBP and 3.25 (SD 3.80) mm Hg for DBP. From these analyses, a total of 71 of 99 differences for SBP presented an absolute difference within 5 mm Hg and 84 of 99 for DBP (vs at least 73 for SBP and 65 for DBP following ESH-IP2 requirements).

A total of 95 of 99 comparisons for SBP displayed an absolute difference within 10 mm Hg and 91 of 99 for DBP (vs at least 87 for SBP and 81 for DBP following ESH-IP2 requirements). A total of 98 of 99 differences for SBP exhibited an absolute difference within 15 mm Hg and 98 of 99 for DBP (vs at least 96 for SBP and 93 for DBP following ESH-IP2 requirements). These data suggest that part 1 device validation was successfully completed.

For part 2 of ESH-IP, 27 of 33 individuals had a minimum of 2 of 3 comparisons within 5 mm Hg difference for SBP and 30 of 33 subjects for DBP (vs at least 24 of 33 subjects for SBP and DBP following ESH-IP2 requirements). None of the subjects had 3 differences outside 5 mm Hg for SBP and DBP (vs a maximum of 3 subjects for SBP and DBP following ESH-IP2 requirements). Because these 2 conditions were validated, part 2 device validation was successfully completed. Thus, part 3 of the QardioArm device validation passed, as parts 1 and 2 were both validated for SBP and DBP.

Table 1. Sociodemographic characteristics of the participants.

Variables	Total group (n=33)		Male (n=14)		Female (n=19)	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
Age in years	59.88 (14.97)	28-83	58.57 (15.70)	30.0-80.0	60.84 (14.76)	28.0-83.0
Weight (kg)	91.06 (11.74)	73.1-125.1	95.35 (13.43)	80.02-125.1	87.90 (9.47)	73.1-105.2
Height (cm)	167.52 (7.06)	156.0-183.0	171.00 (6.74)	160.0-183.0	164.95 (6.28)	156.0-182.0
Body mass index (kg/m^2)	32.34 (2.33)	30.0-37.6	32.46 (2.54)	30.0-37.4	32.24 (2.23)	30.0-37.6
Arm circumference (mm)	320.70 (35.35)	275.0-370.0	308.93 (32.12)	275-370	329.37 (35.91)	280.0-369.0
Baseline systolic blood pressure	140.64 (16.38)	112.0-176.0	144.86 (16.42)	117.0-175.0	137.53 (16.08)	112.0-176.0
Baseline diastolic blood pressure	77.12 (8.51)	55.0-98.0	78.50 (9.93)	60.0-98.0	76.11 (7.41)	55.0-90.0

Table 2. Validation results for the QardioArm blood pressure device part 1 according to European Society of Hypertension–International Protocol 2.

Validation results QardioArm (Part 1[a])	Criteria				
	≤5 mm Hg	≤10 mm Hg	≤15 mm Hg	Grade 1	Mean (SD)
Pass requirements[b]					
Two of	73	87	96	—[c]	—
All of	65	81	93	—	—
Achieved[d]					
Systolic blood pressure	71	95	98	Pass	3.94 (3.65)
Diastolic blood pressure	84	91	98	Pass	3.25 (3.80)

[a]Accuracy is determined by the number differences in these ranges both for individual measurements (part 1) and for individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b]Pass requirements: as required by the international protocol.

[c]Not applicable.

[d]Achieved: as recorded by the device.

Table 3. Validation results for the QardioArm blood pressure device parts 2 and 3 according to European Society of Hypertension–International Protocol 2.

Validation results QardioArm (Part 2[a])	Criteria			
	2/3 ≤5 mm Hg	0/3 ≤5 mm Hg	Grade 2	Grade 3
Pass requirements[b]	≥24	≤3	Pass	Pass
Achieved[c]				
Systolic blood pressure	27	0	—[d]	—
Diastolic blood pressure	30	0	Pass	Pass
Part 3	—	—	—	Pass

[a]Accuracy is determined by the number differences in these ranges both for individual measurements (part 1) and for individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b]Pass requirements: as required by the international protocol.

[c]Achieved: as recorded by the device.

[d]Not applicable.

Table 4. Validation results for the QardioArm heart rate device part 1 according to the European Society of Hypertension–International Protocol 2, presented as beats per minute (bmp).

Validation results QardioArm (Part 1[a])	Criteria				
	≤3 bpm	≤5 bpm	≤8 bpm	Grade 1	Mean (SD)
Pass requirements[b]					
Two of	73	87	96	—[c]	—
All of	65	81	93	—	—
Achieved[d]					
Heart rate	90	94	98	Pass	1.45 (2.04)

[a]Accuracy is determined by the number differences in these ranges both for individual measurements (part 1) and for individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b]Pass requirements: as required by the international protocol.

[c]Not applicable.

[d]Achieved: as recorded by the device.

Heart Rate Measurements

The validation results for the QardioArm HR device according to the ESH-IP2 are shown in Tables 4 and 5. The numbers of HR measurements differing from the standard device Omron M3 by 3, 5, and 8 bpm or less are displayed in Tables 4 and 5 for HR. The mean difference between the standard and the test device was 1.45 (SD 2.04) bpm.

From these analyses, a total of 90 of 99 differences presented absolute differences within 3 bpm, and a total of 94 of 99 comparisons displayed absolute differences within 5 bpm. A total of 98 of 99 differences exhibited absolute differences within 8 bpm. Therefore, part 1 device validation was successfully completed for HR.

For part 2 of ESH-IP, 31 of 33 individuals had a minimum of 2 of 3 comparisons within 3 bpm difference for HR. Only 1 subject had 3 differences outside 3 bpm. Since these 2 above-mentioned conditions were validated, part 2 device validation was successfully completed. Thus, part 3 of the QardioArm device validation passed, as parts 1 and 2 were both validated for HR.

In summary, the QardioArm device met validation criteria of the ESH-IP2 for SBP, DBP, and HR for subjects with BMI greater than 30 kg/m^2. These results agreed with the Bland-Altman graphs showing differences between the measurements with the QardioArm device and the Omron M3 for SBP (Figure 1, part A), DBP (Figure 1, part B), and HR (Figure 1, part C).

Table 5. Validation results for the QardioArm heart rate device parts 2 and 3 according to the European Society of Hypertension–International Protocol 2, presented as beats per minute (bmp).

Validation results QardioArm (Part 2[a])	Criteria			
	2/3 ≤5 bpm	0/3 ≤5 bpm	Grade 2	Grade 3
Pass requirements[b]	≥24	≤3	—[c]	—
Achieved[d]				
Heart rate	31	1	Pass	Pass
Part 3	—	—	—	Pass

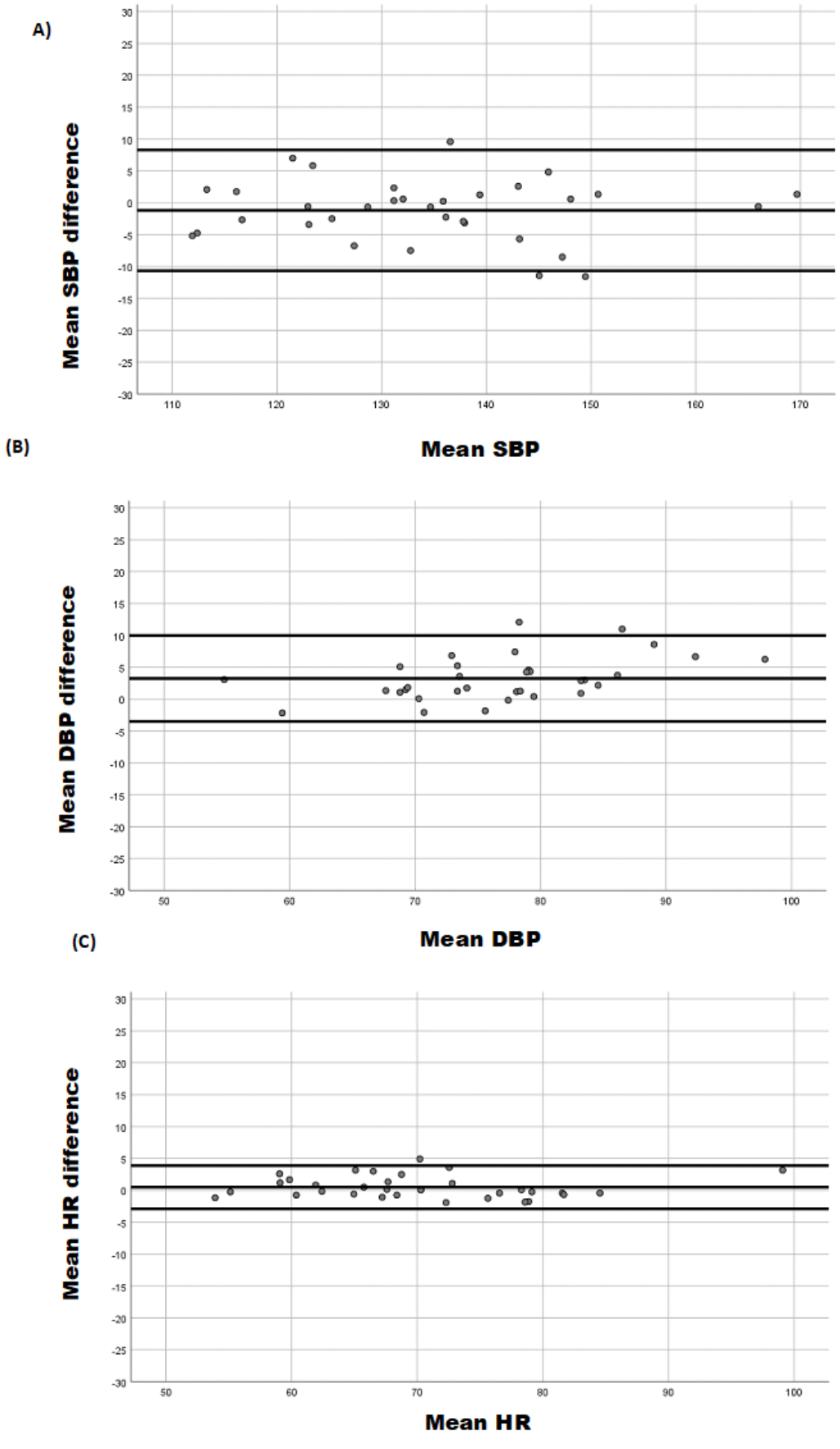
[a]Accuracy is determined by the number differences in these ranges both for individual measurements (part 1) and for individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b]Pass requirements: as required by the international protocol.

[c]Not applicable.

[d]Achieved: as recorded by the device.

Figure 1. Plots of systolic blood pressure (SBP; part A), diastolic blood pressure (DBP; part B), and heart rate (HR, part C) differences between the QardioArm and the Omron M3.



Discussion

Principal Findings

To the best of our knowledge, this was the first study providing information regarding the accuracy of the QardioArm app for measuring BP and HR in an obese population. This device had previously been validated in the general population by our team [45] and by others [46].

According to the ESH-IP2, we found that the QardioArm device successfully passed the validation requirements in obese population [32]. However, our results cannot be extrapolated to other specific populations, including diabetic patients, the elderly subjects, and pregnant women, as we did not address these conditions.

Although it was not the objective of this study, we observed that in obese people it was necessary to study various design aspects. Despite the efforts of the manufacturers to improve the quality of BP measuring devices, both the cuff and wrist characteristics of devices remain a point of weakness in this population [44].

In fact, although every participant was his own control, with 1 measurement recorded with QardioArm versus the reference measurement recorded by the Omron M3, BP measurement in some of our obese subjects presented some difficulties related to arms shaped more like cones than like cylinders. In some arms, the diameter at the top was larger than the diameter in the region of the brachial artery [51]. Recent findings demonstrated that despite using the appropriate cuff size, SBP appeared to be higher in subjects with bigger arms [52], suggesting that a larger limb may require greater pressure simply because there is more tissue to compress and not necessarily because there is fatty tissue. Indeed, they also observed that those with larger and more muscular arms were more likely to be misclassified as prehypertensive or hypertensive than those with smaller arms, whereas those with smaller arms may be misclassified as normal despite having elevated BP. We previously recommended that a further correction factor for arm size may be needed even when using the correct cuff size [52].

The high prevalence of obesity together with the problems introduced by large arm circumferences present risks for hypertension diagnoses [1-5,51,52]. We suggest that more validation studies should be conducted on PA devices in the obese population, as such studies are rare [42-44].

We used the ESH protocol that was published in 2002 [40] and revised in 2010 [32]. This protocol shows many advantages over previous protocols [38,39]. Nevertheless, it presents some limitations. First, the ESH-IP2 did not specify the number of validation studies that are needed to validate the instrument despite some findings reporting that a device should be validated in no fewer than 2 different centers separately [41,45,46,48]. Therefore, it is important to check the validity of BP measuring devices in specific populations as an add-on step to the validation process before widespread application in clinics or homes. Second, the specific conditions required for the recruited subjects in the study exclude children and young people, omitting data from the obese population aged between 18 and 25 years. Third, there was no mention of an explicit criterion for a validation process in specific populations in the ESH-IP, and we highly recommend that this would be taken into account in the next revision. Fourth, despite the fact that sample size calculation was conducted, the consecutive sampling bias should be considered and a simple randomization sampling process could be more adequate for future studies. Finally, despite the sphygmomanometers measure for SBP, DBP, and HR, there is no version of the International Protocol of the ESH to consider validation of HR. Therefore, validation based on the protocol criteria in BP should be added and established, in this case, the required differences based on the scale of values found after HR measurements being even more demanding than those of the ESH.

Conclusions

To the best of our knowledge, this was the first study to show that an app that measures BP and HR meets the requirements of ESH-IP2 in an obese population. We believe the ESH-IP2 should publish explicit criteria for validation of BP devices in specific populations. Finally, we highly recommend assessment of the accuracy of this app in other specific populations such as pregnant women, elderly subjects, arrhythmic patients, and others.

Conflicts of Interest

None declared.

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Abbreviations

BP: blood pressure
BPM: beats per minute
BMI: body mass index
DBP: diastolic blood pressure
ESH: European Society of Hypertension
ESH-IP2: European Society of Hypertension–International Protocol 2
HBP: high blood pressure
HBPM: home blood pressure monitoring
HR: heart rate
SBP: systolic blood pressure

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Original Paper

A Mobile App With Optical Imaging for the Self-Management of Hand Rheumatoid Arthritis: Pilot Study

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Abstract

Background: Patient outcomes are improved and the burden to the health care system is reduced when individuals are active self-managers of their own health. There is a need for technology that facilitates self-management of rheumatoid arthritis (RA) and can reduce the number of patient visits, promptly identify treatment needs, and reduce the costs associated with poor RA management. A mobile app named LiveWith Arthritis (eTreatMD, Vancouver, BC) has been developed that allows patients with RA to use their mobile device to regularly collect self-management data and to take objective measurements of the impact of RA on their finger joints using optical imaging technology.

Objective: The objectives of this pilot study were to (1) gather preliminary data as to whether a mobile app with hand optical imaging capabilities improves self-management behaviors (self-efficacy in managing symptoms and patient activation), (2) determine if app use shows promise in improving health outcomes (Pain, Health Assessment Questionnaire-II [HAQ-II]), and (3) determine barriers to using the mobile app in adults with RA.

Methods: This pilot study used a mixed-methods design. The quantitative portion was a traditional 2-group experimental design, and the qualitative portion was a follow-up telephone interview for intervention participants who did not complete the study. Measures of self-management included the Patient-Reported Outcomes Measurement Information System (PROMIS) self-efficacy in managing symptoms (P-SEMS) and Patient Activation Measure (PAM). Health outcomes included pain by Visual Analog Scale and disability by HAQ-II.

Results: The final sample consisted of 21 intervention participants and 15 controls. There was a statistically significant improvement in P-SEMS and promising trends for improvement in PAM, HAQ-II, and pain scores for participants who used the app. Of the intervention participants who did not complete the study, 12 completed the qualitative interview on barriers to use. Qualitative content analysis revealed 3 themes for barriers to using the app, including (1) frustration with technology, (2) RA made the app difficult to use, and (3) satisfaction with current self-management system.

Conclusions: The LiveWith Arthritis app shows promise for improving self-management behaviors and health outcomes in adults with RA. Future study with a larger sample size is required to confirm findings. Initial app experience is important for adoption and continual use of the app. Individuals with significant disability to the hand would benefit from voice-activated app features. Participants who already have a system of managing their RA may not feel compelled to switch methods, even when a novel optical imaging feature is available.

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KEYWORDS

optical imaging; mobile applications; self-management; rheumatoid arthritis; self efficacy; patient activation; pilot study

Introduction

Background

Rheumatoid arthritis (RA) is a chronic and debilitating systemic inflammatory disease that destroys joints throughout the body. Although RA can manifest in a variety of joints, most patients experience RA symptoms in their hands and wrists [1]. Hand deformities are a common feature of RA as are their related physical deficits such as reduced grip strength and pain which decrease the ability of the individual to perform activities of daily living [2]. Each episode of RA-induced inflammation in the synovial joints of the hand is a painful predictor of future bone loss and long-term deformity [3]. RA induced damage and deformity can be prevented through reduction of individual patient triggers that induce inflammatory *flares* and by early and consistent use of disease-modifying antirheumatic drugs and other pharmacotherapeutics [4].

Although the hand is the primary area for painful and disabling symptoms, it is also an area that can be monitored to predict disease flares and monitor disease progression. While clinicians can use radiographic imaging to monitor RA progression, measurement is infrequent due to the cost of implementation, the availability of radiologists for interpretation, and radiation exposure risks. The use of noninvasive optical imaging methods to analyze interphalangeal joint disease is an emerging technology used mostly in clinical settings [5]. Optical imaging includes optical coherence tomography, diffuse optical tomography, laser transillumination imaging, photoacoustic tomography, and digital imaging of the hands [6-8]. These techniques have historically required specialized equipment for measurement and interpretation. However, with the advances in camera and software technologies in smartphones and tablets, these optical imaging capabilities are now available in consumer devices [9].

In addition to monitoring, self-management of the day-to-day symptoms of RA is critical to reducing disease progression. The Institute of Medicine states that self-management is 1 of the 20 most urgent areas of need to improve health care quality in the United States [10]. Self-management is a daily, interactive process that engages the individual, encourages them to monitor their illness, and empowers them to make decisions and develop and use strategies to maintain an improved quality of life. Active patient participation in the management of an individual's health and disease has been shown to improve health outcomes, including reduction of pain and disability while providing a greater sense of well-being [11]. Increased self-management behaviors are associated with reduced health care utilization and related costs [12]. Key predictors of self-management behaviors are self-efficacy in managing symptoms and patient activation. An individual's perceived self-efficacy refers to their confidence in their ability to be successful and to complete tasks to manage their symptoms and is associated with reduced disability and pain [13-15]. Patient activation is an important element of self-management that includes having the skills and confidence to become actively engaged in one's own health care [16].

Objectives

The objectives of this pilot study were to (1) gather preliminary data as to whether a mobile app with hand optical imaging capabilities improves self-management behaviors (self-efficacy in managing symptoms and patient activation), (2) determine if app use shows promise in improving health outcomes (Pain, Health Assessment Questionnaire-II [HAQ-II]), and (3) determine barriers to use of the mobile app in adults with RA.

Methods

Materials

The LiveWith Arthritis app is a mobile app that allows a patient to monitor the progression of RA inflammation and deformity in their hands using optical imaging from a mobile device camera. The app also supports self-management behaviors with features to monitor and manage the variables associated with RA such as pain levels, treatments, and other lifestyle and environmental data (eg, diet, activity, and weather; see Figure 1). The system can provide reports for individuals, clinicians, and caregivers that might help identify aspects of patient lifestyle that make their arthritis better or worse and let them compare the effectiveness of different treatments. This app is intended to engage the patient in their treatment, facilitate discussions between patient and clinician, and provide information on which clinical decisions can be based. Using this app may help with the day-to-day reduction of RA symptoms and build confidence in the patient in the management of their condition. Additionally, these patients can bring objective data to their health care provider about changes in their hand, allowing clinicians to make individualized and more precise treatment decisions while optimizing time spent in the patient-clinician visit.

The LiveWith system architecture (see Figure 2) consists of (1) the mobile app that acts as an interface for the user, facilitates image capture, creates patient profiles and displays analytical results and (2) the Health Insurance Portability and Accountability Act (HIPPA)-compliant cloud server that stores patient profiles, manages data, and performs image processing. The Web portal (see Figure 3) provides a more advanced review of images and data trends and can be shared with clinicians or even integrated into an electronic health record.

Figure 1. App self-management features.

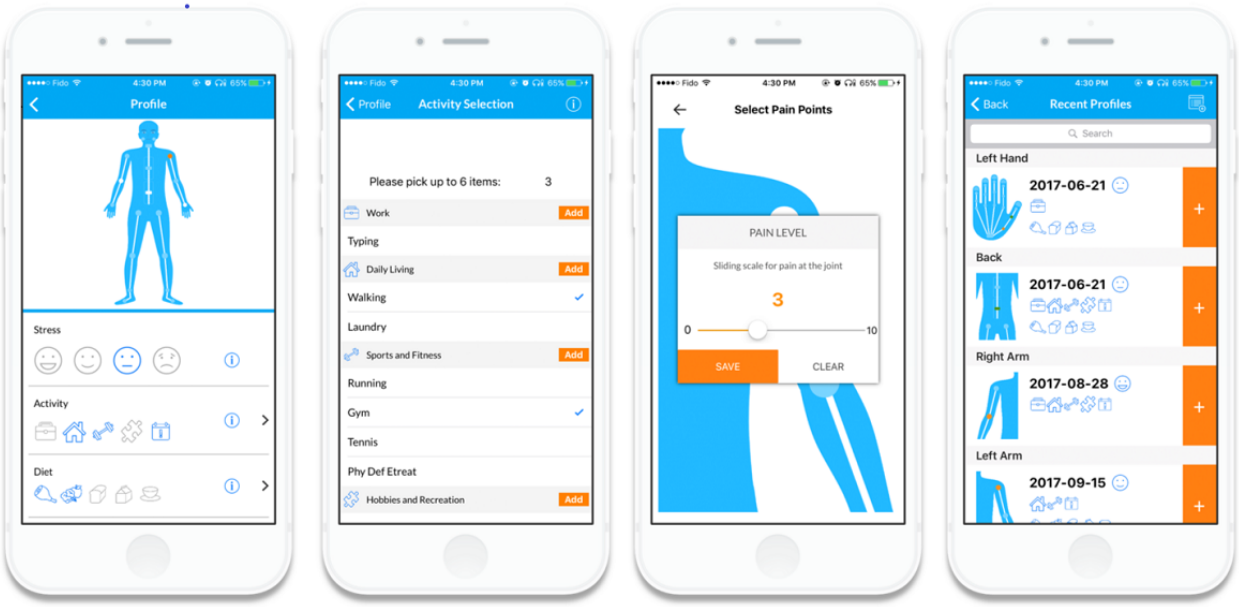
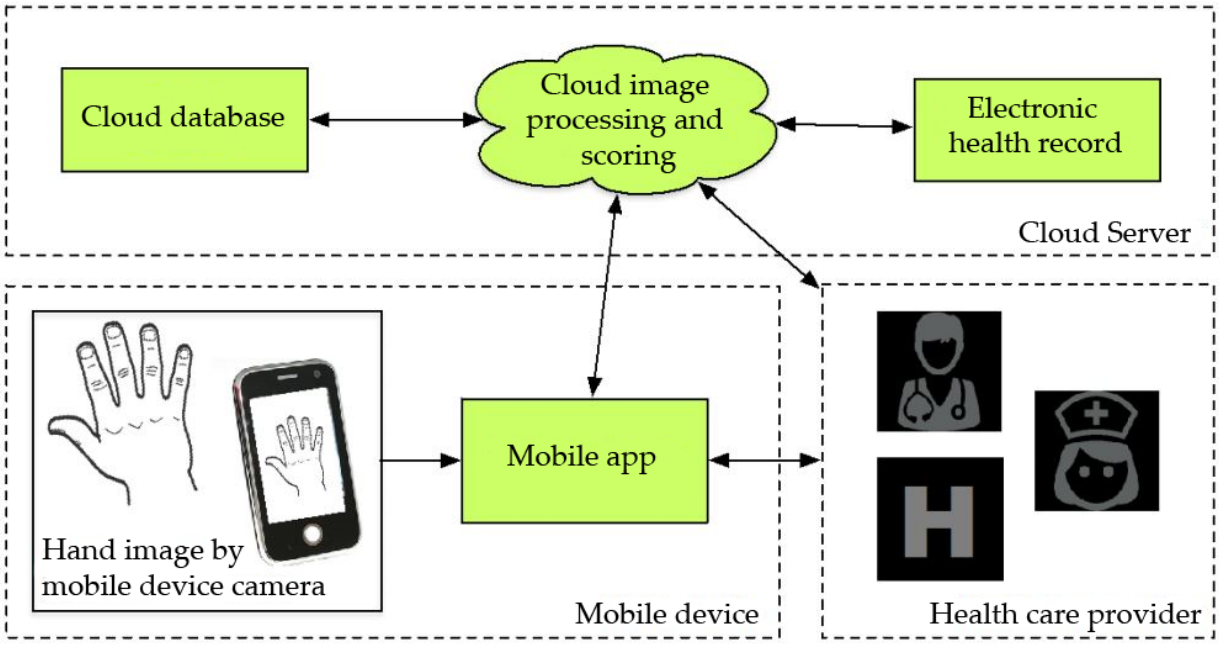


Figure 2. App system architecture.



Hand analysis takes place after the patient takes a digital image of their hand with a standard sheet of white paper (letter size) in the background (see Figure 4). The sheet of paper, placed beneath the hand, provides a spatial calibration reference for the hand image. The measured dimensions of the paper boundary are paired with known dimensions of letter size paper for defining the spatial transformation of the image to real-world coordinates. Figure 5 shows the paper edges and corners detected by Hough transform. After this detection, the distances between the pixels now correspond to specific measurement units (ie, 100 pixel distance = 1.27 mm). The next steps are the segmentation of the hand from the white paper background of the now calibrated image and the detection of the hand boundary. The boundary pixel data are used to identify key anatomical features of the hand including fingertips and vertices and to measure hand geometry including finger and joint thickness, finger segment angulation, and interphalangeal joint angular deviation (see Figure 6).

Figure 3. Web portal.

Figure 4. Hand optical imaging using letter size paper for calibration.

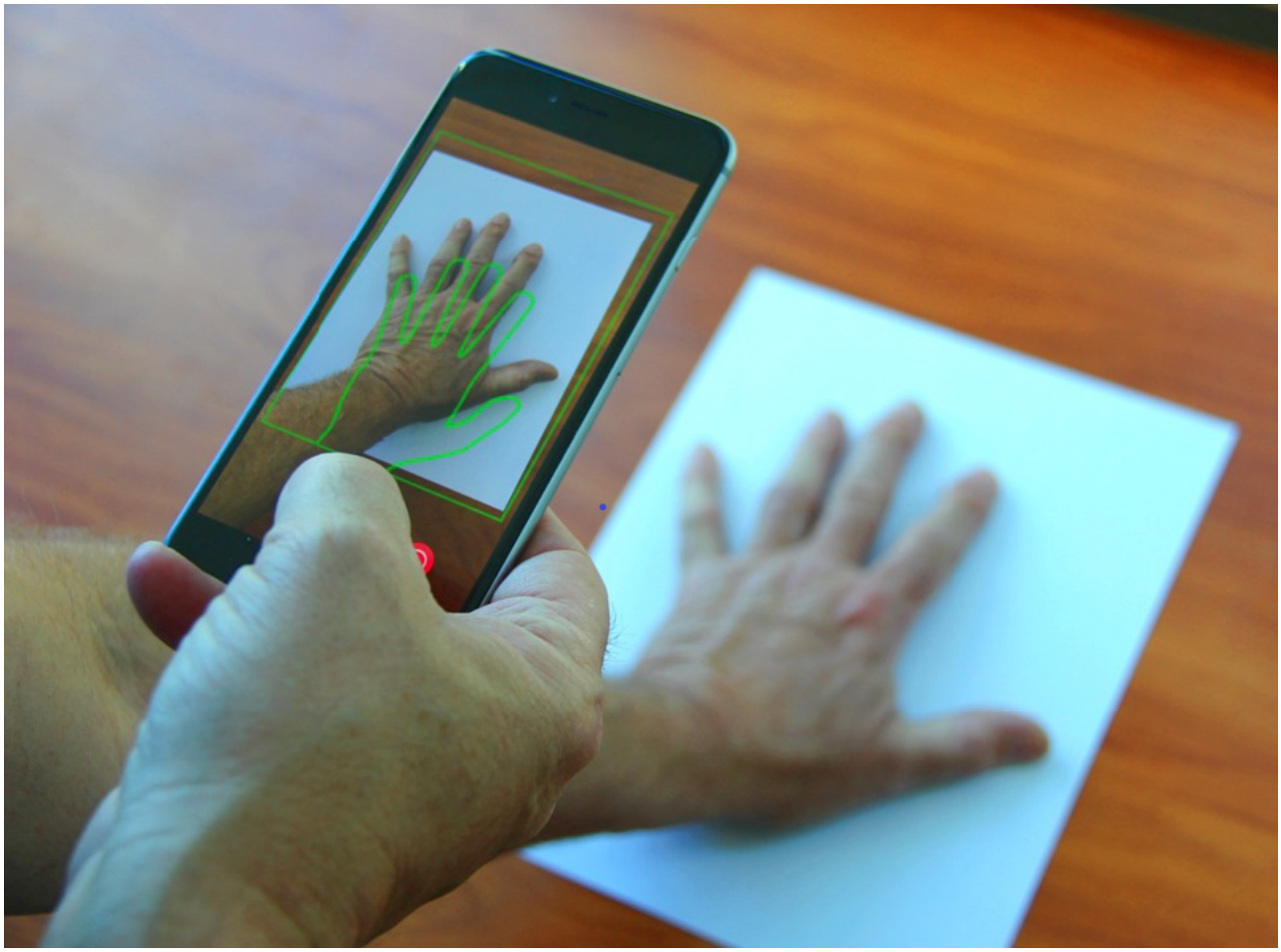
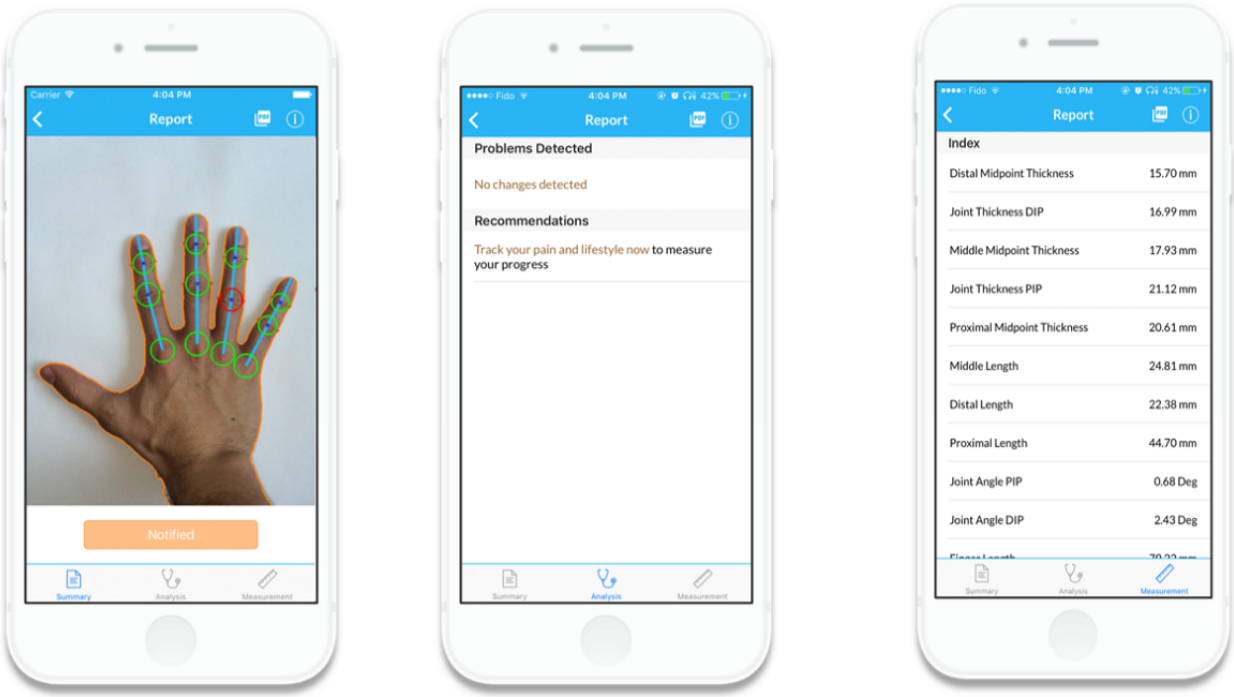


Figure 5. Imaging hand calibration requirements include (1) all 4 corners of the paper are in the photo, (2) the hand is within the paper's edges, (3) fingers are spread, and (4) the background behind the paper is darker and free of clutter.

Figure 6. Output report including analyzed hand image, changes since last image, recommendations, and measurements of anatomical features of hand.



Design and Sample

This was a mixed-methods design. The quantitative portion was a traditional 2-group experimental design, and the qualitative portion was a follow-up telephone interview for intervention participants who did not complete the study. Participants were adults (aged over 18 years) with RA enrolled in a longitudinal cohort called the Rheumatology and Arthritis Investigational Network Database (RAIN-DB) [17,18]. To be included, participants had to be actively seeing a rheumatology provider at the researchers' university rheumatology clinic, own a smartphone, and be able to read and speak English.

We enrolled 34 participants in the intervention group and 29 subjects in the control group. Data were collected at 2 visits, baseline and follow-up, which were 6 months apart. The baseline visit for intervention participants included meeting with a research assistant to download the app on the participant's smartphone and to take an image of the hand to teach the patient how to use this feature of the app. Intervention participants were instructed to use the imaging technology at least once per month and the app for self-management regularly. Intervention participants were compensated US $50 for their time spent using the app. Control participants received usual care.

Instruments

To evaluate whether the mobile app technology could improve self-management and self-efficacy, we used 2 questionnaires, the Patient-Reported Outcomes Measurement Information System (PROMIS) Self-Efficacy Managing Symptoms (P-SEMS) and the Patient Activation Measure (PAM).

Patient-Reported Outcomes Measurement Information System Self Efficacy in Managing Symptoms

The P-SEMS tool measures an individual's perceived self-efficacy in managing the symptoms of their disease. Regarding health, self-efficacy is the foundation for an individual's decision to act and implement healthy behaviors to manage their illness or symptoms and take control of their health through implementation of specific health behaviors to achieve improved outcomes [15,19]. Questions on the 28-item P-SEMS questionnaire assess the level of confidence a patient has in managing their symptoms in a variety of settings and situations such as, "I can keep my symptoms from interfering with the work I need to do" [19].

Patient Activation Measure

The PAM is a 13-item self-report instrument designed to assess an individual's level of patient activation. It measures the patient's self-reported knowledge, skills, and confidence in self-management of their chronic condition [16]. It asks the patient to either agree or disagree with statements such as, "When all is said and done, I am the person who is responsible for managing my health." A highly activated individual is an involved and confident self-manager of their health. In those with chronic conditions, higher activation is associated with treatment adherence, improved self-monitoring, and appropriate care seeking [20]. Every 1-point increase in PAM score has been shown to correlate with a 2% decrease in hospitalization and 2% increase in medication adherence [21]. The PAM is a valid and reliable tool and has been tested in individuals with a variety of health conditions, in multiple languages, and across a variety of races and ethnicities [22,23].

Health Outcomes

Pain was measured using the Visual Analog Scale (VAS). The VAS measures pain from 0 to 10, with 0 meaning no pain and 10 being *worst pain* [24]. Physical function was measured with the reliable and valid 10-item questionnaire HAQ-II. Scores on the HAQ-II range from 0 (minimum loss of function) to 3 (completely disabled) [25].

Qualitative Interview

Intervention participants who did not complete the study were invited to participate in a qualitative telephone interview about the barriers to using the mobile app. Participants were asked, "tell me more about your experience using the app" with follow-up probes about their likes and dislikes of the app features, overall experience, and barriers to using the app. The qualitative interviews were transcribed verbatim.

Analysis

Statistical analyses were conducted using Stata Statistical Software 15 (StataCorp, College Station, TX) [26]. We used *t* tests for comparison between groups on the PAM, P-SEMS, Pain, and HAQ-II. Pearson correlations were used to determine linear relationships between variables. Qualitative data were analyzed using content analysis.

Results

Sample Characteristics

Our final sample consisted of 21 intervention participants (62% original sample, 21/34) and 15 control participants (52% of original sample, 15/29). Intervention participants who withdrew from the study tended to have a slightly higher HAQ-II (0.63 vs 0.54) and pain score (3.2 vs 2.5) and lower PAM (67.4 vs 71.9) and P-SEMS (45.4 vs 47.3) at baseline compared with intervention participants who completed the study. These demographic changes were similar to the control group, with dropouts more likely to have a lower PAM (64.4 vs 68.8) and P-SEMS (46.4 vs 47.1) than controls who completed the study. Control participants who dropped out were more likely to have lower pain (2.6 vs 3.17) and lower HAQ-II (0.54 vs 0.63). None of these differences were statistically significant.

Our qualitative sample consisted of subjects who dropped out of the intervention group. We were able to reach and invite all 13 intervention participants who dropped out of the study. However, 1 intervention participant dropped out due to a diagnosis of lymphoma and ongoing health concerns, preventing her participation. The remaining 12 intervention participants who did not complete the study participated in the qualitative component of our study.

Outcome Variables

The outcome variables are presented in Table 1.

Table 1. Quantitative outcome variables.

Variable	Intervention	Control	*P* value
P-SEMS[a]	2.80	−1.66	.04
PAM[b]	6.37	2.30	.46
HAQ-II[c]	0.02	0.05	.83
Pain	−0.61	0.18	.38

[a]P-SEMS: Patient-Reported Outcomes Measurement Information System Self-Efficacy Managing Symptoms.

[b]PAM: Patient Activation Measure.

[c]HAQ-II: Health Assessment Questionnaire-II.

Self-Efficacy in Managing Symptoms and Patient Activation

A 2-sample *t* test with equal variances for the P-SEMS showed that the intervention group had statistically significant improvement to their score compared with the control group (2.8 vs −1.66, *P*=.04). A 2-sample *t* test with equal variances showed that the intervention group had an increase in PAM score that was 2.8 times greater than the control group (6.37 vs 2.30, *P*=.48).

Health Assessment Questionnaire-II and Pain

Participants with higher PAM and P-SEMS scores had lower HAQ-II scores and lower pain scores at both baseline and follow-up. Changes in PAM and P-SEMS scores were negatively correlated with changes in HAQ-II (Pearson correlations: −0.33, *P*=.10 for PAM and −0.50, *P*=.007 for P-SEMS).

Qualitative Themes

There were 3 themes that arose from the qualitative interviews about the barriers to using the app for intervention participants who dropped out of the study. These themes were (1) frustration with technology, (2) RA made the app difficult to use, and (3) satisfaction with current self-management system. These themes and representative quotes are displayed in Table 2.

Frustration With Technology

Participants described frustration with technology especially with initial use of the app. Participants who did not have a good initial experience did not feel confident to return to the app or use it as directed on their own.

Rheumatoid Arthritis Made the App Difficult to Use

Participants who had more severe hand RA and who were disabled by their disease had difficulty using both the optical imaging and other features of the app. Some participants recruited someone to assist them with photographing their hand, but this also made it difficult for the participants to use the app on a regular basis.

Satisfaction With Current Self-Management System

Some participants explained that the mobile app could not be integrated easily into their lifestyle as they had already had a system to manage their RA. These participants felt that the use of the mobile app would not add to their self-management needs and that their system was working for them.

Table 2. Qualitative themes and representative quotes.

Theme	Representative quote
Frustration with technology	• *Once they did get all the kinks out, it still wasn't working for me to mess with it; so then, by that time, I had just never gone back in to do anything else with it.* [P2] • *I dropped out a long time ago because of the problems they were having with the app at the very beginning, and I just got frustrated and I went, "Forget it.*" [P7]
Rheumatoid arthritis made the app difficult to use	• *Because I live alone, and I have had my neighbors help me, and I just could not hold the telephone the right way, so the app really did not work for me.* [P5] • *I could never get it to come out right, and I gave up. I just completely gave up. I could not get my hand photographed right, and there wasn't always somebody there to help me with it.* [P11]
Satisfaction with current self-management system	• *It's so hit and miss, but, you know, I do my own logs as far as what I eat, what activities I do; and then, the days that I flare, I always go back and look and see if I did anything different, or ate anything different, to see if it coincides.* [P2] • *My rheumatoid arthritis is under good control, so I don't have a lot of flare-ups and that kind of thing; and if I go through a period where I do, to me, it's most helpful just to write it in a journal.* [P1]

Discussion

Principal Findings

Our study showed a statistically significant improvement in P-SEMS and showed promising trends for improvement in PAM, HAQ-II, and Pain scores for participants who used the LiveWith app. These results demonstrated the potential of the LiveWith app for improving self-management and increasing confidence in these behaviors. Future studies with a larger sample size are necessary to confirm these findings.

Pilot studies are generally underpowered to assess evidence of benefit at the 95% CI; therefore, we find it especially promising that those participants who completed the intervention had statistically significant improvement in their self-efficacy scores [27,28]. As self-efficacy in managing symptoms increases, symptoms are more likely to be alleviated [20]. For example, pain has been shown to be inversely related to self-efficacy. By building self-efficacy in managing one's own pain, the individual feels confident to use strategies to reduce pain intensity [14,15]. RA is truly an individual experience with different flares for each affected person. Empowering an individual with tools that can increase self-efficacy can improve symptoms and reduce the burden of this disease.

Our attrition rate was higher than the acceptable level of 20%, with a large percentage of both intervention and control group participants dropping out [29]. On the basis of our qualitative interviews with participants who dropped out, we attribute attrition of the intervention group almost primarily to technology issues. We had technology difficulties at the beginning of the study requiring several updates, and the time frame required to work out the *bugs* tarnished the initial app experience for many. Although we believed our app was study-ready, future studies should consider additional pilot testing and personnel training, or the use of a longer-standing technology platform. It seems critical that participant (or patient's) first experience using the app is positive to promote confidence in continual use. Control group attrition may have been due to a lack of incentive and the already extensive paperwork required to participate in the longitudinal RAIN-DB. In addition, choosing a sample that was associated with a larger database and an actual physical appointment at the rheumatology clinic limited ongoing participation. Future studies should consider a completely digital experience with Web-based surveys and digital prompts to use the app and complete the tasks.

Although the purpose of our study was to learn more about self-managing behaviors, some participants believed collecting optical imaging hand data was the purpose of the study. Therefore, when there was difficulty using the optical imaging technology, the participants did not use the other self-managing aspects of the app. To our knowledge, there were no technology issues with the nonoptical imaging aspects of the app software, even as we went through various updates to the iOS and Android operating systems. Although the optical imaging is novel from a research and clinical perspective, it is unclear if this feature is essential to improve self-management behaviors. We believed that having the participants take an objective measurement of their hand would increase engagement and confidence in self-management. It is possible that requiring a hand image only once a month was too long of a time frame and reduced participant engagement with the app. We chose this length of time to watch for discernable changes in the hand and reduce overall burden to the patient. However, more frequent hand measuring may have reminded the participant about the day-to-day management of their disease and to use the other features of the app more regularly.

Participants who already had significant disability to the hand had difficulty operating the app. Some participants recruited others to aid them in using the app but found this to be additional work for them. It is assumed that traditional methods of self-management such as a pen-and-paper system may also have been difficult for this population. Future mobile app interventions should optimize voice technology and passive measurements to improve accessibility for patients with more progressive RA disability.

Some participants had pre-established routines of self-managing their disease through methods such as pen-and-paper journaling and felt it was sufficient. It is unclear whether a mobile app adds anything for a patient who already has a working system and is successfully managing their disease. Future studies should compare the use of a mobile app with pen-and-paper methods to see if simply using any self-management intervention shows improvement or if the mobile app shows superior improvement.

Limitations

Our study had a small sample size and a large dropout rate. We experienced technology problems that caused delays and reduced the confidence of many of our participants. Our participants were a part of a larger longitudinal study and currently seeing a rheumatologist with regularity; therefore, they might have been more compliant than the general population. We did not include participants who completed the study in our qualitative interview process, which may have impacted our findings. Participants were required to own a smartphone to be included in the study; therefore, they might have had a more advanced knowledge of technology than the general population.

Conclusions

The use of a mobile app with optical imaging capabilities appears to improve self-efficacy in managing symptoms of RA and may improve other outcomes such as patient activation, pain, and disability. Future research should include a larger sample size and comparisons with other self-management interventions, such as traditional pen and paper, to help determine if the use of this app mediates the improvement to health outcomes.

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Conflicts of Interest

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Abbreviations

HAQ-II: Health Assessment Questionnaire-II
PAM: Patient Activation Measure
PROMIS: Patient-Reported Outcomes Measurement Information System
P-SEMS: PROMIS Self-Efficacy in Managing Symptoms
RA: rheumatoid arthritis
RAIN-DB: Rheumatology and Arthritis Investigational Network Database
VAS: Visual Analog Scale

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Original Paper

Behavior Change Techniques in mHealth Apps for the Mental and Physical Health of Employees: Systematic Assessment

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Abstract

Background: Employees remain at risk of developing physical and mental health problems. To improve the lifestyle, health, and productivity many workplace interventions have been developed. However, not all of these interventions are effective. Mobile and wireless technology to support health behavior change (mobile health [mHealth] apps) is a promising, but relatively new domain for the occupational setting. Research on mHealth apps for the mental and physical health of employees is scarce. Interventions are more likely to be useful if they are rooted in health behavior change theory. Evaluating the presence of specific combinations of behavior change techniques (BCTs) in mHealth apps might be used as an indicator of potential quality and effectiveness.

Objective: The aim of this study was to assess whether mHealth apps for the mental and physical health of employees incorporate BCTs and, if so, which BCTs can be identified and which combinations of BCTs are present.

Methods: An assessment was made of apps aiming to reduce the risk of physical and psychosocial work demands and to promote a healthy lifestyle for employees. A systematic search was performed in iTunes and Google Play. Forty-five apps were screened and downloaded. BCTs were identified using a taxonomy applied in similar reviews. The mean and ranges were calculated.

Results: On average, the apps included 7 of the 26 BCTs (range 2-18). Techniques such as “provide feedback on performance,” “provide information about behavior-health link,” and “provide instruction” were used most frequently. Techniques that were used least were “relapse prevention,” “prompt self-talk,” “use follow-up prompts,” and “provide information about others’ approval.” “Stress management,” “prompt identification as a role model,” and “agree on behavioral contract” were not used by any of the apps. The combination “provide information about behavior-health link” with “prompt intention formation” was found in 7/45 (16%) apps. The combination “provide information about behavior-health link” with “provide information on consequences,” and “use follow-up prompts” was found in 2 (4%) apps. These combinations indicated potential effectiveness. The least potentially effective combination “provide feedback on performance” without “provide instruction” was found in 13 (29%) apps.

Conclusions: Apps for the occupational setting might be substantially improved to increase potential since results showed a limited presence of BCTs in general, limited use of potentially successful combinations of BCTs in apps, and use of potentially unsuccessful combinations of BCTs. Increasing knowledge on the effectiveness of BCTs in apps might be used to develop guidelines for app developers and selection criteria for companies and individuals. Also, this might contribute to decreasing the burden of work-related diseases. To achieve this, app developers, health behavior change professionals, experts on physical and mental health, and end-users should collaborate when developing apps for the working context.

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KEYWORDS

behavior change techniques; mHealth; mental health; physical health; lifestyle; workplace; app; employee; work

Introduction

Despite increased awareness and growing efforts to develop measures to effectively manage work-related risk factors and promote workers' healthy behavior, employees are still at risk of developing physical and mental health problems [1,2]. This is caused by physical and psychosocial work demands and unhealthy lifestyle behaviors, such as low physical activity levels and sedentary behavior. This is often provoked by the way current work and working environments are arranged.

The development of new technologies has brought about many changes in the way people work, resulting in a shift away from occupations that require moderate-intensity physical activity to occupations that are composed of sitting [3,4]. Physical inactivity and sedentary behavior (defined as time spent sitting [4]) are associated with deleterious health effects such as cardiovascular diseases, cancer, type 2 diabetes, and obesity [5-8]. Research has shown that employees with low physical activity levels and sedentary behavior are less productive at work (presenteeism), have decreased workability, and take more sick days [9-12].

Furthermore, the number of employees working with computers has increased over the past decades [13]. Research shows a relationship between computer use and the development of musculoskeletal symptoms [13-15]. Static postures and repetitive movements, physical work demands that are associated with computer work, are related to presenteeism, decreased work ability, and sickness absence [16,17].

During the past decade organizations started to organize work flexibly [18]. Employees decide for themselves where, when, and with which (digital) tools they work. This brings advantages such as autonomy, remote collaboration, and increased possibilities for sharing information. However, there are also drawbacks, such as struggling with managing the inflow of information, interruptions and task switching, perceived pressure to respond quickly, decreased perceived social support, and a disturbed work-life balance [18]. High psychosocial work demands are associated with health complaints, sickness absence, decreased workability, and productivity loss [1,3,19-22].

Improved working conditions are needed to create a healthy and productive working population [10,16]. Besides that, the workplace is a fruitful setting for health promotion because of the presence of natural social networks, the possibility of reaching a large population, and the fact that people spend a great deal of their lifetime at work [9,23,24]. For these reasons, much effort has been put into the development and evaluation of interventions in the workplace setting. This includes selective activities to change the individuals' risks, attitudes, behavior, and awareness as well as comprehensive interventions such as workplace health promotion programs [1,9,25,26]. However, research shows that workplace interventions may be beneficial, but not all these interventions are useful, or their overall effects are small [1,9,24-32].

Research shows that workplace interventions are more effective when they involve evidence-based principles that (1) offer a variety of engagement modalities, (2) start with a needs assessment of participants, (3) offer higher intensity of contacts to keep participants actively involved, (4) are tailored to address participants' needs, (5) address multiple risk factors, (6) support self-management, (7) use incentives, (8) provide easy access and easy follow-up, (9) use social support, and (10) are grounded in behavior theory [9,24,28,31,33]. Mobile and wireless technology is a growing area in supporting health behavior change and might offer a promising approach as a workplace intervention since it could offer many of these elements [34-37]. Mobile health, also known as mHealth, covers medical and public health practice supported by mobile devices, such as mobile (smart) phones, personal digital assistants and other wireless devices. It also includes lifestyle and well-being apps that may connect to wearable sensors and personal guidance systems [38]. Various features make them good candidates for the delivery of interventions supporting health behavior change. First, as portable devices, they can continuously monitor the users' behavior using sensors. They offer the opportunity to bring behavioral interventions into important real-life and working contexts where people make decisions about their health and encounter barriers to behavior change. Second, they may provide cheaper, more convenient interventions. Third, the connectedness facilitates the sharing of data with health professionals or peers. Finally, the increasing ability to use sensors to infer context, such as user location, movement, emotion, and social engagement. This has raised the prospect of timely, tailored interventions for specific contexts [39-43]. As a result, these technologies support a participatory role by users, while enhancing their responsibility for their health and performance [38].

mHealth apps are being developed and evaluated to support behavior change of the general population in a variety of domains, such as physical activity [44-48], obesity [49], and stress management [50-52]. Even with the recent proliferation of apps, research evidence regarding their effectiveness is scarce [53]. The vast majority of commercial apps have not been evaluated using scientific methods, and these apps tend not to be grounded explicitly in theories of health behavior [54]. In recent years, mHealth apps have been developed to target the occupational setting [55-57], a context characterized by its specific barriers. Physical working contexts might put additional constraints on the use of mHealth apps, for instance when working in cleanrooms or high-security settings. Likewise, the organizational working context has specific focus points, such as the fit of an app with working schedules, embedding an app within prevention programs, and the role of management in implementation and adoption of an app. However, despite their potential, little research has been published on mHealth apps for employees. Only 1 study was found showing the positive effects of a tailored mHealth intervention on physical activity, snacking behavior, and sleep among airline pilots [58]. Insight is needed to determine whether mHealth apps are a powerful medium for delivering interventions in the workplace setting. Therefore, these apps need to be evaluated on (1) their potential to support healthy work behavior, (2) their consistency with evidence-based practices, and (3) their effectiveness in improving mental and physical health. The aim of this study is to examine the first step: to assess whether mHealth apps for

employees use principles and constructs underlying the processes of behavior change to enhance their mental and physical health.

Research on internet interventions (electronic health) and mHealth shows that they are more likely to be useful if they are firmly rooted in health behavior change theory [34,36,40,59]. Understanding which behavior change techniques (BCTs) are implemented can illuminate mechanisms by which using an app might facilitate behavior change as well as the types of persons for whom a given app may work best [60]. Abraham and Michie [61] and Michie et al [62] suggested several BCTs common to many health behavior theories and developed several versions of a taxonomy to identify BCTs in a range of health promotion interventions [61,62]. The taxonomies have been used to identify techniques or combinations of techniques that might enhance effectiveness [36,40].

A large body of research has been published using the taxonomy in traditional health promotion interventions [40], but few have quantified the extent to which specific BCTs are included in apps. To date, studies have evaluated whether apps for physical activity [40,54,60,63] or apps for physical activity and diet [53] incorporate BCTs. The most frequently applied BCTs in traditional health promotion interventions are "goal-setting," "prompt intention formation," "provide feedback on performance," "self-monitoring," and "review of behavioral goals" [40,61,64]. Studies report inconclusive evidence regarding the number of BCTs that are associated with effectiveness. A systematic review by Webb et al [59] on Web-based interventions reported that interventions that include a larger number of BCTs, using a taxonomy adapted from Hardeman et al [65], are more likely to be effective. In contrast, another meta-analysis by Michie et al [64] using the Abraham and Michie's taxonomy [61], suggested that the number of included BCTs is not associated with a larger effect. The study showed that interventions were most likely to be effective when "self-monitoring" was used as a technique, or when "self-monitoring" plus an additional self-regulation technique were used [64].

When interventions involve multiple BCTs, the effects might be additive, neutral (ie, cancel each other out), or amplified [66]. Accordingly, the inclusion of specific combinations of BCTs appears to be critical. Dusseldorp et al [66] used meta-analysis to conclude that specific combinations of BCTs increase the chances of achieving a change in health behavior, while other combinations decrease them. Specific combinations were more successful than average, and the strongest effects were found with motivation-enhancing BCTs. Most effective combinations were "provide information about behavior-health link" with "prompt intention formation" and "provide information about behavior-health link" with "provide information on consequences" and "use follow-up prompts." Least effective were interventions using "provide feedback on performance" without "provide instruction."

In summary, studies on traditional health promotion interventions show that not only the presence of BCTs, but also specific combinations of BCTs might explain intervention success. Up until now, none of the studies on the inclusion of BCTs in apps for physical activity and diet [36,40,54,60,63] have evaluated the presence of specific combinations of BCTs. Although this has not yet been confirmed in studies on mHealth in general, and specifically for the occupational setting, it can be suggested that certain combinations of BCTs also serve as an indicator for potential effectiveness in mHealth. This study aims to evaluate whether apps for the mental and physical health of employees incorporate BCTs and, if so, which ones can be identified, and which combinations are present.

Methods

Overview

A comparative assessment was made of apps aimed at reducing physical and psychosocial risks at work including stress prevention or coping with stress and to promote a healthy workstyle (ie, prevention of sedentary behavior or promotion of physical activity) for individual workers. Three independent reviewers undertook the assessment of the presence of BCTs and combinations of BCTs in apps: 1 scientist in ergonomics and human factors (EK), and 2 experts on mental health (NW, MBR).

Search Strategy

Since app stores differ in their acceptance policy and therefore might offer different apps, the study sample was identified through systematic searches in 2 app stores: iTunes and Google Play. The algorithms within Google Play and iTunes work differently in how they classify and rank apps and make matches for specific keywords. For instance, the Google Play algorithm considers the keywords from the description of an app, and it will rank the app in the search results accordingly. The first results listed are the most relevant. In iTunes, the app description does not influence the app store algorithm in ranking the apps.

Between December 2014 and April 2015 apps were searched, screened, and downloaded. Search terms were based on Boolean logic and included combinations for domain (work, worksite, workplace, worker, employee), health (activity, health, lifestyle, stress, mental, physical, behavior, risk, sitting, posture, shiftwork, vitality, resilience, wellbeing), and intervention (coach, intervention, assistant, motivation, support, program). Searches were performed without using the app stores' categories.

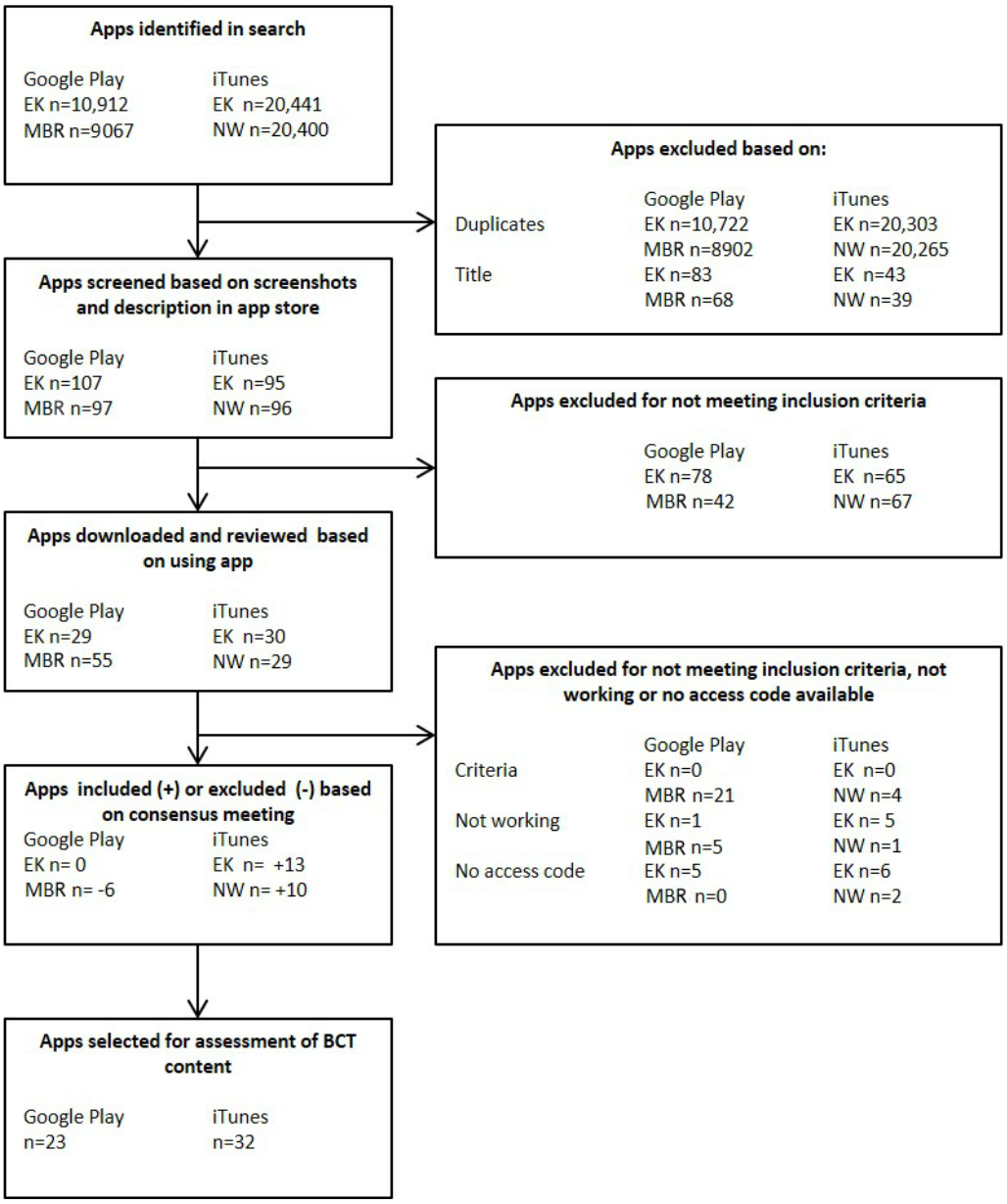
Inclusion

To be included, apps had to meet the following criteria: (1) be work-related, (2) be aimed at stress prevention or coping and/or psychosocial risk reduction and/or physical risk reduction and/or prevention of sedentary behavior and/or promotion of physical activity, (3) be aimed at healthy adults, (4) provide individually tailored feedback, and (5) be English or Dutch. Apps that contained handbooks, product catalogues or Occupational Safety and Health incident reporting were excluded. Apps that focused on older adults, students or individuals with health problems (eg, depression) were also excluded.

Screening and Assessment

Figure 1 shows an overview of the selection and screening procedure.

Figure 1. Overview of the selection and screening procedure of apps for assessment of behavior change techniques (BCTs).



Search, inclusion, screening of apps, and assessment of BCTs were performed by 3 researchers (EK and NW for iTunes; EK and MBR for Google Play). Any differences were resolved by discussion with the 2 reviewers and if necessary with the third reviewer.

First, search terms were entered in the app stores and apps were searched based on their title. Second, using the screenshots and description in the app store, the apps were screened using the inclusion criteria. Third, if an app seemed to be suitable for inclusion, it was downloaded to an iPhone 4 or a Samsung Galaxy S2. If there were doubts whether an app met the inclusion criteria, it was downloaded. If an app had a free version and a paid version, the free version was downloaded first to be reviewed. If the paid version contained additional features, it was downloaded and used for further analysis. Some apps required a unique access code. In this case, the app providers were contacted by email or phone to request a temporary access code or a demo version. While some app providers cooperated, others did not respond. These apps were not included for further analysis. Fourth, the downloaded apps were again assessed based on the inclusion criteria. Some apps appeared to be not working—these were excluded. In a consensus meeting, the final set of apps for assessment on BCTs was selected.

The reviewers used the included apps until they felt that they were familiar with the details. This varied from one hour (for very basic apps) to four weeks (for extensive apps or apps that took time before the user received feedback). The apps were assessed using the taxonomy of BCTs used in interventions, developed by Abraham and Michie [61]. This taxonomy consists of 26 BCTs and has been previously used to identify BCTs in apps [36,40]. For practical reasons we chose not to use the recent and comprehensive taxonomy by Michie et al with 93 BCTs [62]. This involved a high sensitivity of techniques which were considered too sensitive for the evaluation of apps. The taxonomy of the 26 BCTs formed the basis of the more elaborate

taxonomy. In this approach, some of the BCTs used in the earlier taxonomy were specified into more detailed BCTs. To fully understand the content of the 26 BCTs, we studied the 93 BCTs. Before evaluation, all reviewers examined the coding manual and discussed each technique carefully, until a consensus was reached on definitions. Some definitions of BCTs from the taxonomy of Abraham and Michie [61] were adapted to be used for the assessment of apps (Multimedia Appendix 1). For each app, the researchers evaluated and provided a score if the 26 BCTs were present (1) or not (0). In addition to the BCTs, the researchers assessed whether the app was aimed at physical risk prevention, psychosocial risk prevention (including stress prevention or coping) or lifestyle promotion (prevention of sedentary behavior or promotion of physical activity). The apps were scored independently, and Krippendorff alpha was used to evaluate interrater reliability since it can be used regardless of the number of observers, levels of measurement, sample sizes, and the presence or absence of missing data [67]. Also, the app name, a short description, the name of the app store, and the price for each app were collected, and stored in Excel for further analysis. The means and frequencies were calculated for the BCTs and the price of the app. Krippendorff alpha for nominal data was used to evaluate interrater reliability.

Results

General Findings

The reviewers detected 10,912 (EK) and 9,067 (MBR) apps in Google Play and 20,441 (EK) and 20,400 (NW) in iTunes. The difference between Google Play and iTunes is because, for each search, Google Play generates a maximum of 250 results per search term, in contrast to iTunes, which has no maximum.

After the inclusion procedure, 45 apps were selected for the assessment of BCTs (see Table 1 for a general overview of the apps). Thirteen apps were found in Google Play, 22 in iTunes, and 10 were found in both app stores. Of the apps found in both stores, iChange2 and Wellmo were evaluated by NW and EK on an iPhone 4. The other 8 found in both stores were evaluated by MBR and EK on a Samsung Galaxy S2. Thirty-two apps were reviewed by NW and EK on an iPhone 4 while MBR and EK reviewed 23 apps on a Samsung Galaxy S2. In total, 45 different apps were evaluated.

Reliability data is shown in Table 1. Krippendorff alpha coefficients ranged from .23 to 1.00. Of the 45 reliability tests, 34 (76%) apps yielded alphas of at least .61 indicating good reliability. Fair reliability was found for 9 (29%) apps, which yielded alphas ranging from .41 to .60. Inferior reliability was assessed for 2 (4%) apps that scored below .41 [68].

Of the 45 apps, 13 (29%) had to be paid for with a mean price of €2.40 (range €0.99-4.99). Twenty-nine apps (64%) were free, and 3 (7%) apps had an access code. This access code was used when the app was offered as part of a company program. These apps are not free; however, the cost of these apps is unknown.

Fifteen (33%) apps were targeted at physical risk prevention, 23 (51%) at psychosocial risk prevention (including stress prevention or coping with stress), and 34 (76%) at lifestyle promotion (prevention of sedentary behavior or promotion of physical activity). Twenty-three (51%) apps were directed at a minimum of two categories, and 22 (49%) at just 1.

Behavior Change Techniques

The average number of BCTs was 7 (range 2-18). Most BCTs were used in iChange2 (18) and Wellmo (16). Table 1 shows that the least BCTs were identified in Positive Me (2), Ergometer (3), Office health alarm clock (3), and Stress Check by AIIR consulting LLC (3).

Figure 2 shows the BCTs identified most frequently and which BCTs were not. All 45 apps “provided feedback on performance”. This was no surprise since it was one of the inclusion criteria. Other techniques that were used more often were “provide information about behavior-health link” in 37 (82%) apps and “provide instruction” in 32 (71%) apps. Techniques that were used least were “relapse prevention” found in 3 (7%) of the apps, “prompt self-talk” in 2 (4%) apps, “use follow-up prompts” in 2 apps, and “provide information about others approval” in 1 app. “Stress management,” “prompt identification as a role model,” and “agree on behavioral contract” were not used by any of the apps (Figure 3).

Finally, combinations of techniques were analyzed. The combination “provide information about behavior-health link” with “prompt intention formation” was found in 7 (16%) apps (Brightr, iChange2, Move More, Office Buzz, Wellmo, 48-hour stress relief and Office exercise & stretch). The combination “provide information about behavior-health link” with “provide information on consequences” and “use follow-up prompts” was found in 2 (4%) apps (iChange2 and Wellmo). These combinations were found to be the most effective in health behavior change in the meta-analysis by Dusseldorp et al [66] indicating potential effectiveness in mHealth apps. The least effective combination “provide feedback on performance” without “provide instruction,” according to the meta-analysis of Dusseldorp et al [66], was found in 13 (29%) apps (Break Reminder, Darma, Fitlab, iSteplog, My Wellbeing App: Psycare Assist, Office Buzz, Office health alarm clock, Positive Me, Stand-up!, Standing desk companion [Varidesk], Stress Check [AIIR consulting LLC], Walk to Work and Workonit).

Table 1. Descriptive data of the apps that were evaluated for the presence of behavior change techniques.

Name of the app	Krippendorff alpha	App store purchased	Price (€) per code	Category of risk prevention or lifestyle promotion that apply to the apps			BCT[a] score
				Physical risk prevention	Psychosocial risk prevention	Lifestyle promotion	
1-minute desk workout	.59	iTunes	0	Yes	—	Yes	8
48-hour stress relief	.59	iTunes	4.99	—	Yes	—	8
Aetna Resources for Living	.83	Google Play / iTunes	0	—	Yes	—	8
Balance Coach Report Pro	.63	iTunes	2.99	—	Yes	Yes	6
Break Reminder	1.00	Google Play	0	Yes	Yes	Yes	4
Brightr	.95	Google Play / iTunes	Access code	—	Yes	Yes	10
Carecall	.32	iTunes	0	—	Yes	Yes	6
Chair Yoga	.84	iTunes	2.99	Yes	Yes	Yes	6
CNV mijn loopbaan app	.79	iTunes	0	—	Yes	Yes	5
Darma	.76	iTunes	0	—	—	Yes	4
Desk Workout	.73	iTunes	0	Yes	—	Yes	7
Ergo@WSH	.77	Google Play / iTunes	0	Yes	—	Yes	7
ErgoCom	.72	Google Play	0	Yes	—	—	4
Ergometer	.63	Google Play	0	Yes	—	—	3
Ergonomics	.86	iTunes	0	Yes	—	Yes	8
Fatigue Score Calculator	.90	iTunes	1.29	—	—	Yes	5
Fitlab	.79	Google Play	0	—	Yes	Yes	4
Get Off Your Butt!	.91	iTunes	1.99	—	—	Yes	6
Happy@work	1.00	Google Play	3.99	—	Yes	—	5
Headspace.com meditation	.79	Google Play	0	—	Yes	Yes	11
Ichange2	.78	Google Play / iTunes	Access code	—	Yes	Yes	18
iStepLog	.63	iTunes	0	—	—	Yes	11
Ladies' Office Workout	.55	Google Play / iTunes	0	—	—	Yes	9
Measure Workplace Stress	.64	Google Play / iTunes	0	—	Yes	—	4
Minute Stretches	.84	iTunes	0.99	Yes	—	Yes	7
Move More	.62	iTunes	0.99	—	—	Yes	11
My Wellbeing App: Psycare Assist	.23	Google Play / iTunes	0	—	Yes	Yes	4
Office Buzz	.63	Google Play	0	—	Yes	Yes	7
Office exercise & stretch	.62	Google Play	1.18	—	—	Yes	9
Office health alarm clock	.43	iTunes	0.99	Yes	—	—	3
Office Wellness	.92	Google Play	0	Yes	—	Yes	8
Positive Me	.43	iTunes	0	—	Yes	Yes	2
Provider resilience	.65	iTunes	0	—	Yes	—	12
Salute the Desk	.78	iTunes	3.99	Yes	—	Yes	9

Name of the app	Krippendorff alpha	App store purchased	Price (€) per code	Category of risk prevention or lifestyle promotion that apply to the apps			BCT[a] score
				Physical risk prevention	Psychosocial risk prevention	Lifestyle promotion	
Stand up!	.63	Google Play / iTunes	0	—	—	Yes	8
Standing desk companion (Varidesk)	.59	iTunes	0	—	—	Yes	7
Stop Sitting virtual weight loss	.75	iTunes	0.99	—	—	Yes	8
Stress Check (wisdomathand/office harmony)	.61	Google Play	0	—	Yes	—	4
Stress Check (AIIR consulting LLC)	.61	iTunes	0	—	Yes	Yes	3
Stress Releaser Meditation	.61	Google Play	3.82	—	Yes	—	5
VGZ Mindfulness Coach	.51	Google Play	0	—	Yes	—	8
Voom	.63	iTunes	0	Yes	—	Yes	11
Walk to Work	.53	Google Play	0	—	—	Yes	6
Wellmo	.65	Google Play / iTunes	Access code	Yes	Yes	Yes	16
Workonit	.50	Google Play / iTunes	0	Yes	Yes	Yes	8

[a]BCT: behavior change technique.

Figure 2. Frequencies of the behavior change techniques found in apps using the taxonomy by Abraham and Michie [61].

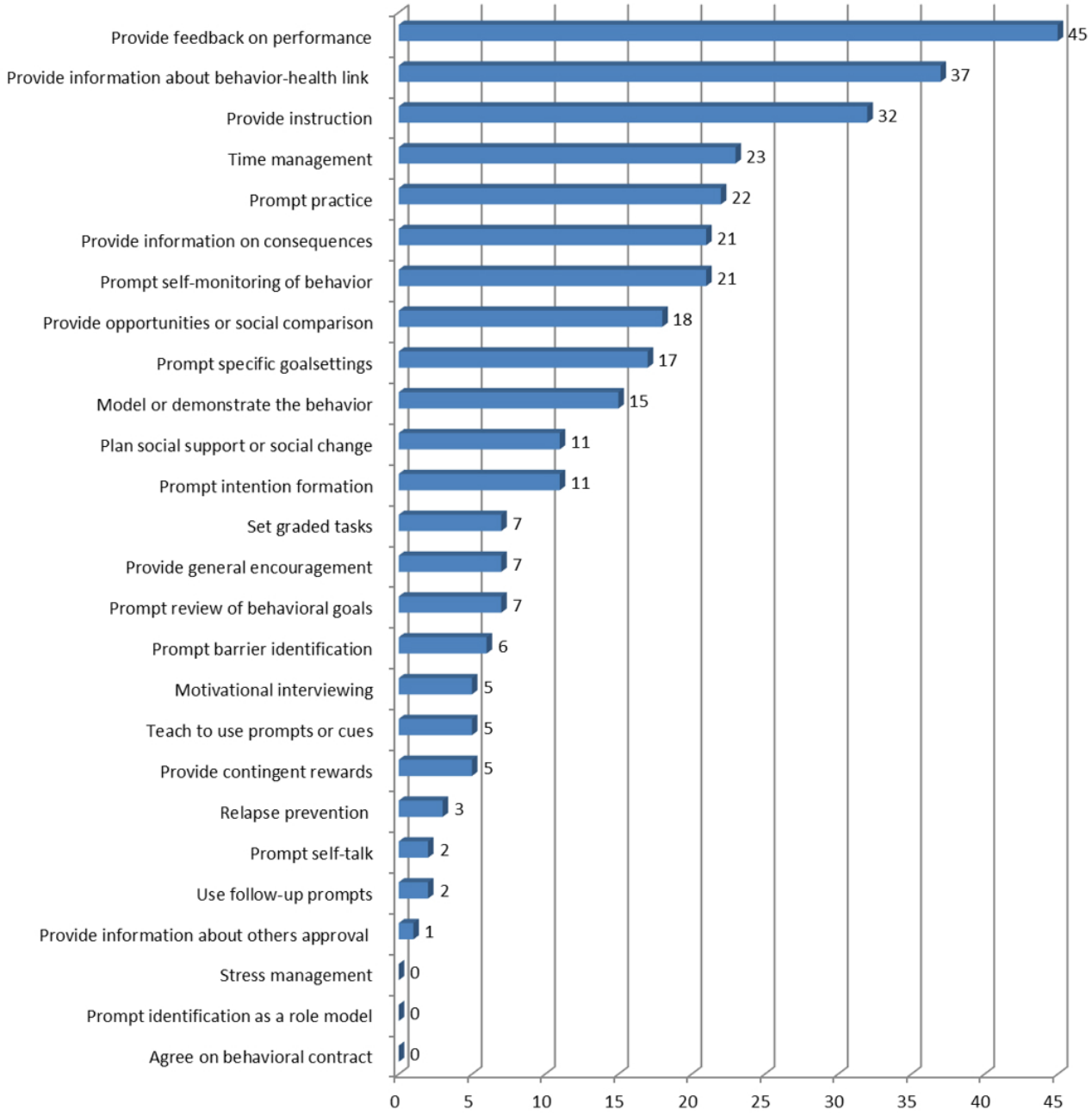
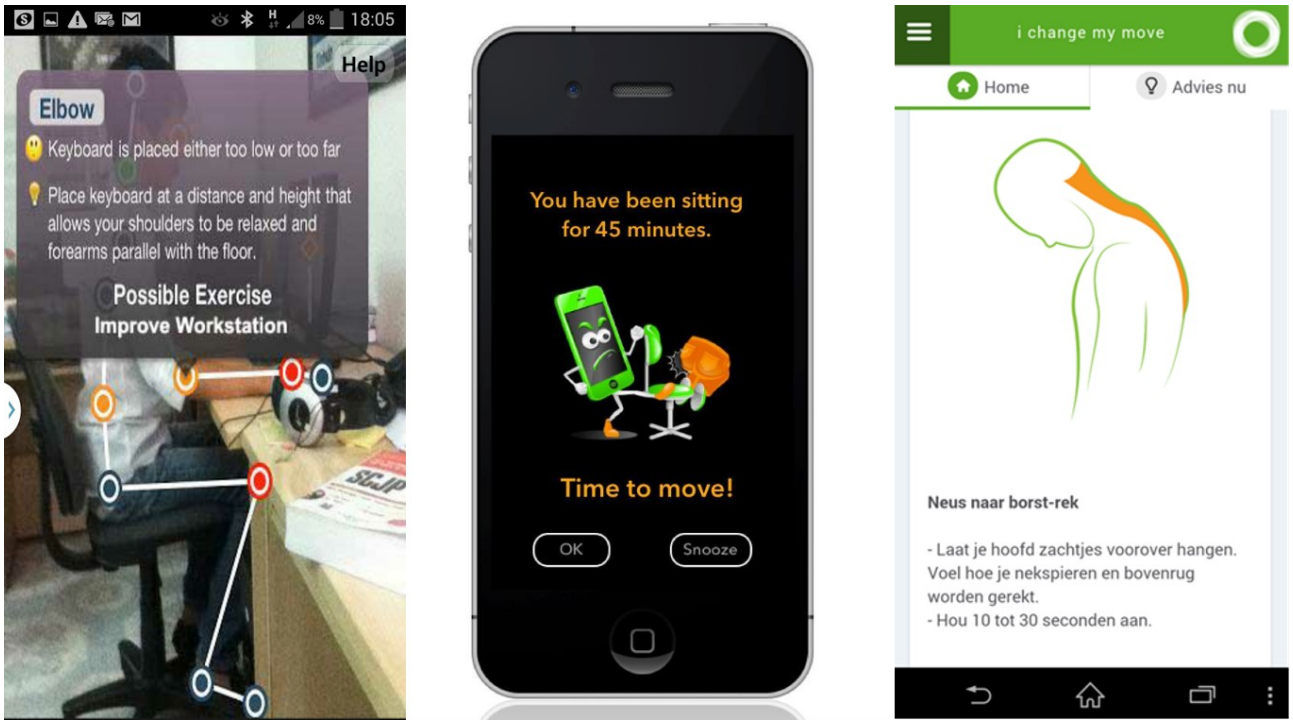


Figure 3. Examples of behavior change techniques used in apps, from left to right: "provide feedback on performance" (Ergo@WSH), "prompt practice" (Get Off Your Butt!) and "model or demonstrate behavior" (iChange2). Pictures have been taken from app descriptions in Google Play store (Ergo@WSH), iTunes (Get Off Your Butt!) and from app provider (iChange2).



Discussion

Principal Findings

In this study, the presence of BCTs was identified in apps for the mental and physical health of employees. Previously, researchers have studied the presence of BCTs in apps, such as physical activity apps [36,40,54,60,63], dietary apps [53], medication adherence apps [69] or cancer survivorship apps [70]. Others have studied the presence of BCTs in wearable lifestyle activity trackers [71,72]. However, this study was the first to assess BCTs in apps aimed at improving the mental and physical health of employees. Also, this app assessment was the first to look at specific combinations of BCTs in apps, which might serve as an indicator of potential effectiveness.

The majority of the apps (34/45, 76%) in this study aimed to improve the health of employees targeted lifestyle promotion, while the number of apps directed at psychosocial risk prevention (23/45, 51%) and physical risk prevention (15/45, 33%) was much lower. About half (22/45, 49%) of the apps targeted just 1 of these categories. Reviewers noticed that lifestyle apps used sensors more often (eg, the accelerometer of the mobile phone used for step counting). In contrast, apps aiming at psychosocial risk prevention rarely used sensors to monitor; these apps generally used questions or questionnaires to gather data. One of the main advantages of mobile technology compared to the traditional nondigital interventions in the workplace setting is the ability to monitor the user's behavior with sensors continuously. This offers the opportunity to bring behavioral interventions into an important working context where people make decisions about their health and encounter barriers to behavior change. Differences in technical possibilities might influence the sort of apps that are being developed and the kind of behaviors they target.

The results of this study showed a limited presence of theoretical behavior change constructs. Previous research has highlighted the shortage of the application of behavior change theory in digital interventions, such as websites and apps designed to promote health behavior change [36,40]. Cowan et al [63] suggest that the general lack of theoretical constructs on behavior change included in apps might not be entirely unexpected, given that app developers' expertise relates to software development and may not include health behavior theory. Therefore, they might not thoroughly incorporate health behavior change theory into their apps [63]. Another explanation for these findings might be that, as per Dusseldorp et al [66], it is the type, quality, and combinations of BCTs, and how they are implemented, rather than the quantity of the techniques that matter. Finally, some techniques might not be detected by the researchers. The low Krippendorff alpha values found in some apps, as well as the discussions, emerged during the consensus meetings showed that reviewers did not always discover all features of the apps. Some features were not explicit during use. For example, reminders, updates, and feedback might have occurred for one reviewer, but not for another. Some BCTs were not easily traceable, for instance only via pop-up messages. This resulted in a different assessment of BCTs and might explain the interrater variability for some of the apps, with the lowest Krippendorff alphas belonging to Carecall and My Wellbeing App: Psycare Assist. However, it is important to note that low Krippendorff alphas might also exist in the case of rare values, especially with binary variables (ie, BCT present or BCT not present) with 1 rare value. Krippendorff alpha compares the "observed" and "expected" disagreements and to satisfy this it takes into account the prevalence of the categories

coded for the variable. Nevertheless, one of the strengths of this study is that all apps have been screened and identified by at least two reviewers and in general, reasonable to good interrater reliability has been established.

In apps for mental and physical health, 7 BCTs were identified on average. Also, the number of applied BCTs showed a large variation between apps (range 2-18). These results are in line with those of Middelweerd et al [40] who found an average of 5 (range 2-8), Conroy et al [54] (average 4, range 1-13), Yang et al [60] (average 7, range 1-21), and Direito et al [36] (average 8, range (2-18), although these studies targeted physical activity and nutrition apps).

In this study, it was shown that the most common BCTs in apps for the health promotion of employees were "feedback on performance," "providing information about the behavior-health link and provide instruction." Middelweerd et al [40], Direito et al [36], and Conroy et al [54] also showed that "provide feedback on performance" and "provide instruction" were among the most identified BCTs. "Provide feedback on performance" was also found by Middelweerd et al [40] to be the most applied technique, although this was, similar to the current study, one of the inclusion criteria.

The current study showed that BCTs "relapse prevention," "use follow-up prompts," "prompt self-talk," and "provide information about others' approval" were identified the least. "Relapse prevention" and using "follow-up prompts" are important for sustained behavior change, but in the current study, these were applied in 3 apps only, which might question the value of these apps for changing behavior in the long-term [36]. However, it is unclear why these BCTs have been found in only a limited number in the sample of apps. For instance, these techniques might work well for interventions targeting addictive behaviors (eg, smoking) but might not be relevant for interventions promoting work style or habit formation.

"Stress management," "prompt identification as a role model," and "agree on behavioral contract" were not applied at all in any of the apps, which is in line with the work of Middelweerd et al [40] and Direito et al [36]. Further findings were not in line with the work of others: "prompt identification as a role model" was the fourth most applied technique in the study by Direito et al [36] but was not applied in that of Middelweerd et al [40], nor in the current study. "Prompt identification as a role model" was found by Direito et al [36] and there seems to be no technical obstacles to also applying "stress management" and "prompt identification as a role model" in apps. It appears that app developers might lack expertise in health behavior theory and therefore not include these techniques in their apps.

Compared to nondigital interventions in the workplace setting, one of the advantages of apps is the ability to monitor users' behavior continuously and to deliver context-aware, personalized interventions. Consequently, these technologies support a participative role of users, while enhancing their responsibility for their health and performance [38,41-43]. For this reason, it was expected that many apps in the current study would have applied "prompt self-monitoring" in 21 (47%) apps, "plan social support or change" in 11 (24%) apps, and "prompt barrier identification" in 6 (13%) apps as a technique. The results did not quite confirm these expectations.

Applying certain combinations of BCTs is also essential. Dusseldorp et al [66] concluded from their meta-analysis that specific combinations of BCTs increase the likelihood of achieving change in health behavior, whereas other combinations decrease the possibility. The results of the current study showed that only a few apps applied most effective combinations and many apps applied the least effective. The meta-analyses by Dusseldorp et al [66] were performed with data on nondigital interventions. It is unclear whether this applies to digital interventions as well, but app developers should at least be conscious on how the number, the use, and combinations of BCTs might influence the effectiveness of an app. Therefore, future research should focus on the evaluation of which BCTs and combinations of BCTs are likely to be successful in effectively changing unhealthy behavior. Also, the present study shows that knowledge on effective BCTs might currently be underused in app development and suggests the need for multidisciplinary collaboration between app developers and behavior change experts. Others have concluded this as well [36,63,73]. Besides, to design tailored and targeted app-based interventions, insight into the preferences of the target population for certain BCTs is of importance. This has been shown by Belmon et al [74] for young adults in physical activity apps. Some BCTs were rated as more positive to apply than others. Ratings of BCTs differed according to personality traits and exercising self-efficacy. This may apply to apps for employees, and therefore, preferably employees should also be engaged in the development.

This study on BCTs in apps for the mental and physical health of employees had certain limitations. The procedure to search, identify, and review apps is susceptible to bias. Reviewers searched, screened, and downloaded apps on different days. Generally, apps are developed very fast and what is offered in app stores varies daily. This might have influenced the search results, especially those based on algorithm ranking (Google Play).

These fast developments also became apparent when some apps that were selected for download appeared to be untraceable. Presumably, many new apps have also appeared in the meantime. Still available apps have likely been changed, and new versions are available in the app stores since apps are updated continuously. This is illustrated by the study of Larsen et al [75] on the availability of mental health apps in iTunes and Google Play stores. They found 50% of search results changing within 4 months and an app being removed every 2.9 days. Therefore, conclusions on the apps that participated in the current study have to be interpreted with caution.

The taxonomy of Abraham and Michie [61] has not been developed specifically for apps. Therefore, reviewers had to translate the BCTs to app characteristics, which might have led to different interpretations than initially intended. For instance, stress management appeared to be a difficult BCT to interpret. It is defined as "may involve a variety of specific techniques (eg, progressive relaxation) that do not target the behavior but seek to reduce anxiety and stress." However, in many apps in

this study, management of stress was the targeted behavior, which was confusing. After a consensus meeting, it was decided to identify this technique only in cases where advice was given on ways to facilitate performance of the targeted behavior.

In addition to methodological limitations, there are also limitations in interpreting the results. As stated in the introduction, the extent to which apps are built upon theoretical models of the themes they address is essential (ie, stress management apps making use of evidence-based stress models). The current study focused on the presence of specific combinations of behavior change theories in apps. However, this is not necessarily an indication of good quality. Some of the apps in the study applied BCTs but also gave feedback that was not in line with current scientific insights. This raises the question of the value of these apps in supporting the user to enhance mental and physical health. Although an app might use principles and constructs underpinning the processes of behavior change, it also needs to be consistent with evidence-based practices. Therefore, designing useful apps requires the application of expertise from diverse fields and would benefit from interdisciplinary collaboration. While there is a consensus among software developers on the importance of engaging users, an mHealth app for employees would also benefit from collaboration with behavior change experts and experts in mental and physical health [76].

Moreover, the current study does not answer the question of whether apps are effective in changing behavior and thereby in the prevention of physical and mental health risk or promotion of a healthy lifestyle. To determine effectiveness, controlled trials are necessary, preferably using evaluation methods that fit with the fast, iterative development processes of apps (eg, a stepped wedge design) [35,37]. To date, the evidence base of apps is still scarce. Many apps are not based on solid evidence or evaluated with scientific methods [54,63,73].

Despite these limitations, this study provides the first analysis of health behavior theory applied in apps for the mental and physical health of employees. This research method cannot establish effectiveness and usability of these apps. Further research is needed to assess the effectiveness and usability of apps as intervention means for employees.

Conclusion

The findings of this study suggest that apps might be substantially improved to bring behavioral interventions into the working context where employees make decisions about their health and encounter barriers to behavior change. This study might be a first step toward implementing BCTs in a manner that is likely to increase behavior change potential.

The results, in general, showed a limited presence of BCTs, limited use of potentially successful combinations of BCTs in apps, and the use of potentially unsuccessful combinations of BCTs. Current knowledge on potentially effective combinations of BCTs seems to be underused in app development for the occupational setting. Knowledge of BCTs should be incorporated more in the development of apps. Combining behavior change theory and providing content with a robust evidence base and taking into account the specific context of the occupational setting could contribute to the development of effective mHealth-based interventions for employees and decrease the burden of work-related diseases. Although BCTs have been shown to be effective in face-to-face or online behavior change interventions, it is still unclear whether they are effective mHealth interventions. Future research should, therefore, focus on evaluating which BCTs and combinations of BCTs are effective in changing health behavior of employees when used in apps. For this evaluation, quantitative and qualitative methods should be used.

To increase potential and effectiveness, a collaboration between app developers, health behavior change professionals, experts on physical and mental health, and end-users is suggested. Combinations of expertise could provide higher quality apps. Until now, it is unclear which criteria could be used by organizations when selecting apps to offer to their employees. Furthermore, for employees, it remains unclear which app would help them best to improve their physical and mental health at work. An increase in knowledge on the effectiveness of BCTs in apps could be used to develop guidelines for app developers and the development of selection criteria for companies and individuals.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Definitions of behavior change techniques.

[PDF File (Adobe PDF File), 583KB - mhealth_v6i10e167_app1.pdf]

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Abbreviations

BCT: behavior change technique
mHealth: mobile health

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Original Paper

The Association Between Engagement and Weight Loss Through Personal Coaching and Cell Phone Interventions in Young Adults: Randomized Controlled Trial

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Abstract

Background: Understanding how engagement in mobile health (mHealth) weight loss interventions relates to weight change may help develop effective intervention strategies.

Objective: This study aims to examine the (1) patterns of participant engagement overall and with key intervention components within each intervention arm in the Cell Phone Intervention For You (CITY) trial; (2) associations of engagement with weight change; and (3) participant characteristics related to engagement.

Methods: The CITY trial tested two 24-month weight loss interventions. One was delivered with a smartphone app (cell phone) containing 24 components (weight tracking, etc) and included prompting by the app in predetermined frequency and forms. The other was delivered by a coach via monthly calls (personal coaching) supplemented with limited app components (18 overall) and without any prompting by the app. Engagement was assessed by calculating the percentage of days each app component was

used and the frequency of use. Engagement was also examined across 4 weight change categories: gained (≥2%), stable (±2%), mild loss (≥2% to <5%), and greater loss (≥5%).

Results: Data from 122 cell phone and 120 personal coaching participants were analyzed. Use of the app was the highest during month 1 for both arms; thereafter, use dropped substantially and continuously until the study end. During the first 6 months, the mean percentage of days that any app component was used was higher for the cell phone arm (74.2%, SD 20.1) than for the personal coaching arm (48.9%, SD 22.4). The cell phone arm used the apps an average of 5.3 times/day (SD 3.1), whereas the personal coaching participants used them 1.7 times/day (SD 1.2). Similarly, the former self-weighed more than the latter (57.1% days, SD 23.7 vs 32.9% days, SD 23.3). Furthermore, the percentage of days any app component was used, number of app uses per day, and percentage of days self-weighed all showed significant differences across the 4 weight categories for both arms. Pearson correlation showed a negative association between weight change and the percentage of days any app component was used (cell phone: r=−.213; personal coaching: r=−.319), number of apps use per day (cell phone: r=−.264; personal coaching: r=−.308), and percentage of days self-weighed (cell phone: r=−.297; personal coaching: r=−.354). None of the characteristics examined, including age, gender, race, education, income, energy expenditure, diet quality, and hypertension status, appeared to be related to engagement.

Conclusions: Engagement in CITY intervention was associated with weight loss during the first 6 months. Nevertheless, engagement dropped substantially early on for most intervention components. Prompting may be helpful initially. More flexible and less intrusive prompting strategies may be needed during different stages of an intervention to increase or sustain engagement. Future studies should explore the motivations for engagement and nonengagement to determine meaningful levels of engagement required for effective intervention.

Trial Registration: ClinicalTrials.gov NCT01092364; https://clinicaltrials.gov/ct2/show/NCT01092364 (Archived by WebCite at http://www.webcitation.org/72V8A4e5X)

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KEYWORDS

mHealth; mobile health; weight reduction; intervention; smartphone; mobile phone

Introduction

Background

Mobile health (mHealth) technology provides innovative ways to create interventions that may help people lose weight and sustain weight loss [1-3]. mHealth weight loss interventions use mobile user interfaces (eg, short message service text messaging and always-nearby touch screens) to deliver the intervention in the midst of everyday life. They sometimes use the wearable sensing capabilities of the mobile devices as well to gather data and provide tailored feedback to people trying to reduce weight. Some meaningful level of engagement is required to ensure the delivery and receipt of intervention components in research studies.

The effectiveness of behavioral weight loss studies that are delivered in person is known to be moderated by dose [4]. Although not much is known about the relationship between engagement in mHealth interventions and weight outcome, previous studies have shown that a higher engagement is associated with a more favorable study outcome [5,6]. Engagement is a complex concept, and its conceptualization and measurement can vary from study to study. Engagement is sometimes used interchangeably with adherence. Various theoretical models of engagement and adherence have been developed, but not all models have been tested against empirical evidence [7]. In general, these models suggest that individual, environmental, technological, and social support factors may influence user engagement and, subsequently, intervention efficacy.

Objectives

In this report, we defined engagement specifically as interaction with components of the intervention and then assessed various types of engagement to understand how and whether engagement relates to weight management. Specifically, we defined engagement as the frequency of use of various intervention components of the cell phone app and the attendance of the in-person group sessions and phone counseling calls. We theorized that a higher engagement may reflect individual motivation and lead to a greater commitment for behavioral change and, thus, a higher intervention efficacy in the Cell Phone Intervention For You (CITY) clinical trial.

In the CITY trial, we compared 2 behavioral interventions for weight loss: the cell phone (CP) intervention arm and the personal coaching (PC) arm [8]. Even though neither arm lost a significantly different amount of weight compared with the control arm at 24 months, the PC arm lost the greatest amount of weight at 6 months (P<.01). There was also a large variability in weight loss within each arm—some participants lost a substantial amount of weight, whereas others did not. The CITY intervention provides an opportunity to examine engagement because it incorporated various strategies for delivering intervention components, such as using sensor technology for capturing data from a wireless scale, providing tailored feedback, and using prompting as a reminder strategy. In addition, detailed and careful collection of both engagement data and weight data allows for examination of the association between engagement and weight and for examination of factors that may influence engagement. Thus, this work examines (1) the patterns of participant engagement overall, and with key intervention components within each intervention arm, in the

CITY trial; (2) the associations of engagement patterns with weight change; and (3) the participant characteristics related to intervention engagement.

Methods

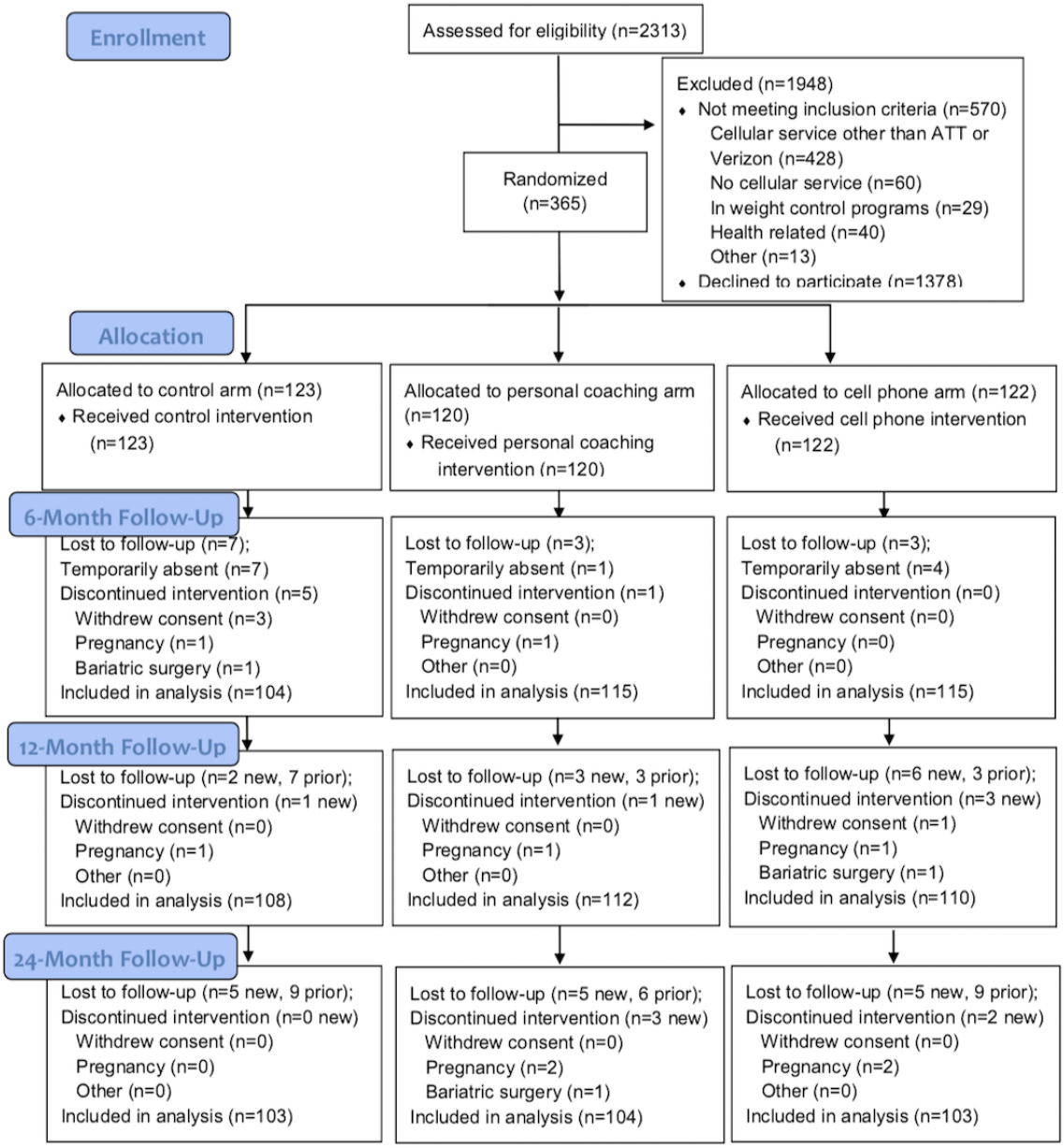
Study Design

The CITY study was 1 of the 7 trials in the Early Adult Reduction of weight through LifestYle Intervention consortium, sponsored by National Heart Lung and Blood Institute (NHLBI, 5U01HL096720) [9]. CITY was approved by the Duke institutional review board and an NHLBI-appointed Protocol Review Committee and Data and Safety Monitoring Board. Enrollment occurred between December 2010 and February 2012. The primary objective of the main CITY study was two-fold: (1) to compare an mHealth intervention delivered by an interactive CP app with usual-care controls and (2) to compare an in-person and phone-supplemented PC intervention enhanced by CP self-monitoring with usual care (Figure 1). For this report, we analyzed data from the 2 intervention arms, not the control arm. The intervention period lasted 24 months, with data collection at baseline and 6, 12, and 24 months post randomization.

Study Population and Randomization

A total of 365 individuals, aged 18 to 35 years, overweight or obese (body mass index [BMI]>25 kg/m^2), and currently using a smartphone were enrolled in the study. Individuals were excluded if they were taking weight loss medications, corticosteroids, or had undergone weight loss surgery.

Figure 1. Cell Phone Intervention For You study CONSORT (Consolidated Standards of Reporting Trials) diagram.



Randomization was stratified by gender and BMI (overweight, BMI≥25-30 kg/m^2 vs obese, BMI≥30 kg/m^2) with equal allocation to each of the 3 study arms.

Interventions

Full descriptions of the CITY study [8] and intervention [10] have been reported elsewhere. The control arm received handouts on healthy eating and exercise for weight management immediately post randomization. No further intervention was offered to the control participants. A summary for each of the 2 active interventions is given below. Both the CP and PC interventions were rooted in theoretical models, and the behavioral framework was based on previous intervention programs that led to significant weight loss in 6 months [11,12].

Behavioral change techniques such as self-monitoring, feedback on behavior, goal setting, problem solving, action planning, behavioral contract, comparison of outcomes, incentive, behavior substitution, habit formation, prompts or cues, modeling of behavior, and shaping knowledge were incorporated into components of the intervention (Multimedia Appendix 1). As self-monitoring has been shown repeatedly to be an important feature of behavioral weight-loss programs [13,14], we emphasized this behavioral strategy in both intervention arms. Participants in the CP arm were prompted by the smartphone app daily to self-weigh, whereas the PC participants were encouraged by their coach to self-weigh during monthly calls. The CP arm also received auditory, vibrotactile, and visual prompting from the app based on a predetermined schedule to record food intake, set goals, and engage in physical activity. The prompting schedule was designed by the intervention team based on collective research experience and the consensus to (1) focus on 1 behavioral technique of self-weighing and (2) emphasize a few key self-monitoring techniques during the first 6 months and then reduce the frequency of prompting over time. We believed that regular prompting initially could help establish new behaviors, but that too much sustained prompting might be disruptive and not sustainable. In addition to the study phone, participants were given a scale (HD-351BT, Tanita Corp, Tokyo, Japan) to record weight readings. The scale wirelessly communicated with the CITY app via Bluetooth and allowed participants to take a measurement without entering data into the smartphone, thereby possibly reducing participant burden [10]. The CITY app uploaded the weight data and other app use data to the research server, and these summary data were available to the study investigators and interventionists. Participants in both of the intervention arms were provided with a smartphone that was used as their personal phone, and they were compensated for monthly smartphone data coverage and for attending the data collection visits. The participants could uninstall the CITY app themselves.

Personal Coaching Intervention

Participants randomized to the PC intervention arm attended 6 weekly 2-hour group sessions within 2 months of randomization. The sessions included 5 to 10 participants each and were conducted by a coach with registered dietitian training, with multiple years of coaching experience, and trained in motivational interviewing techniques. At the conclusion of all 6 group sessions, participants received a monthly coaching call from the coach for an additional 22 months (21 calls total). No other intervention contact was made between the coach and participants outside of group sessions and monthly phone coaching. To supplement the coaching, PC participants were encouraged to use the CITY smartphone app to track weight, diet, and physical activity. The uploaded weight data allowed the coach to know if a participant was recording weight measurements daily, as recommended, and to discuss such behavior (or lack of it) during the monthly calls.

In contrast to the app used by the CP arm, the app available to PC participants was entirely passive, requiring participants to self-initiate use by opening the app icon. It did not proactively present the user with information, prompt for information, or send reminders to use the app, and thus, it was unlikely to be seen every time participants used their smartphones.

Cell Phone Intervention

The CP intervention was designed following the same behavioral framework. However, the behavioral framework was implemented for a smartphone, without interaction with a live coach. The delivery mode for the CP intervention was through a fully automated smartphone app that included auditory, vibration, visual, and peripheral prompting intended to encourage use and gather data. This app was designed and developed by the study team. Coaches communicated with the CP participants every 6 months for a quick *check-in* by phone to make sure the smartphone was working properly, but otherwise, the CP intervention was delivered entirely through the smartphone app.

The smartphone app had 24 components within 10 behavioral strategies such as tutorials; tips and news; goal-setting; a buddy system; food tracking; physical activity tracking; feedback and challenge games to increase self-monitoring and physical activity; and an *other* component including components such as sending feedback about the app, sending requests for help to the research team, and updating the app. Multimedia Appendix 1 describes the components that the CP participants were prompted to use and how engagement was tracked from use of those components. The app also included proactive visual, vibratory, and auditory prompting to grab the user's attention and peripheral display reminders [15] that appear regularly on the lock and home screens and may capture the user's attention at times. Prompting (both active and peripheral) may be helpful to increase engagement because it (1) might influence general attitude (eg, message sent through prompting: "You have been in the CITY study for 150 days"), (2) remind participants about specific goals (eg, "Take one weight measurement each day"), (3) encourage immediate performance of a task such as self-monitoring (eg, "Track your veggie intake now") or goal setting (eg, "Set your weekly weight loss goal"), (4) increase knowledge transfer (eg, "Popcorn without butter is a healthy snack"), (5) provide positive reinforcement (eg, "Great job tracking your food"), and (6) deliver social support (eg, "Your weight loss buddy says 'Good job tracking'"). The prompting was only designed for certain app components for the CP arm. The frequency of prompting for each app component was averaged for each of the 3 study periods (months 1-6, 7-12, and 13-24 months) and is shown in Multimedia Appendix 1.

The visual prompts moved the home screen of the app to the smartphone's foreground (regardless of what other apps the person might be using at that time), displaying the app content along with a 4 2 seconds audio chime and/or a 4 seconds vibration pattern, depending upon the smartphone's audio settings at the time. The app also included peripheral always-on reminders, achieved in 2 ways: (1) messages appeared on the smartphone's lock screen, so that every time the smartphone was used and turned on, a CITY message related to tips or motivation for weight loss was visible and (2) participants were requested to set the CITY app to control their smartphone's home screen *wallpaper*, so that once the smartphone was unlocked, CITY displayed a message on the smartphone's app home screen constantly. The wallpaper display included a link to open the main app with a tap. However, the participants could disable the home screen display, and the app could not prevent them from doing so. Participants could also simply cover up the home screen display with other images. As in the PC arm, participants in the CP arm were provided with a wireless scale that could send data to the smartphone app [10].

Measurement and Recording of Engagement

Programmatically, it is beyond the scope of this report to measure the dosage of most components of the app accurately such as the duration of time the app component was used for but rather only initiation or use of the component. This work, therefore, focuses on the app use as a proxy for the level of engagement. The CITY app logged participant use of every major app component-action (eg, obtaining weight from the scale, dietary tracking, and physical activity tracking) for both intervention arms. There were a total of 18 app component-actions logged for the PC arm and 24 actions logged for the CP arm (see Multimedia Appendix 1) [10]. These data were uploaded daily from the smartphones into the study server. Completion of group sessions and monthly calls in the PC arm were also counted toward engagement and were recorded by the coach into the study database. For this report, we defined engagement as the use of specific app components. For the PC arm only, we additionally defined engagement as attendance at group sessions and phone counseling calls.

Statistical Analysis

Recognizing that engagement with different components of the intervention demands different amounts of time and effort (ie, attending group session vs weighing self), we evaluated all components of engagement combined and separately for specific app components. For this manuscript, we considered a discrete instance of *use* of each app component to be achieved when a participant completed an important, but also measurable, interaction with that component. In other words, looking at a screen that asks a participant to take a weight reading does not count as use, but entering a weight value when asked to do so does count as use. Engagement data were summarized for each participant for each app component for each day; then, the participant-level data were averaged for the CP and PC arms (separately and combined) over time by month and by 3 specific intervention periods: from baseline to 6 months, 7 to 12 months, and 13 to 24 months. These periods correspond to distinct phases of the intervention with regard to availability and frequency of different app components.

We also examined the relationship between categories of weight change and engagement during the 3 study periods. Weight change was grouped into 4 categories: gained (≥2%), stable (±2%), mild loss (lost ≥2% to <5%), and greater loss (lost ≥5%). These categories were chosen to reflect current guidelines that support 2% to 5% weight loss as clinically meaningful and stable weight as within ±2% of weight gain or loss [16]. One-way analysis of variance (ANOVA) was used to compare each of the 5 selected engagement measures across these weight change categories separately for the CP and PC arms for each intervention period. The 5 engagement measures included (1) mean percentage of days any app component was used (including self-weighing; PC and CP), (2) the mean number of times any app component was used per day (including self-weighing; PC and CP), (3) the mean percentage of days participants self-weighed (PC and CP), (4) the mean completion rate of group sessions (PC only), and (5) the mean completion rate of group sessions and monthly calls combined (PC only). In addition to examining the relationship between categories of weight change and the engagement measures during the 3 intervention periods, we used the Pearson linear correlation coefficient to assess the linear association of these 5 engagement measures with continuous weight change separately for the PC and CP arms for each of the 3 intervention periods.

To understand whether baseline characteristics were associated with higher levels of engagement during the first 6 months of the intervention, we examined the distribution of selected baseline characteristics across quartiles of the mean number of times any app component was used per day (including self-weighing) for the PC and CP arms separately. Baseline characteristics such as age, gender, race, ethnicity, education, income, weight, BMI, energy expenditure, healthy eating index score, and hypertension status were examined. All statistical tests were two-sided, and a P value of <.05 was considered statistically significant. All analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC).

Results

Table 1 describes the baseline characteristics of the participants randomized to the CP and PC arms, combined and separated. On average, participants were 29.3 (SD 4.2) years old, weighed 100.9 (SD 24.3) kg, and had a mean BMI of 35.3 kg/m^2 (SD 7.9). Approximately 69.8% (169/242) of these participants were female and 37.1% (90/242) were black.

Figure 2 shows the overall pattern of use of the app components by 3 engagement measures: percentage of days apps used including weighing, number of times apps used including weighing, and percentage of days self-weighed in the 2 intervention arms over time because weighing was used the most among all app components. Use was highest during month 1 for both CP and PC arms for all 3 engagement measures. Use dropped substantially during the subsequent 2 to 3 months for the percentage of days used app component and the number of times used app component, and the decrease in use continued until the end of the study. The percentage of days participants

self-weighed also decreased steadily after month 1 but not as dramatically as for use of the other components.

Table 2 reports the engagement pattern in the 2 intervention arms during the first 6 months using the 5 engagement measures. The mean percentage of days any app was used (including self-weighing) during the first 6 months was higher (mean 74.2%, SD 20.1) for the CP arm than for the PC arm (mean 48.9%, SD 22.4). The CP arm used any app component (including self-weighing) an average of 5.3 times per day (SD 3.1) during the first 6 months, whereas the PC arm used any app component an average of 1.7 times per day (SD 1.2).

Similarly, during the first 6 months, the CP arm had a higher mean percentage of days self-weighed compared with the PC arm (mean 57.1%, SD 23.7 vs mean 32.9%, SD 23.3). Within the PC arm, engagement in the face-to-face group coaching sessions was high during the first 6 months (mean 93.3%, SD 15.8), as was engagement with monthly calls and group sessions combined (mean 95.2%, SD 9.6).

The pattern of early reduction in engagement is also observed when we examined the engagement pattern for each of the app components by intervention arm and over time. Overall, not counting the use of the CITY home screen component, the CP arm used the app components about 3.24 times a day during the first 6 months, whereas the PC arm used components about 1.08 times a day during the same timeframe (data not shown). Table 3 describes the median daily mean use of the top 10 components by the intervention arm by time. Use for all components was higher in the CP arm than in the PC arm for every period (1-6 months, 7-12 months, and 13-24 months). The most used app component was the main CITY home screen (which could be clicked to launch the rest of the app), implying that the CITY app was actively installed and functioning.

Table 1. Demographics by intervention assignment.

Demographic variables	Combined (n=242)	Cell phone (n=122)	Personal coaching (n=120)
Age (years) at randomization			
Mean (SD)	29.3 (4.2)	29.2 (4.2)	29.4 (4.3)
Median (Q1[a], Q3[b])	29.7 (26.3, 32.8)	29.6 (26.6, 32.6)	29.8 (26.2, 33.3)
Range	19.2-36.0	19.2-36.0	20.0-36.0
Female, n (%)	169 (69.8)	84 (68.8)	85 (70.8)
Race category, n (%)			
White	133 (54.9)	68 (55.7)	65 (54.1)
Black	90 (37.1)	42 (34.4)	48 (40.0)
Other	19 (7.8)	12 (9.8)	7 (5.8)
Hispanic ethnicity, n (%)	16 (6.6)	9 (7.3)	7 (5.8)
Education level, n (%)			
Some college or less	90 (37.1)	39 (31.9)	51 (42.5)
College degree	152 (62.8)	83 (68.0)	69 (57.5)
Working, n (%)	212 (87.6)	107 (88.4)	105 (87.5)
Weight (kg)			
Mean (SD)	100.9 (24.3)	102.4 (25.2)	99.3 (23.4)
Median (Q1, Q3)	96.1 (83.1, 116.0)	97.8 (83.7, 120.4)	93.5 (83.0, 111.5)
Range	62.7-189.2	62.7-177.1	64.1-189.2
Body mass index[c] (kg/m^2)			
Mean (SD)	35.3 (7.9)	35.7 (8.2)	34.9 (7.5)
Median (Q1, Q3)	33.1 (29.2, 40.8)	33.3 (28.9, 41.6)	32.9 (29.8, 39.3)
Range	24.9-62.4	25.1-62.4	24.9-58.9

[a]Q1: first quartile.

[b]Q3: third quartile.

[c]Calculated as weight in kilograms divided by height in meters squared.

Figure 2. Engagement patterns by arms over time: the pattern of percentage of days any app component, including weighing, was used for each arm over the 24 months, the number of times any app, including weighing, was used, and the percentage of days self-weighing was used. CP: cell phone; PC: personal coaching.

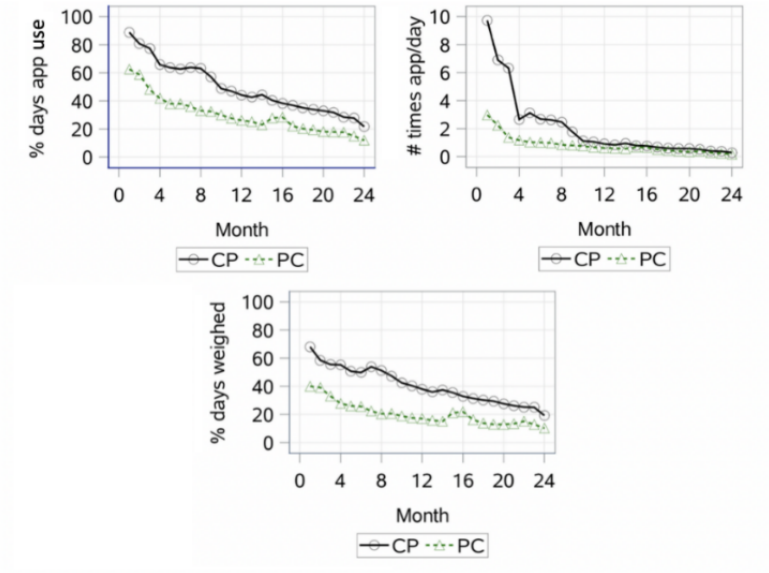


Table 2. Engagement during months 1 to 6 for cell phone and personal coaching intervention arms.

Engagement measures	Cell phone (n=122)	Personal coaching (n=120)
Percentage of days an app component (including self-weighing) was used		
Mean (SD)	74.2 (20.1)	48.9 (22.4)
Median (Q1[a], Q3[b])	78.2 (65.2, 90.1)	46.7 (29.8, 67.4)
n (range)	114[c] (16.6-100.0)	110 (7.2-96.7)
Number of times per day an app component (including self-weighing) was used		
Mean (SD)	5.3 (3.1)	1.7 (1.2)
Median (Q1, Q3)	4.8 (3.2, 6.7)	1.4 (0.9, 2.2)
n (range)	114 (0.5, 14.7)	110 (0.2, 6.6)
Percentage of days self-weighed		
Mean (SD)	57.1 (23.7)	32.9 (23.3)
Median (Q1, Q3)	55.2 (38.7, 76.2)	25.1 (13.8, 53.0)
n (range)	114 (5.0-100.0)	110 (1.7-92.6)
Percentage of group sessions[d] completed		
Mean (SD)	N/A[e]	93.3 (15.8)
Median (Q1, Q3)	N/A	100.0 (100.0, 100.0)
n (range)	N/A	110 (17.0-100.0)
Percentage of group sessions and monthly calls completed		
Mean (SD)	N/A	95.2 (9.6)
Median (Q1, Q3)	N/A	100.0 (91.5, 100.0)
n (range)	N/A	110 (46.0-100.0)

[a]Q1: first quartile.

[b]Q3: third quartile.

[c]Participants who dropped out before 6 months were not included in engagement calculations.

[d]Group sessions were only conducted during the first 2 months.

[e]N/A: not applicable. Data were not available for the arm because the component was not offered.

Table 3. Median daily mean use of top 10 app components by intervention arm by time.

App component	Example of engagement	Cell phone[a,b]			Personal coaching		
		Months 1-6	Months 7-12	Months 13-24	Months 1-6	Months 7-12	Months 13-24
CITY[c] app home screen used	Activated CITY home screen	1.06	0.41	0.16	0.76	0.27	0.13
Detailed food tracker used	Entered data in detailed food tracker	0.46	0.14	0.05	0.35	0.04	0.01
Self-weighing component used	Registered weight in app	0.55	0.43	0.22	0.25	0.12	0.08
Sugar-sweetened beverage tracker used	Entered data in SSB[d] tracker	0.4	0.09	<0.01	0.01	<0.01	<0.01
Physical activity tracker used	Entered data in the PA[e] tracker	0.31	0.03	<0.01	0.01	<0.01	<0.01
Veggie tracker used	Entered data in veggie tracker	0.22	<0.01	<0.01	0.01	<0.01	<0.01
Meat tracker used	Entered data in meat tracker	0.2	0.01	<0.01	<0.01	<0.01	<0.01
Goals checked off	Checked off a previously set goal	0.1	<0.01	<0.01	<0.01	<0.01	<0.01
Fruit tracker used	Entered data in fruit tracker	0.14	0.06	<0.01	0.01	<0.01	<0.01
“Right now in CITY” viewed	Clicked “Right now in CITY” component	0.04	0.01	<0.01	0.01	<0.01	<0.01

[a]Means were computed as the total number of times each participant used a particular app component during the respective period, divided by the number of days in that period. Then, the median of these means was computed across all participants within cell phone and personal coaching arms separately.

[b]Data were arranged in descending order of use according to the month 1-6 data of the cell phone arm.

[c]CITY: Cell Phone Intervention For You.

[d]SSB: sugar-sweetened beverage.

[e]PA: physical activity.

The second most used app component was the detailed food tracker, with a median daily mean use of 0.46 and 0.35 times per day during the first 6 months in the CP and PC arms, respectively, which is approximately every 2 to 3 days. The detailed food tracker use decreased by more than half during months 7 to 12 and further reduced to about once every 1 to 3 months during the last 12 months in both arms (months 13-24). In the CP arm, where participants were prompted daily to self-weigh, use of the self-weighing component was about every other day during months 1 to 6, which decreased slightly during months 7 to 12 and further reduced to about once every 4 to 5 days during months 13 to 24. For the PC arm participants who did not receive prompting from the smartphone but were encouraged by their coach during monthly calls, the self-weighing component was used about once every 4 days during months 1 to 6 and dropped to about once every 8 days during months 7 to 12 and once every 12 days during months 13 to 24. The CP participants used other components of the app every 2 to 20 days during months 1 to 6, and the use reduced to almost none for the rest of the study. These other components consisted of the sugar-sweetened beverage tracker, physical activity tracker, veggie tracker, meat tracker, goal setter, fruit tracker, and a screen with updates titled *Right Now in CITY*.

Other than the detailed food tracker and self-weighing, the PC participants rarely used any of the rest of the app components that were available to them during the entire study.

Figure 3 illustrates the overall pattern of prompting by selected app components and the actual median daily mean use (Table 3). During the first 6 months, prompting may have helped because all components were consistently used initially. However, use dropped dramatically for all components, possibly related to the reduction in prompting, except for weighing, which was prompted daily until the end of the study. Even though the detailed food tracker was also prompted somewhat regularly through the end of the study, it was prompted less frequently than the weight tracker and use continued to drop after the first 6 months.

Table 4 examines the association between the weight change category by intervention arm across the 3 periods (months 1-6, 7-12, and 13-24) and the 5 measures of engagement: mean percentage of days any app was used (including self-weighing), the mean number of times an app component was used per day (including self-weighing), the mean percentage of days participants self-weighed, the mean completion rate of group sessions for the PC arm, and the mean completion rate of group sessions and monthly calls combined for the PC arm. For each of the 3 periods, weight change was grouped into the same 4 categories mentioned earlier: gained (+2%), stable (±2%), mild loss (lost ≥2% to <5%), and greater loss (lost ≥5%). During the first 6 months, engagement was associated with weight change category when assessed as the mean percentage of days any app component was used, the mean number of times any app

component was used per day, or the mean percentage of days self-weighed. These associations persisted until months 7 to 12 for the PC arm. Furthermore, for this arm, the completion of group sessions and group session plus monthly calls combined were not associated with weight change categories. Similarly, when the association between the engagement measures and percentage change in weight change was examined using Pearson correlation coefficients for each period, increased engagement was associated with weight loss (last column in Table 4). The mean percentage of the days any app component was used (CP: r=−.213, PC: r=−.319), the mean number of times app was used per day (CP: r=−.264, PC: r=−.308), or the mean percentage of days participants self-weighed (CP: r=−.297, PC: r=−.354) were each correlated with weight change during the first 6 months.

We also examined selected baseline characteristics of mean number of times the app was used per day during the first 6 months in CP and PC arms separately, across the 4 quartiles. None of the characteristics examined appeared to be related to the varying engagement patterns of the participants (see Multimedia Appendices 2 and 3).

Figure 3. Overall pattern of prompting and actual use of selected app components within the cell phone arm.

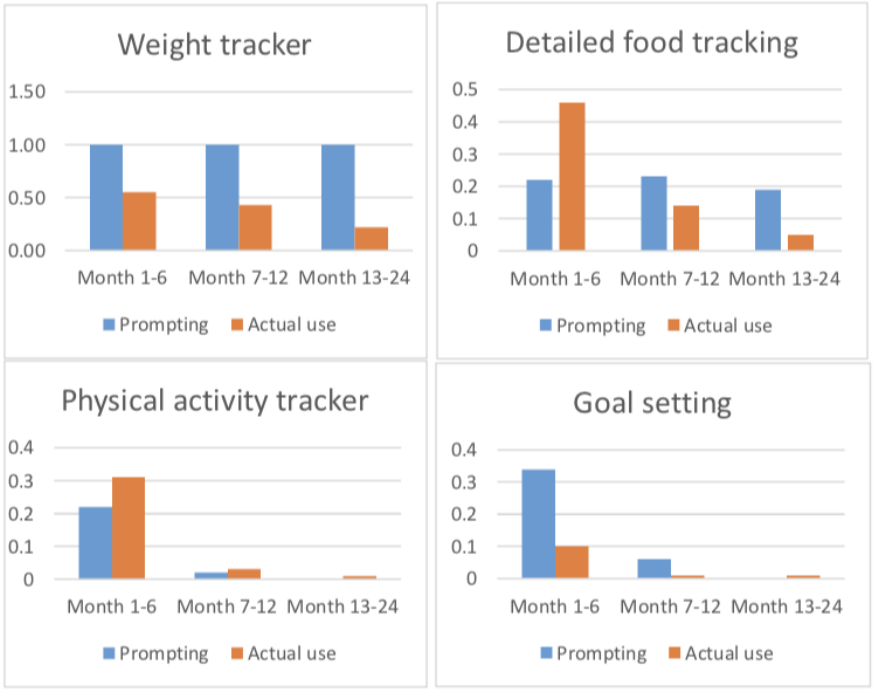


Table 4. Five measures of engagement over time (months 1-6, 7-12, and 13-24) by weight change category for cell phone and personal coaching intervention arms.

Engagement measures and time	Weight change categories								*P* value[a]	*r* [b]
	Gained >2%		Gained ≤2% or lost <2%		Lost ≥2% to <5%		Lost ≥5%			
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)		
Percentage of days apps used[c]										
1-6 months										
CP[d]	31	74.4 (17.0)	41	68.5 (21.3)	20	75.4 (23.6)	22	83.4 (15.5)	.04	−.213
PC[e]	16	40.2 (23.0)	39	42.4 (22.5)	29	52.5 (19.6)	26	59.9 (20.4)	.004	−.319
7-12 months										
CP	24	52.2 (23.6)	46	59.2 (24.3)	24	56.0 (24.9)	11	60.6 (31.5)	.68	.004
PC	27	24.3 (19.9)	44	31.8 (23.8)	21	44.2 (26.4)	13	27.7 (13.1)	.02	−.124
13-24 months										
CP	30	28.7 (24.7)	43	40.9 (25.4)	13	34.2 (21.4)	10	43.3 (20.5)	.15	−.127
PC	43	22.0 (21.2)	32	19.0 (18.8)	15	19.7 (20.7)	8	24.8 (19.6)	.86	.058
Number of app uses per day[c]										
1-6 months										
CP	31	5.0 (2.5)	41	4.3 (2.5)	20	6.4 (3.8)	22	6.8 (3.5)	.006	−.264
PC	16	1.2 (1.0)	39	1.3 (0.9)	29	1.9 (1.4)	26	2.3 (1.3)	.001	−.308
7-12 months										
CP	24	1.7 (1.5)	46	1.8 (1.1)	24	1.7 (1.3)	11	2.2 (1.8)	.70	−.035
PC	27	0.5 (0.5)	44	0.8 (0.9)	21	1.3 (1.2)	13	0.6 (0.3)	.02	−.109
13-24 months										
CP	30	0.6 (0.6)	43	0.7 (0.6)	13	0.6 (0.4)	10	0.8 (0.4)	.56	−.053
PC	43	0.5 (0.6)	32	0.4 (0.5)	15	0.5 (0.5)	8	0.5 (0.4)	.96	.042
Percentage of days weighed self										
1-6 months										
CP	31	52.1 (22.4)	41	51.9 (23.9)	20	60.8 (25.6)	22	70.2 (18.8)	.01	−.297
PC	16	24.2 (19.2)	39	26.3 (22.6)	29	35.4 (21.3)	26	45.4 (24.0)	.003	−.354
7-12 months										
CP	24	40.8 (25.6)	46	50.6 (24.1)	24	48.8 (27.0)	11	52.5 (34.0)	.46	−.031
PC	27	14.2 (18.6)	44	20.3 (20.2)	21	30.7 (26.1)	13	17.6 (12.5)	.05	−.139
13-24 months										
CP	30	24.4 (25.2)	43	36.3 (25.8)	13	28.3 (21.8)	10	36.5 (20.6)	.20	−.109
PC	43	16.4 (19.8)	32	13.0 (16.2)	15	14.3 (17.8)	8	20.3 (15.9)	.73	.066
Percentage of group sessions[f] attended										
1-6 months										
PC	16	87.5 (22.3)	39	92.3 (17.8)	29	96.5 (8.2)	26	94.8 (14.1)	.29	−.194
Percentage of group sessions[f] and monthly calls attended										
1-6 months										
PC	16	90.6 (14.0)	39	94.2 (10.2)	29	97.4 (5.6)	26	96.9 (7.8)	.09	−.246
7-12 months										
PC	27	98.7 (4.5)	44	90.9 (21.7)	21	95.2 (16.0)	13	100.0 (0.0)	.13	−.066

Engagement measures and time	Weight change categories								*P* value[a]	*r* [b]
	Gained >2%		Gained ≤2% or lost <2%		Lost ≥2% to <5%		Lost ≥5%			
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)		
13-24 months										
PC	43	89.6 (18.8)	32	89.8 (18.5)	15	92.9 (15.2)	8	88.6 (18.2)	.92	.019

[a]*P* value for the one-way analysis of variance (ANOVA) test comparing mean engagement measures across weight change categories.

[b]Pearson correlation coefficient for measuring linear association between engagement and percentage change in weight over time (where weight loss is indicated by a percentage change less than zero; a negative correlation indicates a positive association between increased engagement and weight loss).

[c]Includes self-weighing.

[d]CP: cell phone.

[e]PC: personal coaching.

[f]Group sessions only occur in the first 2 months.

Discussion

Principal Findings

Our results demonstrate that engagement in mHealth delivery of a behavioral weight loss intervention was associated with weight loss. Our findings suggest that the more the participants used the smartphone app or self-weighed, the more weight loss was observed during the first 6 months of the study for both intervention arms. This association continued to be true for the PC arm into months 7 to 12, but not for the CP arm. Despite the fundamental differences in the time and effort needed in using various components of the smartphone app or in completing personal contacts (ie, group sessions and monthly calls), the finding is consistent—engagement with the intervention is associated with weight loss. It is unclear, however, what level of engagement is required for effective weight loss, and if a different level of engagement is effective for weight loss maintenance.

Comparisons With Prior Studies

Our findings are consistent with previous research showing that greater engagement with an intervention was associated with greater weight loss, even with different types of engagement measures [17-19]. For example, in a weight loss clinical trial testing the use of interactive voice response (IVR) technology for self-monitoring, 91 participants were randomized to either control or IVR for 12 months [18]. Completion of the IVR calls was significantly correlated with weight loss. Two other studies also found that more daily weighing was associated with greater weight loss during a 6-month intervention [20] or during the first 6 months of an 18-month intervention [21]. In the CITY study, among all components of the smartphone app, a greater percentage of the days participants weighed themselves was independently correlated with greater weight loss in both arms. Other research has also shown that weight loss was associated with greater engagement with participant self-weighing [17,20,22,23]. A 6-month intervention showed that participants in the intervention arm self-weighed more days per week (mean 6.1, SD 1.1) than controls (mean 1.1, SD 1.5), and these participants lost significantly more weight than controls (−6.55% vs −0.35%) [21]. Another 6-month randomized study of 101 participants also showed that weekly self-weighing significantly impacted weight change [24]. These findings demonstrate that mHealth can use behavior change techniques such as self-monitoring effectively for weight loss intervention, with sufficient engagement.

Unlike self-weighing, other components of self-monitoring components such as dietary tracking were only used during the first month and almost never used beyond the first month. This low engagement in dietary tracking may result from low motivation [25,26] or dissatisfaction with the study app; however, we are not able to distinguish the causes. In a study examining differences in dietary intake between participants randomly assigned to monitor their diet via a handheld electronic device or paper journal, no differences were seen between the arms in weight loss, energy intake, or percentage of energy (kcal) from fat [27]. The study showed that adherence to self-monitoring of dietary intake is important for weight loss across several methods of self-monitoring. However, participants using a mobile device recorded twice as many days per week of the self-monitoring diet as those using a paper method [27], and providing feedback was associated with a greater use of self-monitoring. Even though the CITY app included limited feedback within the diet-tracking component, it is unclear how this aspect of the design affected the engagement. Nevertheless, in the aforementioned study, self-monitoring in all 3 groups declined over time, so that by 6 months, only 7 participants (16% of the group) in the smartphone device group continued to record their dietary intake every day (no participants in the diary and Web group had done this) [27]. Thus, long-term adherence is challenging even with early engagement. Tailoring self-monitoring methods that meet users' needs and circumstances and provide individualized feedback may be helpful in increasing engagement. In addition, future research is needed to develop effective diet tracking strategies that require minimal effort and time, similar to the ease of self-weighing via the Bluetooth scale. Although still in its infancy, technologies including object recognition and voice activation are being actively researched for diet tracking purposes and have the potential to become effective and streamlined strategies.

Indeed, ours and other studies have shown that the engagement dropped drastically, even after the first month, and declined continuously over time [19,28-30]. In a study testing self-monitoring strategies delivered via either IVR or the Web

among 180 participants, self-monitoring declined in both modalities over the 24 months of intervention [19]. The decline in long-term engagement may explain, at least partially, why self-weighing was significantly associated with weight change during the first 6 months for both CP and PC arms, and during months 7 to 12 for PC arm only. In an 18-month weight loss study [21], participants were advised to weigh every other day or at least 3 days a week. Adherence to self-weighing only affected weight change during the first 6 months, but not during the remaining 12 months. It is possible that the lack of continued impact of self-weighing on weight change may be due to the decline in self-weighing and/or due to the fact that some participants entered into maintenance mode and, thus, used self-monitoring for a different purpose than during active weight loss phase. As the CITY intervention protocol did not distinguish between initiation and maintenance of weight loss, some participants may weigh less after the first 6 months because they were not actively trying to lose weight but primarily desired maintenance. The switch from an active weight loss mode to a maintenance mode may also explain the substantial drop in percentage of days the app was used in the PC arm from months 0 to 6 to months 7 to 12 among those who lost the most weight (≥5%). This observation was also similar for the self-weighing pattern. This drop in engagement may have contributed to the relapse in weight loss, but this needs to be verified in future studies.

In a 12-month behavioral weight loss study, the self-monitoring pattern of 148 participants also varied and declined over time [30]. Indeed, it may be unrealistic to expect that engagement with any intervention will persist long term. Similar to the 3-stage model used in the medical adherence research (initiation, implementation, and persistence) [31], different strategies may be needed to address engagement needs during different periods of an intervention. Future research should design and test specific strategies to promote and maintain engagement for different stages of intervention, because different types of intervention may require different types of engagement and prompting. Future research should also investigate the effective dose of engagement because there may be a threshold effect. Effective engagement during each app use may be more important than simply more app use [32]. Identifying other factors that contribute to behavior change is important because engagement itself may not be sufficient.

Although traditional personal contact has been perceived as the ideal mode of intervention delivery, in this study, completion of the group sessions alone or combined with monthly calls in the PC arm was not significantly associated with weight change. However, engagement as assessed by overall app use or self-weighing was significantly associated with weight loss, even for the PC arm that received regular and sustained personal support. This finding suggests that mHealth for behavioral interventions could supplement and even enhance interventions based on personal contact, even in the setting of a reduced engagement pattern. Combining mHealth intervention with human support may be more efficient than using either of them alone. This is consistent with a recent study that randomized 102 participants into 3 weight loss intervention arms versus control for 12 weeks: a personal contact arm, an mHealth app-only arm, and a combined arm with personal contact and an mHealth app. The authors reported that the combined personal contact and mHealth app arm was as effective as the personal contact arm and tended to be more effective than the mHealth app arm [33]. Thus, future research should explore novel combination of effective components of conventional and mHealth strategies.

Our data suggest that prompting may be helpful to generate engagement to some degree because the CP arm that received prompting regularly used the smartphone app components more than the PC arm did across all measures of engagement. A meta-analysis of 14 studies with varying designs showed that technology-based prompting had a small to moderate effect on engagement as compared with no-strategy [34]. Participants who received the promptings were significantly more likely to engage with the intervention (relative risk 1.27, 95% CI 1.01-1.60). However, our results suggest that prompting may be helpful only initially, losing impact over time. We speculate that excessive prompting may promote habituation, resulting in reduced use and decreased compliance. The tradeoff is that increased audio, vibration, and visual prompting that interrupts and distracts the user from the current task almost certainly leads to increased user burden and resistance, which would likely reduce acceptability and use of the app and, subsequently, long-term engagement. Habituation may also play a role in interpreting why participants may ignore prompting over time, thus reducing its impact. Future studies are needed to understand how to design smartphone interventions that balance intensity and timing of prompting with stimulation of engagement to maximize utility and minimize burden. Unfortunately, our study was not able to distinguish the difference between the true impact of individual motivation and that of prompting on engagement. Future studies should also examine the impact of different types of prompting on responses and engagement. In this study, we only emphasized regular prompting for weighing; it is possible that consistent prompting of other behavioral change strategies such as physical activity tracking may also yield encouraging engagement patterns that can potentially contribute to effective weight management.

Strengths and Limitations

This study has several strengths. The engagement data reported here were collected objectively with a smartphone app, and the main outcome of weight was reliably measured at each of the study visits in the clinic and does not rely on self-reporting. Furthermore, this study generated a relatively large amount of engagement data of young adults (n=242) for an extended period (24 months). Another strength of this study is the ability to collect engagement data with each of the cell phone app's components and with the personal interactions, where the design of the intervention components was based on behavioral theories and prior research evidence.

The study has several limitations that must be considered when interpreting data. Regardless of the reason for joining the CITY study, the varying motivation for weight loss among the participants may have contributed to the varying level of engagement in the intervention arms. Increasing motivation may increase engagement and subsequent weight loss; however,

identifying effective level of engagement may also be important for all weight loss studies and programs. Another weakness of the study is that limited study resources prevented development of an intervention app as attractive, polished, and robust as some commercial apps, which could have an impact on engagement. Unfortunately, it was beyond the scope of this study to tease apart whether the reduction in engagement over time may have been due to lack of motivation or challenges with the app design and other technical reasons. Our study compensation for smartphone data coverage, which was offered to both the PC and CP arms, may have incentivized participants to stay in the study but would not contribute to the differences in engagement between the 2 arms. This compensation would not be available to app users if the app were widely deployed. Our compensation, however, did not require any substantial level of engagement or use of app components, and so, participants with low motivation who may have otherwise dropped out of the study may have continued until the end. The overall engagement was lower than expected and desired, but the pattern was consistent with other studies. Messages and tips to encourage healthy lifestyle and weight loss management were delivered through the app home screen, but the smartphone's operating system prevented the measurement of whether participants covered them up with other app icons or even turned off the messages altogether; this behavior would affect engagement. The fact that engagement dropped substantially early suggests that a more effective intervention that automatically adapts to behavior and self-measured engagement, such as using just-in-time adaptive design, may be needed [35,36]. Another limitation of the study is that participants' perception of the intervention, which may affect the effectiveness of the intervention, was not included in this assessment. It should also be noted that there is room for optimizing the intervention content that may contribute to a more effective intervention, which may or may not be associated with engagement. For example, optimizing the intervention content may include using a lower carb diet approach instead of a lower fat approach or incorporating a time-restricted eating approach. Future studies should consider not only effective behavioral strategies but also combining those with additional evidence-based dietary and lifestyle approaches for weight loss.

Conclusions

In this study, engagement assessed using different measures was associated with weight loss. Nevertheless, engagement declined over time at varying rates for different intervention engagement components. This study suggests that a variety of strategies may be needed during different stages of an intervention to increase and sustain engagement required for intervention effectiveness. Self-weighing was associated with weight loss regardless of the baseline characteristics of the participants, suggesting that an effective weight loss program may not need to include multiple behavioral strategies. Focusing on a single effective strategy in conjunction with prompting may be better than offering more components that most participants may not use. Future studies should clarify the definition of effective engagement. In addition, future studies should explore the motivations for participant engagement and nonengagement to design effective strategies for addressing those specific challenges.

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Authors' Contributions

All authors contributed to the design, conduct, and analysis of the CITY study results. All authors also contributed to the preparation of the manuscript, and they reviewed and approved the manuscript.

Conflicts of Interest

SG currently receives consulting fees from Gilead Sciences for serving on multiple Data Monitoring Committees. Although the relationship is not perceived to represent a conflict with this work, it has been included in the spirit of full disclosure. GGB holds equity in Coeus Health and serves on the scientific advisory board of Nutrisystem. These organizations had no role in study design, data collection, data analysis and interpretation of data, in the writing of the report, or in the decision to submit the article for publication.

Multimedia Appendix 1

Description of the major components of the Cell Phone Intervention For You app, the user actions within each component that count toward engagement, and the prompting frequency for selected components.

[PDF File (Adobe PDF File), 44KB - mhealth_v6i10e10471_app1.pdf]

Multimedia Appendix 2

Baseline characteristics of cell phone participants by quartile of mean number of apps used per day (including self-weighing) in the first 6 months.

[PDF File (Adobe PDF File), 23KB - mhealth_v6i10e10471_app2.pdf]

Multimedia Appendix 3

Baseline characteristics of personal coaching participants by quartile of mean number of app uses per day (including self-weighing) in the first 6 months.

[PDF File (Adobe PDF File), 23KB - mhealth_v6i10e10471_app3.pdf]

Multimedia Appendix 4

CONSORT‐EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 752KB - mhealth_v6i10e10471_app4.pdf]

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
CITY: Cell Phone Intervention For You
CP: cell phone
IVR: interactive voice response
mHealth: mobile health
NHLBI: National Heart Lung and Blood Institute
PC: personal coaching

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Original Paper

Effect of a Mobile Phone Intervention on Quitting Smoking in a Young Adult Population of Smokers: Randomized Controlled Trial

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Abstract

Background: Digital mobile technology presents a promising medium for reaching young adults with smoking cessation interventions because they are the heaviest users of this technology.

Objective: The aim of this study was to determine the efficacy of an evidence-informed smartphone app for smoking cessation, Crush the Crave (CTC), on reducing smoking prevalence among young adult smokers in comparison with an evidence-informed self-help guide, On the Road to Quitting (OnRQ).

Methods: A parallel, double-blind, randomized controlled trial with 2 arms was conducted in Canada to evaluate CTC. In total, 1599 young adult smokers (aged 19 to 29 years) intending to quit smoking in the next 30 days were recruited online and randomized to receive CTC or the control condition OnRQ for a period of 6 months. The primary outcome measure was self-reported continuous abstinence at the 6-month follow-up.

Results: Overall follow-up rates were 57.41% (918/1599) and 60.48% (967/1599) at 3 and 6 months, respectively. Moreover, 45.34% (725/1599) of participants completed baseline, 3-, and 6-month follow-up. Intention-to-treat analysis (last observation carried forward) showed that continuous abstinence (N=1599) at 6 months was not significantly different at 7.8% (64/820) for CTC versus 9.2% (72/779) for OnRQ (odds ratio; OR 0.83, 95% CI 0.59-1.18). Similarly, 30-day point prevalence abstinence at 6 months was not significantly different at 14.4% (118/820) and 16.9% (132/779) for CTC and OnRQ, respectively (OR 0.82, 95% CI 0.63-1.08). However, these rates of abstinence were favorable compared with unassisted 30-day quit rates of 11.5% among young adults. Secondary measures of quit attempts and the number of cigarettes smoked per day at 6-month follow-up did not reveal any significant differences between groups. For those who completed the 6-month follow-up, 85.1% (359/422) of young adult smokers downloaded CTC as compared with 81.8% (346/423) of OnRQ, $\chi^2_{1(N=845)}=1.6$, $P=.23$. Furthermore, OnRQ

participants reported significantly higher levels of overall satisfaction (mean 3.3 [SD 1.1] vs mean 2.6 [SD 1.3]; t_{644}=6.87, P<.001), perceived helpfulness (mean 5.8 [SD 2.4] vs mean 4.3 [SD 2.6], t_{657}=8.0, P<.001), and frequency of use (mean 3.6 [SD 1.2] vs mean 3.2 [SD 1.1], t_{683}=5.7, P<.001) compared with CTC participants.

Conclusions: CTC was feasible for delivering cessation support but was not superior to a self-help guide in helping motivated young adults to quit smoking. CTC will benefit from further formative research to address satisfaction and usage. As smartphone apps may not serve as useful alternatives to printed self-help guides, there is a need to conduct further research to understand how digital mobile technology smoking cessation interventions for smoking cessation can be improved.

Trial Registration: ClinicalTrials.gov NCT01983150; http://clinicaltrials.gov/ct2/show/NCT01983150 (Archived by WebCite at http://www.webcitation.org/6VGyc0W0i)

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KEYWORDS

health behavior; smoking cessation; young adult; mobile phone; mHealth; randomized controlled trial

Introduction

Tobacco use among young adults remains a global public health issue as young adults continue to maintain high prevalence rates [1]. For example, compared with the national average of 13%, the prevalence of smoking among young adults in Canada was 18.5% among those aged 20 to 24 years in 2015 [2]. Globally, smoking is responsible for taking approximately 6 million lives and costing about US $500 billion per year [3]. However, quitting before the age of 40 years significantly reduces the morbidity and mortality rates related to smoking [4], making young adults a priority for smoking cessation efforts.

Younger age groups have the highest quit attempt rates, which decline with age [2], indicating that young adults are a ripe audience for assisting in smoking cessation. However, young adults are reported to not use cessation interventions, including pharmacological or psychological treatments [5-7], compared with their older counterparts. The lack of tailored cessation interventions for this age demographic has been cited as a major reason for this underutilization [7]. In addition, the personal and societal values of independence and autonomy may influence the general trend of unassisted smoking cessation among young adults [2,8,9].

A promising new direction for reaching and engaging young adults in smoking cessation interventions is the use of mobile phones, particularly smartphone apps. Smartphone ownership among young adults aged 18 to 34 years in both the United States and Canada is almost ubiquitous at 92% and 94%, respectively [10]. It is not surprising then that young adults lead the way in downloading and using health apps [11] and are the most frequent users of health-related apps [12].

The advanced processing capabilities, global reach, and unmatched accessibility of smartphones render them ideal channels for delivering health-related interventions [13]. In addition, the complex functionalities enabled in smartphone apps facilitate high user engagement, which is a strong predictor of smoking cessation [14]. Encouragingly, smartphone apps have shown to be particularly appealing to young adults for receiving cessation support [15]. In light of their growing popularity, many cessation apps are now available [14,16,17]. However, very few are based on evidence or theory or have been rigorously evaluated [18,19].

Although there is a growing body of evaluative evidence on the efficacy and effectiveness of smartphone-based technologies for smoking cessation, this has largely been through small pilot studies. Although most evaluative evidence consists of studies of short message service (SMS) text-messaging-based interventions for smoking cessation [20,21], the body of evidence in relation to apps specifically is nascent. Two recent systematic reviews focused on smartphone apps for smoking cessation. Haskins et al identified 7 studies of smoking cessation apps and searched 177 unique smoking cessation apps on the iTunes app store and 139 unique smoking cessation apps on Google Play. They concluded that of the top 50 apps from these leading app stores, only 2 had any published scientific support [22].

A systematic review of 8 studies found mixed evidence regarding the effectiveness of smoking cessation apps and observed that user engagement and adherence to app features influenced quit rates and that larger sample size studies are needed [23]. Two of the apps examined were supported by small randomized controlled trials (RCTs) [14,24], and 1 was an observational study [25]. Only 1 small study specifically targeted young adults aged 18 to 30 years, and the authors found that the smartphone app did not move smokers to quit as quickly as SMS text messaging [24]. Another pilot study with older adults tested the efficacy of a smoking cessation app based on acceptance and commitment therapy and found that it was feasible to deliver a theory-based smartphone app; however, the quit rates were not significantly different between conditions [14]. The third small observational study tested a smoking cessation app based on behavior change theory and found that participants were more likely to be abstinent from smoking for 28 days or longer as compared with the general smoking population [25].

One recent RCT examined the effect of an evidence-informed decision-aid app on continuous abstinence at 1, 3, and 6 months among adults aged 18 years and older who were motivated to quit [26]. The authors found that the decision-aid app, based on the Ottawa Decision Support Framework, significantly predicted abstinence at all 3 time points compared with the control app, which did not provide any structured process for considering

options, benefits and harms of quitting methods, and ongoing support of a decision [26].

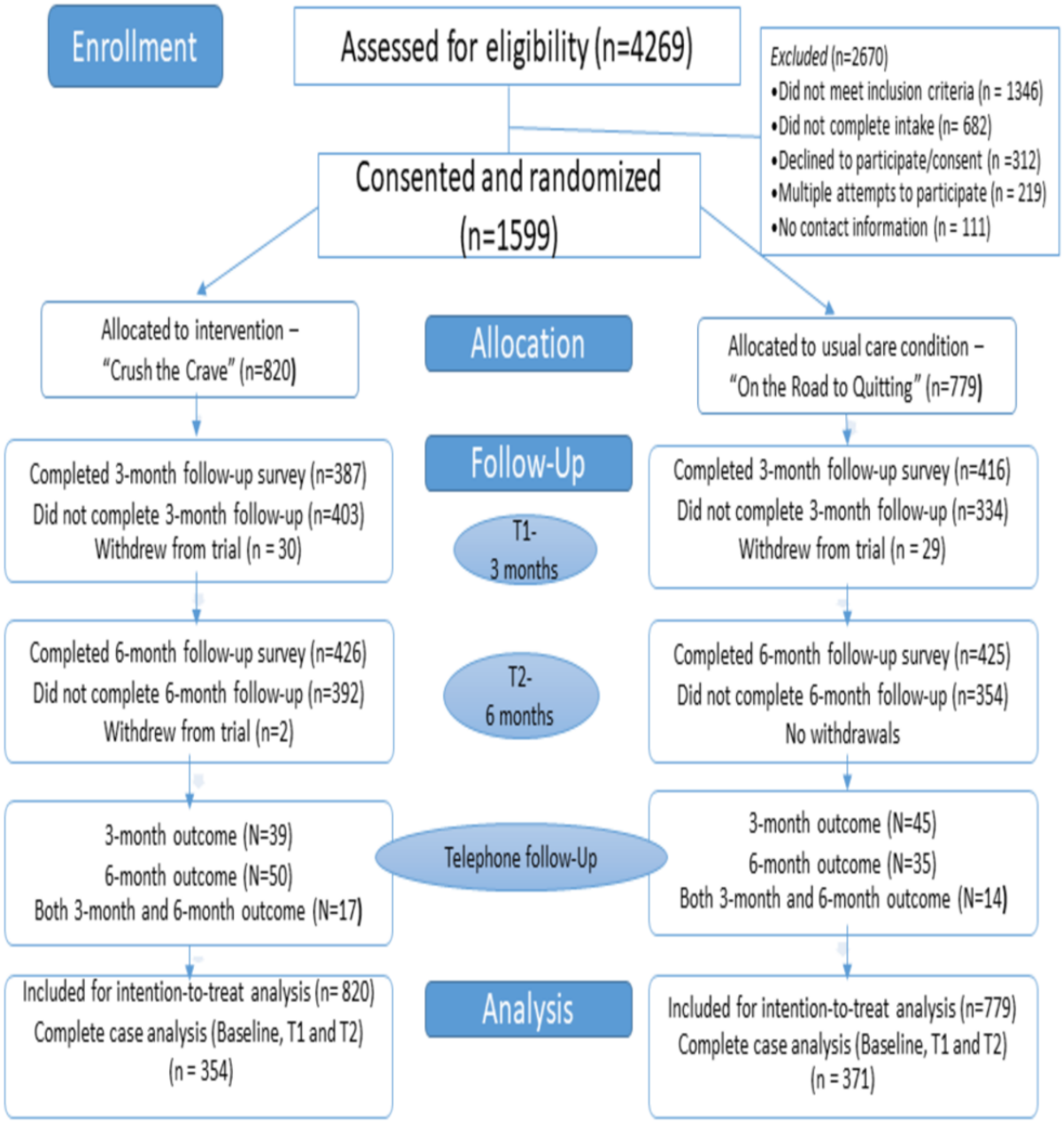
Our aim was to conduct a large and methodologically rigorous evaluation of smartphone cessation technology to address the identified gap in the published literature. We compared the effects of an evidence-informed smoking cessation mobile phone app known as Crush the Crave (CTC) with a self-help booklet on reducing smoking prevalence among young adult smokers after 6 months. The mobile phone app was hypothesized to yield higher rates of continuous abstinence, 30-day point prevalence abstinence (PPA), 7-day PPA, quit attempts, and reduction in consumption of cigarettes. This is the first full-scale and long-term study that we are aware of to assess the efficacy of a quit smoking app that specifically targets young adults.

Methods

Study Design

The study was a 6-month, 2-arm, parallel RCT conducted in Canada with participants assigned with an equal probability to the mHealth intervention, CTC, or to the self-help booklet. Investigators, data collectors, and participants were blinded to the group assignments. Follow-up was conducted at 3- and 6-months post randomization. A superiority trial design was used [27] and the protocol was in accordance with the Consolidated Standards of Reporting Trials (CONSORT)-EHEALTH checklist [28]. See Figure 1 for a CONSORT diagram of the proposed study design. A complete description of the study protocol has been published elsewhere [29].

Figure 1. Consolidated Standards of Reporting Trials (CONSORT)-EHEALTH diagram.



Participants and Recruitment

Participants were eligible if they were between the ages of 19 and 29 years, smoked cigarettes daily, resided in Canada, were considering quitting smoking in the next 30 days, had an Android (Version 2.0 to 5.0) or iPhone (Version 4.0 to 7.0) smartphone, were able to provide informed consent, were able to comprehend English, and were not referred to the study by an existing study participant—a friend or family member already participating in the study—to avoid possible contamination bias.

Recruitment sources were primarily Web-based media and included 72% from Facebook advertisements, 24% Google advertisements, and 4% from other sources (a Web-based classified message board and offline recruitment through a commercial survey panel). Interested young adults were referred to a website describing the study. Potential participants were screened at the entry webpage where their eligibility was determined, informed consent was sought, and registration for the study conducted. Participants who met the inclusion criteria and consented to participate completed the Web-based baseline questionnaire and were then randomly allocated to either the control or intervention arm and were sent a computer-generated email confirming registration and containing instructions for downloading their randomly assigned quit smoking program (see Multimedia Appendix 1). Participants were sent a reminder email at 1 month after completing the baseline questionnaire to download the assigned program if they had not already done so. Participants were provided a Can $35 incentive for registering to the study, and a raffle of an iPad Air tablet was used as an incentive to complete 6-month follow-up.

Interventions

Crush the Crave

The intervention group received a comprehensive and evidence-informed smoking cessation smartphone app, CTC version 2.1. CTC was developed in early 2012 by a team of population health researchers, social media experts, and computer programmers as an evidence-informed quit smoking smartphone and social media app for young adults aged 19 to 29 years [29]. CTC enabled users to customize a quit plan by choosing a quit date and then deciding whether to quit immediately or reduce the number of cigarettes they smoke every week up to their quit date. CTC then assisted smokers in staying on track by reminding them of how much money they had saved and how much their health had improved over time after quitting. On the basis of contingency reinforcement, milestones were tracked as rewards, which smokers could choose to share with their social network via Facebook and Twitter, and rally support from friends and family. Participants could also link to the CTC Facebook community for additional support for quitting. Users of the app received supportive messages and inspirational photos via the app tailored to their specific quit plan and where they were in the quitting experience. Participants could also record when, where, and why they were smoking to understand the triggers and psychosocial factors related to smoking. The app provided both graphic and tabular performance feedback; Web-based distractions to help deal with cravings; evidence-informed information for assisting smokers on topics such as relapse and dealing with cravings, push notifications on rewards received, and helpful reminders to continue to use the app; and access to evidence-based cessation services such as smoking cessation quitlines and information on the use of nicotine replacement therapy (NRT).

Recently, Ubhi et al conducted a review of 137 smoking cessation apps for the presence or absence of evidence-based behavior change techniques and CTC addressed 4 out of 5 behavior change strategies as compared with an average of only 1 across the 137 apps reviewed. They also assessed CTC as having an ease-of-use score of 95%, which was similar to the average of all apps reviewed and 82% for engagement compared with only 45% overall [30]. A more fulsome description of the evidence for and development of the CTC app is available elsewhere [31]. The development of CTC was frozen during the study.

Self-Help Booklet

The control group received a standard print-based self-help guide known as On the Road to Quitting (OnRQ) [32] that was developed by Health Canada for young adult smokers. Participants were able to both view and download the self-help guide via the internet and request a printed version of the guide. Moreover, 47.0% (366/779) of participants allocated to the control group requested a printed version of the guide. The guide contained similar content to the CTC app. It contained information on the health benefits of quitting, the monetary rewards of quitting, smoking triggers, suggestions on how to deal with withdrawal and cravings, setting a quit date or quitting *cold turkey*, seeking counseling or NRT, linking to a social support network of family or friends, telephone quitline support, preventing weight gain, and dealing with slip-ups or relapse.

Study Procedures

All study procedures were reviewed and approved by the clinical research ethics review committee of the University of Waterloo (Full ethics clearance October 29, 2013, 19275).

Randomization and Blinding

Participants had an equal probability of being allocated to the intervention or control group using a computer-generated simple randomization procedure. Participants were blinded to group allocation and were not aware of which was the control and intervention condition. Investigators were blinded to group allocation until completion of the trial after initial analysis of the primary and secondary outcomes.

Data Collection

Baseline data were collected via a self-administered and Web-based questionnaire completed by all participants who provided Web-based consent to participate in the study for both intervention and control groups from July 2014 to March 2015. The baseline questionnaire included the following demographic items: age, gender, ethnicity, marital status, education, income, and employment status. Variables related to tobacco consumption included current smoking status, amount smoked, number and duration of past quit attempts, and the degree of nicotine dependence. Participants were also asked a series of psychosocial questions, including beliefs and attitudes about quitting, self-efficacy or confidence in quitting, perceived stress

and social support, and social norms related to smoking. Furthermore, participants were asked about the experience with smartphone apps and self-help, use of NRT, e-cigarette use, and other cessation aid or supports, such as quitlines.

Follow-up data were collected from the same participants at 3- and 6-months postrandomization in the same manner as the baseline. In addition to the questions asked at baseline, participants were asked core smoking status questions. Participants were also asked questions on nicotine withdrawal, level of support received from friends and family for quitting smoking, use of e-cigarettes, additional cessation services that they sought for help to quit, overall satisfaction with the app or self-help guide, use of and opinions and beliefs about the app and the guide, and challenges they experienced in quitting smoking. All instruments were piloted with a convenience sample (n=10) that comprised an equal number of male and female young adult smokers. A modified Dillman method [33] was used for the follow-up of participants completing the Web-based survey questionnaires. Participants who did not complete 3- or 6-month follow-up questionnaires within 2 weeks were contacted by telephone and up to 10 attempts (email or phone) were made to collect smoking status at 3-month and 6-month follow-up or both. Following the intention-to-treat principle, participants were analyzed in the groups to which they were allocated, regardless of whether they received or adhered to the allocated intervention [34].

Measures

The primary outcome measure was continuous self-reported abstinence defined as having been abstinent for 3-months post baseline [35]. Secondary outcome measures were self-reported 30-day PPA from smoking at 3 and 6 months, operationalized as not having smoked any cigarettes, even a puff, or used other tobacco in the last 30-days [36]; 7-day PPA at 3 and 6 months [36]; the number of quit attempts—"How many times did you stop using tobacco for 24 hours or longer?"—over the past 3 and 6 months [37]; and the reduction in consumption of cigarettes at 3 and 6 months ("On average, how many cigarettes do you smoke per day on the days that you smoke") [36]. Biochemical validation of smoking status was not performed.

Secondary measures included nicotine dependence using the 2-item Heaviness of Smoking Index (HSI) from the Fagerstrom Test for Nicotine Dependence that combines the number of cigarettes smoked per day and the time to the first cigarette in the morning [38]. High scores on the HSI indicate higher levels of addiction and greater difficulty in quitting. HSI was categorized as low (scores of 0-2), medium (scores of 3 and 4), and high (scores of 5 and 6). Self-confidence in quitting was measured using a 5-item Likert scale from 1 (*not at all*) to 5 (*extremely*) and the question, "How confident were you in your ability to quit smoking?" [39]. Perceived stress was measured with 4 question items on feelings of control and the ability to handle personal problems using 5-item Likert scales of 0 (*never*) to 4 (*very often*) and totaled to create a score [40]. Stress was categorized as low (scores of 0-6), medium (scores of 7 to 9), and high (scores 10 to 16). Current and past use of NRT and e-cigarettes were measured with the question, "Did you use or are you currently using NRT/e-cigarettes to help you quit smoking?" with a yes or no response option to current use and past use. A partner who smokes was measured by asking the question, "Does your partner, spouse, or significant other currently smoke?" and the number of friends smoking was measured by asking, "Of the five closest friends or acquaintances that you spend time with on a regular basis, how many of them are smokers?" Social support was measured with 3 question items on feelings of support from family and friends using 5-item Likert scales of 1 (*not at all*) to 5 (*extremely*) and totaled to create a score [39]. Support was categorized as low (scores of 3-8), medium (scores of 9-11), and high (scores 12-15).

Process measures included having downloaded the intervention and measures of use, satisfaction, and helpfulness at 3 and 6 months. Participants completed a brief satisfaction instrument that included 4 5-point Likert scale items such as "I used the program frequently" and "I thought the program was easy to use," with response choices that ranged from *strongly agree* to *strongly disagree* [41]. Perceived overall satisfaction was measured on a 5-point Likert scale that ranged from *not at all satisfied* to *very satisfied* and helpfulness was measured on a 10-point scale that ranged from *not at all helpful* to *very helpful*.

Sample Size

Sample size calculations were based on the difference in the objective measure of the primary outcome event—continuous abstinence from smoking—between intervention and control groups. Assuming a ratio of 1:1 for intervention to control subjects, an alpha of .05, power of 80%, and an effect size equal to 10% in the intervention versus 6% in the control condition for self-reported continuous abstinence, the required sample size was 800 per group for a total of 1600 participants using a 2-tailed test of proportions [42].

Statistical Analysis

Demographic and smoking characteristics (eg, HSI, use of e-cigarettes, and self-confidence to quit) were compared between groups at baseline using a chi-square test of association or a Fisher exact test for binary variables. All participants were analyzed in the study arm to which they were randomized.

Logistic regression was used to test between-group comparisons on the primary outcome variable—continuous abstinence—and the secondary outcomes 7-day and 30-day PPA at 3- and 6-month follow-up. For comparisons of secondary continuous outcomes (number of quit attempts and cigarettes per day) that did not meet normal distribution assumptions, a nonparametric Mann-Whitney test was conducted. For the process measures of having downloaded the intervention, frequency of use, satisfaction and helpfulness, a chi-square test of association was applied to binary and categorical variables, and for the ordinal variables approximating a normal distribution, a *t* test for independent groups was applied.

The intention-to-treat principle was followed for the analysis of continuous abstinence and the outcomes 30-day and 7-day PPA using 3 approaches to handle missing information about smoking status: (1) imputation using the baseline observation carried forward or classifying nonresponders at 3 and 6 months as smokers in accordance with the Russel standard [35]; (2)

imputation using the last observation of smoking status carried forward for nonresponders at 6 months; and (3) multiple imputation (n=18) by chained equations which used the observed predictors of outcome and the predictors of lost to follow-up to impute missing outcome data to correct for any potential bias caused by missing data [43]. The imputation model included age, sex, education, province, marital status, ethnicity, income, heaviness of smoking, self-efficacy, perceived stress, and intervention group. In addition, a complete case analysis was performed in which any participant with missing information on any outcome was excluded. Finally, a subgroup analysis was undertaken for key demographics, smoking and cessation characteristics, social support, and use of intervention variables to assess homogeneity in treatment effects using logistic regression. Tests were 2-sided, and statistical analyses were completed using SAS software version 9.4 (SAS Institute Inc, Cary, NC, USA).

Results

Participant Characteristics

Participants were enrolled from July 4, 2014 to March 31, 2015. Follow-up was completed in October 2015. As shown in Figure 1, a total of 4269 completed the Web-based screening survey, of whom 2670 were excluded because they did not meet the inclusion criteria, did not consent to participate, did not complete the baseline intake survey, or provided no contact information. Participants with repeat log-ins from the same IP address were recorded and excluded. In total, 1599 young adult smokers were eligible and consented to participate. Participants were randomly allocated to the CTC intervention condition (n=820) or to the OnRQ self-help control condition (n=779). The survey follow-up rates were 57.41% (918/1599) and 60.48% (967/1599) at 3 and 6 months, respectively. Moreover, 45.34% (725/1599) of participants were considered complete cases having completed baseline intake, 3-, and 6-month follow-up for the primary outcome (see Figure 1), without any significant difference between the intervention and control conditions in complete case follow-up proportions (43.2% vs 47.6%, $\chi^2_{1(N=1599)}$=3.2, *P*=.08).

The intervention and control groups were balanced with regard to demographic, behavioral, and social support characteristics at baseline as well as at 6-month follow-up (see Table 1). Furthermore, there were no significant differences between conditions among participants lost to follow-up, confirming no apparent differential attrition between conditions [44]. Overall, the majority of participants were male (54.06%, 858/1587), white (75.06%, 1168/1556), had postsecondary education or higher (55.22%, 878/1590), and had incomes of less than CAD $45,000 (65.12%, 941/1445). At baseline, 26.81% (424/1581) of participants had moderate to high nicotine dependence and 25.67% (408/1589) smoked a pack of cigarettes per day or more. In addition, 52.72% (843/1599) were currently using or had used NRT in the past, and 60.79% (972/1599) were currently using or had used e-cigarettes in the past. Moreover, 32.17% (478/1486) reported a high level of social support at baseline whereas 84.68% (1321/1560) reported having 2 or more friends who smoked and 28.69% (457/1593) reported living with a partner who smokes (see Table 1).

Smoking Cessation

Table 2 shows the primary and secondary smoking cessation outcomes after 3 and 6 months for intention-to-treat (n=1599) and complete cases (n=725). Intention-to-treat (baseline observation carried forward) continuous abstinence after 6 months was not significantly different at 6.1% (50/820) for CTC versus 7.3% (60/779) for OnRQ (odds ratio; OR 0.81, 95% CI 0.54-1.20, *P*=.28). Last observation carried forward was also not statistically significant for continuous abstinence at 7.8% (64/820) for CTC versus 9.2% (72/779) for OnRQ (OR 0.83, 95% CI 0.59-1.18, *P*=.30). Similarly, 30-day PPA at 6 months was not significantly different for baseline observation carried forward at 12.9% (106/820) and 15.8% (123/779, OR 0.79, 95% CI 0.60-1.05, *P*=.10) and for last observation carried forward at 14.4% (114/820) and 16.9% (132/779, OR 0.82, 95% CI 0.63-1.08, *P*=.16) for CTC and OnRQ participants, respectively. However, 7-day PPA at 6 months using baseline observation carried forward showed a significant difference in favor of OnRQ at 22.3% (174/779) versus 18.3% (150/820) for CTC (OR 0.79, 95% CI 0.61-0.99, *P*=.05). The significant difference for 7-day PPA at 6 months was not apparent with last observation carried forward at 22% (180/820) and 24.4% (190/779) for CTC and OnRQ participants, respectively (OR 0.87, 95% CI 0.69-1.10, *P*=.25).

Intention-to-treat continuous abstinence using multiple imputation analysis [43] to impute status for lost to follow-up participants was 12.6% (103/820) for CTC and 12.1% (94/779) for OnRQ participants (OR 1.05, 95% CI 0.78-1.41, *P*=.76). Intention-to-treat analysis based on multiple imputations for 7-day and 30-day PPA at 6 months showed no significant differences between conditions (see Table 2).

Findings for complete cases (n=725) showed continuous abstinence rates of 13.8% (49/354) for CTC and 15.4% (57/371) for OnRQ (OR 0.89, 95% CI 0.59-1.34, *P*=.56). For self-reported 7-day and 30-day PPA at 6 months findings were similar to the multiple imputation intention-to-treat analysis (see Table 2). At 3 months, no statistically significant differences were observed between CTC and OnRQ for 7-day and 30-day PPA according to the complete cases and the intention-to-treat analyses (see Table 2).

Secondary measures of quit attempts and the number of cigarettes smoked per day at 6-month follow-up for those who had not quit smoking at 6 months (n=671) did not reveal any significant difference between the groups. Moreover, 94.3% (249/264) of OnRQ participants and 91.4% (265/290) of CTC participants had made at least 1 quit attempt ($\chi^2_{1(N=554)}$=1.8, *P*=.19]). Furthermore, there was no difference in the number of quit attempts between groups (Median=4, *P*=.82) and in the number cigarettes smoked per day between groups (Median=5 for OnRQ vs Median=6 for CTC, *P*=.44).

Table 1. Baseline characteristics of participants randomized to each arm, those lost to follow-up, and those remaining at 6 months.

Baseline variable	All participants			Participants lost to follow-up			Remaining participants		
	CTC[a] (n=820), n (%)	OnRQ[b] (n=779), n (%)	*P* value	CTC (n=394), n (%)	OnRQ (n=354), n (%)	*P* value	CTC (n=426), n (%)	OnRQ (n=425), n (%)	*P* value
Demographics									
Female	364 (44.9)	365 (47.0)	.39	172 (44.3)	160 (45.2)	.81	192 (45.4)	205 (48.6)	.35
Age 19 to 23 years	409 (49.9)	376 (48.3)	.52	206 (52.3)	182 (51.4)	.81	203 (47.7)	194 (45.7)	.56
Single–never legally married	508 (62.6)	486 (62.8)	.92	242 (62.2)	213 (61.0)	.74	266 (62.9)	273 (64.2)	.68
High school or less education	351 (43.0)	361 (46.6)	.15	183 (46.7)	181 (51.6)	.18	168 (39.6)	180 (42.6)	.39
White	599 (75.4)	569 (74.8)	.79	285 (74.6)	265 (76.6)	.53	314 (76.0)	304 (73.3)	.36
Paid work	539 (67.5)	527 (69.6)	.38	259 (67.5)	242 (70.4)	.50	280 (67.6)	285 (69.0)	.67
Income < CAD $45,000	484 (65.6)	457 (64.6)	.71	249 (69.4)	213 (67.0)	.51	235 (62.0)	244 (62.7)	.84
Smoking and quitting behavior									
Moderate to high nicotine dependence	219 (27.1)	205 (26.5)	.79	111 (28.7)	97 (27.6)	.73	108 (25.7)	108 (25.7)	.99
Smokes at least a pack per day or more	210 (25.7)	200 (25.7)	.99	109 (27.8)	97 (27.4)	.90	101 (23.8)	103 (24.4)	.86
Very or extremely confident to quit	330 (40.8)	302 (39.2)	.52	162 (41.7)	133 (37.9)	.30	168 (40.0)	169 (40.3)	.92
High stress level	240 (30.5)	237 (31.7)	.60	123 (32.4)	104 (30.6)	.61	117 (28.7)	133 (32.6)	.22
Used NRT[c] currently or in the past	424 (51.7)	419 (53.8)	.41	196 (49.8)	169 (47.7)	.58	228 (53.5)	250 (58.8)	.12
Used e-cigarettes currently or in the past	500 (61.0)	472 (60.6)	.87	242 (61.4)	210 (59.3)	.56	258 (60.6)	262 (61.7)	.75
Friends or partner smoking and level of support									
Two or more close friends smoke	682 (85.1)	639 (84.2)	.60	331 (86.0)	287 (83.7)	.39	351 (84.4)	352 (84.6)	.92
Living with partner who smokes	228 (28.0)	229 (29.4)	.52	106 (27.2)	107 (30.2)	.36	122 (28.7)	122 (28.8)	.98
High social support level	235 (31.1)	243 (33.2)	.38	110 (30.7)	110 (33.1)	.50	125 (31.5)	133 (33.3)	.58

[a]CTC: Crush the Crave.

[b]OnRQ: On the Road to Quitting.

[c]NRT: nicotine replacement therapy.

Table 2. Comparison of Crush the Crave and On the Road to Quitting on primary and secondary outcomes at 3 and 6 months (intention-to-treat).

Outcomes	CTC[a] (N=820)	OnRQ[b] (N=779)	Odds ratio (95% CI)	*P* value
Continuous self-reported abstinence at 6 months, n (%)				
Complete cases (n=725)	49 (13.8)[c]	5 (15.4)[d]	0.89 (0.59-1.34)	.56
ITT[e]–baseline observation carried forward	50 (6.0)	60 (7.3)	0.81 (0.54-1.20)	.28
ITT–last observation carried forward	64 (7.8)	72 (9.2)	0.83 (0.59-1.18)	.30
ITT–multiple imputation of outcomes[f]	103 (12.6)	94 (12.1)	1.05 (0.78-1.41)	.76
Secondary outcomes (3 months)				
Self-reported non-smoking in past 7 days, n (%)				
Complete cases (n=708)[g]	105 (30.4)[h]	107 (29.5)[i]	1.05 (0.76-1.44)	.78
ITT–baseline observation carried forward	133 (16.2)	124 (15.9)	1.02 (0.78-1.34)	.87
ITT–multiple imputation of outcomes	268 (32.7)	243 (31.2)	1.07 (0.87-1.32)	.52
Self-reported non-smoking in past 30 days, n (%)				
Complete cases (n=712)[g]	61 (17.6)[j]	61 (16.7)[k]	1.06 (0.72-1.57)	.76
ITT–baseline observation carried forward	72 (8.8)	71 (9.1)	0.96 (0.68-1.35)	.82
ITT–multiple imputation of outcomes	151 (18.4)	146 (18.7)	0.98 (0.76-1.26)	.87
Secondary outcomes (6 months)				
Self-reported non-smoking in past 7 days, n (%)				
Complete cases (n=708)[g]	114 (33.3)[l]	143 (39.1)[m]	0.78 (0.57-1.06)	.11
ITT–baseline observation carried forward	150 (18.3)	174 (22.3)	0.79 (0.61-0.99)	.05
ITT–last observation carried forward	180 (22.0)	190 (24.4)	0.87 (0.69-1.10)	.25
ITT–multiple imputation of outcomes	295 (36.1)	302 (38.8)	0.89 (0.73-1.09)	.27
Self-reported non-smoking in past 30 days, n (%)				
Complete cases (n=709)[g]	84 (24.4)[n]	107 (29.3)[o]	0.78 (0.56-1.09)	.14
ITT–baseline observation carried forward	106 (12.9)	123 (15.8)	0.79 (0.60-1.05)	.10
ITT–last observation carried forward	114 (14.4)	132 (16.9)	0.82 (0.63-1.08)	.16
ITT–multiple imputation of outcomes	199 (24.3)	220 (28.2)	0.81 (0.65-1.02)	.07

[a]CTC: Crush the Crave.

[b]OnRQ: On the Road to Quitting.

[c]N=354 for CTC for cases with continuous self-reported abstinence at 6 months.

[d]N=371 for OnRQ for cases with continuous self-reported abstinence at 6 months.

[e]ITT: intention-to-treat.

[f]Multiple imputation by chained equations (number of imputations=18).

[g]Number of cases is less than 725 because of missing data.

[h]N=345 for CTC for cases with self-reported non-smoking in past 7 days (secondary outcome at 3 months).

[i]N=363 for OnRQ for cases with self-reported non-smoking in past 7 days (secondary outcome at 3 months).

[j]N=347 for CTC for cases with self-reported non-smoking in past 30 days (secondary outcome at 3 months).

[k]N=365 for OnRQ for cases with self-reported non-smoking in past 30 days (secondary outcome at 3 months).

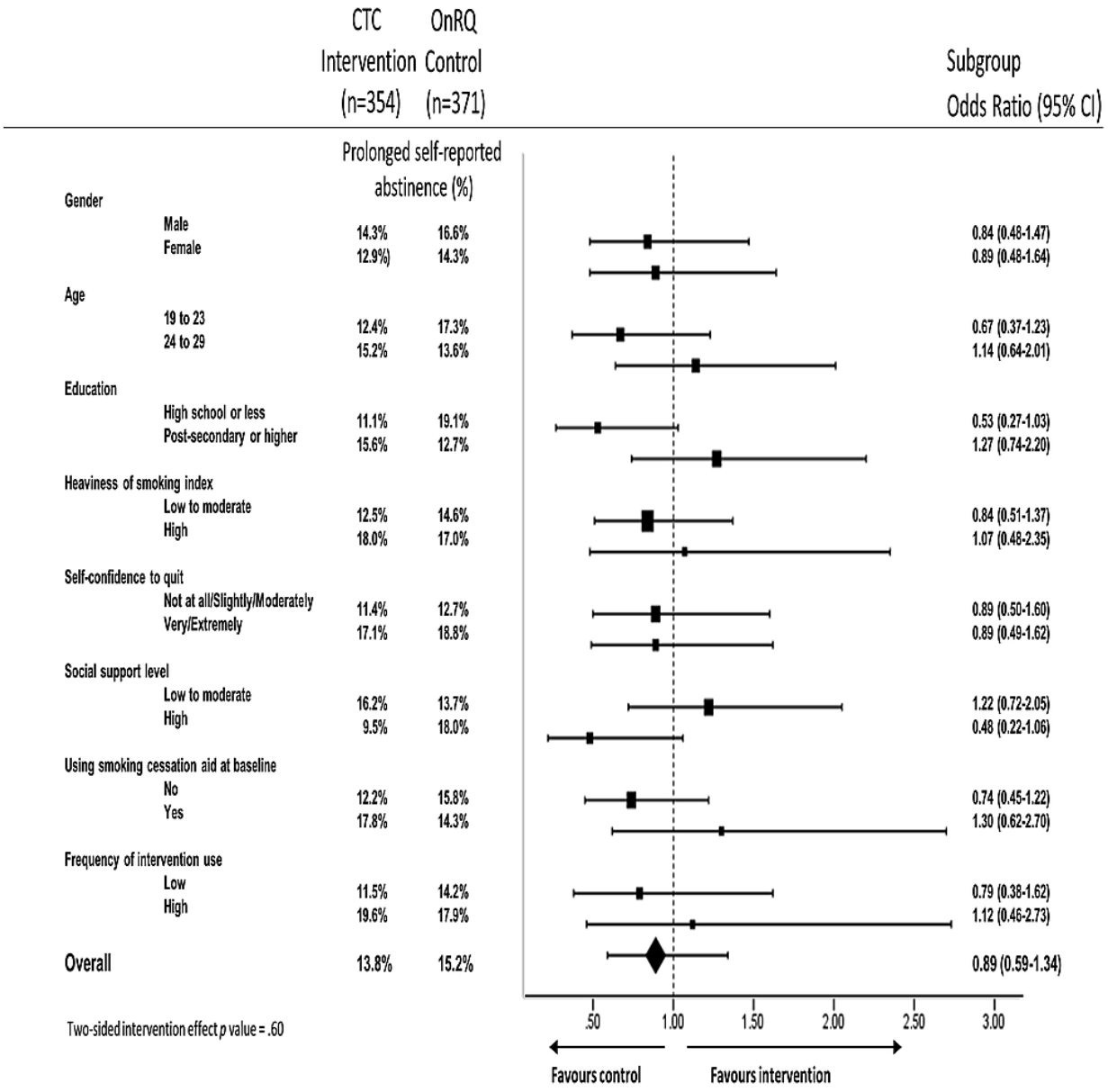
[l]N=342 for CTC for cases with self-reported non-smoking in past 7 days (secondary outcome at 6 months).

[m]N=366 for OnRQ for cases with self-reported non-smoking in past 7 days (secondary outcome at 6 months).

[n]N=344 for CTC for cases with self-reported non-smoking in past 30 days (secondary outcome at 6 months).

[o]N=365 for OnRQ for cases with self-reported non-smoking in past 30 days days (secondary outcome at 6 months).

Figure 2. Effect of the Crush the Crave intervention on primary outcome by subgroup (N=725). CTC: Crush the Crave; OnRQ: On the Road to Quitting.



Subgroup Analysis

For complete cases (N=725), the sub-group analysis for prespecified variables included gender, age, education, heaviness of smoking, self-confidence to quit, level of social support, use of a smoking cessation aid at baseline, and frequency of assigned intervention use. No statistically significant subgroup effects were found when comparing continuous self-reported abstinence between the intervention (CTC) and control (OnRQ) conditions (see Figure 2). Although not statistically significant, higher cessation outcomes favored the OnRQ condition for participants with high school education or less (71/371, 19.1% vs 39/354, 11.1%, OR 0.53, 95% CI 0.27-1.03, *P*=.06). Similarly, higher cessation outcomes favored the OnRQ condition for those reporting high levels of social support (64/354, 18.2% vs 35/371, 9.5%, OR 0.48, 95% CI 0.22-1.06, *P*=.07; see Figure 2).

Satisfaction and Use

As shown in Table 3, at 6 months 85.1% (359/422) of the CTC participants downloaded the app as compared with 81.8% (346/423) of OnRQ participants having downloaded or requested a printed copy of the self-help guide, ($\chi^2_{1(N=845)}$=1.6, *P*=.23). Furthermore, OnRQ participants reported significantly higher levels of overall satisfaction (mean 3.3 [SD 1.1] vs mean 2.6 [SD 1.3]; t_{644}=6.87, *P*<.001) and perceived helpfulness (mean 5.8 [SD 2.4] vs mean 4.3 [SD 2.6], t_{657}=8.0, *P*<.001), as well as higher levels of frequency of use, confidence in using, ease of use, and perceptions of the intervention being well laid out as compared with the CTC participants (see Table 3).

Table 3. Comparison of Crush the Crave and On the Road to Quitting on use and satisfaction measures at 3 and 6 months.

Satisfaction and use	CTC[a], n	Summary	OnRQ[b], n	Summary	*P* value
3 months (N=791)					
Downloaded	384	329 (85.7)[c]	407	325 (79.9)[c]	.03
Satisfaction with app, mean (SD)					
Used frequently	325	3.6 (1.1)	317	3.3 (1.0)	.003
Easy to use[d]	312	2.2 (1.0)	308	2.1 (0.8)	.14
Well laid out[d]	307	2.4 (0.9)	306	2.1 (0.7)	<.001
Confidence in using[d]	306	2.7 (1.1)	310	2.6 (0.9)	.23
Overall satisfaction[e]	306	2.6 (1.1)	299	3.1 (1.0)	<.001
Overall helpfulness[f]	308	4.2 (2.6)	299	5.2 (2.3)	<.001
6 months (N=845)					
Downloaded	422	359 (85.1)[c]	423	346 (81.8)[c]	.23
Satisfaction with app, mean (SD)					
Used frequently[d]	351	3.6 (1.2)	334	3.2 (1.1)	<.001
Easy to use[d]	340	2.3 (1.1)	324	2.1 (0.8)	.01
Well laid out[d]	337	2.5 (1.1)	324	2.1 (0.8)	<.001
Confidence in using[d]	331	2.8 (1.1)	318	2.5 (0.9)	.002
Overall satisfaction[e]	332	2.6 (1.3)	314	3.3 (1.1)	<.001
Overall helpfulness[f]	337	4.3 (2.7)	322	5.8 (2.4)	<.001

[a]CTC: Crush the Crave.

[b]OnRQ: On the Road to Quitting.

[c]The values present n (%).

[d]Scale of 1 to 5: *strongly agree* to *strongly disagree.*

[e]Scale of 1 to 5: *not at all satisfied* to *very satisfied.*

[f]Scale of 1 to 10: *not at all helpful* to *very helpful.*

Discussion

Findings

This is the first RCT of a smoking cessation app compared with a self-help guide with a large sample size of Canadian young adults followed up at 3 and 6 months. Studies of smoking cessation apps to date have had SMS text messaging or another app as control conditions [14,24,26]. The results of this study show that there were no statistically significant differences between the intervention and control conditions on the key outcome measures. With participants lost to follow-up treated as smokers (last observation carried forward), the CTC app and OnRQ resulted in continuous abstinence rates of 7.8% (64/820) and 9.2% (72/779), respectively. Unlike this study, BinDhim et al [26] recently assessed the efficacy of an interactive smoking cessation smartphone app compared with a static information only smartphone app on adults using a double-blind RCT and found a significant difference in continuous abstinence rates of 3.2% and 7.3% for the control and intervention conditions, respectively. In comparison, our trial found a continuous abstinence rate comparable with BinDhim et al of 7.8% (64/820) for the intervention condition. In addition, Bricker et al [14] conducted a small sample size (n=196) double-blind RCT with adults to assess the efficacy of the smartphone app SmartQuit as compared with the National Cancer Institute's QuitGuide smartphone app. The primary outcome for this smaller study was 30-day PPA at 2-month follow-up, and based on complete cases no statistically significant difference was found between the intervention (13%) and the control (8%) conditions. In comparison, our study found 30-day PPA rates at 3 months of 18% and 17% for the CTC intervention and comparison condition, respectively. Finally, Buller et al [24] conducted a very small sample size RCT with young adults (n=102) to compare a smartphone app versus an SMS text messaging app for smoking cessation. With participants lost to follow-up treated as smokers, continuous abstinence at 3 months for the smartphone app was 16% in comparison with SMS text messaging at 27%. Although substantive, this difference was not statistically significant because of the small sample.

In Canada, the typical unassisted abstinence rate based on 30-day PPA (having not smoked in the previous 30 days before being interviewed 6 months after baseline) is 5% (95% CI

4%-6%) among adult smokers based on a large sample size (n=4355) population-based longitudinal cohort study of Ontario smokers [45]. According to the same Ontario longitudinal cohort study of smokers, the unassisted 30-day PPA for young adult smokers (aged 18-29 years) was 11.5% (68/592) as assessed 6 months after baseline [46]. Similar to the findings of Ubhi et al [25], ccomparing rates of cessation with a smartphone app against population-based estimates of unaided cessation, this study also found the CTC smartphone app had favorable 6-month intention-to-treat 30-day PPA rates at 6 months compared with the unassisted abstinence rates for young adult smokers (see Table 2).

CTC was not superior to the control condition OnRQ. Rather, the primary outcome and secondary outcome measures at 6 months favored the self-help booklet control condition. However, the continuous abstinence rate and 30-day abstinence rate for CTC is comparable with previous research on smoking cessation smartphone apps [14,26] and is more favorable than what is typical among unassisted young adult smokers [46]. This study is unique in that both the CTC app and OnRQ were similar in their content and evidence base but very different in their mechanism of delivery. Furthermore, this is a large sample size study comparing a smoking cessation smartphone app with the usual self-care and low-intensity intervention of a self-help guide. This is contrary to the approach by BinDhim et al, for example, who examined 2 different apps (one was based on evidence and theory, whereas the other was not based on an evidence-informed structure). Evidence to date has demonstrated the effectiveness of mobile phone SMS text messaging interventions [20]; however, this study has revealed that although the quit rates are comparable with other studies of smoking cessation apps, an evidence-informed smoking cessation app is not superior to an evidence-informed self-help guide. These findings pave the way to examine specific evidence-informed components that do or do not translate well in the mHealth context that has implications for future research and successful scale-up [47].

It is interesting that those with higher education and those with low social support favor the CTC app and that some populations may prefer alternative low-intensity evidence-informed interventions such as self-help guides. In addition, men's interest in using CTC is noteworthy. In our recently published qualitative work, it was found that men were particularly receptive to CTC's ability to present personalized and relevant information in relation to their smoking behavior and engage them in autonomous behavior change [48]. That men prefer the tailoring capabilities inherent in technology-based health interventions is supported in the general mHealth literature [49]. Intervention preferences for those with perceived lower levels of social support from friends and colleagues in quitting smoking along with gender and other characteristics can be further explored.

Despite the independent and positive assessment of Ubhi et al [30] regarding user engagement and usability of CTC, findings indicate significantly higher satisfaction and perceived helpfulness with the self-help booklet OnRQ compared with the CTC app. The participants likely perceived CTC as too complex to use as compared with a self-help booklet. Therefore, there is the potential for improvements to the content and usability of CTC that may result in higher abstinence rates. This brings forward the need for qualitative research to understand user experiences and preferences in relation to an app's design and related functions to enhance user satisfaction [48].

Limitations

This study has several limitations. Despite a rigorous process for encouraging participants to complete follow-up, an overall response rate of 60.48% at 6-month follow-up is considered suboptimal. However, this level of follow-up response is similar to other Web-based cessation intervention studies such as BecomeAnEX with a 3-month follow-up rate of 59% [50]. Despite the less than optimal response rate, there was no differential attrition between groups as the groups were balanced with regard to all characteristics measured at baseline and at follow-up (see Table 1). As the baseline characteristics of those lost to follow-up did not differ between conditions, any possible differences in the outcome measures between conditions are unlikely to be associated with these characteristics [44]. Furthermore, the intention-to-treat principle was followed for the analysis of outcomes using 3 standard approaches to handling missing data [35,43,51].

Although it was demonstrated that the rates of continuous abstinence and 30-day PPA for the CTC intervention condition were comparable with the few trials of smoking cessation apps to date, an important limitation of this study is the lack of a no intervention control group. However, it is often difficult to avoid attrition bias when conducting trials with inactive controls [52], and inactive controls are sometimes challenged as unethical in settings in which participants could be given an existing usual care intervention [53].

Although participants were blinded, both interventions were potentially available to any participant, implying a risk of contamination. However, we took measures to minimize this through ensuring unique IPs at recruitment and only 2.2% reported use of a self-help guide and 3.2% use of a smartphone app at 6-month follow-up in groups not allocated to these interventions.

Recall bias with regard to the self-reported use of interventions is possible. Although the automated recording of the use of CTC is possible as reported elsewhere [31], it was not possible to automatically record the use of the self-help guide OnRQ and, consequently, self-reported satisfaction and use measures were chosen to allow for comparison between conditions, and there is no evidence that recall bias was different across conditions.

Finally, the lack of biochemical validation of smoking abstinence is a limitation that may have resulted in an overestimation of smoking abstinence [54]. However, a Cochrane review of low-intensity internet-based interventions for smoking cessation found that very few studies used biochemical validation given the difficulties in obtaining samples from participants [55], and expert consensus suggests that biochemical verification of abstinence is impractical and unnecessary in large studies such as this one because of cost considerations and limited face-to-face contact [56]. Furthermore, accurate estimates of the prevalence of cigarette

smoking among Canadians can be derived from self-reported smoking status data [57].

Generalizability

This study reached a large sample of Canadian male and female young adults from various ethnicities, education, and income groups, including unemployed and low-income young people, who owned smartphones and were motivated to quit smoking. The inclusion criteria of understanding, reading, and speaking English resulted in a lack of representation from young adult francophone smokers. French is the mother tongue of approximately one-fifth of the Canadian population, most of whom live in Quebec. Therefore, the study sample is limited to English-speaking Canada, and the findings may not be generalizable to young adult smokers with smartphones in other settings.

Implications for Practice

CTC did not show a significant difference from a usual care self-help guide. Despite the rates of quitting being comparable with other smoking cessation app interventions, research into improving the overall satisfaction and helpfulness of CTC is needed before practitioners may recommend an evidence-informed mHealth app, such as CTC, to smokers willing to quit. In addition, the widespread reach that cessation apps, such as CTC, can have, particularly for hard-to-reach populations, supports the relevance and need for mHealth cessation interventions. For example, among 18- to 29-year-old people, smartphone ownership is nearing saturation among all socioeconomic groups [10], and as a result, population health practitioners need to consider the impact and the reach of these interventions as mHealth cessation interventions could potentially help to eliminate tobacco-related health disparities. Given the potential for widespread reach, effective smoking cessation apps may warrant inclusion in the overall cessation picture for Canadian young adults. Furthermore, as smartphone apps for health and healthy behavior change are so numerous and often downloaded, it is important that studies such as this are conducted and findings, particularly if not overly supportive of the effects of these apps, are published.

Future Research

To date, the effects of smartphone apps for smoking cessation are largely unknown and this study is one of the very few trials that have been undertaken. A number of larger RCTs are underway to assess the effect of smartphone apps for smoking cessation [58-61]. In the near future, the evidence from these studies will be brought together and reviewed to determine the overall effectiveness of mHealth for smoking cessation, under what conditions and for whom. In the interim, future research to establish the cost-effectiveness of mHealth cessation interventions is needed [62]. Although the findings from this study indicate comparability with another low-intensity intervention, lower levels of satisfaction and helpfulness suggest that future research should explore the app's usability using qualitative research [48], followed by an evaluation of the improvements and exploration of the program features or components that account for differences among smokers [63]. Due to the multicomponent nature of CTC, there is a limited understanding as to what intervention mechanisms are associated with behavior changes such as quitting smoking. Research to disentangle which elements of a multicomponent intervention are accounting for change may be useful [64]. Similar to the experience of BinDhim et al [26] testing of a smoking cessation decision-aid app, this study experienced the loss of some CTC app functionality, notably push notifications, likely because of the Apple app store and Google Play changing their regulation policies and technical specifications. Future research on smartphone apps should take into consideration these potential changing policy and technical issues. Finally, a superiority trial was conducted, and future research may consider inferiority or equivalence designs when comparing mHealth against established evidence-based low-intensity interventions such as self-help guides [65,66].

Conclusions

CTC was feasible for delivering cessation support but was not superior to a self-help guide in helping motivated young adults to quit smoking. Both conditions in this trial are considered low-intensity self-help interventions and achieved rates of continuous abstinence comparable with other mHealth studies for smoking cessation. As smartphone apps may not serve as useful alternatives to printed self-help guides, there is a need to conduct further research to understand how smartphone apps for smoking cessation can be improved and become better in supporting population health efforts to reduce the overall prevalence of smoking.

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Authors' Contributions

NBB led the conceptualization and design of the study, and GEG, DH, CDN, RW, CB, and KSB contributed to the design of the study. NBB and LS drafted the manuscript. NBB, LS, GEG, CDN, RW, CB, DD, DH, and KSB critically revised the manuscript

for important intellectual content. NBB and DH are coprincipal investigators, and CDN, GEG, RW, CB, and KSB are coinvestigators on the research funding application. DD conducted research as a graduate student for the study. LS conducted research as a graduate student and as a postdoctoral fellow for the study. NBB supervised the study. NBB is the guarantor. NBB led the initial design and development of Crush the Crave.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Online recruitment, informed consent, and randomization.

[PDF File (Adobe PDF File), 63KB - mhealth_v6i10e10893_app1.pdf]

Multimedia Appendix 2

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 2MB - mhealth_v6i10e10893_app2.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
CTC: Crush the Crave
HSI: Heaviness of Smoking Index
ITT: intention-to-treat
NRT: nicotine replacement therapy
OR: odds ratio
OnRQ: On the Road to Quitting
PPA: point prevalence abstinence
RCT: randomized controlled trial
SMS: short message service

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Original Paper

Acceptability of Continuous Glucose Monitoring in Free-Living Healthy Individuals: Implications for the Use of Wearable Biosensors in Diet and Physical Activity Research

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Abstract

Background: Wearable sensors have been increasingly used in behavioral research for real-time assessment and intervention purposes. The rapid advancement of biomedical technology typically used in clinical settings has made wearable sensors more accessible to a wider population. Yet the acceptability of this technology for nonclinical purposes has not been examined.

Objective: The aim was to assess the acceptability of wearing a continuous glucose monitor (CGM) device among a sample of nondiabetic individuals, and to compare the acceptability of a CGM between a mobile diet tracking app (MyFitnessPal) and an accelerometer.

Methods: A total of 30 nondiabetic adults went through a 7-day observational study. They wore a CGM sensor, tracked their diet and physical activity using the CGM receiver and MyFitnessPal, and wore an accelerometer on their waist. After the monitoring period, they completed a 10-item survey regarding acceptability of each of the study tools. Two-tailed paired-sample *t* tests were conducted to examine whether the summary acceptability scores were comparable between the CGM sensor/receiver and MyFitnessPal/accelerometer.

Results: More than 90% of the study participants agreed that the CGM sensor and receiver were easy to use (28/30 and 27/30, respectively), useful (28/30 and 29/30, respectively), and provided relevant information that was of interest to them (27/30 and 28/30, respectively). The summary acceptability scores (out of a 5-point Likert scale) were mean 4.06 (SD 0.55) for the CGM sensor, mean 4.05 (SD 0.58) for the CGM receiver, mean 4.10 (SD 0.68) for MyFitnessPal, and mean 3.73 (SD 0.76) for the accelerometer.

Conclusions: The high acceptability of using a CGM from this study suggests a great potential for using CGMs in nondiabetic adults in research settings. Although potential selection bias might contribute to the high acceptability in this study, the continued advancements in wearable sensor technology will make the barriers to tracking and collecting personal physiological data more and more minimal.

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KEYWORDS

wearable sensors; remote monitoring; physiological monitoring; accelerometry; user experience

Introduction

Diet and physical activity are the two leading modifiable lifestyle behaviors that could significantly impact future health outcomes such as obesity, hypertension, diabetes, and heart disease [1]. Nevertheless, in the United States, adherence to meeting the dietary and physical activity guidelines has remained low for the past few decades [2-4]. Numerous efforts have been devoted to understanding the determinants and correlates of diet and physical activity behavior with the goal of developing novel and more effective interventions to promote and sustain positive health behavior changes. In recent years, behavioral research has seen a sharp increase in the use of mobile and wearable technology in diet and physical activity assessment and interventions [5]. Some of the most widely used technologies in behavioral research include mobile apps and wearable activity trackers [5-7], reflecting researchers' interests in utilizing wearable devices to understand and improve behavioral health.

New technologies are being developed to capture an extraordinary array of health-related information. Biosensors, wearable devices that either continuously or frequently measure physiological parameters [8,9], are becoming more affordable and accessible, providing opportunities for their application beyond clinical settings. One example of wearable biosensors with the potential to be used in behavioral research is the continuous glucose monitor (CGM). The CGM measures the concentration of glucose subcutaneously (interstitial fluid) in real time through a tiny sensor inserted under the skin [10]. It has been primarily utilized by type 1 diabetic patients treated by intensive insulin therapy to make treatment decisions that promote glycemic control [11]. In recent years, the use of CGMs has increased in primary care of patients with uncontrolled type 2 diabetes to improve patient's self-management skills (ie, treatment adherence, lifestyle changes) [12], demonstrating a broader application potential for CGMs.

Related to the use of CGMs for disease management, an increasing number of studies have begun to use CGMs in research to examine the acute effect of dietary intake and physical activity on insulin concentrations and glucose metabolism in both diabetic [13-16] and nondiabetic populations [17-21]. For example, using CGM in free-living settings, Brynes and colleagues [13] demonstrated the beneficial effect of a low glycemic diet on the 24-hour glucose profile in type 2 diabetic individuals, as well as in healthy young people [17]. In a controlled laboratory setting (whole-room calorimeter) with 2-day CGM assessment, DiPietro and colleagues [18] found that both sustained (45 minutes) morning walking and short (15 minutes) postmeal walking improved the 24-hour glucose profile in inactive older adults without diabetes. Multiple behavioral theories (eg, self-determination theory, social cognitive theory) address the importance of perceived benefits and outcome expectancy in influencing changes in dietary and physical activity behaviors [22-24]. Since glucose is a biological marker that could be acutely impacted by diet and physical activity, the richness of data collected from a CGM could potentially be used in health behavior interventions in a way to illustrate the immediate physiological consequences of one's behavior and subsequently encourage behavioral changes (eg, biologically based behavioral feedback).

Despite the growing utilization of CGMs in diet and physical activity research beyond the diabetic population, and its potential as a tool to promote diet and physical activity behavior change, questions have remained about the acceptability of CGMs to nondiabetic individuals. As such, the goal of this study was to describe the acceptability of a CGM and compare it to other widely used mobile diet and physical activity data collection methods (ie, MyFitnessPal and an accelerometer) from a sample of nondiabetic individuals. Knowledge gained from these results intends to support the use of CGMs in diet and physical activity research and could inform the planning and development of future diet and physical activity studies that use CGMs.

Methods

Study Overview

Data used for this study were from Project SENSE, an observational study aimed at testing the feasibility and utility of CGMs to detect and characterize consummatory (eating and drinking) events in free-living adults without diabetes. All study participants gave their written informed consent. Project SENSE was approved by the Institutional Review Board at the University of Texas MD Anderson Cancer Center.

Participants

Adults were recruited through public and private announcements (eg, email listserv, word-of-mouth) around the Texas Medical Center in Houston, Texas. These included healthy individuals working/living in the communities near the medical center, as well as patients from the MD Anderson Cancer Center who were free from cancer and diabetes. Interested individuals contacted the study team to assess their eligibility to participate in the study. Eligible individuals were between ages 21 and 65 years; able to speak, read, and write in English; and had a mobile phone with internet access. Individuals were excluded if they reported being diagnosed with diabetes, reported use of any medication known to affect glucose levels (eg, corticosteroids, antidepressants, metformin), had fasting blood glucose >125 mg/dL as measured by glucometer, were pregnant or lactating, had a reported diagnosis of a chronic condition with dietary restrictions or an eating disorder, or were unable or unwilling to use a CGM. The recruitment goal was to enroll 30 study participants. This sample size was chosen based on previous mHealth studies that tested acceptability [25,26].

Procedures

Interested individuals, who passed the initial eligibility screening, were invited for an in-person visit to have their fasting blood glucose measured by a commercially available glucometer to confirm their eligibility and enroll in the study. On enrollment, participants were introduced to the study equipment, which included a CGM system (Dexcom G4 Platinum, San Diego, CA, USA), a glucometer for CGM calibration, a mobile app to track dietary intake (MyFitnessPal), and an accelerometer to measure physical activity. The 7-day self-monitoring period started after the completion of the in-person visit. Participants were asked to track all dietary intake and exercise events using

both the CGM receiver and the MyFitnessPal app. Participants were told not to change their usual behaviors during the monitoring period. Participants came back for another in-person visit on day 8 to return the study equipment and to complete an exit survey. Participants received a compensation (up to US $200) for completing the study.

Study Tools

Continuous Glucose Monitor

The Dexcom G4 Platinum CGM system included a sensor, transmitter, and receiver (Figure 1). On insertion and activation of the sensor, glucose levels were recorded every 5 minutes. The receiver screen displayed the real-time glucose reading, a trend arrow indicating rate of change, and a graph showing the glucose trend in the past 24 hours. In addition, the receiver had the function to mark (ie, time stamp) eating events and exercise sessions. Participants were asked to record all eating and drinking of calorie-containing beverages using the receiver within 5 minutes of initiating the consummatory event. To ensure proper data transmission between the CGM transmitter and receiver, participants were asked to keep the receiver within 18 feet of them at all times. Lastly, with the Dexcom G4 Platinum CGM system, participants were required to perform a finger prick calibration using the supplied glucometer set at least every 12 hours.

Diet Tracking App

Participants kept a detailed food log (ie, food and caloric-beverage consumed, portion size, time of consumption) using the MyFitnessPal mobile app. In addition, participants were asked to take a time-stamped photo of all food and caloric beverages consumed using their mobile phone and email the images to the study coordinator at the end of each day. Food photos were used to confirm the time stamp marked in the CGM receiver for each of the recorded consummatory events. The MyFitnessPal app was also used by participants to enter all exercise events (ie, time, duration, and type).

Accelerometer

The ActiGraph GT3X was used to objectively measure physical activity. Participants wore the accelerometer on their waist during all waking hours, except when bathing or swimming.

Figure 1. Dexcom G4 Platinum continuous glucose monitoring system.

Measures

Acceptability

A 10-item survey was developed to assess the acceptability of all study tools used in Project SENSE. The survey items were chosen from previous mHealth feasibility studies [25,26] with a focus of addressing barriers and facilitators in the use of mHealth tools [27-29], such as convenience, value, and relevance. The survey was pilot-tested in the targeted population before launching. The response options were on a 5-point Likert scale, ranging from “strongly disagree” to “strongly agree.” All participants completed the survey during their exit visit. Two additional questions were later added to the survey to specifically ask about participants’ opinions on using a CGM for health and wellness purposes: “How likely or willing are you to use a wearable glucose sensor, like the one you used in this study, to help you achieve your health and wellness goals (healthy eating or weight management)?” and “How likely or willing would you be to use a wearable glucose sensor to help you achieve your health and wellness goals (healthy eating or weight management), if the sensor did not have to be inserted under your skin (ie, noninvasive)?” The response options were on a 5-point Likert scale, ranging from “very unlikely” to “very likely.” Half of the participants answered these two questions.

Statistical Analysis

Statistical analyses were conducted using the SPSS version 24.0 (IBM Corp, Armonk, NY, USA). Descriptive statistics were generated for all variables, including the mean and standard deviation for continuous variables and percentages for categorical variables. Cronbach alpha for the acceptability scale ranged from .757 (CGM sensor) to .853 (MyFitnessPal). A summary score of acceptability was created for each study tool (ie, CGM sensor, CGM receiver, MyFitnessPal, and accelerometer) by calculating the mean of the 10 survey items (the Privacy item was reverse-coded). Two-tailed paired-sample *t* tests were used to examine whether the acceptability score was comparable between CGM sensor, CGM receiver, MyFitnessPal, and accelerometer. A *P* value of .05 or less was considered significant.

Results

Participant Characteristics

A total of 66 individuals completed the eligibility screening. Eight were ineligible due to having been diagnosed with diabetes (type I or II), four were taking medication that would impact glucose levels, two had dietary intake restrictions due to health conditions, one was unwilling to have the sensor inserted, and nine were due to other reasons (eg, age, time commitment, pregnancy, other health reasons). A total of 42 individuals, who passed the initial eligibility screening, were scheduled for an in-person visit to determine final eligibility. Of these individuals, eight did not attend their appointment and were unable to be rescheduled and four had elevated fasting blood glucose levels.

A total of 30 participants enrolled in Project SENSE. Average age was 38 (SD 13, range 24-64) years. In all, 73% (22/30) of the participants were female, 17% (5/30) were Hispanic, and 64% (19/30) were overweight or obese. Table 1 shows the detailed demographic characteristics of the participants.

Of the 30 participants, three experienced an unexpected failure of their CGM adhesive, which caused the sensor to be removed prematurely (two participants had four days' wear and one participant had five days' wear). All other participants wore the CGM for the entire 7-day observational period. The daily eating events recorded by participants was mean 5.6 (SD 2.2) for the CGM receiver and mean 5.4 (SD 2.1) for MyFitnessPal.

Acceptability

Overall, more than 90% (27/30) of participants agreed with the statements regarding usability, value, relevance, and confidence for both the CGM sensor and the CGM receiver. Table 2 shows the results from the acceptability survey for all tools used in Project SENSE. Of the 15 participants who answered the additional questions regarding using CGM for health and wellness purposes, 6 (40%) indicated that they were likely to do so using a similar CGM system, and 12 (80%) indicated that they were likely to do so if the CGM system became noninvasive.

Table 1. Participant characteristics (N=30).

Characteristic	Participants
Age (years), mean (SD)	37.9 (13.2)
Female, n (%)	22 (73)
Hispanic, n (%)	5 (17)
Overweight, n (%)	14 (47)
Obese, n (%)	5 (17)
College graduated, n (%)	28 (93)
Full-time employed, n (%)	22 (73)

Table 2. Participant experiences of each study tool (N=30)[a].

Acceptability survey item	CGM[b] sensor, n (%)	CGM receiver, n (%)	MyFitnessPal, n (%)	Accelerometer, n (%)
Usability: this tool is easy to use and user friendly	28 (93)	27 (90)	28 (93)	28 (93)
Convenience: this tool is convenient for me to use in my everyday lives	22 (73)	19 (63)	22 (73)	18 (60)
Value: this tool is useful and beneficial	28 (93)	29 (97)	28 (93)	23 (77)
Relevance: this tool provides information that is of interest to me	27 (90)	28 (93)	27 (90)	13 (43)
Motivating: I am motivated to use this tool to track my daily behaviors	19 (63)	20 (67)	24 (80)	11 (37)
Tech support: there is adequate availability and quality of professional assistance throughout use of this tool	21 (70)	20 (67)	21 (70)	18 (60)
Confidence: I feel confident that I use this tool correctly	29 (97)	28 (93)	27 (90)	28 (93)
Privacy: I am concerned about my privacy when using this tool	1 (3)	1 (3)	4 (13)	1 (3)
Recommend: I would recommend this tool to my friends and family	19 (63)	20 (67)	28 (93)	14 (47)
Like: I like using this tool	20 (67)	23 (77)	24 (80)	17 (57)

[a]Values are number of participants who agreed or strongly agreed with the statement.

[b]Continuous glucose monitor.

Table 3. Mean of acceptability score for each data collection tool and comparisons of their mean scores[a].

Data collection tool	Acceptability score, mean (SD)	Tool, absolute mean difference (SD)		
		CGM[b] sensor	CGM receiver	MyFitnessPal
CGM sensor	4.06 (0.55)	—	0.01 (0.21)	0.04 (0.90)
CGM receiver	4.05 (0.58)	0.01 (0.21)	—	0.05 (0.90)
MyFitnessPal	4.10 (0.68)	0.04 (0.90)	0.05 (0.90)	—
Accelerometer	3.73 (0.76)	0.33 (0.55)[c]	0.32 (0.55)[c]	0.37 (0.98)[c]

[a]The Likert scale used in the ratings was 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=strongly agree.

[b]Continuous glucose monitor.

[c]$P<.05$ based on a two-tailed paired-sample *t* test.

Table 3 shows the mean summary acceptability score for each data collection tool. The summary acceptability score was comparable between the CGM sensor and MyFitnessPal (mean difference=–0.04, $P=.79$), and the CGM receiver and MyFitnessPal (mean difference=–0.05, $P=.76$). The summary score was approximately 4 for these data collection tools, suggesting participants overall "agreed" with the different aspects of acceptability for CGM sensor, CGM receiver, and MyFitnessPal. The accelerometer had a summary score of mean 3.73 (SD 0.76), which was significantly lower compared to the CGM sensor ($P=.003$), CGM receiver ($P=.003$), and MyFitnessPal ($P=.048$). This suggests that participants' overall perception of the acceptability for accelerometer was between neutral to "agreed."

Discussion

Principal Findings

Results from this study suggest high acceptability of using a CGM in a sample of free-living, nondiabetic adults. The overall acceptability for a CGM sensor and receiver was comparable to the diet tracking app MyFitnessPal and was higher than the waist-worn accelerometer. Participants recorded 5 to 6 eating events per day on average using the CGM receiver and MyFitnessPal, which is similar to other studies that used digital tools to collect dietary data [30]. These data suggest that participants were using the two devices as instructed during the monitoring period. After wearing the CGM sensor and using the CGM receiver for 1 week, more than 90% of the study participants agreed that the CGM sensor and receiver were easy to use, useful, and provided relevant information that was of interest to them. These results demonstrate a great potential for using CGM in nondiabetic adults as previous research has suggested that individuals will not engage with technology that is challenging to use or is perceived as irrelevant to their needs [28,31].

Percent agreement was low for the statement regarding feeling motivated to use the CGM sensor (63%) and receiver (67%). However, a post hoc analysis showed that these scores were comparable to the one for MyFitnessPal (80%; $P=.20$ and $P=.29$, respectively) and significantly higher than the one for the accelerometer (37%; $P=.009$ and $P=.005$, respectively). Potentially contributing to this finding is that both the CGM and the MyFitnessPal app provide feedback to the user regarding their glucose dynamics and their dietary intake, respectively, whereas the accelerometer does not. Feedback that is person-specific, actionable, and goal related tends to improve outcomes in interventions [32]. Furthermore, for Project SENSE, no specific explanations were given to participants about how their glucose pattern might reflect their behaviors (eg, dietary intake or physical activity). Therefore, this lack of knowledge of how data from CGMs might be related to their behaviors might have contributed to a low motivation score. To increase motivation, future studies considering the use of CGMs might want to provide a few examples of the potential effects of dietary intake and physical activity on glucose levels (eg, glucose will rise sharply after consuming high carbohydrate food; the more you move the more glucose you burn).

The CGM receiver also had lower agreement for the statement regarding convenience (63%). It is worth noting that the CGM model used in this study (Dexcom G4) required the receiver to be within 18 feet of the sensor at all times to ensure proper data transmission. Therefore, participants might have found it burdensome to always carry an additional device with them. Nevertheless, the need to have a receiver is being phased out in newer CGM models. For example, Dexcom G5 and G6 users can have the option to download a mobile app and use their mobile phone to receive and view glucose data instead of the receiver. For FreeStyle Libre CGM users (Abbott, Alameda, CA, USA), a receiver (ie, reader) is only needed at the time of retrieving glucose data (through scanning the reader over the sensor). Hence, as the technology for CGM system keeps advancing, it is expected that the concern regarding convenience will be minimized.

The overall acceptability score was similar for the CGM system and MyFitnessPal, but lower for the accelerometer. Other than the reasons discussed previously, one potential factor that might explain the differences in acceptability could be the different behaviors that were tracked by these tools. It is possible that individuals in this study perceived a food tracking tool (eg, MyFitnessPal) as more acceptable than a physical activity tracking tool (eg, accelerometer).

Although the CGM system could be regarded as an acceptable data collection tool in research settings, its usage beyond assessment purposes might be limited in the nondiabetic population if being used as is. Only 40% of the assessed participants from this study agreed that they would use the

CGM, in its current form, for health and wellness purposes. As discussed previously, one of the reasons for this low endorsement for personal use of a CGM could be the lack of knowledge and ability to associate glucose number with health and wellness goals in this population. Individuals might need specific education and guidance to help them understand how their daily behaviors might impact their glucose pattern and subsequently influence their health. Future behavioral interventions exploring the use of CGMs in the nondiabetic population for health promotion purposes could provide appropriate information sessions and develop meaningful and actionable feedback messages to fully utilize the rich data from the CGM.

Limitations

Although this study was among the few that used a CGM in a sample of nondiabetic adults and was the only one that assessed participant acceptability, it had some limitations. First, the study was not powered to formally test any difference in acceptability across different study tools (ie, CGM, mobile app, and accelerometer). Second, the majority of the study participants were highly educated and female. Therefore, findings from this study might not be generalizable to males or individuals with lower socioeconomic status. Further, participants in this study could be highly motivated because they volunteered to take part in the study. One of the possible reasons that individuals learned about the study but did not sign up could be they were not willing to wear the CGM. Therefore, this potential selection bias might contribute to the high acceptability of CGM in the study sample. Third, findings regarding the accelerometer might be limited to the specific model that was used in this study, which was a waist-worn passive device (ActiGraph GT3X) that participants were not able to interact with. This limitation in the user interface of the accelerometer could have greatly impacted participants' rating in value, relevance, and motivation. Devices such as the ActiGraph GT3X have been considered "research grade" and thus remain one of the popular tools to monitor activity. However, as the technology of wearable activity monitors keeps improving, researchers will have more options when choosing assessment and intervention tools and should consider how different characteristics of the device (eg, placement location, integration with mobile phones) might affect users' experiences. As an example, consumer devices such as Fitbit have been increasingly used in research [33,34] and have been shown to accurately quantify energy expenditure and steps taken [35-39]. Similarly, findings regarding CGMs might be limited to the specific type of technology (eg, the requirement of finger prick calibration, insertion site of the sensor). For example, the finger prick requirement could be perceived as a barrier for CGM use. Yet, the CGM system scored higher on overall acceptability compared to the accelerometer. It is possible that the novelty of the CGM and the ability to see their glucose number outweighed the temporary burden of finger pricks in this study population. Whereas participants could have viewed the accelerometer as more encumbered because they had to wear it on their body without getting any information out of it. It is worth noting that the newer generation of CGMs have eliminated the need for finger prick calibration (ie, the Dexcom G6 and Freestyle Libre). As the CGM technology keeps improving (ie, becomes less invasive), the acceptability of its use in the nondiabetic population could potentially increase. This is evidenced by feedback from this study showing that 80% would use the CGM for health promotion purposes if it was less invasive. Another potential difference in CGM models that could impact acceptability is the insertion site of the sensor. For example, Dexcom devices are inserted on the abdomen, whereas the Freestyle Libre devices are inserted on the back of the upper arm. Some individuals might perceive the abdomen area as a more hidden placement site than the back of the upper arm, although other individuals might have the opposite preference. Nevertheless, this difference in insertion sites might have a greater impact for individuals that need to wear the device long term (ie, diabetic patients) compared to individuals that only need to wear the device short term such as for research purposes. Further, findings from this study could be limited by the design in which participants were required to log meals and physical activity using both the CGM receiver and MyFitnessPal. This could have potentially increased participant fatigue and affected their acceptability ratings. Often the reason for using multiple data collection tools simultaneously in a research setting is to obtain information about participant behaviors and the subsequent impact that is as complete as possible, with each tool will providing different kinds of data (eg, glucose response from CGM and calories consumed from MyFitnessPal). Therefore, participants will be more likely to be required to use multiple devices for research purposes. Nevertheless, it should be kept in mind that participants could have different feelings toward the tools if each of them was used disjointedly. Lastly, this study assessed feasibility using a purely quantitative approach. Although this approach allowed a more straightforward comparison between tools and is easier to administer compared to a qualitative approach, a qualitative approach using interviews or focus groups would have offered some more in-depth information about acceptability from the participants. Nevertheless, this study did include an open-ended question asking participants what they liked most about this study. The most frequently mentioned aspect was "being able to see the glucose number in real time" (mentioned by 73% of the participants) followed by "monitoring food intake using MyFitnessPal" (mentioned by 60% of the participants).

Implications and Conclusions

The continued advancement in technology will further diversify the use of wearable devices and foster innovative approaches in diet and physical activity research. The CGM represents one type of biological sensor that has the potential to provide personalized physiological data for a biomarker that is closely related to dietary and physical activity behaviors. These data could potentially be used to present the immediate or short-term (eg, past 24 hours) physiological consequences of dietary and physical activity behaviors as a strategy to encourage positive changes in those behaviors [21]. The ability to frequently assess a marker related to a behavioral goal is the foundation for providing just-in-time feedback that could ultimately optimize strategies for impactful behavioral changes [32].

Results from this study suggest that although healthy individuals do not mind wearing a minimally invasive CGM device for 1 week, the motivation for wearing it was moderate, possibly due

to the lack of ability to interpret or make sense of all the data that were available to them. As the barriers to tracking and collecting health behavior data are overcome by technological advancements, the challenge ahead will be determining how to most efficiently and effectively use these data to provide meaningful insights and useful feedback to users. Thus, more behavioral research that uses CGMs and other biological sensors is needed to offer evidence-based recommendations that assist individuals with their behavior change goals.

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Conflicts of Interest

None declared.

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Abbreviations

CGM: continuous glucose monitor

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Original Paper

A Mobile Sleep-Management Learning System for Improving Students' Sleeping Habits by Integrating a Self-Regulated Learning Strategy: Randomized Controlled Trial

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Abstract

Background: Insomnia can significantly affect students' learning performance. Researchers have indicated the importance and challenge of coping with insomnia using nondrug treatments, such as cognitive behavioral therapy (CBT) for insomnia. However, it is easy for the traditional CBT for insomnia to be interrupted owing to the overly lengthy period of sleep therapy. Self-regulated learning (SRL) strategies are known to be an effective approach for helping students improve their time management, as well as their ability to set learning goals and adopt learning strategies.

Objective: The objective of this study was to propose a mobile sleep-management learning system integrated with SRL strategies and CBT.

Methods: A total of 18 undergraduate students from a university in northern Taiwan participated in the 2-week experiment of using this sleep-management system.

Results: The experimental results showed that the proposed approach was useful and easy for students to use. In addition, the number of students with insomnia significantly decreased; that is, the proposed approach could help students improve their sleep quality and cultivate better sleeping habits, which is important for them to enhance their learning efficiency.

Conclusions: With the assistance of this proposed approach, students can plan their daily life by setting goals, applying strategies, monitoring their life habits process, and modifying strategies to cultivate good learning and healthy lifestyle habits.

Trial Registration: Government Research Bulletin MOST104-3011-E038-001; https://www.grb.gov.tw/search/planDetail?id=11568383&docId=467988 (Archived by WebCite at http://www.webcitation.org/73MnPHNri)

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KEYWORDS

cognitive behavioral therapy; insomnia; mobile phone; self-regulated learning

Introduction

Background

Sleep problems, especially insomnia, affect many people in their daily life. It is found that >25% of adults experience insomnia [1]. They also indicated that insomnia has a negative impact on both health and psychological well-being. Researchers argued that sleep problems such as sleep disturbances are highly associated with several issues such as psychological demands, low recognition, low social support, perception of danger, emotional demands, and work-life imbalance [2]. Moreover, some studies indicated that unhealthy lifestyles and habits (eg, smoking) are associated with increased risk of sleep problems [3]. For example, Shimura et al. showed that caffeine intake at night, using electronic displays within 2 hours of sleep, and irregular timing of meals may be associated with sleep problems such as sleep disturbance and daytime sleepiness [4]. In the past

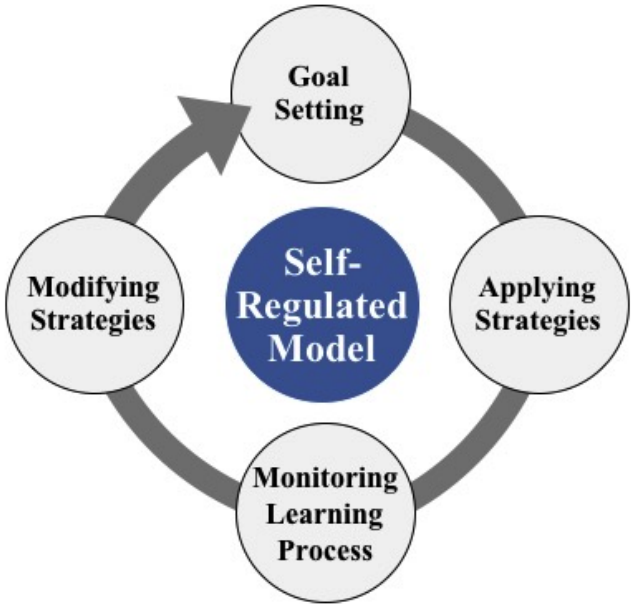
decades, numerous studies have investigated sleep medical care issues, and a large portion of these studies have recommended nondrug treatment, in particular, CBT for insomnia [5,6]. Researchers have also indicated that insomnia is usually caused by poor time management and could significantly affect students' learning performance [7-9].

Self-regulated learning (SRL) is known to be an effective way to help students manage their learning plans [10-12]. With the help of the SRL approach, students are guided to plan their own learning goals and time management as strategies to improve their learning outcomes; moreover, they are guided to periodically make reflections and modify their plans [13,14]. Zimmerman et al proposed a self-regulatory learning cycle consisting of 4 stages, as shown in Figure 1 [15]. In the learning field, students need to do "goal setting" in the first SRL stage. They are asked to analyze their learning process and set their goals based on the proposed learning strategies. They usually set goals based on their prior experience, such as the degree of completion of reading learning materials, average time to learn, and the choices of learning environments such as learning with their peers, so that they could learn at their own pace by setting a series of learning goals. The second stage is "applying proper strategies." Students need to carry out the learning plan that was outlined in the goal-setting stage to complete their learning tasks by using the chosen learning strategies such as "asking questions online" and "making annotations." The third stage is "monitoring the learning process." Students realize what they have done and the effectiveness of the strategies depending on whether their performance reaches the goals they have set. The last stage is "modifying strategies." In this stage, students would evaluate whether the goals they set in the goal-setting stage are suitable for their learning performance. In addition, they evaluate the completion of their goals. Therefore, they could modify their strategies to suit them better to cultivate adequate sleeping habits.

Researchers have indicated that the self-regulated model can help students regulate themselves and help them have better learning habits [14]. In addition, Shimura et al addressed that each type of sleep problem has its own associated life habit factors [4]. Unhealthy lifestyle or habits (eg, playing with mobile electronic devices before sleep time) may easily lead to sleep problems. Therefore, to help students cultivate a good lifestyle, healthy habits, and readiness for higher quality sleep, a mobile sleep-management learning system, the sleep-management system based on the self-regulated learning strategy (SMSR) is proposed in this study; it is designed on the basis of 4 stages of the SRL strategy proposed [15].

The application of smartphones to deliver health-related content has experienced rapid growth in recent years, with >325,000 mobile health (mHealth) apps currently available in the digital marketplace [16]. However, most of these apps play the role of delivering accessible health-related knowledge and support to users. The effectiveness of an mHealth app usually depends on users' initiative. When it comes to effective data logging and feedback to users, researchers showed that using a mobile app with a wearable device as a nondrug treatment to treat insomnia could effectively reduce the number of sleeping pills taken [17]. Researchers mentioned that showing the discrepancy between recorded data and sleep diaries is more effective than verbal feedback when users monitor themselves [18]; that is, it is necessary to include both score feedback and diary review functions to guide users to double check their conditions. It is, therefore, important to propose an effective approach integrated with wearable devices to assist students in fostering good daily life habits and managing their time.

Figure 1. The self-regulatory learning cycle.



After developing the proposed approach, an experiment was conducted to evaluate the effectiveness of the mobile system with the following questions:

- Is the SMSR mobile learning system useful and easy for users to use?
- Can the SMSR mobile learning system help users to improve their sleep quality and manage their sleep habits actively?
- Can the SMSR mobile learning system that provides indicators and feedback based on the rule-based expert system help users to keep a diary?

Literature Review

Sleep Quality Issues

Sleep problems include difficulty falling asleep and low sleep quality such as insomnia, sleep disturbances, and sleep disorders. Researchers indicated that insomnia negatively impacts both health and psychological well-being [1]. Specifically, sleep problems may also increase the risk of morbidity and mortality [19]. Various studies have found that sleep problems affect the quality of life and daytime energy, and lead to anxiety and depression [1,2,19-21]. In addition, researchers have indicated that sleep problems could be highly associated with several issues such as psychological demands, low recognition, low social support, perception of danger, emotional demands, and work-life imbalance [2], and could influence both older and younger people [19].

Several studies have found that students often suffer from lack of sleep [9,22-24]; these studies also reavealed that suffering from poor sleep quality could greatly impact students' daily life, learning performance, motivation, self-efficacy, and so on. Moreover, some researchers pointed out that students with sleep problems tend to have a low intention to seek help [24].

In the past decades, many studies have investigated sleep medical care issues, and pharmacotherapy is the most frequently used intervention for insomnia [25]. A large portion of these studies have also recommended nondrug treatment; in particular, CBT for insomnia is effective for improving the sleep quality [5,6]. In addition, a study conducted with 3 groups, CBT, pharmacotherapy, and combination therapy, found that the CBT alone had a greater long-term effect on sleep latency and sleep efficiency than the combined treatment group [25]. Researchers argued that the sleep quality of university students is usually impaired because of high academic stress and time management problems [22]. Therefore, improving the sleep quality through CBT, time management, and sleep-related personal traits is a critical issue.

Mobile Technologies for Enhancing Health

With the rapid development of technology, smart devices, such as smartphones, tablets, and all kinds of wearable devices, have become popular all over the world [26]. At the same time, mHealth apps have stepped in [27]. Mobile devices could help with data collection, care delivery, patient communication, and real-time monitoring of health conditions [28]. In addition, mHealth apps have been used as interventions for various diseases. For example, Seiler et al [29] reviewed the treatment of fatigued cancer survivors and found that electronic health interventions appeared to be effective for managing their fatigue. Researchers have also predicted that mHealth and electronic health interventions would play critical roles in future personal care delivery [29]. Moreover, researchers carried out clinical evaluation of an mHealth app for stress management and found that patients who used the mobile classifier and an associated mHealth app were more willing to continue the treatment and significantly improved on measures of stress, anxiety, and anger compared with those who controlled with CBT alone [30].

When it comes to the effective collection of data logs and feedback to users, researchers showed that using a mobile app with a wearable device as a nondrug treatment to treat insomnia could effectively reduce the number of sleeping pills taken [17]. Researchers mentioned that showing the discrepancy between recorded data and sleep diaries is more effective than verbal feedback when users monitor themselves [18]; that is, it is necessary to include both score feedback and diary review functions to guide users to double check their condition. It is, therefore, important to propose an effective approach integrated with wearable devices to assist students in fostering good daily life habits and managing their time. mHealth approaches integrated with mobile apps and wearable device sensors could potentially provide treatment and personal care at a low cost [30]. In their study, mobile apps were used to measure the users' health condition and collected data logs and feedback from users.

Methods

The Design of a Mobile Sleep-Management System Integrating the Self-Regulated Learning Strategy

In this study, a mobile sleep-management system integrating an SRL strategy was developed for use on Android mobile devices. Figure 2 shows the structure of the system. The *self-regulated mechanism* consists of setting sleeping goals and strategies and keeping a sleep diary for morning and evening activities. This module was designed for users to provide their daily behavior information and set their sleep goals. The *wearable device connection module* providing physiological data could help users to keep a diary based on the physiological data provided. The *sleep quality and feedback module* consists of clinical sleep records and clinical sleep assessment. The clinical sleep records are uploaded to the following databases: the user information database containing background information, the self-discipline behavior database containing users' self-regulated behavior data, the sleep portfolio database containing sleep behavior data, and the material database providing health educational materials for users. The clinical sleep assessment provides users with sleeping suggestions, such as guided instructions, for sleep, daily reminders, and daily and weekly feedback.

Figure 2. The sleep-management system based on the self-regulated learning strategy (SMSR) structure. DB: databases.

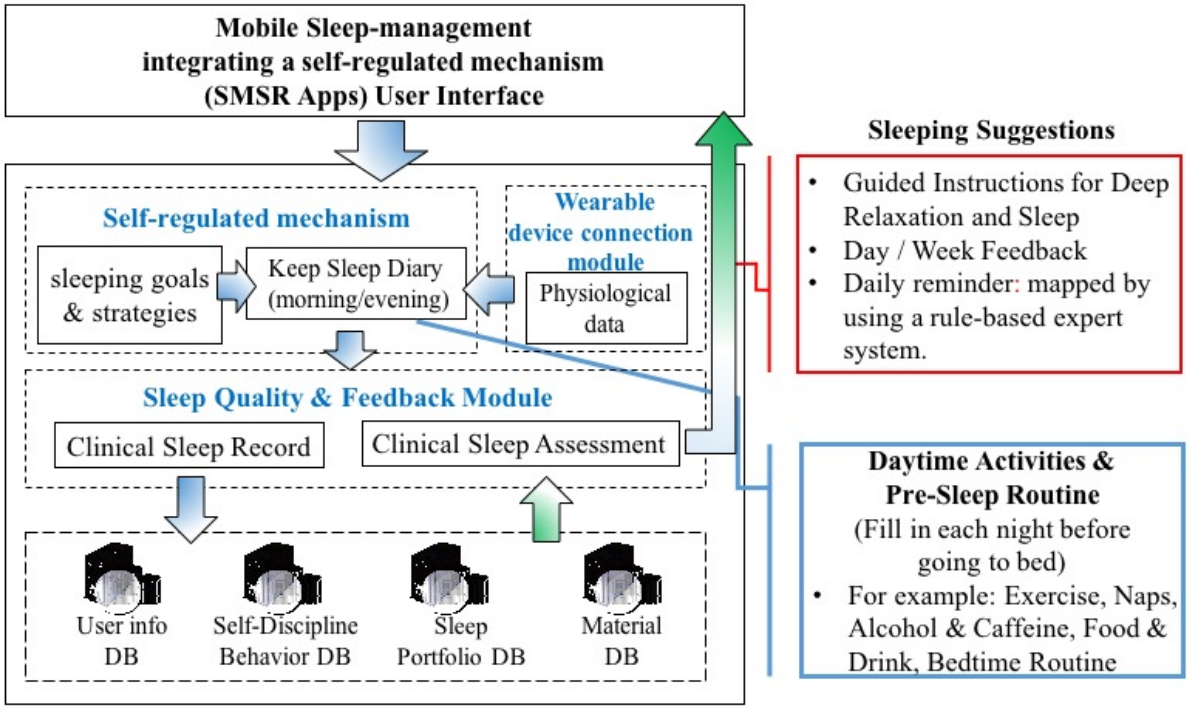


Figure 3 shows the procedure of using the mobile sleep-management system. Users register to use the SMSR and answer several questions for insomnia severity diagnosis. After the initial sleep and health habits evaluation, users will start using the self-regulated model based on their individual condition. The first step is the goal-setting stage; the SMSR lets users set goals for 5 items, namely sleep, exercise, relaxation activities, drinking and eating (including caffeine drinks), and sleep environment. In the second stage, users can set up the strategies they want to follow in the next week. The SMSR system will ask users to keep a diary every day of their activities in the morning and evening for applying their strategies.

In the third stage, the monitoring stage, users keep a diary to meet the goals they set. The SMSR will calculate their self-regulated scores and sleep diagnosis according to the rule-based expert system and their weekly system log. The system then provides the sleep scores to show users' completion of their goals.

In the fourth stage, modifying strategies, users will receive self-regulated scores and sleep suggestions. The SMSR provides sleep suggestions that could diagnose users' sleep quality and lifestyle habits. The information provided will help users in the next-stage goal setting.

By using this SMSR lifestyle strategy, users could see the evaluation of their lifestyle self-regulated performance. At the end of the week, users can modify their strategy more effectively based on the self-regulated scores and sleep suggestions. The SMSR cycle lasts for 7 days, with users receiving feedback from the system every Sunday. After that, they should modify their strategies and set goals for the following week.

Figure 4 shows the main function on the home screen of the SMSR, including goal setting, diary, sleep score, sleep suggestions, and menu buttons.

Figure 5 shows the interface of the goal-setting function. The goals are divided into 5 items, namely, sleep goals, exercise goals, drink and food goals, sleep environment goals, and relaxation activity goals. Users check the goals they want to set, and then fill in the specific content. For example, a user could set a sleep goal and fill in the time he/she will go to sleep by, such as 10 pm. In addition, the goal setting has a light bulb button to help users get proper concepts to support their goal-setting process (Figure 5). For instance, sleep tips will be given such as "taking a bath for half an hour or light music would make your mind relax before sleep."

Figure 6 shows the evening diary interface. Users can click the events that happened during the day and click the button to go to the next page. The diary will be formed according to the events the users clicked, meaning that they can complete the process easily and that the complexity is reduced.

Figure 3. The mobile sleep-management system procedure.

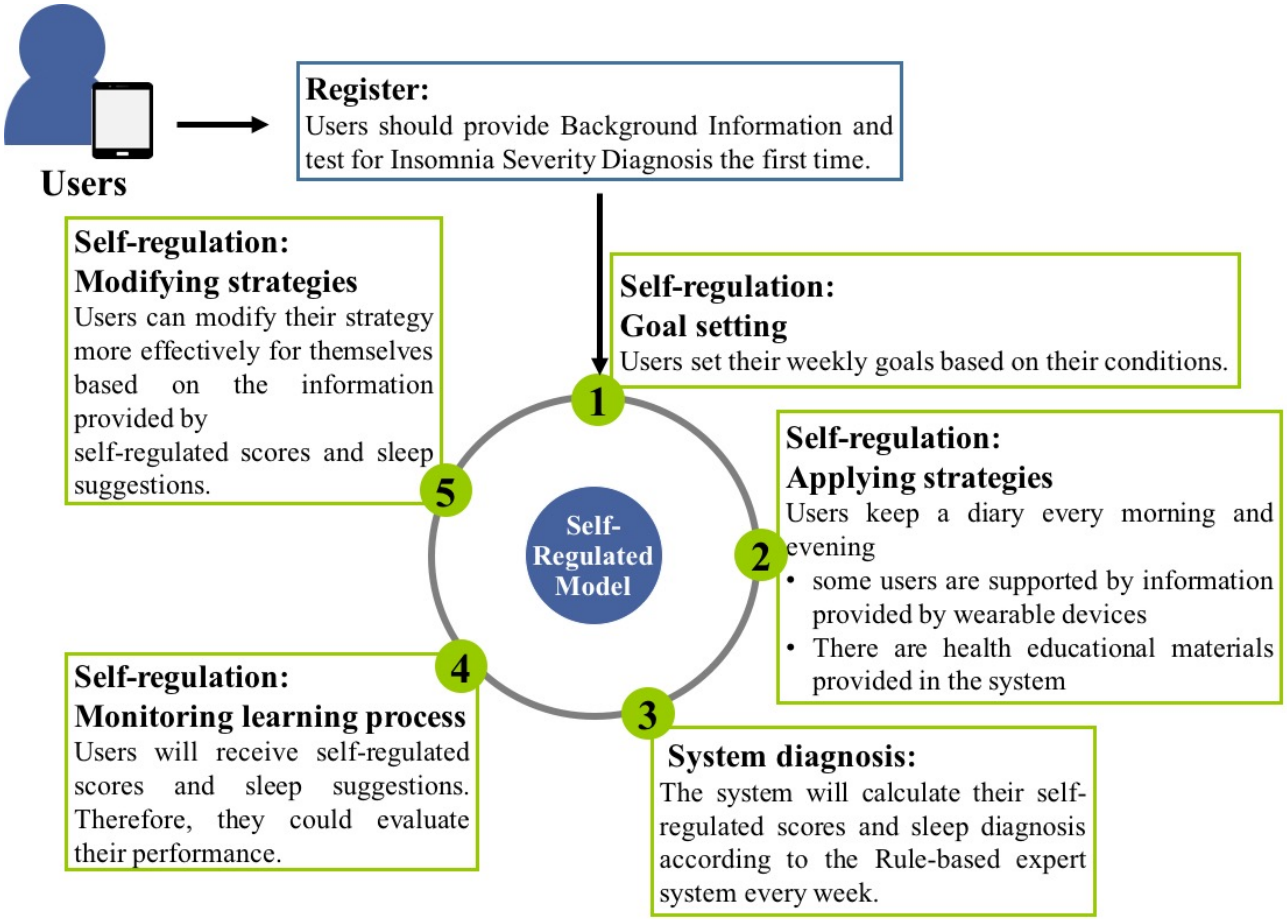


Figure 4. The home screen of the sleep-management system based on the self-regulated learning strategy mobile sleep-management system.

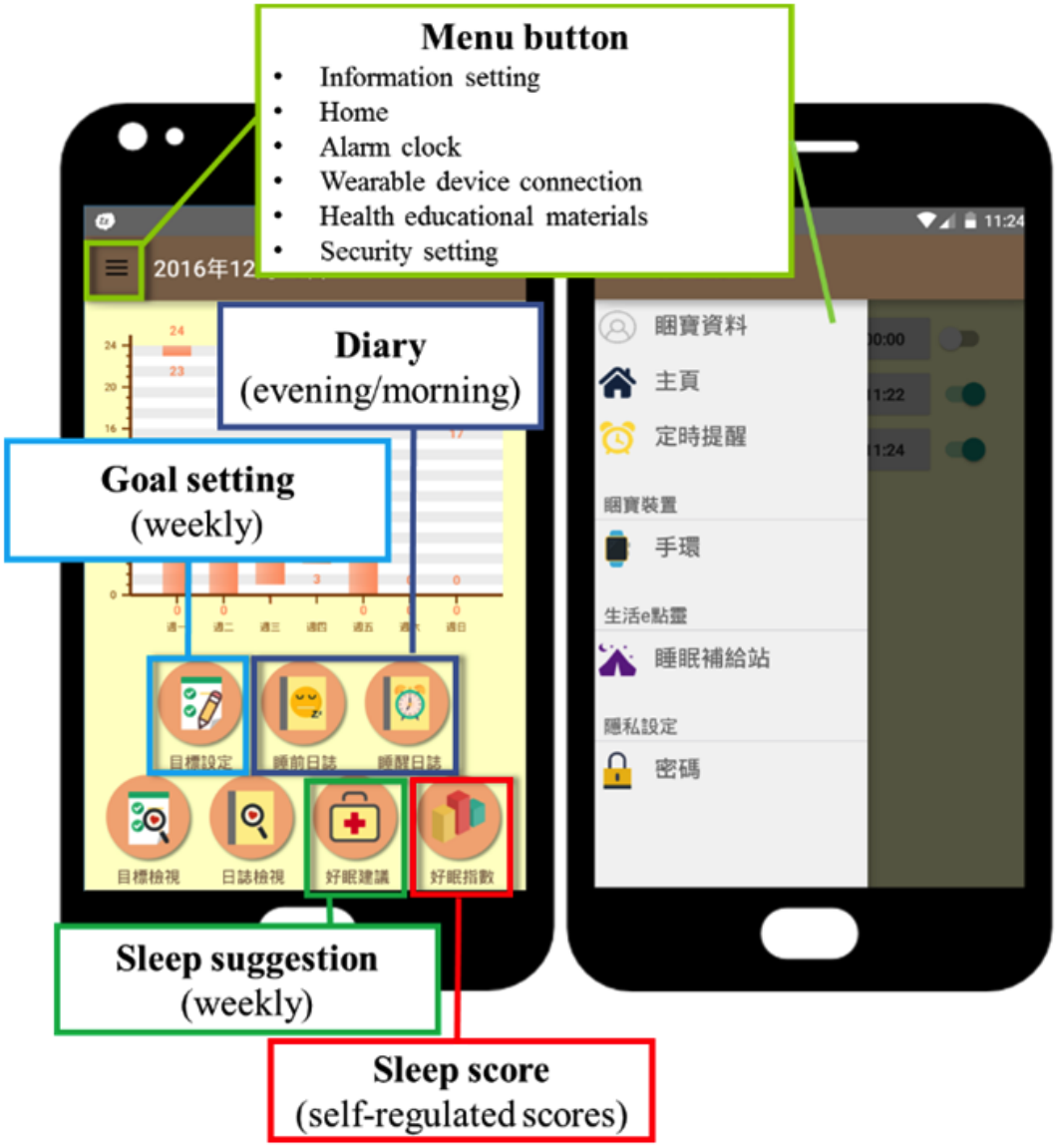


Figure 5. The goal-setting stage interface.

Figure 6. The diary recording interface based on cognitive behavioral therapy for insomnia.

Figure 7. The feedback interface.

Figure 7 shows the feedback interface. Users receive the information every week to learn about their self-regulated performance and sleep suggestions. Figure 7 shows the self-regulated scores calculated by the expert system. Users can have scores for the goal items they set. They can monitor themselves by the feedback of the scores. Figure 7 also shows that users are allowed to modify their strategies based on the sleep suggestions provided by the rule-based expert system.

Experimental Design

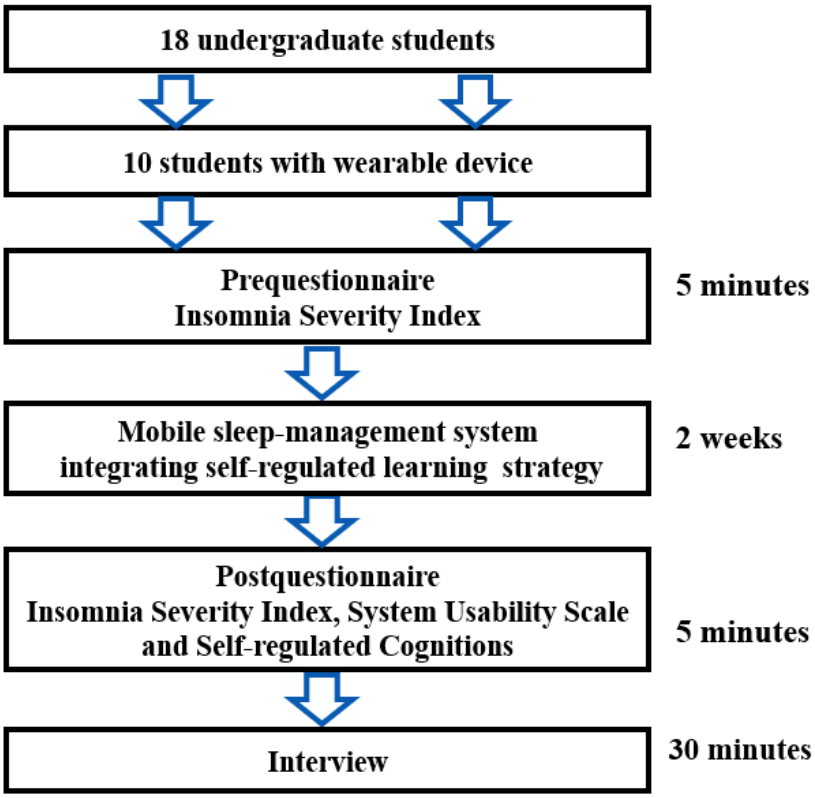
Participants

In this study, participants were undergraduate students from a university in northern Taiwan; there were 18 students, including 3 males and 15 females. Among them, 1 was diagnosed with severe insomnia, 4 with moderate insomnia, and 12 with subthreshold insomnia. Most of them had had experience of sleep disturbance; some of them also mentioned that they had suffered from sleep problems for >3 months. Of 18 participants, 10 used the SMSR with wearable devices, while the other 8 used the SMSR without wearable devices. The participants' average age was 22 years: mean 22 (SD 1.286) years.

Experimental Procedure

Figure 8 shows the experimental procedure. Before students started using the SMSR mobile sleep-management system, they were required to complete the prequestionnaire Insomnia Severity Index (ISI) to identify their sleep conditions. After that, they were asked to use the mobile sleep-management system for 2 weeks. After the 2 weeks, they completed 3 postquestionnaires, the ISI, the content of which was the same as the prequestionnaire, the System Usability Scale (SUS), and the self-regulated cognitions questionnaire. We asked students to complete the ISI for both the pre- and postquestionnaire so that we could compare them to find whether using the mobile sleep-management system could help them improve their sleep quality by self-regulation. Finally, we interviewed students about using the SMSR.

Figure 8. The experimental procedure.



Measuring Tools

The postquestionnaires used in this study were the ISI, SUS, and self-regulated cognition questionnaire. The ISI consists of 5 items with a 5-point Likert scale. The first item is about the current severity of insomnia problems, including difficulty falling asleep, difficulty staying asleep, and problems waking up too early, on a scale of 0 (*None*) to 4 (*Very Severe*). The second item is about satisfaction with the current sleep pattern on a scale of 0 (*Not At All Noticeable*) to 4 (*Very Much Noticeable*). The third item is the degree to which sleep problems are noticeable to others on a scale of 0 (*Not At All Worried*) to 4 (*Very Much Worried*). The fourth item is about worry over your current sleep pattern on a scale of 0 (*Not At All Worried*) to 4 (*Very Much Worried*). The last item is interference of current sleep on a scale of 0 (*Not At All Interfering*) to 4 (*Very Much Interfering*). The total score could sort respondents into 4 groups according to their insomnia severity as follows: absence of insomnia (score range: 0-7); subthreshold insomnia (score range: 8-14); moderate insomnia (score range: 15-21); and severe insomnia (score range: 22-28).

We summed the scores and measured the degree of insomnia, where the higher the score, the more serious the problem [31]. Reportedly, the ISI was used to measure insomnia and found to have a Cronbach alpha of 0.74 [31]; in this study, it reached a Cronbach alpha of 0.77.

The SUS and the questionnaire of self-regulated cognition were developed by 1 experienced teacher and 4 assistants who had used a mobile sleep-management system and wearable devices. The SUS has 4 items. The first is about whether the app is a good way to record daily behavior. The second is about whether the app helps them to reach their goals. The third is whether the users mind if they reach their goals when filling in the diary. The last item is about whether wearable devices help users to fill in the diary faster. The Cronbach alpha was 0.76. Finally, the questionnaire of self-regulated cognition has 4 items about whether the SMSR functions help users with self-regulation. The Cronbach alpha value was 0.88.

The interviews focused on whether the mobile sleep-management system could help build proper sleep concepts and knowledge and improve the users' sleep quality. In addition, we asked those students who used a wearable device with the SMSR whether it improved their motivation, and whether the support system improved their self-regulation.

Results

In this study, a paired *t* test was used to investigate the differences between the pre- and postquestionnaires of the ISI to identify whether there was any improvement in their sleep quality (Table 1). For scale 1 items, "*Difficulty falling asleep*," a significant difference was found (*P*=.04), indicating a decrease in the difficulty of falling asleep for participants. For scale 5, "*To what extent do you consider your sleep problems to INTERFERE with your daily functioning (e.g., mood) CURRENTLY?*", there was a significant difference (*P*=.002); that is, the interference of sleep problems decreased. Scale 6, "*How NOTICEABLE to others do you think your sleep problems are in terms of impairing the quality of your life?*" shows that the mean of the scores decreased when comparing the pre- and postquestionnaires, indicating that participants' sleep problems

reduced (*P*=.005). For scale 7, "*How WORRIED/DISTRESSED are you about your current sleep problems?*," significant differences showed that the worry about sleep problems reduced (*P*=.02). The mean of the total scores decreased to 14.94 from 18.50; that is, the SMSR was successful in reducing the severity of participants' insomnia, and their sleep quality improved as well. Table 2 shows the percentage of people divided into 4 groups according to the degree of insomnia severity. After using the SMSR system, the numbers in the absence of insomnia and subthreshold insomnia groups increased, whereas the numbers in the moderate insomnia and severe insomnia groups decreased.

Table 3 shows the statistics of the SUS. It was found that users thought that using the SMSR could help them keep a diary, and the interface of the SMSR was user-friendly and easy to use, with means of 3.78 and 3.89. In addition, users showed a positive attitude toward wearable devices when using it with the SMSR system, with means of 3.69 and 3.75, indicating that wearable devices could enhance their motivation and provide information about sleep routines to help them know more about their sleeping habits.

After the postquestionnaire for the system usability, students were asked about the usability of the system. Most expressed positive comments on the ease of use and friendly interface of the SMSR system as in the following example:

> *The system interface is very friendly and the provision of system logs is helpful to me for tracing my daily situation. These facilities enable me to understand time management and my sleep routine.*

Table 1. Paired *t* test for the pre- and postquestionnaires of the Insomnia Severity Index.

Items	Pre, mean (SD)	Post, mean (SD)	*t*
Scale 1. Please rate the CURRENT (ie, LAST 2 WEEKS) SEVERITY of your insomnia problem(s). (Q1. Difficulty falling asleep)	2.33 (0.84)	1.78 (0.55)	t_{17}=2.26[a]
Scale 5. To what extent do you consider your sleep problems to INTERFERE with your daily functioning (e.g., mood) CURRENTLY?	3.50 (0.62)	2.61 (0.98)	t_{17}=3.69[b]
Scale 6. How NOTICEABLE to others do you think your sleep problems are in terms of impairing the quality of your life?	2.83 (1.15)	2.00 (1.19)	t_{17}=3.22[b]
Scale 7. How WORRIED/DISTRESSED are you about your current sleep problems?	3.11 (0.96)	2.33 (1.08)	t_{17}=2.61[a]

[a]p<.05.
[b]p<.01.

Table 2. Paired *t* test for the pre- and postquestionnaires of the Insomnia Severity Index.

Level of insomnia	Before experiment (%)	After using SMSR[a] (%)	Difference (%)
Absence of insomnia (total score: 0-7)	0	5.5	>5.5
Subthreshold insomnia (total score: 8-14)	5.5	55.6	>50.1
Moderate insomnia (total score: 15-21)	77.8	27.8	−50
Severe insomnia (total score: 22-28)	16.7	11.1	−5.6

[a]SMSR: sleep-management system based on the self-regulated learning strategy.

Table 3. Statistics of the System Usability Scale (n=18).

Items	Mean (SD)
Scale 1: I think it's quite nice to log my daily diary using the SMSR.	3.78 (0.65)
Scale 2: I think the SMSR interface is user-friendly and easy to use.	3.89 (0.96)
Scale 3: Wearable devices let me know more about my sleep routine.	3.69 (1.03)
Scale 4: Wearable devices can motivate me to modify my sleep routine.	3.75 (1.14)

[a]SMSR: sleep-management system based on the self-regulated learning strategy.

Table 4. The statistics of self-regulated cognition (n=18).

Scale and items	Mean (SD)
Scale 1. Goal setting	
Q1. Setting the goals (eg, sleep goals, exercise goals) could make me pay more attention to my daily routine.	3.89 (0.32)
Q2. It could make me modify my daily routine according to the goals (eg, sleep goals, exercise goals).	3.94 (0.64)
Q3. The light bulb hint could help me know proper life routines.	3.56 (0.62)
Scale 2. Applying strategies	
Q1 The evening/morning diaries make me notice my life routine.	4.00 (0.69)
Q2 The evening/morning diaries force me to reach my goals.	3.78 (0.65)
Q3 I will be more attentive to whether I reach the goals when keeping a diary.	4.00 (0.69)
Q4 Wearable devices could help me keep the diary.	3.83 (1.19)
Scale 3. Monitoring process	
Q1 The sleep scores make me notice more about my life routine.	3.78 (1.11)
Q2 Sleep scores can help me modify my life routine.	3.50 (1.10)
Q3 Sleep scores can help me improve my sleep quality.	3.44 (0.98)
Scale 4. Modifying strategies	
Q1 Sleep suggestions could make me notice my life routine.	3.83 (1.15)
Q2 Sleep suggestions could let me know my status of reaching goals.	3.78 (1.06)
Q3 Sleep suggestions could help me modify my strategies.	3.78 (1.00)

Table 4 presents the statistical results for the questionnaire of self-regulated cognition. For scale 1, "*goal setting*," the mean scores were >3.5, showing that most users agreed with keeping a diary by the SMSR. For scale 2, "*Applying strategies*," the items of "*The evening/morning diaries make me notice my life routine*" and "*I will be more attentive to whether I reach my goals when keeping a diary*" have mean scores of 4, indicating that the SMSR could help users notice their life routine and whether they reach their goals. Every mean score in scale 3 was >3, indicating that sleep scores could help users to monitor themselves. For scale 4, "*modifying strategies*" shows that every mean score was >3.5; that is, sleep suggestions help modify the strategies for the coming week. For the self-regulated cognition, students expressed their ideas about the self-regulated strategy embedded in the CBT in the interview process, with one respondent stating:

> *The system could guide me to achieve better sleeping quality step-by-step by means of the self-regulated strategy. I think it is quite an important factor to manage our own sleeping behaviors and monitor time management ourselves, which is a potential way to enhance sleep-related traits.*

Specifically, 10 students who used the SMSR with wearable devices were surveyed to identify the extent to which the wearable devices facilitated the execution of the plan. There were totally 3 questions for students, including 2 items for the usability of the devices, and 1 for the diary record, as shown in Table 5. Each mean score for the 3 items was >4.0, showing that most of them agreed with the usability of SMSR with a wearable device for recording their sleep routine and keeping a diary.

For the usability of a wearable device, most of them expressed positive comments on the functions of the SMSR system with the wearable device, as below:

> *The wearable device enables me to know and adjust my sleep routine easily. That really helps me pay attention to my sleep situation.*

Table 5. The statistics of the usability of the sleep-management system based on the self-regulated learning strategy (SMSR) with wearable devices (n=10).

Items	Mean (SD)
Q1. Wearable devices let me know more about my sleep routine.	4.00 (0.67)
Q2. Wearable devices provide motivation for me to modify my sleep routine.	4.10 (0.74)
Q3. Wearable devices could help me keep the diary.	4.20 (0.79)

Discussion

Prinicpal Findings

In this study, a mobile sleep-management system integrating SRL strategies, named the SMSR, was designed and tested; it was designed on the basis of most well-known CBT for insomnia and the effective learning strategy, SRL [15,32].

From the experimental results, it was found that the proposed systems effectively reduced students' worry about their sleep problems. To sum up, the SMSR mobile system is easy to use and useful to users according to the SUS. It seems that users are satisfied with the SMSR interface and think it is easy to use. Moreover, it could help users to improve their sleep quality and manage their sleeping habits on their own by providing them with sleep scores and sleep suggestions, as indicated elsewhere [18]. The well-designed feedback in the mHealth app could help users monitor themselves by providing logging information. According to the findings, the SMSR helps the most in the applying strategies phase; it could also provide indicators and feedback based on the rule-based expert system to help users keep a diary. The researchers found that those who used mobile apps and stress algorithm were more likely to complete their goals and demonstrated reduced stress and anger compared with the control group. It can be inferred from the results that the SMSR integrated with CBT and the SRL strategy helped enhance users' cognition of sleep hygiene; this finding is consistent with that reported in another study [33], showing that CBT integrated with mobile apps would be a positive treatment for patients with insomnia. On the other hand, this study also found that users could gain benefits by using the SRL strategy integrated with a mobile app, no matter whether they were using wearable devices or not; this implies that the guidance provided in the self-monitoring process could help users be aware of their own situations and, hence, improve their sleep quality. Therefore, it is suggested that researchers not only need to develop innovative technologies but also need to focus on how to cultivate patients' living habits by using efficient autonomy-learning strategies.

Researchers also pointed out that mHealth approaches integrated with mobile apps and wearable device sensors could potentially provide treatment and personal care at a low cost [30]. The SMSR integrated with CBT, and the SRL strategy could help students manage their sleep time, monitor the extent to which their goals are achieved, and modify their strategies accordingly for the coming week; this finding is consistent with that of another study [22], indicating that university students may significantly improve their sleep quality and sleep-related personality traits. Furthermore, some studies reported similar findings, showing that the use of mobile devices could improve users' management of their sleep hygiene and quality [34].

Conclusions

It is found that few students seek help for sleep problems. In this study, the SMSR may help students reduce their sleep problems by self-regulation [24]. Based on the preliminary findings of this pilot study, we will increase the number of the targeted population and keep collecting more qualitative and quantitative evidence for the proposed model regarding the sleep quality of university students. Moreover, researchers aimed to predict the sleep quality by analyzing the data collected by a wearable medical device using deep learning [35]. It may be an important issue in the future to integrate deep learning techniques into this study to analyze users' behavior patterns and analyze how users reach or lose the goal for improving their sleep quality. It is expected that the proposed model could be applied in clinical settings for patients with insomnia.

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Authors' Contributions

HCC conceived and designed the study. YML designed and developed the system. HCC and YML drafted the manuscript. FRK critically reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 1MB - CONSORT-EHEALTH(V1.6.1)-Submission_Publication_Form.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
ISI: Insomnia Severity Index
SMSR: sleep-management system based on the self-regulated learning strategy
SRL: self-regulated learning
SUS: System Usability Scale

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Original Paper

The Web-Based Physician is Ready to See You: A Nationwide Cross-Sectional Survey of Physicians Using a Mobile Medical App to Evaluate Patients With Sexually Transmitted Diseases in China

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Abstract

Background: Web-based medical service provision is increasingly becoming common. However, it remains unclear how physicians are responding to this trend and how Web-based and offline medical services are linked.

Objective: The objectives of this study were to examine physicians' use of mobile medical apps for sexually transmitted disease (STD) consultations and identify the physicians who frequently use mobile medical apps to evaluate patients with STD.

Methods: In August 2017, we conducted a nationwide cross-sectional survey among physicians registered on a mobile medical app in China. We collected data on physicians' demographic information, institutional information, and Web-based medical practices. We compared physicians who used mobile medical apps to evaluate patients with STD frequently (at least once a week) with infrequent users. Bivariate and multivariate logistic regressions were used to identify physicians who frequently evaluated patients with STD on mobile medical apps.

Results: A total of 501 physicians participated in the survey. Among them, three-quarters were men and the average age was 37.6 (SD 8.2) years. Nearly all physicians (492/501, 98.2%) recommended their last Web-based patient with STD to subsequently see a physician in the clinic. More than half (275/501, 54.9%) of physicians recommended STD testing to Web-based patients, and 43.9% (220/501) provided treatment advice to patients with STD. Of all physicians, 21.6% (108/501) used mobile medical apps to evaluate patients with STD through Web more than once a week. Overall, 85.2% (427/501) physicians conducted follow-up consultation for patients with STD using mobile medical apps. Physicians working at institutions with STD prevention materials were associated with frequent evaluation of patients with STD on mobile medical apps (adjusted odds ratio=2.10, 95% CI 1.18-3.74).

Conclusions: Physicians use mobile medical apps to provide a range of services, including Web-based pre- and posttreatment consultations and linkage to offline clinical services. The high rates of referral to clinics suggest that mobile medical apps are used to promote clinic-seeking, and not replace it. Physicians' use of mobile medical apps could benefit sexual minorities and others who avoid formal clinic-based services.

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KEYWORDS

STD; physician; mobile app; China; mobile phone; mHealth

Introduction

In recent years, the growth of mobile health (mHealth) technology has created new ways for physicians to evaluate and follow-up patients. Physicians now use smartphone mobile medical apps to counsel patients, recommend testing, write prescriptions, and monitor them after clinical visits [1,2]. In addition, mobile medical apps provide physicians a tool to communicate with patients, contact other physicians in their network, follow trends in their specialties, and streamline office workflow [3,4]. Globally, mobile medical apps are an emerging technology [5], with physician users in developed (eg, the United States and the United Kingdom) [6-8] and developing countries (eg, Turkey and rural South Africa) [9,10].

Despite the proliferation of omnibus usage, mobile medical apps may particularly appeal to male patients seeking care for sexually transmitted diseases (STDs). Young men are less likely than their female counterparts to discuss sexual health, STD risk reduction, and relationships during routine clinic visits [11]. Patients seeking STD care are often reluctant to seek health care due to concerns about inhospitable clinical environments and perceived lack of confidentiality [12,13]. Meanwhile, Web-based environments provide relative convenience, low price, and anonymity for patients compared with seeing a physician in-person [13,14].

Smartphone use is rising rapidly around the world, especially in China and other low- and middle-income countries. In China, smartphone ownership among adults aged 18-34 years reached 93% in 2015 [15]. In addition, mobile medical apps are rapidly developing, with substantial growth rates each year [16]. However, little is known about physicians' use of mobile medical apps for communicating with patients in China. Mobile medical apps have the potential to facilitate physician-patient interactions and promote linkage to care, that is, Web-based patients with an STD who receive in-person treatment [17,18]. The functions of mobile medical apps may include the following: appointment-making (free); medical education and scholarly articles (free); and telemedicine, such as Web-based pretreatment consultation and posttreatment consultation (fee for service) [16]. Mobile medical apps can allow patients living in remote areas to consult physicians in first-tier cities via phone, short message service (SMS) text message, or image. Furthermore, patients can save time from waiting in queues and traveling to facilities for in-person consultations.

In this study, we describe physicians who have evaluated male patients with STD through a mobile medical app in China. Physicians who frequently use mobile medical apps to evaluate patients might play crucial roles in expanding STD services as they could provide some knowledge and information to those patients who are concerned about inhospitable clinical environments and perceived lack of confidentiality. We aimed to examine physicians' use of mobile medical apps, for example, physician reasons for using apps and the linkage between Web-based consultation and offline practice and also investigate factors associated with physicians' frequent use of mobile medical apps.

Methods

Study Design, Setting, and Participants

We conducted a cross-sectional, nationwide Web-based survey from August 14 to August 23, 2017. We partnered with Xingren Doctor app (Xingren app), a popular mobile medical app in China, for participant recruitment (Multimedia Appendix 1). The app has >400,000 unique, verified physician users since its launch in 2014 and allows physicians to communicate with their patients remotely. Eligible physicians were those who practiced in specialties that had a higher chance of managing patients with STD, that is, dermatovenereology, urology, proctology, internal medicine, pediatrics, infectious disease, and general practice. We chose to select 500 physicians because of feasibility considerations and discussions with the physician app. A total of 120,126 physicians were registered in these specialties on the Xingren app. We distributed the participation link to physicians through the app messaging system, excluding users who had not logged into the app in the past 6 months. The whole distribution was conducted in 4 rounds. Randomization algorithms with RIGHT and RANDBETWEEN functions in Excel were used to select the identity numbers of physicians to distribute the survey link. After receiving the survey link, physicians who were interested in participation could click the survey link, which would direct them to a Web-based survey hosted on Sojump, a popular Web-based survey tool in China.

Eligible physicians included those who had seen at least 1 male patient with STD in the past 12 months. We aimed to exclude physicians who only evaluated female patients with STD (largely gynecologists), but who never managed any male patients with STD. We chose to focus on examining the last male patients with STD seen by physicians as we were particularly interested in physicians' practice to ask about men's sexual behavior, condom use, and history of STDs. Participants were asked to sign an electronic informed consent form before starting the survey. Eligible participants received a small financial incentive (~US $4.50) for their participation.

Variables

Our survey instrument included domains of sociodemographic information, clinic information, clinical practice with male patients with STD, and use of mobile medical apps. The outcome variable was the binary variable of the frequency at which physicians saw patients with STD using mobile medical apps (more than once a week vs less than once a week). The exposure variables included physicians' sociodemographic information, clinic information, and clinical practice with male patients with STD.

Quantitative Variables

We assessed the frequency of using mobile medical apps to evaluate patients with STD among physicians as a binary outcome variable to compare physicians who saw patients with STD more or less than once a week (frequent users vs infrequent users) [19]. Physicians who use mobile medical apps to frequently evaluate patients at this stage tend to be early adopters of new mHealth care technologies [20]. Examining the early adoption behaviors can inform the further adoption among other STD physicians.

Measures

Physicians' sociodemographic characteristics included age, sex, education, and medical specialty. Physicians' clinic information included the following data: type of affiliated medical institution, level of care (primary, secondary, or tertiary), type of hospital (public or private), availability of condoms and lubricants, and availability of STD prevention pamphlets. Physicians' clinical practices with male patients with STD regarding obtaining sexual histories and addressing risk reduction were asked, such as whether they asked about patients' sexual experience with other men or transgender individuals and whether they recommended patients to test for STDs (HIV and syphilis) [21].

Furthermore, physicians were asked about their use of mobile medical apps (including but not limited to the Xingren app) to provide medical services. All physicians were asked about their reasons for using mobile medical apps for consultations and how the Web-based advice service was connected with their offline clinical services.

Furthermore, we collected data on physicians' Web-based consultation behaviors. We defined consultations as interactions that provided medical advice to patients either in real-time or in a delayed manner. We assessed physicians' experience in whether they had used mobile medical apps to provide initial consultation or follow-up consultation through Web in the last 12 months. We assessed whether physicians recommended HIV or STD testing and provided treatment advice for a patient, based only on a Web-based encounter without seeing a physician in-person. Moreover, we asked whether physicians conducted any follow-up consultations through Web after an initial in-person clinical encounter. The questions about how the Web-based consultation services were linked with their offline medical services were also asked. The approaches of linkage included third-party medical platforms, the medical institutions' services on WeChat (which is the most popular social media platform in China), the clinic's self-developed Web-based physician-patient communication platform, or others.

In addition, we asked physicians to recall their use of mobile medical apps with their last Web-based patient with STD. We assessed the medium (ie, through SMS text message, image, audio, or video) that physicians used to assess their patient's STD symptoms and the time physicians spent on the mobile medical apps to evaluate their patients. Besides, we asked physicians whether they felt more or less comfortable to ask the patients' experiences on sexual behaviors, condom use, and history of STDs compared with during an in-person consultation. Physicians were asked whether they asked their patients to visit a hospital or a clinic in-person after the Web-based consultation. The survey was designed and reported following the Checklist for Reporting Results of Internet E-Surveys [22]. Overall, 15 individuals were pretested, and their feedback was incorporated into the final survey.

Study Size

Overall, the survey link was distributed to 8098 physicians, and 1556 physicians opened the survey link. Among the 701 physicians who started the survey, 2 did not provide informed consent, 186 were excluded for having not seen at least 1 male patient with STD in the past 12 months, and another 12 surveys were invalidated due to a survey instrument error. Eventually, 501 physicians fulfilled eligibility criteria and completed the survey and were included in our data analysis.

Ethics Statement

We obtained approval for this study from the ethics review committee to ensure participants' confidentiality and anonymity at the Nanshan Center of Chronic Disease Control, Shenzhen, China (ll20170016) prior to survey launch.

Statistical Analysis

Descriptive statistics were used to describe physicians' sociodemographic information, medical institution information, medical practice experiences, and usage of mobile medical apps. We conducted bivariate and multivariate analyses using SPSS software (IBM SPSS Inc) to examine factors associated with physicians who saw patients with STD more than once a week. In addition, chi-square test and *t* test were used to compare the physicians who used mobile medical apps to evaluate patients with STD at least once a weak with those who did less than once a weak. Multivariable logistic regression models were adjusted for potential confounding variables, including age (continuous variable), sex, and education, as informed by previous studies [23,24].

Results

Physicians' Personal, Institutional, and Behavioral Characteristics

The average age of the 501 physicians was 37.6 (SD 8.2) years, of whom 53.9% (270/501) were in the age range of 35-50 years. The majority of them (376/501, 75.0%) were men. Less than one-tenth (36/501, 7.2%) of physicians had an associate's degree, 39.5% (198/501) had a bachelor's degree, 43.1% (216/501) had a master's degree, and 10.2% (51/501) had a PhD degree. The most common subspecialty was dermatovenerology (166/501, 33.1%), followed by urology (151/501, 30.1%), and general medicine (72/501, 14.4%).

Table 1. Personal, institutional, and behavioral characteristics of physicians who saw male patients with sexually transmitted diseases (STDs) in the past 12 months in China, 2017 (N=501).

Characteristics	Values
Personal characteristics	
Age (years), mean (SD)	37.6 (8.2)
Age group (years), n (%)	
18-34	191 (38.1)
35-50	270 (53.9)
51-69	38 (7.6)
>70	2 (0.4)
Sex, n (%)	
Male	376 (75.0)
Female	125 (25.0)
Education, n (%)	
Associate degree	36 (7.2)
Bachelor	198 (39.5)
Master	216 (43.1)
PhD	51 (10.2)
Specialty, n (%)	
Dermatovenerology	166 (33.1)
Urology	151 (30.1)
General medicine[a]	72 (14.4)
Proctology	41 (8.2)
Infectious Disease	34 (6.8)
Others	37 (7.4)
Institutional characteristics, n (%)	
Level of care	
Primary	34 (6.8)
Secondary	145 (28.9)
Tertiary	322 (64.3)
Type of medical institute	
Public	449 (89.6)
Private	52 (10.4)
Free condom and lubricants available	
Yes	260 (51.9)
No	241 (48.1)
STD prevention pamphlets available	
Yes	377 (75.2)
No	124 (24.8)
Offline medical practice in the last 12 months, n (%)	
Had seen men who have sex with men patients with STD	
Yes	267 (53.3)
No	234 (46.7)
Had seen transgender patients with STD	

Characteristics	Values
Yes	92 (18.4)
No	409 (81.6)
Asked about condom use all the time	
Yes	136 (27.1)
No	365 (72.9)
Recommended STD testing[b] all the time	
Yes	211 (42.1)
No	290 (57.9)

[a]General medicine includes internal medicine, general practice, and pediatrics.

[b]STD testing means HIV testing and syphilis testing.

Most physicians worked at tertiary care medical institutions (322/501, 64.3%), 28.9% (145/501) worked at secondary care medical institutions, and only 6.8% (34/501) worked at primary care medical institutions. The majority of physicians (449/501, 89.6%) worked at public hospitals and only 10.4% (52/501) worked in private hospitals. Nearly half (260/501, 51.9%) of the institutions where physicians worked provided free condom and lubricants to patients. Three-quarters (377/501, 75.2%) of individuals reported that their medical institutions had STD prevention pamphlets or educational materials.

Slightly more than half (267/501, 53.3%) of physicians had seen men who have sex with men (MSM) patients with STD and 18.4% (92/501) had seen transgender patients with STD in the last 12 months. Around one-quarter of physicians (136/501, 27.1%) asked about condom use all the time during patient encounters, and less than half of physicians (211/501, 42.1%) recommended STD testing for patients all the time in outpatient settings (Table 1).

Physicians' Usage of Mobile Medical Apps

Among all physicians, 6.2% (31/501) used mobile medical apps to evaluate patients with STD through Web several times a day, 2.8% (14/501) used once a day, 12.6% (63/501) used once a week, 21.2% (106/501) used once a month, 14.2% (71/501) used once every 3 months, and 42.9% (216/501) used less than once every 3 months. Overall, 21.6% (108/501) physicians used mobile medical apps to evaluate patients with STD through Web at least once a week (frequent users). The most commonly cited reason to adopt mobile medical apps was convenience (435/501, 86.8%), followed by usefulness (231/501, 58.1%), novelty (205/501, 40.9%), and extra money (155/501, 30.9%).

More than half of the physicians surveyed (275/501, 54.9%) recommended HIV or STD testing and 43.9% (220/501) provided treatment advice for patients with STD through Web via mobile medical apps in the past 12 months. Of all physicians, 85.2% (427/501) had seen a patient with STD in-person first and then had a Web-based follow-up conversation.

About one-quarter (127/501, 25.3%) of all physicians reported that their Web-based services were organized by the clinics where they saw patients with STD in-person. Of these, nearly half (55/127, 43.3%) of the Web-based services were implemented through third-party platforms. Furthermore, WeChat services (40/127, 31.5%), clinics' Web-based physician-patient communication platforms (25/127, 19.7%), and others (7/127, 5.5%) were used.

Regarding physicians' last encounter with male patients with STD on mobile medical apps, most patients (455/501, 90.8%) used SMS text message to describe symptoms, 77.0% (386/501) used an image, 30.5% (153/501) used audio, and 5.2% (26/501) used video. More than three-quarters (394/501, 78.6%) of patients used more than one medium of communication. The majority (432/501, 86.2%) of physicians felt more comfortable on mobile medical apps asking about sexual behaviors, condom use (429/501, 85.5%) and STD history (429/501, 85.5%) compared with asking in-person (Multimedia Appendix 2). Physicians, on average, spent 10 minutes (interquartile range: 5.5-20 minutes) to provide Web-based consultation or advice on treatment to the last seen male patient with STD. Nearly all (492/501, 92.8%) physicians recommended the last seen Web-based patient to visit clinics in-person after the Web-based consultation (Table 2).

Correlates of Evaluating Male Patients With Sexually Transmitted Disease Using Mobile Medical Apps

The odds of being a frequent user of mobile medical apps was greater for those who worked at institutions with STD prevention materials (odds ratio [OR]=2.18, 95% CI 1.23-3.87) and those who had seen an MSM patient with STD in the last 12 months (OR=1.58, 95% CI 1.02-2.44). Multivariate analyses showed that physicians who worked at institutions with STD prevention materials (adjusted odds ratio [aOR]=2.10, 95% CI 1.18-3.74) and saw MSM patients with STD in the last 12 months (aOR=1.66, 95% CI 1.06-2.58) were associated with frequent evaluation of patients with STD more than once a week on mobile medical apps (Table 3).

Table 2. Usage of mobile medical apps among physicians who saw male patients with sexually transmitted diseases (STDs) in the past 12 months in China, 2017 (N=501).

Characteristics	Values
General usage of mobile medical apps with patients with STD, n (%)	
Frequency of using mobile medical apps to see male patients with STD	
At least once a week	108 (21.6)
Less than once a week	393 (78.4)
Reasons to adopt mobile medical apps	
Convenience	435 (86.8)
Usefulness	291 (58.1)
Novelty	205 (40.9)
Extra money	155 (30.9)
Trendiness	96 (19.2)
Others	17 (3.4)
Recommended STD testing for Web-based patients	
Yes	275 (54.9)
No	226 (45.1)
Provided treatment advice for Web-based patients	
Yes	220 (43.9)
No	281 (56.1)
Conducted follow-up consultation through Web	
Yes	427 (85.2)
No	74 (14.8)
The clinic itself as an organizer of Web-based services	
Yes	127 (25.3)
No	374 (74.7)
The linkage between Web-based and offline medical services	
Through the clinic's WeChat page	40 (31.5)
Through the clinic's Web-based physician-patient communication platform	25 (19.7)
Through a third-party platform	55 (43.3)
Others	7 (5.5)
Usage of mobile medical apps with the last seen male patient with STD	
Media used by patients to describe symptoms, n (%)	
Short message service text message	455 (90.8)
Image	386 (77.0)
Audio	153 (30.5)
Video	26 (5.2)
Felt more comfortable using mobile medical apps to ask about sexual behavior compared with in-person, n (%)	
Yes	432 (86.2)
No	69 (13.8)
Felt more comfortable using mobile medical apps to ask about condom use compared with in-person, n (%)	
Yes	429 (85.5)
No	72 (14.4)
Felt more comfortable using mobile medical apps to ask about STD experiences compared with in-person, n (%)	

Characteristics	Values
Yes	429 (85.5)
No	72 (14.4)
Time spent on providing consultation or treatment to the patient (in minutes), mean (SD)	13.86 (SD 12.74)
Asked the patient to visit a hospital or clinic in-person, n (%)	
Yes	492 (98.2)
No	9 (1.8)

Table 3. Factors associated with the frequency of using mobile medical apps to evaluate male patients with sexually transmitted diseases (STDs) among physicians in China, 2017 (N=501).

Characteristics	Using mobile medical apps to evaluate male patients with STD		*t* test or chi-squared test	*df* [a]	Bivariate or multivariate logistical regression	
	At least once a week, n (%)	Less than once a week, n (%)			Odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Age (years)	38.7 (8.1)[b]	37.25 (8.2)[b]	1.6[c]	499	1.02 (1.00-1.05)	N/A[d]
Sex						
Male	86 (79.6)	290 (73.8)	1.5[e]	1	1.39 (0.83-2.33)	
Female	22 (20.4)	103 (26.2)			Ref[f]	
Education						
Associate degree	10 (9.3)	26 (6.6)	2.4[e]	3	2.07 (0.72-5.91)	
Bachelor	46 (42.6)	125 (38.7)			1.63 (0.71-3.71)	
Master	44 (40.7)	172 (43.8)			1.38 (0.60-3.14)	
PhD	8 (7.4)	43 (10.9)			Ref	
Specialty						
Dermatovenerology	54 (50.0)	112 (28.5)	30.5[e,g]	5	1.50 (0.66-3.40)	1.50 (0.65-3.46)
Urology	34 (31.5)	117 (29.8)			0.90 (0.39-2.10)	0.74 (0.31-1.75)
Proctology	6 (5.6)	35 (8.9)			0.53 (0.17-1.68)	0.47 (0.15-1.49)
General medicine	2 (1.9)	70 (17.8)			0.09 (0.02-0.44)[h]	0.08 (0.07-0.39)[h]
Infectious Diseases	3 (2.8)	31 (7.9)			0.30 (0.07-1.23)	0.28 (0.07-1.14)
Others	9 (8.3)	28 (7.1)			Ref	Ref
Level of care						
Primary	7 (6.5)	27 (6.9)	1.3[e]	2	1.03 (0.43-2.46)	0.86 (0.34-2.18)
Secondary	36 (33.3)	109 (27.7)			1.31 (0.82-2.08)	1.19 (0.70-2.02)
Tertiary	65 (60.2)	257 (65.4)			Ref	Ref
Type of medical institute						
Public	98 (90.7)	351 (89.3)	0.2[e]	1	1.17 (0.57-2.42)	1.41 (0.65-3.06)
Private	10 (9.3)	42 (10.7)			Ref	Ref
Free condom and lubricants available						
Yes	63 (58.3)	197 (50.1)	2.3[e]	1	1.39 (0.91-2.14)	1.38 (0.89-2.13)
No	45 (41.7)	196 (49.9)			Ref	Ref
STD prevention pamphlets or educational materials available						
Yes	92 (85.2)	285 (72.5)	7.3[e,h]	1	2.18 (1.23-3.87)[h]	2.10 (1.18-3.74)[i]
No	16 (14.8)	108 (27.5)			Ref	Ref
Had seen men who have sex with men patients with STD in the last 12 months						
Yes	67 (62.0)	200 (50.9)	4.2[e,i]	1	1.58 (1.02-2.44)[i]	1.66 (1.06-2.58)[i]
No	41 (38.0)	193 (49.1)			Ref	Ref
Had seen transgender patients with STD in the last 12 months						
Yes	21 (19.4)	71 (17.1)	0.1[e]	1	1.10 (0.64-1.88)	1.08 (0.63-1.88)
No	87 (80.6)	322 (77.2)			Ref	Ref
Recommended STD testing for Web-based patients						

Characteristics	Using mobile medical apps to evaluate male patients with STD		*t* test or chi-squared test	*df* [a]	Bivariate or multivariate logistical regression	
	At least once a week, n (%)	Less than once a week, n (%)			Odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Yes	67 (62.0)	208 (52.9)	2.8[e]	1	1.45 (0.94-2.25)	1.37 (0.88-2.13)
No	41 (38.0)	185 (47.1)			Ref	Ref
Provided treatment advices for Web-based patients						
Yes	63 (58.3)	157 (39.9)	11.6[e,h]	1	2.10 (1.37-2.24)[g]	2.10 (1.36-3.25)[h]
No	45 (41.7)	236 (60.1)			Ref	Ref
Ever conducted follow-up consultation through Web						
Yes	104 (96.3)	323 (82.2)	13.4[e,g]	1	5.64 (2.01-15.81)[g]	5.93 (2.10-16.79)[g]
No	4 (3.7)	70 (17.8)			Ref	Ref

[a]*df*: degrees of freedom.
[b]Mean (SD).
[c]*t* test.
[d]N/A: not applicable.
[e]Chi-squared test.
[f]Using mobile medical apps to evaluate patients with STD less than once a week as the reference group; Ref: reference group.
[g]*P*<.001.
[h]*P*<.01.
[i]*P*<.05.

Discussion

Principal Findings

Web-based medical services are becoming increasingly common [25]. We described how physicians in China use mobile medical apps to evaluate patients with STD and how Web-based consultations are linked to offline medical services, contributing to the emerging eHealth field from a physician's perspective. This study expands on previous studies by examining physicians' frequency of using mobile medical apps to evaluate patients, by exploring how Web-based recommendations correlate with in-person clinic visits, and by focusing on Web-based medical services.

Use of mobile medical apps by physicians to provide medical services is a growing trend. This study found a higher rate of physicians frequently using mobile medical apps to see patients with STD (108/501, 21.6%) compared with a study in Canada (14%) [26]. Chinese physicians are directly incentivized to provide services through the mobile app, receiving approximately US $3 (range, US $0-$30) per Web-based consultation [27]. A survey of urologists in the United States found that 28% used mobile medical apps for professional purposes [28]. Mobile medical apps allow physicians to interact with their patients, regardless of geography or time [29]. In addition, mobile medical apps allow patients to play a more active role in disease management [30]. However, in a survey of Chinese urologists, 76% of physicians complained that mobile medical apps took time away from clinical practice, and some mentioned that negative comments on Web diminished their enthusiasm for Web-based practice [24].

Physicians who have STD prevention materials available in their institutions were more likely to use mobile medical apps frequently to evaluate male patients with STD. Disease prevention materials are part of health promotion strategies to improve health literacy and access to care [31]. Carefully selected information and educational materials can have a positive effect on patients' health literacy, risk behaviors, and, in turn, clinical outcomes [32]. In particular, STD prevention materials are aimed at successfully motivating behavioral change, knowledge, and attitudes [33]. When health education and communication materials are available in a medical institution, its physicians may be more interested in adopting new technologies to improve health care services.

We found that more than half of the surveyed physicians recommended STD testing. This is consistent with the Chinese STD guidelines that encourage prompt STD testing for at-risk individuals [34]. Studies have found that individuals who have sought STD information on Web might have higher STD risks [27]. Following this logic, those who have consulted about STDs on mobile medical apps might also have higher risks for STD; thus, recommending testing for STDs is necessary. In addition, studies in high-, middle-, and low-income countries have demonstrated that Web-based medical service experiences can promote STD testing [35,36]. A study in the United Kingdom found that offering internet-accessed STD testing increased test uptake and decreased time to get tested. However, it did not reduce time to treatment [37]. Physicians play a crucial role in patient counseling and recommending HIV or STD testing, and interactions with physicians have been correlated with increased HIV or STD test uptake among MSM [38].

Nearly all physicians in our survey recommended their Web-based patients to see a physician in-person after the Web-based consultation. This finding suggests that Web-based consultations can supplement, but do not replace, in-person clinical encounters [39,40]. This also indicates that mobile medical apps can facilitate the linkage of patients with STD to care and disease management. The convenience of using mobile medical apps may broaden clinical service access and provide a means of increasing initial care seeking, counseling, and support, particularly among sexual minorities or patients with STD who may not otherwise seek care [41]. Although a majority of physicians surveyed reported receiving SMS text messages and images from Web-based patients, Web-based encounters still provide less information compared with face-to-face encounters [42]. Inadequate information through Web-based consultation may lead to an inaccurate assessment or misdiagnosis, and physicians may, thus, be reluctant to rely on Web-based consultation alone [43]. Further research is needed to understand the benefits and risks associated with Web-based medical services. A systematic review of the clinical use of mobile medical apps, including video-based Skype, suggested that this approach is feasible for chronic disease management [44].

This study has practical and research implications. From a practice perspective, Web-based consultation can provide a supplementary channel for patients to receive medical advice. Mobile medical services may be particularly useful for patients with STD and sexual minorities who hesitate to seek formal clinic-based services. Future research should investigate how to improve mobile medical services and build patient-centered, physician-friendly platforms to facilitate physician-patient communication. In addition, future studies should investigate how best to implement mobile interventions targeting key populations.

Limitations

This study has some limitations. First, the response rate for our Web-based survey (6.2%) was relatively low, but it was similar to other Web-based surveys among physicians (8.6%) [45]. Second, we conducted the survey using a mobile medical app platform, which may also result in selection bias of high-frequency mobile medical apps users. Although this study presented a common form of mobile medical apps, various mobile medical apps exist on the market [5]; thus, our findings should be transferred to other settings with caution. Third, the services provided by physicians using mobile medical apps were self-reported rather than based on the electronic records of their practice. Fourth, this study had a small proportion of physicians at lower-level clinical facilities. Nonetheless, this is consistent with the proportion of physicians in primary, secondary, and tertiary care settings who comprise roughly 10%, 30%, and 60% of all users, respectively, for the Xingren mobile app. Future studies can use other sampling methods to examine the patterns of physicians using mobile medical apps for clinical services.

Conclusions

Mobile medical apps have been adopted by physicians to provide Web-based medical advice. Physicians' use of mobile medical apps provides patients with STD with more opportunities to seek Web-based STD health services and link to offline services. Leveraging mobile medical apps to provide high-quality services for patients with STD symptoms may improve access to STD clinical care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Flowchart of participants' recruitment.

[PDF File (Adobe PDF File), 110KB - mhealth_v6i10e10531_app1.pdf]

Multimedia Appendix 2

Physician experiences during the last online encounter with a patient with sexually transmitted disease (STD) in China, 2017.

[PDF File (Adobe PDF File), 26KB - mhealth_v6i10e10531_app2.pdf]

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Abbreviations

***df*:** degrees of freedom
mHealth: mobile health
MSM: men who have sex with men
SMS: short message service
STD: sexually transmitted disease

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Original Paper

A Tablet-Based Mobile Hearing Screening System for Preschoolers: Design and Validation Study

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Abstract

Background: Hearing ability is important for children to develop speech and language skills as they grow. After a mandatory newborn hearing screening, group or mass screening of children at later ages, such as at preschool age, is often practiced. For this practice to be effective and accessible in low-resource countries such as Thailand, innovative enabling tools that make use of pervasive mobile and smartphone technology should be considered.

Objective: This study aims to develop a cost-effective, tablet-based hearing screening system that can perform a rapid minimal speech recognition level test.

Methods: An Android-based screening app was developed. The screening protocol involved asking children to choose pictures corresponding to a set of predefined words heard at various sound levels offered in a specifically designed sequence. For the app, the set of words was validated, and their corresponding speech power levels were calibrated. We recruited 122 children, aged 4-5 years, during the development phase. Another 63 children of the same age were screened for their hearing abilities using the app in version 2. The results in terms of the sensitivity and specificity were compared with those measured using the conventional audiometric equipment.

Results: For screening purposes, the sensitivity of the developed screening system version 2 was 76.67% (95% CI 59.07-88.21), and the specificity was 95.83% (95% CI 89.77-98.37) for screening children with mild hearing loss (pure-tone average threshold at 1, 2, and 4 kHz, >20 dB). The time taken for the screening of each child was 150.52 (SD 19.07) seconds (95% CI 145.71-155.32 seconds). The average time used for conventional play audiometry was 11.79 (SD 3.66) minutes (95% CI 10.85-12.71 minutes).

Conclusions: This study shows the potential use of a tablet-based system for rapid and mobile hearing screening. The system was shown to have good overall sensitivity and specificity. Overall, the idea can be easily adopted for systems based on other languages.

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KEYWORDS

hearing screening; mobile health; speech audiometry; hearing loss

Introduction

Hearing loss in one of the most common disabilities. The World Health Organization estimated that, in 2012, there were 360 million people in the world with disabling hearing loss (5.3% of the world's population); 328 million (91%) were adults, and 32 million (9%) were children [1]. The incidence of permanent congenital hearing loss, or childhood hearing loss, in low- and middle-income countries can be 3 times higher than the incidence in high-income regions [2]. Among all types of

hearing loss, the sensorineural hearing loss is the most common. In this case, the damaged hair cells of the inner ear diminish sounds to be effectively converted into nerve signals to the brain. Unfortunately, the sensorineural hearing loss cannot be reversed, and the patient is usually advised to use a hearing aid or a cochlear implant in the case of profound hearing loss. Other types of hearing loss include conductive and mixed hearing losses. Conductive loss occurs when there is an obstruction of, or damage to, the outer or middle ear that blocks sound from being conducted to the inner ear. The conductive hearing loss may be temporary or permanent depending on the cause, sometimes requiring medical or surgical treatments to improve the hearing ability of those affected. The final type of hearing loss is a mixed hearing loss, which is a combination of sensorineural and conductive hearing loss. Even though the universal hearing screening can detect permanent neonatal hearing loss, it does not identify late-onset, acquired, or many cases of progressive hearing loss. Approximately 60% of childhood hearing loss is due to preventable causes such as otitis media, recreational noise-induced hearing loss, and ototoxicity. Early detection and intervention are, therefore, extremely important in children, as hearing loss affects the ability to learn and hinders crucial language, speech, and emotional development [2]. Learning tonal languages, such as Thai in particular, can be greatly affected in children with hearing difficulties, as described previously [3]. Therefore, preschool and school hearing screening are effective tools for early identification and management of childhood hearing loss [4].

Hearing testing in children is challenging and usually requires specialist supervision. Depending on the age, each child can have varying capability to cooperate. For newborn up to 3 years of age, objective measurements, such as otoacoustic emission or auditory brainstem response, may be more appropriate [5]. The objective tests measure how the ear or nerve respond to sounds; these tests are sufficiently sensitive to diagnose hearing abnormalities but cannot represent the true hearing threshold. Subjective tests, such as pure-tone audiometry, which is the gold standard for measuring hearing acuity, are usually considered for older children who can provide appropriate responses [6]. The reliability of pure-tone audiometry depends on the machines, noise environments, experience of test operators, and pupils.

Many strategies have been attempted to make the preschool or school-age hearing screening feasible, fast, accurate, and cost-effective; however, to date, these strategies have not managed to meet the target goal [7-12]. The most widely preferred, and still considered the gold standard hearing screening in 4-6-year-old children, is the pure-tone audiometric sweep test [8-13]. In limited-resource countries, implementing this method nationwide can be a challenge. Furthermore, as the abstraction of pure-tone is difficult to understand, the response to pure tones in preschool or school-aged children may not as effective or reliable as speech [14]. For speech screening, the Verbal Auditory Screening for Children of Griffing et al has been used since 1962. However, the Verbal Auditory Screening for Children failed to identify children with mild hearing loss [15]. Another disadvantage of speech audiometry is that the results are not frequency-specific, especially for high-frequency hearing loss. However, the advantage of speech screening is that it assesses the auditory perceptual development, composed of sound awareness, phonetic discrimination, and word recognition [16]. Many techniques of speech audiometric tests have been developed; some were interfered with by nonauditory influences, such as maturity, experience, processing skills, and motor skills, of children [16]. Furthermore, young toddlers could be more responsive to a social interaction, particularly with their caregivers. Therefore, integrating auditory testing into a type of scripted interaction between child and caregiver could be more successful [16]. As such, even though they tend to be superior to pure-tone audiometry, such testing is not comparable with the standard one in large groups [17,18].

Recent advances in wireless telecommunication have made great changes in public health practice. A mobile app can potentially change a smartphone or a tablet into a medical device. These mobile devices are becoming increasingly powerful while the costs are becoming progressively lower, and the pervasive nature of the existing network answers the accessibility question. Hearing screening and measurement could be considered one of the early apps in the age of mobile or digital health care [19]. Some reports discuss this approach for individual hearing screening. Davison et al showed the effectiveness of using tablet-based hearing screening system compared with that of traditional audiometry for populations aged >60 years [20]. He proposed and validated the ability to use the tablet for a hearing assessment. Shouneez et al investigated the community-based identification of hearing loss using smartphones [21] and found that smartphone-based hearing screening allowed community health workers to bring hearing health care to underserved communities at the primary care level. Rourke et al used portable tablets to test hearing loss of 218 children in Northern Canadian communities [22]. The study provided positive and valuable evidence for using the tablet-based audiometer in remote areas. Whitton et al compared hearing measurements made at home using self-administered audiometric software against the standard tests in clinical settings [23]; the results showed statistical equivalence between the 2 approaches. Samelli et al confirmed the results of Whitton et al [24].

This study was designed to develop an appropriate tool to be used as a hearing screening device for preschool children. The system was implemented on an Android-based tablet, details of which are discussed in the following sections.

Methods

Overview

The study was approved by the Khon Kaen University Ethical Committee for Human Research (HE 571278) and was registered in the Thai Clinical trial (TCTR2014092201). This study was composed of 2 phases. The first phase was the development of the speech audiometry app software and was conducted during 2015-2016. The second phase was the validity of the software and was conducted during 2016-2017. The details of each phase are provided below.

Development of the Speech Audiometry App Software

Concept Design

Word Selection

To select appropriate words for the screening device, first, an audiologist in our research team chose 36 two-syllable words from an elementary school book that varied in terms of pitch. Corresponding pictures of the words were drawn with the consultation of 3 external audiologists. These words and corresponding pictures were then tried out with 2 groups of 30 preschool children aged between 4 and 5 years. One group was recruited from an urban area, and another group was recruited from a rural area. Parental consents were obtained before the test date. In addition, verbal child assent was also obtained. Each child would first be presented with the set of 6 pictures. There were 6 sets of pictures; these pictures were grouped by category as things, actions, fruits, etc. The researcher pronounced only one word at a time in a random order. A child was asked to point to the picture that represented the word they heard. The number of times the child correctly identified the picture was noted. After completing the 6 sets, the child was again presented with the pictures, this time one by one. They were asked what the picture was and the answer was recorded. The 24 words that 95% of children recognized correctly would be used for the software.

Sound Recording

All recordings were made in a sound-proof booth at a music studio. A high-sensitivity microphone (Brüel & Kjær type 4188) was positioned approximately 20 cm from the speaker at 0° azimuth and was covered with a 6.5-cm diameter windscreen. The microphone was connected to a sound level meter (B & K model 2239A), and the signal from the linear-weighted AC output of this meter was fed to an analog-to-digital converter (National Instruments, model PXI-4461) that acquired the mono sounds at a sampling frequency of 44.1 kHz with 16-bit amplitude resolution. A female speaker, who was a professional announcer with 25 years' experience, enunciated with normal vocal effort, corresponding to approximately 63 decibels sound pressure level (dBSPL; as monitored by the sound level meter) and recorded at a sampling rate of 44.1 kHz.

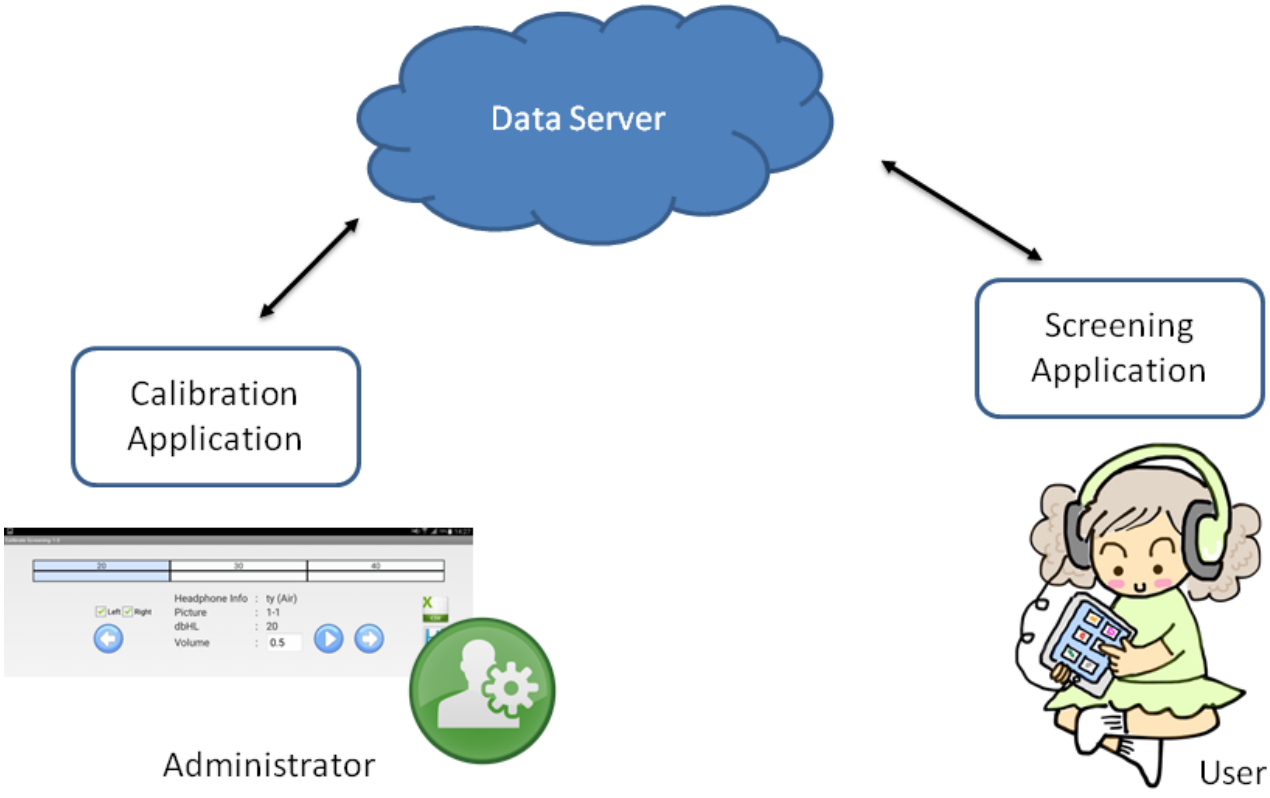
The sound intensity of each word was edited to yield the same average intensity as that of a 1000-Hz calibration tone.

System

The system consisted of a tablet device running 2 Android apps. We used the Samsung Galaxy Tab S 10.1. The tablet was plugged in with an approved headphone to be worn by the child being tested. The app "Calibrate Screening" was used by the support team to provide an Web-based update to the library of calibrated headphones that are selectable within the "Screening" app. Figure 1 shows the system overview.

The app "Screening" was for the child to perform under the administration of audiologist or trained personnel. The main function of the app is to perform the following test protocol (Preschool Audiometry Screening System, PASS).

Figure 1. System overview.



After completing the test at the end of the screening test, there is a page reporting the scoring. Suggestions and recommendations, should the child fail and have to see a specialist, are also provided.

Speech Signal Measurement and Calibration

Figure 2 presents an example of a speech signal. To calibrate the system to prepare for the trial, we first equalized the word files to have equal root mean square. We then calibrated each word individually at 20, 30, and 40 decibels hearing level (dBHL). This calibration was done by comparison to a reference standard speech audiometer.

Figure 3 shows the setups. Through a 2-cc coupler, a sound level meter was used to measure the peak power (in A-weighted decibels, dBA) outputs from the standard audiometer and the tablet for each word at 20, 30, and 40 dBHL settings. The calibration coefficient calculated at each measuring point was basically an additional gain required that would make the tablet output the word with the same dBA peak when measured using the same sound level meter.

Validity of the Software

Participants

We recruited 2 groups of 60 preschoolers from the northeastern part of Thailand. The first group was tested for the PASS speech audiometer version 1 using the commercial headphone, Creative EP-210. The second group was tested for the PASS speech audiometer version 2 using standard audiometric headphones, TDH39. The same inclusion and exclusion criteria were applied to both groups. The inclusion criteria were as follows: age between 4 and 5 years; use of standard Thai to communicate; and physical health, with the ability to cooperate with a medical examination. Candidates were excluded if they were uncooperative during conditioning play audiometry tests or they had incomplete conditioning play audiometry test results. An otolaryngologist examined the child's ears without any intervention to clean the external ear. The PASS speech audiometry app tests were performed according to the test protocols in the quiet room.

Test Protocol in the Preschool Audiometry Screening System Speech Audiometry Version 1

Starting from the right ear, the program randomly picks 1 set (6 pictures) out of an available 4 sets of pictures. The program first randomly outputs a 2-syllable word corresponding to 1 picture of the set at 40 dBHL. It then shows the 6 pictures to a user, who is required to pick the correct picture corresponding to the word from the picture set. The program continues with another word from the set. Only 4 words will be used for each speech level. Users move on to the next speech level if they answer correctly 2 of 3 or 4 times (passing the level) or 4 words out of the 6 have been used. In the latter case, the user is considered to have failed at that speech level. The test continues with the same procedure with lower power speech at 30 dBHL and, finally, at 20 dBHL. Other conditions that are observed are as follows: if the user fails the test at 40 dBHL or 30 dBHL, testing is stopped for the right ear and proceeds to the left ear and if the user passes all 3 levels, testing proceeds to the left ear. Figure 4 illustrates the entire testing protocol in the flowchart.

Test Protocol in The PASS Speech Audiometry Version 2

For this phase of the trial, we tested the PASS speech audiometry app with standard audiometric headphones (TDH39). The headphones were embedded inside an earmuff with up to 20-dB ambient noise reduction, as it was intended for use in practical situations, such as school or normal rooms, rather than in an audiometric booth or sound-proof room, which are usually required for audiometric measurements. An additional Phono-to-Tip-Ring-Sleeve adaptor was required so that the TDH39 headphones could be plugged to the tablet. Figure 5 shows the complete system.

Starting from the right ear, the program randomly picks 1 set (6 pictures) out of the available 4 sets of pictures. The program first randomly outputs a 2-syllable word corresponding to 1 picture of the set at 40 dBHL. It then shows the 6 pictures to a child, who is required to select the correct picture corresponding to the word from the picture set. The program continues with another word from the set. The 40-dB sound is presented 4 times for each ear. The test continues with the same procedure with a softer speech at 30 dBHL and, finally, at 20 dBHL. Sounds were presented for each ear 12 times in total. Users will be considered as having passed the test at that speech level if they answer correctly, at least, 2 times out of 4. If a user cannot answer all 4 words correctly at each intensity, the user is considered to have failed at that level. The whole procedure is then repeated for the left ear. Figure 6 shows the protocol for PASS version 2.

Outcome Measurement

The audiologist who performed the test was not involved in the inventor team and was trained to use the PASS speech audiometry. Children were asked to hear the sound in each ear and point to the picture that they heard. The time used for the PASS speech audiometry was recorded.

The pediatric audiologist, who was blinded to the results of PASS speech audiometry, performed the conventional play audiometry. Children's hearing threshold was evaluated with air-conduction pure-tone audiometry at 0.5, 1, 2, 3, and 4 kHz and with spondee words for the speech reception threshold (SRT) measurement in the standard sound-proof room. The procedure's timing was recorded. Tympanometry was also carried out.

Statistical Analysis

The sensitivity and specificity of speech audiometry app to detect a mild hearing loss in either ear (pure-tone average, PTA, or SRT >20 dB) were tested. The mean difference between speech audiometry and conventional play audiometer for each protocol testing was then compared.

Figure 2. Speech signal.

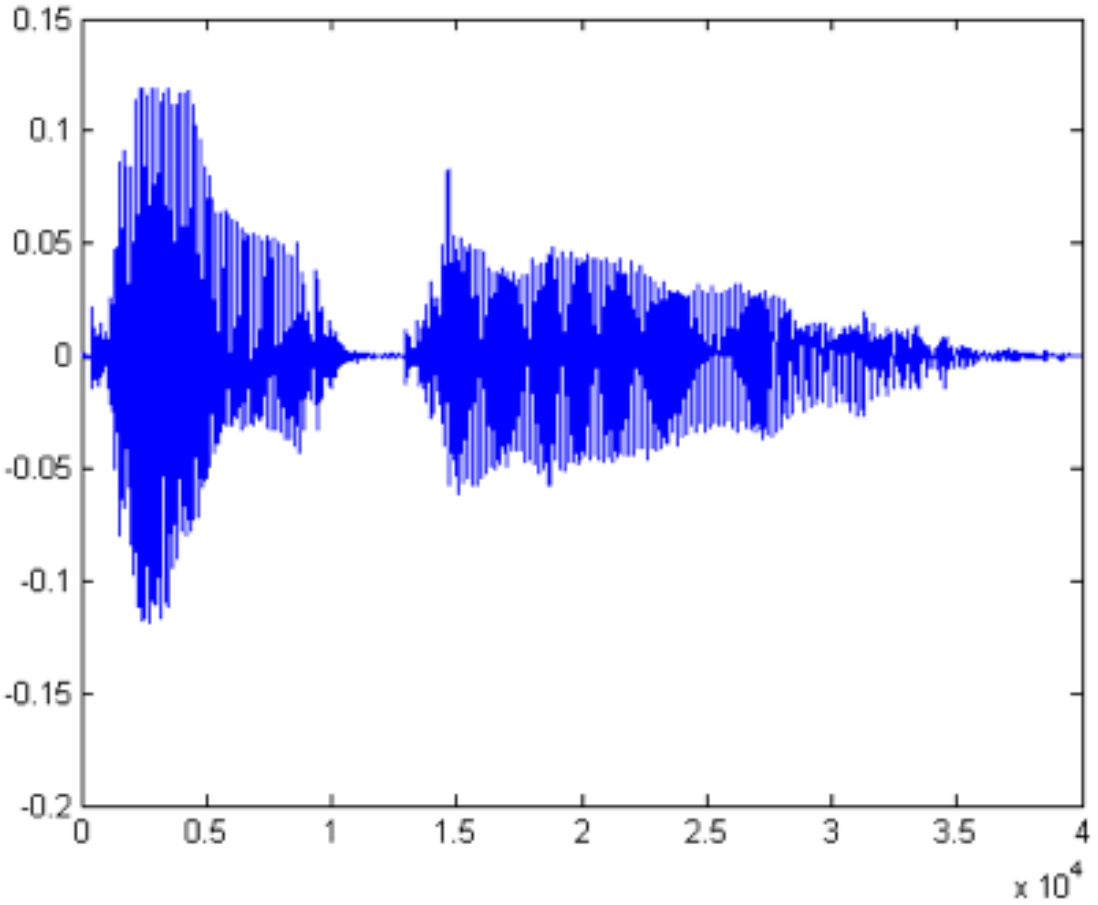


Figure 3. Calibration setups.

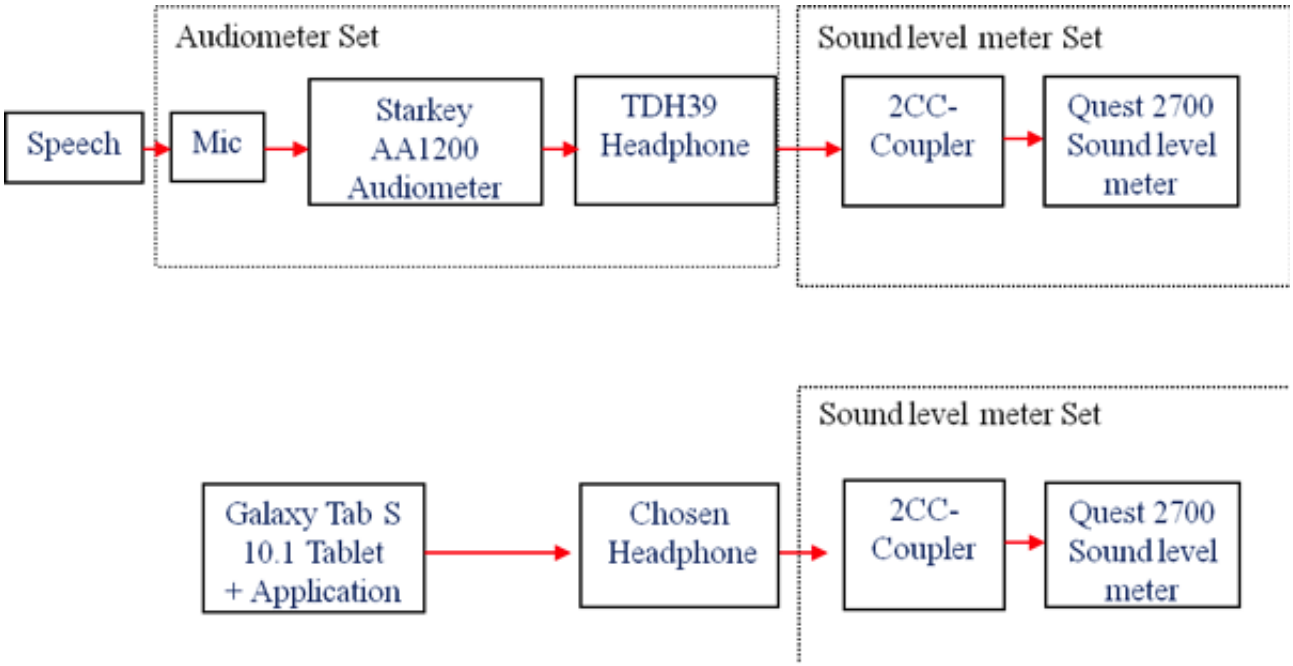


Figure 4. Screening protocol in Preschool Audiometry Screening System (PASS) speech audiometry app version 1. dBHL: decibels hearing level.

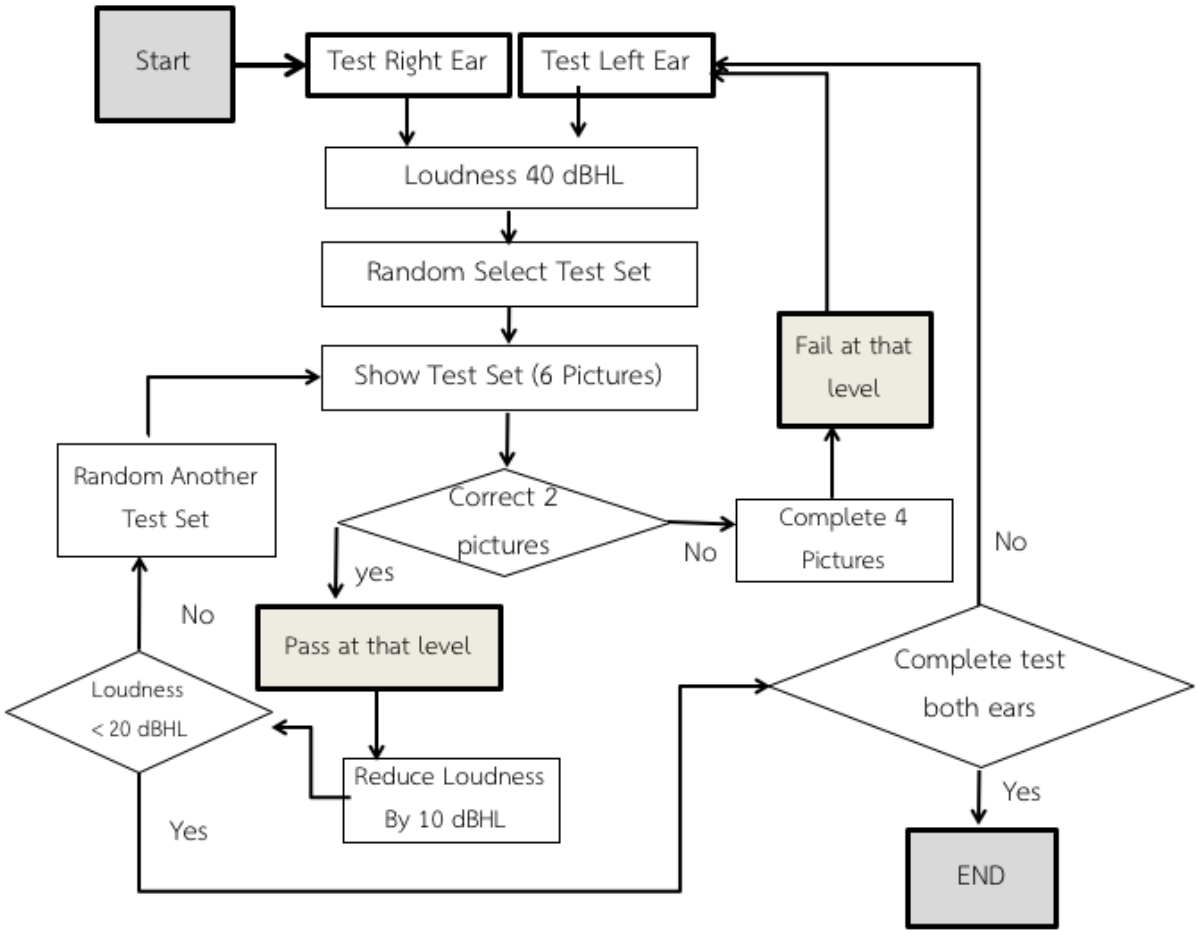
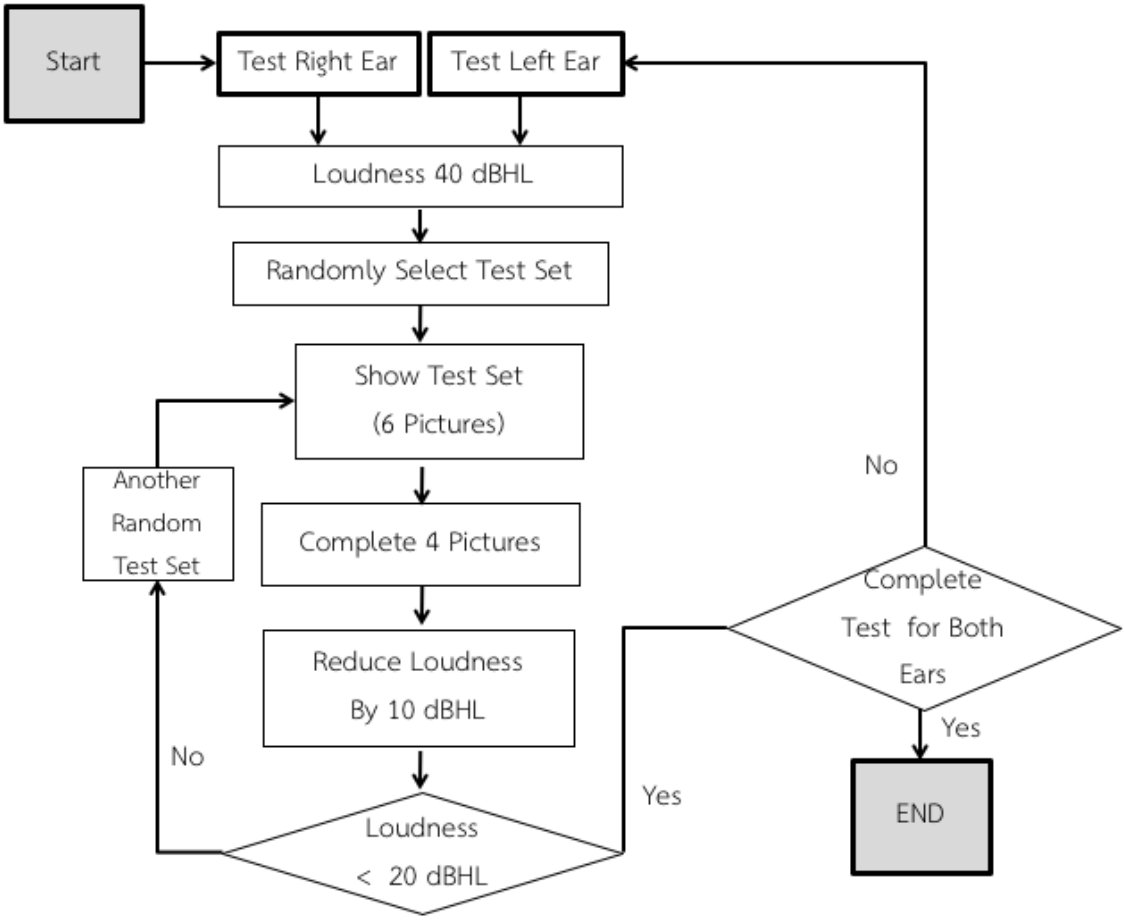


Figure 5. Tablet with TDH39 earmuffs.

Figure 6. Screening protocol in Preschool Audiometry Screening System (PASS) speech audiometry app version 2. dBHL: decibels hearing level.



Results

Words Selected

For this part of the study, 63 children (51% (32/63) boys and 49% (31/63) girls) volunteered. Of these, 57% (36/63) were between 4 years, 7 months and 5 years of age, and 24% (15/63) were between 5 and 5.5 years. Each child would then go through the word selection trial as discussed in the previous section. Having all the results, audiologists finally grouped them into 4 sets of 6. Table 1 and Figure 7 present selected examples of the words and the corresponding pictures, respectively.

PASS Speech Audiometry Version 1 Evaluation

There were 32 boys and 28 girls. The mean age was 4 years and 11 months. Although 2 children had impacted cerumen, 5 had otitis media; 10 children had a unilateral hearing loss, all of which was a mild hearing loss. No bilateral hearing loss was found. Commercial headphones, Creative EP-210 was used. The average time used for the speech audiometry program was 82.9 (SD 24.13) seconds (95% CI 76.67-89.13 seconds). The fastest time was 58 seconds, and the slowest was 195 seconds. The average time used for conventional play audiometry was 11.87 (SD 4.06) minutes (95% CI 10.79-12.87 minutes). The fastest was 6.3 minutes, and the slowest was 32.46 minutes. Table 2 shows the results in terms of the sensitivity and specificity compared with that of standard audiometric measurements.

Results of PASS Speech Audiometry Version 2

A total of 63 children participated in the second version trial; there were 22 boys and 38 girls, and the mean age was 4 years and 9 months. Four children had impacted cerumen, 15 had otitis media, and 14 had hearing loss. The unilateral hearing loss was found in 10 children, and bilateral hearing loss was found in 4 children, including 2 with the moderate hearing loss. The average time used for the speech audiometry program was 150.52 (SD 19.07) seconds (95% CI 145.71-155.32 seconds). The average time used for conventional play audiometry was 11.79 (SD 3.66) minutes (95% CI 10.85-12.71 minutes). Figure 8 shows the relation of the corrective score for each intensity and hearing threshold.

From Figure 8, we can see that a cutoff score of 2 would be appropriate to be used to classify pass or fail for each intensity test. Tables 3 and 4 show the sensitivity, specificity, and positive likelihood ratio of the PASS speech audiometry app under such a condition.

Table 1. Some of the test words.

Set 2	Set 3
door	car
can	wash hands
driving	train
bag	cry
balloon	red color
jump	sock

Figure 7. An example of picture sets.

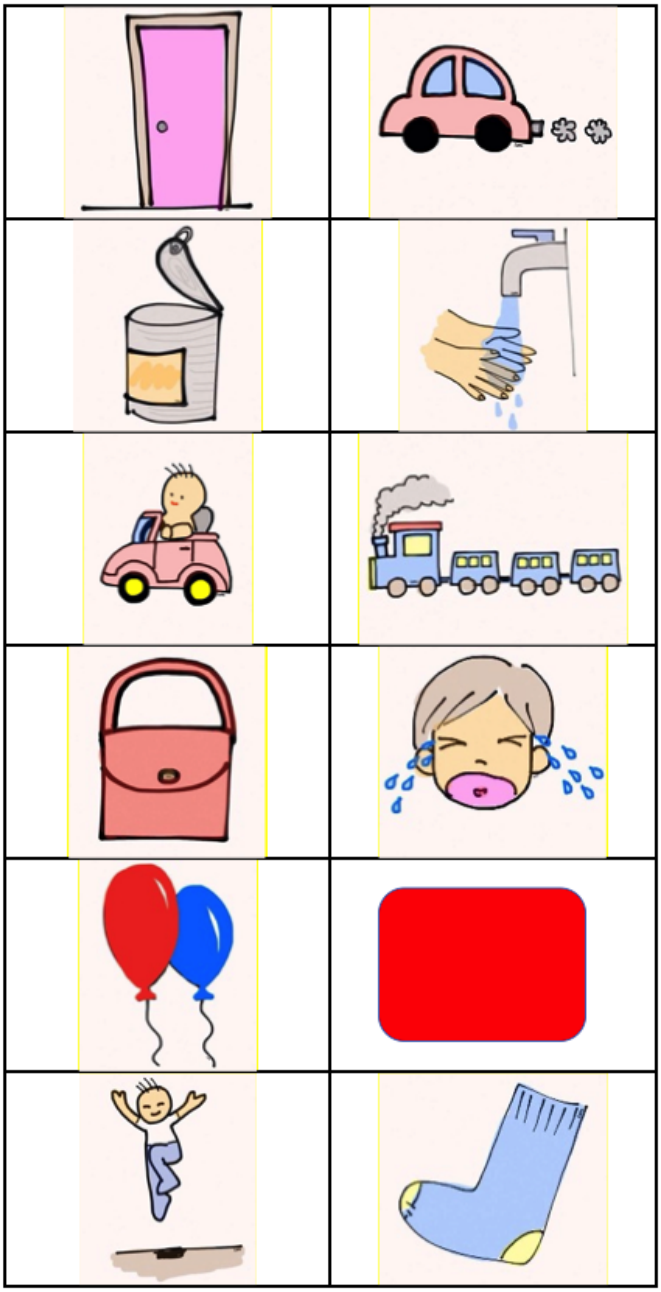


Table 2. The sensitivity and specificity of Preschool Audiometry Screening System speech audiometry app version 1 compared with that of Conventional Play Audiometry.

Test performance	Conventional play audiometry	
	Speech reception threshold 20 decibel, % (95% CI)	Pure-tone average$_{0.5\text{-}2\ KHz}$ 20 decibel, % (95% CI)
Sensitivity	62.50 (28.95-96.05)	60.00 (29.64-90.36)
Specificity	93.75 (89.27-98.23)	94.60 (90.30-98.79)
Positive likelihood ratio	10 (4.08-24.49)	11 (4.35-27.83)

Figure 8. The relation of number of correction responses for each intensity and speech reception threshold. dBHL: decibels hearing level.

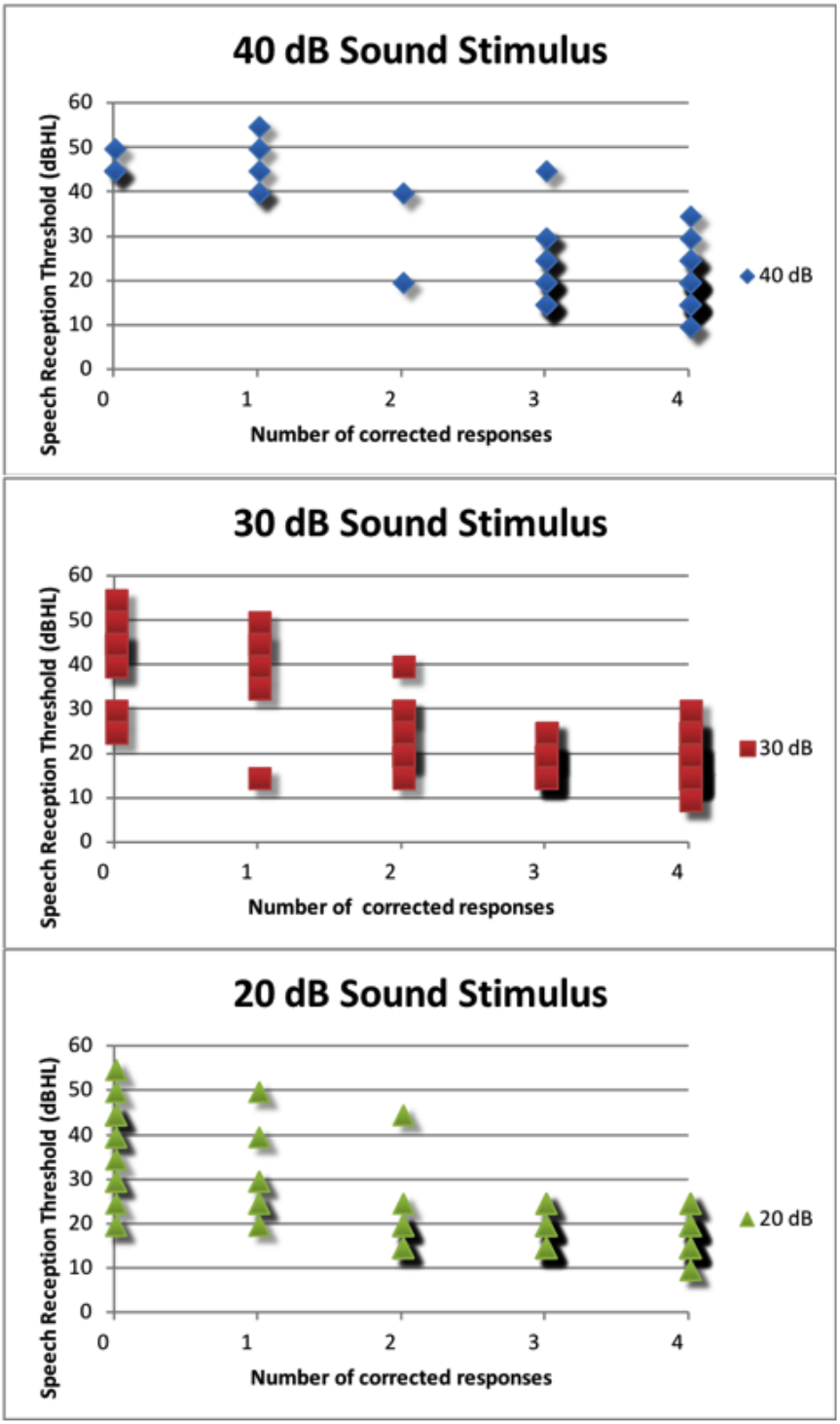


Table 3. The sensitivity, specificity, and positive likelihood ratio of the Preschool Audiometry Screening System speech audiometry app version 2 compared with speech reception thresholds.

Stimuli and performance	SRT[a]>20 dB[b], % (95% CI)	SRT>25 dB, % (95% CI)	SRT>30 dB, % (95% CI)	SRT>35 dB, % (95% CI)	SRT>40 dB, % (95% CI)
PASS[c]-20					
Sensitivity	77.42 (60.19-88.60)	100 (83.18-100)	100 (78.47-100)	100 (77.19-100)	100 (72.25-100)
Specificity	82.11 (73.20-88.52)	79.44 (70.83-86.01)	77.68 (69.12-84.40)	75.22 (66.52-82.26)	73.28 (64.57-80.49)
LR+[d]	4.32 (2.70-6.93)	4.86 (3.35-7.06)	4.48 (3.17-6.33)	4.04 (2.93-5.57)	3.74 (2.77-5.06)
PASS-30					
Sensitivity	65.63 (48.31-79.59)	94.74 (75.36-99.06)	100 (78.47-100)	100 (77.19-100)	100 (77.25-100)
Specificity	93.62 (86.77-97.04)	91.59 (84.78-95.51)	91.07 (84.34-95.08)	87.61 (80.27-92.47)	86.21 (78.76-91.33)
LR+	10.28 (4.56-23.20)	11.26 (5.97-21.24)	11.2(6.20-20.24)	8.07 (4.95-18.18)	7.25 (4.60-11.43)
PASS-40					
Sensitivity	56 (37.07-73.33)	63.16 (41.04-80.85)	100 (78.47-100)	92.31 (66.69-98.63)	100 (67.56-100)
Specificity	98.98 (94.44-99.82)	99.07 (94.90-99.83)	77.68 (69.12-84.40)	99.12 (95.16-99.84)	95.76 (90.46-98.18)
LR+	54.88 7.52-397.74)	67.58 (9.32-489.84)	4.48 (3.17-6.33)	104.31 (14.73-738.72)	23.6 (10.01-55.65)

[a]SRT: speech reception threshold.

[b]dB: decibel.

[c]PASS: Preschool Audiometry Screening System.

[d]LR+: positive likelihood ratio.

Table 4. The sensitivity, specificity, and positive likelihood ratio of Preschool Audiometry Screening System speech audiometry app version 2 compared with average pure-tone air-conduction threshold of different frequencies.

Stimuli and performance	$PTA^{a}_{0.5,1,2}$ >20 dB[b], % (95% CI)	$PTA_{0.5,1,2,4}$ >20 dB, % (95% CI)	$PTA_{1,2,4}$ >20 dB, % (95% CI)	$PTA_{0.5,1,2,4}$ >25 dB, % (95% CI)	$PTA_{1,2,4}$ >25 dB, % (95% CI)
PASS[c]-20					
Sensitivity	55.00 (39.83-69.29)	68.99 (50.77-82.72)	76.67 (59.07-88.21)	90.0 (69.9-97.21)	89.47 (68.61-97.06)
Specificity	96.51 (90.24-98.81)	97.93 (92.79-99.43)	95.83 (89.77-98.37)	93.40 (86.99-96.76)	92.52 (85.94-96.19)
LR+[d]	15.77 (5.01-49.62)	33.45 (8.30-134.71)	18.4 (6.91-48.99)	13.63 (6.56-28.30)	11.97 (6.04-23.72)
PASS-30					
Sensitivity	40.54.00 (26.35-56.51)	50.00 (33.15-66.85)	60.00 (40.74-76.60)	66.67 (45.37-82.81)	78.95 (56.67-91.49)
Specificity	98.87 (93.91-99.8)	100.00 (96.15-100.0)	99.01 (94.60-99.83)	99.05 (94.80-99.83)	98.13 (93.44-99.49)
LR+	36.08 (4.94-263.32)	N/A[e]	60.6 (8.39-473.30)	70 (9.72-503.92)	42.24 (10.50-169.98)
PASS-40					
Sensitivity	29.72 (17.49-45.78)	40.00 (24.59-57.68)	36.67 (50.5-89.82)	57.14 (36.55-75.53)	63.16 (41.04-80.85)
Specificity	100 (95.86-100)	100 (96.15-100)	100 (96.15-100)	100 (96.47-100.0)	100 (96.53-100)
LR+	N/A	N/A	N/A	N/A	N/A

[a]PTA: pure-tone average.

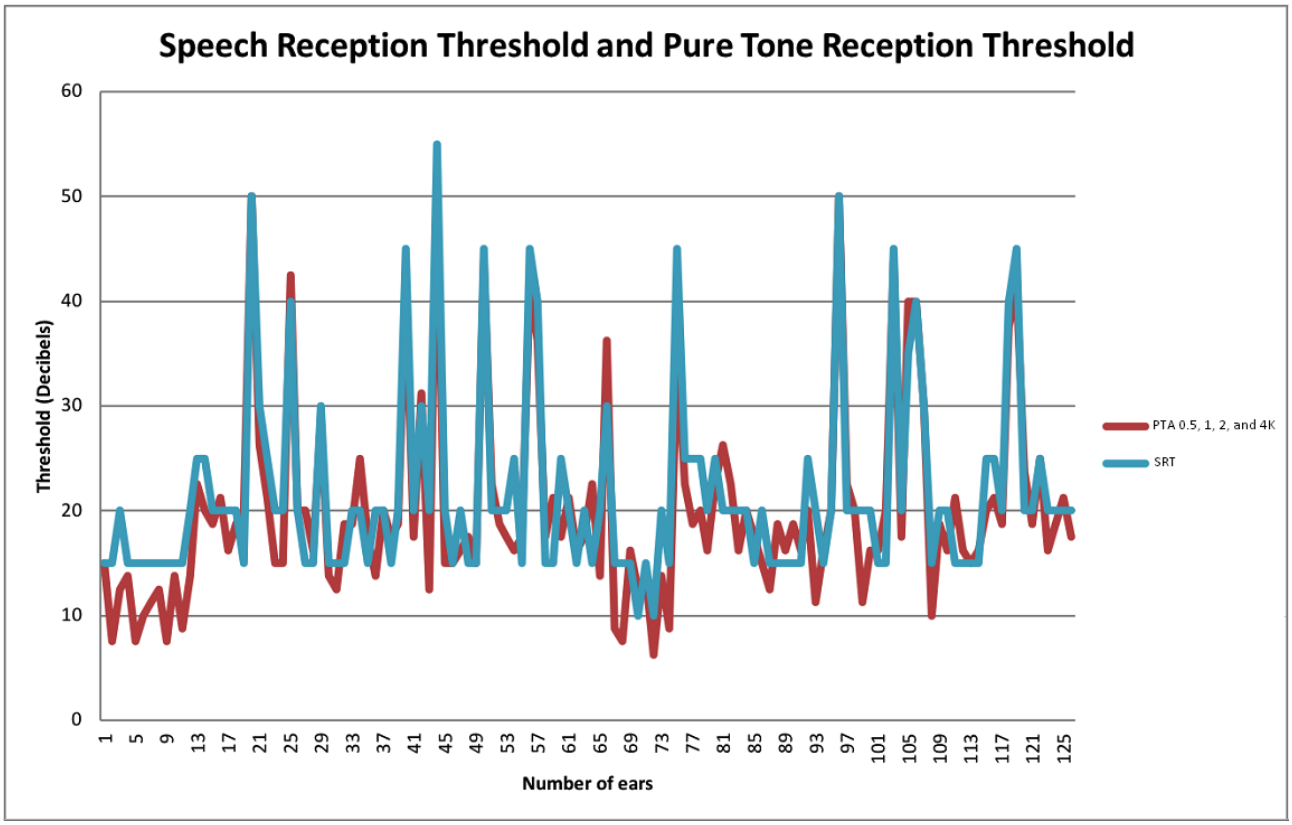
[b]dB: decibel.

[c]PASS: Preschool Audiometry Screening System.

[d]LR+: positive likelihood ratio.

[e]N/A: not applicable.

Figure 9. Speech reception threshold (SRT) and pure-tone average (PTA) threshold at 4 frequencies (0.5, 1, 2, and 4 kHz.) for each ear.



Under the cutoff score of 2 conditions, the sensitivity and specificity of the PASS speech audiometry app version 2 with the stimulus at a 20-dB sound intensity to detect the SRT >20 dBHL were 77.42% (95% CI 60.19-88.60) and 82.11% (95% CI 73.20-88.52), respectively. When using the SRT >25 dBHL, or $PTA_{0.5,1,2,4\,kHz}$>25 dBHL, or $PTA_{1,2,4\,kHz}$>25 dBHL as criteria for mild hearing loss, the sensitivity of the PASS speech audiometry app version 2 was greater and the specificity was similar. Increasing the sound stimulus intensity did not improve the sensitivity of the screening. Using the discrimination criterion of 20 dB, the sensitivity of the PASS speech audiometry version 2 was slightly variable among the frequencies of average pure-tone thresholds. If the PTA threshold at 500 Hz was omitted, the sensitivity was increased, and the specificity remained high. The sensitivity to screen mild hearing loss of $PTA_{1,2,4\ kHz}$>20 dBHL was 76.67% (95% CI 59.07-88.21), and the specificity was 95.83% (95% CI 89.77-98.37). Furthermore, the relation of the PTA threshold and SRT for individual ears was compared (Figure 9).

Discussion

Principal Findings

Hearing loss can be preventable and is much more manageable if detected early. To do so, we must equip our medical personnel, especially in low-resource countries, with tools that are appropriate, available, and accessible [19]. The tablet-based system, because of its relatively low cost and its internet connectivity, already fits the availability and accessibility demands. In Thailand, for example, the 3G cellular network has increasingly become the communication platform of choice for both voice and data, with penetration fast outstripping those offered by landlines. Potential reliability issues of the network can be addressed with appropriate system design. In PASS speech audiometry, data are stored locally and are only updated to the server when a connection is available.

The mobile hearing test apps, such as uHear [26] and hearScreen [27], use pure tones as the sound stimuli, whereas ShoeBOX Audiometry [28] uses warble tones [29]. The uHear was validated for the sensitivity in adults and the elderly, and it was found that it overestimated the PTA in all ears. The uHear was not suitable to screen mild hearing loss but had a potential benefit for the detection of moderate hearing loss [26,30-33]. The sensitivity and specificity to detect moderate hearing loss (PTA >40 dBHL) were 100% and 88%, respectively [30]. The hearScreen app was validated in 1070 school-age children to screen the hearing threshold of 25 dB at 1000 Hz [27,34]. The app had a sensitivity of 75% and a specificity of 98.5% for conventional screening and was 12.3% faster than that of conventional screening [34]. ShoeBOX Audiometry was validated in 80 children older than 4 years, and it was found that the obtained threshold in an uncontrolled environment did not correlate with the diagnostic threshold [29]. There was a sensitivity of 91.2% and a specificity of 57.8% when using a discrimination threshold of 30 dB. Using a discrimination threshold of 25 and 20 dB, the specificity decreased to 48.7% and 31%, respectively [29].

From the primary result of the PASS version 1 trial using SRT or PTA >20 dB as a criterion of mild hearing loss, the sensitivity of PASS speech audiometry was too low to be used as the hearing screening tool to detect mild hearing loss, though the specificity was very high. The test time was evidently very

short, 8.6 times faster than that of conventional play audiometry, an encouraging result. We analyzed the results and considered 2 further changes so that we may learn more about its true potential. First, the test protocol could be modified to find the appropriate number of correct responses to determine pass or fail for each sound pressure level test; this may not be 2 of 4 as in the original protocol. Second, the headphone used in this trial should be the same standard used in conventional pure-tone audiometry for initial reference.

Using SRT or $PTA_{1,2,4}$ >20 dB, the PASS speech audiometry app version 2 showed higher sensitivity and more specificity than version 1. While being able to complete the screening task much faster than when using standard tool, the PASS speech audiometry app version 2 had a sensitivity of 90% and 100%, and a specificity of 93.40% and 79.44% to differentiate children with normal hearing from those with the PTA or SRT >25 dB, respectively. Normally, the SRT is within 5 dB above PTA. Speech discrimination was increased if tested with the suprathreshold of sound stimuli. The PASS app uses the principle that the comprehension of sound will lead children to correctly choose the right picture. The sound stimulus may require higher intensity than that of the stimulus used for finding SRT.

For adults, the pure-tone, air-conduction threshold (PTA) at 500, 1000, and 2000 Hz >25 dBHL is considered to be a mild hearing loss. As mild hearing loss affects the academic performance in young school-age children, the criterion for mild hearing loss is set lower than that of adults [35]. The American Speech-Language-Hearing Association and the World Health Organization recommend using a PTA at 1000, 2000, and 4000 Hz >20 dBHL as screening levels for children. Dodd-Murphy et al investigated the use of 20 or 25 dBHL for screening educational significant hearing loss. The authors found that the sensitivity and specificity were different [36]; they suggested that pure-tone screening at 20 dBHL had the best combined sensitivity and specificity rates for educational significant hearing loss in children but unacceptable sensitivity when screening for PTA >25 [36].

The proposed system was based on the screening in Thai words for Thai children; however, we believe that the PASS app is universal and can be easily adopted for screening in other languages as well.

In the first trial, we used the same concept of the test protocol that we used in normal practice. If children could respond correctly to half of the test (at least 2 times), we could skip to the next loudness. In the second trial, we tested 4 times for each loudness regardless of the number of correct responses. We found that the cutoff point to determine pass or fail remained, at least, 2 correct responses. The mean test time used for each child in the second trial was twice as much as the time used for each in the first trial. For future improvement in terms of testing time and arrangement as that in the first test protocol may be considered.

Another point of consideration would be the selection of headphones. We were able to obtain good results using TDH39 headphones, which have a very flat response and loudness linearity that are important for quality speech measurement. This situation is not always the case for consumer headphones, and we should, therefore, be very specific if possible about which headphones should be used with the app. A pair of THD39 headphones can cost up to US $200, whereas reasonably priced headphones may be 5-10 times less expensive, making them more accessible.

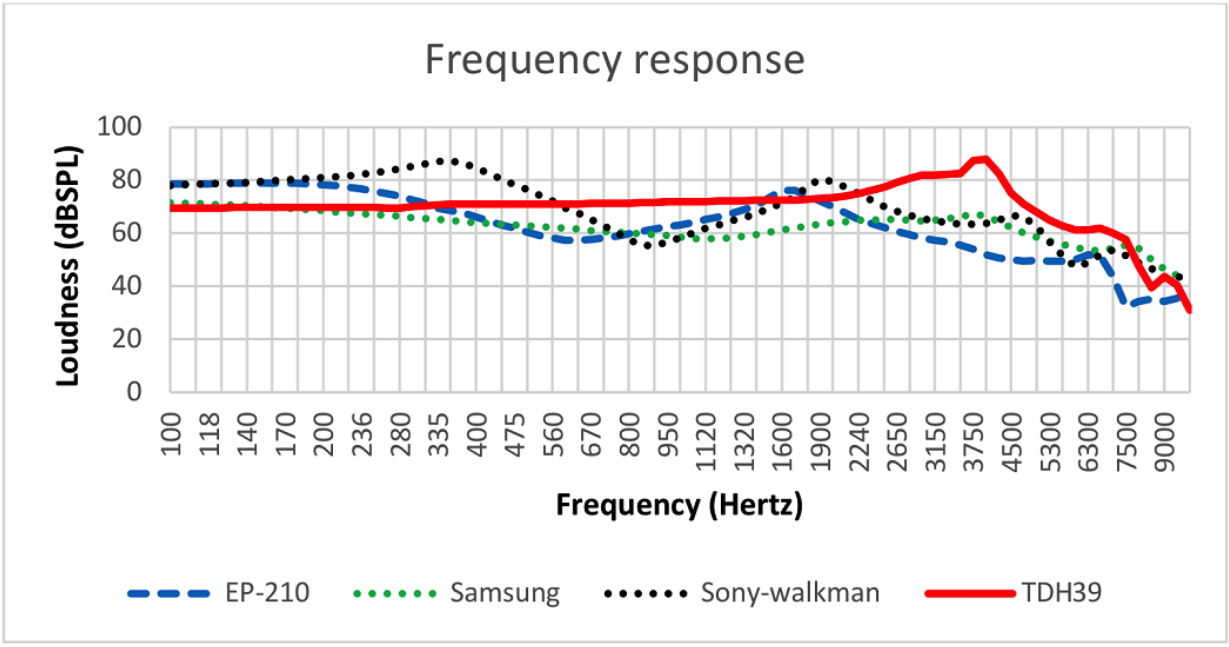
Figure 10 shows sample electroacoustic measurements of 3 midrange consumer headphones against those of TDH39. The stimulus input was a pure-tone sweep at 100 dBSPL, with each pair of headphones driving a 2-cc coupler used to simulate the load response of a simple ear canal [37]. High-intensity levels, such as 100 dBSPL, were used as an example here, as it would be the level that would approach the maximum level for many less expensive headphones such that they could begin to saturate. We can see that the low-end headphones had a fuzzier frequency response. At higher frequencies, the response of the midrange headphone was evidently nonideal. In the speech range (200-400 Hz), the frequency response was reasonably flat, making it a better candidate for the screening app. When comparing consumer headphones with TDH39, there remained nonlinearity in certain frequencies (Figure 11).

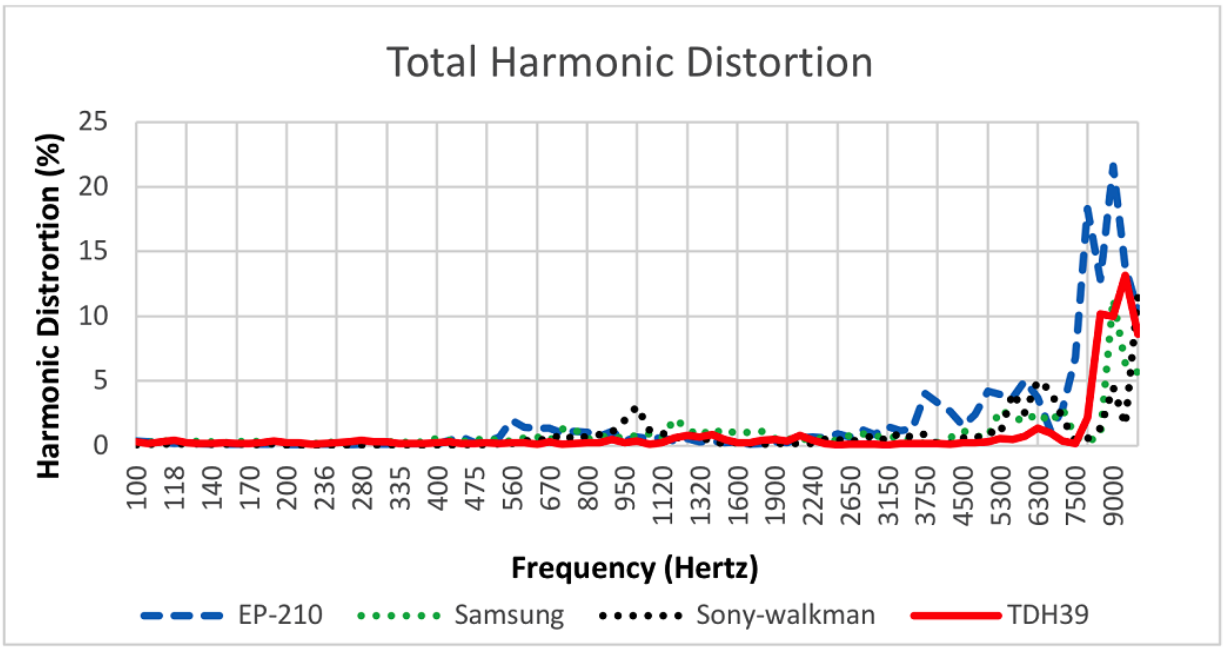
As the screening system must be accurate only for specific words at predefined loudness levels, we can simplify the calibration process by only finding the calibration coefficient at those points. This process could be done by adjusting the internal gain at each word-power level so that the output measurement by the sound level meter yields the same dBA as that measured when driving the TDH39 headphones. Masalski et al studied the reference sound level by means of biological calibration on 8620 devices representing models [38]. The reference sound levels were not very different among subjects and showed small deviations in the same model. Therefore, it is feasible to do the hearing test on mobile devices calibrated for the predefined reference sound level. Building up the library of supported headphones is the role of the app administration team, and we will continue to expand the usable headphone list. This situation is also true for the tablet itself, and we hope to be able to support Android tablets from various manufacturers.

Limitations

A few limitations of this study deserve mention. First, because of the small sample size and the population that evidently had a low prevalence of hearing loss, some of the 95% CIs were rather wide. Future tests can be designed with increased sample sizes to cover more children with hearing loss. In addition, PASS version 2 was developed as an improvement to PASS version 1. For its trial evaluation, different populations with identical inclusion and exclusion criteria as those of PASS version 1 were used; this fact makes a direct comparison between the 2 trial results less straightforward. Finally, to practically reduce ambient noise to a minimum, an earmuff was used to cover the headphones. In cases where this is not possible, the true effect of using unprotected headphones on the screening performance must be studied.

Figure 10. Electroacoustic measurements of sample headphones versus TDH39. dBSPL: decibels sound pressure level.





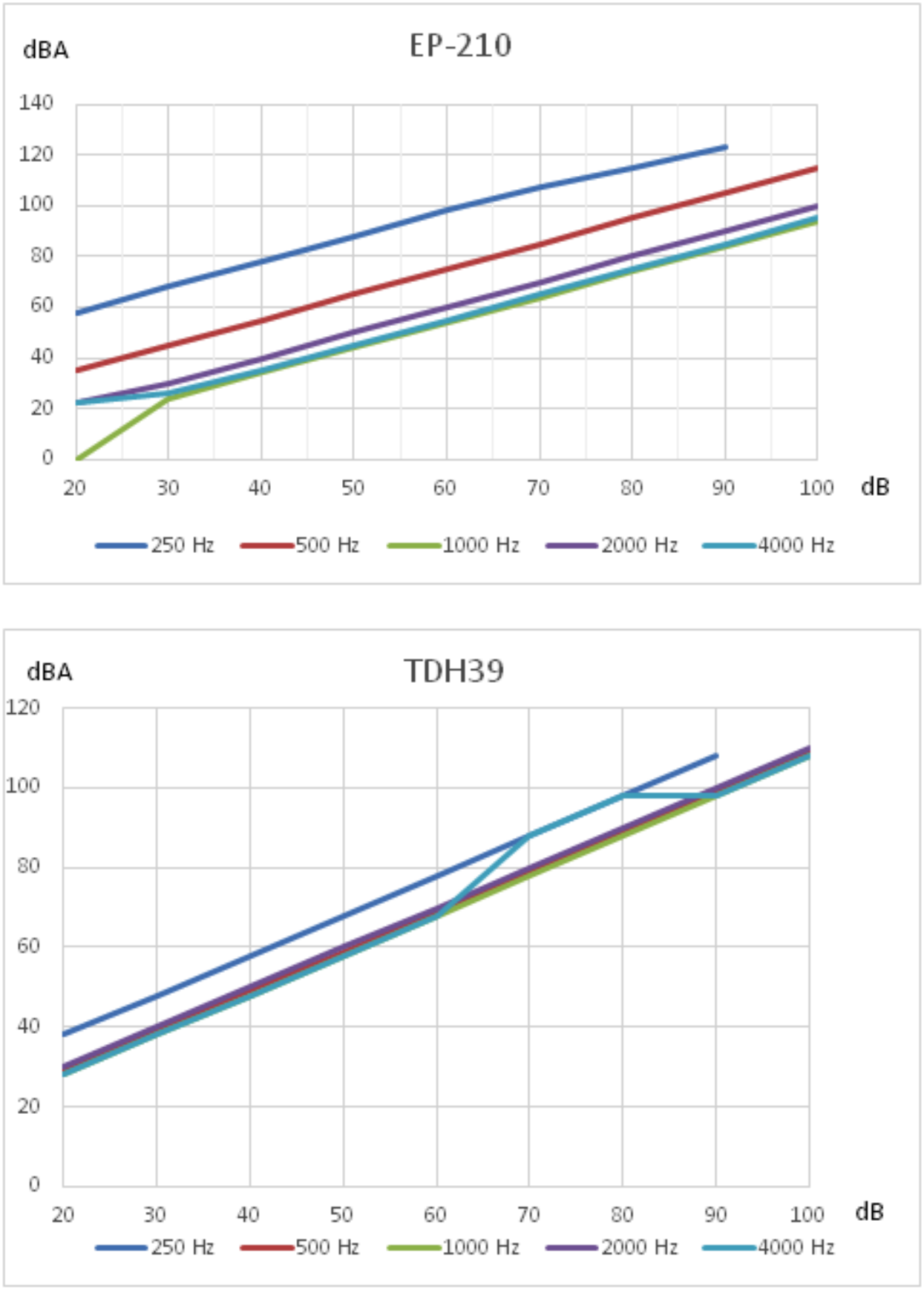
Future Directions

The screening program should add the function of headphone calibration before beginning the test to make it more feasible to accommodate other marketed devices. The test should be modified to make it more attractive to preschool toddlers. It would be ideal if the screening program could be complemented by other audiometry programs to offer more flexibility to the medical professional. Additional options could be standard pure-tone audiometry to study in detail the hearing loss characteristics of each. Conversely, it may be desirable to include a teleconsultant function that can bring a remote audiologist closer to the actual service field to validate hearing loss diagnostics, and any follow-up rehabilitation program can be done as close as possible to the primary practice. Being able to do these steps would address the low accessibility to qualified audiologists, which is a real concern in many countries. All this could be packaged together to form a teleaudiometry service that is an excellent example of mobile health. For the screening program itself, a new test algorithm that reduces the test time even further could be worth exploring. All these aspects are subjects of this work, which we will report in due course.

Conclusions

This study demonstrates the potential use of a tablet-based system for rapid and mobile hearing screening. The system was shown to have good overall sensitivity and specificity. The idea can be easily adopted for systems based on other languages.

Figure 11. THD39 versus EP-210 loudness response. dBA: A-weighted decibels.



Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

dBA: A-weighted decibels
dBHL: decibels hearing level
dBSPL: decibels sound pressure level
PASS: Preschool Audiometry Screening System
PTA: pure-tone average
SRT: speech reception threshold

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Original Paper

A Short Message Service Intervention for Improving Infant Feeding Practices in Shanghai, China: Planning, Implementation, and Process Evaluation

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Abstract

Background: Although mobile health (mHealth) has been widely applied in health care services, few studies have reported the detailed process of the development and implementation of text messaging (short message service, SMS) interventions.

Objective: Our study aims to demonstrate the process and lessons learned from a community-based text messaging (SMS) intervention for improving infant feeding in Shanghai, China.

Methods: The intervention included planning and development, implementation, and process evaluation. A 3-phase process was adopted during planning and development: (1) a formative study with expectant and new mothers to explore the barriers of appropriate infant feeding practices; (2) a baseline questionnaire survey to understand potential intervention approaches; and (3) development of the text message bank. The text messaging intervention was delivered via a computer-based platform. A message bank was established before the start of the intervention containing information on the benefits of breastfeeding, preparing for breastfeeding, early initiation of breastfeeding, timely introduction of complementary foods, and establishing appropriate feeding practices, etc. An expert advisory committee oversaw the content and quality of the message bank. Process evaluation was conducted through field records and qualitative interviews with participating mothers.

Results: We found that the text messaging intervention was feasible and well received by mothers because of its easy and flexible access. The weekly based message frequency was thought to be appropriate, and the contents were anticipatory and trustworthy. Some mothers had high expectations for timely response to inquiries. Occasionally, the text messages were not delivered due to unstable telecommunication transmission. Mothers suggested that the messages could be more personalized.

Conclusions: This study demonstrates the feasibility and value of text messaging intervention in filling gaps in delivering health care services and promoting healthy infant feeding practices in settings where personal contact is limited.

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KEYWORDS

mHealth; short message service; breastfeeding; infant feeding practices; health services; planning and development; implementation; process evaluation

Introduction

The Life Course Health Development Model suggests that health interventions should focus on early childhood to build a solid basis for long-term health [1]. Infant feeding practices may have long-term effects by influencing eating behaviors and obesity risk in later life [2-6].

Inappropriate infant feeding knowledge and practices have been widespread among new parents or caregivers. Examples include the perception that the nutritional value of infant formula is higher than breastmilk, too long or too short feeding intervals, providing few varieties of fruit, no chance for the baby to learn eating, and using food as a reward [7-10]. Parents are the "gatekeepers" of children's eating environments. Their feeding practices strongly influence children's eating patterns, which lay the foundation of future eating habits and children's weight [11,12]. Research has shown that rapid early weight gain before 2 years of age is associated with the increased risk of later overweight or obesity, and infant feeding practices have a high potential for long-term health effects [13-15]. Undoubtedly, first-time mothers are in greater need of guidance and support on appropriate infant feeding practices.

Mobile phone ownership and subscription have been rising sharply in the past decade, including in developing countries such as India and China. Globally, there are approximately 7.6 billion mobile phone subscriptions, growing 4% year-on-year [16]. The application of mobile phones in delivering health care, known as mobile health (mHealth), has attracted much attention [17,18]. Short message service (SMS) text messaging, as an example of mHealth, represents an innovative channel for information to be delivered cheaply to people wherever they are located and whenever available [19]. In recent years, the use of SMS text messaging for health service delivery and public health interventions has also been on the rise [20-22]. Despite the rapid growth and application of mHealth, including SMS text messaging, in public health, to date, few studies have detailed the experience and lessons learned from planning, development, and implementation of SMS text messaging interventions. The aim of this paper is to present the planning and development, implementation, and process evaluation of a community-based SMS text messaging intervention targeted at improved infant feeding practices in Shanghai, China.

Methods

Short Message Service Text Messaging Intervention Design

A 3-year community-based SMS text messaging intervention research was developed and implemented in Shanghai to explore an innovative approach to support new mothers for establishing appropriate infant feeding practices in an effort to prevent childhood obesity. The study is a quasi-experimental design. We purposively selected 4 community health centers (CHCs) from 2 districts of Shanghai. In each district, 2 CHCs with a similar population size were selected; one CHC was randomly assigned as the intervention and the other as the control site. Therefore, 2 CHCs were assigned as intervention group and 2 as control group. During the first antenatal visit to the CHCs in the first trimester, pregnant women who gave consent were recruited for the study. Before the third trimester, the pregnant women recruited for the study were contacted to confirm their eligibility and willingness to participate in the study. Participants in the intervention group would then receive weekly SMS text messages on breastfeeding and infant feeding from the third trimester to 12 months postpartum in addition to the usual health care they received from CHCs. Participating mothers in the control group received the usual health care services during late pregnancy and postpartum, as did the intervention group. Infants of mothers in both groups had the same routine physical checkups at the CHCs in the first year. The median duration of exclusive breastfeeding (EBF) and the prevalence of EBF at 6 months were the main outcome measures and were compared between the two groups [23]. Other outcomes included any breastfeeding rate at 12 months and some infant feeding practices (eg, food for reward, etc). In this paper, we report the process of the planning and development, implementation, and process evaluation of the intervention using documentation such as researchers' diaries, field records, project meeting minutes, and qualitative interviews with participants. The study was conducted between September 2010 and December 2013.

Intervention Planning and Development

The development of this SMS text messaging intervention was informed by the Healthy Beginnings Trial, which was a staged, home-based, early obesity intervention in the first 2 years of life [24]. However, the home visiting approach is a very costly approach that may not be feasible in the Chinese context. With emerging evidence regarding the use of SMS text messaging in health promotion interventions, we considered whether SMS text messaging could act as an alternative means to deliver staged early interventions to mothers of young children, at a lower cost and with greater population reach.

In planning and developing the SMS text messaging intervention, we adopted a 3-phase process, including: (1) qualitative interviews with pregnant women and new mothers to explore barriers in appropriate infant feeding practices; (2) a baseline questionnaire survey to understand the preferred intervention approaches among pregnant women and new mothers; and (3) the development of an SMS text message bank.

Phase 1: Qualitative Interviews to Explore the Barriers

The initial qualitative study aimed to: (1) enquire about any existing infant feeding-related interventions the women have received from the health system during perinatal care; (2) explore barriers to EBF and the reasons preventing women from breastfeeding for the recommended duration and to elicit any perceived difficulties in introducing complementary foods to infants; (3) identify culturally appropriate ways to access and

interact with pregnant women and new mothers; and (4) explore the preferred frequency and time for receiving messages.

We conducted in-depth interviews with 24 new mothers who had infants younger than 12 months of age and conducted two focus groups, each with 7 pregnant women in the late third trimester. Methods of data collection and analysis have been published elsewhere [25]. We found that: (1) there was limited communication between health professionals and either pregnant women or new mothers about breastfeeding; (2) there was inadequate support from health professionals for dealing with breastfeeding difficulties and problems of infant feeding; (3) the participants thought that the mobile phone could potentially be an effective channel of communication between themselves and health professionals; and (4) the preferred frequency and time of receiving messages were on a weekly basis and during daytime (from 9:00 am to 6:00 pm) [26].

Phase 2: Baseline Questionnaire Survey

A baseline survey was carried out in the 4 communities selected for the intervention study. A total of 653 pregnant women who consented to join in the SMS text messaging intervention were invited to participate in the baseline survey during their first visit to the prenatal care service in the CHCs before 22 weeks' gestation. The survey results showed that (1) awareness of World Health Organization (WHO) breastfeeding guidelines among these women was low; (2) intention to breastfeed exclusively during the first 6 months among these women was also low; and (3) nearly all women owned mobile phones, and around 94.6%(618/653) of women continued to use mobile phones during their pregnancy [25,26].

Phase 3: Development of a Message Bank

The above results were used to inform the development of an SMS text message bank and intervention model. A message bank was established before the start of the intervention and evolved during the project. The information source included the WHO Breastfeeding Guidelines [27], the Chinese Residents Nutrition Guidelines [28], and recommendations from the infant feeding literature, through consultations with pediatricians and community child health workers as well as findings from the formative qualitative study and baseline survey. The key information on infant feeding was edited to be suitable for delivery via an SMS text message. The guiding principles for designing messages included consideration of key knowledge of infant feeding, use of an evidence-based approach, use of simple language, avoidance of technical terminology, and a supportive and friendly tone. Each message usually covered one issue or topic and was between 180 to 210 characters, allowing it to be shown on one mobile phone screen as a complete message.

The research team, including researchers in maternal and child health areas from both Fudan University, China, and the University of Sydney, Australia, designed the message bank. An expert advisory committee was established to provide guidance and review the contents of breastfeeding and infant feeding messages for children aged 0-12 months of age. The advisory committee included pediatricians and child health care professionals from municipal, district, and community levels and academic researchers of maternal and child health care in China.

The Implementation of the Short Message Service Intervention

The intervention was implemented in 4 purposively selected CHCs from 2 administrative districts of Shanghai [23]. Of these, 2 CHCs were assigned as the intervention group (n=281), and the other 2 were the control group (n=301). All participants were first-time mothers. The intervention group received a weekly message relating to appropriate infant feeding practices via their mobile phone as well as routine perinatal and child health care. Participating mothers in the control group only received the routine perinatal and child health care services.

Platform for Short Message Service Text Messaging Delivery

Messages were sent from 2 free computer-based platforms: (1) "Fetion" for sending messages to China Mobile subscribers, that is, >90% of the study participants, with no cost for sending or receiving messages and (2) "Frontline SMS" for sending messages to subscribers of China Telecom and China Unicom, which cost 0.1 renminbi per message (≈US $0.017), but there is no cost for receiving messages (Figure 1). The research team at Fudan University was responsible for sending messages to participants through the platforms.

Figure 1. The short message service (SMS) text messaging operation platform.

Textbox 1. Examples of short message service (SMS) text messages for infant feeding (translated from Chinese to English).

Late pregnancy (1st message in the 3rd trimester)

- To all mothers:

Dear Mom, congratulations! You are now entering the third trimester. In 2-3 months, your baby will be born. Have you started thinking about the way you will give birth and feed your new baby? From now on, we will help you with these issues. World Health Organization recommends that exclusively breastfeeding baby in the first 6 months can help achieve optimal growth, development, and health. From next week, we will send information to you through SMS text message. You are welcome to contact us by sending us SMS text messages or call us directly!

The 4th week after birth

- To mothers practicing exclusive breastfeeding:

Dear Mother, your baby is going to enter the 2nd month. In this month, your baby will be able to raise his or her head. Some mothers would ask whether they should add formula to baby's milk to meet the baby's growth needs. Your breast milk can meet all nutritional needs of your baby before 6 months. We strongly suggest you to exclusively breastfeed in the first 6 months. This means breastfeeding without adding any other food or drink, including water, since water is the main component of breast milk.

- To mothers practicing mixed breastfeeding or formula feeding:

Dear Mother, for whatever reasons you cannot exclusively breastfeed your babies, it is recommended that you feed your baby with infant formula for appropriate age. Please follow the instructions for the appropriate quantity of water. Baby could have diarrhea if the formula is too concentrated. If the formula is too thin, it can cause malnutrition. Please apply hygienic practice when handling formula. Leftover milk should be disposed.

Content Delivered

The SMS text messaging intervention was delivered from the beginning of the third trimester (28 weeks gestation) to 12 months postpartum (ie, 66 weeks in total). Before the intervention commenced, mothers in the intervention group were sent a greeting message, alerting them to the beginning of the intervention with a brief introduction of the project. This was followed by the first weekly intervention message.

The SMS text messages were tailored initially for mothers in the third trimester of pregnancy and then for the different stages of child development in the first 12 months. For example, during the third trimester, key messages were focused on the benefits of breastfeeding for both babies and mothers and on advising mothers to be mentally and physically prepared for breastfeeding. Within the first week of giving birth, the emphasis was on helping mothers with different delivery modes to initiate breastfeeding. There were 3 sets of messages according to mothers' breastfeeding and work status after childbirth [23]. The corresponding messages were sent once the infant feeding practices changed. SMS text messages were also used for collecting information on infant feeding status from mothers to trigger the delivery of appropriate messages. From the 35th gestational week, in addition to weekly messages about specific content, separate messages were also sent to mothers inquiring whether they had given birth, their breastfeeding status, whether they had returned to work, or the timing of introduction of solids to determine the relevant types and content of messages to be sent. For any other conditions, for example, if the infant became sick, mothers were encouraged to contact the research team through SMS text messages and to seek medical attention. Routine health check-up records in CHCs were also reviewed to obtain or confirm information on the change in infant feeding practices.

Since most Chinese women return to work around 4 months after childbirth, from the 3rd month, specific messages were sent to the mothers who would go back to work, encouraging them to continue EBF. At the 4th and 5th month postpartum, mothers were advised how to introduce complementary foods from the 6th month and how to establish appropriate feeding practices. Tactics and strategies on how to deal with problems during infant feeding in the next several months were also suggested (examples are shown in Textbox 1).

Results

In this paper, we report the results of the intervention process evaluation. The effect of the intervention on breastfeeding practices has been previously reported [23]. Briefly, compared with the control group, the intervention group had a significantly longer median duration of EBF at 6 months (11.41 weeks, 95% CI 10.25-12.57 vs 8.87 weeks, 95% CI 7.84-9.89). The intervention resulted in a significantly higher rate of EBF at 6 months (adjusted odds ratio=2.67, 95% CI 1.45-4.91) [23].

The process evaluation was conducted across the entire duration of the intervention and included: (1) records of questions received from mothers via SMS text messages, records of mothers' reports on changes in feeding practices, and records of the number of messages sent; (2) qualitative interviews with mothers in the midterm of the intervention; and (3) qualitative interviews with mothers at the end of the intervention.

The rate of feedback from mothers on the status of infant feeding through messages was 73.0% (205/281) and 60.4% (160/265) at the end of the 1st and 4th postnatal months, respectively. By the end of the intervention, a total of 19,108 messages had been sent, an average of 68 messages to each participant.

While we delivered weekly SMS text messages to mothers, they were encouraged to ask questions and communicate with the research team about problems and concerns encountered during infant feeding. If the research team received inquiries about breastfeeding or complementary feeding, we would either respond directly or consult members of the expert committee.

If inquiries were about a medical condition, we would suggest mothers seek medical attention. By the end of the intervention, 43.4% (122/281) of mothers in the intervention group made inquiries through SMS text messages. A total of 601 messages were received from the participants. These inquiries covered three main areas:

1. Breastfeeding (eg, insufficient milk supply, reflux, baby falling asleep while breastfeeding, breastfeeding while the mother had an upper respiratory tract infection, dietary restrictions, approaches to expressing milk, dealing with mastitis)
2. Introduction of complementary food (eg, when and how much of the calcium and vitamin A supplement to give)
3. Other issues (eg, neonatal jaundice, eczema, diarrhea, upper respiratory tract infections, sucking hand, etc)

A midterm evaluation was conducted through in-depth interviews with mothers 6-8 months after the start of the intervention to obtain feedback on whether the intervention was implemented as designed and whether the intervention frequency and content were appropriate. A total of 22 mothers with various infant feeding practices (EBF, mixed breastfeeding, infant formula feeding) were purposively selected by the CHCs. Mothers were asked about their overall reflection on the intervention and were prompted for issues emerging from the intervention process.

Table 1 shows the themes identified from the interviews. There was positive feedback from mothers on the intervention frequency, content, feedback to questions, and the suitability of the language level of SMS text messaging intervention. Concerns that emerged from the interviews included occasional failure of receiving messages in one residential area due to an unstable telecommunication signal and unmet expectations in the time to respond to questions. In addressing these issues, a follow-up message was sent to all mothers in that area, asking whether they had received a message in the past 7 days. In addition, mothers were encouraged to inform the research staff if they did not receive the scheduled message. The research team also developed a protocol to ensure that all inquiries should be replied to within the same working day. If the inquiries were made at night or weekends, they would be replied to on the following morning or the following Monday morning.

At the completion of the intervention, in-depth interviews were carried out with 15 mothers in the intervention group to elicit perspectives of service users on the strengths and limitations of the SMS text messaging intervention. Interviewees were purposely selected based on their different types of infant feeding practices and mothers' work status (returned to work or still staying at home). The perceived strengths of the SMS text messaging intervention included convenient and information can be accessed repeatedly, information could be shared with friends and family members, timely support and anticipatory guiding, and trust to the information as it came from a trustworthy source. The main perceived weakness of the SMS text messaging in this study included the limited information load because of the word limit in a message and lack of personalized contents (Table 1).

Table 1. Themes and selected quotes from the process evaluation.

Themes	Selected quotes
Midterm evaluation	
Positive reflections on short message service (SMS) text messaging intervention	
Timely delivery in most intervention areas	*[I remember receiving messages] once a week…sometimes two to three messages in the week [including messages inquiring BF[a] status from research group].* [EBF[b], 4 months postpartum]
Acceptable and appropriate intervention frequency and intensity	*I feel the weekly message is good. I feel this frequency can cover all information of my needs during the week.* [EBF, 5 months postpartum]
Anticipatory and appropriate SMS text messaging contents	*The messages were sent timely, [the contents are] always a bit earlier than what will happen.* [EBF, 4 months postpartum]
	I learnt not to feed sugar water to baby in one message. My parents used to feed my baby sugar water. But since I received the message, we do not give it anymore. [Mixed infant feeding, less than 1 month postpartum]
Replying to questions being helpful in dealing with problems of infant feeding	*I made an inquiry of what to do with inadequate breast milk after returning to work through the message. I felt the response was very helpful.* [EBF, 5 months postpartum]
Problems emerging at midterm evaluation	
The occasional failure of message sending in one neighborhood due to unstable mobile signal in the area	*It seems every a couple of weeks [for receiving messages]…the telecom signal is not very good in my house area.* [Mixed infant feeding, 4 months postpartum]
High expectation on timely response to inquiries	*Sometimes I got responses very quickly, but I received the message on the following day if I sent the question at night.* [Having stopped breastfeeding, 4 months postpartum]
Final qualitative evaluation	
Strength of SMS text messaging	
Convenient to save, read, repeatedly review, and share with others	*I saved all messages. And usually I shared them with my mother-in-law…Sometime she does not agree with me on some infant feeding practice, so I show the message to her. For example, she wanted to feed egg to the baby at 4 months, I declined, but she continued to try and said she already fed my husband when he was 4 months old. But after I showed the message to her, she then stopped.* [BF to 10 months, returned to work at 4 months]
Timely support and anticipatory guiding	*To me, messages allow me continuously learn about [infant feeding]. The contents [of messages] match the age of my baby, and they can be applied to the practice soon.* [EBF to 6 months, BF to 9 months, return to work 14 months postpartum]
Easy to build the trust	*I feel the messages like a friend of mine. I do not go to the internet to search for specific information now. I am accustomed to receiving the weekly message and feel this is a very natural thing.* [EBF to 6 months, returned to work at 4.5 months]
Weakness of SMS text messaging	
Limited information due to the word limit of messages	*I feel messages could be a reference for me, but the content is not long enough.* [Infant formula feeding, returned to work at 6.5 months]
Messages could have been more "personalized"	*I feel the messages were similar to those on the internet and books. I would prefer information that could not be found in the internet, particularly on how to let my baby eat more.* [BF to 9 months, returned to work at 4 months]

[a]BF: breastfeeding.

[b]EBF: exclusive breastfeeding.

Discussion

In this paper, we have documented the planning and development, implementation, and process evaluation of an SMS text messaging intervention aimed at improving infant feeding practices. Given the limited literature on the detailed process of mHealth interventions, this paper contributes to informing and improving the development and implementation of future mHealth interventions and infant feeding research.

The strengths of the study are 2-fold. First, the study took a systematic approach based on the health promotion management framework [29], including planning and development, implementation, and process evaluation. Second, the development of the intervention was evidence based. The overall intervention strategy was to establish a supportive environment for mothers, which was informed by the needs assessment from the qualitative interviews during intervention planning and development. For example, we adopted mothers' preferences of receiving a weekly push message rather than a higher frequency. This was also indicated by two previous mHealth studies that showed behavior changes were significantly better among patients who received a weekly supporting message

when compared to those with a daily reminding message [30-32].

The implementation of the SMS text messaging intervention used a computer-based device that was easy to operate, even in resource-limited settings. The process evaluation revealed some positive qualities of the study. Mothers viewed the SMS text messaging intervention favorably as they enjoyed the easy and flexible access in terms of cost and time as well as the ability to view SMS text messages repeatedly and share with others. In addition, mothers felt confident about applying practices promoted in messages from trustworthy sources, for example, health care service providers or public health researchers. This indicates that information from trusted sources is important for the SMS text messaging acceptability and information dissemination. The issue of trusted sources is reinforced by a recent evaluation study of 26 free-download Chinese infant and young child feeding apps developed by commercial entities [33].

As text messaging has the minimal requirement of a mobile phone, it can be readily expanded to many health care services and regions of limited resources [34]. SMS text messaging has shown its value in filling gaps in delivering health care services in settings where personal contact is limited. However, as an innovative way of care delivery, SMS text messaging intervention should not simply replace other forms of interventions, especially those with direct face-to-face contact, such as antenatal clinics and consultation with maternal and child health professionals.

The results also revealed several areas for improvement and lessons learned. It appears that the study did not always meet some mothers' expectations, such as the need to respond immediately to their text inquiries. Clear communication upfront with the mothers is a way to manage such expectations. Although the SMS text messages were tailored to different stages of the child's development, it was difficult to meet all specific needs of all users. The requirement for more personalized support is also advocated in the contemporary mHealth literature [35]. This might be achieved through the design of message texts based on participant's detailed individual data, as has been done in a healthy lifestyle promotion project [36]. However, this undoubtedly will need more time and human resources. The time commitment required from the research team has also been highlighted by others [37]. The quality of telecommunication service might affect the SMS text message delivery, which, in turn, could affect the effectiveness of the intervention. Therefore, monitoring the delivery of the intervention should be considered.

For future research of using mHealth to improve infant and young child feeding, implementation research is needed to explore the facilitators and barriers before upscaling the intervention. As smartphone users have increased rapidly in recent years, there are opportunities to develop an evidence-based infant feeding app. The cost-effectiveness analysis of SMS text messaging interventions, or mHealth interventions in general, which is understudied, should be enhanced [34,38]. Finally, mHealth interventions should be based on health promotion theory to improve the likelihood of being effective [39,40].

Leveraging mobile phone technology promises to overcome barriers to accessing health systems, service delivery, and improved health promotion. Systematically documenting the planning and development, implementation, and process evaluation of an intervention is useful for informing and improving the development of future mHealth interventions.

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Conflicts of Interest

None declared.

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Abbreviations

BF: breastfeeding
CHC: community health center
EBF: exclusive breastfeeding
mHealth: mobile health
SMS: short message service
WHO: World Health Organization

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Original Paper

Development of an mHealth platform for HIV Care: Gathering User Perspectives Through Co-Design Workshops and Interviews

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Abstract

Background: Despite advances in testing and treatment, HIV incidence rates within European countries are at best stable or else increasing. mHealth technology has been advocated to increase quality and cost-effectiveness of health services while dealing with growing patient numbers. However, studies suggested that mHealth apps are rarely adopted and often considered to be of low quality by users. Only a few studies (conducted in the United States) have involved people living with HIV (PLWH) in the design of mHealth.

Objective: The goal of this study was to facilitate a co-design process among PLWH and clinicians across 5 clinical sites in the European Union to inform the development of an mHealth platform to be integrated into clinical care pathways. We aimed to (1) elicit experiences of living with HIV and of working in HIV care, (2) identify mHealth functionalities that are considered useful for HIV care, and (3) identify potential benefits as well as concerns about mHealth.

Methods: Between January and June 2016, 14 co-design workshops and 22 semistructured interviews were conducted, involving 97 PLWH and 63 clinicians. Data were analyzed thematically and iteratively, drawing on grounded theory techniques.

Results: Findings were established into 3 thematic clusters: (1) *approaching the mHealth platform*, (2) *imagining the mHealth platform*, and (3) *anticipating the mHealth platform's implications*. Co-design participants *approached* the mHealth platform with pre-existing concerns arising from their experiences of receiving or providing care. PLWH particularly addressed issues of stigma and questioned how mHealth could enable them to manage their HIV. Clinicians problematized the compatibility of mHealth with existing information technology systems and questioned which patients should be targeted by mHealth. *Imagining* the potential of mHealth for HIV care, co-design participants suggested *medical functionalities* (accessing test results, managing medicines and appointments, and digital communication channels), *social functionalities* (peer support network, international travel, etc), and *general features* (security and privacy, credibility, language, etc). Co-design participants also *anticipated* potential implications of mHealth for self-management and the provision of care.

Conclusions: Our approach to co-design enabled us to facilitate early engagement in the mHealth platform, enabling patient and clinician feedback to become embedded in the development process at a preprototype phase. Although the technologies in question were not yet present, understanding how users approach, imagine, and anticipate technology formed an important source of knowledge and proved highly significant within the technology design and development process.

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KEYWORDS

mHealth; mobile applications; telemedicine; information technology; sexual health; HIV; self-management; patient participation; sociology, medical; community-based participatory research; health services

Introduction

Since the availability of effective antiretroviral therapy (ART) by the end of the 1990s, HIV has transformed, in developed countries at least, from a fatal to a chronic disease. People living with HIV (PLWH) who have access to testing, treatment, and care can enjoy a good quality of life and the same life expectancy as the general population [1]. However, despite several advances in HIV testing and new biomedical HIV prevention modalities (such as early ART for prevention), the incidence rates within European countries are at best stable, and in some cases, they are even increasing [2]. In association with longer life expectancy, this leads to a continuously increasing number of people requiring long-term treatment and follow-up.

mHealth technologies, based on smartphone and Web 2.0 apps, are seen by policy makers, developers, and some medical professionals as an opportunity to increase the quality and cost-effectiveness of health services while dealing with growing numbers of patients [3-6]. Systematic reviews in the field of HIV care have highlighted that mHealth interventions have significant potential to support patients' self-management and treatment adherence [7,8]. Self-management is understood as care that is led, owned, and undertaken by patients' themselves. To this end, mHealth tools can provide patients with ubiquitous access to health data, information, and counseling beyond the face-to-face clinical encounter, which might reduce the need for routine clinical appointments and thus lower both the impact of HIV on patients' lives and health care expenditure. Effective ART requires a 95% adherence to the antiretroviral medication regime. In this respect, mHealth can be utilized to send medication and appointment reminders to patients or provide them with information about prescribed medicines and drug interactions. A high level of treatment adherence contributes to viral suppression and thus increases HIV patients' life expectancy and quality while decreasing the risk of forward transmission of HIV [9].

Systematic reviews identify several smartphone apps for HIV self-management and medication adherence available in app stores [10-12]. However, the authors highlight that most of these apps were infrequently downloaded and were considered of low quality by users as they did not have desirable features. The reviews stress the need for formative evaluations that include end users within the design, development, and implementation of mHealth devices to make them more accessible and meaningful. In addition, studies on the general adoption of health apps show that despite a vast range of available apps, only a small number are actually used [13]. If the ambitions of mHealth to improve quality and utilization of health care are to be realized, *co-design* processes that bring together health care providers, researchers, technology developers, and end users are crucial to produce useful and usable mHealth technologies.

Only a few studies have involved PLWH to inform the design of smartphone apps for HIV prevention, treatment, and care [14-16] or to test prototypes [17]. Furthermore, in the context of HIV care, clinicians are almost never considered as potential adopters of mHealth technology and so are rarely included in co-design initiatives. So far, only 1 study has assessed HIV clinicians' attitudes toward mHealth and, thereby, outlined perspectives of how this technology could be integrated into clinical care pathways [18]. Moreover, the involvement of users—most often PLWH—tends to be restricted to the initial mHealth design phase, and only very recently are studies beginning to extend user involvement (focusing on young men who have sex with men) to the implementation phase of mHealth interventions [17,19]. Although critical decisions about what desired functionalities are included in the final product can be made in the design phase, it is only later in the implementation phase that actual experiences with mHealth devices can be captured and reflected upon. Finally, most participatory studies were conducted in the United States [14-19], and to our knowledge, there is no evidence of how PLWH and clinicians in European health care systems evaluate the potentials and risks of mHealth for use in HIV treatment and care.

In this paper, we address these gaps by presenting results from the first phase of an mHealth co-design process involving 97 PLWH and 63 clinicians from 5 clinical sites in the European Union (EU). We asked co-design participants to reflect, in the design phase, on the potentiality and risks they associated with mHealth in the context of HIV treatment and care and on the precise functionalities that they thought could support self-management of HIV. These findings were used to inform the development of a comprehensive mHealth platform that is currently being implemented within clinical treatment pathways in the 5 clinical sites. Later phases of the co-design work will seek to capture patients' and clinicians' experiences in the use of the platform to support continuous improvement as new pathways and technologies become embedded into HIV care.

Methods

The Evaluating mHealth Technology in HIV to Improve Empowerment and Health Care Utilization: Research and Innovation to Generate Evidence for Personalized Care Project

The co-design process presented in this paper is part of the *Evaluating mHealth Technology in HIV to Improve Empowerment and Health Care Utilization: Research and Innovation to Generate Evidence for Personalized Care (EmERGE) project* (please refer to [20]), which is funded under the EU's Horizon 2020 Programme (project period: 2015-2020). The project aims to develop, implement, and evaluate an mHealth platform to support self-management among HIV patients in 5 clinical sites (Brighton, Antwerp, Zagreb, Barcelona, and Lisbon). The platform is currently being integrated into clinical HIV pathways and provides users (PLWH and clinicians) with smartphone and Web apps to facilitate access to personal health data and improve patient-provider communication. Through these functionalities, the EmERGE mHealth platform aims to reduce some routine clinic visits of HIV patients and support patients to better self-manage their own care. According to international guidelines, PLWH are currently seen every 3 to 6 months [21]. However, the EmERGE mHealth care pathway requires HIV patients to see their consultant face-to-face only every 12 months, while they can continuously monitor their blood results

and maintain contact with their clinic through the smartphone app. Previous studies that have investigated the potential of mHealth in HIV care have suggested that such reductions in hospital visits are desirable for increasing the quality of life of PLWH [18]. The EmERGE project, as a whole, aims to validate the acceptability, usability, and effectiveness of the mHealth platform; assess its impact on patient self - management and empowerment; analyze its cost-effectiveness; and disseminate the mHealth platform across various European health care settings as a sustainable, effective, safe, and economic modality for HIV care. The co-design process, outlined in this paper, constitutes an essential part of the *sociotechnical evaluation* work package, which seeks to identify and support factors that can help facilitate the successful introduction of the new care pathway. In the first year of the project (June 2015 to June 2016), in the platform's initial *design phase*, we undertook a co-design process among potential users of the EmERGE platform—PLWH and clinicians. The results from this process are presented in this paper and have informed the technology development. Further research is currently being carried out, as the platform is implemented, to investigate how it reconfigures practices of HIV care [22]. Study approval was obtained from the ethics committee of the University of Brighton, the National Health Service (NHS) Health Research Authority, and governance boards at each clinical site.

Facilitating Co-Design

Co-design research is recognized as an important means to establish the effective and responsible delivery of mHealth technologies [23-25]. In this section, we highlight how we engaged PLWH and clinicians in co-design to elicit current challenges of HIV care and to consider the potential uses and implications of integrating an mHealth platform within existing care pathways.

To initiate co-design, we worked closely with HIV clinicians and patient organizations, in particular, the European Aids Treatment Group (EATG) and its local partners within each study site. Collaboratively, we designed a protocol for engaging PLWH and clinicians alongside the iterative phases of the platform's design and implementation. We decided to use co-design workshops as the main method through which potential users in design activities to develop ideas and identify challenges could be involved [26]. However, co-design workshops are also recognized as a challenging method. Time-constrained clinicians as well as some of the more vulnerable and often stigmatized HIV patients can find it difficult to participate in lengthy, group-based workshops. To attend to this potential shortcoming, individual interviews were offered as an alternative means to engage participants who were unwilling or unable to attend workshops.

With our clinical and PLWH-community partners, we established a schedule for workshops and interviews. First, the idea of using an mHealth platform for HIV care was presented as a narrative stimulus to identify ideas and new ways of *doing* HIV care. Thereafter, co-design activities were conducted in 3 phases that all drew on the *use situation* as a fundamental starting point for design [27]. First, participants were encouraged to discuss current practices of HIV care and uses of apps and mHealth technologies in their everyday lives. Second, they were prompted to imagine potential functionalities and features that could be provided through mHealth platforms and used within HIV care. Finally, participants were encouraged to anticipate potential implications of the use of mHealth platforms. Together, these open areas of questioning facilitated a range of views and experiences, including apparently contradictory ones.

PLWH-community partners at each of the study sites were trained as peer researchers to mobilize interest in the study, support the recruitment of patients, and facilitate co-design workshops and interviews in the local languages in cases where participants were not fluent in English. Community partners were regarded as trustworthy and knowledgeable by most PLWH, and they were experienced in moderating groups and working with vulnerable people.

Recruitment and Data Collection

We attempted purposive sampling to recruit a diversity of PLWH (eg, gender, age, and nationality) and clinicians (eg, having a good representation of doctors and nurses) while accepting that fieldwork pragmatics (such as study timelines, access to potential participants, etc) will limit its success. A total of 97 PLWH and 63 clinicians were recruited into the co-design process. From the 97 PLWH we recruited, 19 were women. Moreover, 65 PLWH identified themselves as gay or lesbian, 26 as heterosexual, 3 as bisexual, and 3 belonging to none of these categories. The age range was 23 to 78 years with 11 participants under 30 years, 75 between 30 and 59 years, and 7 were 60 years or above (4 missing values). The length of diagnosis of HIV ranged from 0.5 to 31 years. Furthermore, 64 of the PLWH were working or studying, 21 were unemployed, and 12 were retired. PLWH had 14 different nationalities and 13 identified themselves as belonging to a migrant community. From the group of 63 clinicians, 19 were male. Clinicians included 40 doctors, 10 nurses, 4 psychologists, 4 pharmacists, 2 social workers, 2 nutritionists, and 1 sexologist.

A total of 14 workshops and 22 interviews were conducted at the offices of community partners, at hotels, or in the clinic, depending on what was appropriate. Table 1 shows the distribution of data collection and participants across the 5 study sites. The small number of clinicians (n=4) who participated in Zagreb is due to the size of the HIV clinic there (just 8 clinicians and a total of 862 patients). The other sites have between 2246 and 4846 patients and employ between 26 and 30 clinicians (according to 2014 data). In workshops indicated as *mixed*, PLWH and clinicians were involved in discussions together. While workshops with clinicians and *mixed* ones were conducted in English by the academic researcher, workshops with PLWH were facilitated in the local language by a community partner, with the academic researcher and a member of the EATG also present. An instant translator enabled the researchers to take notes and raise additional questions, as appropriate. Moreover, 15 interviews were conducted in English by the academic researcher and 7 interviews with PLWH by community partners in local languages. Throughout the data collection, the EATG member and the lead author exchanged and discussed their notes and debriefed impressions of the workshops with community partners. Workshops and interviews were audio recorded

(average recording length: 95 min and 45 min, respectively). All recordings were transcribed verbatim and non-English transcripts were thoroughly translated. Participants provided written informed consent before the interview or workshop, and PLWH received €25 or £20 remuneration for participation.

Analytic Approach

Data were analyzed thematically and iteratively, drawing on grounded theory techniques [28]. First, transcripts were carefully read-through by the first author of this paper (BM), and initial thoughts were documented. Open coding, conducted by BM, involved a sequential analysis where sentences with significant meaning were assigned first conceptual labels. These initial codes were then discussed among the whole academic research team (BM, FH, and MD) on a bimonthly basis, whereby they were continuously revised and established into thematic clusters and categories. Furthermore, preliminary findings were continuously discussed with the EATG, PLWH-community partners, and the whole EmERGE Consortium. NVivo 11 software (QSR International Pty Ltd) was used to support the management of the textual data and to organize the codes being assigned to the transcripts.

Table 1. Data collection across study sites.

Study site and mode of data collection	Participants' characteristics					
	Male		Female		Total participants	
	PLWH[a]	Clinicians	PLWH	Clinicians	PLWH	Clinicians
Brighton (Br)						
1 workshop PLWH	7	—	1	—	8	—
1 workshop PLWH	6	—	3	—	9	—
2 interviews PLWH	1	—	1	—	2	—
1 workshop clinicians	—	3	—	8	—	11
1 interview clinicians	—	—	—	1	—	1
Lisbon (Li)						
1 workshop PLWH	4	—	4	—	8	—
1 workshop PLWH	7	—	3	—	10	—
4 interviews PLWH	4	—	—	—	4	—
1 workshop clinicians	—	2	—	11	—	13
1 interview clinicians	—	1	—	—	—	1
Antwerp (An)						
1 workshop PLWH	9	—	1	—	10	—
1 workshop (mixed)	5	1	1	2	6	3
3 interviews PLWH	3	—	—	—	3	—
1 workshop Clinicians	—	4	—	9	—	13
Zagreb (Za)						
1 workshop PLWH	5	—	2	—	7	—
1 workshop (mixed)	3	2	—	2	3	4
5 interviews PLWH	4	—	1	—	5	—
Barcelona (Ba)						
1 workshop PLWH	9	—	1	—	10	—
1 workshop (mixed)	5	1	1	4	6	5
6 interviews PLWH	6	—	—	—	6	—
1 workshop clinicians	—	5	—	7	—	12
Total (7 workshops PLWH; 3 workshops [mixed]; 20 interviews PLWH; 4 workshops clinicians; and 2 interviews clinicians)	78	19	19	44	97	63

[a]PLWH: people living with HIV.

Design Specification and Priorities

A further step in co-design involved ensuring that the outcomes of workshops and interviews were embedded in decision making. Therefore, the outcomes of our study were presented and discussed at EmERGE Consortium meetings, where lead clinicians from each study site, PLWH (represented through EATG), researchers (from University of Brighton), and technology developers were represented and had the opportunity to provide feedback. Following these initial discussions, a technical co-design group, consisting of 2 representatives from these parties (clinicians, PLWH, researchers, and developers), was formed to outline a design specification document and discuss priorities for the development of functionalities and features to be included in the prototype platform. This group held several meetings and worked in partnership with community partners, clinicians, and the project consortium on an ongoing basis to ensure that priorities were reviewed and rearticulated in light of ongoing changes and specific contexts. In the following section, we present the results from co-design workshops and interviews. Thereby, we use quotes from participants, only indicating participant (P=PLWH; C=clinician), study site (by first 2 letters), and mode of data collection (WSm=workshop mixed, I=interview), for example, P_Za_WSm. In the discussion section of the paper, we will outline how these results informed the development of the EmERGE prototype platform.

Results

Overview

As Textbox 1 illustrates, we established our findings into 3 broad thematic clusters: (1) *approaching the mHealth platform*, (2) *imagining the mHealth platform*, and (3) *anticipating the mHealth platform's implications*. At the start of the co-design workshops and interviews, we introduced the aim of the co-design study, namely, to explore the concept of an mHealth platform to participants. One specific aim of our study was to elicit experiences of living with HIV or working in HIV care. Therefore, before discussing the possible functionalities that could be included within such a platform, we asked participants to broadly reflect on their experiences of living with HIV or of working as an HIV clinician. Throughout the data analysis, it became evident that these general experiences formed the ways in which PLWH and clinicians were reflecting upon possible functionalities, opportunities, and drawbacks of an mHealth platform. To indicate this, we labeled initial themes as questions by which PLWH and clinicians were *approaching the mHealth platform*. From the backdrop of these approaches, our participants started *imagining the mHealth platform* and articulated tentative interpretations about what an mHealth platform for HIV care could *do*. Thereby, linked to our second study aim, potential functionalities and components of the platform were discussed. Once potential functionalities were conceptualized, study participants then elaborated connections between technology functions and the wider context within which it will be utilized. Thereby, participants anticipated the platform's potential implications for self-management and the provision of health care and, thus, contributed to our third study aim to understand the potential benefits of, and concerns about, mHealth.

Approaching the mHealth Platform

Both PLWH and clinicians approached discussions about the proposed mHealth platform with pre-existing concerns arising from their experiences of receiving or providing HIV care. While broadly reflecting on experiences of living with HIV, PLWH particularly addressed the issue of stigma and the ways in which they attempt to take control of HIV. Clinicians working in the field of HIV care focused on their experiences with digital technologies and questioned what type of patient will be capable of engaging with mHealth.

Patients' Approaches

Renegotiating Stigma?

Experiences of stigma were a topic within most of the workshops and interviews. Several PLWH argued that the general public as well as some health care professionals still lack knowledge about HIV. To illustrate this impression, 1 participant reported an incident where his neighbor, while inviting him for coffee, told him: "...but bring your own mug" (P_Za_WS). Other participants referred to situations where they have been suspended from work when their employer found out that they were HIV positive. Due to such experiences, many participants stated that they do not disclose their HIV status to friends or even their families and thus often feel isolated as they "don't have someone to talk about [HIV]" (P_Za_WSm, male). Moreover, when engaging with health care professionals, some PLWH are reluctant to disclose their HIV status:

> *So even when you go for medical check-ups, you keep quiet...you don't want to be put in that situation where you're labelled, and where you wouldn't get the best possible medical care just because you are HIV positive.* [P_Za_I, male]

Due to such experiences, PLWH approached the mHealth platform by questioning how it would *renegotiate stigma*. Thereby, the platform's functionalities and features were discussed against the backdrop of protecting or jeopardizing confidential HIV data (see section Security and Privacy), and suggestions were made to use the platform to inform the broader public to reduce the stigma of HIV (see the section Changing Public Attitudes Toward HIV).

New Opportunities for Control?

The heterogeneous practices of keeping in control of one's condition were an integral part of patients' illness narratives. Thereby, the adherence to the antiretroviral medication regime was a pressing element: "I know if I don't take the pills I die" (P_Br_WS, male). Most PLWH argued that they use alarms to remember taking their medicines: "with my mobile phone, I set the time...to take medication. For otherwise I forget" (P_An_I, male). Some PLWH, however, stated that they manage their medication intake by integrating it within their "natural schedule" (P_Li_I, male) of everyday routines and thus do not rely on additional reminders.

Textbox 1. Thematic clusters and categories.

- Approaching the mHealth platform (experiences)
  - Patients' approaches: Renegotiating stigma? New opportunities for control?
  - Clinicians' approaches: Compatibility and added value? Who constitutes the target group?
- Imagining the mHealth platform (functionalities)
  - Medical functionalities: accessing test results; managing medicines; managing appointments; and digital communication channels
  - Social functionalities: peer support network; international travel; and changing public attitudes toward HIV
  - General features: security and privacy; credibility; language; sensitivity for disabilities; costs; training and tutorials; and other technicalities
- Anticipating the mHealth platform's implications (benefits and concerns)
  - Implications for self-management: Creating (un)certainty? Reconfiguring relationships? Altering the understanding of health?
  - Implications for health care provision: Replacing traditional care pathways? Rationalities of mHealth? Effects on workload?

Dealing with situations of uncertainty was another important aspect of managing HIV. Such situations can occur when pain or certain symptoms are experienced by PLWH, but they are unsure if these are side effects of HIV medication or part of the normal process of "getting older" (P_Li_WS, female). To deal with such situations, PLWH have to seek for information and advice. Although the HIV consultant was seen as the most trusted source of health information, several PLWH argued that general practitioners (GPs) are often not capable of providing adequate advice as they often lack basic knowledge about HIV and thus are inclined to relate every medical problem to HIV: "you go to the GP, he will tell you 'It's HIV'" (P_Br_WS, female). Community groups were perceived as another important source of health information. For specific health-related problems (eg, side effects of medication), PLWH valued expertise based on experiences from someone who has *lived through it*. With these concerns in mind, PLWH approached the mHealth platform by questioning how it could create new opportunities for control. For example, they asked whether the platform could be seen as a device to keep on top of one's treatment adherence (see the section Managing Medicines and Managing Appointments) and if it could offer new ways to get in touch with health care providers (see the section Digital Communication Channels) or community groups (see the section Peer Support Network).

Clinicians' Approaches

Compatibility and Added Value?

Clinicians often discussed their hospital's technological systems and reflected on whether the mHealth platform would be compatible and provides added value. Some clinicians expressed a general impression that the health care sector is slow in adopting new technologies, saying, "...in the NHS we fall way behind the rest of the world in terms of using social media and electronics in managing our patients" (C_Br_WS, male doctor).

This was seen as problematic because by considering technological advances, the limits of *old* technological systems became apparent. In this way, a clinician in Zagreb illustrated the limits of discussing blood test results through telephone lines:

> *...we ask people [patients living remote from the clinic] to call in approximately two to three weeks after they have been to the visit [where blood was drawn] so that we can discuss the new lab result and I don't think that the system is working perfectly because we cannot answer the phone every time…it happens that the patient doesn't know his lab result until his next appointment.* [C_Za_WSm, male doctor]

In similar ways, the limits of existing email communication with patients (Brighton) with respect to data security were addressed or an existing telecommunication platform for virtual video consultations (Barcelona) was criticized for being only accessible through a conventional Web interface (and not through a smartphone app). Established technological systems, however, were also valued because they have already been adopted within work practices. Therefore, some clinicians questioned if the proposed mHealth platform could be integrated into established systems:

> *I think that [the mHealth platform] is useful if we have one instrument...if it's just one more instrument it's not worth it 'cos it's time-consuming, so I think it it's important to be a platform that connects with the existing ones.* [C_Li_WS, female clinician]

From the backdrop of their work routines and experiences with established technological systems, clinicians approach the mHealth platform by questioning its added value and compatibility. In this regard, clinicians asked how the integration of the platform would affect their workloads (see the section Effects on Workload).

Who Constitutes the Target Group?

Clinicians also addressed the diversity of the patient population. Several clinicians emphasized how important it is "to identify very carefully what kind of patient can improve with this [platform]" (C_Ba_WS, male doctor). In terms of patients' health conditions, most clinicians argued that only patients that "have been doing well for many years" (C_Li_WS, female doctor) and are medically "stable" (C_An_WS, female clinician) should be considered as target group for the mHealth platform. Stable HIV patients have controlled viral loads and cluster of differentiation 4 (CD4) counts, and this was seen as essential

in relation to the platform's functionality *accessing blood results* (see below). It was outlined that, for stable patients, the blood test is rather a routine checkup, and thus, the results are hardly surprising because they are mostly within a certain range. These patients, therefore, would—presumably—not become unsettled when retrieving lab results on a smartphone app. In the case of nonstable patients, however, results are fluctuating, and several clinicians emphasized that such patients would not be able to interpret and make sense of these fluctuations outside of a face-to-face consultation. In a clinical consultation, the meaning of the result can be assessed and implications for the treatment negotiated from the backdrop of patients' broader psychosocial health issues. Hence, it was argued that nonstable patients should not have access to their results before a clinical consultation. Furthermore, it was emphasized that patients require "a certain skill set" (C_Br_I, female nurse) to use the smartphone app (provided with the mHealth platform) and to interpret data and information that are made available on it. Therefore, most clinicians considered only "highly educated" (C_Li_WS, female clinician) and "experienced" (not newly diagnosed) patients (C_Ba_WS, female clinician) as potential target group for the mHealth platform (see the section Creating (Un)certainty?). These approaches had a significant impact on how clinicians discussed potential functionalities and implications of mHealth. This will be outlined in the following section.

Imagining the mHealth Platform

From the backdrop of the experiences of receiving or providing care, participants imagined and articulated potential functionalities and features that could be provided through mHealth. Although clinicians largely suggested functions that we conceptualized as *medical functionalities*, PLWH, additionally, considered *social functionalities* and *general features* in more depth.

Medical Functionalities

Accessing Test Results

Co-design participants discussed whether the mHealth platform, or rather *the app* provided for use by patients through this platform, could provide access to blood test results:

> *If I could receive...the results of my blood tests through the app, I wouldn't have to go to the internist...the app could save me a whole lot of health expenses.* [P_An_WS, male]

In line with this statement, several PLWH and clinicians argued that for some patients (see the section Who Constitutes The Target Group?), regular appointments are just an exertive routine to collect blood results. By having remote access to results, it was argued that some routine visits to the clinic could be avoided, and this would contribute to patients' quality of life (by saving traveling and waiting time and/or avoiding the potential disclosure of the HIV status by encountering people in the clinics' waiting rooms). Furthermore, it was emphasized that by having access to medical data, patients can become more knowledgeable about their condition (see the section Altering the Understanding of Health?) and could share data with health professionals to agree on treatment decisions: "the analysis could be showed to other doctors" (P_Li_WS, male). However, questions were raised about how patients could best be enabled to interpret results. Most clinicians suggested that only "a selected part of the blood analysis" (C_Ba_WS, male doctor) should be sent to the patient. There was a certain consensus among clinicians that, rather than sending the whole analysis, results should be restricted to viral load, CD4 count, cholesterol levels, and kidney and liver function. Furthermore, it was emphasized that results could be accompanied with a "small message" (C_An_WS, female clinician) from the doctor or a "sort of colour coding" (P_Br_WS, male) that helps to interpret the results.

Managing Medicines

As described above, patients approached the mHealth platform with concerns about maintaining control over their health. The adherence to the medication regime, in particular, was perceived as a considerable stress factor among several PLWH. These concerns were reflected in how they *imagined* the platform and its functionalities. PLWH and clinicians mentioned that a tool to assist the management of medicines would be an important function in the app. In particular, such a function would include reminders to take medicines. Although several PLWH stated that they already set reminders on their smartphones, it was argued that an app, provided by the mHealth platform, could offer a more comprehensive reminder system. In this regard, PLWH referred to complex social situations where they were not immediately able to take their medication when the alarm on the smartphone goes off and thus were unsure at a later point whether they had actually taken their medication. Therefore, PLWH discussed the possibility of a "snooze" button (P_Br_WS) and additional reminders that "will just keep reminding you until you do it [take the medicine]" (P_Za_I). Another problem was drug interactions, as 1 participant pointed out:

> *[Doctors] give me medication that interfered with my retroviral drugs...there should be something that we ourselves could manage this situation...An application where we could see if we can take the drugs A, B or C with this cocktail of antiretroviral drugs.* [P_Li_WS, female]

In line with this quotation, several PLWH stressed that health care professionals (aside from the HIV consultant) often lack knowledge about the interactions of the medicines. Therefore, an option to recheck interactions within an mHealth platform was seen as essential.

Managing Appointments

Some PLWH reported that they quite often miss appointments for their medical check-ups:

> *I have missed a lot of appointments. I think it would be useful to have some reminders to tell me.* [P_Li_WS, female]

Accordingly, both PLWH and clinicians regarded reminders as an important tool to ensure "that people come to their appointments" (C_An_WS, female clinician). Moreover, the booking of appointments was experienced as stressful by some PLWH, who said, "...many times I've had to change my

appointments, and I'm ringing up and I can't get through." (P_Br_WS, female).

Both arranging appointments through the telephone and at the reception desk were experienced as time consuming. Therefore, PLWH stated that the mHealth platform could offer "an online calendar, if there is an empty spot that suits you...you click on it" (P_Ba_WS, male).

Digital Communication Channels

Participants explored the different ways in which the mHealth platform might offer communication channels between PLWH and health care providers. One option, particularly emphasized by clinicians, was indicated as "push notifications" (C_Br_WS, female clinician). This was seen as a way for clinicians to inform specific patients about new trials, medical innovations, or ways to maintain a healthy lifestyle. Some PLWH emphasized that they would appreciate a "newsfeed" (P_Ba_WS, male) that notifies "if something new comes out in the world of HIV inventions" (P_An_WS, female) or provides information about "diets, sports, sex, whatever!" (P_Ba_WSm, male). However, several PLWH proposed a "direct messaging service" (P_Ba_WS, male) where messages could be exchanged in both ways—between patients and clinicians; this would help in situations of uncertainty where medical advice is required. Among clinicians, however, two-way communication messaging was seen as more controversial. Although some clinicians regarded it as essential that patients could contact their clinician in case of problems or questions, others had "misgivings about having a two-way communication...because we're fighting the wolf...volumes of free text" (C_Br_WS, male doctor). The quotation illustrates that some clinicians feared that a two-way messaging system would produce an unmanageable workload (see the section Effects on Workload?). Another option for communication that participants discussed was *virtual consultations*. Although video consultations seem to most appropriately simulate the face-to-face consultation, they are still embedded within potentially constraining spatiotemporal contexts. As 1 participant puts it:

> *I probably wouldn't use video calling, because...you have to schedule in a time, make sure you're in a specific place that can be completely private to have that conversation.* [P_Br_I, male]

Social Functionalities

Peer Support Network

While reflecting upon functionalities of the mHealth platform, the distinction between medical and social aspects was emphasized by PLWH:

> *I do see a difference between the medical world and the rest of the world...nearly all information comes from doctors...there is no community anymore...managing, eh, your infection is also about sharing your experience.* [P_An_WSm, male]

To complement medical knowledge with experiential expertise, some PLWH argued that the platform should facilitate a peer support network through a chat function. Besides the exchange of experiences, a chat forum was also seen as an opportunity for PLWH to overcome isolation. In this way, 1 participant argued that:

> *[T]hey [clinicians] are not here at midnight...when you are scared and wake up in tears and shaking: "What do I do, oh my God, I'm HIV positive." So I think that it will be a very good thing that you can go on the app and see someone online and only talk about HIV or about the weather...* [P_Za_WSm, male]

International Travel

PLWH mentioned international travel as another aspect of social life that could be supported by the new mHealth platform. It was suggested that it could provide general information about the implications of traveling with HIV, such as travel restrictions to certain countries, information about travel documents (eg, certificates for the antiretroviral medication), and advice for situations of emergency (eg, losing the medications). Furthermore, PLWH discussed whether an mHealth platform could help to manage medicines between different time zones, saying, "...it's important to address the issue of schedules of intakes of the medicines when traveling and changing time zones" (P_Li_I, male).

Changing Public Attitudes Toward HIV

In regard to the target group of the mHealth platform, some PLWH stated that it should not only be for "us [PLWH], but for everyone" (P_Ba_WS, male), as by providing information on HIV to the general population, the platform could "take away a bit of the discriminatory burden of this disease" (P_Li_WS, male).

General Features

Security and Privacy

As a general feature, the mHealth platform (and its related app) needs to provide "some other standard of security" (C_Ba_WS, male doctor). This quotation illustrates the perspective of most study participants (PLWH and clinicians) who emphasized that because of the high stigma around HIV, the platform should accomplish the highest level of security and privacy. In this way, participants argued that the app design should be discrete—"it should not have 1000 red ribbons" (P_An_WSm, male)—and posed questions such as how the medical records would be encrypted, how the data would be stored, and by whom it would be managed or shared. Although there were several questions with regard to security and privacy, most PLWH stated that they already use apps for banking and other purposes and thus would trust an mHealth platform if it accomplishes a similar level of security. Some other participants, however, rejected the idea of having their confidential HIV data processed through an mHealth platform:

> *Even though it has codes and all kind of stuff…this app is online…Anybody can hack my email…I don't want it to maybe one day, come out…if you say, "This app is here you can download it,"I will say:"No, thank you.*" [P_Za_I]

In discussing these security concerns with the EATG and our community partners, it was elaborated that there is a central distinction between banking apps and HIV health apps. The

point was made that there is a general expectation that banks will return any money lost to you through security failure on their part. Money can be paid back, but the disclosure of sensitive health information cannot be undisclosed and may have a significant impact on people's lives.

Credibility

Credibility was another topic that emerged in our data. PLWH often stated that it is important that the mHealth platform and its related app come from a trusted institutional body. PLWH pointed out that, for them, health care providers and patient organization have more credibility than pharmaceutical companies.

Language

The language used by the mHealth platform was another discussion point among PLWH who underlined that it should be available in their local language and the language should not be "over-complicated" (P_Br_WS, male).

Sensitivity for Disabilities

Sensitivity for disabilities was an issue mentioned by some participants. In particular, an option for voice recognition and a text narrator built within the mHealth platform was considered as important to make the app accessible for users with less eyesight, dyslexia, or for people who are analphabetic.

Costs

The app provided by the mHealth platform, according to most PLWH, should be free of cost. However, some PLWH expressed willingness to pay for a good-quality app, saying, "...it would not necessarily have to be completely free of charge, because you don't get something for nothing, but maybe the basic version could be free" (P_An_WS, male).

Training and Tutorials

The importance of some kind of training to use the mHealth platform and its app was stressed by both clinicians and PLWH. It was argued that PLWH could be introduced to the app by health care professionals, within specific training workshops or through tutorials that are included within the app.

Other Technicalities

PLWH addressed a range of other technicalities that they perceived as relevant for an app. Thereby, the app's battery and memory consumption within the smartphone as well as its speed were questioned. An offline access to the information within the app was considered useful. Moreover, it was suggested that an option to individualize the app would be important. Options to individualize the app were seen in selecting the functionalities one wants to see on the app's dashboard, choosing one's own app icon, or selecting different types of reminders (eg, for medication intake).

Anticipating the mHealth Platform's Implications

Co-design participants also discussed the potential implications of an mHealth platform for self-management and for the provision of health care. These implications were debated quite controversially, emphasizing both benefits and risks. To indicate these controversies, we labeled the following themes as questions.

Implication for Self-Management

Creating (Un)certainty?

Both PLWH and clinicians debated whether an mHealth platform would contribute toward certainty or uncertainty within the self-management of HIV. Some participants were convinced that receiving results through an mHealth platform would create more certainty and reassurance. In this way, 1 participant explicated:

> *To access something, that seems quite interesting, you know, and perhaps just to check the percentage of your CD4 and your viral loads...that's all about reassuring and taking care of your health condition, even just doing those quick checks. But you're in control of it.* [P_Br_I, female]

In addition, some clinicians were convinced that experienced patients would be able to interpret blood test results, acknowledging that "patients have learnt quite quickly to speak the language of HIV bloods" (C_Br_I, female nurse). It was argued that through an mHealth platform, PLWH could become more informed and reassured. These positive perspectives toward the platform were rejected by other participants who pointed out that having instant access to medical results outside of a face-to-face clinical encounter could create anxiety and uncertainty among PLWH.

> *...anxiety about your results, because you don't know how to interpret them, you may have a blip on your viral load and that means nothing, but if you have access you may be anxious for a couple of days before going to the doctor, and she explains to you that's nothing.* [P_Li_I, male]

From the perspective of these participants, medical results are best discussed within a face-to-face clinical encounter. Thereby, assistive measures that could help to interpret the results accessible through the platform (eg, color coding, see the section Accessing Test Results) are not seen as sufficient to inform health decisions. Such decisions, according to these participants, are best embedded in the physical clinical encounter where individual feelings and illness experiences can be expressed and treatment decisions can become the product of a deliberative process of care, balancing experiential and medical knowledge.

Reconfiguring Relationships?

Another discussion emerged around the question of how mHealth would affect the relationship between patients and clinicians. Most PLWH mentioned that they have built a strong relationship with their HIV consultant and were "loyal" (P_Li_I, male) to them over a long period. In this regard, some were worried that, if communication would move from the physical encounter toward mHealth, "the relationship [with the consultant] is not the same" (P_Ba_I, male). Furthermore, clinicians emphasized that it is crucial to first establish a relationship with patients in face-to-face interactions but emphasized that this could then be moved to digital communication. In this way, a female doctor suggested to PLWH in a mixed workshop:

> *once...we already have a previous relationship, we already know each other...I want to propose to you to stop seeing you in face-to-face visits.* [C_Ba_WSm]

Some PLWH stressed the potential of the mHealth platform and the related app to create a closer relationship with clinicians, suggesting "an app that you can use to be in touch with your own doctors" (P_An_I, male). To do this, as was acknowledged, the platform would need to provide two-way communication (see the section Digital Communication Channels).

Altering the Understanding of Health?

Another point discussed among PLWH was how far the mHealth platform could contribute toward a more pronounced understanding of one's HIV condition. Most PLWH saw data as essential to gain knowledge about one's condition. In this way, the potential of the platform to store the medical history and visualize it on images or graphs was outlined. This was valued for enabling an in-depth understanding of the body and new options to monitor and control HIV:

> *Regarding the history, it's always important. I think that it's through there that we can reach conclusions about what is doing us better, doing us worst and maybe one day to see a marker and realize "Look, after all THIS is what degraded THIS."* [P_Li_WS, female]

> *...it might be nice to have something that's sort of telling you, you know, where you are on the scale.* [P_Br_WS, male]

Other PLWH, however, argued that to become knowledgeable about their health, they privilege their own (bodily) experience, feelings, and self-awareness:

> *I know myself and I know when I don't feel good...Sometimes it's better to ignore some things like that [medical data]. I mean you are living with the disease, but you don't want to think about it every day.* [P_Za_I, female]

These participants emphasized that through an mHealth platform that pushes health data and alerts, they would be constantly confronted with their disease. Technology was thus perceived as invasive, disrupting practices of everyday life, and exposing PLWH to the risk of becoming "obsessed" (P_Ba_I, male) with their condition.

Implications for Health Care Provision

Replacing Traditional Care Pathways?

Participants questioned whether an mHealth platform would replace or complement routine face-to-face consultations within the traditional pathway of HIV care. In this respect, both clinicians and PLWH agreed that some face-to-face clinical encounters are essential for effective HIV care. As the following quote illustrates, some participants argued that social aspects such as sexual practices, relationships, and family problems could not be appropriately discussed through digital communication channels:

> *I don't see myself sitting behind a computer and having a discussion about relationships...for me that's a drawback.* [C_An_WS, male doctor]

Furthermore, it was stressed that only a personal relationship with the patient would facilitate a good consultation around social issues. Some clinicians also emphasized that:

> *We do a physical exam and patients sometimes are not aware of...physical appearance or the presence of symptoms.* [C_Li_WS, female clinician]

An appropriate physical examination, it was argued, could not occur outside the face-to-face encounter. By pointing to such restrictions, both clinicians and PLWH emphasized that an mHealth platform should complement, rather than substitute, face-to-face visits:

> *I don't think that this kind of...application should be a substitute of the medical visit...But, they can work together.* [P_Li_I, male]

Rationalities of mHealth?

Other concerns were related to the rationalities behind the utilization of an mHealth platform. In particular, it was questioned whether such a platform would be utilized to improve the quality of care or to downsize health care expenditure. Some clinicians pointed out that an mHealth platform would probably save resources but, at the same time, could contribute in "improving convenience and facilitating the access [to healthcare]" (C_Ba_WS, male doctor). However, some PLWH expressed worries that the platform "was intended to make savings in healthcare and decrease the number of visiting hours at the doctors' [office]" (P_An_WSm).

Effects on Workload?

A discussion point among several clinicians was whether the mHealth platform would increase or decrease their workload. In this way, 1 clinician stated:

> *I'm interested in how this [the mHealth platform] would work around our end and to see how much...drudgery can be taken out of the work...'cos...there's a lot of work processing records.* [C_Br_WS, male doctor]

Although some participants were convinced that the platform could save time and clinicians "would have more resources for other things" (C_Ba_WSm, female doctor), others argued that it would require more work:

> *...for a clinician if you have to do that, you have to go to the results, interpret the results and then loading them onto the website or the app or the platform, and then there's also additional, yeah, workload.* [C_An_WS, male doctor]

Discussion

Implications and Comparison With Prior Work

Participation is considered a key principle for designing health interventions and technologies in ways that are accessible and meaningful to people in different life situations [23,29,30]. In this section, we compare the outcomes of our co-design process

with the results of previous studies that involved PLWH in the design of HIV apps and highlight how co-design findings can inform mHealth developments. We detail this by illustrating how the findings informed the development of the EmERGE platform.

Target Group for HIV mHealth

The complexities of interpreting the meanings of viral load and other numerical definitions of HIV health have been widely discussed in relation to self-managing HIV [31,32]. Our results reflect this literature by highlighting patients' and clinicians' concerns that having access to one's health data requires the ability to interpret and use these data. These capacities were not anticipated to be equally distributed among population groups. In the context of HIV care, we found that years since diagnosis with HIV and the relative stability of the HIV condition can configure the meaning of having access to blood test results and other quantified health data [22]. In the case of newly diagnosed and unstable HIV conditions, direct access to numbers was associated with bringing anxiety and uncertainty into care practices. In the study of Swendeman et al [18], clinicians suggested several ways in which mHealth devices should particularly address newly diagnosed patients and patients with comorbidities. Our data support the view that medication reminders, options to monitor blood results, etc, are particularly useful for these patient populations. However, our analysis suggests that when implementing mHealth with newly diagnosed or unstable patients, the most recent test results should be discussed within the context of a face-to-face clinical encounter before being sent to a patient's mobile devices.

Medical Functionalities

In current HIV medicine, there is a strong focus on viral suppression as the ultimate goal of ART. Therefore, both the collection of biomarkers by means of blood tests and the close surveillance of patients' adherence to the treatment regime play a key role in monitoring HIV progression [33]. This is reflected in our findings as well as those of other studies where the storing and tracking of lab results and medication and appointment reminders were identified as desirable app functionalities for PLWH [14-18]. Access to blood test results has been imagined and anticipated as being an important function by both patients and clinicians. Clinicians in the study of Swendeman et al [18] additionally pointed out that messages or feedback from health care providers to patients could be used to enhance patient motivation to treatment adherence. Although two-way communication features have not yet been considered within the development of comprehensive HIV mHealth platforms based on interacting apps and Web interfaces [14-16], with options to exchange messages between patients and clinics currently being implemented through basic cell phone text messaging (short message service) services [34], many of our co-design participants did regard this as an important functionality to maintain relationships and exchange information and concerns with their care providers. However, although the inclusion of two-way communication functions might be considered as an important direction for the development of mHealth, there remain significant challenges concerning how to achieve this in practice. In the case of EmERGE, discussions about how two-way communication between clinicians and patients could be facilitated in a way that does not significantly increase clinicians' workloads are still ongoing, and this feature is not yet realized within the new care platform.

Social Functionalities

PLWH imagined several social functionalities that would support them in managing their HIV condition. Continued exchange among peers is important for individuals to feel less alone while engaging in chronic illness self-management and to generate knowledge that is based on personal experiences [35]. However, frequent interaction with peers may often not be feasible because of spatiotemporal limitations or fears of stigmatization in face-to-face environments. Along with other studies, our findings underscore perceptions of potential users that mHealth could facilitate a comfortable and safe environment for PLWH to engage in peer support [14-17,36]. In addition, our participants imagined an app supporting them while traveling internationally (eg, managing HIV intake across time zones) or help to make the general public more knowledgeable about HIV. At the time of writing, this has not been included in the first iteration of the platform but remains an option for later developments.

General Features

Our findings have highlighted that both patients and clinicians anticipated it as essential that an mHealth platform for HIV care should be based on the highest standards of security measures. Concerns about security and privacy implications of mHealth for HIV have also been stressed by previous studies [14-16]. However, our study (as well as one other [18]) has also revealed clinicians' perspectives that novel mHealth platforms could provide higher standards of security as compared with older technologies such as email communication. Many other general features (such as credibility, news feeds, simplicity, cost, and customizability) have been identified as important through our research as well as previous studies [15,17] and should be considered in mHealth developments. Working in a multilingual European context, we found that it was of great importance that mHealth apps are available in the local language. In the case of EmERGE, the app will offer the option to choose between the 5 main languages spoken in our study sites.

Implications for Further Research

In the field of digital health studies, it has been stressed that many of the social and ethical consequences of mHealth remain under-researched [37]. Through the first stage of a co-design process, developed and implemented as a central component of the EmERGE project, participants had the opportunity to express their concerns and anxieties about mHealth, and our analysis of the results of this process has enabled us to help fill this gap in the literature. This paper has illustrated how working closely with clinicians and PLWH in a process of co-design can contribute to a fuller understanding not only of the perceived benefits associated with mHealth but also of the potential unintended or negative consequences that users envisage and how these insights can be reflected in mHealth platform design. However, this is just the first stage of the co-design work in EmERGE. Our approach to co-design is set within a broad

sociotechnical understanding of digital health developments that recognizes design as a continuous and co-constituting process that begins before the technology itself is present and continues well into implementation and use phases. Once in use, platforms, apps, and websites are in a continuous process of transformation [38]. They require constant *fixes*, *updates*, and *versions*, not only because of technological changes but also because of necessary sociocultural developments that accompany them. Co-design thus requires ongoing engagement with actual practices where technology has to be tamed and tinkered with to fit specific situations of usage [39]. Engaging with practices of design and use provide valuable insights into how people approach, imagine, anticipate, and ultimately interact with technologies, and this can contribute toward an understanding of the situations and conditions within which mHealth can facilitate or undermine practices of care [22,40]. We propose that co-design approaches that are continuous throughout the lifecycle of mHealth interventions are likely to provide timely and relevant insights toward the creation of meaningful and effective mHealth solutions. As the EmERGE mHealth platform is fully integrated into the local care pathways, we will continue this co-design work with clinicians and PLWH as we seek to investigate and to improve the technology *in-use* in specific contexts.

Limitations

Although we aimed to recruit a broad variety of co-design participants, among PLWH, white gay men were over-represented compared with women and migrant groups. Among clinicians, female doctors were over-represented in comparison with male participants and clinicians from other medical backgrounds (nurses, psychologists, etc). We also have to assume that participants that were more likely to be interested in the use of mobile technology agreed to participate in this study. These recruiting issues restrict the potentialities to generalize the outcomes of this study. Another constraint might be intrinsic to technology development projects. The limited time frame between data collection and the start of the development of the mHealth platform meant that the actual coding of the data could only be performed by 1 researcher. However, to enhance the rigor of the data analysis, initial codes and categories were discussed and negotiated between the research team on a bimonthly basis. Confirmation of reliability was also provided through feedback from community partners and the whole project consortium gathered at various meetings. Although findings presented in this paper have highlighted patients' and clinicians' *perspectives* toward desirable, or hypothetical, functionalities for HIV mHealth apps, the next phases of our project will enable us to evaluate the actual impact of these functionalities on health *experiences* and *practices*.

Conclusions

In this study, participatory co-design methods have been used to (1) elicit experiences of living with HIV and of working in HIV care, (2) identify functionalities and features for an mHealth platform that PLWH and clinicians regard as useful for HIV treatment and care, and (3) identify potential benefits as well as risks and concerns of such a platform. Through our analysis, we have highlighted how this process allowed us to better understand how clinicians and patients were approaching, imagining, and anticipating what it is that the platform could *do* for HIV care. Our approach to co-design enabled us to facilitate early engagement in the mHealth platform, enabling patient and clinician feedback to become embedded in the development process at a preprototype phase. Although the technologies in question were not yet present, understanding how users approach, imagine, and anticipate technology formed an important source of knowledge and proved highly significant within the technology design and development process. At the time of writing, the platform has been implemented and is being more fully evaluated in 5 clinical sites in the context of the wider EmERGE study. Co-design work will continue as users' experiences of the new mHealth-based care pathway are captured and shared both within and between sites to inform further developments of the EmERGE HIV platform. Future papers will explore these later phases of co-design and draw out the implications of our approach and findings for mHealth developments in HIV care.

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Conflicts of Interest

None declared.

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Abbreviations

ART: antiretroviral therapy
CD4: cluster of differentiation 4
EATG: European Aids Treatment Group
EmERGE: Evaluating mHealth Technology in HIV to Improve Empowerment and Health Care Utilization: Research and Innovation to Generate Evidence for Personalized Care
EU: European Union
GP: general practitioner
NHS: National Health Services
PLWH: people living with HIV

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Original Paper

Assessing the Privacy of mHealth Apps for Self-Tracking: Heuristic Evaluation Approach

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Abstract

Background: The recent proliferation of self-tracking technologies has allowed individuals to generate significant quantities of data about their lifestyle. These data can be used to support health interventions and monitor outcomes. However, these data are often stored and processed by vendors who have commercial motivations, and thus, they may not be treated with the sensitivity with which other medical data are treated. As sensors and apps that enable self-tracking continue to become more sophisticated, the privacy implications become more severe in turn. However, methods for systematically identifying privacy issues in such apps are currently lacking.

Objective: The objective of our study was to understand how current mass-market apps perform with respect to privacy. We did this by introducing a set of heuristics for evaluating privacy characteristics of self-tracking services.

Methods: Using our heuristics, we conducted an analysis of 64 popular self-tracking services to determine the extent to which the services satisfy various dimensions of privacy. We then used descriptive statistics and statistical models to explore whether any particular categories of an app perform better than others in terms of privacy.

Results: We found that the majority of services examined failed to provide users with full access to their own data, did not acquire sufficient consent for the use of the data, or inadequately extended controls over disclosures to third parties. Furthermore, the type of app, in terms of the category of data collected, was not a useful predictor of its privacy. However, we found that apps that collected health-related data (eg, exercise and weight) performed worse for privacy than those designed for other types of self-tracking.

Conclusions: Our study draws attention to the poor performance of current self-tracking technologies in terms of privacy, motivating the need for standards that can ensure that future self-tracking apps are stronger with respect to upholding users' privacy. Our heuristic evaluation method supports the retrospective evaluation of privacy in self-tracking apps and can be used as a prescriptive framework to achieve privacy-by-design in future apps.

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KEYWORDS

privacy; usable security and privacy; mHealth apps; mobile phone

Introduction

The quantified self (QS) movement refers to the use of self-tracking technologies to capture data about different facets of a person's life [1]. Recent advances in sensing technologies have allowed people to track a variety of life attributes, ranging from physical exercise to mood, sleep, and work productivity [2]. Collecting these data allows people to engage in self-improvement or behavioral change or to satisfy intellectual curiosity [3]. In the medical domain, self-tracking is increasingly being used to support health-related outcomes, with patients using data to reflect on their recovery [4] and clinicians deploying tracking technologies to monitor patients [5].

While many of the services that enable self-tracking are free or low cost, users may unwittingly be paying a price by surrendering their privacy to these services [6]. That is, users of self-tracking apps may find that their privacy is eroded because they lack control over how their data are collected, stored, and analyzed by self-tracking apps, and they may, in turn, have no say in how these data are shared with third parties. These issues point toward a need to understand privacy issues in self-tracking apps, particularly mobile health (mHealth) apps, which collect medical and health-related data. Such technologies frequently operate in an uncertain regulatory space and may not be afforded the protections and scrutiny that are given to other medical data, for example, the Health Insurance Portability and Accountability Act in the United States or National Health Service oversight in the United Kingdom.

Research has shown that self-tracking apps can give rise to privacy concerns. For example, apps that collect data about dementia often fail to disclose how the data are processed [7], and the vast majority of mHealth apps have, at least, some potential for information security and privacy infringements [8]. Other work has examined the privacy policies of self-tracking app vendors and identified privacy concerns [9]. However, these studies only focused on a small subset of apps. Recent years have witnessed increased public awareness of privacy issues [10-12], and users are known to be concerned about the improper use of sensitive data [13]. This suggests a need to evaluate the broader landscape in order to provide a characterization of privacy risks that can emerge in mHealth apps that are intended for self-tracking. Understanding potential privacy risks will, then, allow designers to account for such issues when creating self-tracking apps in the future.

However, currently, there is a lack of techniques for evaluating the privacy-related features of self-tracking apps. While researchers have developed frameworks for eliciting privacy requirements and achieving privacy-by-design [14-16], these are general frameworks that do not consider the specifics of self-tracking and mHealth apps. Similarly, privacy impact assessments [17-19] can offer a generalized analysis for large systems but are not designed for issues specific to mHealth apps. The Data Protection Impact Assessments mandated by Article 35 of the European Union's (EU's) General Data Protection Regulation (GDPR) [20] specify that the assessment must be systematic but give no guidance regarding the method or, even, regarding whether health-related data, such as those in mHealth apps, need special treatment. Recent privacy frameworks that focus on the Internet of Things [21] are closer to the mHealth domain, but these frameworks provide few insights into the effectiveness of features that are intended to control the sharing and access of personal data in self-tracking apps.

The aim of this study was to understand how current self-tracking apps perform with respect to privacy. To do this, we used a set of 26 heuristics to evaluate privacy in self-tracking technologies. These heuristics span 4 dimensions: notice and awareness, choice and consent, access and participation, and social disclosure usability. The heuristics are intended to support systematic appraisal of the ways in which self-tracking apps can either uphold or impinge on users' privacy. We demonstrated the practical value of the heuristics by evaluating the privacy-related features of 64 popular self-tracking apps. Furthermore, we identified which dimensions of privacy were best met and explored whether certain types of services performed better than others. In addition, we examined a number of nonhealth-related apps, which enable self-tracking, allowing us to determine whether mHealth apps exhibit distinctive privacy characteristics.

The paper makes two contributions. First, the heuristics provide a low-cost approach for evaluating privacy in mHealth services, building on the use of the heuristics in studies of privacy in other domains [22-25] and extending the work of Furano et al [26], who developed a set of privacy heuristics for evaluating personal health records. Our heuristics can support the evaluation of self-tracking apps more generally and will allow researchers to gauge the ways in which privacy is met in future apps. Furthermore, the heuristics can provide a prescriptive privacy framework for designers, allowing them to achieve privacy-by-design in new mHealth services.

Our second contribution is an investigation of the state of privacy in mHealth services. We found that the category of data collected by an app is not a useful predictor of its overall privacy score, suggesting that poor support for privacy is an issue that pervades the self-tracking landscape. In addition, we showed that mHealth apps perform worse than other types of self-tracking apps in terms of privacy. This draws attention to the need for careful scrutiny of privacy practices within these apps, as well as the need to develop standards to ensure that mHealth apps pay sufficient regard to user privacy in the future.

Methods

Developing the Heuristics

Our heuristic analysis focuses on the information and controls given to the users to help them decide whether they wish to use a particular app, and which later help them selectively disclose their data to others. This includes the app's user interface as well as its terms of service and privacy policies. Our heuristics do not focus on the "invisible" facets of privacy, which can affect end users, such as the sharing or selling of data without users' consent; this is because it is difficult to assess whether these outcomes will arise when deciding to use an app. We, therefore, focused on what is known about an app at the point

of use, given the claims made in its supporting documentation and the user interface design.

Our heuristic analysis addresses four key questions that users may ask when using self-tracking apps:

1. Am I informed about what happens to my data before I use this app?
2. Do I have control over my data once I start using the app?
3. Do I have access to the data I have provided?
4. Can I use features that allow me to control the disclosure of data to third parties?

With these questions in mind, we began by reviewing sources in the regulatory landscape and relevant privacy literature (Figure 1; Multimedia Appendix 1) [27]. First, we used 3 categories from the FTC's Fair Information Practices [28] policy as an initial guiding framework; these were *notice or awareness*, *choice or consent*, and *access or participation*. Each of these addresses a different aspect of information privacy (Table 1).

To populate these categories with appropriate heuristics, we considered some of the primary privacy concerns that manifest in self-tracking, such as ambiguous ownership and access to data, the significance of where data are stored, whether consent to store and process data can be revoked, and changes in privacy policies [29]. We then considered the EU's GDPR, which updates and harmonizes data protection legislation across the EU, and incorporated considerations from this into our framework. Example provisions include the requirement for data to be portable, unambiguous consent, and the right to be forgotten [30]. In addition, we drew on the STRAP Framework [22], a technique that is aimed at supporting analysts in identifying privacy and security concerns during early design.

Finally, we used Inostroza et al's usability heuristics for touchscreen mobile devices [31] to define the category of *social disclosure usability*, which refers to the usability of features that allow users to share QS data with a third-party service, for example, a social networking site (SNS). These heuristics assess concerns including the ability to prevent errors and the availability of support, both of which are relevant when considering interfaces that permit the disclosure of QS data. For example, an interface for supporting disclosure may include features for selecting the audience and subsets of content to share. Difficulty in the use of these features may lead to errors in sharing, causing privacy violations.

An initial set of heuristics was pilot-tested by 3 reviewers, all of whom were experts in HCI or software engineering and had personal experience of using self-tracking apps. The pilot tests explored whether the heuristics could be applied consistently across different apps and whether they were sufficiently exhaustive to capture the interactions encountered. Examples of improvements that arose from these tests included the rearrangement of 4 heuristics to better fit the Fair Information Practices categories and the addition of 1 heuristic to assess the granularity of disclosures to social networking services.

These improvements led to a final set of 26 heuristics (Multimedia Appendix 1) [27]. The heuristics include a combination of dichotomous and ordinal items, where a higher score for each item indicates better privacy-preserving characteristics within the target app. Figure 1 shows how the regulatory and market landscape led to the choices of heuristics and apps for this study.

Figure 1. How the regulatory and market landscape was fed into the design of the heuristics and the choice of apps to study. GDPR: General Data Protection Regulation; FIPS: Fair Information Practices; QS: quantified self.

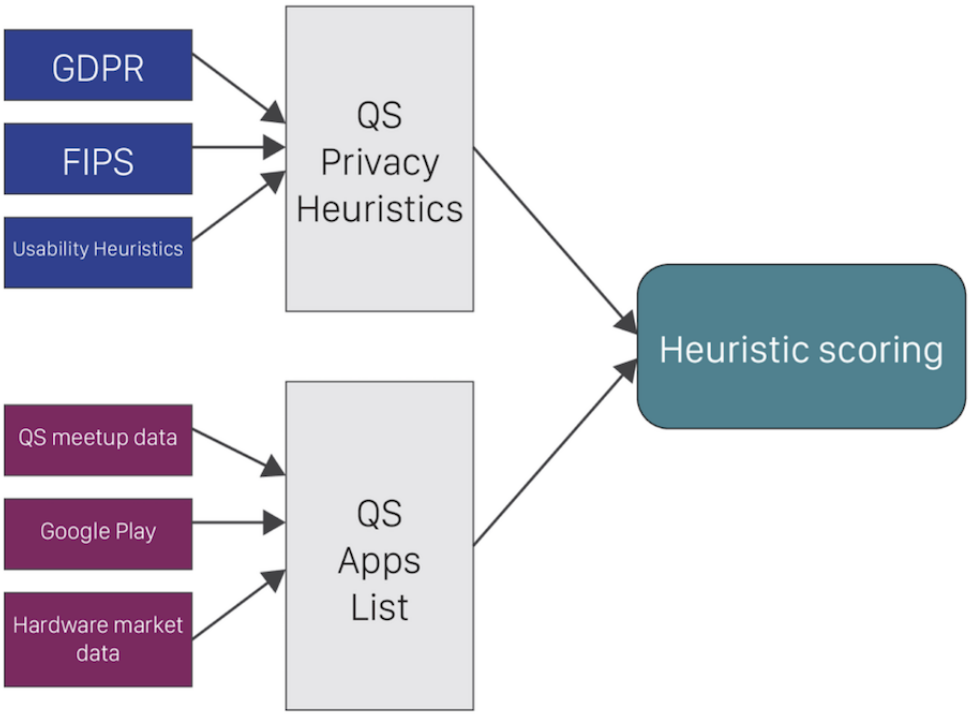


Table 1. The 26 heuristics (H) present in our evaluation technique.

Category description and number[a]	Heuristic
Notice or Awareness: These heuristics concern what people are told about how their data are used before their personal information is collected, such as the terms of service or privacy policies.	
H1	Before data are shared with a remote actor, the entity collecting the data is explicitly identified.
H2	Before data are shared with a remote actor, the uses of the data are explicitly identified.
H3	Before data are shared with a remote actor, the potential recipients are explicitly identified.
H4	The nature and means of the data collected are explicitly identified.
H5	Steps taken to ensure confidentiality, integrity, and quality of data are explained.
H6	For those of above satisfied, notice is sufficiently explicit.
H7	Can control when data are used for nonoperational secondary use, such as marketing or research.
Choice or Consent: These include the controls people have over use of their data, such as whether to permit secondary uses of their data, including marketing.	
H8	Consent acquired before data shared with remote actor.
H9	Consent is explicitly opt-in: no preticked checkboxes, etc.
H10	Can choose which data types are automatically collected from sensors or other sources, for example, connect a finance app to a single bank account or track steps but not heart rate.
H11	Data collection consent is dynamic: if new types of data are being collected, consent is renewed *in situ*.
H12	Data processing consent is dynamic: if the purpose of processing changes, consent is renewed.
H13	Data distribution consent is dynamic: if the actors' data are distributed to changes, consent is renewed.
H14	Consent to store and process data can be revoked at any time: with the service and any other actors.
H15	Can control where data are stored.
Access or Participation: These address issues such as whether people are able to view the data they have provided and whether they can verify its accuracy in a timely manner.	
H16	All raw collected data can be extracted from the service (in-app or via vendor's website).
H17	All data are available in standard text formats (CSV[b], XML, JSON[c], GPX[d], etc).
H18	Data extraction is available from within the service, for example, without raising a request with support.
H19	Programmatic access to data is possible, for example, app programming interfaces are exposed.
Social Disclosure Usability: These relate to the usability of interface elements that allow users to share data with third-party services, for example, social networking sites.	
H20	Privacy controls are per-disclosure, for example, individual workouts can be published to a social networking site, not relying solely on global defaults.
H21	Privacy controls allow granular sharing of data types, for example, when sharing a workout, the distance can be shared but not the pace.
H22	Error prevention: is explicit confirmation acquired before a disclosure?
H23	Minimize user memory load: Effects of a disclosure are visible throughout the disclosure flow (ie, memory of earlier decisions not required).
H24	Minimalist: During the disclosure flow no extraneous information (such as adverts or irrelevant user interface elements) is displayed.
H25	Consistency: Information shown during the disclosure flow is consistent with the effect of the disclosure.
H26	Help and documentation: Contextual help with making privacy decisions is available.

[a]See Multimedia Appendix 1 for the scoring criteria.

[b]CSV: comma-separated values.

[c]JSON: JavaScript Object Notation.

[d]GPX: GPS eXchange Format.

Table 2. The categories of apps used in our evaluation and the constituent search keywords for each group.

Purpose and app category	Keywords
mHealth	
Cycling	Cycling
Diet	Diet, eating
Exercise	Exercise, workouts
Apps with wearable hardware	N/A[a]
Heart	Heartrate, heart rate
Mood	Mood, happiness
Running	Walking, running
Sleep	Sleep
Step count	Steps
Weight	Weight, body fat
Other self-tracking metrics	
Spending	Spending, income
Time	Time keeping

[a]N/A: not applicable.

Using the Heuristics to Evaluate Self-tracking Apps

To demonstrate the value of the heuristics for assessing privacy, we conducted a formal evaluation using a subset of mHealth and self-tracking apps from the Google Play Store. We focused on this platform because the Android mobile operating system was installed on approximately 85% of new smartphones shipped worldwide from 2016 to 2017 [32] and because Google's policy for vetting apps is less restrictive than Apple's or Microsoft's policy [33], making it an attractive platform to collect a broad range of self-tracking apps.

To gather apps for our analysis, we used the responses to a 2014 survey of 105 members of the London Quantified Self Meetup Group [34] (Multimedia Appendix 2) to identify the types of data they collected. We then translated these into potential categories of apps to inform our search. We did this because no comprehensive taxonomy of self-tracking apps currently exists and because the London Group is one of the most well-established QS groups with a large number of early adopters who have experience with a broad range of tracking technologies.

After aggregating and ranking the survey responses, we used the 20 most-frequently reported types of data to produce a series of keywords such as "weight," "sleep," and "mood." These keywords were supplied as input to a script that performed a keyword search on the Google Play Store. Each keyword search returned a list of apps relevant to that term. Next, metadata about each app was parsed from the Google Play Store and saved to a CSV file.

Our search produced an initial list of 345 apps; this was reduced to 292 after excluding instructional apps that demonstrate how to perform an exercise correctly. We excluded these apps because they do not capture data that can permit self-tracking. After this, we used market data from International Data Corporation via Statista [35] to identify major commercial vendors whose apps were not included in our search. Identified vendors were Xiaomi and Jawbone, whose Mi Fit and UP apps were manually added to the dataset. (The code used to produce this dataset and the dataset used in this analysis are available in a public repository [36].)

To sort the 292 apps into categories, we grouped keywords on the basis of similarity and characterized each app as either pertaining to mHealth or other self-tracking activities. Table 2 shows the outcomes of this classification and lists the 12 categories with the associated keywords that were used in this study.

To narrow the scope of our privacy evaluation and make the process more manageable, we elected to focus on a subset of the 292 apps. We did this by selecting the 7 most popular apps in each of the 12 categories (or as many as possible in categories with <7 apps); this resulted in a final list of 64 apps [37] (Multimedia Appendix 3).

Each of these apps was allocated to 1 of 4 reviewers to apply the heuristics independently. These reviewers had experience with self-tracking and evaluation of software systems, meaning that they were appropriately skilled to perform the evaluation. Apps were installed on an Android smartphone running Android 6.0 (chosen because it was the most popular version throughout 2017 [38]). Reviewers were instructed to review the user interface of each app, the terms of service, and the app's privacy policy to check the app against each of the 26 heuristics thoroughly. During the evaluation, if a heuristic did not apply to a particular app, it was scored as "not applicable" and that app was not considered in the analysis of a particular heuristic. (This is a common approach in the use of heuristics in usability evaluation [25].) For example, many apps do not allow data to be shared with SNSs, and it would not make sense to apply H20 to H26 to these apps. The relevance of particular heuristics

should, therefore, be made at the discretion of the evaluator, given the particular functionality of the app under consideration.

To assess the interrater reliability in applying the heuristics, 12 apps were chosen at random to be evaluated by a second reviewer. Apps were allocated such that all reviewers had evaluated the work of each of their peers at least once. The interrater reliability was assessed using Cohen kappa [39], which suggested a moderate agreement between raters (kappa=.45). Disagreements between the raters arose primarily from confusion over the apps' privacy policies, which were often unclear in terms of language and intent. Reviewers discussed these issues to resolve the disagreement and come to a consensus.

The outcome of the analysis was an overall privacy score for each of the 64 apps, with the score calculated by summing the ratings that each app achieved against each of the applicable heuristics, implying that scores should not be interpreted linearly but rather as a reflection of the total number of heuristics that were applicable to the app. (This means that the score can also be expressed as a percentage by calculating the total possible score that an app could have achieved, given the total number of heuristics that are applicable to it.) In the next section, we discuss the results of the heuristic evaluation in terms of differences between app categories and significant effects.

Results

Of the 64 examined apps, only 1 failed all of its applicable heuristics. This app, a "gratitude journal" named Bliss (Figure 2), invites users to create an account when first launching the app, but does not offer any information about how user data are handled, which was a common issue among self-tracking apps in general. The gratitude journal Bliss performed poorly in the heuristic evaluation, satisfying none of the heuristics it was tested against. No mHealth apps had a maximum possible score on all applicable heuristics, but one self-tracking app (adhk's *Timesheet*) performed well on all applicable heuristics. This app only stores data locally on the user's device, avoiding most of the issues regarding the sharing and storage of data that are covered by the heuristics. The mean heuristic satisfaction (of the maximum possible score) for each app was 46.2% (SD 24.3%), with high variability between apps. To analyze these data, we fit an appropriate cumulative link mixed model (CLMM), an ordinal regression model that exploits the categorical nature of our heuristic scoring, with the ability to account for random effects such as multiple ratings of the same app [40]. This allows for an investigation of the differences between different categories of apps, as well as whether apps for mHealth differ from other types of self-tracking apps in terms of privacy.

While the relationship between the app category (as listed in Table 2) and its performance was variable, the CLMM demonstrated that the type of app was not a useful predictor of its performance. Figure 3 shows the wide variability in performance across apps of different types. Weight-tracking apps performed best, and cycling apps performed worst; however, the type of app is not a significant predictor of performance. One interesting finding was that apps from broadly similar categories (in terms of their purpose and functionality) often scored very differently when evaluated against our heuristics. For example, apps that track "exercise" performed well, achieving a mean of 69.2% (SD 48%) of the maximum heuristic score on average, whereas functionally similar cycling apps were among the worst performers, scoring only a mean of 27.4% (SD 37.9%). This result is surprising given that we might intuitively expect the sensitivity of the data collected by an app to relate to the privacy strategies adopted by its developers.

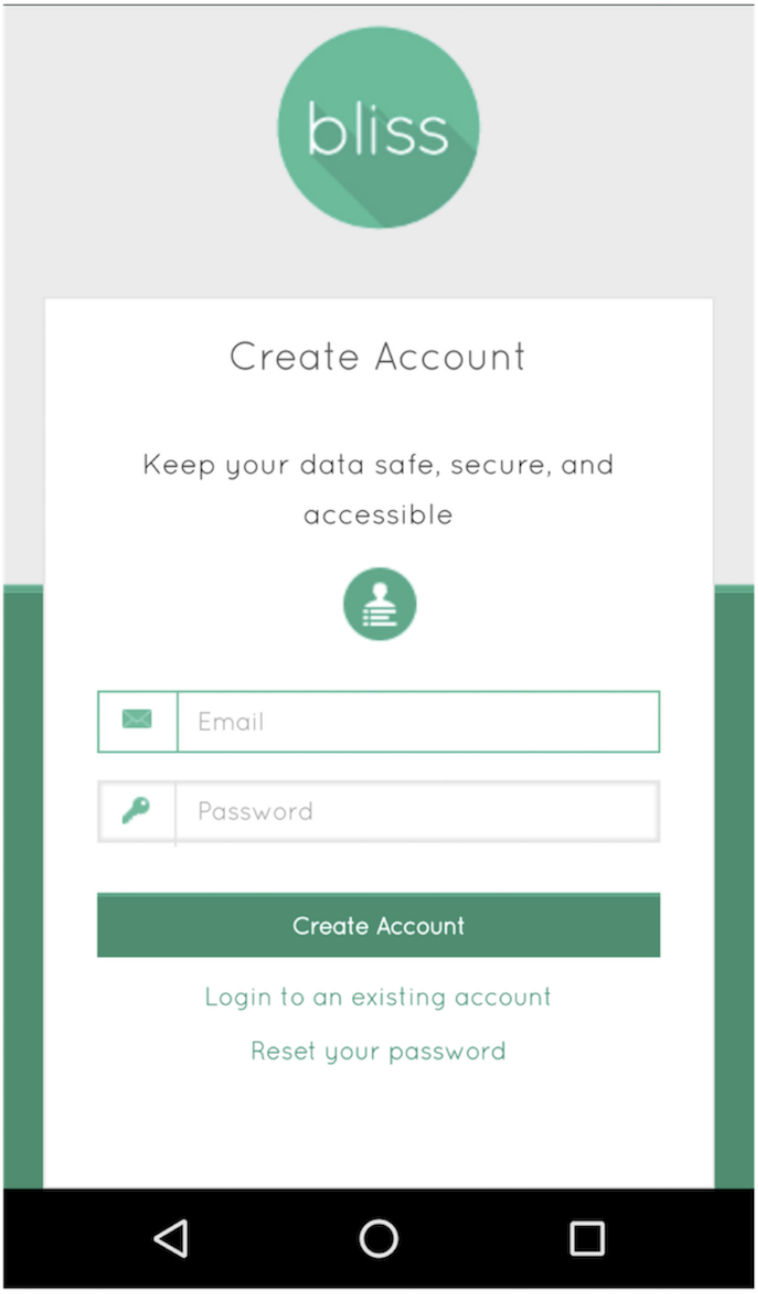
Following this, we considered whether the maturity of an app's position in the marketplace led to a better performance. For example, one might imagine that the developers of higher profile and more established apps would have had time to respond to increased scrutiny with better privacy controls. However, our attempts to explore this question using the number of downloads, the average star rating, or the total number of ratings as a proxy for maturity failed to indicate a significant relationship.

We next explored differences among 4 dimensions of privacy captured by our heuristics, focusing on how the dimensions are upheld at a high level. Figure 4 demonstrates the differences in performance among the 4 categories, which was broadly similar except for access to user data, which was significantly poorer. Most apps failed to offer users sufficient access to their own data, despite this being a fundamental aspect of many data protection regimes. The CLMM showed significantly higher performance for the consent and notice heuristics than for access, but not for social disclosure usability [1.5 (95% CI 0.8 to 2.2), $P<.001$; 1.6 (95% CI 0.9 to 2.3), $P<.001$; and 0.2 (95% CI −0.7 to 1.1), $P=.63$, respectively]. The relatively low scoring of apps on the access dimension can be partly attributed to the dichotomous manner in which apps allow users to access (and, thus, keep a personal record of) their data. We found that apps either allow the user to export all of their data in a range of text formats or offer no export capabilities whatsoever. Some apps restrict the ability to export data unless the user pays money to "unlock" the app or subscribe to a premium tier. We considered a paywall between users and their own data to be unsatisfactory in terms of meeting the heuristics for the analysis.

Looking closer at the performance of apps with respect to individual heuristics, we observed a great variability in performance. Figure 5 shows the distribution of scores across all heuristics. Note that the horizontal length of bars differs because not all heuristics are applicable to each app. A CLMM suggested significantly poor results for 13 heuristics. The most pertinent examples include the following:

- H19, concerning programmatic access to data, had a particularly low score (−2.5 [95% CI −3.2 to −1.7], $P<.001$). Only 20% (13/64) of apps offered any kind of access to data.
- H21, concerning the ability to share granular QS data with SNSs (−4 [95% CI −5.6 to −2.5], $P<.001$), was permitted by a mere 6% (4/64) of apps.
- H26, concerning the availability of contextual support when making privacy decisions (−3.1 [95% CI −4.3 to −1.9], $P<.001$), was met by 10% (6/64) of apps.

Figure 2. Screenshot of initial login screen of the Bliss app.



Only 2 heuristics indicated a significant positive effect:

- H9, concerning the requirement for consent processes to be opt-in rather than opt-out (1.4 [95% CI 0.7 to 2.1], $P<.001$), was the best-performing heuristic, with 78% (50/64) of apps scoring above 0.
- H14, concerning the ability to revoke consent for services to use data (1.6 [95% CI 0.8 to 2.3], $P<.001$), was met by 54% (35/74) of apps.

Finally, we compared the performance of mHealth apps with self-tracking apps, which focus on nonhealth data, that is, productivity and time keeping (see Table 2). A CLMM revealed that nonhealth-related self-tracking apps performed significantly better in the heuristic analysis (95% CI 0.1 to 0.7, $P=.02$). This is of concern given that data collected by mHealth apps are likely to be highly personal and individualized, which, combined with the performance of these apps on the heuristic analysis, suggests that the risk of privacy violations may be higher than what is desired.

Figure 3. Boxplot showing how performance on the privacy heuristics varies across different types of apps.

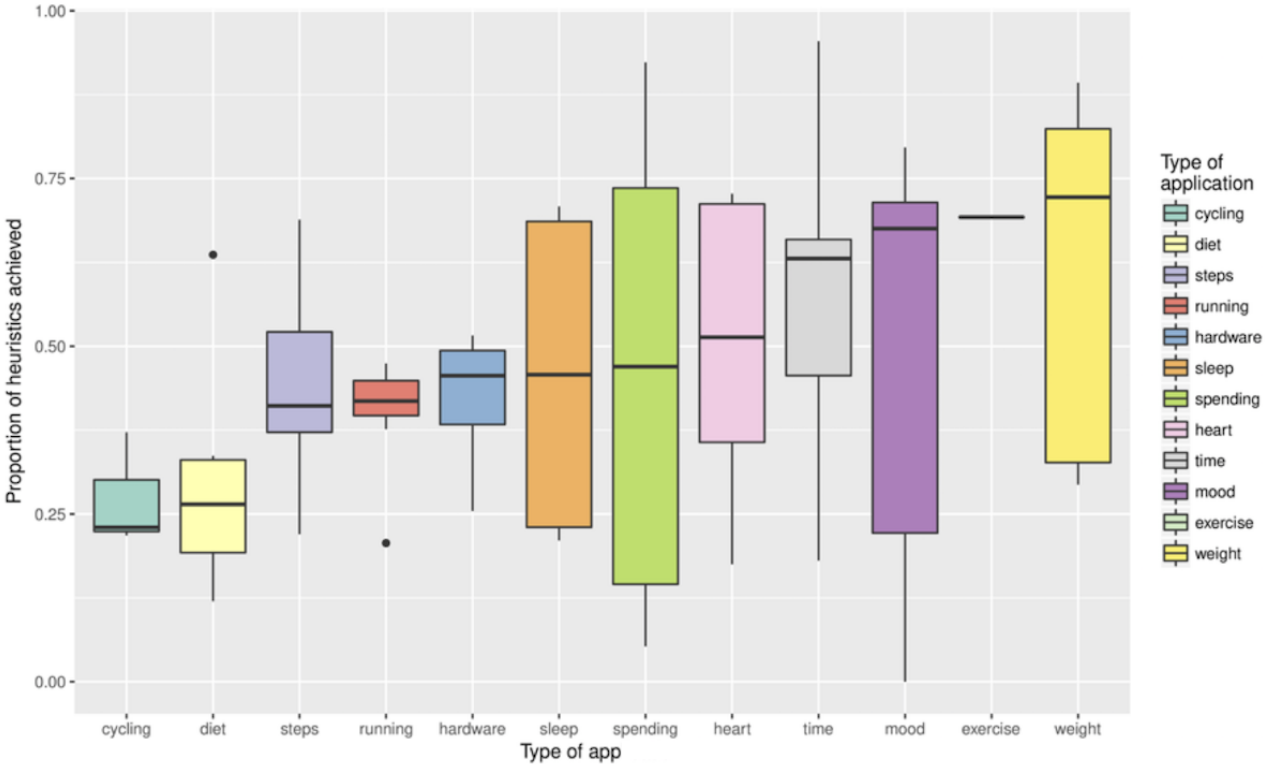


Figure 4. Boxplot showing the differences in performance among the 4 groups of heuristics.

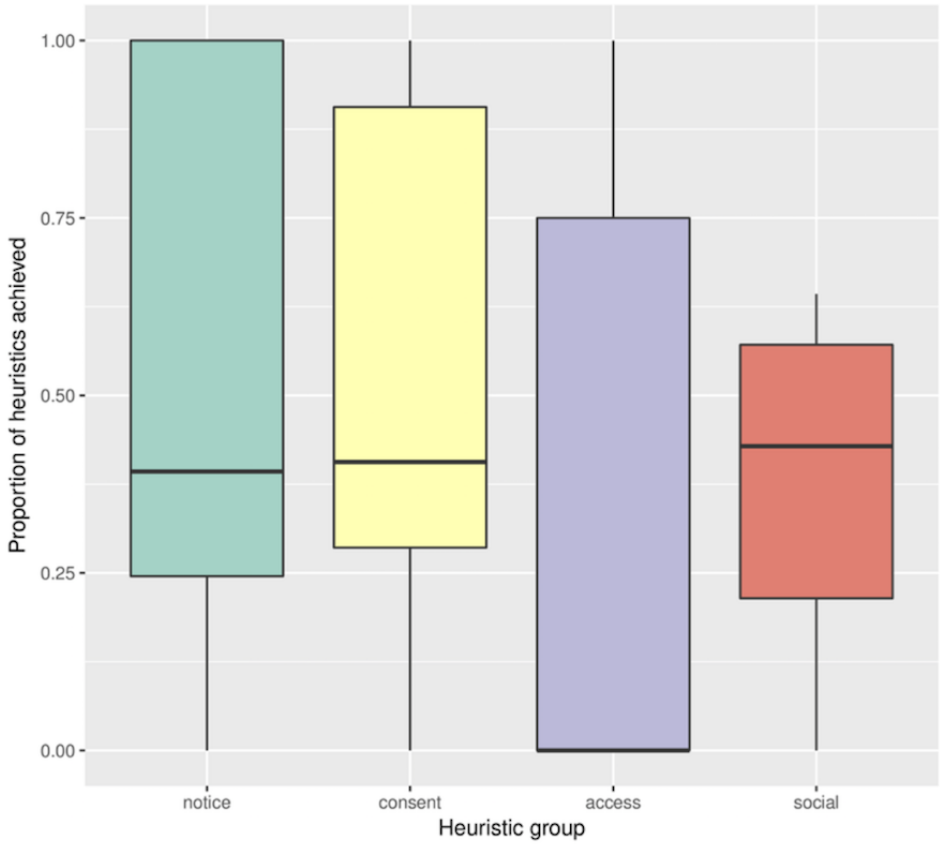


Figure 5. Boxplot showing differences in performance among the 4 groups of heuristics.

Discussion

Principal Findings

This paper presented a heuristic approach for assessing the privacy features of self-tracking apps. Our heuristics cover 4 key dimensions of information privacy and provide a method for evaluating privacy across a wide range of self-tracking and mHealth apps. We used the heuristics to evaluate 64 popular Android apps that were designed to collect QS data. Our analysis produced several key findings that provide a view on the current state of privacy in self-tracking apps.

First, we found that the majority of apps performed poorly when gauged against our heuristics, with access to user data particularly lacking (see Figure 4). Examples of areas in which the majority of apps scored poorly include providing programmatic access to data (H19), allowing control over the granularity of data when they are shared (H21), and the availability of help and documentation to support decision making (H26). Moreover, we found the category of data collected by the app was not a significant predictor of its privacy performance. This demonstrates that there is no single category of app that performs universally well; rather, the strength of privacy features tends to vary across app categories. In addition, Figure 3 demonstrates that the strength of privacy features often varies *within* app categories. These findings are important because they suggest that privacy stands to be improved across the spectrum of self-tracking apps, warranting the development of standards that can ensure that users' privacy is upheld in future designs.

The second finding was that app maturity was not a predictor of its strength in terms of privacy. Intuitively, consumers with privacy concerns might favor the services of established market players under the assumption that the apps provided by them are mature and, hence, stronger in terms of privacy [41]. However, our analysis shows that common proxies for an app's maturity such as the number of downloads or the rating an app has received are not useful predictors of how privacy-preserving an app will be. This again draws attention to the potential for privacy features to be enhanced across the self-tracking app landscape, irrespective of the reputation of an app's developer. One noteworthy point here is that the measures we used to evaluate an app's maturity cannot be taken as a ground truth measure, suggesting that this variable should, therefore, be explored more thoroughly in future work.

Our third main finding was that apps classed as tracking data relevant to mHealth (physical activity, mood, and so on) exhibited significantly higher privacy issues than other self-tracking apps. This is of significant concern given that mHealth data have the potential to be highly revealing about a users' life and, in turn, could lead to harmful or embarrassing situations if the privacy of these data is not upheld. During our evaluation, we noticed that nonmHealth apps tend to store data on users' devices rather than sharing them with third parties, and it is this practice that gives them a higher privacy score. It is not clear from this analysis, however, why this disparity has emerged in the design of these apps. A cause of concern is that health data may be perceived to be of significant commercial value by designers, so a requirement to share data with vendors is built into the design of such apps to exploit this. In turn, designers might gloss over this issue by "marketing" the sharing of data as something that is solely beneficial to users, for example, to allow synchronization of data between devices, without drawing attention to the associated privacy issues. The inadequate consent mechanisms frequently employed in self-tracking apps mean that users cannot make an informed decision about whether this trade-off is acceptable.

Overall, the importance placed on privacy in QS and mHealth apps is highly variable, and it may, therefore, be difficult for end users to make informed decisions about which apps will provide the functionality they desire while meeting their privacy requirements. We believe that drawing attention to these issues should motivate the development of standards and guidelines that can ensure that future self-tracking apps are stronger with respect to upholding users' privacy. In addition, our study provides evidence on the value of our heuristic evaluation approach for assessing privacy issues more generally. Using the heuristics will allow designers to consider key privacy concerns when developing and evaluating self-tracking apps in the future. The heuristics should also orient the designers to look toward the regulatory landscape for guidance on privacy-upholding features. Furthermore, the heuristics may guide data controllers in conducting impact assessments for privacy and data protection, such as those mandated by Article 35 of the EU's GDPR [20], which state that the review must be systematic but offer no guidance as to which aspects to prioritize or how to ensure coverage. The heuristics could be used to perform an initial "triage" assessment of data protection, with low scores in sections 1 and 2 indicating areas of concern. This could then flag that a more detailed impact assessment is necessary.

While we have applied the heuristics to a set of 64 self-tracking apps, we note that the heuristics were created on the basis of the wider regulatory landscape, and thus, they might also be generalizable to other types of apps that collect data from users. However, our study was focused on self-tracking apps, and thus, we see this as an area that should be explored in future work.

Reviewing the Heuristics

Our heuristics were designed to address 4 key questions regarding user privacy. We now consider the extent to which the apps we examined satisfy these 4 questions.

Do Users Know What Will Happen to Their Data Before Using an App?

The 7 *notice* heuristics (H1 to H7) address fundamental descriptive aspects of a user's relationship with a particular service in terms of who is responsible for the user's data, what the service will do with it, and who the data will be shared with. Of the 80% (51/64) apps in our sample that collected personal data from users, only 29 included terms of service or a privacy policy to explain how data will be used and none required these policies to be read or comprehended before proceeding with registration. Basic information was missing in many cases, such as the name of the organization collecting the data (25% of apps, 16/64) and who such data might be shared with (39% of apps,

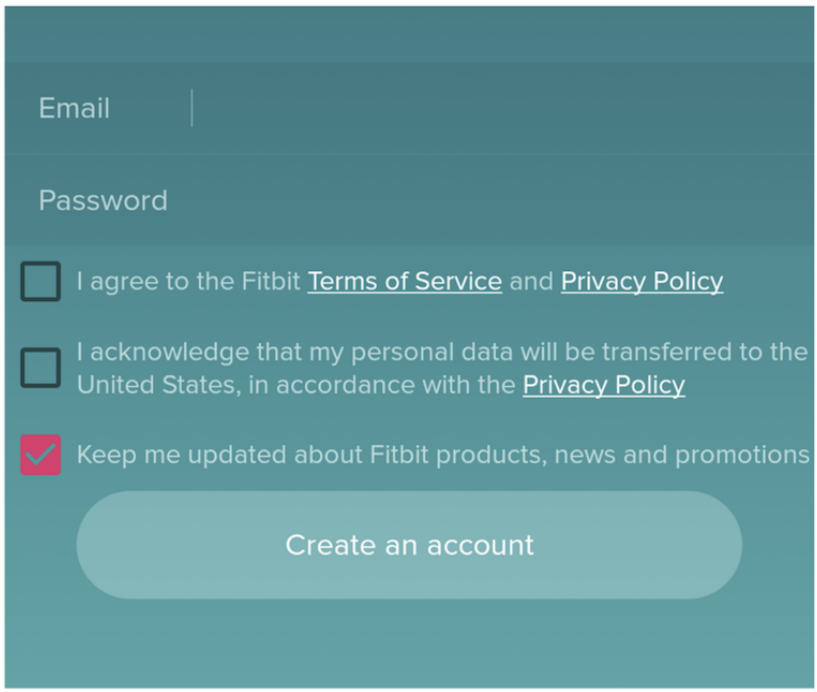
25/64). Many apps allow registration via several routes, using the single sign-on app programming interfaces provided by companies such as Facebook or Google to simplify the registration process for users and to provide the developer with a valuable connection to a user's Web-based identity. However, many apps that we examined exhibited a pattern whereby using such a registration route bypassed the usual exposure to an app's terms of service or consent to marketing communications, despite the potential added sensitivity of giving the providers access to their social network identity. High-profile apps from Nike+, Endomondo, and MapMyRide all exhibited this behavior. While Fitbit includes a link to its terms of service and privacy policy from within the app, these are dated 2011 and 2012, respectively, despite both documents having been updated in 2015 and 2016.

While it is well understood that lengthy terms of service are often not sufficiently readable [42] and that most people do not read them [43], it is of concern that so many apps, including those from QS market leaders, fail to provide information about the way their services function *in situ*. With data protection regimes such as the EU's GDPR strengthening the requirements for clear privacy notices at the time of data collection, it is evident that this is being regularly subverted by many self-tracking apps. US-based companies can self-certify their compliance with the Privacy Shield framework to signify that data exchanged between the United States and EU broadly correspond with EU data protection requirements. Notably, Under Armour, which provides MyFitnessPal, Endomondo, and MapMyRide, among a number of other successful self-tracking apps and devices, has a Privacy Shield certification that explicitly excludes these apps [44].

Do Users Have Control Over Their Data?

The 8 *choice and consent* heuristics (H8 to H15) concern the ability of users to sanction particular uses of their data and revoke consent from the app or connected services and devices. Most apps require an explicit form of consent before collecting data; however, the extent to which such consent is meaningful or sufficient is difficult to determine, with people's privacy attitudes frequently changing and potentially voiding their previous consent decisions [45], with a sustained approach to acquiring the consent necessary to renegotiate this relationship over time [46]. In some instances, the consent process includes a combination of opt-in, opt-out, or prefilled elements, which can be confusing for users and lead to oversharing of information or exposure to unexpected marketing communications, as shown in Fitbit's sign-up interface in Figure 6. In addition, most apps reserve the ability to renegotiate the user's relationship with the service unilaterally by changing terms of service or privacy policies without gaining explicit consent from users. Even if a user is satisfied with the way a company operates its service at the time of registration, the service can change significantly without the user's knowledge, thereby compromising the value of his or her consent. While some apps, such as Nike+, commit to notifying users and gaining consent if the use of personal data changes, this is still uncommon among self-tracking apps. While 36% of apps examined only keep data on the user's device, among those that involve sharing data with a remote provider, 63% do not provide users with control over where their data are stored, requiring users to trust that the vendor, or their choice of storage provider, can be trusted upon. Such efforts to ensure that data provided by users remain proprietary and siloed is a concern, which is further confirmed in our study of the third dimension of privacy.

Figure 6. Partial screenshot of the Fitbit Android app account creation page.



Do Users Have Access to the Data They Have Provided?

The 4 *access and participation* heuristics (H16 to H19) concern users' ability to extract the data they have provided from an app. Data portability is an increasingly sensitive issue in Internet services, with data protection regimes increasingly acknowledging portability as a right. Despite the fact that self-tracking requires the disclosure of potentially sensitive data to a range of data controllers, most services do not give people unfettered access to their own data, as indicated by the low scores for these access heuristics reported in Figure 4. Only 26% of services allow people to export all of their data, and 60% provide no means of exporting data. Our finding that only 16% apps provide programmatic access to data through public app programming interfaces supports the conclusion that mHealth and QS services are encouraging people to silo their data to prevent portability.

Can Users Control Their Disclosures to Third Parties?

While many services are keen to function as self-contained entities, some permit users to disclose their activity to third-party services such as SNSs. Such functionality has benefits for users who use SNSs to build social capital [47], which can be reinforced through the presentation of self-tracking activity such as weight loss or running performance; this, in turn, can support behavioral change [48]. For the developers of self-tracking services, this is a simple way to promote their service through evangelical users and associate their brand with positive behaviors. Over 40% of apps allow users to publish their activity to third-party services and meet most of the fundamental usability measures. Only 11% of apps, however, provide contextual privacy help, such as explaining the effect of sharing information with different audiences. Most of the heuristics in this category (H20 to H26) had high scores for the apps examined, which, in part, may be attributed to the use of the authentication software development kit provided by major SNSs, such as Facebook and Twitter, which provide their own native privacy controls and audience selectors in response to ongoing privacy issues with their platforms.

As self-tracking apps continue to evolve, they will incorporate new types of sensors, a greater fidelity of captured data, the ability to provide richer analysis, and more accurate inferences. Current apps are mostly delivered through smartphones and wristwear; however, this is often associated with usability issues due to small or absent displays. Therefore, we can anticipate that in the near future, sensors will increasingly be embedded in biological and interfaceless apps, reducing the usability barriers to adopting such technologies, while potentially introducing new privacy risks when it becomes harder to configure the appropriate sharing of information. We, therefore, propose that these heuristics can be used as a form of certification attached to the marketing of products in app stores and other channels. This would allow people to compare the privacy characteristics of apps that offer similar functionality and encourage developers to incorporate innovative privacy-preserving functionality, thus, treating privacy as a value-adding marketable feature.

Limitations

This study has several limitations. First, using the results of a survey from a QS meetup group was sufficient to capture the types of data people are interested in tracking. It is not clear, however, whether the self-selected QS community is representative of the cohort of users who use such technologies but may not consider themselves self-trackers, nor have any affinity with self-tracking as a practice. For example, by far, the most popular app that we examined was Simple Design Ltd's *Period Calendar*, which was 38% more popular than the next-ranked app *MyFitnessPal*. The former was only included in our scrape of Google Play as it matched the "mood" keyword. Considering the popularity of the app, it is plausible that the QS community is significantly biased toward men, and therefore, our analysis may have omitted some self-tracking apps. Similarly, regional differences may have caused us to miss some apps. Our study used the UK Google Play Store, and the list of apps returned may differ from that produced if the scrape was performed in another region. For example, the financial tracking app *Mint* [49] is only available in the United States, and so it did not appear in our list of apps, despite having nearly 10 million downloads.

In terms of our findings, we have designed the heuristics and the process of obtaining and reviewing apps to be reproducible, but we do not yet know how robust the heuristics are to changes in technology, as the privacy implications and usability challenges we observe may be tightly coupled to the modalities of smartphones and wearables, which currently dominate the self-tracking landscape. Cohen kappa for our interrater reliability only showed moderate agreement, which may be attributed to the varying interpretation of legal language in privacy policies and term & conditions as well as the fact that only on a subset of apps was compared by pairs of raters. Increasing the number of raters per app might address this issue.

In addition, the finding that mHealth apps performed worse on privacy is worthy of deeper investigation given the aforementioned possibility of selection bias in our app sample and differences in sample size between the mHealth and nonmHealth app categories. In addition, it would be helpful to consider how the heuristics can be reconciled with the fact that different aspects of privacy can become more or less relevant to users depending on their context [50,51]. The heuristics in our study were applied by expert evaluators without attending to the context, primarily because the heuristics are designed to embody a set of issues that should be applicable across a range of settings (eg, the usability of disclosure controls). Nevertheless, understanding whether users might actually desire less stringent privacy controls in certain contexts is an area for future work.

In terms of our method, the heuristics can be time consuming to apply because they require a close reading of terms of service. In addition, they require many functional routes of an app to be explored in order to identify discrepancies. In future work, we plan to investigate whether natural language processing can be used to parse and semiautomatically apply some of the heuristics to the terms of service and privacy policies. Work by Slavin et al [52] has focused on detecting privacy policy violations in

Android app code, and similar techniques could be used to automatically apply the privacy policy heuristics as well as those concerned with exporting data.

Conclusions

In this paper, we have introduced a novel heuristic evaluation method for examining the state of privacy in QS apps. We found that the majority of apps do not meet our privacy criteria, including notification of fundamental data protection characteristics, or the criteria on ability to export user data. High-profile apps are among those that exhibit poor privacy behaviors, which can make it difficult for users to make informed choices about which apps to trust with their data. Our heuristics can provide designers with a resource to maintain privacy in the design of self-tracking services and avoid common pitfalls, which can engender mistrust or lead to privacy issues. As the heuristics were guided by both the EU and US regulatory environment, they may also help guide data controllers to perform impact assessments for both privacy and data protection. We have provided the tools and documentation necessary to replicate our findings and confirm the usability of the heuristics and allow the evolving privacy landscape to be evaluated. In future work, we will examine the *usefulness* of the heuristics by using them to capture people's privacy preferences and recommend services that meet their requirements.

Acknowledgments

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Authors' Contributions

AKB, BAP, and BN conceived this project in consultation with MM and TH. LH drafted the original heuristics and refined them with BAP, AKB, and CM; then, this group applied them to the selected apps. RK redrafted the paper in response to reviewers' comments and reframed arguments. CM wrote the software to scrape the Google Play Store. LH analyzed the data and wrote the first draft of the paper, which was then edited by AKB and BAP.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Quantified Self Privacy Heuristics v1.

[PDF File (Adobe PDF File), 26KB - mhealth_v6i10e185_app1.pdf]

Multimedia Appendix 2

London Quantified Self Tool Use Survey 2014.

[XLSX File (Microsoft Excel File), 114KB - mhealth_v6i10e185_app2.xlsx]

Multimedia Appendix 3

Apps chosen for heuristics evaluation.

[PDF File (Adobe PDF File), 30KB - mhealth_v6i10e185_app3.pdf]

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Abbreviations

CLMM: cumulative link mixed model
EU: European Union
GDPR: General Data Protection Regulation
mHealth: mobile health
QS: quantified self
SNS: social networking site

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Original Paper

Features, Behavioral Change Techniques, and Quality of the Most Popular Mobile Apps to Measure Physical Activity: Systematic Search in App Stores

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Abstract

Background: It is estimated that 23% of adults and 55% of older adults do not meet the recommended levels of physical activity. Thus, improving the levels of physical activity is of paramount importance, but it requires the use of low-cost resources that facilitate universal access without depleting the health system. The high number of apps available constitutes an opportunity, but it also makes it quite difficult for the layperson to select the most appropriate app. Furthermore, the information available in the app stores is often insufficient, lacks quality, and is not evidence based, and the systematic reviews fail to assess app quality using standardized and validated instruments.

Objective: The objective of this study was to systematically assess the features, content, and quality of the most popular apps that can be used to measure and, potentially, promote physical activity.

Methods: Systematic searches were conducted on Apple App Store, Google Play, and Windows Phone Store between December 2017 and January 2018. Apps were included if their primary objective was to assess the aspects of physical activity, if they had a user rating of at least 4, if their number of ratings was ≥100, and if they were free. Apps meeting these criteria were independently assessed by two reviewers regarding their general and technical information, aspects of physical activity, presence of behavioral change techniques, and quality. Data were analyzed using means and SDs or frequencies and percentages.

Results: Of 51 apps included, none specified the age of the target group and only one mentioned the involvement of health professionals. Most apps offered the possibility to work in background (n=50) and allowed data sharing (n=40). Regarding physical activity, most apps measured steps and distance (n=11) or steps, distance, and time (n=17). Only 18 apps, all of which measured number of steps, followed the guidelines on recommendations for physical activity. On average, 5.5 (SD 1.8) behavioral change techniques were identified per app; the most frequently used techniques were “provide feedback on performance” (n=50) and “prompt self-monitoring of behavior” (n=50). The overall quality score was 3.88 (SD 0.34).

Conclusions: Although the overall quality of the apps was moderate, the quality of their content, particularly the use of international guidelines on physical activity, should be improved. Additionally, a more in-depth assessment of apps should be performed before releasing them for public use, particularly regarding their reliability and validity.

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KEYWORDS

behavioral change techniques; mobile phone app; physical activity; quality; technical features; mobile phone

Introduction

Physical inactivity is considered as the biggest public health problem of the 21st century [1]. It is the fourth leading risk factor for global mortality, contributing to 6% of deaths globally, and is one of the main risk factors for many major noncommunicable diseases such as cardiovascular disease, diabetes, and cancer [2]. The World Health Organization (WHO) has defined the levels of physical activity per age group with an impact on health. For example, WHO recommends that adults perform at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity every week [2]. However, 23% of adults and 55% of older adults are not meeting these recommended physical activity levels and are, thus, insufficiently active [3]. Thus, while improving the levels of physical activity is of paramount importance, it requires the use of low-cost resources that facilitate universal access without depleting the health system.

Smartphones and mobile apps constitute a potential means to promote physical activity and one that is available to potentially everyone at low or no cost. Smartphone ownership is expected to grow from 1.86 billion in 2015 to around 2.87 billion in 2020 [4]. Similarly, the number of apps, particularly those related to health and fitness, has been increasing. As of June 2018, there were 3,509,819 and 3,249,721 apps in the Google Play and Apple App Store [5,6], respectively; of them, 102,962 and 97,844 were categorized as Health and Fitness apps, respectively [7,8]. This high number of apps available constitutes an opportunity, but it also makes it quite difficult for the layperson to select the most appropriate app. Furthermore, as the information available in the app stores is often insufficient, lacks quality, and is not evidence based [9], it is essential to use standardized instruments to assess the content and quality of the available apps that claim to measure or promote physical activity in terms of what they measure and how, whether they follow international health and fitness guidelines, and their use of behavioral change techniques. Existing systematic reviews assessing apps that measure or promote physical activity have focused mainly on characterizing their content, particularly regarding the use of behavioral change techniques [10-13] because these interventions are associated with greater effectiveness [14]. Nevertheless, app quality has not usually been assessed using standardized and validated instruments. Therefore, the present study aims to systematically assess the features, content, and quality of the most popular apps that can be used to measure and, potentially, promote physical activity and that are available in the Apple App Store, Google Play, and Windows Phone Store.

Methods

Search Strategy

Systematic searches were conducted independently by two researchers (PS and JA) in the Apple App Store, Google Play, and the Windows Phone Store between December 2017 and January 2018. Apps were identified using the following search terms: “physical activity,” “tracker,” “distance,” and “pedometer.” The search terms were entered in the platforms separately or in combinations based on the Boolean logic.

Inclusion Criteria and Selection Process

The selection process was conducted in two phases. In the first phase, apps were retrieved and registered in a database if they (1) were written in English or Portuguese (description and application); (2) had “physical activity” or related words featured in the keywords or text description; and (3) had a primary objective to assess the aspects of physical activity. For the purpose of this study, physical activity was defined as any movement of the body produced by the skeletal muscles that results in energy expenditure that can be objectively characterized by measuring body displacement [15,16]. Apps could be used alone or in combination with an external device (eg, physical activity tracker) or a back-office system, for example, to communicate with a health professional. Apps were excluded if they were intended for use in a clinical context only (eg, hospital or other health care context) or primarily targeted health behaviors other than physical activity (eg, diet). Two reviewers (PS and JA) independently assessed the names and descriptions of mobile apps against the inclusion criteria. Disagreements were resolved through discussion with a third reviewer (AGS). The apps identified in this first phase were then included in the second phase of selection. In this phase, a second set of criteria was used to identify the apps that would enter this review. Apps were included if (1) they had a user rating of at least 4 (scale range: 1-5) in line with previous app reviews [9,17]; (2) they had a number of ratings ≥100; and (3) they were free (as we believed these to be the most commonly used by the general population). This selection was performed between the January 25 and 30, 2018, by one reviewer (PS). Apps meeting these criteria were then installed into appropriate devices and independently assessed by two reviewers (PS and JA) using standardized forms. Disagreements were resolved through discussion with a third reviewer (AGS). When the same app was available from more than one store, it was downloaded from one store only (usually the Google Play).

Data Extraction

Data extraction was performed using customized forms specifically designed for this assessment and that had been piloted using 3 apps (“C25K 5K Trainer,” “Wokamon–Fitness Game,” and “Pedometer, Step Counter & Weight Loss Tracker”) to standardize the rationale and procedures. Data retrieved from the platforms and apps covered the following:

1. The general and technical information, which was assessed using both the app classification subscale from the Mobile Applications Rating Scale (MARS) [18] and a set of criteria defined by the authors of the present study (involvement of health professionals in the development of the app, presence or absence of a back-office, possibility to connect to other peripheral devices, possibility to work in the background, calendarization, possibility to give geographic

information, types of authorizations needed, and the existence of videos showing exercises or other information), totalizing a maximum of 12 features.

2. The aspects of physical activity such as the number of steps, distance, time, and velocity; whether they could be used indoors or outdoors; and the accuracy of the content in accordance with guidelines, such as the WHO recommendations of at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity in a week [2] and the recommendation of 10,000 steps per day [19].
3. The presence or absence of behavioral change techniques, which were assessed using the taxonomy of behavioral change techniques developed by Abraham & Michie [20]; this taxonomy includes 26 behavioral change techniques, but 3 of them (provide information on consequences, provide general encouragement, and provide information about other's approval) showed low interrater reliability [20]. Thus, they were not included, and the remaining 23 behavioral change techniques were categorized as being present or absent.

Quality Assessment

App quality was assessed using the App Quality Ratings subscale of MARS, which includes 19 items grouped into 4 sections: (1) engagement (entertainment, interest, customization, interactivity, target group); (2) functionality (performance, ease of use, navigation, gestural design); (3) aesthetics (layout, graphics, visual appeal); and (4) information quality (accuracy of app description, goals, quality and quantity of information, visual information, credibility, evidence base) [18]. All items were assessed using a 5-point scale (1: inadequate to 5: excellent). A mean score for each of the 4 subscales as well as an overall score resulting from the mean of the 4 subscale scores was calculated [18]. MARS has been found to be reliable and to have very high to excellent internal consistency [18]. App quality assessment was conducted independently by two reviewers (PS and JA). Disagreements between the two reviewers were resolved through discussion with a third reviewer (AGS).

Statistical Analysis

Data were analyzed using means and SDs for continuous variables and frequencies and percentages for nominal and ordinal variables. The agreement between the reviewers was characterized using agreement percentages for nominal variables (eg, behavioral change techniques) and the intraclass correlation coefficient (ICC; model: two-way mixed effects, absolute agreement) for continuous variables (eg, MARS subscales and total score). The acceptable level of percentage agreement and interrater reliability was set at 80% and 0.70, respectively [21].

Results

App Selection

A flowchart for the app selection process is presented in Figure 1. One reviewer (JA) identified 614 apps in the Apple App Store, 642 apps in the Google Play, and 46 apps in the Windows Phone Store, while the other reviewer (PS) identified 598 apps in the Apple App Store, 658 apps in the Google Play, and 44 apps in the Windows Phone Store. After screening for eligibility against the inclusion and exclusion criteria in both phases 1 and 2, 51 apps were selected for this assessment (21 apps from the Apple App Store and 30 apps from the Google Play; Multimedia Appendix 1).

General Characteristics of the Selected Apps

The general characteristics of the included apps are presented in Table 1. Of the 51 free apps, 27 had an upgraded version with an average cost of 3.27€ (range: 0.89€-10.99€); the mean user rating was 4.39 (SD 0.25), and the mean number of user ratings was 27,852.96 (SD 12,339.92). None of the apps specified the age of the target group, but 3 apps were not recommended for children and adolescents (age<18 years). Only 1 app ("The Walk: Fitness Tracker Game" from the Apple App Store, which was developed by the National Health Service and Department of Health in the United Kingdom) of the 51 included in this study mentioned the involvement of health professionals in its development. The mean number of app features per app was 3.2 (SD 1.7) out of a maximum of 12 (range: 1-7). Most apps offered the possibility to work in the background (50/51, 98%), most allowed data sharing (40/51, 78%), and none required internet access to measure the physical activity. In terms of the physical activity types, most apps measured steps and distance (11/51, 22%) or steps, distance, and time (17/51, 33%); 96% (49/51) apps could be used both outdoors and indoors, and the remaining 2 apps ("Sports Tracker for All Sports" and "Walking Odometer Pro-GPS Pedometer & Fitness") were for outdoor use only as they needed a global positioning system signal. Only 18 apps, all of which measured the number of steps, followed the guidelines recommended for physical activity (number of steps).

Presence of Behavioral Change Techniques

The percentage of agreement between reviewers regarding the presence of behavioral change techniques in the included apps was 93.1%. The mean number of behavioral change techniques per app was 5.5 (SD 1.8), and overall, all apps included at least 3 behavioral change techniques. The maximum number of behavioral change techniques was 10 in one app ("Pedometer-Six pack Workout" from the Google Play). Commonly included behavioral change techniques were "Provide feedback on performance" (50/51, 98%), "Prompt self-monitoring of behavior" (50/51, 98%), "Prompt specific goal setting" (42/51, 82%), "Provide opportunities for social comparison" (40/51, 78%), and "Plan social support or social change" (38/51, 75%). Some behavioral change techniques were not found in any of the included apps: "Prompt intention formation," "Prompt barrier identification," "Teach to use prompts or cues," "Agree on behavioral contract," "Prompt identification as a role model," "Prompt self-talk," "Relapse prevention," "Stress management," "Motivational interviewing," and "Time management." Figure 2 shows the absolute frequencies for the behavioral change techniques used in the 51 apps included in the present assessment.

Figure 1. Flowchart of the selection process for apps included in the study. PA: physical activity.

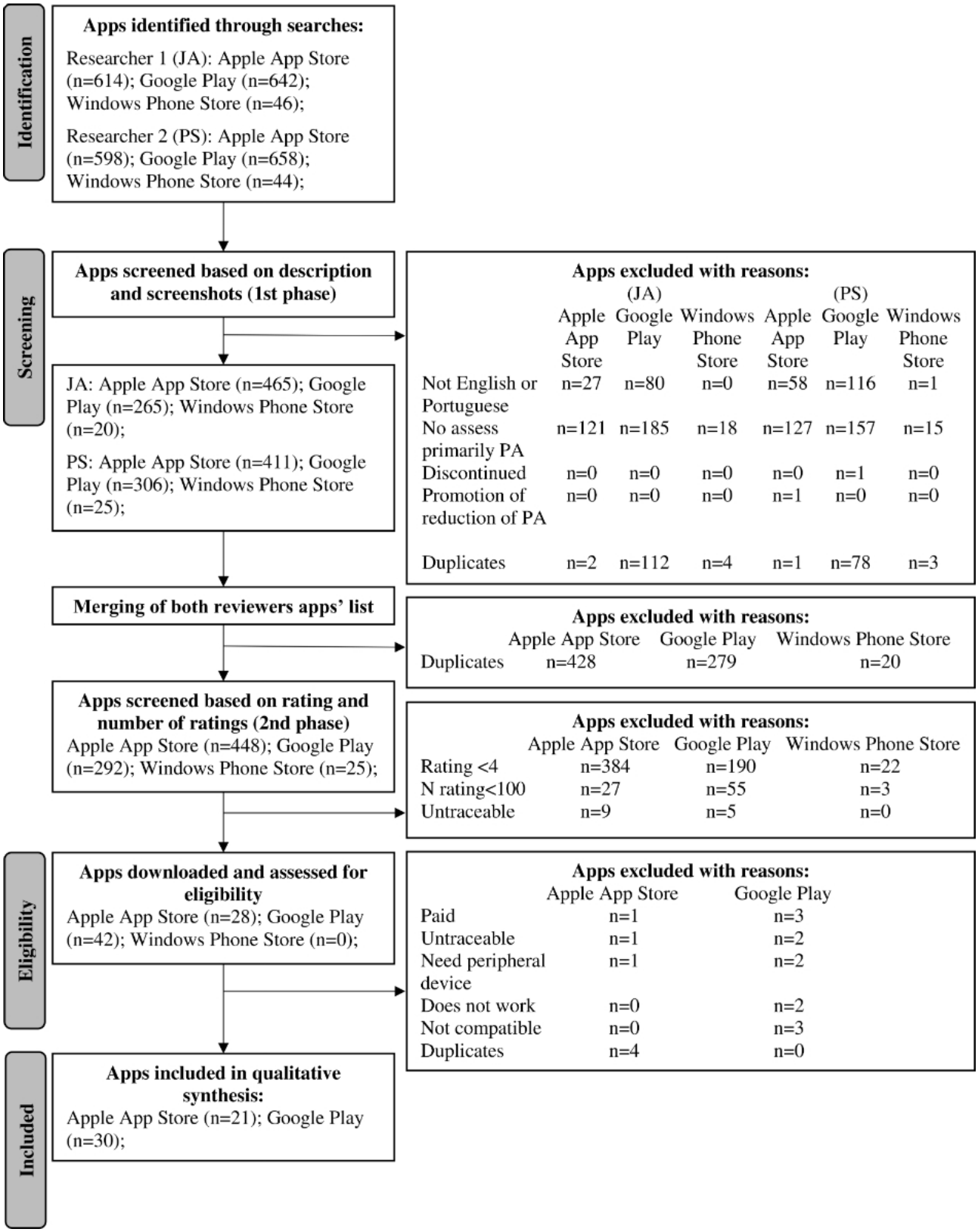
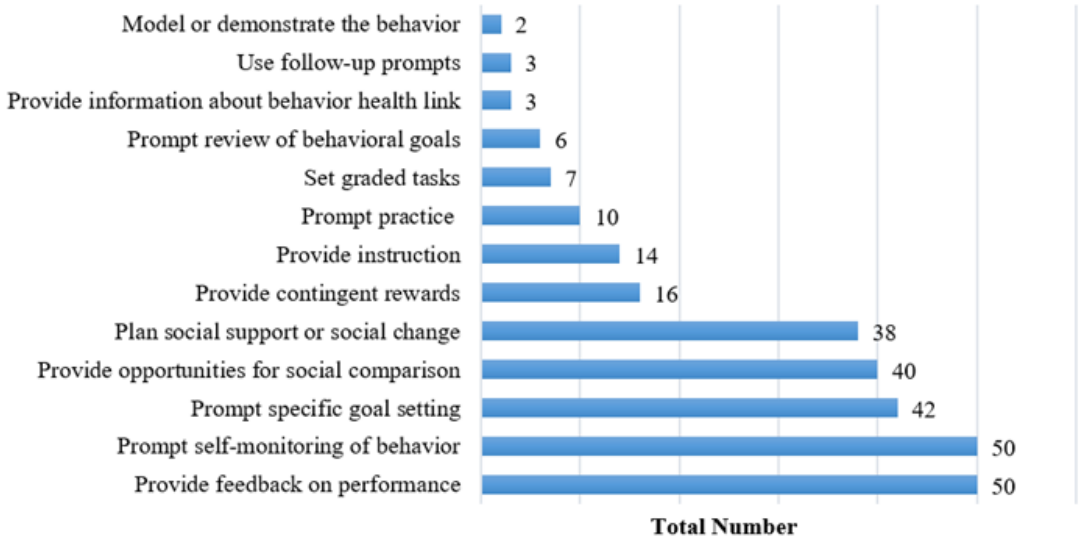


Table 1. General characteristics of the included apps (N=51).

Characteristics	Value
Store, n (%)	
Apple App Store	21 (41)
Google Play	30 (59)
User rating, mean (SD)	
Average rating	4.4 (0.3)
Average number of user ratings	27,853 (12,339.9)
Health professional involvement, n (%)	1 (2)
Age (years), n (%)	
All age groups	48 (94)
Adults only (age>17)	2 (4)
Adults and adolescents (age>12)	1 (2)
Number of app features (out of a maximum of 12), mean (SD)	3.2 (1.7)
Allows sharing, n (%)	40 (78)
Allows password protection, n (%)	2 (4)
App community, n (%)	17 (33)
Calendarization, n (%)	4 (8)
Connects with peripheral devices, n (%)	9 (18)
Geographic information, n (%)	10 (20)
Has a back-office, n (%)	7 (14)
Has videos showing exercises or other information, n (%)	4 (8)
Needs internet to work, n (%)	0 (0)
Requires log-in, n (%)	7 (14)
Sends reminders, n (%)	11 (22)
Works in background, n (%)	50 (98)
Type of measurements for physical activity (PA), n (%)	
Steps only	2 (4)
Time only	2 (4)
Steps and distance	11 (22)
Distance and time	1 (2)
Steps, distance, and time	17 (33)
Steps, distance, and velocity	3 (6)
Distance, time, and velocity	6 (12)
Steps, distance, time, and velocity	9 (18)
Guidelines for PA, n (%)	
Follows guidelines[a]	18 (35)
Does not follow guidelines	33 (65)
Environment where apps measure PA, n (%)	
Indoors and outdoor	49 (96)
Outdoors only	2 (4)

[a]All apps that followed the guidelines measured the number of steps.

Figure 2. Frequencies of the 23 behavioral change techniques presented in the included apps (N=51).



App Quality

Overall, the reliability regarding the assessment of the app quality was excellent with an ICC of 0.93 (95% CI 0.70-0.97) for the MARS total score. For subscale A, the reliability for the MARS ICC was 0.83 (95% CI 0.63-0.92); for subscale B, it was 0.88 (95% CI 0.78-0.93); for subscale C, it was 0.90 (95% CI 0.78-0.95); and for subscale D, it was 0.93 (95% CI 0.70-0.97). The mean MARS total score was 3.88 (SD 0.34) out of 5; it ranged between 3.16 ("StepWalk Pedometer" from the Google Play) and 4.41 ("Accupedo + Pedometer" also from the Google Play). The subscale with the highest score was "Functionality" (mean 4.30 [SD 0.68]), followed by "Aesthetics" (mean 4.15 [SD 0.68]), "Information Quality" (mean 3.78 [SD 0.28]), and "Engagement" (mean 3.28 [SD 0.34]).

Discussion

Main Findings and Comparison With Prior Work

This study assessed the features, content, and quality of the most popular physical activity apps available in the Apple App Store, Google Play, and Windows Phone Store. Most of the included apps targeted all age groups and none specifically targeted children, adolescents, or older adults. Schoeppe et al [17] conducted a similar systematic assessment of apps that targeted diet, physical activity, and sedentary behavior in children and adolescents and found only 18 apps specifically designed for children and adolescents that targeted physical activity. Nevertheless, WHO recommendations for physical activity for children, adolescents, adults, and older adults are different [2]. Moreover, it is likely that an app that is adequate for and captivates adolescents would be different from an app that is adequate and easy to use by older adults, who are also a high-risk age group for low levels of physical activity [3]. When assessing whether the apps considered the established guidelines for physical activity, 18 of the 42 apps that measured the number of steps followed the guidelines (ie, mentioned 10,000 steps per day); however, none followed the WHO guidelines for intensity, duration, and frequency (ie, at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity per week). The lack of apps following the WHO recommendations was also mentioned in the review of Knight et al [22], highlighting the need to develop apps that measure intensity, frequency, and duration and that make recommendations based on the established guidelines. For example, an app could register the weekly frequency and duration of physical activity and match these against the guidelines every week. The app could also prompt the user to classify the intensity of the activity based on existing scales such as the Borg scale [23].

Of the 51 reviewed apps, only 1 ("The Walk: Fitness Tracker Game" from the Apple App Store) mentioned the involvement of health professionals in its development. The low involvement of health professionals in the development of apps has also been found in other reviews of physical activity apps [24], pain apps [25], obesity apps [26], and apps that target medication adherence [27]. The involvement of health professionals in the development of apps targeting health behaviors is crucial if the app content is to be evidence based, ie, based on information that is scientifically accepted and appropriate for the target population, and it also contributes to decrease the possibility of apps being harmful and misleading.

Most apps included technical features such as the possibility to share the accomplishments on social media, such as Facebook, and the possibility to work in the background. The possibility of sharing accomplishments on social media can help individuals stay motivated and increase the levels of physical activity; however, there are also concerns regarding what to share and with whom [28].

The number of behavioral change techniques included in the apps ranged between 3 and 10 with a mean of 6 per app. This is consistent with previous reviews that found the mean number of behavioral change techniques per app to range between 4 and 8 [10-13,24]. Nevertheless, the optimal number of behavioral change techniques per app remains unclear. According to Michie et al [14], interventions targeting diet and physical activity that include feedback on performance combined

with self-monitoring, goal setting, intention formation, and review of goals are associated with greater effectiveness. While providing feedback on performance, goal setting, and self-monitoring were among the most common behavioral strategies present in the reviewed apps, intention formation and goal review were not.

The quality of the reviewed apps was moderate, with a mean MARS total score of 3.88. Similar to other reviews that assessed app quality using MARS [9,17], the domains with the highest scores were functionality and aesthetics, while the domains with the lowest scores were engagement and information quality. These results suggest that developers are more concerned with the ease of use, functionality, and aesthetics than with engagement and content based on high-quality evidence. Furthermore, none of the reviewed apps had been assessed for usability, validity, reliability, and effectiveness, which raises further concerns regarding the quality and impact of the apps that are freely available to everyone in the commonly used app stores. These aspects should be assessed before the apps are released, or at least, a reference to their absence should be made.

Limitations

In this study, only the most popular apps were assessed, which limits the generalizability of results to all available apps. Another limitation was the short period used for the individual assessment of each app, which may have led to the nondetection of some features (for example, presence of reminders) and behavioral change techniques that required more time, such as "Use of follow-up prompts" and "Prompt review of behavioral goals," and prevented the assessment of engagement to the apps. However, app quality was assessed by two independent reviewers using a standardized instrument, which minimized the potential errors. In addition, the apps were tested by the researchers only and not by any potential users.

Conclusion

The results suggest that the popular apps for measuring and, potentially, promoting physical activity are of moderate quality. The app content quality, particularly the use of international guidelines on physical activity, could be improved. Furthermore, based on the findings from this assessment, we suggest that health professionals should be involved in the development of apps targeting health behaviors; that apps should be developed considering the target group and the respective recommendations for physical activity established by the WHO; and that more in-depth assessments, particularly for reliability (consistency of results) and validity (accuracy of results), be performed before apps are released to the general public, which would allow the public to make more informed choices.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

List of the apps included and their major characteristics.

[PDF File (Adobe PDF File), 233KB - mhealth_v6i10e11281_app1.pdf]

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Abbreviations

ICC: intraclass correlation coefficient
MARS: Mobile Applications Rating Scale
WHO: World Health Organization

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Original Paper

Health Care Apps Reported in Newspapers: Content Analysis

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Abstract

Background: Newspapers are considered one of the most viewed and influential media sources in both the United Kingdom and United States. However, information about how newspapers portray health care apps to the readers has been lacking.

Objective: This study investigated the reporting on health care apps in newspapers published in the United Kingdom and United States.

Methods: The Nexis UK database was used to identify and select relevant articles. Systematic content analysis of the articles that met the inclusion criteria (articles of any format that contained reference to health care apps or medical apps) within the highest circulated newspapers in the United Kingdom and United States over a period of 10 years (2006-2015) was conducted. Interrater reliability of coding was established using a 10% sample of the chosen articles.

Results: A total of 220 (151 UK and 69 US) relevant newspaper articles were retrieved. Health care apps were most frequently reported on in the Daily Mail and The Guardian (UK newspapers) and in the New York Times and the Washington Post (US newspapers). An exponential rise in published scientific articles (PubMed) on health care-related apps was noted during the study period. A total of 26.4% (58/220) and 19.1% (42/220) of the retrieved newspaper articles appeared in the features and main news sections, respectively. General information about health care apps was the main theme coved by the newspapers (45.9%, 101/220). Most of the articles represented a societal point of view (72.3%, 159/220). The main focus of the articles was on general health matters (48.2%, 106/220) and specific disease matters (36.8%, 81/220). Diabetes was the most frequently mentioned disease in the articles. A high proportion (91.4%, 201/220) of the articles mentioned benefits of using health care apps mainly for personalized care, whereas 24.1% (53/220) of the articles commented on related risks such as anxiety and confidentiality issues. Almost half (45.9%, 101/220) of the articles mentioned potential facilitators to the use of apps; less than 10% (16/220) discussed barriers. Most of the articles (83.6%, 184/220) were judged as having balanced judgment on the present topic and more than half (60.0%, 132/220) of the articles were judged to be of generally low quality.

Conclusions: Health care apps were not widely reported in newspaper articles in the United Kingdom and United States over the study period; however, there appeared to be much more recent interest. Characteristically, the articles focused more frequently on societal impact and on general health rather than on disease-specific apps.

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KEYWORDS

apps; newspaper articles; newspapers; health

Introduction

Health care apps are defined by the US Food and Drug Administration (FDA) as "software programs that run on smartphones and other mobile communication devices in order to, for example, provide health information to the public, provide other health-related support to patients and health care professionals and remotely transfer data to health care providers." These apps can also be used to facilitate decision making and provide the opportunity for consultations to take place remotely [1].

Mobile phone apps are becoming increasingly popular globally and are being used by a substantial proportion of the population both in the developed and the developing world. They are used on a daily basis to communicate with friends and relatives, perform online shopping, read news, and for monitoring health-related parameters including diet, exercise, and sleep. Such apps can have a positive impact on promoting improved health and well-being and are increasingly being embraced by health care professionals [2,3].

The two major app stores are the iPhone Apple Store, which was launched in July 2008, and Google Play, which was introduced to the public in April 2010 [4]. Apps for health care-related use were initially introduced in 2011 within the Apple Store, which led to their widespread uptake across both healthy and ill individuals [5]; by the beginning of 2014, around 1 million general apps were available [6]. Health apps are used on mobile phones to track, for example, an individual's heart rate, exercise, weight, food consumption, and sleep patterns. Apps have also been used in many research studies to collect data, send patient reminders, and to convey educational or motivational messages [7]. Health care apps are also becoming increasingly used in health care management to provide individual and population levels of support to health care recipients [8]. Therefore, mobile devices and information technology have been combined to promote health care and reinforce disease management. The National Health Service (NHS) health apps library was introduced in 2013 to provide information on recommended medical apps to help members of the public and patients in the selection of apps to manage their health. App developers can send their apps for review by the NHS library. Apps that are deemed beneficial (eg, the iBreastCheck app) are then added to the library list [9]. As detailed in a recent report, the four most frequently downloaded apps from the NHS library were related to general health and well-being, mainly related to the topics of fitness, drink trackers, healthy food, and quitting smoking. The fifth most downloaded app was for recording and tracking blood pressure [10]. One survey in the United States showed that approximately 25% of adult Americans use one or more mobile phone apps to monitor their health and 33% of health care professionals have recommended at least one app to their patients [11].

As well as widespread use by the public, health care providers increasingly use mobile phones to access health information at the point of patient care, such as electronic clinical decision-making programs, laboratory systems, and medical resource tools (eg, the Medscape app) [1,9]. According to a UK survey published in 2012, 74.8% of junior doctors and 79% of medical students owned a mobile phone, with the majority of both groups reporting that they used between one and five health care apps on their mobile phones [4]. All these numbers have likely increased in the interim within a burgeoning information technology marketplace. Many health apps are currently used for supporting disease management and monitoring patient health care, such as the Mobile MIM app that has been approved by the FDA as a portable x-ray scan viewer. With the high-definition screens available on the new generation of mobile phones, it has been reported that the assessment of images on mobile phones can be as effective as their evaluation at a workstation [12].

Health care apps can also facilitate access to a patient medication regimen and can be used to arrange an appointment with a physician. Apps can be utilized to educate patients and help change their behavior; for instance, healthy food apps can be used to monitor an individual's behavior related to calorie intake and provide advice about healthy eating habits including fat and carbohydrate content of different food items [3,13]. Recent advances in mobile technologies have opened up new approaches to support health care delivery and patient education. These approaches have the potential to encourage patients to be more actively involved in their own health care and to be part of the decision-making process [8]. Some health apps are focused only on specific diseases such as the ophthalmology ("Eye Handbook" app [14]) and "Diabetes: M" for diabetes [15].

Most patients do not visit their general medical practitioner regularly; therefore, the public in general often gain information on health care innovations via the mass media (eg, television, radio, newspapers, magazines). The internet is also frequently searched to obtain answers to specific health queries. Newspapers are one of the main sources for providing health knowledge and medical information passively to the public [16,17]. In addition, it has been reported that although different mass media outlets differ in the quantity of coverage, newspapers are equivalent to other forms of news media in terms of content [18,19]. The print media is widely accessible to most people and is available at low cost [20]. Although newspapers are traditionally available in hardcopy, increasing numbers of the public access newspapers online. Research has revealed that mass media has a positive impact on changing behavior; for example, relating to alcohol use, diet, smoking, and breast feeding [21,22]. Furthermore, the impact of the media on cancer awareness has been well documented. Several studies reported increased screening for cancer and improved awareness in the United States and Australia after mass media campaigns involving newspapers [23,24].

Print media is a key source of health information that influences public understanding of health care-related matters. Print media can also influence public opinion and perceptions regarding a particular topic [25,26], and is an important vehicle by which health-related information is diffused within society [27]. Interestingly, public health professionals have a bimodal relationship with the media; they use health media to influence health practice, while at the same time they have to counteract the influence when the media promotes unhealthy or

nonevidence-based practices [28]. Therefore, print media significantly contributes to the definition and understanding of health-related matters and health care practice. It has also been reported that policy responses to health-related issues are affected by media coverage of the problem rather than the true impact of the problem, and both policymakers' perceptions and the public's acceptance of possible policy responses are substantially influenced by the media [29]. The influence of the media on health-related issues has been reported frequently in the literature regarding, for example, obesity [30], smoking cessation [27], immunization in children [31], and AIDS [32].

The media of course can present material to the public within a particular framework and with a particular emphasis or slant, and indeed there is extensive literature on this effect (framing theory). Through the use of differing "framing" approaches, journalists can selectively influence how a particular piece of information is interpreted by the reader [33-35].

With the knowledge that newspapers represent an important source of health-related information [36], and because no published research has investigated newspaper reporting on health care apps, the aim of this study was to explore what the general public have been told about health care apps within published newspaper articles in the United States and United Kingdom over a 10-year period (2006-2015) and to analyze the content of the articles.

Methods

Study Design

We conducted a systematic content analysis of articles contained in the highest circulated newspapers in the United Kingdom and United States that dealt with health care apps (2006-2015). A summary of the methodology is presented in Figure 1.

Newspaper Selection

The electronic archive of published international newspapers (Nexis UK database) was used as the source of the selected articles. A purposive sample of the 10 daily UK newspapers (including their Sunday equivalents) with the highest circulation according to the Audit Bureau of Circulation Ltd [37] at the commencement date of the study (June 2015) was selected. This sample comprised *The Sun* (*The Sun on Sunday*), *Daily Mail* (*Mail on Sunday*), *Daily Mirror* (*The Sunday Mirror*), *Daily Star* (*Daily Sunday Star*), *The Daily Telegraph* (*The Sunday Telegraph*), *The Daily Express* (*The Sunday Express*), *Daily Record* (*Daily Sunday Record*), *The Times* (*The Sunday Times*), the *i*, and *The Guardian* (*The Observer*).

In an equivalent manner, a sample of the top 10 daily US newspapers, ranked by the total average circulation [37], was identified which consisted of *USA Today*, *The New York Times*, *Los Angeles Times*, *The Washington Post*, *New York Post*, *New York Daily News*, *Orange County Register*, *Newsday*, *The Denver Post*, and *Tampa Bay Times*. All except *USA Today* (published on weekdays) are published daily and on Sundays. Several highly circulated US newspapers, including the *Dallas Morning News*, *Chicago Tribune*, and *Chicago Sun-Times*, were not included in the study because they were not available in the Nexis database at the time the research was being carried out.

Search Strategy, Inclusion, and Exclusion Criteria

A systematic approach using different search terms to maximize relevant article retrieval was used. The search terms that yielded the highest number of articles from the Nexis UK database were: (health apps OR mobile medical apps OR smartphone health apps OR fitness apps OR exercise apps OR health care apps OR diet apps OR weight loss apps OR blood pressure apps OR diabetes apps). The addition of "OR asthma apps," for example, did not increase the number of retrieved articles.

Articles of any format, such as news articles, editorials, and letters to the editor, were included in the analysis if they contained reference to health care apps or medical apps. Articles were excluded from the analysis if the health care apps were only mentioned briefly (ie, less than 10% of the article content), if the article focused only on health care app announcements (eg, advertising fitness apps), or in the case of duplication (eg, in a daily and Sunday equivalent), in which case only the article with the highest word count was included.

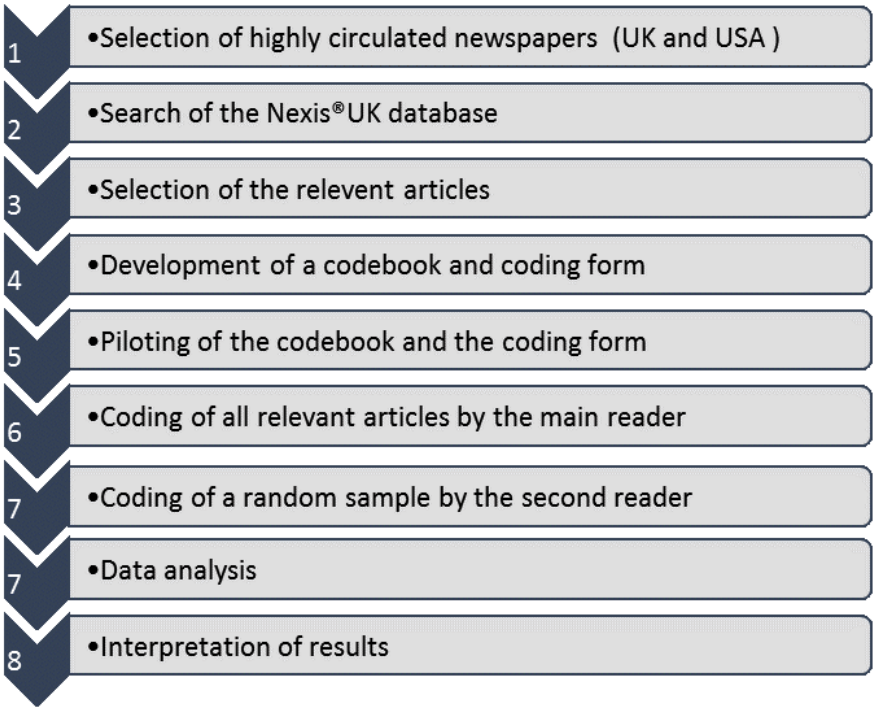
Data Extraction and Coding Frame

Based on previous work utilizing systematic content analysis, an a priori standardized coding book was developed. A pilot exercise was conducted in which 10 articles, chosen randomly, were coded independently by two of the authors (FA and JM) and the results were compared. During this pilot, minor modifications were made to the coding framework to increase code specificity. The final coding framework contained the following three main sections:

1. Basic information: the name of the newspaper, the title of the article, the year of publication, and the positioning of the article within the newspaper.
2. Article content: the themes covered, the perspective from which the article was written, the focus of the article, and benefits and risks or facilitators and barriers relating to the use of the health care apps outlined in the article.
3. Judgment and rating: the subjective judgment and rating of the reviewer on the main emphasis of the article, claims, and quality of information.

One researcher (FA) retrieved and read all the relevant archived newspaper articles and used the final coding form to manually code each article. To obtain a quantitative estimate of the coding reliability, a 10% random sample (random.org) of articles (n=22) were coded by the second reviewer (JM). Cohen kappa scores were calculated to evaluate interrater agreement for codes with mutually exclusive answers. The PubMed database was also searched for relevant articles over the same study period to gain an insight on how trends in newspaper reporting followed trends in scientific research publications on mobile apps used within health care. Following data extraction, codes were entered into SPSS version 21 for the analysis of trends and for comparing the variables between countries (United Kingdom and United States). Descriptive statistics were used to summarize the data. The Mann-Whitney *U* test was used to test for differences between means of continuous variables. Differences in the reporting of categorical variables were assessed using the chi-square test (χ^2) or the Fisher exact test, as appropriate. Statistical significance was set at $P \leq .05$.

Figure 1. Flow diagram of content analysis methodology used in this study. UK: United Kingdom, US: United States.



Results

Article Frequency

The initial search yielded a total of 714 UK and US newspaper articles reporting on health care apps between 2006 and 2015. After removing duplicate articles, 689 articles were retrieved, of which 220 articles met the inclusion criteria; 151 articles were published in UK newspapers and 69 articles were published in US newspapers. The distribution of the articles across the different newspapers is presented in Figure 2. In the United Kingdom, the *Daily Mail* and *The Guardian* were the newspapers that reported on health care apps most frequently; in the United States, health care apps were most frequently reported in the *New York Times* and the *Washington Post*.

In the United Kingdom, the number of published articles on health care apps increased notably over the study period, particularly during 2014, whereas in the US newspapers, the articles reached peak incidence in 2013 and 2015. The overall trends for both UK and US newspaper articles were upward across the study period as shown in Figure 3. Based on study title and abstract, a total of 944 research articles that involved health care apps were retrieved from PubMed over the study period. As indicated in Figure 3, the number of the scientific articles increased exponentially over the study period.

Newspaper Section

Of the 220 identified newspaper articles, 58 articles (26.4%) appeared in the features section and 42 articles (19.1%) appeared in the main news section. Less than 10% of the articles (19 articles) appeared in the health/life sections of the newspapers included in the evaluation. Although less frequently, health care apps also appeared in the business/financial section (13.2%, 29/220) and editorial section (1.8%, 4/220) of the newspapers.

Interrater Agreement

The calculated interrater reliability (Cohen kappa) agreement between the codes from the two coders were all positive and ranged from .421 to .889. Cohen suggested the kappa result be interpreted as follows: values ≤0 as indicating no agreement, .01-.20 as none to slight, .21-.40 as fair, .41-.60 as moderate, .61-.80 as substantial, and .81-1.00 as almost perfect agreement [38]. Accordingly, the current interrater analysis revealed that seven of 19 items (37%) illustrated moderate agreement, seven items (37%) illustrated substantial agreement, and five items (26%) illustrated almost perfect agreement between the two coders, demonstrating objectivity in elemental judgment as illustrated in Table 1.

Content of Newspaper Article

Within the 220 articles selected, the most frequent areas covered in the newspapers were general information about health care apps (101 articles; 45.9%), sport and fitness apps (63 articles; 28.6%), and disease-specific apps (20 articles; 9.1%). The remaining articles (36 articles; 16.4%) covered a range of topics, such as apps as sources of information, diet/healthy food apps, and apps used to communicate between health care professionals and between patients and health care professionals (Table 2). Most articles (Table 3) were written from a societal perspective (159 articles; 72.3%) followed by an industry point of view (30 articles; 13.6%); the other viewpoints included policy-related (16 articles; 7.3%), scientific (8 articles; 3.6%), legal (4 articles; 1.8%), and economic perspectives (2 articles; 0.9%). There was no significant difference between the key perspective of UK and US articles (χ^2_6=6.5, *P*=.36).

Figure 2. Frequency of articles about health-related apps in UK and US newspapers from 2005 to 2016.

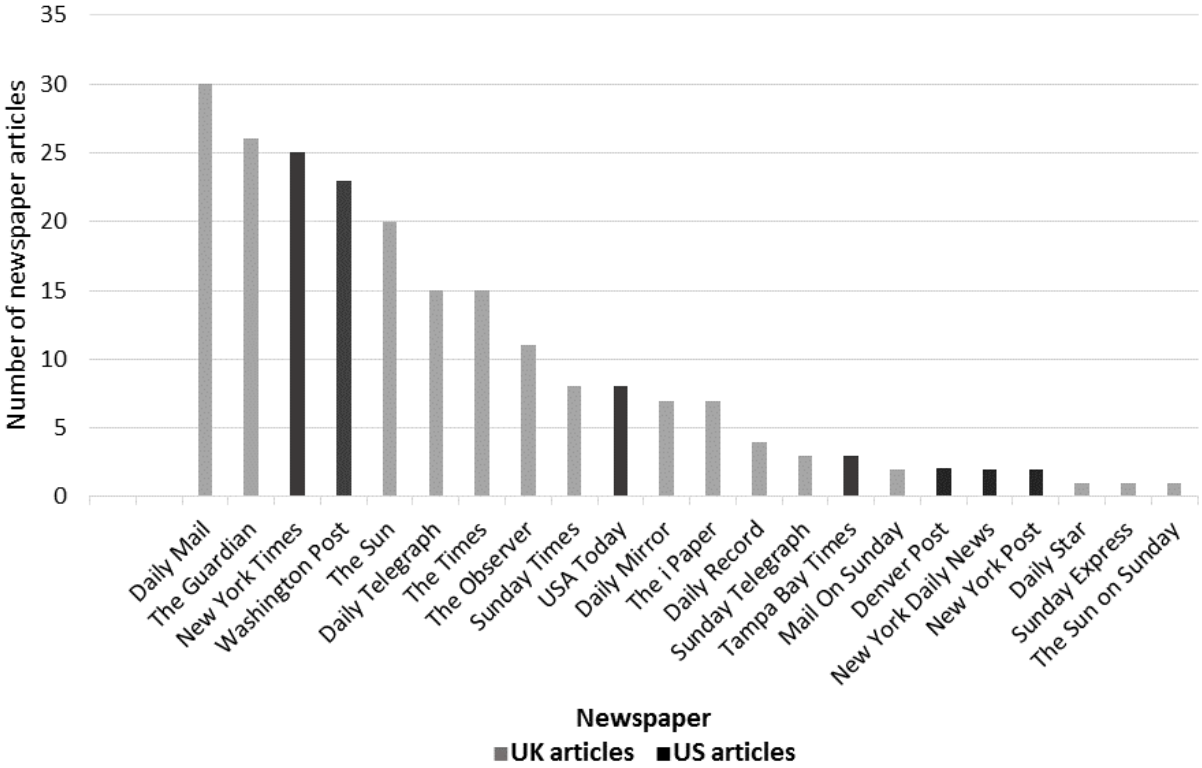


Figure 3. Number of articles about health-related apps in UK and US newspapers (left axis), and in PubMed (right axis) from 2005 to 2016.

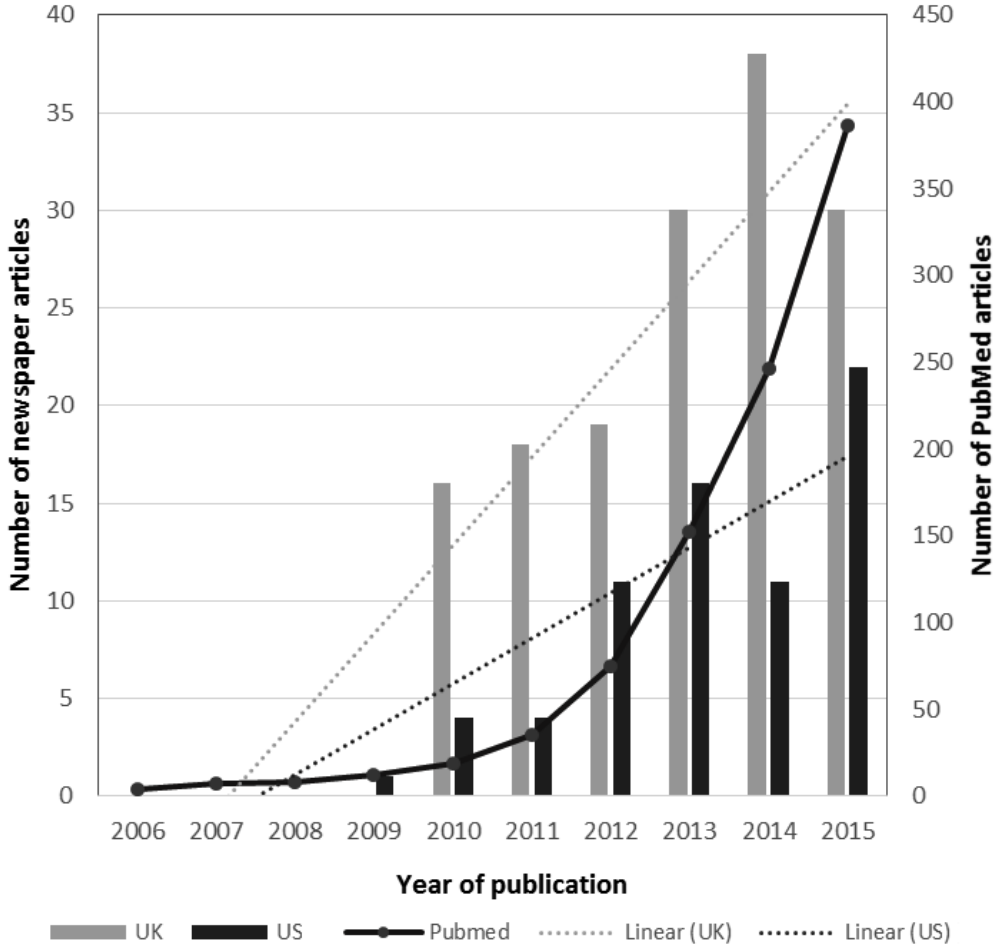


Table 1. Kappa values and interrater agreement for the coding of newspaper articles (n=10).

Item	Kappa value	Agreement (%)
Health care apps is main theme	.45	91
Other health care-related themes covered	.90	96
Key perspective	.46	91
First mention of health care app	.58	86
Linked disease (or group of diseases)	.80	82
Main voice of information	.50	68
Type of benefits of health care-related use of the mobile app(s)	.81	95
Type of harm or risk of health care-related use of the mobile apps	.53	91
Are direct quotes about health care app(s) used in the article?	.62	82
Barrier to the use of the health care app in routine clinical practice stated	.81	91
Facilitators to the use of the health care app in routine clinical practice stated	.75	86
Who or what is cited as the main source of information for the newspaper article?	.61	68
Article slant about health care-related app in this article	.63	82
Is the main claim about the health care app(s) in newspaper article/presentation style?	.49	86
The quality of information presented from the researcher's perspective	.69	95
Main theme regarding the use of health care app(s) in this article	.88	91
Relevant apps mentioned in the newspaper can be downloaded on operating mobile system	.42	82
Benefit or advantage of health care-related use of the mobile app(s)	.62	95
Potential harm or risk of health care-related use of the mobile app(s)	.63	91

Table 2. The main themes of the reviewed newspaper articles (N=220).

Main theme	United Kingdom articles (n=151), n (%)	United States articles (n=69), n (%)	Total (N=220), n (%)
Other	1 (0.7)	3 (4.3)	4 (1.8)
Communication tool	1 (0.7)	2 (2.9)	3 (1.4)
Diet/healthy food	11 (7.3)	5 (7.2)	16 (7.3)
Disease specific	16 (10.6)	4 (5.8)	20 (9.1)
Information source	9 (6.0)	4 (5.8)	13 (5.9)
Sport and fitness	43 (28.5)	20 (29.0)	63 (28.6)
Health care apps	70 (46.4)	31 (44.9)	101 (45.9)

Table 3. The key perspectives of the reviewed newspaper articles.

Key perspective	United Kingdom articles (n=151), n (%)	United States articles (n=69), n (%)	Total (N=220), n (%)
Political	0 (0.0)	0 (0.0)	0 (0.0)
Other	1 (0.7)	0 (0.0)	1 (0.5)
Economic	1 (0.7)	1 (1.4)	2 (0.9)
Legal	3 (2.0)	1 (1.4)	4 (1.8)
Scientific	4 (2.6)	4 (5.8)	8 (3.6)
Policy related	6 (4.0)	10 (14.5)	16 (7.3)
Industry	22 (14.6)	8 (11.6)	30 (13.6)
Societal	114 (75.5)	45 (65.2)	159 (72.3)

Table 4. The frequency of mentioning health conditions related to health care apps in newspaper articles.

Medical condition (*British National Formulary*, 65th edition, 2014, classification)	Frequency, n (%)	
	United Kingdom (n=75)	United States (n=44)
Cardiovascular	17 (22.7)	11 (25.0)
Central nervous system	8 (10.7)	3 (6.8)
Respiratory system	4 (5.3)	2 (4.5)
Gastrointestinal system	0 (0.0)	1 (2.3)
Endocrine	19 (25.3)	12 (27.3)
Cancer	9 (12.0)	1 (2.3)
Infection	3 (4.0)	1 (2.3)
Eye	4 (5.3)	1 (2.3)
Skin	5 (6.7)	3 (6.8)
Ears, nose, and throat	4 (5.3)	4 (9.1)
Obstetrics and gynecology	2 (2.7)	2 (4.5)
Other	3 (4.0)	3 (6.8)

Although most of the articles (124 articles; 56.4%) did not refer to a specific mobile operating system, 58 articles (26.4%) mentioned iOS (Apple) as the operating system; both Apple and Android operating systems were mentioned together in 42 articles (19.1%). There was no significant difference in the reporting of mobile operating systems between the United Kingdom and United States (Mann-Whitney U=12.0, P=.39).

Of the 220 articles, approximately 106 articles (48.2%) related to general health. including smoking cessation, alcohol use, weight loss, fitness. and exercise tracking, whereas 81 (36.8%) were linked to specific diseases. A smaller number of articles (33 articles; 15.0%) mentioned multiple diseases and/or medical uses (eg, first aid apps, thermometer apps, ear examination apps, diabetes apps).

Endocrine diseases (mainly diabetes) were frequently mentioned in relation to the use of health care apps; however, cardiovascular diseases (including blood pressure and heart rate monitoring) were the most commonly mentioned conditions in the relevant newspaper articles (Table 4). There was no difference between UK and US newspapers in terms of the frequency of mentioning specific disease indications (Mann-Whitney U=41.5; P=.08).

The vast majority of the newspaper articles (201 articles; 91.4%) mentioned at least one benefit related to the use of health care apps, whereas only 53 articles (24.1%) reported at least one risk. There was no significant difference in the frequency of benefits or risks reported between the UK and US articles (χ^2_1=1.3, P=.44). The three main benefits associated with the use of health care apps related to personalized care were improvement in general health and fitness (in 124 articles; 56.3%), public/patient access to health information (in 32 articles; 14.5%), and improved health outcomes for the public/patients (in 32 articles; 14.5%). Conversely, a breach in confidentiality was the most commonly cited risk (in 25 articles; 11.3%). In addition, approximately 9% of the articles (20 articles) reported that health anxiety could be induced because of the use of health care apps (Table 5). For example, in one of *The Guardian* articles, it was debated whether fitness tracking apps are "untested and unscientific and they open a door of uncertainty," and uncertainty may ignite anxiety in people [39].

Approximately half of the articles (101 articles; 45.9%) mentioned potential facilitators to the use of health care apps, whereas less than 10% of articles (16 articles) reported real or potential barriers to their use. The main recorded facilitator was improved technology (87 articles; 39.5%). No difference was found between UK and US newspapers in terms of the frequency of reporting of facilitators or barriers to the use of health care apps (P=.12) as shown in Table 6.

Most of the articles had a positive slant regarding the use of health care apps (146 articles; 66.4%), whereas 26.4% (58 articles) were classified as having a mixed slant. Relatively few articles reported negative views (11 articles; 5.0%) or a neutral view (5 articles; 2.2%). The majority of the articles (184 articles; 83.6%) were judged as having balanced judgments (ie, the authors did not exaggerate or understate the main message). The quality of the information presented in the newspaper articles was classified into three categories: poor, average, and excellent. Articles were classified as poor if judgment was not balanced and/or if only anecdotal evidence was presented; articles were classified as excellent if they presented information based on firm evidence, often also presenting quotations from experts in the field. Overall, 132 articles (60.0%) were scored as having poor information about health care apps, 75 articles (34.1%) were judged to have good quality information, and 13 articles (5.9%) were judged to provide excellent quality information. There was no significant difference between the quality of the reporting process in UK articles and US articles (χ^2_2=1.8, P=.29).

Table 5. Summary of the mentioned benefits and risks associated with using health care apps in newspaper articles.

Benefits and risks mentioned in newspaper articles	Frequency, n (%)	
	United Kingdom	United States
Benefits (n=222)	n=151	n=71
Personalized care	88 (58.3)	36 (50.7)
Public/patient access to health information	25 (16.6)	7 (9.9)
Improved health outcomes for public/patients	20 (13.2)	12 (16.9)
Communication between public/patients and health care providers	7 (4.6)	7 (9.9)
Public/patient satisfaction	6 (4.0)	7 (9.9)
Economic benefit to society	2 (1.3)	1 (1.4)
Communication among public/patients	1 (0.7)	1 (1.4)
Communication among health care providers	0 (0.0)	0 (0.0)
Other	2 (1.3)	0 (0.0)
Risks (n=60)	n=36	n=24
Anxiety	15 (41.7)	5 (20.8)
Confidentiality	16 (44.4)	9 (37.5)
Deterioration of outcome	2 (5.6)	10 (41.7)
Other	3 (8.3)	0 (0.0)

Table 6. Summary of the facilitators and barriers mentioned in the newspaper articles.

Facilitators and barriers mentioned in the newspaper articles	Frequency, n (%)	
	United Kingdom	United States
Facilitators (n=101)	n=61	n=40
Access	1 (1.6)	2 (5.0)
Commercial	2 (3.3)	0 (0.0)
Evidence to support adoption	2 (3.3)	1 (2.5)
Positive beliefs	2 (3.3)	2 (5.0)
Technology	52 (85.2)	35 (87.5)
Other	2 (3.3)	0 (0.0)
Barriers (n=16)	n=10	n=6
Access	2 (20.0)	0 (0.0)
Commercial	1 (10.0)	3 (50.0)
Lack of evidence	2 (20.0)	1 (16.7)
Negative beliefs	4 (40.0)	1 (17.7)
Other	1 (10.0)	1 (17.7)

Discussion

Methodology Used

Newspapers are read by a high proportion of the population in the United Kingdom and United States on a regular basis. There is also a strong correlation between newspaper publishing and other mass media platform reporting on the same topic or issue [40]. The methodology adopted for this research was based on earlier published research using content analysis of newspapers [41-44]. In this study, there was a substantial level of agreement between coders as the median kappa statistic score among the two researchers for all variables was .624 (range .421-.889). This indicated moderate to almost perfect agreement for all coding variables [35]. This finding is similar to the level of interrater agreement previously reported in published research on content analysis of newspaper articles [45,46]. The validity of this study was enhanced by precoding 10 articles followed by adjustment to the coding framework. There is no specific requirement for a particular sample size in kappa calculations. In this study, a random sample of 10% of the published articles was included.

Frequency of Relevant Articles

A total of 220 articles were identified in the highest circulation of UK and US newspapers over the period of 10 years investigated in the study (2006-2015). For the same period, the number of scientific articles published in PubMed was 944, with the number increasing exponentially over time. In September 2013, the FDA issued guidance relating to medical apps that stated that the majority of health care apps pose a low risk for users or patients and indicated that they would only get involved in regulating those mobile apps that transform mobile devices into medical devices [47,48]. This may have caused the decline in the number of articles published about health care apps in 2014 in the United States. For the United Kingdom, establishing the NHS health app library in 2013 led to a more widespread consideration of health apps; this was reflected the relatively high reporting in UK newspapers in that year (Figure 2).

Content of the Selected Articles

The main theme of articles on health care apps was found to be related to public health and well-being, including lifestyle management. Unsurprisingly, the related matters of sport and fitness were frequently reported themes. Many of the articles were reported from a societal perspective. This was expected because a high proportion of the newspaper articles focused on general public health topics, including fitness, well-being, and good diet. This finding concords with the finding of a recent report which stated that apps that remind, monitor, and track are intended for the general public, as is the case with social media apps [49]. These kinds of innovative apps can play an important role in general health and lifestyle and can help motivate people to make healthy lifestyle choices [3]. In 2014, a study was conducted to identify the number of health and fitness apps in the Apple Store and Google Play. The author found 23,490 and 17,756 health and fitness apps available in the Apple Store and Google Play, respectively. Moreover, the number of health and fitness apps had grown by 62% over the previous year (2014) in comparison with a 33% growth for apps in general [50]. This vast number of available health and fitness apps helps explain why such apps were reported more frequently in the media when compared with disease-specific apps.

Diabetes was the illness for which apps were most frequently reported by the newspapers; other diseases frequently mentioned were cardiovascular disease and those affecting the central nervous system. A total of 422 million people have been diagnosed with diabetes worldwide and the number is increasing in many countries due to an increasing age demographic together with an increased incidence of obesity and low physical activity [51]. Diabetes is a progressive disease that is associated with several complications including cardiovascular, kidney, and eye complications. Control of diabetes requires self-monitoring of blood glucose levels. Advanced mobile technology allows patients to record these blood levels electronically. Some available apps provide several advantages to manual recording including graphing daily blood sugar levels together with calorie intake and exercise undertaken [52]. A recent review of diabetes-related apps recorded a range of functions that these apps can perform, including documentation, data forwarding, information provision, analysis, recipe suggestions, reminder, and advisory functions [53]. Despite the high prevalence of asthma worldwide, reporting on apps for respiratory illness was infrequent. Available apps in this domain are used to record symptoms of asthma, peak flow readings, and number of attacks, and to provide information about asthma triggers.

As anticipated, in this study the benefits of health care apps were more frequently discussed within articles than were risks. Improved personalized health and fitness were the main benefits described and the issue of confidentiality was the most frequent risk discussed. The literature has documented that newspapers in general overreport the benefits and underestimate the risks when publishing information about health intervention research [47,54]. If the benefits of health care apps are overstated, this could raise public expectations about improved health, whereas overstating risk could generate anxiety and may negatively affect the uptake of what could be a helpful intervention.

In this study, the quality of reporting on health care apps was judged to be poor in most of the articles (60%). These articles in general were brief and did not add sufficient supporting evidence or refer to health agencies. A third of the articles were classified as having average/good quality of reporting, whereas only 5.9% were considered excellent. This was consistent with previous research articles that highlighted the general poor quality of information in the print media about health-related matters [55,56]. It has been reported that high quality newspaper articles often flow from a press release, generally from a scientific journal [19]. Therefore, researchers in the field should ensure that such press releases are written alongside their publications in order to help better information reach the public via the mass media.

There are several limitations to this study. This study examined reporting on health care apps in newspapers only and did not cover other mass media sources such as television and radio. However, as mentioned earlier, it has been reported that the content of newspaper articles correlates closely with other media sources [57]. In addition, some highly circulated US newspapers such as the *Dallas Morning News*, *Chicago Tribune*, and *Chicago Sun-Times* were not included in the study because they were not archived by Nexis. Moreover, limited articles were accessible in Nexis for the *Los Angeles Times* and *Newsday* as only articles from the previous 6-month period were available.

Conclusions

This study has revealed that health care apps are indeed reported on by UK and US newspapers. The number of articles reporting on health care-related apps increased over time in UK and US newspapers over the 10-year study period. Several benefits were reported relating to app use, especially in relation to promotion of a healthy lifestyle, whereas reporting on risk was less frequent. Improving personalized care was the most frequently mentioned benefit; confidentiality breaches were the most commonly reported risk. Diabetes was the disease most commonly linked with the use of health care apps. In general, the main claims about benefits had a positive slant, but articles generally were balanced in their judgment.

Authors' Contributions

AQAB contributed to the analysis and interpretation of data, and drafting the manuscript. JM and FA contributed to the conception and design of the study; acquisition, analysis, and interpretation of data; and drafting the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

FDA: Food and Drug Administration
NHS: National Health Service

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Original Paper

Measuring the Quality of Mobile Apps for the Management of Pain: Systematic Search and Evaluation Using the Mobile App Rating Scale

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Abstract

Background: Chronic pain is a major health issue requiring an approach that not only considers medication, but also many other factors included in the biopsychosocial model of pain. New technologies, such as mobile apps, are tools to address these factors, although in many cases they lack proven quality or are not based on scientific evidence, so it is necessary to review and measure their quality.

Objective: The aim is to evaluate and measure the quality of mobile apps for the management of pain using the Mobile App Rating Scale (MARS).

Methods: This study included 18 pain-related mobile apps from the App Store and Play Store. The MARS was administered to measure their quality. We list the scores (of each section and the final score) of every app and we report the mean score (and standard deviation) for an overall vision of the quality of the pain-related apps. We compare the section scores between the groups defined according to the tertiles via analysis of variance (ANOVA) or Kruskal-Wallis test, depending on the normality of the distribution (Shapiro-Wilk test).

Results: The global quality ranged from 1.74 (worst app) to 4.35 (best app). Overall, the 18 apps obtained a mean score of 3.17 (SD 0.75). The best-rated sections were functionality (mean 3.92, SD 0.72), esthetics (mean 3.29, SD 1.05), and engagement (mean 2.87, SD 1.14), whereas the worst rated were app specific (mean 2.48, SD 1.00), information (mean 2.52, SD 0.82), and app subjective quality (mean 2.68, SD 1.22). The main differences between tertiles were found on app subjective quality, engagement, esthetics, and app specific.

Conclusions: Current pain-related apps are of a certain quality mainly regarding their technical aspects, although they fail to offer information and have an impact on the user. Most apps are not based on scientific evidence, have not been rigorously tested, and the confidentiality of the information collected is not guaranteed. Future apps would need to improve these aspects and exploit the capabilities of current devices.

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KEYWORDS

mobile app; chronic pain; Mobile App Rating Scale; mHealth; mobile phones

Introduction

Pain is defined by the International Association for the Study of Pain (IASP) as a "distressing experience associated with actual or potential tissue damage, with sensory, emotional, cognitive, and social components" [1]. This problem may eventually become chronic, in which case it should be seen as a disease rather than as a symptom. In this case, it is called "chronic pain," defined by the IASP as pain that has persisted beyond the normal tissue healing time. The IASP proposes 3 months as a convenient cut-off point [2]. Chronic pain is a major public health problem that must be addressed, with prevalence ranging from 10% to 40% in different countries and populations [3-8].

"Chronic" and "pain" have been constantly popular keywords on search engines over the last 5 years, which could be related to the increasing prevalence of this condition in recent years [9,10]. In relation to this issue, Figure 1 shows the trend of searches for "chronic pain" on Google. It is noteworthy that the largest volume of searches occurred throughout 2017, indicating that it is currently a major concern.

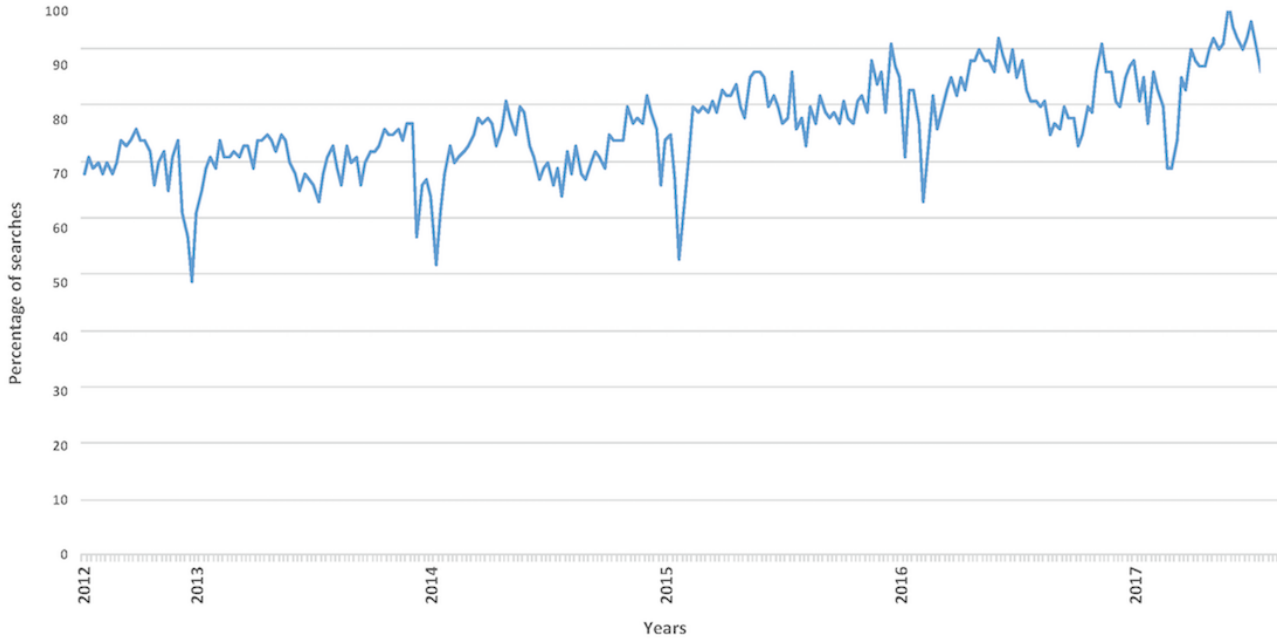
Treating chronic pain is a tricky task because it should involve much more than simply drugs. The biopsychosocial model states that pain is "a dynamic interaction among and within the biological, psychological, and social factors unique to each individual" [11]. In fact, chronic pain is related to many other factors, such as sick leave or job loss [12], cognitive impairment [13], perception of a negative impact on the family and social environment [3], anxiety, depression [3], and stress [14], and it also has work, social, and family-related consequences [5,12,15]. All these factors should be taken into account when treating chronic pain. In view of this, there is a need for new ways of dealing with chronic pain that can include these factors, and new technologies to support the assessment and tracking of chronic pain, as they include the social sphere, can assess and modify daily activities, and can focus on factors such as mood status.

The number of mobile health apps has grown recently, having been classified as an "exploding market," with more than 100,000 specific apps [16]. The possibilities offered by new devices and their sensors can be very useful for this type of app [17], although they are not being well exploited.

Mobile apps specifically for pain have also increased, with there now being over 350 apps according to the review by Portelli and Eldred [18], which is an extension of a previous review [19]. However, in these articles the authors concluded that one of the main problems with the existing apps is the lack of scientific value, effectiveness testing, and evidence-based results and conclusions. The biopsychosocial approach is not included in most of the apps because social support, for instance, is not usually implemented by the software developers. Nevertheless, there are some limitations of these reviews, mainly related to the use of a checklist, which is not a validated tool to measure the quality of mobile phone apps. Therefore, there is a need for an adequate tool to measure the quality of the apps, although it does not seem that the existing apps are of a high quality or meet all the expected requirements. In some cases, it might be even harmful to trust them [20,21].

The traditional systems to try to measure the quality of the apps include the opinions and/or satisfaction of the users, the stars rating system, the app description, or checklists. None of these strategies seems to be adequate to scientifically measure the quality of the apps. For instance, the descriptions of the apps in the stores may be incomplete or imprecise, the scores and opinions may include the subjectivity of nonexpert users or be based on the opinion of very few people making it difficult to generalize, and checklists do not actually assess quality [15].

Figure 1. Interest over time in the term "chronic pain." Results obtained through Google Trends. The values, expressed in percentages, reflect the number of searches done for the term relative to the total number of searches done on Google over time.



There is an alternative tool for assessing the quality of health mobile apps, namely the Mobile App Rating Scale (MARS) [17], which, to the best of our knowledge, has not been used previously to measure the quality of pain-related apps in any review. The psychometric properties of this scale have been proven, and it has been shown to be a simple, objective, and reliable tool to measure the quality of apps [17] (see the Methods section for a more detailed explanation of the scale). This is the reason for using this tool in this evaluation, and we believe that it provides greater strength to the results obtained compared to previous studies.

Finally, given the changing nature of the apps market, there is always a need for an updated review which includes the new apps that may have been released recently. In view of the preceding, this study aims to evaluate and measure the quality of mobile apps for the management of pain using the MARS.

Methods

This study included pain-related mobile apps (both free and paid) found in the official stores of Apple iPhone (App Store) and Android (Play Store) in June 2017. These two systems are the most widely used according to the latest report by Kitagawa et al [22], accounting for 99.6% of all mobile phone sales in the fourth quarter of 2016. The search was carried out in both English and Spanish.

Firstly, we defined the disease of interest using the following generic terms: “pain” and “*dolor* ” (Spanish for “pain”). Then, the results were refined using specific terms such as “chronic pain” and “*dolor crónico*.” The apps focused on specific pain conditions; those that were not available or presented major technical errors were excluded.

A total of 18 apps were finally included (2 from the App Store, 11 from the Play Store, and 5 multiplatform). These apps were randomly divided into three groups, each of which was assigned to two reviewers, who downloaded the assigned apps on their devices, used, and evaluated them by means of the MARS [17]. A total of three reviewers were involved, so that each of them could review two groups of apps to avoid the potential subjectivity of a single reviewer. The online platform SurveyMonkey was used to help them complete the MARS.

The MARS [17] consists of 23 items grouped into the following sections: engagement, functionality, esthetics, information quality, and subjective quality. There are also six final items (app specific) that can be adapted to include or exclude specific information on the topic of interest, as well as an initial section collecting general and technical information on the app. Each item is scored from 1 (inadequate) to 5 (excellent), and a final mean score is given for each section. Finally, the mean values of the first four sections (ie, engagement, functionality, esthetics, and information quality) are used to give a final measurement of the app quality, which is the average value of the four means. The complete structure of the scale can be seen in Table 1.

The discrepancies in the scores between reviewers were assessed and if major differences were found in a specific app (more than 2 points of difference), the items of the MARS were compared. In case of disagreement, the third reviewer intervened to evaluate and reach a consensus, except for one app (Change Pain), which was no longer available when the third reviewer tried to evaluate it and was eventually removed from the study. The final score for each app was calculated as the mean of the scores of each reviewer, after verifying that the scores were similar and that there was consensus. The apps were then classified as worst-rated apps, average apps, and best-rated apps according to the tertiles of the final scores. This classification based on tertiles gave us a cut-off point for an app to be considered a best-rated app.

A descriptive analysis was performed. We list the scores (of each section and the final score) of every app and we report the mean score (and standard deviation) for an overall vision of the quality of the pain-related apps. Additionally, we compare the section scores between the groups defined according to the tertiles via analysis of variance (ANOVA) or Kruskal-Wallis tests, depending on the normality of the distribution (Shapiro-Wilk test). The analyses were performed with SPSS version 21, and the figures with Excel 2016.

Table 1. Structure of the MARS.

Section	Definition
A: Engagement	Fun, interesting, customizable, interactive (eg, sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience
B: Functionality	App functioning, easy to learn, navigation, flow logic, and gestural design of app
C: Esthetics	Graphic design, overall visual appeal, color scheme, and stylistic consistency
D: Information	Contains high-quality information (eg, text, feedback, measures, and references) from a credible source. Select N/A if the app component is irrelevant
App quality	Mean score of sections A, B, C, and D
E: App subjective quality	Personal interest in the app
F: App specific	Perceived impact of the app on the knowledge, attitudes, and intentions to change of the users, as well as the likelihood of actual change in the target health behavior

Results

A total of 47 nonduplicate apps were initially identified as potential pain apps to be included in this study. Of these, 28 did not meet the inclusion criteria and were excluded, making a total of 19 apps analyzed, although one of the apps was eventually removed due it being unavailable in the stores when trying to solve the lack of consensus. Therefore, a final total of 18 apps were included (Figure 2; Table 2).

Table 3 shows the main characteristics of the apps included in the study. According to the users, on a scale of 1 to 5 stars, the apps had a quality score ranging from 1 to 4.8, with a mean score of 3.61 (SD 0.93). Generally, the paid apps received higher ratings, usually between 4 and 5 stars, although some free apps were also highly rated. The affiliation of most of the apps was commercial, but three of them came from university environments. The apps were mainly focused on physical health, and sometimes on depression/anxiety, increasing happiness/well-being, or reducing negative emotions. The most frequent theoretical background or strategies of the apps were monitoring/tracking, assessment, feedback, and information/education. Finally, their technical aspects included sharing options (eg, Facebook, Twitter), app communities, reminders, password protection, and log-in or Web connection required.

The specific scores for each app are shown in Table 4. The mean app quality score ranged from 1.74 (worst-rated app) to 4.35 (best-rated app), and a similar situation was observed in each section: 1.20 to 4.60 (engagement), 1.88 to 4.75 (functionality), 1.83 to 4.83 (esthetics), 1.14 to 4.00 (information), 1.00 to 4.38 (app subjective quality), and 1.00 to 4.42 (app specific). As a whole, the 18 apps obtained a mean score for quality of 3.17 (SD 0.75). On average, the best-rated section was functionality (mean 3.92, SD 0.72), followed by esthetics (mean 3.29, SD 1.05) and engagement (mean 2.87, SD 1.14), whereas the worst-rated sections were app specific (mean 2.48, SD 1.00), information (mean 2.52, SD 0.82), and app subjective quality (mean 2.68, SD 1.22). The minimum score to be considered as a best-rated app was 3.73, according to the application of the tertiles previously described.

Figure 3 illustrates the differences found between tertiles regarding the scores of each section of the MARS. No major functionality (section B) differences between the best-rated and the worst-rated apps were found (P=.06), with a score range of 0.9 points. The highest differences were related to app subjective quality (section E), with a score range of 2.67 points (P<.001). Moreover, sections A (engagement), C (esthetics), and F (app specific) also had a score range greater than 2 points. All the differences were statistically significant except for section B.

Figure 2. Flowchart of the pain-related app selection.

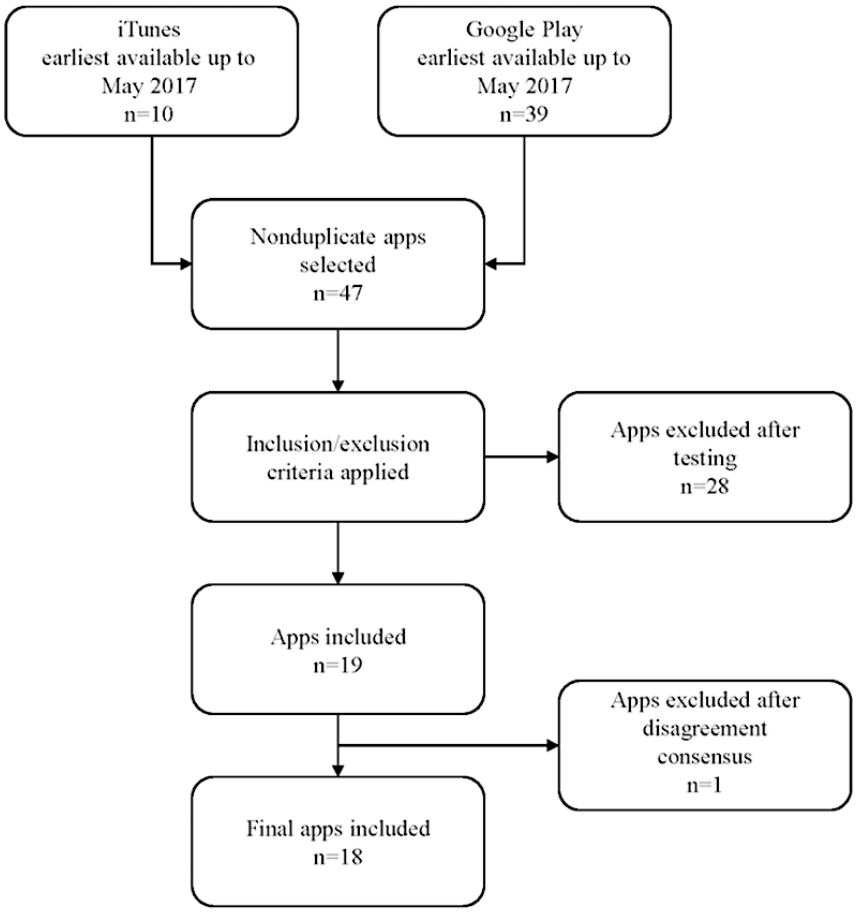


Table 2. Description of the pain-related apps included in the study.

App name	Platform	Price (€)	Downloads	Developer	Affiliations
Manage My Pain (Lite & Pro)	Android	Free (Lite); €3.99 (Pro)	50,000-100,000	ManagingLife	Commercial
Diario de Dolor CatchMyPain (Lite & Pro)	Android-iOS	Free (Lite); €3.59 (Pro)	50,000-100,000	Sanovation AG	University
Mi registro de dolor	Android-iOS	Free	1000-5000	Subinprara Infotech Inc	Commercial
Pain Companion	Android	€1.09-€33.20 per element	5000-10,000	Sanovation AG	Commercial
OurHurt-Dolor Crónico	Android	Free	1000-5000	Labs Health Company	Commercial
My Pain Diary	Android	€3.66	1000-5000	DemoLab, LLC	Commercial
ACPA Pain Logs	Android-iOS	Free	500-1,000	ACPA	Commercial
Chronic Pain Diary	Android	Free	5000-10,000	Jet5	Commercial
Pain Tracker HD	Android-iOS	€0.89 per element	100-500	AppYourWay	Commercial
Painometer v2	Android	Free	1000-5000	Algos-Research on Pain	University
My Pain Diary & Symptom Tracker: Gold Edition	iOS	€5.49	1000-5000	Damon Lynn	Commercial
PainTrakr	iOS	Free	1000-5000	Black Slate Software Inc	Commercial
Pain Tracker & Diary by Nanulume	Android-iOS	€2.99	1000-5000	Nanolume, LLC	Commercial
GP Pain Help	Android	Free	1000-5000	Australian College of Rural & Remote Medicine	University
Pain Log	Android	Free	1000-5000	Raúl R	Commercial
Pain Score	Android	Free	500-1000	Trinstor	Commercial
Pain Rating Scales	Android	Free	1000-5000	ETZ	Commercial
Pain Treatment	Android	Free	10,000-50,000	Entertain2Dunia	Commercial

Table 3. Characteristics of the included pain-related apps.

App name	Focus (what the app targets)	Theoretical background/strategies	Technical aspects of app
Manage My Pain (Lite & Pro)	Physical health	Monitoring/tracking	Allows sharing (eg, Facebook, Twitter); allows password protection; requires log-in; sends reminders; needs Web access to function
Diario de Dolor. CatchMyPain (Lite & Pro)	Increase happiness/well-being emotions; reduce negative; anxiety/stress; physical health	Assessment; feedback; monitoring/tracking	Allows sharing (eg, Facebook, Twitter); allows password protection; requires log-in; sends reminders; needs Web access to function
Mi registro de dolor	Physical health	Assessment; feedback; monitoring/tracking	Allows password protection; requires log-in; sends reminders
Pain Companion	Increase happiness/well-being; goal setting; entertainment; relationships; physical health	Assessment; feedback; information/education; monitoring/tracking; advice tips/strategies/skills training; gratitude	Allows sharing (eg, Facebook, Twitter); has an app community; allows password protection; requires log-in; sends reminders; needs Web access to function
OurHurt-Dolor Crónico	Physical health	Monitoring/tracking; strengths	Allows sharing (eg, Facebook, Twitter); allows password protection; requires log-in
My Pain Diary	Depression; anxiety/stress; physical health	Monitoring/tracking	Allows sharing (eg, Facebook, Twitter)
ACPA Pain Logs	Physical health	Assessment; feedback; monitoring/tracking	Allows sharing (eg, Facebook, Twitter); allows password protection; requires log-in
Chronic Pain Diary	Physical health	Monitoring/tracking	—[a]
Pain Tracker HD	Physical health	Monitoring/tracking	Allows password protection; requires log-in; sends reminders
Painometer v2	Physical health	Assessment; monitoring/tracking	Allows sharing (eg, Facebook, Twitter)
My Pain Diary & Symptom Tracker: Gold Edition	Depression; anxiety/stress; physical health	Feedback; monitoring/tracking	Allows sharing (eg, Facebook, Twitter); has an app community
PainTrakr	Physical health	Monitoring/tracking	Sends reminders
Pain Tracker & Diary by Nanulume	Physical health	Monitoring/tracking	Requires log-in; sends reminders
GP Pain Help	Physical health	Assessment; information/education	—
Pain Log	Physical health	Monitoring/tracking	—
Pain Score	Physical health	Assessment; information/education	—
Pain Rating Scales	Physical health	Assessment; information/education; monitoring/tracking	—
Pain Treatment	Physical health	Assessment; information/education; advice/tips/strategies /skills training	Allows sharing (eg, Facebook, Twitter)

[a]The app does not have any of the technical aspects considered in the MARS.

Table 4. Mobile App Rating Scale (MARS) scoring of the pain-related apps.

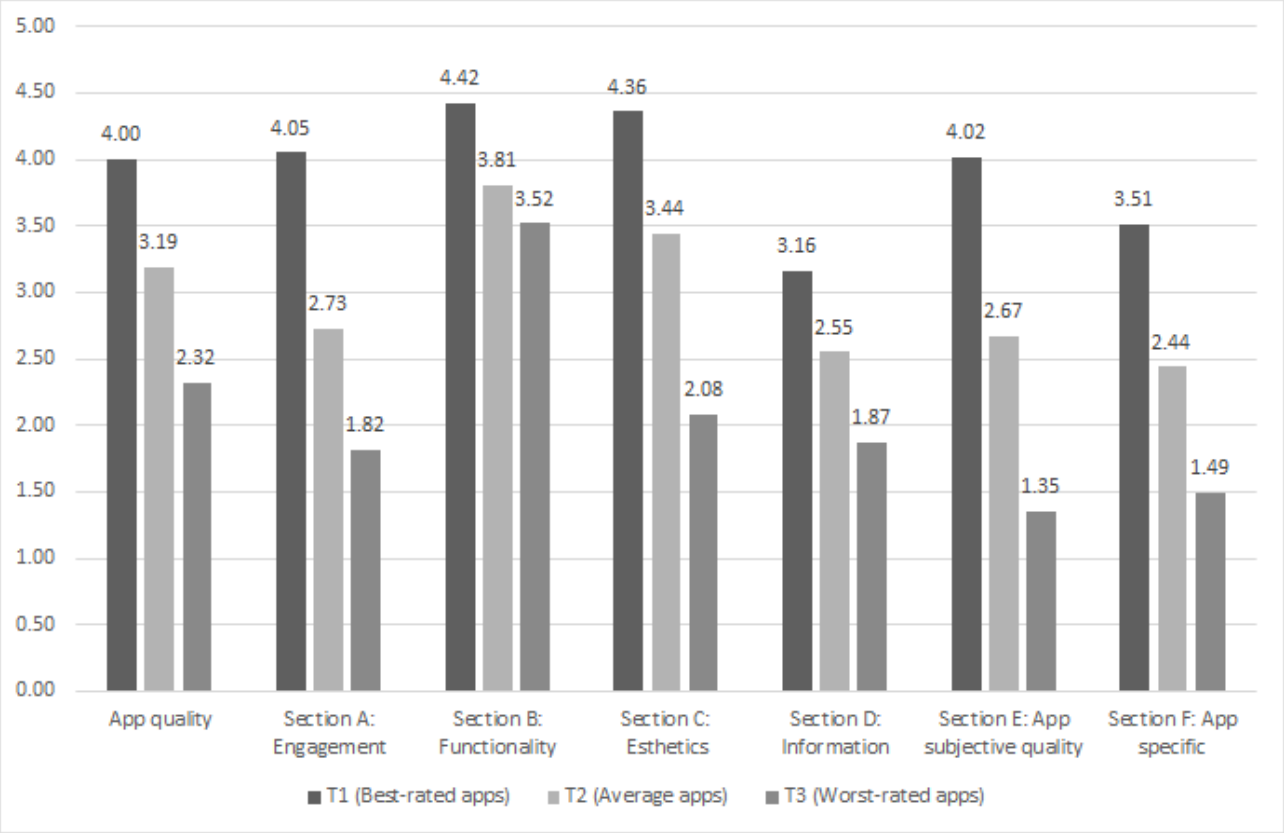
App name	App quality, mean (SD)	T[a]	Section[b], mean (SD)						User's stars score
			A	B	C	D	E	F	
Pain Companion	4.35 (0.49)	T1	4.60 (0.55)	4.25 (0.05)	4.83 (0.06)	3.72 (1.62)	4.25 (0.50)	4.42 (0.52)	4.30
Manage My Pain (Lite & Pro)	4.22 (0.18)	T1	4.40 (0.89)	4.13 (0.03)	4.33 (0.03)	4.00 (0.38)	3.75 (1.00)	3.67 (0.82)	4.00
My Pain Diary & Symptom Tracker: Gold Edition	4.02 (1.08)	T1	4.30 (0.84)	4.50 (0.50)	4.83 (0.58)	2.43 (2.15)	4.38 (0.82)	3.42 (0.82)	N/A[c]
OurHurt-Dolor Crónico	3.88 (0.65)	T1	3.40 (1.14)	4.75 (0.05)	4.00 (0.58)	3.36 (1.50)	3.88 (0.50)	3.17 (0.52)	3.90
Pain Tracker & Diary by Nanulume	3.79 (0.43)	T1	3.50 (1.52)	4.38 (0.50)	3.83 (0.58)	3.43 (1.70)	3.88 (0.82)	3.33 (0.63)	2.50
My Pain Diary	3.73 (1.17)	T1	4.10 (0.71)	4.50 (0.50)	4.33 (1.00)	2.00 (1.51)	4.00 (0.82)	3.08 (0.55)	4.20
Mi registro de dolor	3.60 (1.20)	T2	4.30 (0.84)	3.75 (0.50)	4.50 (0.58)	1.86 (1.57)	3.50 (1.50)	3.34 (1.26)	3.70
Diario de Dolor. CatchMyPain (Lite & Pro)	3.35 (0.48)	T2	3.60 (0.45)	3.50 (0.58)	3.67 (0.07)	2.64 (1.98)	2.88 (0.50)	2.75 (0.98)	4.00
ACPA Pain Logs	3.16 (0.41)	T2	2.40 (0.55)	3.00 (0.50)	3.33 (0.06)	2.64 (1.07)	3.75 (0.50)	2.25 (0.41)	3.00
GP Pain Help	3.10 (0.90)	T2	2.30 (1.34)	4.38 (0.50)	3.00 (0.58)	2.71 (2.37)	2.13 (0.96)	2.83 (1.22)	4.80
Pain Log	3.08 (1.03)	T2	1.70 (1.30)	4.13 (0.04)	3.50 (1.00)	3.00 (1.50)	2.00 (1.26)	1.83 (0.52)	4.40
Pain Rating Scales	2.83 (0.89)	T2	2.10 (0.02)	4.13 (0.82)	2.66 (0.03)	2.43 (1.11)	1.75 (0.05)	1.67 (0.55)	4.30
Painometer v2	2.65 (0.53)	T3	2.10 (1.30)	3.25 (0.58)	2.33 (0.58)	2.93 (0.69)	1.75 (0.82)	1.00 (0.00)	4.10
Chronic Pain Diary	2.61 (0.58)	T3	2.40 (0.55)	3.38 (0.03)	2.00 (0.00)	2.64 (1.50)	1.50 (0.58)	1.83 (0.41)	3.20
Pain Score	2.41 (1.59)	T3	1.60 (0.89)	4.75 (1.00)	2.00 (0.00)	1.29 (1.50)	1.00 (0.00)	1.00 (0.00)	3.50
Pain Treatment	2.36 (1.35)	T3	1.20 (0.02)	4.25 (0.50)	2.33 (0.58)	1.64 (1.21)	1.38 (0.50)	2.33 (0.82)	3.00
PainTrakr	2.17 (1.04)	T3	1.90 (0.55)	3.63 (0.50)	2.00 (0.58)	1.14 (0.95)	1.38 (0.04)	1.33 (0.03)	N/A
Pain Tracker HD	1.74 (0.14)	T3	1.70 (0.55)	1.88 (0.50)	1.83 (0.58)	1.57 (1.29)	1.13 (0.50)	1.42 (0.75)	1.00

[a]T: tertile. Tertile legend: T1: best-rated apps; T2: average apps; T3: worst-rated apps.

[b]A: Engagement; B: Functionality; C: Esthetics; D: Information; E: App subjective quality; F: App specific.

[c]N/A: not applicable.

Figure 3. Differences in the mean MARS (Mobile App Rating Scale) scores between tertiles.



Discussion

Principal Results

This paper presents a systematic search and evaluation of apps related to pain in the App Store and Play Store. First, it is important to note that the mobile app market is very volatile, unpredictable, and constantly changing, and it is likely that the situation at the time of publication of this paper is not exactly the same as the one presented here. Indeed, during the completion of this study, we detected some changes in the market. Specifically, we had to remove an app from our study because it no longer worked (or even existed in the store) when we tried to use it again to solve some doubts over its rating. Despite this, we present here what, as far as we are concerned, are the most accurate results regarding the quality of the pain apps available at present because it includes an assessment using a validated tool such as the MARS.

Before discussing the scores obtained and the quality of the apps in general, there are some aspects that we would first like to highlight due to their importance in the scientific field: the theoretical support of the apps and the need for randomized controlled trials to test them on people. There is one specific item in the MARS assessing the "evidence base," which explores the extent to which the app has been scientifically tested. Although the results of the MARS are shown in terms of dimensions and not specific items, it is important to mention here that only two of the apps (Manage My Pain Lite & Pro and Painometer v2) had been tested or trialed to some extent, showing positive or partially positive results. Surprisingly, the latter is not very well positioned in terms of its score on the MARS (it belongs in the worst-rated apps tertile), for reasons that will be discussed later. However, above other criteria, it is crucial for a health app to be tested if it aspires to become a useful tool for health professionals and patients, ensuring safety and good functioning. This is particularly important when dealing with new technology, as discussed in the Introduction [19,20]. In this regard, many studies that propose the use of new technologies conclude that more evidence is needed to support their use [23-26]. A possible explanation for the lack of scientific support could be that most of the apps are commercial (in our sample, only three came from academia), which suggests the need to promote the development of apps from scientific institutions.

Another important issue to bear in mind is security and privacy. A recent article by Papageorgiou et al [27] highlights the sensitive nature of the data collected by health-related apps and the need to follow standards of good practice and comply with data protection laws. Although not restricted to pain apps, their conclusions are alarming because most health apps do not even comply with the law. Regarding our results, MARS collects information on security and privacy on two occasions: it asks if the app allows password protection and if it requires log-in. None of them is part of the scored sections, and they do not cover security after the information is collected by the app. Half of the apps included in this evaluation allowed password protection and/or required log-in. However, we cannot know to what extent data protection laws and standards of good practice are met, although the answers to these two MARS items, as well as the conclusions of Papageorgiou et al, do not give great cause for optimism in this regard. Future apps should consider this aspect.

An ideal app, apart from being based on scientific evidence and respecting the law and privacy, should be user friendly, attractive, simple, and functional, and exploit the sensors and other capabilities of the devices for the benefit of the patient. However, we already argued in the Introduction that the use of certain technologies or apps could sometimes be harmful, although a recent review by Lee et al [28] states that mobile health (mHealth) intervention studies show promising aspects such as improving self-management and some health indicators. In this sense, it would be desirable to have the authorization of the corresponding health authority to recommend (and even finance) the use of certain devices and/or apps. In countries such as the United Kingdom, there is a policy of promoting and sometimes financing wearable mHealth devices for chronic pain management [29], although the situation is not the same in other countries, where this goal seems distant.

Regarding the quality of the apps included in this study, we can say that they are mostly good, although the best scores correspond to technical aspects of the app itself, such as "functionality," while the worst relate more to what is offered to the user and their opinion ("information" and "app subjective quality"). This means that the apps seem to be more or less well designed but fail to fully convince the users. Surprisingly (and apparently in contrast to the previous statement), we observed in our sample that 68.75% of the users' ratings (via the stars system) in the corresponding stores were higher than those obtained with the MARS. However, it is a single and completely subjective score based on the criteria of the users themselves compared to the result of having applied a validated assessment tool whose results are more reliable. In any case, our results show that it would be necessary to improve less valued aspects such as the information offered to the user, which turns out to be a crucial aspect in this kind of app.

It is important to note that some apps are very specific or perform a single task and this could lead to a decrease in their score in the MARS. It is necessary to bear this in mind when making a critical reading of the classification of the apps that we present here. Some of them might be worse rated not because they were actually worse, but because a high score could not be given to some items of the MARS; these apps can still be excellent in other aspects. For this reason, it is important to observe not only the global score (used to determine the tertiles), but the scores in each dimension. In fact, in our sample we found apps that are among the worst rated but have better scores in dimensions such as "functionality" than the best-rated apps. This study does not intend to make recommendations about what app to use, but merely to show reliable information that can be used by the reader according to their own criteria and all the aspects discussed.

In view of this, one might wonder what determines how an app achieves a higher global score. That is, which aspects characterize a highly valued app or make an app more highly valued than another? In a way, the comparison carried out between tertiles can give us some clues about this because it highlights the differences between the three groups. The main differences were found in app subjective quality, engagement, and esthetics, so these should be the aspects to improve in order to "climb positions" in the app ranking. Nevertheless, in this case, as they are apps intended for health care, these aspects must be secondary, always less important than other relevant aspects already mentioned, such as the scientific basis, security, and privacy.

Limitations

Finally, this study has the usual limitations of these types of studies, and particularly those due to the nature of the items studied (mobile apps). We highlight the possibility of having missed some pain apps that did not contain the word "pain" in its title or its description. Another possible limitation is that the reliability of the MARS was originally piloted on iPhone apps. However, the same authors state that the scale has been applied to multiple Android apps, finding no compatibility issues. Also, the apps market is constantly changing, and this fact can significantly shorten the validity period of this evaluation. This, in turn, can also be seen as a strength, as this is the most recent update at the time of its publication, and hence the closest approximation to the current situation of pain-related apps. Moreover, unlike other authors, we use an adequate tool to measure the quality of the apps, which is a substantial improvement over previous reviews. Additionally, we include paid apps, which are likely to have different characteristics, options, and ratings, and which are not always included in other reviews, possibly leading to bias.

Conclusions

The pain-related apps that are currently available in the market are of a certain quality, mainly regarding their technical aspects, although they fail to offer information and have an impact on the user. On the other hand, the vast majority of apps are not based on scientific evidence, have not been rigorously tested, and the confidentiality of the information collected is not guaranteed. Future apps would need to improve these aspects, exploit the capabilities of the latest devices, and comply with some other requirements, such as being user friendly, attractive, simple, and functional for the benefit of the patient. These conclusions provide, in our opinion, a more objective perspective than the previous reviews in which no validated tools were used to measure the quality.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
IASP: International Association for the Study of Pain
MARS: Mobile App Rating Scale
mHealth: mobile health

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Original Paper

mHealth App Patient Testing and Review of Educational Materials Designed for Self-Management of Gout Patients: Descriptive Qualitative Studies

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Abstract

Background: Gout is a form of chronic arthritis caused by elevated serum uric acid (SUA) and culminates in painful gout attacks. Although effective uric acid-lowering therapies exist, adherence is low. This is partly due to the lack of support for patients to self-manage their disease. Mobile health apps have been used in the self-management of chronic conditions. However, not all are developed with patients, limiting their effectiveness.

Objective: The objective of our study was to collect feedback from gout patients to design an effective gout self-management app.

Methods: Two descriptive qualitative studies were conducted. In Study 1, researchers developed a short educational video and written materials about gout management, designed to be embedded into an app; 6 interviews and 1 focus group were held with gout patients to gather feedback on these materials. Usability testing in Study 2 involved additional gout patients using a pilot version of *Healthy.me Gout*, a gout self-management app, for 2 weeks. Following the trial, patients participated in an interview about their experiences using the app.

Results: Patients viewed the gout educational material positively, appreciating the combined use of video, text, and images. Patients were receptive to using a mobile app to self-manage their gout. Feedback about Healthy.me Gout was generally positive with patients reporting that the tracking and diary features were most useful. Patients also provided suggestions for improving the app and educational materials.

Conclusions: These studies involved patients in the development of a gout self-management app. Patients provided insight to improve the app's presentation and usability and general lessons on useful features for chronic disease apps. Gout patients enjoyed tracking their SUA concentrations and gout attack triggers. These capabilities can be translated into self-management apps for chronic diseases that require monitoring of pathological values, medication adherence, or symptoms. Future health app design should integrate patient input and be developed iteratively to address concerns identified by patients.

(JMIR Mhealth Uhealth 2018;6(10):e182) doi:10.2196/mhealth.9811

KEYWORDS

mobile apps; gout; self-management; chronic disease; uric acid

Introduction

Mobile health (mHealth) technologies present opportunities for improving patient self-management of chronic diseases [1,2]. Smartphones and tablets are increasingly used worldwide, and more than 100,000 health-related apps are available to users [1]. Studies have shown that user-centered design is key to ensuring that mobile self-management apps are effective in heart health, diabetes, and asthma [3-6]. However, very few apps are codeveloped with end users, limiting their uptake and effectiveness.

Gout is a chronic form of arthritis that causes a significant health burden worldwide [7]. It results from elevated serum uric acid (SUA) concentrations and culminates in debilitating gout attacks [8-10]. Successful gout self-management is dependent on behavioral factors but ultimately upon medication adherence. Highly effective uric acid-lowering therapies (ULTs) are available. However, adherence to ULTs in gout patients is very low; in fact, it has the lowest adherence rate of all chronic diseases [11]. Poor quality educational resources and limited patient knowledge have been identified as key barriers to adequate ULT adherence [12,13]. An intervention that was delivered by nurses comprised personalized education, lifestyle advice, and appropriate prescribing of ULTs resulted in 92% of patients achieving target SUA concentrations 1-year post intervention [14]. Although effective, this intervention was very labor and resource intensive and therefore, unlikely to be sustainable in the long term. A more automatic and far-reaching method of delivering education and lifestyle and treatment advice could be via an app. Previous research has identified that no completely electronic app existed that contained all the required features to support patients in self-managing their gout effectively. One app incorporated these features; however, it required patients to manually complete print-outs to record their SUA and gout attacks [15]. Further, there was no evidence that these apps were developed using patient input. In response to the limitations of the existing gout management apps and the potential for a high-quality app to improve patient self-management of chronic gout, a pilot version of the *Healthy.me Gout* app was developed. *Healthy.me Gout* is an adaptation of *Healthy.me*, a general health app and website, with personal health records, educational information, and Web-based patient support. This study aimed to build an effective gout self-management app by seeking patient input on prototypes of educational material designed to be embedded into the app and to obtain patient feedback of a pilot version of *Healthy.me Gout*.

Methods

Ethics

Ethics approvals for these studies were obtained from the University of New South Wales Human Research Ethics Advisory Panel (references #HC16263 and #HC15199).

Study Design

This paper describes 2 studies that were conducted in parallel. Study 1 explored the opinions of gout patients on the content and format of prototypes of educational material on gout management. In Study 2, gout patients participated in app testing where they were given 2 weeks' access to an initial iteration of *Healthy.me Gout*, an app designed for patients to self-manage their gout. Following this period, patients participated in an interview about their experiences in using the app.

Recruitment

To recruit patients with gout, 2 strategies were adopted. The first approach involved contacting general practitioners throughout Sydney, Australia, via email, phone, fax, or in person to distribute invitation letters to their patients with gout. General practitioners were asked to provide the researchers with the contact details of patients who expressed an interest in participating in the study. These patients were then contacted by researchers. This recruitment strategy was supplemented by posting study flyers in pharmacies and medical practices across Sydney and public spaces at St Vincent's Hospital, Sydney. Rolling recruitment for Study 1 lasted approximately 12 weeks until theme saturation was reached. Recruitment for Study 2 was conducted concurrently. All participants were reimbursed with an Aus $50 gift card. Inclusion criteria for both studies were adults with a diagnosis of gout, and exclusion criteria included cognitive impairment or limited understanding of English such that participation in an interview or focus group would be difficult. Participants in Study 2 also had to have access to a smart device.

Study 1: Assessing Gout Educational Resources to be Embedded Into a Mobile App

Design of Educational Materials

Written Information

Written educational materials were developed using a combination of resources obtained from consumer group organizations, Australian Rheumatology Association, Arthritis Australia, and the European League Against Rheumatology guidelines for gout management [16]. The materials addressed important aspects of gout and its management. The topics included symptoms of gout attacks, diagnosis of gout, hyperuricemia as a cause of gout, risk factors for gout, consequences of chronic hyperuricemia, acute gout treatments, use of ULTs and the importance of ULT adherence, and prophylaxis during ULT initiation. The research team, which

included a senior rheumatologist, reviewed the information to validate the content. The information, written in plain English, was embedded into paper prototypes to simulate how the information would appear on a smart device screen in terms of the size and location of text, as seen in Figure 1. Blue-colored text was used to indicate hyperlinked keywords, simulating how users would be able to use these to click to different pages in the app. Images were included in the written materials.

Animated Video

A 2-minute animated video was developed to introduce gout management and highlight the importance of adherence to ULTs. The video was designed to be conversational in tone and employed a persona, "Gout Man," who depicted a stereotypical gout patient, as seen in Figure 2.

The video included a graph that represented monitoring SUA over time, as seen in Figure 3. The graph highlighted the relationship between SUA and gout attacks, demonstrating that as SUA concentrations decrease, the likelihood of pain from gout attacks decreases. The target for SUA was displayed on this graph as a perforated line.

Interviews and Focus Groups

Patients were provided with the option of attending either an interview or focus group based on their preference and convenience. Using a semistructured interview guide (Multimedia Appendix 1), 6 one-on-one interviews (average duration, 45 minutes; range, 15-56 minutes) and 1 focus group (with 5 patients, 102 minutes in duration) were held to obtain feedback on the educational materials. Broadly, patients were asked questions covering their opinions of the presentation and content of the written and video educational resources. All interviews were carried out by a fourth-year medical student, and the focus group was cofacilitated by a PhD research student.

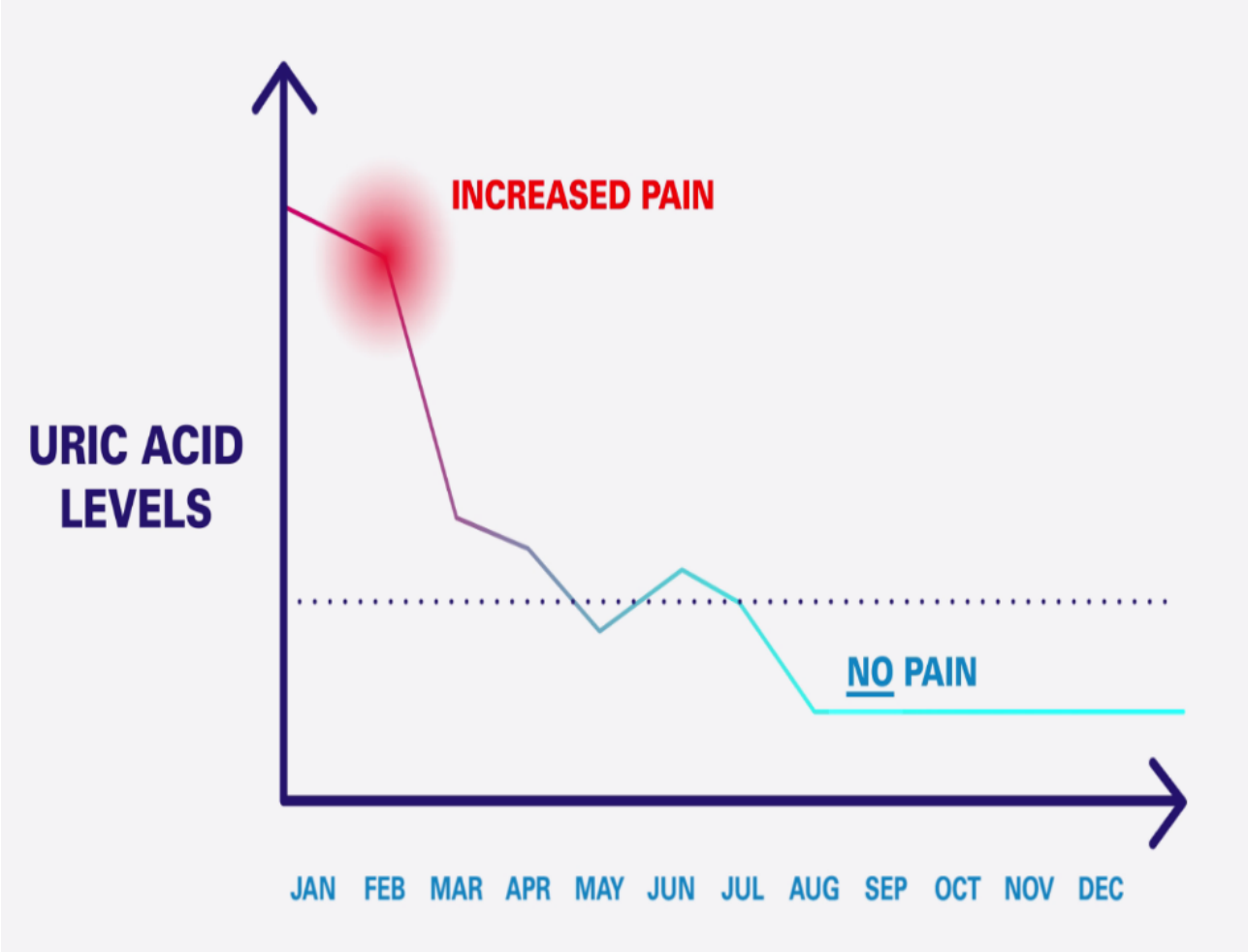
Analysis

The interviews and focus group were audiotaped and transcribed verbatim for analysis. Thematic analyses of the transcripts were carried out concurrently but independently by 2 researchers (AN and MW) to determine when thematic saturation occurred [17]. Transcripts from approximately half of the participants were initially reviewed and coded for themes after which researchers convened and developed a coding framework using an inductive approach, allowing for the most predominant themes to be identified. Emerging themes were categorized into patient perspectives of the educational materials and suggestions for improvements. All transcripts were then reanalyzed using this framework and coded under the predetermined themes; 2 coders resolved any discrepancies by consensus.

Figure 1. Example of the paper prototype of written educational materials shown to gout patients.

Figure 2. "Gout Man" as depicted in the animation video.

Figure 3. Graph of serum uric acid tracker shown in the educational animation video.



Study 2: Pilot Testing of the Gout Self-management Mobile App

Healthy.me Gout Design

The written materials and animated video were incorporated into an app called *Healthy.me Gout*. *Healthy.me Gout* is a modified version of *Healthy.me*, a general health app that has been shown to improve influenza vaccination rates and address the needs of breast cancer survivors [18-20]. *Healthy.me Gout* was developed after interviews with patients regarding their current gout management [21], a review of commercially available apps for patient self-management of gout [15], and subsequent feedback from gout patients on these apps and the generic version of *Healthy.me* [22]. *Healthy.me Gout* contained 6 features, as depicted in Figure 4 and summarized in Table 1.

Two-Week Use of App

Patients were asked to use *Healthy.me Gout* for 2 weeks and explore each feature of the app to assess for app usability. Patients were advised that they would be emailed 4 mock SUA values approximately 4 days apart for them to enter into the "Uric Acid Tracker" feature of the app, and these SUA values were 0.70, 0.50, 0.34, and 0.25 mmol/l, respectively. Because it was unlikely that patients would have their SUA measured during the 2-week trial period, this allowed patients to experience inputting data and visualizing SUA values being plotted on the "Uric Acid Tracker" graph. Throughout the 2-week period, activity log data were collected in the background with times of patient log-in and use of the features recorded.

Figure 4. Screenshot of *Healthy.me Gout* home screen. Source: Image created by the authors, together with "The Explainers".

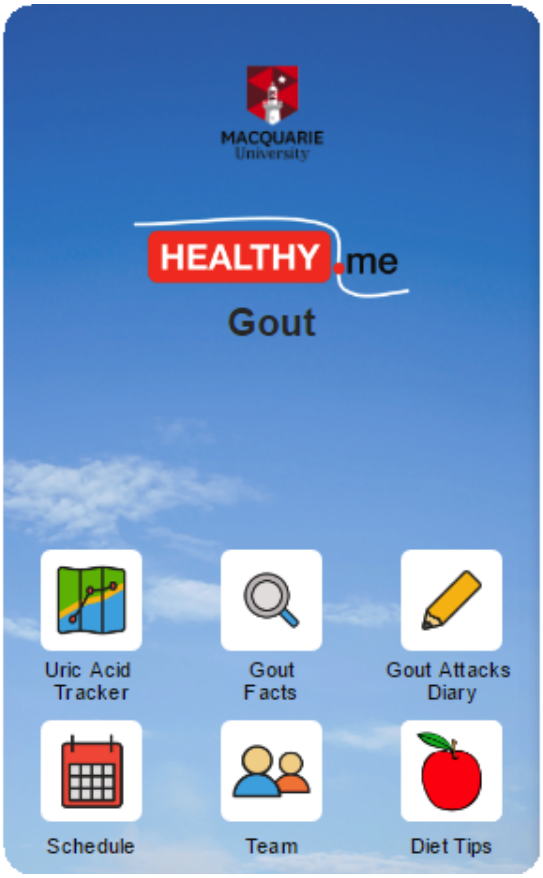


Table 1. Features of *Healthy.me Gout.*

Feature	Summary
Uric Acid Tracker	Patient's serum uric acid concentrations represented in a graph over time and in relationship to the target serum uric acid concentration (0.36 mmol/l)
Gout Facts	Educational materials including brief written information with hyperlinks and images, and animation video about gout and its management
Gout Attacks Diary	Ability to record gout attacks including pain intensity, the location of attack(s), and trigger(s)
Schedule	Option for patients to set reminders such as to take their medications, have blood tests, record gout attacks, and see their general practitioner
Team	Option for patients to input contact details (eg, of their general practitioner, pathology service, or researchers)
Diet Tips	Evidence-based list of foods that raise and lower serum uric acid

Interviews

Following the 2-week pilot, patients participated in a short interview conducted by a postdoctoral researcher (average duration, 26 minutes; range, 15-33 minutes). The interview guide is presented in Multimedia Appendix 2. Patients were asked about their experiences of using *Healthy.me Gout*, including any challenges faced and the perceived benefits of the app.

Analyses

The interviews were audiotaped and transcribed verbatim. The review and coding of themes were carried out by 2 postdoctoral researchers (AN and LF). The researchers discussed the themes that were identified individually and agreed upon the main themes that arose. Activity log data were tabulated to calculate patient usage of the app (ie, the number of times each feature of the app was accessed and by which patient).

Results

Study 1: Assessing Gout Educational Resources to be Embedded Into a Mobile App

Overall, 11 gout patients participated in Study 1, at which point theme saturation was reached; 5 patients were recruited via their general practitioners, and 6 responded to flyers. All 11 patients were male and aged between 32 and 85 years (mean, 60 years). The time since their gout diagnosis ranged from 3 to 25 years with 8 patients reporting having experienced 2 or more attacks of gout in the past year. Although all 11 patients owned a computer with access to the internet and were frequent users, only 8 reported owning a smartphone. Patients provided their opinions on the content and presentation of the information shown in the video and written formats (Textbox 1). Patients also provided suggestions for improvement to the written materials and educational video, summarized in Textbox 2.

Study 2: Pilot Testing of the Gout Self-Management Mobile App

Overall, 5 patients were provided access to *Healthy.me Gout*. Of these 5, 3 also participated in Study 1. The patients were all male and were between the ages of 50 and 69, except for 1 who was younger than 40 years old. The patients had had gout for an average of 7 years and reported experiencing 4 attacks, on average, in the last year. All gout patients in Study 2 owned a smartphone and computer and accessed the internet frequently. Patients were interviewed following their use of *Healthy.me Gout*, and the findings are summarized in Textbox 3.

Textbox 1. Patient feedback on gout educational resources; example quotes are in italics.

Presentation

1. Liked the combination of videos, images, and written text
2. Found informal and conversational tone of video comforting and fostered a sense of inclusion
   - *It makes you feel like you're not completely out on your own.* [P8]
3. Amount of text in the written material was appropriate
   - *You don't lose interest.* [P4]
   - *Provided you get the message across it's fine. It's not overkill.* [P4]
4. Appreciated video's length, stating it was short and succinct
5. Concerned about the font of written material being too small, especially when displayed on a mobile phone screen

Content

1. The written material described gout well and focused on the importance of regularly taking uric acid-lowering therapies
   - *Gout is curable; you just need to take your pill.* [P8]
2. Images were accurate (ie, similar to patient experiences with gout attacks)
3. List of foods that could trigger gout attacks was not useful, as food triggers are inconsistent across gout patients, and patients were already aware of their dietary triggers
   - *Yeah, that's [other patient's trigger] different with me. They tell me you shouldn't eat oysters and mussels, but I find when I'm eating them I don't have the attacks.* [P9]
4. Liked tips in written material for remembering to take medications
   - That's not a bad idea, putting it [medications] next to the toothpaste. [P7]
5. Including the target serum uric acid concentration motivated patients to adhere to medications, and patients liked it visually represented as a line on the graph in the video
6. "Gout Man" seen as representative of gout patients in the community, and having a persona helped patients relate to video's message
   - *Yeah, he [Gout Man] looks like me.* [P11]

Textbox 2. Suggestions from patients to improve presented gout educational resources; example quotes are in italics.

Presentation

1. Include dropdown menus to hide or expand written material, enabling personalization of information
   - *Your choice, you're in charge of how much you read.* [P4]
2. Search bar to navigate through written material more efficiently

Content

1. More emphasis on permanent joint damage resulting from long-term untreated gout in video and written material
   - *I've seen some terrible joints affected by gout that's been left untreated, and I thought if I don't want to end up in that situation, I'd go on permanent medication.* [P4]
2. Include effects of gout on daily life in the written material
   - *Trying to walk, it was difficult. So, yeah, how it affected me is what sticks in my mind.* [P1]
3. Greater number of more alarming and graphic images in the written material
   - *You need more horrific pictures, that's for sure.* [P7]
   - *The only way you're going to really impact and scare people is with pictures of tophi deposits.* [P3]
   - *What about a picture of that white blood cell skewered by a little crystal? It'll explain why it's just like having a fork driven into it.* [P3]

Textbox 3. Summary of patient perceptions and suggestions for improvement of Healthy.me Gout.

Patient perceptions

- Straightforward and easy to use
- Appreciated being able to monitor their gout with "Uric Acid Tracker"
- Visualization and feedback of being in the "Danger Zone" of serum uric acid (SUA) concentrations was useful
- "Gout Attacks Diary" useful to see patterns and trends of attacks
- "Team" useful only for contact details of nonregular healthcare providers (eg, specialists)

Patient suggestions for improvement

- Automatic input of SUA values into "Uric Acid Tracker"
- "Gout Attacks Diary" determines trends in attack triggers and generates summaries of attacks
- "Schedule" reminders pop up on mobile phone screens, rather than sent via email, and are integrated into device's native calendar
- Ability to personalize the list of foods to avoid in "Diet Tips"

Patient Perceptions of Healthy.me Gout

Patients perceived the app to be straightforward and easy to use. Patients appreciated the ability to monitor their condition using the "Uric Acid Tracker" available within the *Healthy.me Gout* app. Being able to determine whether they were in the "Danger Zone" of SUA concentrations was liked, as was the graph providing individualized feedback with prompts to see their doctor if they were out of range. Similarly, patients found the "Gout Attacks Diary" useful to record their gout attacks, allowing patients to see patterns and trends in their gout attack triggers and to report attacks to their doctors at a later date. One patient explained,

> *With any medical condition...if one is relying on memory...It's hard to remember. Whereas if the gout app retains those records then it's a great help to look at the current condition.* [P17]

The sliding scale to record pain intensity was also viewed positively. Similar to patients in Study 1, those in Study 2 appreciated that "Gout Facts" was written in simple language with sentences of appropriate length that were easy for them to understand; one patient described,

> *It's [the written information] good because they're apt sentences but they're not lengthy ones, and in reading an app or data...it's a real turn-off to read an inch or a long, long paragraph — so, short and sweet sentences are great.* [P17]

Patients reported that the content included in the "Gout Facts" and "Diet Tips" sections was useful and that the still images served to help the patients visualize what was described in the text. In contrast, the animated video incorporated into "Gout Facts" was described as too general and would only be viewed once.

The "Team" feature of the app was noted to be useful for the contact details of nonregular healthcare providers, such as specialists. However, patients did not find this feature useful otherwise, particularly for including contact details of their general practitioners who they regularly visit.

Patients' Suggestions for Improvements to Healthy.me Gout

Gout patients expressed a preference for their SUA values being automatically updated in the "Uric Acid Tracker" because they usually do not have access to this result unless they are with their doctor. A patient explained,

> *The results don't come to me so I won't actually know what my uric acid level is until I'm sitting opposite Dr [name withheld]...I don't get a copy of the report. So, yeah, automatically inputted in.* [P16]

For the "Gout Attacks Diary," gout patients suggested that this record-keeping feature would be more useful if it could summarize patterns in the triggers of their gout attacks. This information would be helpful in identifying foods or situations for the patient to avoid. One patient elaborated,

> *If you have an attack it's probably good to see if there's a pattern...if there's certain times of the year or certain triggers. It would be nice to use it in the long term.* [P13]

Patients suggested that if a report of their gout attack history were generated, it would be useful to take to their doctor with a patient describing,

> *If the individual entries can generate a report, that is either printable or emailable to the doctor; that makes sense to me. In other words, it's creating a history.* [P16]

"Schedule" and "Team" were the features least liked by patients. Regarding the "Schedule" feature, patients did not like that the reminders arrived as emails and would have preferred it if they popped up on their mobile phone screens. In particular, reminders to take ULTs on a daily basis were seen as potentially useful for patients with medication adherence issues. Incorporation of these reminders into the device's native calendar was suggested as a way to integrate the "Schedule" feature into patients' current use of their smart devices. As smart devices have contact lists, patients reported that the "Team" feature was redundant. A patient reported,

> *To be honest, I don't really see the purpose of this one 'cause if I am going to call my [general practitioner], I can just go to my phone book and just go to dial the [general practitioner].* [P14]

"Diet Tips," which was a list of foods that they could or should not eat, was perceived as a useful feature, but patients wanted to personalize the list. This was because the food triggers of gout attacks are highly individual. One patient expressed,

> *I really would like to have [a list that] is relevant to me, so...proven high purine fruit and veg and drinks, yes, but then allow me to create my personal, relevant lists...so as I'm putting in an attack I can access the relevant triggers that have caused me issues in the past.* [P16]

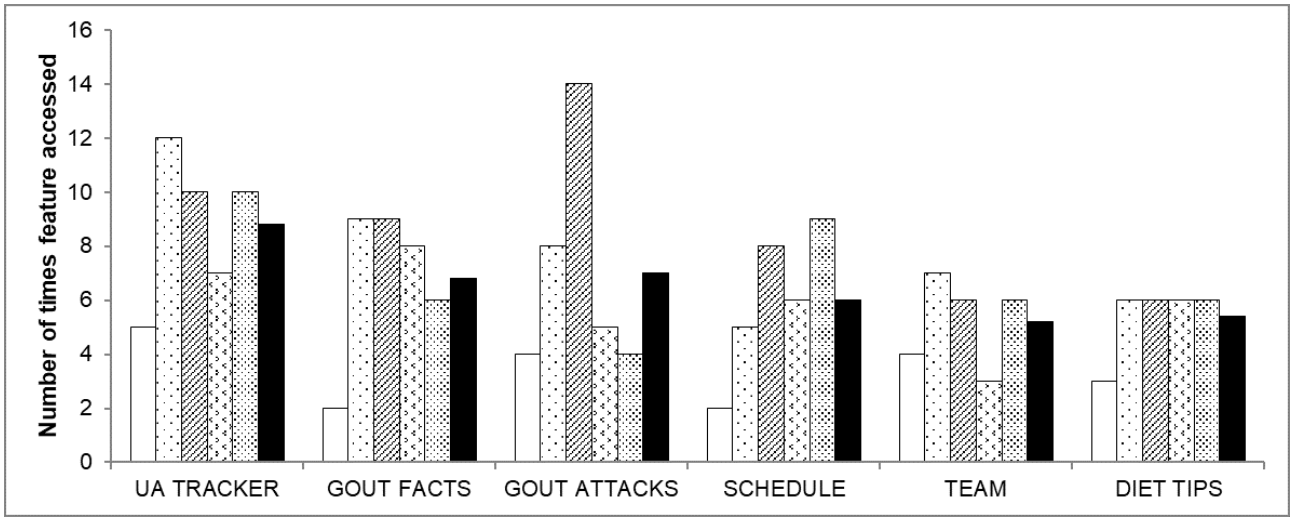
Some patients also stated that the list of restricted foods was not extensive enough.

Continuity of Use

Patients reported that they would continue to use the app with access to the "Uric Acid Tracker" and "Gout Attacks Diary" being stated as 2 of the main drivers for this. App usage data showed that the "Uric Acid Tracker" was the most accessed feature of the *Healthy.me Gout* app, as seen in Figure 5, and that, on average (final bar of each feature), patients (individually represented as the first 5 bars of each app feature) accessed the app on 5 separate days in the 2-week trial period (range, 4-7; data not shown).

Patients said that they would recommend the app to other gout patients, particularly newly diagnosed gout patients, those who were interested in tracking their SUA, and those who wanted to identify their gout attack triggers. A patient stated,

Figure 5. Number of times each feature of Healthy.me Gout was accessed by patients during the 2-week pilot. UA: uric acid.



> *If you've just been diagnosed, it's got some good facts, and if you're interested in working out some patterns, it's good.* [P13]

Another patient agreed saying,

> *I think newly diagnosed people can learn more from the gout facts, and also tracking their uric acid index...this is pretty straightforward, answers all your questions about gout, so I think it will be good.* [P14]

Discussion

Principal Findings

This study demonstrated the importance of involving patients in the design and development of a self-management app for gout patients. Patients said that they were open to using an app to support the self-management of their condition. Patients reported that the most useful features of the app were the ability to monitor their SUA, record gout attacks, and access educational resources. Importantly, patients provided feedback to improve the app and the educational material embedded within it.

Previous studies have shown that incorporating images into educational materials increases their effectiveness specifically by improving patient attention, comprehension, recall, and adherence to the content of the materials [23]. Employing a health app to deliver patient education, as opposed to paper-based formats (eg, leaflets and booklets), enables the use of a combination of media to engage patients in learning about their disease, which was noted as important by patients in this study with patients being particularly receptive to the dynamic educational video.

A self-management app that facilitates longer-term management is important for chronic diseases. Patients expressed that the "Uric Acid Tracker" and "Gout Attacks Diary" in *Healthy.me Gout* were valuable tools to enable them to track their disease over time. However, enhancing the tool by incorporating features, such as automatic input of SUA values, ideally through data linkage with electronic patient records, may encourage patients to continue using the app long term. The integration of *Healthy.me Gout* with native features of smart devices, such as the calendar and contacts list as well as enabling in-device pop-up alerts, were seen to be important for incorporating the app into the patients' daily lives, which could improve the longevity of app use. Indeed, the "Team" and "Schedule" features of the app were not well liked because they did not integrate with native apps of devices.

Successful behavior change using self-management strategies should include not only education but also support through tools, such as alerts and personalized content and feedback [24,25]. This was reflected in our study with the ability for patients to personalize their *Healthy.me Gout* app viewed as being important; for example, patients wanted to create personalized lists of potential food triggers in "Diet Tips" and liked that they could collapse (if irrelevant) or expand (if relevant) information boxes in the written educational materials. In this way, patients could customize their learning journey. Similarly, patients in this study wanted the app to produce personalized summaries of their clinical gout symptoms to share with their healthcare providers during medical consultations. The findings of this study are similar to those of other mHealth app usability studies in which patients with other chronic conditions have stressed the importance of health apps being able to support patient-doctor communication during clinical encounters [26].

Involving end users in the development of apps can improve effectiveness [3-6,26]. However, not all app developments incorporate this. By incorporating the feedback from gout patients in this study to modify the *Healthy.me Gout* app, it is anticipated that use of the app will be substantially improved, subsequently increasing app uptake and improving long-term gout management. Because most health app evaluations are predominantly usability studies, the ability of an improved iteration of *Healthy.me Gout* to support patient self-management of gout will be evaluated in a larger randomized controlled trial, wherein gout patients will use the app for a longer period and clinical outcomes will be assessed [27,28]. This is of particular importance given the movement toward the promotion of greater use of digital health interventions, particularly with healthcare providers now being encouraged to integrate patient-focused mHealth apps into their delivery of patient care [26,29].

Limitations

Given that gout is a chronic condition and the studied patients presented with varying degrees of gout severity, being restricted to a 2-week period of app use meant that it was unlikely that all patients would have a gout attack or have SUA measured in this time. Thus, interactions of patients with the features of the app were highly variable. Further studies with longer monitoring of app usage are required to identify features that are utilized by gout patients in the longer term. In this study, the app was tested by only 5 gout patients who were all male, owned a smartphone, and accessed the internet frequently. Because differences among treatment regimens, treatment monitoring, and existing comorbidities are present between male and female gout patients, further app testing in female gout patients is required [30]. Testing the app with patients with varying characteristics would enable the provision of further evidence of the feasibility of the app for a broader gout population. Additionally, the participants were a self-selecting sample. Patient responses to the recruitment strategies likely reflect higher levels of interest in learning more about their gout diagnosis or using self-management health apps and, for Study 2, required patients to have access to a smart device to participate.

Conclusions

Experiences from this study provide important insights for the development of future self-management mHealth apps. This paper demonstrates the importance of integrating patient input into health app design and iterative development to identify and address the concerns of affected patients. Similar to many other chronic conditions, optimal management of gout requires the monitoring of a pathological value or surrogate indicator of risk, namely, SUA. SUA is influenced by medication adherence and monitoring its concentration reduces the risk of gout attacks from occurring by promoting adherence. The use of graphs to display the pathological value and risk of symptoms that occur

as well as a facility to record symptoms, as in this gout app, were highly valued by patients. Future self-management apps for other chronic conditions should involve patients in their design and development and also incorporate similar features to present the relationship between a pathological value and risk of a negative clinical outcome. Additionally, once an app is deemed user friendly by end users, it is necessary to undertake clinical evaluations to determine the health benefits of introducing apps into routine healthcare.

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Conflicts of Interest

AYSL is the only author involved in this project that could benefit from any commercialization of *Healthy.me* or its technologies. However, no plans have been made for this particular application. All other authors declare no conflict of interest.

Multimedia Appendix 1

Interview guide to obtain feedback on developed prototypes of gout educational materials.

[PDF File (Adobe PDF File), 24KB - mhealth_v6i10e182_app1.pdf]

Multimedia Appendix 2

Interview guide for post-two-week use of Healthy.me Gout.

[PDF File (Adobe PDF File), 31KB - mhealth_v6i10e182_app2.pdf]

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Abbreviations

SUA: serum uric acid
ULT: uric acid-lowering therapy

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Review

Self-Management Education Through mHealth: Review of Strategies and Structures

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Abstract

Background: Despite the plethora of evidence on mHealth interventions for patient education, there is a lack of information regarding their structures and delivery strategies.

Objective: This review aimed to investigate the structures and strategies of patient education programs delivered through smartphone apps for people with diverse conditions and illnesses. We also examined the aim of educational interventions in terms of health promotion, disease prevention, and illness management.

Methods: We searched PubMed, Cumulative Index to Nursing and Allied Health Literature, Embase, and PsycINFO for peer-reviewed papers that reported patient educational interventions using mobile apps and published from 2006 to 2016. We explored various determinants of educational interventions, including the content, mode of delivery, interactivity with health care providers, theoretical basis, duration, and follow-up. The reporting quality of studies was evaluated according to the mHealth evidence and reporting assessment criteria.

Results: In this study, 15 papers met the inclusion criteria and were reviewed. The studies mainly focused on the use of mHealth educational interventions for chronic disease management, and the main format for delivering interventions was text. Of the 15 studies, 6 were randomized controlled trials (RCTs), which have shown statistically significant effects on patients' health outcomes, including patients' engagement level, hemoglobin A_{1c}, weight loss, and depression. Although the results of RCTs were mostly positive, we were unable to identify any specific effective structure and strategy for mHealth educational interventions owing to the poor reporting quality and heterogeneity of the interventions.

Conclusions: Evidence on mHealth interventions for patient education published in peer-reviewed journals demonstrates that current reporting on essential mHealth criteria is insufficient for assessing, understanding, and replicating mHealth interventions. There is a lack of theory or conceptual framework for the development of mHealth interventions for patient education. Therefore, further research is required to determine the optimal structure, strategies, and delivery methods of mHealth educational interventions.

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KEYWORDS

health education; mHealth; mobile apps; mobile phone; patient education; self-management education

Introduction

Health Education

Health education is a key strategy in the process of acquisition of behaviors that promote and maintain health; it has serious implications for health promotion, disease prevention, and illness management. According to the World Health Organization, health promotion is defined as the process of enabling the general public to improve their own health and covers a broad range of social and environmental interventions. These interventions are developed to improve individuals' health and quality of life by addressing and preventing the underlying causes of illnesses and not merely focusing on treatment and cure. Health promotion consists of educational strategies to inform people of what they can do to stay healthy and to address the issues in the community that influence mostly health and well-being [1].

Disease prevention is an individual or group-based intervention for primary and secondary prevention, which aims to decrease the burden of diseases and associated risk factors. While primary prevention is defined as actions taken to avoid the manifestation of a disease, secondary prevention consists of interventions for early detection, which may improve patients' health outcomes [1]. Education on secondary prevention and illness management for patients with chronic disease who require day-to-day self-monitoring and symptom recognition is vital. Furthermore, it is important for patients to not only attain knowledge but also involve in the process of care and gain empowerment over their conditions. As a result, the provision of information, knowledge, self-management skills, and self-efficacy encouragement to patients is essential to produce active participation and consequently improve their health outcomes [2-4]. Health care providers play an integral role in collaborating with their patients to enhance knowledge, develop skills, and build confidence.

For those with chronic diseases, patient education is focused on alleviating complications and optimizing the quality of life. Hence, patient education is directed toward behavioral change, and the development of essential skills and knowledge for self-management [5,6]. The focus of behavioral change is either the adoption of new behavior, such as daily exercise or the discontinuation of old behavior, such as smoking. Weight loss, smoking cessation, and increasing physical activity levels are the main target areas for behavior change of chronic patients [6].

To manage chronic conditions, in addition to education, patients require long-term support to improve their self-management skills and achieve the desired behavioral change [7,8]. Self-management education (SME) has been recognized as a complementary intervention for fostering behavioral changes; this has been supported by the internationally influential Chronic Care Model [7]. It is now evident that the efficient provision of SME is challenging for many health care professionals. Clinicians pointed out the lack of time, competing demands, health care systems that are structured to focus on individual conditions rather than multiple comorbidities, and limited patient motivation as barriers for the implementation of SME [9,10]. Previous research identified effective strategies for educating patients and providing SME [6,7]. The implementation of such interventions and tailoring them based on patients' needs and preferences demand significant resources and multiple face-to-face educational sessions, which traditionally happen in health care settings [11].

mHealth For Patient Education

Information and communications technologies and digital devices, such as smartphones, offer a potentially powerful means for patient education and behavioral change reinforcements [12-14]. A large number of health-related software apps have been designed and are available for both health care professionals and patients [15]. The number of medical or health-related apps in the major app stores (Apple App Store and Google Play Store) is increasing rapidly [16]. The use of smartphones is changing the provision of patient education in health care through convenient, individually tailored, and contextually meaningful delivery of interventions [17]. Furthermore, smartphone apps have lower costs, reduce the burden on patients, and overcome some limitations of traditional in-person interventions [18].

A number of systematic reviews and meta-analyses have investigated the effect of smartphone apps on patients and consumers health outcomes [19-21]. In addition, a broad range of smartphone educational apps has been used to improve public health knowledge. However, these interventions are not found equally effective [22]. Effective patient education strategies were identified as traditional lectures, discussions, simulated games, computer technology, written material, audiovisual sources, verbal recall, demonstration, and role-playing [23]. Research showed that internet-based interventions, which were developed based on a theory, were more effective than those with no theoretical basis [24]. None of the existing literature reviews have investigated mHealth SME interventions with respect to the evidence around the theoretical frameworks. Furthermore, a limited number of studies on smartphone apps provided sufficient information related to educational contents and methods of delivering such interventions. Hence, this review aims to investigate smartphone-based educational interventions for patient self-management. The review also aims to explore the structures and strategies (including format, interactivity, use of theory, duration of education, and health care professionals' follow-up) of the educational interventions along with any documented theory or framework, which informed the design of such interventions. To investigate the studies, we categorized the aim of patient education with respect to World Health Organization health education interventions into health promotion, disease prevention, and illness management.

Methods

Search Strategy

We conducted a comprehensive electronic search of 4 major biomedical databases (PubMed, Cumulative Index to Nursing and Allied Health Literature, Embase, and PsycINFO) for peer-reviewed papers published from 2006 to 2016. A sensitive search strategy was developed by a combination of controlled vocabulary (Medical Subject Headings terms) and free text terms according to recent recommendations for searching the

PubMed database [25-27]. The electronic search incorporated 3 main concepts: (1) mHealth; (2) patient education; and (3) self-management (see Multimedia Appendix 1). The search strategy was modified specifically for every other database based on their individual guide. Furthermore, search results were downloaded to EndNote citation manager software, and the duplicates were removed.

Inclusion and Exclusion Criteria

The criteria for considering studies for this review were as follows.

Design

We considered peer-reviewed studies for inclusion. Primary or secondary studies reporting clinical trials were included regardless of their study design, except for case reports. We reviewed papers with a broad range of methodology, including qualitative and quantitative. However, conference abstracts, book reviews, letters, editorials, and unpublished studies were excluded.

Participants

We considered patients with diverse conditions regardless of their age, gender, or ethnicity in this review. However, the authors might have established the diagnostic criteria in their respective papers.

mHealth Educational Interventions

Any mHealth educational intervention designed or delivered for health promotion, disease prevention, or illness management was included. We considered interventions that consisted of educational modules or materials either as the main intervention or part of health care delivery for patients with chronic conditions.

Data Extraction and Synthesis

Three reviewers extracted data from the final set of included papers. In case of discrepancy, the reviewers discussed the issues and reached an agreement. Owing to resource limitation, we excluded papers published in other than the English language. Data extracted from each paper were summarized in 3 separate tables. Multimedia Appendix 2 reports study characteristics and includes the name of the first author, study design, disease or condition, aims of education, sample size, theory-based and description of the app. Study designs were categorized as randomized controlled trials (RCTs), case-control, proof-of-concept, or pilot research. In addition, we categorized the aims of education to health promotion, disease prevention, and illness management. Table 1 details the results of the RCTs. Multimedia Appendix 3 was used to detail intervention strategies and structures, including educational topics, modes of delivery, and measurement tools.

Literature Search Results

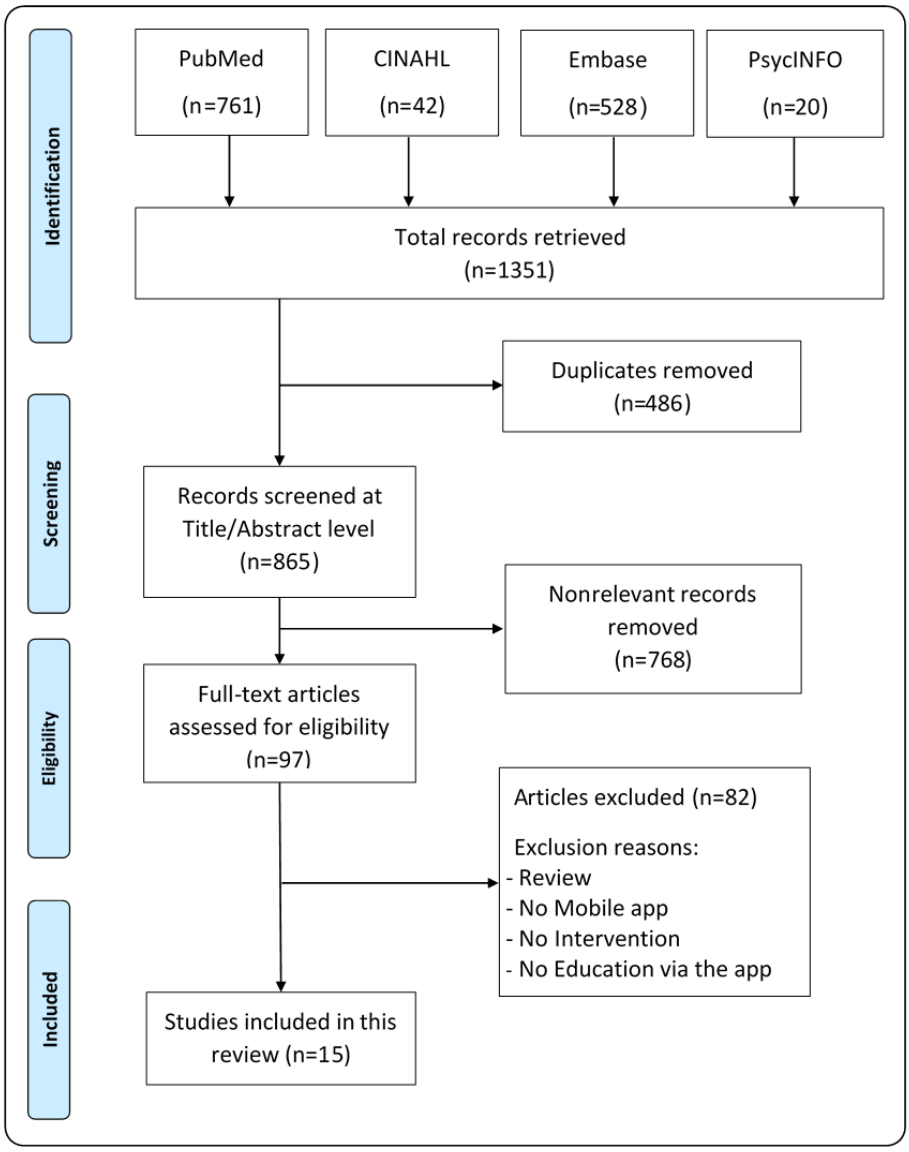
The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram was used to document the paper selection process (Figure 1). A total of 1351 papers were retrieved from the electronic search of 4 databases. After removing duplicate records, we screened 865 records at the title or abstract level and examined the full text of 97 potentially relevant papers. Finally, we included 15 studies in this review.

Table 1. Summary of the intervention and results of the included randomized controlled trials.

Study	Study design	Disease or condition	Primary outcome	Follow-up	Results
Ledford et al, 2016 [28]	Pilot RCT[a]	Pregnancy	Patient activation	32 weeks	There was a statistically significant difference in the patient activation between notebook and mobile groups (P=.02).
Zhou et al, 2016 [29]	Open RCT	Diabetes	Hemoglobin A_{1c}	3 months	Diabetic patients in the intervention group (using the Welltang app) achieved statistically significant improvements in hemoglobin A_{1c} (P<.001).
Direito et al, 2015 [30]	RCT (3-arm)	Physical activity	Cardiorespiratory fitness	8 weeks	There was no significant intervention effect on the primary outcome using either of the apps.
Fukuoka et al, 2015 [31]	RCT	Overweight	Percentage change in weight and body mass index	5 months	There was a statistically significant difference in weight loss between the intervention and control groups (P<.001).
Depp et al, 2015 [32]	RCT	Bipolar disorder	Depressive symptoms	24 weeks	Participants in the intervention group showed significantly greater reductions in depressive symptoms after 6 and 12 weeks (Cohen d values for both were.48). However, these effects were not maintained at 24-week follow-up.
Ly et al, 2014 [33]	Open RCT	Depression	Depression	6 months	No significant interaction effects of group and time on the Patient Health Questionnaire-9 and the Beck's Depression Inventory-II were found between the groups, either from pretreatment to posttreatment.

[a]RCT: randomized controlled trial.

Figure 1. Study flow diagram. CINAHL: Cumulative Index to Nursing and Allied Health Literature.



Quality Assessment

We graded the quality of the evidence using the new mHealth evidence and reporting assessment (mERA) checklist [34]; this checklist has been developed by the World Health Organization mHealth Technical Evidence Review Group. mERA guides in assessing the reporting quality of mHealth interventions covering both feasibility and effectiveness studies. The checklist is a valuable tool and consists of 16 essential criteria to support the completeness of reporting and replication of the mHealth interventions by addressing its content, context, and implementation features. Effective and comprehensive reporting may help to improve the program design, foster collaboration among service providers, reduce duplication of efforts, and ultimately increase the impact and ability to scale effective mHealth interventions. Furthermore, the checklist has been previously used to assess the reporting quality of mHealth interventions [35].

Results

Study Characteristics

Multimedia Appendix 2 summarizes the study characteristics of mHealth educational interventions. Overall, 115 papers have reported on the use of smartphone apps for patient education. Of these, 3 studies targeted cardiovascular disease, including cardiac rehabilitation, coronary artery disease, and heart failure [36-38]; 3 studies focused on overweight adults and physical activity [30,31,39]; 2 smartphone apps reported on asthma [40,41]; and 3 studies targeted mental illnesses such as depression and bipolar disorder [32,33,42]. Diabetes was the focus of 2 mobile-based interventions [29,43]. Furthermore, 1 study reported the feasibility of engaging adolescents with smartphone education [44], and 1 study focused on parental education and engagement [28]. Papers included in the review reflected study designs across the research spectrum including RCTs (n=6) [28-33] and case-control (n=1) [39], proof-of-concept (n=2) [36,40], and feasibility and pilot studies (n=5) [37,41-44]. One paper did not report the design of the

study [38]. Sample sizes were diverse and ranged from 10 participants who were engaged in heart failure education [36] to 173 pregnant women for parental education [28].

As shown in Table 1, a number of primary outcomes were measured in 6 RCTs, including clinical health, patient activation, or psychological indicators [28-31,33]. In 1 study, a group of pregnant women had a statistically significant (P=02) higher level of patient engagement than their comparators [28]. In another study on diabetes, the intervention group that used a smartphone app achieved lower glucose levels than the control group (P<.001) [29]. A 3-arm RCT comparing 2 smartphone apps reported no significant intervention effect on the cardiorespiratory fitness level of young adults [30]. An RCT of a novel smartphone app recruited overweight adults who were at risk of diabetes, and the results showed that participants in the intervention group lost an average of 6.2 kg (SD 5.9) between the baseline and 5-month follow-up compared with the control group's gain of 0.3 kg (SD 2.7; P=.001) [31]. In addition, 2 studies measured patients' depressive symptoms as primary outcomes. While 1 study reported a statistically significant (Cohen d=.48) reduction of depressive symptoms in the intervention group [32], the other reported no significant effect of intervention [33].

Quality of Evidence

Based on the mERA criteria for the quality of reporting in mHealth, (13/15, 86%) of included studies reported on the content of smartphones interventions, modes of delivery, and testing usability. Of 15, none of the studies reported on the measures taken to protect data security, privacy, and confidentiality. While (12/15, 80%) of studies reported on users' feedback, (6/15, 40%) described patient or user satisfaction. Only (2/15, 13%) of the studies provided some level of information on the cost associated with the development or delivery of mHealth interventions (Figure 2).

Educational Aims

Smartphone interventions identified in this review reflected on 3 different aspects of health education, including health promotion, disease prevention, and illness management.

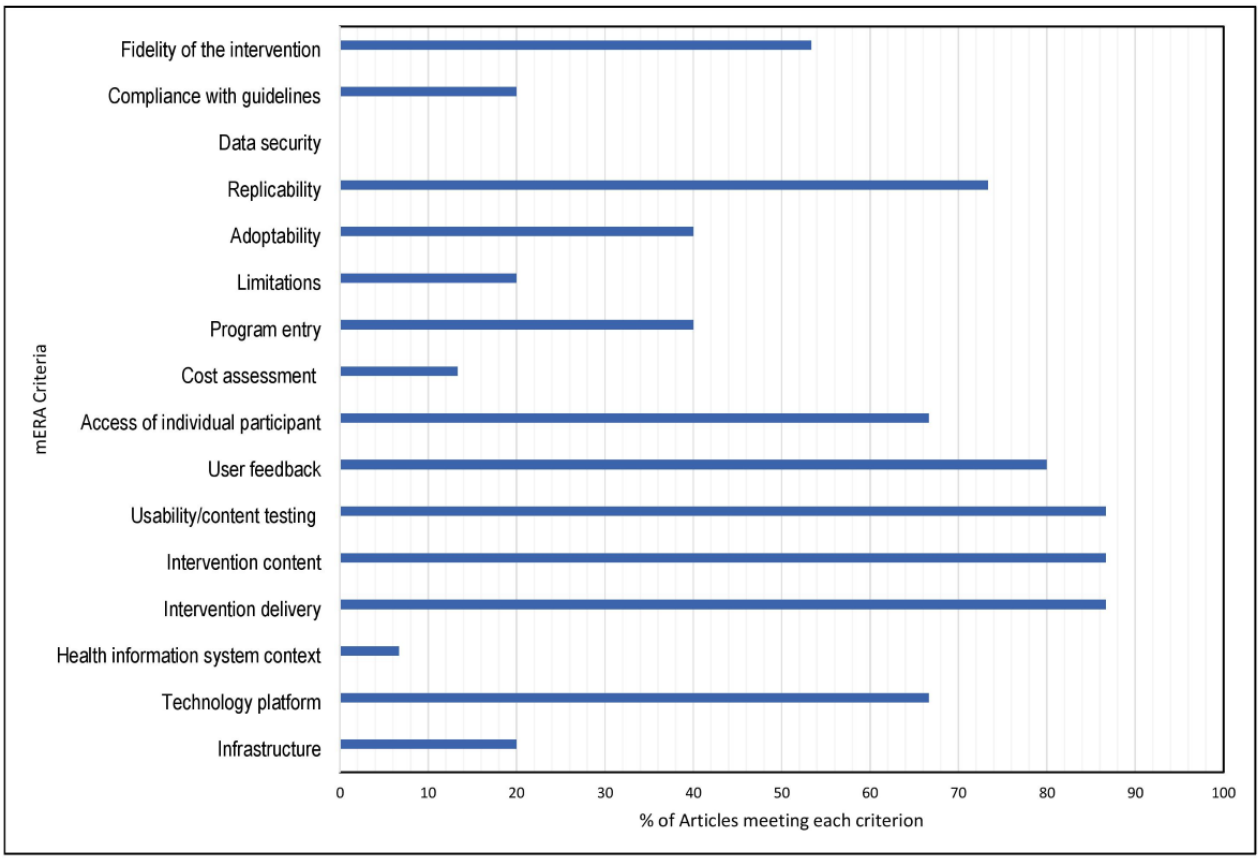
Health Promotion

A total of 3 smartphone interventions targeted health promotion in adolescent and pregnant women. It is evident that pregnant women who used a mobile app for prenatal education and engagement were more engaged than their control counterparts (pregnant women who used a notebook) [28]. Kenny et al [44] reported that the overall engagement was high in the health promotion program for adolescents.

Disease Prevention

Of the 15 studies, 2 aimed to reduce diseases' risk factors (ie, primary prevention) using smartphone apps; these studies focused on overweight participants and showed a reduction in weight and blood glucose levels [31,39].

Figure 2. The mHealth evidence and reporting assessment checklist. mERA: mHealth evidence and reporting assessment.



Illness Management

Heart failure, coronary heart disease, diabetes, and asthma were the main chronic diseases reported in the included papers [36-38,40,41,43]. In addition, we considered mobile-based education for mental illnesses such as bipolar disorder and depression as part of illness management [32,33,42]. Reviewed studies that focused on illness management (ie, secondary prevention) reported interventions on different aspects of education such as knowledge, self-management skills, and behavioral change interventions.

Structure of Interventions and Delivery Strategies

A total of 8 studies reported that their interventions were developed by the research team and health care professionals [31,33,36-38,40-42]. The educational materials covered by the smartphone apps were diverse and consisted of broad topics such as causes of diseases, monitoring signs and symptoms, exercise instructions, diet recommendations, and coping strategies. Random coping tips were provided to adolescents and covered "think positively" themes and emotional self-monitoring advice [44]. The most commonly used format of educational materials was text [28,32,33,36-40,44]. In addition, video clips [31,37,40,41,43] and audio files [30,36] were used in 7 studies. With regard to the knowledge assessment, 2 studies reported the assessment of patients' knowledge following the educational intervention [29,36]. In 1 study [36], authors developed a feature in the smartphone apps for users to assess their knowledge, and in another study authors used the diabetes knowledge survey [29] (Multimedia Appendix 3).

Theoretical Frameworks for the Development of the App

In total, 4 studies reported using a theory or a conceptual model to underpin the educational materials of smartphones apps [33,36,38,41]. Athilingam et al [36] used a number of theories, including Mayers' cognitive theory of multimedia learning, Swellers' cognitive load theory, industrial design approach utilizing a pedagogical agent and problem-based learning, for designing smartphone apps for patients with heart failure. Behavioral activation was used to develop apps for patients with depression [33]. Technology acceptance model and analysis, design, development, implementation, evaluation model were used in 2 studies [38,41].

Discussion

Principal Findings

This study reviewed 15 studies on innovative educational interventions using smartphone apps for participants with diverse conditions. Interventions that were identified in this review aimed to deliver educational materials through smartphones to promote health, prevent diseases, and manage chronic illnesses. The results of our review showed that mHealth interventions were mainly focused on the illness management of patients with chronic disease. Although we considered self-management as one of the key constructs of our search strategy, none of the studies included in this review formally assessed self-management as the primary outcome. However, behavioral change, as an indirect outcome of self-management, was assessed by a number of studies.

Although short message service were the most common format used to deliver educational materials through smartphones, 7 studies used audio or visual aids. The use of audio or visual format provides an additional means of communication for conveying educational information that may be difficult to communicate through words alone. Furthermore, audio or visual educational aids may increase patient understanding of a particular situation or specific procedure [2]. Yet, there remains limited knowledge on the best format of smartphone communication for patient education. As smartphone adoption is rapidly increasing, health care professionals should give more consideration to the development and evaluation of audio or visual materials for patient education.

The findings from the reviewed studies highlighted the fact that there is insufficient evidence to inform the underpinning theory or framework in the development of current smartphones apps. In many studies, the theoretical rationale for the development of apps and various components of the intervention, including educational materials, were not reported (Multimedia Appendix 2). The application of the theory is widely recognized as a crucial component of health interventions, and it is evidenced that strong theory is critical in identifying the effectiveness of specific components of interventions and optimizing their intensity [45]. However, the role of theory in developing mobile-based interventions with educational components has been largely disregarded.

Surprisingly, only 2 papers included in this review utilized measurement tools to assess participants' knowledge following their interventions. As patients can control their illness and limit worsening symptoms when they understand the principles of chronic disease management and learn to undertake simple interventions [46], the evaluation of educational interventions must be an integral part of practitioners plan for education. The assessment of knowledge completes a feedback loop, enabling health care professionals to determine the intervention's effectiveness. If the intervention did not have the intended effect, the content or delivery methods of the educational intervention may need to be modified to improve their effectiveness [47]. A previous systematic review identified patients' recall as an effective teaching strategy [23]. Hence, we recommend assessing patients' knowledge following an educational intervention.

As shown in Figure 2, an average of (42/100, 42.0%) of recommended essential criteria for reporting mHealth were met. Although most ethical organizations are now requiring researchers to provide reports on the details of steps taken for maintaining data security and confidentiality, no study has reported about it. Notably, only (3/15, 20%) of studies reported on the compliance of their interventions with national guidelines. It can be concluded that there is a lack of evidence to support the use of national guidelines or other authoritative sources of information for the development of mobile-based interventions for patient education. Nevertheless, the mERA checklist is relatively new; therefore, the low percentage of met criteria for reporting in several mHealth studies should not be surprising [34].

Of the 15 studies included in this review, 6 were RCTs that examined a range of health outcomes on patients with different conditions. The results of 4 RCTs showed statistically significant effects of smartphone-based interventions on health outcomes, including the patient engagement level, hemoglobin A_{1c}, weight loss, and depression. However, the 3-arm RCT evaluating the smartphone intervention for improving young adults' physical activity did not show statistically significant effect on cardiorespiratory fitness and physical activity level. Furthermore, a smartphone app based on the behavioral activation did not show a statistically significant reduction on major depression disorder.

Although the results of RCTs were mainly positive, studies varied significantly with regard to mHealth educational interventions. Furthermore, only one RCT reported the theoretical underpinning of the educational intervention, and this highlights the lack of theory in developing and evaluating mHealth interventions. As the reporting quality of reviewed studies was poor, it was impossible to compare the effects of interventions based on their educational interventions' structures and strategies.

Conclusions

The results of this review generally support that patients with diverse conditions benefit from mobile-based educational interventions. However, we were unable to identify any effective specific structure or strategy for the delivery of such interventions owing to the scarcity of high-quality studies and suboptimal reporting quality of the reviewed papers. Thus, additional research is needed to determine the optimal structure, format, and delivery methods for educational instructions that are used in mHealth interventions for patient education. We strongly recommend adoption of standard tools, such as mERA essential criteria, for reporting mHealth interventions. This will facilitate better reporting and improve the ability to synthesize the evidence in future.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Medical Subject Headings (MeSH) terms and free-text keywords used for the PubMed search.

[PDF File (Adobe PDF File), 465KB - mhealth_v6i10e10771_app1.pdf]

Multimedia Appendix 2

Characteristics of the included studies describing mobile apps for self-management education of chronic patients.

[PDF File (Adobe PDF File), 28KB - mhealth_v6i10e10771_app2.pdf]

Multimedia Appendix 3

Description of the interventions strategies for self-management.

[PDF File, 32KB - mhealth_v6i10e10771_app3.pdf]

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Abbreviations

mERA: mHealth evidence and reporting assessment
RCT: randomized controlled trial
SME: self-management education

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Original Paper

Design Rationale and Performance Evaluation of the Wavelet Health Wristband: Benchtop Validation of a Wrist-Worn Physiological Signal Recorder

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Abstract

Background: Wearable and connected health devices along with the recent advances in mobile and cloud computing provide a continuous, convenient-to-patient, and scalable way to collect personal health data remotely. The Wavelet Health platform and the Wavelet wristband have been developed to capture multiple physiological signals and to derive biometrics from these signals, including resting heart rate (HR), heart rate variability (HRV), and respiration rate (RR).

Objective: This study aimed to evaluate the accuracy of the biometric estimates and signal quality of the wristband.

Methods: Measurements collected from 35 subjects using the Wavelet wristband were compared with simultaneously recorded electrocardiogram and spirometry measurements.

Results: The HR, HRV SD of normal-to-normal intervals, HRV root mean square of successive differences, and RR estimates matched within 0.7 beats per minute (SD 0.9), 7 milliseconds (SD 10), 11 milliseconds (SD 12), and 1 breaths per minute (SD 1) mean absolute deviation of the reference measurements, respectively. The quality of the raw plethysmography signal collected by the wristband, as determined by the harmonic-to-noise ratio, was comparable with that obtained from measurements from a finger-clip plethysmography device.

Conclusions: The accuracy of the biometric estimates and high signal quality indicate that the wristband photoplethysmography device is suitable for performing pulse wave analysis and measuring vital signs.

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KEYWORDS

wearable electronic devices; vital signs; monitoring, ambulatory; photoplethysmography; benchmarking

Introduction

Wearable and Connected Devices in Digital Medicine

Wearable and connected health devices have been increasingly popular with the general population to track metrics related to their personal health and wellness such as vital signs, activity, and sleep [1]; a purchase of over 300 million wearable devices was reported in 2017 worldwide [2]. Not surprisingly, wearables have recently been adopted by clinical researchers to paint the most complete picture of patients' health and well-being by offering continuous, long-term, and multiparametric monitoring [3]. Leveraging mobile, wearable and connected devices, and cloud computing and machine learning algorithms, the modern era of health care—known as digital health—promises new and better ways to screen, diagnose, manage, and treat patients, thereby improving health-related outcomes and decreasing the

cost of health care delivery. It is well known that measuring health is the key to (1) improve screening and preventative methods; (2) optimize disease management, drug titration, and adherence to therapy; and (3) prevent hospitalization and reduce adverse events. Wearable and connected devices offer a promising solution to streamline health data collection needs and address the lacking personalized oversight in the current health system.

Clinical research organizations and pharmaceutical companies have already started embracing digital health. Recently, several large-scale research initiatives involving parties across government agencies, health institutions, and private technology and pharmaceutical companies [4-6] have announced collecting biological, psychological, and social signals and biometrics derived from these signals in longitudinal studies to understand underlying risk factors leading to disease and hospitalizations. There is also a growing interest in the pharma community to use mobile, wearable, and connected health technologies to improve the operational efficiency during the product development cycle and to accelerate bench-to-bedside translational science. Digital operational efficiency here refers to the use of digital health to increase patient adherence, trial data collection speed, and efficiency, thereby reducing the time and cost to market. Electronic patient-reported outcomes and remote patient monitoring are good examples of how digital health has been transforming the operational workflow of biopharma and clinical research organizations [7]. Digital biomarker development has also been a key application of digital health in the biopharma and clinical research spaces for developing new end points that have not previously been possible to assess or existing end points that can be measured in new and possibly better ways [8]. Recently, Green et al have reported a digital biomarker for detecting patients with obstructive hypertrophic cardiomyopathy using signals collected from a wrist-worn wearable device and machine learning algorithms [9]. Other example applications in therapeutic areas including atrial fibrillation and obstructive sleep apnea [10-12] can potentially be used for evaluating the safety and efficacy of the drugs and interventions; for screening and referring patients who can benefit from lifesaving therapies; and as a companion tool for dose titration, decision support, and disease management. In summary, wearable and connected device technologies are evolving rapidly and may soon become the new standard in health monitoring to improve and accelerate the way drugs are developed, new therapies are identified, and patients are cared for.

The new era of personalized digital medicine requires devices that are convenient and engaging to the patient and have validated accuracy to enable a streamlined collection of biosignals and clinically meaningful health metrics. Many of the currently available remote monitoring options, including electrocardiography (ECG)-based Holter devices, event recorders, or mobile cardiac telemetry devices, require frequent replacements to extend their utility beyond 7 to 14 days and often cause discomfort to the patient or complications because of their intrusive nature. There is consensus on neither the benefit of continuous monitoring with implantable loop recorders on patient outcomes nor on whether these invasive devices are suitable for large-scale population-level disease surveillance and health screening. Advances in semiconductor and sensory technologies, in particular, the wide adoption of near-infrared (IR) light spectroscopy or photoplethysmography (PPG) in consumer health and clinical applications, along with mobile and cloud computing technology have generated a new class of wearable devices for health data collection and monitoring. Leveraging sophisticated signal processing algorithms such noninvasive devices allow near-real-time, continuous, and long-term monitoring of several key physiological parameters including heart rate (HR), heart rate variability (HRV), and respiration rate (RR) [13]. This study focuses on the performance evaluation of such a wrist-worn PPG device (Wavelet wristband, Wavelet Health, Mountain View, USA) and its data collection platform, which is shown in Figure 1.

Figure 1. The data collection platform comprises wearable and connected devices that use low energy Bluetooth technology to communicate with the mobile and computer tablet software apps to collect and transmit raw sensor data and cloud servers; algorithms; and a Web interface to analyze, store, and access data.

Measuring Health: Vital Signs

Measurement of vital signs enables detection and monitoring of a number of conditions and diseases. Continuous HR monitoring is critical to the management of cardiovascular disease as elevated HR is an independent predictor of cardiovascular events, mortality, and hospitalization for worsening heart failure [14,15]. HRV is another clinically important metric often regarded as a measure of neurocardiac function and homeostasis [16]. Fluctuations in beat-to-beat timing arise from the interaction of different physiological systems including the heart, brain, and autonomic nervous system in healthy and diseased states. Although the study of HRV has been a topic of active research for over two decades [17,18], there are still inconsistencies in the literature probably because of methodological differences between studies [19-21]. Several investigators found that relatively high resting HRV is indicative of a healthy, resilient, and responsive nervous system regulating the heart's activity, whereas reduced HRV is associated with unbalanced, sympathetic, and parasympathetic activity negatively affecting cognitive performance [22], physical training capacity [23], congestive heart failure [24,25], multiple sclerosis [26], Guillain-Barre syndrome [27], and diabetic neuropathy [28]. In contrast, other studies suggest a lack of a clear correlation between HRV and other biological and lifestyle factors [19,29,30].

RR, an often overlooked vital sign, enables early detection of life-threatening diseases, such as sleep apnea [31], pneumonia [32], sudden infant death syndrome [33,34], or chronic obstructive pulmonary disease [35]. As abnormal RR is predictive of a future critical illness [36,37], continuous monitoring would provide clinicians with a real-time indicator of their patients' health. Current methods for measuring RR include manually counting chest movements, estimated RR from ECG patch devices, a spirometer, and capnography monitors [38]. These methods do not allow long-term continuous monitoring because of the need for manual supervision, cost, or discomfort to the patient. Alternatively, RR can be estimated from PPG devices by leveraging 3 signal processing methods: baseline wander, amplitude modulation, and frequency modulation—each stem from 3 main physiological mechanisms: changes in tissue blood volume, stroke volume, and respiratory sinus arrhythmia, respectively, caused by intrathoracic pressure changes during respiration [39-41]. Several PPG-based RR algorithms have been reported in the literature with variable levels of accuracy, that is, mean error of approximately 1 to 6 breaths per minute (brpm), depending on which combination of signal processing methods is incorporated in the algorithm formulation [42,43]. Birrenkott et al demonstrated the importance of establishing proper signal qualification methods to achieve accurate RR estimations from PPG signal [44]. In this study, we present the validation of a PPG-based RR estimation algorithm that combines the frequency modulation and baseline wander methods along with threshold-based respiratory signal qualification.

It is worthwhile to mention that unlike ECG devices, PPG technology does not measure the electrical activity of the heart but measures the changes in pulse volume. Therefore, the interbeat intervals of the PPG can deviate from RR intervals of the ECG, particularly during physical activity and some mental stressors [45] and in patients with peripheral arterial disease and structural heart problems [29]. However, as the standard of care for monitoring of vital signs requires continuous long-term measurements of HR and HRV rather than pulse rate and pulse rate variability, this study evaluates the performance of the Wavelet wristband to estimate HR and HRV in healthy subjects at the resting state.

Objective

The aim of the study was to evaluate the accuracy of resting HR, HRV, and RR estimates of the Wavelet wristband and to benchmark its performance as a wrist-worn PPG device compared with gold standard reference devices. In addition, the signal quality of the Wavelet wristband is compared with a reference device.

Methods

Wristband Technology

The core technology of the Wavelet wristband relies on PPG, that is, an optical technique for detecting blood volume changes within the microvascular bed to estimate physiological parameters [46]. PPG has been used since the early 1960s, particularly for pulse oximetry, which is the standard-of-care tool for measuring peripheral arterial oxygen saturation (SpO_2) [47]. By positioning a light sensor and a light-emitting diode (LED) on the same plane, that is, the reflectance-type sensor configuration, wrist-worn PPG devices can perform measurements from the skin surface [48]. Light emitted by the LEDs into the wrist is mostly absorbed by the underlying tissue. The reflected light is captured by a photodiode, which is sampled many times within a second to construct the PPG signal. The absorption of light varies with the changes in pulsatile arterial blood flow and generates a time-varying pulse waveform [47]. This signal can be recorded, transmitted, and used as a noninvasive longitudinal measurement of the underlying blood volume changes. Due to its good tissue penetration characteristics [49], PPG devices often rely on IR light for estimating the relative volumetric changes in the microvascular bed because of pulsatile blood flow. Using the IR signal, several biometrics including arterial pulsatility, HR, HRV, RR, and vascular tone along with others related to the cardiovascular and autonomic nervous systems can be computed noninvasively [13]. When paired with the IR signal, the red light signal enables estimating SpO_2, which is known as pulse oximetry.

Figure 2. The Wavelet wristband is a configurable photoplethysmography and motion sensing device placed on the wrist to collect pulse wave signal, estimate vital signs, and physical activity. The sensor carriage can be removed from the plastic band.

During the measurement, the wristband is placed snugly on the arm above the wrist bone. The wristband comes with a removable sensor carriage and a plastic band as shown in Figure 2. The sensor carriage contains LEDs of 2 wavelengths and an optical sensor along with a battery and an inductive charging coil. The LEDs fire at a rate configurable between 20 and 95 Hz driven by a submillisecond resolution low-jitter external clock signal. A fully integrated analog front end receives and digitizes PPG signals. In addition, the wristband is capable of collecting inertial motion data using the 3-axis accelerometer and 3-axis gyroscope built into the sensor carriage. The sampling rate and duty cycle of the light and motion sensors are configurable. For this validation study, light sensor data were collected at 86 Hz and the motion data were collected at 10 Hz. Raw PPG and motion signal data collected from the wrist were transferred by the mobile app to the cloud server, where it is processed by signal processing and machine learning algorithms.

The general workflow of the algorithms developed for the extraction of HR, HRV, and RR from the PPG signals collected from the wrist is summarized below:

1. Segments of the PPG signal containing artifacts related to wrist movement are removed.
2. The PPG signal is segmented into heartbeats:
   - Peaks are detected in the PPG signal using a wavelet transform–based peak detection algorithm [50].
   - Peaks representing systolic onsets of beats are selected from this list of peaks by time and frequency domain heuristics. The location of the peaks is refined using interpolation techniques to improve the signal time resolution.
   - Beats are extracted from the PPG signal by taking segments from one systolic onset to the next and performing additional qualification.
3. From each heartbeat, HR and a number of other morphological features are extracted [51,52].
4. RR is measured by a combination of analyses of baseline wander and frequency modulation [41]:
   - In the time domain, inspiration and expiration are detected by a wavelet transform–based peak detection algorithm [52].
   - In the frequency domain, HR modulation because of respiration is measured by tracing the respiration ridge in the continuous wavelet transform of the HR signal [53].
5. HRV is estimated using the standard deviation (SD) of the normal-to-normal (SDNN) interbeat intervals and also the root mean square of the successive differences (RMSSD) between adjacent interbeat intervals over the course of the signal [54].

The beat segmentation approach enables the output of processed metrics on a beat-to-beat level, which is exemplified in the results section.

Study Design

Healthy subjects (n=35) with no known cardiovascular conditions were recruited for the validation study. Participants were asked to determine their skin type using the Fitzpatrick questionnaire [55] and provided their height, weight, age, and gender. Before each test, subjects rested in a seated position for 15 min to ensure the measurement of the resting HR [56]. Demographics of the participants are summarized in Table 1. The study was approved by the institutional review board of San Jose State University. Written informed consent was obtained from all subjects.

The parameters estimated by the wristband were compared with the simultaneously recorded gold standard measurements from the ECG and spirometry sensors. For these measurements, a

BIOPAC MP36 system (BIOPAC, Goleta, CA, USA) was set up to acquire ECG and spirometry data. ECG (LEAD110A and ECG100C, BIOPAC, Goleta, CA, USA) was acquired at a rate of 2000 Hz while the subject was at rest in a seated position. Spirometry data were acquired simultaneously and at the same rate using a handheld airflow transducer (SS11LA, BIOPAC, Goleta, CA, USA) connected to the BIOPAC system. Subjects were instructed to breathe through a mouthpiece while wearing a nose clip. Before the measurements, the ECG sensor was calibrated as per the manufacturer's instructions [57]. No digital filtering was applied to the raw ECG and airflow data. Raw data were exported and analyzed to obtain HR and other metrics. A Nonin finger-clip pulse oximeter (8000 AA, Nonin, Plymouth, USA) was placed on the subject's right index finger to compare the quality of the PPG signal recordings of the Wavelet wristband with a typical clinical grade finger-clip PPG device. For each test, 2 wristbands were placed on each participant, 1 on each wrist. Each test lasted between 2 and 4 min. For several subjects (n=12), the test was halted before the 3-min mark because of discomfort while breathing into the spirometer. Each subject repeated the test twice with 5 min rest in between. Overall, 70 tests were conducted each with 2 wristbands and reference ECG, spirometer, and finger-clip pulse oximeter device recordings. The synchronous recordings from ECG, Nonin, and Wavelet wristband devices were aligned manually based on time stamps and agreement of interbeat intervals, although a small misalignment was inevitable because of the lacking information on the pulse transit time.

Signal Quality Analysis and Statistical Methods

Once each test session is recorded by the wristband and transferred to the cloud server, the algorithms described above calculate the beat-to-beat metrics. For the analysis, we separated each signal into 60-second nonoverlapping measurements and calculated HR, HRV, and RR for each of these windows to compare with HR, HRV, and RR of corresponding windows of the ECG signal. As PPG signals are inherently sensitive to motion and light artifacts, the biometrics algorithm evaluates each beat's signal quality based on multiple heuristics including short-time Fourier transform, motion, and correlation with other beats. If not enough good-quality beats are found in the signal, the algorithm may not output some of the biometrics for a particular 60-second window. In this study, each qualified biometric assessment over a 60-second window was referred to as a valid measurement. Left and right wrists' recordings were analyzed independently. The total number of valid sessions and the valid measurements qualified by the algorithm for each biometric are provided in the Results section.

To evaluate the signal quality of the Wavelet wristband, the harmonic-to-noise ratio (HNR) computed from the IR signal of the wristband was compared with that of the Nonin finger-clip pulse oximeter. HNR is calculated using the autocorrelation method described by Boersma et al [58]. This frequency-based signal quality assessment method yields an objective measure of the periodicity of the PPG signal from the maximum frequency of the signal's normalized autocorrelation function [58]. The HNR is computed for 6-second overlapping windows centered 1 second apart. The average of all HNR windows is reported as the HNR of the 60-second recording. Recordings that fail to meet a threshold HNR level do not qualify for vital sign analysis. It is important to note that the HNR criterion assumes that all signals other than the signal of interest are noise. Therefore, to estimate HNR of the PPG signal accurately, a preprocessing step removes other physiological contributions to the signal such as respiration. The HNR reported herein follows the cardiovascular component of PPG signal after using a bandpass filter with lower and upper limits set to 0.3 Hz and 10 Hz, respectively.

To compare the HNR of the Wavelet wristband with the finger-clip pulse oximeter, we present the mean and SD of HNR for both devices for each valid measurement as well as box plots to compare distributions. The reference HR and HRV were computed from the reference ECG measurements using the Python BioSPPy biosignal processing toolbox [59], and Python is used for all statistical analysis. Ectopic and other non-normal beats were detected by a median absolute deviation–based outlier detection method and removed without replacement. An interbeat interval is considered an outlier if its logarithm is more than 6.25 median absolute deviations away from the median logarithm of interbeat intervals in the full recording. The use of logarithm and the threshold are determined from the visual inspection of the interbeat interval distribution. To compare the biometric estimates by the wristband with those measured in the same time window by the ECG and spirometer, Pearson correlation coefficients along with Bland-Altman plots and Bland-Altman limits of agreement are presented [60]. The Bland-Altman limits of agreement took into account multiple observations collected over time from the same set of individuals using 2 reference devices [61]. The effect of the averaging window size on the accuracy of HR estimates and the variation in biometric measurements collected from the left versus right wrists were also evaluated.

Results

Participant Demographics

Study participant demographics are summarized in Table 1. The average and SD of height, weight, and age were 172 cm (SD 10), 74 kg (SD 18), and 25 years (SD 4), respectively. The Fitzpatrick score indicates a good coverage of light, medium, and dark skin tones, with a slight skew to the darker pigmentation range.

Photoplethysmography Signal Qualification

The PPG signals obtained from the Wavelet wristband have a physiological morphology similar to those collected from the Nonin finger-clip device, as shown in Figure 3. Compared with the reference finger-clip PPG measurements, the diastolic peak is located closer to the systolic peak and the diastolic decay is steeper, in agreement with the earlier studies comparing different measurement sites of PPG [62] and arterial pressure [63]. Figure 4 shows the continuous HR estimate of the Wavelet wristband, indicating strong agreement across right and left wrists and with the reference ECG device.

Table 1. Participant demographics (N=35).

Characteristics	Value
Height (cm), mean (SD)	172 (10)
Weight (kg), mean (SD)	74 (18)
Age (years), mean (SD)	25 (4)
Gender (female), n (%)	16 (46)
Fitzpatrick score[a], n (%)	
Type I	2 (6)
Type II	6 (17)
Type III	12 (34)
Type IV	14 (40)
Type V	1 (3)

[a]Self-reported Fitzpatrick scores classify subjects' skin tones as follows: type I, pale white; type II, white; type III, cream white; type IV, moderate brown; and type V, dark brown.

Figure 3. Signal traces recorded simultaneously from electrocardiography (ECG), Nonin finger-clip pulse oximetry device, and 2 Wavelet wristbands placed on the left and right wrists. Peaks (ECG and Nonin) or valleys (Wavelet) are marked. Signs were aligned based on time stamps and agreement of interbeat intervals in the absence of accurate pulse transit time information.

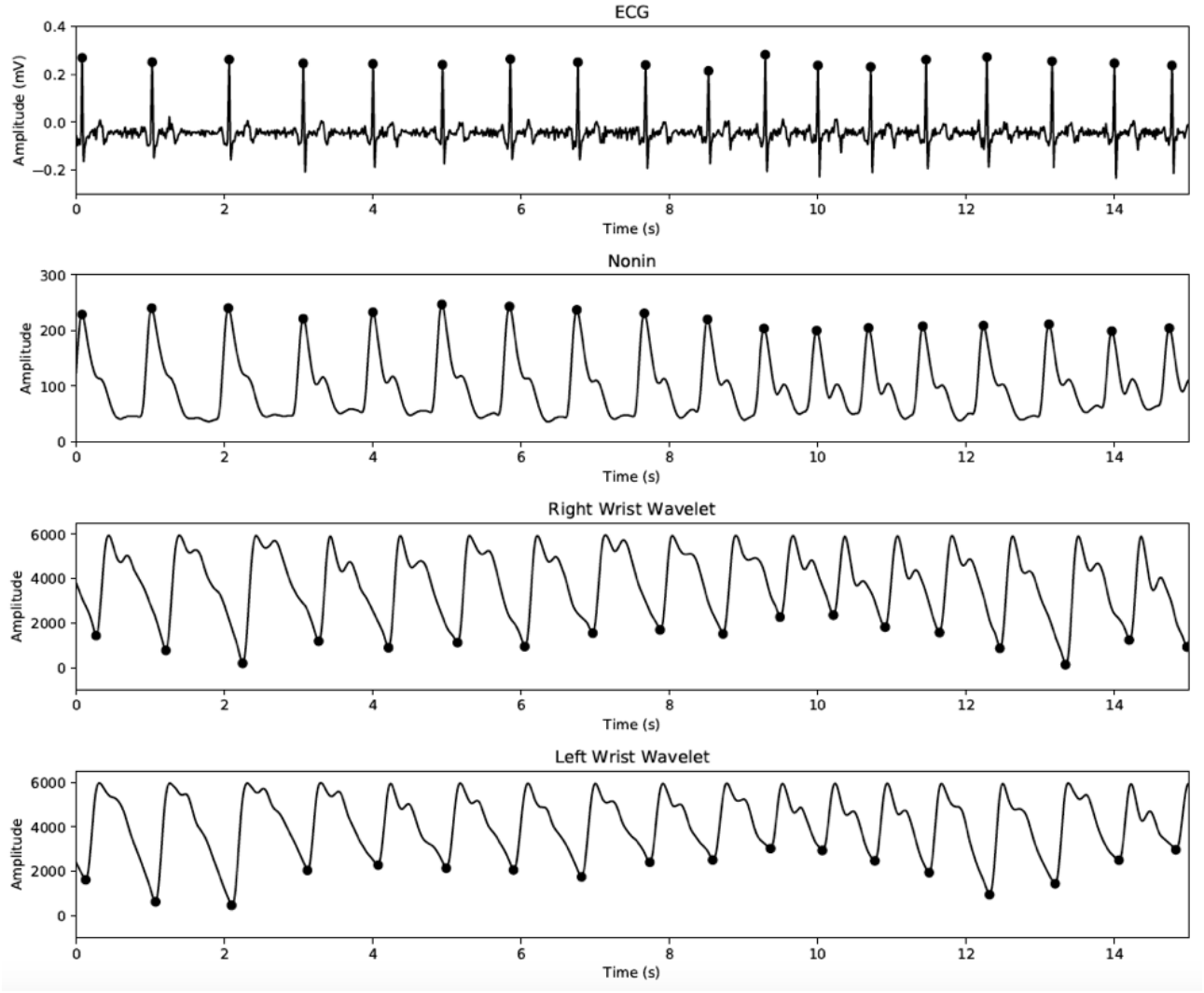
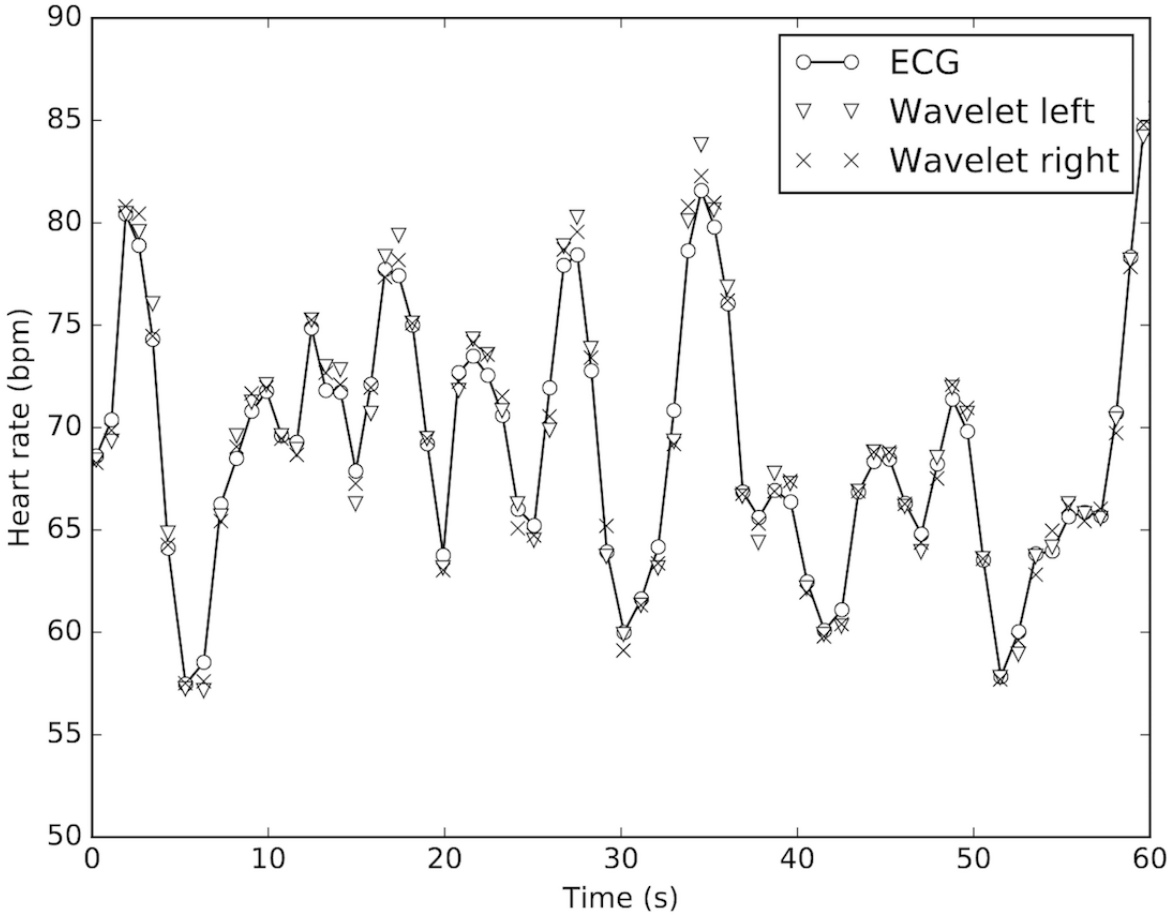


Figure 4. Representative instantaneous heart rate (HR) estimates from the wristbands on the left and right wrists show good agreement with the electrocardiography (ECG) HR measurements. Note that the beat-level HR data are computed in the background to estimate 60-second window HR averages reported in this study. Wavelet 1 and 2 labels refer to the wristband placed on the left and right wrists, respectively.



To assess the quality of the signal at each LED wavelength, average HNR values for each 60-second nonoverlapping window were computed for signals collected by the Nonin finger-clip PPG device and the wristband. Table 2 shows the mean (SD) of HNR as 7.7 (SD 2.0), 6.4 (SD 2.2), and 4.7 (SD 2.7) for Nonin IR, Wavelet IR, and Wavelet red, respectively. The distribution of HNR for each group is illustrated in Figure 5 using boxplots. Note that not all Wavelet wristband recordings had a corresponding Nonin recording available because of equipment availability on the test day. The difference histogram in Figure 5 illustrates the pairwise mean difference (with 1 SD) between the wristband IR HNR and Nonin HNR as −1.34 (SD 2.75) dB. Thus, the wristband IR HNR is slightly lower than that of the finger-clip sensor.

In this study, a total of 366 min of PPG signal recordings were collected from 35 subjects. Approximately 12.0 % (44/366) of the PPG recordings were flagged invalid because of subtle arm motions during the test. In addition, 74 measurements from 23 test sessions failed to meet the desired HNR level and did not qualify to vital sign analysis. The signal processing algorithm generated valid HR, HRV SDNN, HRV RMSSD, and RR measurements for 78.9% (254/322), 76.7% (247/322), 77.3% (249/322), and 39.8% (128/322) of the signals, respectively. Importantly, the signal quality preprocessing step disqualified all readings from 2 type II and 1 type I subjects. Furthermore, it was later found that for 1 subject, the ECG probe was dislocated; therefore, no valid ECG reference data were collected. The number of valid vital sign measurements for which the corresponding reference data exist is shown in Table 3.

Heart Rate Validation

Table 3 shows the mean absolute error and mean absolute percentage error of the HR, HRV, and RR estimates of the Wavelet wristband compared with the reference devices. Across 254 measurements of 60-second nonoverlapping windows, the mean pairwise absolute error of HR was 0.7 beats per minutes or bpm (SD 0.9; 0.9%, SD 1.3) against the reference ECG. Figure 6 shows the distribution of ECG and Wavelet HR estimates with scatter and Bland-Altman plots. The Pearson correlation coefficient (R) of HR between wristband estimates and reference ECG measurements was .994, and the mean difference (bias) between Wavelet and ECG HR (with 95% CI) was −0.32 bpm (SD 0.13). All measurements stay within 5% absolute percent error, except one outlier for which the Wavelet wristband underestimated the HR by 7% (6.8 bpm). The Bland-Altman ratio, that is, the ratio of 1.96 x SD divided by the mean of the pairwise measurement means, is equal to 0.03, which indicates good agreement between measurements [60].

Table 2. The mean and SD of the average harmonic-to-noise ratio for the photoplethysmography recordings collected from the Wavelet wristband and reference Nonin finger-clip pulse oximeter.

Photoplethysmography signals	Valid sample size[a]		Mean HNR[b] (SD)
	Measurements, n	Subjects, n	
Nonin IR[c] (dB)	216	28	7.7 (2.0)
Wavelet IR (dB)	266	33	6.4 (2.2)
Wavelet red (dB)	266	33	4.7 (2.7)

[a]Valid sample size: the number of measurements and subjects that were eligible for signal quality analysis.

[b]HNR: harmonic-to-noise ratio.

[c]IR: infrared.

Figure 5. Boxplot comparison (left) of average harmonic-to-noise ratio (HNR) estimated over 60-second nonoverlapping windows for each photoplethysmography wavelength: Nonin finger-clip pulse oximeter (Nonin IR), the wristband infrared (Wavelet IR), and the wristband red (Wavelet red). The histogram for pairwise difference of average HNR between Wavelet IR and Nonin IR signals (right). IR: infrared.

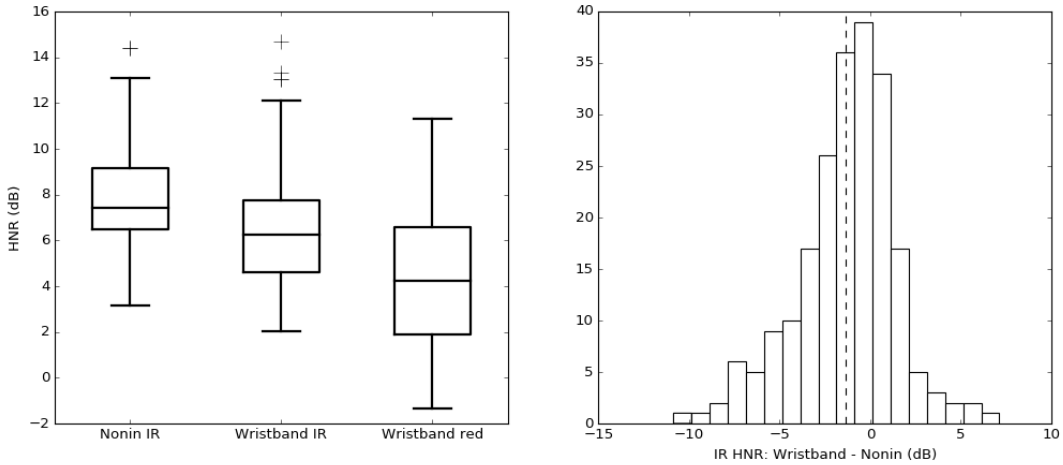


Table 3. The accuracy of the biometric estimates (mean, SD) of the Wavelet wristband compared with the reference electrocardiography and respirometer measurements.

Measurement	Valid sample size[a]		Mean absolute error (SD)	Mean absolute percentage error (SD)	Mean error (SD)	Pearson correlation
	Measurements, n	Subjects, n				
HR[b] (bpm[c])	254	31	0.7 (0.9)	0.9 (1.3)	−0.3 (1.1)	.994
HRV SDNN[d] (ms)	247	31	7 (10)	11 (13)	−1 (12)	.907
HRV RMSSD[e] (ms)	249	31	11 (12)	28 (30)	3 (16)	.924
RR[f] (brpm[g])	128	26	1 (1)	2.5 (2.5)	1 (2)	.863

[a]Valid sample size refers to the number of measurements and subjects where both valid wristband and reference data were available.

[b]HR: heart rate.

[c]bpm: beats per minute.

[d]HRV SDNN: heart rate variability standard deviation of normal-to-normal intervals.

[e]HRV RMSSD: heart rate variability root mean square of successive differences.

[f]RR: respiratory rate.

[g]brpm: breaths per minute.

Figure 6. The distribution of measured heart rate (HR) by the electrocardiography (ECG) and the wristband (left). The Pearson correlation coefficient is shown in the lower-right corner of this scatter plot. Bland-Altman plots of the absolute error of HR between the wristband and the simultaneously recorded ECG measurements versus the mean of the measurements in beats per minute (right). The solid black line indicates the mean difference. The dotted lines mark the 95% limits of agreement (LoA) at −2.6 and 1.9 bpm.

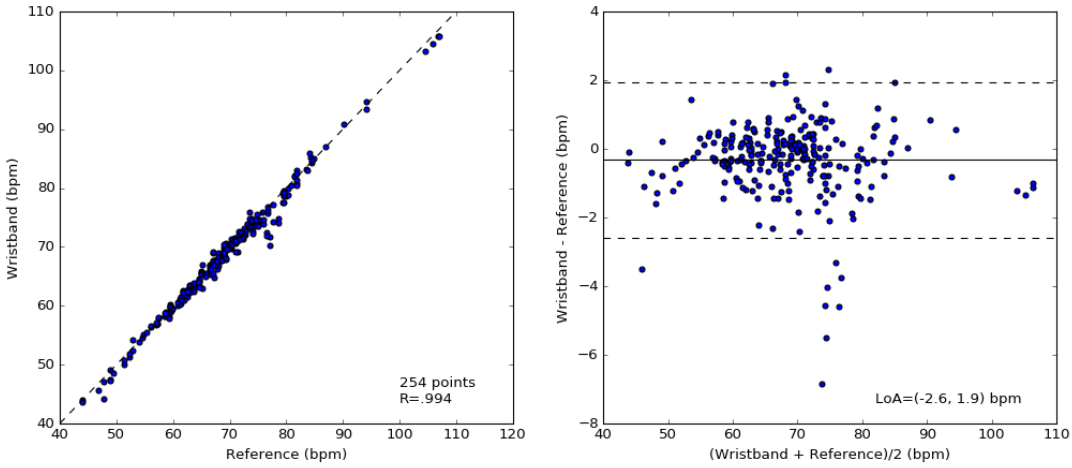
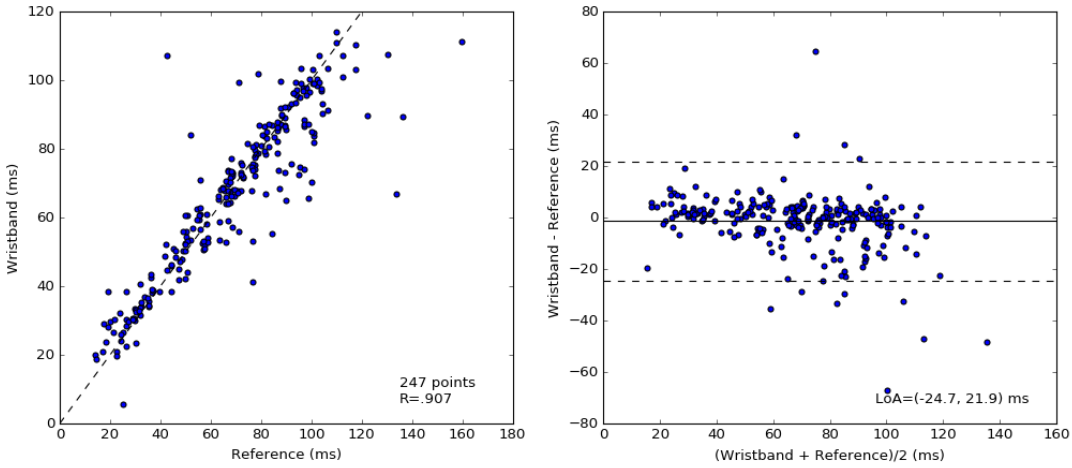


Figure 7. The distribution of measured heart rate variability standard deviation of normal-to-normal intervals (HRV SDNN) by the electrocardiography (ECG) and the wristband (left). The Pearson correlation coefficient is shown in the lower-right corner of this scatter plot. Bland-Altman plots of the absolute error of HRV between the wristband and the simultaneously recorded ECG measurements versus the mean of the measurements in milliseconds (right). The solid black line indicates the mean difference. The dotted lines mark the 95% limits of agreement (LoA) at −25 and 22 ms.



Heart Rate Variability

The SDNN and RMSSD HRV are computed over 60-second nonoverlapping windows for ECG and Wavelet wristband recordings. The mean absolute errors for SDNN and RMSSD were estimated as 7 ms (SD 10; 11%, SD 13) and 11 ms (SD 12; 28%, SD 30), respectively, as shown in Table 3. The mean difference (with 1 SD) between Wavelet and ECG-based SDNN and RMSSD was −1 ms (SD 12) and 3 ms (SD 16), respectively. The relationship between the Wavelet SDNN HRV estimates to the ECG is visualized with scatter plots as well as with Bland-Altman plots (Figures 7 and 8). Pearson correlation coefficients for HRV SDNN and RMSSD were estimated as .907 and .924, respectively. The Bland-Altman ratios for HRV SDNN and RMSSD were 0.35 and 0.42, which indicate strong correlation between the wristband HRV estimates and the reference measurements. Relatively lower correlation for RMSSD estimates is attributed to the outliers at the high RMSSD range (>150 ms).

Respiration Rate

Figure 9 shows the comparison of the RR estimates of the wristband with the reference spirometry measurements. The Pearson correlation coefficient was .863, and the mean difference (bias with 1 SD) between Wavelet and spirometer RR was 1 brpm (SD 2). The pairwise mean absolute error is 1 brpm (SD 1; 2.5%, SD 2.5) as shown in Table 3.

To assess the agreement between the HR and HRV computed by a Wavelet wristband on the left and right wrists, the mean absolute error is computed for subjects where both valid simultaneous left and right wrists' readings are available (n=23). Table 4 shows that the mean absolute difference between the right and left wrists' measurements was 0.6 bpm (SD 0.8), 6 ms (SD 10), 9 ms (SD 10), and 1 brpm (SD 2) for HR, HRV SDNN, HRV RMSSD, and RR, respectively.

Figure 8. The distribution of measured heart rate variability root mean square of successive differences (HRV RMSSD) by the electrocardiography (ECG) and the wristband (left). The Pearson correlation coefficient is shown in the lower-right corner of this scatter plot. Bland-Altman plots of the absolute error of HRV between the wristband and the simultaneously recorded ECG measurements versus the mean of the measurements in milliseconds (right). The solid black line indicates the mean difference. The dotted lines mark the 95% limit of agreement (LoA) at −30 and 36 ms.

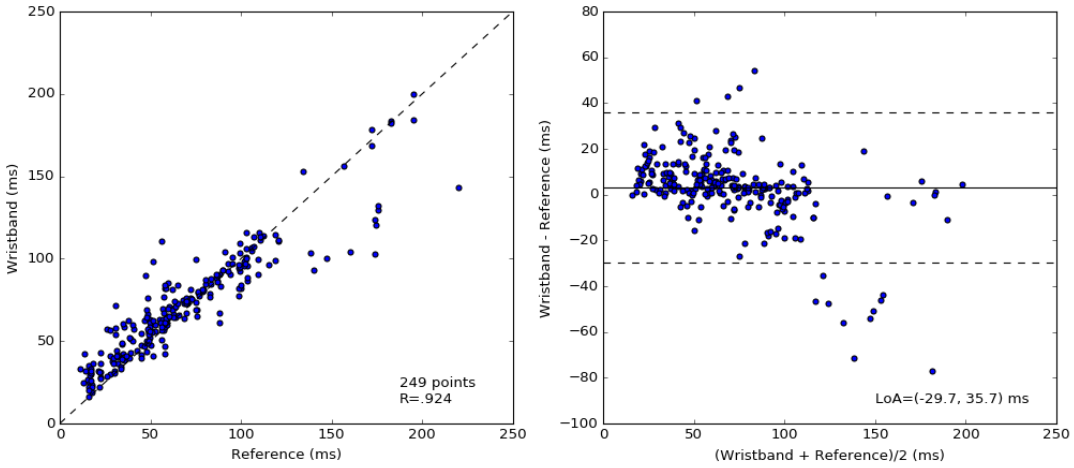
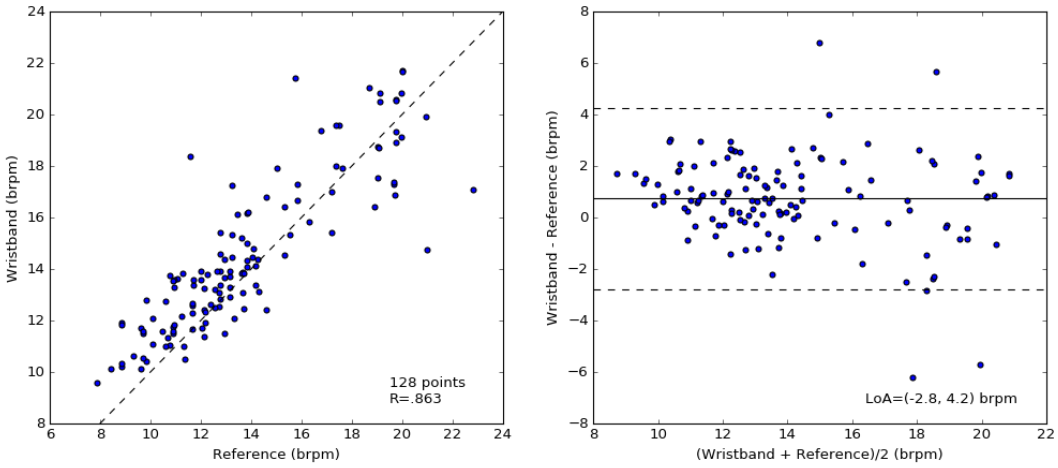


Figure 9. The distribution of measured respiration rate (RR) by spirometer and the wristband (left). Each data point represents the average RR over a 60-second nonoverlapping measurement window. Bland-Altman plots of the absolute error of RR between the wristband and the simultaneously recorded control measurements versus the mean of the measurements in breaths per minute (right). The solid black line indicates the mean difference. The dotted lines mark the 95% limit of agreement (LoA) at −3 and 4 brpm.



Influence of Recording Window Duration on Biometric Estimation Accuracy

For certain use cases, the estimation of biometrics over durations shorter than 60 seconds may be desirable. To assess the accuracy of the biometric estimations over shorter recording durations, the absolute error and absolute percentage errors from the reference were computed by reanalyzing the test and reference signals over 45 and 30 seconds long windows. Results shown in Table 5 indicate that the mean absolute error in HR remains stable, that is, within 1 bpm, as the recording duration shortens from 60 to 30 seconds. Similarly, mean absolute error in HRV RMSSD estimates remained at 12 ms without displaying dependence on recording duration. However, the mean absolute error of SDNN was influenced by the recording duration. For 30-second recording duration, mean absolute error for RR estimations increased to 2 brpm (SD 2).

Table 4. The pairwise mean absolute difference between the left and right wristbands.

Measure	Valid sample size[a] (pairs)		Mean absolute difference (SD)
	Measurements, n	Subjects, n	
HR[b] (bpm[c])	108	23	0.6 (0.8)
HRV SDNN[d] (ms)	102	23	6 (10)
HRV RMSSD[e] (ms)	101	23	9 (10)
RR[f] (brpm[g])	48	23	1 (2)

[a]Valid sample size refers to the number of measurements and subjects where two wristband recordings (pairs) from the same subject were available.

[b]HR: heart rate.

[c]bpm: beats per minute.

[d]HRV SDNN: heart rate variability standard deviation of normal-to-normal intervals.

[e]HRV RMSSD: heart rate variability root mean square of successive differences.

[f]RR: respiratory rate.

[g]brpm: breaths per minute.

Table 5. Mean absolute error and SD of biometrics estimations from reference measurements at different recording window durations.

Recording window duration	HR[a] (bpm[b])		HRV SDNN[c] (ms)		HRV RMSSD[d] (ms)		RR[e] (brpm[f])	
	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n
60 (s)	0.7 (0.9)	254	7 (10)	247	11 (12)	249	1 (1)	128
45 (s)	0.8 (1.0)	381	7 (11)	361	11 (13)	364	1 (1)	163
30 (s)	1.0 (1.4)	559	8 (12)	516	11 (14)	520	2 (2)	218

[a]HR: heart rate.

[b]bpm: beats per minute.

[c]HRV SDNN: heart rate variability standard deviation of normal-to-normal intervals.

[d]HRV RMSSD: heart rate variability root mean square of successive differences.

[e]RR: respiratory rate.

[f]brpm: breaths per minute.

Discussion

Principal Findings

To access the clinical utility of wearable health devices, it is imperative to validate the accuracy of the metrics derived by these devices against gold standard measures and, importantly, to characterize their limitations. In this study, we evaluated the performance of the Wavelet wristband by comparing the accuracy of the estimated biometrics with the ground truth references. The mean absolute error of HR, HRV SDNN, HRV RMSSD, and RR was 0.7 bpm (SD 0.9), 7 ms (SD 10), 11 ms (SD 12), and 1 brpm (SD 1), respectively. Bland-Altman graphs demonstrate good agreement between the wristband biometric estimates with the reference measurements. These results indicate that the Wavelet wristband can estimate multiple vital signs in the resting state and provide a continuous noninvasive health monitoring solution as an alternative to other devices typically incorporating ECG.

To our knowledge, this study is the first of its kind exploring the PPG signal quality collected by a wrist-worn reflective PPG device as compared with more traditional devices placed on measurement sites such as the finger, where the subcutaneous tissue is perfused more strongly with dense microvasculature. Previously, several investigators reported accurate estimation of vital signs using PPG signal collected from the finger in comparison with ECG in healthy [64-68] and disease settings [69-71]. Investigations by Maeda et al [62] showed that relatively high signal strength can be obtained from the wrist but lacked signal-to-noise ratio assessments, which are essential for estimating accurate biometrics. In this study, we suggest HNR can be used to characterize PPG signal quality collected from different measurement locations, benchmark PPG devices, and aid in establishing signal quality standards in PPG research. Comparable HNR of the Wavelet wristband and Nonin finger-clip pulse oximeter devices indicates that good quality PPG signal can be collected from the wrist.

Strengths and Limitations

Although both PPG and ECG signals convey physiological information, the underlying physiology of PPG stems primarily from hemodynamics rather than the electrical activity of the heart depicted in the ECG signal. The well-defined morphology of the ECG signal allows relatively simple extraction of beat-to-beat intervals in the absence of artifacts related to drift, electromagnetic, and biological interferences [66]. In contrast, PPG signal hosts inherently more rounded peaks and valleys and therefore requires more sophisticated algorithms to extract

physiological measures. Similar to blood pressure, PPG signal morphology depends strongly on the timing of reflected waves from the downstream vasculature [72], which is negatively correlated with vascular stiffness and age [13]. It is reasonable to assume changes in pulse transmit time, which is due to within-subject vascular stiffness variations, add another layer of challenge to accurate extraction of salient features from the PPG signal and contribute, in part, to deviations reported herein from the reference device measurements.

PPG signal quality is affected by multiple factors including improper sensor-skin coupling because of device malposition, ambient light, pressure on skin, and biological factors (blood perfusion, tissue composition, and skin temperature) and is highly sensitive to motion [47,73]. To eliminate inaccurate readings from PPG devices, it is necessary to incorporate proper signal qualification checks and biometric-specific heuristics to the signal processing algorithm. Only then will the PPG device be able to estimate biometrics within the desired accuracy range while providing a sufficient number of biometric readings for the designed use case. In this study, 78% of HR measurements and only 40% RR measurements were qualified by the vital sign algorithms, as the latter is highly sensitive to artifacts. It is important to note that cloud computing and storage of raw signals enable retrospective processing of the physiological signals collected by digital health devices. Leveraging more advanced algorithms, this framework will allow further improvement of the accuracy and the number of the valid readings generated from the same signals.

In addition to postprocessing strategies, the choice of the PPG wavelength also impacts the quality of the PPG signal and accuracy of the computed metrics. This choice is a trade-off and depends on the targeted application but is usually between 510 and 940 nm, corresponding to green and IR lights, respectively. Measurements performed on light skins and at normal ambient temperature (around 20°C) have shown that reflected green light maintains a good signal-to-noise ratio during motion compared with IR [74], which is the main reason why many consumer devices that target ambulatory HR measurements use a green light source. The advantage of IR light over green light is that it is less sensitive to skin tone variations and perfusion level because of its better tissue penetration characteristics [49]. The darker the skin pigmentation, that is, higher melanin concentration, the harder it is to receive good signal with light wavelengths shorter than 650 nm. Furthermore, for individuals with relatively lower superficial skin perfusion, thicker skin, and larger wrist circumference or body mass indices, particularly in cold ambient conditions, blood microcirculation is significantly lower, and it becomes advantageous to reach deeper tissues. Therefore, to serve particularly for resting state biometrics monitoring across the population, the Wavelet wristband uses IR light as its primary light source.

As a limitation of this study, the biometrics reported herein were tested at the resting condition and lacked physical activity settings. It is well known that the accuracy of biometrics derived from PPG-based devices is affected by motion artifacts [75,76]. Recent studies evaluating HR estimates from several commercially available wrist-worn PPG devices reveal variable degrees of accuracy during physical activity [77,78]. Accuracy of the biometrics estimation during motion requires robust motion reduction algorithms [79-81], which is not incorporated in the current version of the product. Future research in this area is needed to preserve the original signal morphology and extract more information than just ambulatory HR. Another limitation is that the subjects recruited for the study have no known health conditions and come with restricted age range and skin tones available. The correlation between measurement error and Fitzpatrick score indicates higher deviations at the extremes. Further studies are needed to demonstrate the utility of the devices for larger more diverse populations. Moving forward, well-designed clinical studies are required to demonstrate the impact of new wearable and connected devices on clinical outcomes and to build real-world evidence for indications that benefit most from these new technologies.

Conclusions

This study demonstrates that the Wavelet wrist-worn PPG device can estimate physiological measures including HR, HRV SDNN, HRV RMSSD, and RR within 0.6 bpm (SD 0.9), 7 ms (SD 10), 11 ms (SD 12), and 1 brpm (SD 1), respectively, of the reference ECG and spirometer devices. The quality of the PPG signal generated by the Wavelet wristband and the commercially available finger-clip pulse oximeter was evaluated at the identical conditions and quantified by HNR estimations as 6.40 dB (SD 2.16) and 7.70 dB (SD 1.99), respectively. Next-generation wearable and connected devices provide unprecedented means for continuous long-term remote health monitoring. Due to their noninvasive, convenient-to-patient, and engaging nature, these technologies will be gradually becoming part of our everyday lives and act as companion tools for clinical decision support, supplementing the established gold standard methods. This new streamlined health data collection modality will enable new and better ways to measure personal health, generate insights that are otherwise not available, and ultimately improve health care delivery.

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Conflicts of Interest

OD, CR, MSN, and RvM have declared conflicts of interest in that they are either current or former employees of Wavelet Health. MDM has a conflict of interest as a medical advisor to Wavelet Health. No conflicts of interest have been declared for RE.

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Abbreviations

bpm: beats per min
brpm: breaths per minute
ECG: electrocardiography
HR: heart rate
HRV: heart rate variability
HNR: harmonic-to-noise ratio
IR: infrared
LED: light-emitting diode
PPG: photoplethysmography
RR: respiration rate
RMSSD: root mean square of successive differences between adjacent interbeat intervals
SDNN: standard deviation of normal-to-normal intervals
SpO2: peripheral arterial oxygen saturation

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