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Original Paper

Usability of a Novel Mobile Health iPad App by Vulnerable Populations

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Abstract

Background: Recent advances in mobile technologies have created new opportunities to reach broadly into populations that are vulnerable to health disparities. However, mobile health (mHealth) strategies could paradoxically increase health disparities, if low socioeconomic status individuals lack the technical or literacy skills needed to navigate mHealth programs.

Objective: The aim of this study was to determine whether patients from vulnerable populations could successfully navigate and complete an mHealth patient decision aid.

Methods: We analyzed usability data from a randomized controlled trial of an iPad program designed to promote colorectal cancer (CRC) screening. The trial was conducted in six primary care practices and enrolled 450 patients, aged 50-74 years, who were due for CRC screening. The iPad program included a self-survey and randomly displayed either a screening decision aid or a video about diet and exercise. We measured participant ability to complete the program without assistance and participant-rated program usability.

Results: Two-thirds of the participants (305/450) were members of a vulnerable population (limited health literacy, annual income < US $20,000, or black race). Over 92% (417/450) of the participants rated the program highly on all three usability items (90.8% for vulnerable participants vs 96.6% for nonvulnerable participants, *P*=.006). Only 6.9% (31/450) of the participants needed some assistance to complete the program. In multivariable logistic regression, being a member of a vulnerable population was not associated with needing assistance. Only older age, less use of text messaging (short message service, SMS), and lack of Internet use predicted needing assistance.

Conclusions: Individuals who are vulnerable to health disparities can successfully use well-designed mHealth programs. Future research should investigate whether mHealth interventions can reduce health disparities.

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KEYWORDS

decision support techniques; technology assessment; primary care; health literacy; vulnerable populations

Introduction

Income, education, and race are powerful social determinants of health. Low socioeconomic status (SES) individuals and underrepresented minorities are at heightened risk for a variety of poor health outcomes, including shorter life expectancy and increased incidence of cancer and chronic diseases [1-4]. One pathway by which limited income and education, in particular, affect health negatively is by hampering the individuals' ability to access, acquire, and understand health information needed to engage in preventive and self-care practices [5]. Some of this effect is mediated by lower levels of health literacy [5,6].

Recent advances in mobile technologies have created new opportunities to reach broadly into vulnerable populations, potentially decreasing informational barriers. Over the last 10 years, the growing ownership of cell phones, smartphones, and tablet devices has shrunk the digital divide. Over 90% of Americans own a cell phone with no significant differences seen by income, education, or race [7]. Additionally, two-thirds of Americans own a smartphone, including over half of adults with household incomes less than US $30,000 or only a high school education [7].

Many health care professionals are now using tablets or other mobile devices to assist patient care delivery [8,9], and there are a growing number of cell phone- and smartphone-based interventions published in the literature [10,11]. While the use of mobile health (or mHealth) strategies could decrease health disparities by better educating and empowering low SES individuals, they could also paradoxically increase health disparities if low SES individuals lack access to or the technical and literacy skills needed to use mHealth programs [12].

Colorectal cancer (CRC) is a source of health disparities. Individuals who are less educated, poorer, and members of minority populations are less likely to be screened for CRC and consequently, more likely to develop and die from CRC [4,13-15]. Therefore, we designed an mHealth patient decision aid about CRC screening specifically for use by individuals with limited resources and limited literacy skills.

If members of vulnerable populations experience greater difficulty using our mHealth program, our intervention could increase, rather than decrease, CRC-related health disparities. Indeed, prior studies found that members of vulnerable populations frequently encounter difficulties using Web-based or mHealth apps [16,17]. However, many of these previously studied apps assumed users have basic computer skills. Therefore, we sought to determine whether patients from populations vulnerable to health disparities could successfully navigate our program, which was designed under the assumption that users would have no prior experience with computers and would have difficulty reading. We analyzed baseline data from an ongoing randomized controlled trial (Trial ID NCT02088333) that is testing the effect of the intervention on completion of CRC screening. We compared usability metrics between patients vulnerable to health disparities (low income, limited health literacy, or black race) and other patients in the primary care setting.

Methods

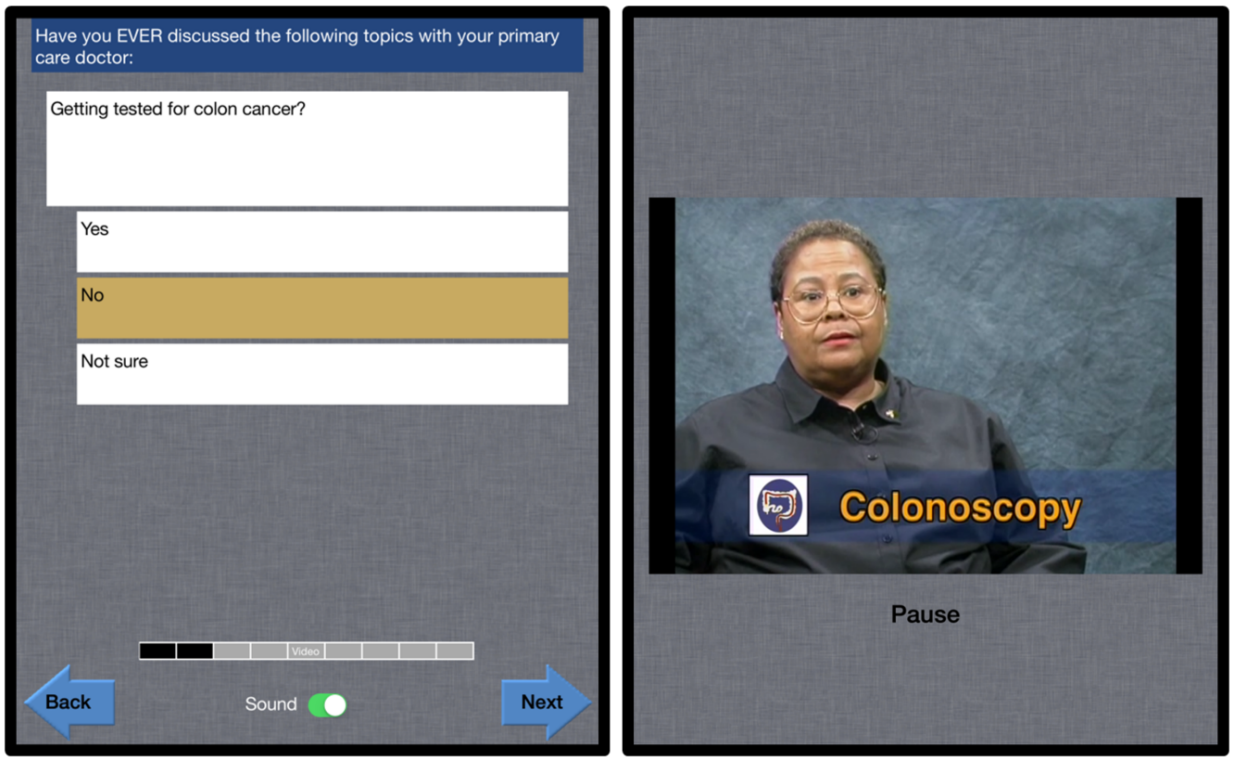
Program Design

We designed a user-friendly mHealth iPad program for use by older individuals, many of whom we assumed would have little prior technology experience. Because over one-third of Americans have limited literacy skills, we also assumed many users would have reading difficulties [18]. We chose a touch screen interface, given its advantages over a mouse and keyboard. Touch-screen input mimics a user's natural way of interacting with the world and requires less cognitive burden than manipulating external input devices [19]. Usability studies have demonstrated that older adults complete tasks more quickly and with less errors on touch-screen devices in comparison to using a computer mouse [20,21]. Moreover, novice and expert older users of touch-screen devices complete tasks with similar low error rates [22]. Some older adults also view touch-screen devices as less intimidating than computers [23].

Our program, called mPATH (mobile Patient Technology for Health), begins with a self-administered survey to collect basic health information. Each screen displays a single question with large intuitive response buttons, as recommended by others (Figure 1) [19,24]. A narrator reads each question as well as the answer the user selects, both reducing literacy barriers and providing feedback that enhances usability [25]. The narrator also gives users basic instructions for navigating the program, such as instructing them how the "Back" and "Next" arrows function. Following the self-survey, the mPATH program displays a video about either CRC screening or healthy lifestyles, and then the program concludes with a short follow-up survey. All material in the program was written at the sixth grade level or below, which is a general recommendation for the development of patient education materials [26].

A team of experts in mobile app development, health literacy, and CRC screening developed the prototype, which was then refined based on pilot testing with a convenience sample of 40 primary care patients.

Figure 1. Sample screenshots from mobile Patient Technology for Health (mPATH) iPad program.



Study Setting and Participant Recruitment

We enrolled English-speaking patients scheduled for a routine medical visit at one of six community-based primary care practices affiliated with a large academic medical center in North Carolina. All six practices shared a common electronic health record. We queried the electronic health record weekly to identify patients who were between the ages of 50 and 74 years and had no evidence of current CRC screening (colonoscopy within the last 10 years, flexible sigmoidoscopy within the last 5 years, or fecal testing for blood within the last 12 months).

We excluded patients who were already scheduled for a colonoscopy, were flagged as needing an interpreter, had a personal history of CRC, or had a potentially short life expectancy (receiving chemotherapy or radiation therapy for cancer within the last year, having advanced stage cancer, receiving hemodialysis, or being prescribed a medication for dementia). A research assistant called potentially eligible patients to inform them of the study and confirm their eligibility using a brief telephone survey. Additional study exclusion criteria assessed in the telephone eligibility survey included having a prior history of colon polyps, having a family history of CRC, and presence of rectal bleeding in the last month.

Eligible patients were asked to arrive at the clinic 45-60 minutes before their scheduled medical visit to enroll in the study and complete the mPATH iPad program. All participants provided a written informed consent, and the study was approved by the Wake Forest Health Sciences Institutional Review Board (IRB# 00023575).

Study Procedures

The participants completed the mPATH program in a private location in the clinic immediately before their scheduled medical visit. They were given minimal instructions about how to use the program. The research assistant simply handed the participants the iPad, told them to touch the “start” button on the screen when they were ready to begin, and stated the narrator would walk them through the program. The research assistant then waited outside the room while the participants completed the program and instructed them to come to the door when they needed help using the program.

As described previously, the mPATH program begins with a 29-item self-administered survey. Then it randomly displays either a previously validated 8.7-minute CRC screening decision aid [27] or a 4.3-minute video about diet and exercise produced by the Center for Disease Control [28]. After the video, the program closes with another 35-item self-administered survey that includes 4 validated usability items [29]. The participants who viewed the CRC screening decision aid were shown an additional 1-4 items that allowed them to request a CRC screening test and sign up for follow-up text messages (short message service, SMS) or emails to support them through the screening process.

Study Measures

The participants self-reported their race or ethnicity, cell phone ownership, use of the Internet, and use of SMS text messaging. We assessed health literacy using the validated item, “How confident are you filling out medical forms by yourself?” with responses varying on a 5-point Likert scale from “Extremely” to “Not at all” [30]. Consistent with published recommendations,

individuals answering "Somewhat" (the midpoint) or less were defined as having limited health literacy [30]. We classified participants as members of a vulnerable population if they reported limited health literacy, annual household income < US $20,000, or black race. Races other than white or black comprised less than 4% of our study sample. Income was missing for 13 participants, and we classified those cases based only on race and health literacy.

Our primary outcome of interest was program usability, measured objectively and subjectively. Objectively, the research assistant counted the number of times a participant came to the door to ask for assistance to complete the program. The research assistant also recorded if a caregiver was present and helped the participant use the program. We measured the participants' subjective rating of the program using three items from the System Usability Scale (ease of use, ease of learning to use the program, confidence using the program; scored on a 5-point Likert scale from strongly agree to strongly disagree) and an additional adjective rating of the overall user-friendliness (excellent, good, ok, poor, or awful) [29].

Statistical Analysis

This study was designed to assess the impact of mPATH on 6-month CRC screening rates. The participants were randomly assigned with equal probability to receive within the mPATH program either the CRC screening decision aid or the diet and exercise video. A total sample size of 450 participants was required to detect a 12% absolute difference in screening rates between the two groups, with 80% power at the 5% two-sided level of significance assuming a 20% screening rate in the control group. The participants are still being followed for the primary objective; in this paper we review the baseline data associated with the usability of the mPATH program.

The participants were classified as being a member of a vulnerable population if they met the criteria described above. Time spent completing the mPATH program was calculated in minutes based on timestamps recorded by the iPad when the program began and when it ended. Chi-square tests (or Fisher exact tests) were used to assess the differences in user-friendliness and the usability scale items between those participants who were and were not classified as vulnerable. Needing assistance was dichotomized as none versus some, and chi-square tests were used to assess the association of this measure with demographic variables, health literacy, and technology use.

Logistic regression was used to determine whether being a member of a vulnerable population was associated with needing assistance after adjusting for other factors. Covariates included age, gender, owning a cell phone, Internet use, and frequency of texting. Separate logistic models included the components used to define vulnerability. To create more parsimonious models, we used a backward stepping algorithm removing any covariate that was not significant at a level < .20. All analyses were done using SAS, version 9.3 (SAS Institute, Inc); *P* values < .05 were considered significant.

Results

Participant Demographic Characteristics

Between June 2014 and May 2016, we enrolled 450 participants, all of whom completed the mPATH iPad program. Participant demographics are displayed in Table 1. Over two-thirds of the participants (305/450) were members of a vulnerable population; 36.9% had limited health literacy, 52.9% had annual incomes < US $20,000, and 37.6% were black. Many participants had not used the Internet in the last 30 days (36.0%), but 88.6% owned a cell phone.

Table 1. Sociodemographic and technology use characteristics of the participants enrolling in a colorectal cancer screening trial (N=450).

Characteristics	n (%)
Female	242 (53.8)
Age in years, median (range)	57 (50-74)
Member of vulnerable population[a]	305 (67.8)
Limited health literacy	166 (36.9)
Annual household income < US $20,000 (n=437)	231 (52.9)
Black race	169 (37.6)
Own a cell phone (n=449)	398 (88.6)
Frequency of texting[b]	
Daily or almost daily	219 (48.8)
3-5 days per week	33 (7.3)
1-2 days per week	41 (9.1)
1-2 times per month	23 (5.1)
Less than once per month	14 (3.1)
Never	120 (26.7)
Used the Internet in the last 30 days (n=445)	285 (64.0)

[a]Vulnerable population=limited health literacy, annual income < US $20,000, or black race.

[b]How often a participant sends or receives a text message.

Subjective Usability

The participants rated the overall user-friendliness of mPATH highly. Over 97% of both vulnerable and nonvulnerable participants rated the user-friendliness as “excellent” or “good” (Table 2). Similarly, over 90% of the participants in both groups moderately or strongly agreed with all three items of the System Usability Scale, although the percentage of participants who strongly agreed to each question was significantly lower in the vulnerable group (Table 2). Almost all participants from vulnerable and nonvulnerable groups stated they preferred the program over reading a brochure (97.7% and 95.2%, respectively, *P*=.15).

Table 2. Participant-rated usability of the mPATH mHealth program.

Usability rating	Vulnerable[a] participants, n (%)	Nonvulnerable participants, n (%)	*P* value
Number of participants	305 (100)	145 (100)	
Overall rating of user-friendliness			.08
Excellent	241 (79.0)	128 (88.3)	
Good	56 (18.4)	16 (11.0)	
OK	7 (2.3)	1 (0.7)	
Poor	0 (0)	0 (0)	
Awful	1 (0.3)	0 (0)	
System Usability Scale items[b]			
The program was easy to use			.001
Strongly agree	153 (50.2)	99 (68.3)	
Agree	139 (45.6)	44 (30.3)	
Neutral or less	13 (4.3)	2 (0.7)	
Most people would learn to use the program very quickly			.008
Strongly agree	137 (44.9)	82 (56.6)	
Agree	152 (49.8)	62 (42.8)	
Neutral or less	16 (5.2)	1 (0.7)	
I felt very confident using the program			.009
Strongly agree	148 (48.5)	92 (63.4)	
Agree	146 (47.9)	51 (35.2)	
Neutral or less	11 (3.6)	2 (1.4)	
Strongly agree to all three questions	118 (38.7)	76 (52.4)	.006
Agree to strongly agree to all three questions	277 (90.8)	140 (96.6)	.03
Prefer program over a brochure	298 (97.7)	138 (95.2)	.15

[a]Vulnerable population = limited health literacy, annual income < US $20,000, or black race.

[b]Each item is rated on a 5-point Likert-type scale ranging from strongly agree to strongly disagree.

Objective Usability

The mean (standard deviation) time to complete the mPATH program was 22.8 (5.2) minutes for the CRC screening version (which included a few more survey items and a longer video), and 17.6 (4.6) minutes for the control version. Overall, adjusting for arm, the vulnerable group averaged 3.9 (0.46) minutes longer in completing the mPATH program (*P*<.001).

Only 6.9% (31/450) of the participants needed some assistance to complete the program (3.3% required only one episode of assistance, 2.0% required two or more episodes of assistance, and 1.6% had a caregiver help them use the program). The main reason that participants needed assistance was forgetting to touch the "Next" button to advance the program. A few participants became confused when they kept their finger too long on a phrase, which triggered the iPad to highlight the text. We prevented future occurrences of this user error by disabling the "copy and paste" native functionality of the iPad.

In unadjusted analyses, 9.5% (29/305) of vulnerable participants needed some assistance compared with 1.4% (2/145) of nonvulnerable participants (*P*<.01). Factors associated with needing assistance to complete the program in bivariate analyses included limited health literacy, low household income, older age, and less technology use (Table 3). Race was not associated with the need for assistance.

Table 3. Proportion of participants completing the mPATH mHealth program without any assistance.

Characteristics	n values (N=450)	n (%)	*P* value
Health literacy level			.004
Limited	166	147 (88.6)	
Normal	284	272 (95.8)	
Annual household income			.02
< US $20,000	231	209 (90.5)	
≥ US $20,000	206	198 (96.1)	
Race			.20
Black	169	154 (91.1)	
Nonblack	281	265 (94.3)	
Vulnerable population[a]			.002
Yes	305	276 (90.5)	
No	145	143 (98.6)	
Gender			.90
Male	208	194 (93.3)	
Female	242	225 (93.0)	
Age in years			<.001
≤57	235	229 (97.4)	
>57	215	190 (88.4)	
Cell phone ownership			.006
Yes	398	376 (94.5)	
No	51	43 (84.3)	
Text messaging frequency			<.001
≥3 days per week	252	248 (98.4)	
<3 days per week	198	171 (86.4)	
Internet use in past 30 days			<.001
Yes	285	279 (97.9)	
No	160	136 (85.0)	

[a]Vulnerable population = limited health literacy, annual income < US $20,000, or black race.

In a multivariable logistic regression model, being a member of a vulnerable population was no longer associated with needing assistance (*P*=.11). As vulnerable population was not significant, we looked at models that included the individual components that defined it (race, health literacy, and income). None of these components were statistically significant; only older age, less use of SMS text messaging, and lack of Internet use remained associated with needing assistance in both the full and reduced models (Table 4).

Table 4. Odds of needing assistance to complete the mPATH mHealth program by sociodemographic factors.

Factors	Full model OR[a] (95% CI)	*P* value	Reduced model OR (95% CI)	*P* value
Texting <3 days per week	3.74 (1.12-12.5)	.033	4.05 (1.26-13.0)	.02
No Internet use in the past 30 days	3.63 (1.19-11.1)	.024	4.09 (1.50-11.1)	.006
Age >57 years	3.69 (1.39-9.80)	.009	3.63 (1.42-9.31)	.007
No cell phone ownership	1.08 (0.41-2.87)	.877	-[b]	
Limited health literacy	1.33 (0.57-3.10)	.515	-	
Black race	1.19 (0.50-2.87)	.693	-	
Annual income < US $20,000	1.01 (0.37-2.77)	.991	-	
Male gender	0.93 (0.41-2.14)	.868	-	

[a]OR: Odds ratio.

[b]Factor was removed from the reduced model by the backward stepping algorithm.

Discussion

Principal Findings

In this multisite study in which two-thirds of the participants were members of a low SES group or an underrepresented minority, over 90% of individuals were able to complete the mPATH iPad program without any assistance. Similarly, the participants rated ease-of-use very highly. In contrast, others have found that members of vulnerable populations frequently encounter difficulties in using Web-based or mHealth apps [16,17,31,32]. In contrast to our mPATH program, many of these apps require users to have advanced literacy, numeracy, and computer skills [17,33-36].

Our program's ease-of-use is likely due to it being specifically designed for those with low health literacy and low computer literacy. We purposefully created a simple interface that displayed only one question per screen and used large response buttons, similar to what would be found at an automated teller machine or self-checkout kiosk. Likewise, we used simple language and included audio narration to assist those with literacy barriers. Other health apps with more complex navigational designs, denser text, and sophisticated terminology may explain the differences in usability observed.

Although low-income and low-literacy individuals were more likely to need help using the mPATH program in unadjusted analyses, this additional need for help disappeared after controlling for age, Internet use, and frequency of sending or receiving text messages. This indicates that older age and prior experiences with technology are drivers of usability, which is consistent with studies reporting that low-literacy and low-income individuals are less likely to use the Internet or own smartphones [7,37-39]. Relatedly, other studies have found that prior computer or Internet experience is associated with greater ease of use of health apps [33].

How age affects ease of use after accounting for differences in prior experiences with technology is less clear. We did not assess for the presence of health conditions that could affect usability, such as visual impairment, mild cognitive impairment, or conditions affecting dexterity. We also did not assess participants' attitudes about technology, which could affect their confidence in using the program. In particular, computer anxiety may be a barrier for older adults [36,40,41]. Consequently, differences in these health conditions or attitudes may be responsible for the age-related differences in usability observed.

Although the participants with less technology experience were more likely to need help using the mPATH app, approximately six out of seven of these individuals were able to complete the program with no help at all. When the participants did require help, the most common reason for needing assistance was forgetting to press the "Next" button to advance the program. Simple changes to the design, such as highlighting the "Next" button to draw attention to it, could provide additional cues and increase usability further.

Although our results indicate that carefully designed mHealth programs can be used by vulnerable populations, care should be taken to ensure mHealth interventions do not increase health disparities [42-45]. The participants used our program on devices in the clinic setting. Cell phone ownership is consistent across socioeconomic strata, but an income- and education-related digital divide persists for smartphones and home broadband Internet access [7,46]. If the program was instead administered as a home app or on the Internet, low-income and low-literacy individuals would have less access. Similarly, the small differences in usability seen among older adults and those with less prior technology experience highlight the importance of ensuring apps are specifically designed for those who are computer naïve. Asking patients about use of the Internet or text messaging could be valuable screening questions for predicting who may have difficulty navigating mHealth programs.

Limitations

Our study has limitations. Whereas we tested our program in several different clinic sites, we only included English-speaking patients. We also did not assess patients for specific health conditions that could impact usability (eg, vision impairment, hearing loss, paresis); usability in specific subpopulations could differ from what we observed. Finally, to decrease participant

response burden, we included only a subset of items from the System Usability Scale.

Future Work

Future studies should investigate which program features are most important for usability, and whether mHealth interventions can reduce health disparities. Results from our study examining the impact of mPATH on receipt of CRC screening will be forthcoming.

Conclusions

In summary, we found that members of vulnerable populations could successfully use an mHealth program designed for individuals with limited literacy and technology skills. After controlling for other factors, literacy level and income did not predict usability. Race did not predict usability even in unadjusted analyses. These results indicate that properly designed mHealth interventions can reach broadly across populations.

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Conflicts of Interest

None declared.

References

1. Braveman P, Egerter S, Williams D. The social determinants of health: coming of age. Annu Rev Public Health 2011;32:381-398. [doi: 10.1146/annurev-publhealth-031210-101218] [Medline: 21091195]
2. Marmot M. Social determinants of health inequalities. The Lancet 2005 Mar;365(9464):1099-1104. [Medline: 15781105]
3. Braveman P, Cubbin C, Egerter S, Williams D, Pamuk E. Socioeconomic disparities in health in the United States: what the patterns tell us. Am J Public Health 2010 Apr 01;100(Suppl 1):S186-S196. [doi: 10.2105/AJPH.2009.166082] [Medline: 20147693]
4. Ward E, Jemal A, Cokkinides V, Singh GK, Cardinez C, Ghafoor A, et al. Cancer disparities by race/ethnicity and socioeconomic status. CA Cancer J Clin 2004;54(2):78-93 [FREE Full text] [Medline: 15061598]
5. Nutbeam D. The evolving concept of health literacy. Soc Sci Med 2008 Dec;67(12):2072-2078. [Medline: 18952344]
6. von Wagner C, Semmler C, Good A, Wardle J. Health literacy and self-efficacy for participating in colorectal cancer screening: the role of information processing. Patient Educ Couns 2009 Jun;75(3):352-357. [Medline: 19386461]
7. Anderson M. Pew Research Center. 2015 Oct. Technology Device Ownership URL: http://www.pewinternet.org/files/2015/10/PI_2015-10-29_device-ownership_FINAL.pdf [accessed 2017-01-04] [WebCite Cache ID 6nH2OOIco]
8. Ventola C. Mobile devices and apps for health care professionals: uses and benefits. Pharm Ther 2014 May;39(5):356-364 [FREE Full text] [Medline: 24883008]
9. Mickan S, Tilson J, Atherton H, Roberts N, Heneghan C. Evidence of effectiveness of health care professionals using handheld computers: a scoping review of systematic reviews. J Med Internet Res 2013 Oct 28;15(10):e212 [FREE Full text] [doi: 10.2196/jmir.2530] [Medline: 24165786]
10. Fiordelli M, Diviani N, Schulz P. Mapping mHealth research: a decade of evolution. J Med Internet Res 2013 May 21;15(5):e95 [FREE Full text] [doi: 10.2196/jmir.2430] [Medline: 23697600]
11. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med 2013;10(1):e1001362 [FREE Full text] [doi: 10.1371/journal.pmed.1001362] [Medline: 23349621]
12. Gibbons MC. A historical overview of health disparities and the potential of eHealth solutions. J Med Internet Res 2005 Oct 04;7(5):e50 [FREE Full text] [doi: 10.2196/jmir.7.5.e50] [Medline: 16403714]
13. American Cancer Society. Colorectal Cancer Facts & Figures 2014-2016. Atlanta: American Cancer Society; 2014.
14. Siegel R, DeSantis C, Jemal A. Colorectal cancer statistics, 2014. CA Cancer J Clin 2014 Mar 1;64(2):104-117. [Medline: 24639052]
15. Joseph D, Redwood D, DeGroff A, Butler E. Use of evidence-based interventions to address disparities in colorectal cancer screening. MMWR Suppl 2016 Feb 12;65(1):21-28. [Medline: 26915961]
16. Sarkar U, Gourley G, Lyles C, Tieu L, Clarity C, Newmark L, et al. Usability of commercially available mobile applications for diverse patients. J Gen Intern Med 2016 Dec;31(12):1417-1426. [doi: 10.1007/s11606-016-3771-6] [Medline: 27418347]
17. Czaja S, Zarcadoolas C, Vaughon W, Lee C, Rockoff M, Levy J. The usability of electronic personal health record systems for an underserved adult population. Hum Factors J Hum Factors Ergon Soc 2015 May 01;57(3):491-506. [Medline: 25875437]

18. Kutner M, Greenberg E, Jin Y, Boyle B, Hsu Y, Dunleavy E. Literacy in Everyday Life: Results from the 2003 National Assessment of Adult Literacy (NCES 2007-490). Washington, DC: National Center for Education Statistics; 2007.
19. Caprani N, O'Connor N, Gurrin C. InTechopen. 2012. Touch screens for the older user URL: http://www.intechopen.com/books/assistive-technologies/touch-screens-for-the-older-user [accessed 2017-03-07] [WebCite Cache ID 6onBoZoVq]
20. Findlater L, Froehlich J, Fattal K, Wobbrock J, Dastyar T. Age-related differences in performance with touchscreens compared to traditional mouse input. In: Proc SIGCHI Conf Hum Factors Comput Syst. New York: ACM; 2013 Presented at: SIGCHI Conference on Human Factors in Computing Systems; 2013; Paris p. 343-346.
21. Orphanides AK, Nam CS. Touchscreen interfaces in context: a systematic review of research into touchscreens across settings, populations, and implementations. Appl Ergon 2017 May;61:116-143. [Medline: 28237011]
22. Motti L, Vigouroux N, Gorce P. Ease-of-Use of Tactile Interaction for Novice Older Adults. In: Zhou J, Salvendy G, editors. Human Aspects of IT for the Aged Population. Design for Aging. Cham: Springer International Publishing; 2015:463-474.
23. Piper A, Campbell R, Hollan J. Exploring the accessibility and appeal of surface computing for older adult health care support. In: Proc SIGCHI Conf Hum Factors Comput Syst. New York: ACM; 2010 Presented at: ACM Conference on Human Factors in Computing Systems; 2010; Atlanta p. 907-916.
24. Centers for Disease Control and Prevention. CDC. 2009. Simply put: a guide for creating easy-to-understand materials URL: https://www.cdc.gov/healthliteracy/pdf/Simply_Put.pdf [accessed 2017-03-07] [WebCite Cache ID 6onCJmoxE]
25. Lee S, Zhai S. The performance of touch screen soft buttons. In: Proc SIGCHI Conf Hum Factors Comput Syst. New York: ACM; 2009 Presented at: CHI Conference on Human Factors in Computing Systems; 2009; Boston p. 309-318.
26. Safeer R, Keenan J. Health literacy: the gap between physicians and patients. Am Fam Physician 2005;72(3):463-468. [Medline: 16100861]
27. Miller DP, Spangler JG, Case LD, Goff DC, Singh S, Pignone MP. Effectiveness of a web-based colorectal cancer screening patient decision aid. Am J Prev Med 2011 Jun 1;40(6):608-615.
28. CDC. 2013. CDC-TV Video: Finding Balance Internet URL: https://www.cdc.gov/cdctv/healthyliving/healthyeating/finding-balance-obesity.html [accessed 2017-01-04] [WebCite Cache ID 6nH2U28F9]
29. Bangor A, Kortum P, Miller J. An Empirical Evaluation of the System Usability Scale. Int J Hum-Comput Interact 2008;24(6):574-594. [doi: 10.1080/10447310802205776]
30. Chew L, Griffin J, Partin M, Noorbaloochi S, Grill J, Snyder A, et al. Validation of screening questions for limited health literacy in a large VA outpatient population. J Gen Intern Med 2008 May;23(5):561-566 [FREE Full text] [doi: 10.1007/s11606-008-0520-5] [Medline: 18335281]
31. Bravo C, O'Donoghue C, Kaplan C, Luce J, Ozanne E. Can mHealth improve risk assessment in underserved populations? Acceptability of a breast health questionnaire app in ethnically diverse, older, low-income women. J Health Dispar Res Pract 2014;7(4) [FREE Full text] [Medline: 25705576]
32. Hess R, Santucci A, McTigue K, Fischer G, Kapoor W. Patient Difficulty Using Tablet Computers to Screen in Primary Care. J Gen Intern Med 2008 Apr;23(4):476-480. [Medline: 18373148]
33. Taha J, Sharit J, Czaja S. The impact of numeracy ability and technology skills on older adults' performance of health management tasks using a patient portal. J Appl Gerontol 2014 Jun 1;33(4):416-436. [doi: 10.1177/0733464812447283]
34. Lyles C, Sarkar U. Health literacy, vulnerable patients, and health information technology use: where do we go from here? J Gen Intern Med 2015 Jan 15;30(3):271-272. [Medline: 25588688]
35. Georgsson M, Staggers N. Quantifying usability: an evaluation of a diabetes mHealth system on effectiveness, efficiency, and satisfaction metrics with associated user characteristics. J Am Med Inform Assoc 2016 Jan 1;23(1):5-11. [Medline: 26377990]
36. Kim EH, Stolyar A, Lober W, Herbaugh A, Shinstrom S, Zierler B, et al. Challenges to using an electronic personal health record by a low-income elderly population. J Med Internet Res 2009 Oct 27;11(4). [Medline: 19861298]
37. Levy H, Janke A, Langa K. Health literacy and the digital divide among older Americans. J Gen Intern Med 2014 Nov 12;30(3):284-289. [Medline: 25387437]
38. Jensen J, King A, Davis L, Guntzviller L. Utilization of internet technology by low-income adults: the role of health literacy, health numeracy, and computer assistance. J Aging Health 2010 Sep 1;22(6):804-826. [Medline: 20495159]
39. Choi NG, Dinitto DM. The digital divide among low-income homebound older adults: internet use patterns, eHealth literacy, and attitudes toward computer/Internet use. J Med Internet Res 2013 May 02;15(5):e93 [FREE Full text] [doi: 10.2196/jmir.2645] [Medline: 23639979]
40. Lober W, Zierler B, Herbaugh A, Shinstrom S, Stolyar A, Kim E, et al. Barriers to the use of a Personal Health Record by an Elderly Population. 2006 Presented at: AMIA Annual Symposium; 2006; Washington, DC p. 514-518.
41. Venkatesh V, Bala H. Technology acceptance model 3 and a research agenda on interventions. Decis Sci 2008 May 1;39(2):273-315. [doi: 10.1111/j.1540-5915.2008.00192.x]
42. Gordon N, Hornbrook M. Differences in access to and preferences for using patient portals and other eHealth technologies based on race, ethnicity, and age: a database and survey study of seniors in a large health plan. J Med Internet Res 2016 Mar 4;18(3):e50. [Medline: 26944212]
43. Lyles C, Schillinger D, Sarkar U. Connecting the dots: health information technology expansion and health disparities. PLoS Med 2015 Jul;12(7):e1001852 [FREE Full text] [doi: 10.1371/journal.pmed.1001852] [Medline: 26172977]

44. Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities, Board on Population Health and Public Health Practice, Health and Medicine Division, National Academies of Sciences, Engineering, and Medicine. In: Anderson KM, Olson S, editors. The Promises and Perils of Digital Strategies in Achieving Health Equity: Workshop Summary. Washington, DC: National Academies Press; 2016.
45. Mackert M, Mabry-Flynn A, Champlin S, Donovan EE, Pounders K. Health literacy and health information technology adoption: the potential for a new digital divide. J Med Internet Res 2016 Oct 04;18(10):e264 [FREE Full text] [doi: 10.2196/jmir.6349] [Medline: 27702738]
46. Horrigan J, Duggan M. Pew Research Center. 2015. Home Broadband 2015 Internet URL: http://www.pewinternet.org/2015/12/21/home-broadband-2015/ [accessed 2017-01-04] [WebCite Cache ID 6nH2sIiqQ]

Abbreviations

CRC: colorectal cancer
mHealth: mobile health
mPATH: mobile Patient Technology for Health
SES: socioeconomic status
SMS: short message service

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Original Paper

Processes and Recommendations for Creating mHealth Apps for Low-Income Populations

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Abstract

Background: Mobile health (mHealth) apps have shown to improve health indicators, but concerns remain about the inclusion of populations from low- and medium-income countries (LMIC) in these new technologies. Atrial fibrillation (AF) is a chronic condition with a challenging management. Previous studies have shown socioeconomic differences in the prescription of anticoagulant treatment and shared decision strategies are encouraged to achieve better outcomes. mHealth can aid both doctors and patients in this matter.

Objective: We describe the development of an mHealth app (*aFib*) idealized to aid shared decision between doctor and patient about anticoagulation prophylaxis in AF in a low-income and low-literacy population in Brazil. On the basis of our research, we suggest the processes to be followed when developing mHealth apps in this context.

Methods: A multidisciplinary team collected information about the target population and its needs and detected the best opportunity to insert the app in their current health care. Literature about the subject was reviewed and important data were selected to be delivered through good navigability, easy terminology, and friendly design. The app was evaluated in a multimethod setting.

Results: The steps suggested to develop an mHealth app target to LMIC are: (1) characterize the problem and the target user, (2) review the literature, (3) translate information to knowledge, (4) protect information, and (5) evaluate usability and efficacy.

Conclusions: We expect that these recommendations can guide the development of new mHealth apps in LMIC, on a scientific basis.

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KEYWORDS

mHealth; atrial fibrillation; low-income population

Introduction

Mobile device usage has increased dramatically over the years and recent data has shown that 64% of adults in the United States own a mobile phone. About 62% of mobile phone owners have used their phones in the past year to look up information about a health condition [1], often using software programs, or "apps" of mobile health (mHealth) [2]. In 2016, there were around 3.2 billion of downloads of mHealth apps around the globe [3]. Apps have shown to improve treatment adherence [4] and risk factors control [2,5] for chronic diseases. However, there are concerns about the proper inclusion of populations

from low- and medium-income countries (LMIC) in this new health care resource [2,6]. In Brazil, for instance, the current number of mobile devices in use is around 168 million [7], but most of these are basic phones with poor or no Internet access, which let their users relegated to the sidelines of this technology.

One of the diseases that can have its management improved with the help of mHealth is atrial fibrillation (AF), a common arrhythmia largely associated with stroke risk [8]. Anticoagulation therapy reduces this risk [9], but it can be challenging due to associated comorbidities and bleeding risk [10]. Hence, it is paramount that decisions about AF treatment be shared between health care providers and patients [11]. It is recognized that there are socioeconomic differences in AF treatment. Among different socioeconomic strata, those with lower income were less frequently prescribed anticoagulants [12].

mHealth apps targeted to low-resource settings must be evidence-based, efficient, safe, and tailored to the users and their needs. To achieve these goals and maintain usability, special focus should be given to four specific themes: interface design, feedback, navigation, and terminology [13]. However, most of these recommendations are not followed and systematically evaluated in a real-world setting before the go-live phase [2,13].

In this paper, we describe the development of an mHealth app idealized to aid shared decision about anticoagulation in AF in a low-income and low-educational level population in Brazil. On the basis of our research and results, we suggest processes and recommendations to be followed when developing mHealth apps adapted to use in LMIC.

Methods

aFib Study Overview

We developed an mHealth prototype, named *aFib*, targeted for patients with AF and their doctors. The main purpose was to facilitate shared decision on anticoagulation therapy during clinical appointment.

Our study population comprised patients with AF followed at the outpatient anticoagulation clinic of our institution. *Instituto de Cardiologia do Rio Grande do Sul* is a hospital specialized in treating heart diseases, supported by the Brazilian public health system. Every month, around 700 patients with AF are followed by the anticoagulation clinic and the majority of them have low-income and low-educational level. Previous studies showed that only half of these patients are adherent to therapy or within the therapeutic range of international normalized ratio (INR) [14,15], showing that existing strategies are not effective.

App Development Process

The *aFib* team comprised a cardiac electrophysiologist with expertise in AF, a clinical cardiologist, a software developer, and a designer. After a comprehensive literature review to support all information provided by the app, we used the behavioral intervention technology (BITs) model to ensure that the development process was systematic and replicable [16]. Our process comprised the following steps:

- Establishing the clinical aims (WHY): (a) increase knowledge about AF, stroke risk, bleeding risk, and anticoagulants [17,18] and (b) promote a shared decision about the therapy [19].
- Selecting behavioral strategies to increase knowledge in low-income populations and aid shared decision (HOW): (a) education, (b) dialog with their doctors, and (c) motivation enhancement.
- Designing app elements to deliver selected behavioral strategies (WHAT): (a) a 1.5-min long educational video about how AF can cause stroke; (b) a one-screen-only calculator for the two most recommended risk scores for stroke and bleeding [11]; (c) a screen with pictograms for a better understanding of the scores by poor literacy patients; and (d) an short message service (SMS) system to continue delivering information to users about their disease and treatment.
- Defining when and under what conditions the app will be used (WHEN): as many of our patients have basic handsets that can accommodate only voice and SMS text messaging, our option was to provide this first mHealth interaction during clinical consultation, using the physician's mobile device.

All information collected could be saved and reviewed later. This was motivated by 3 reasons: (1) risk factors often change over time, which means that risk stratification must be updated and recalculated; (2) to allow a staff nurse to collect primary data that could be expanded and modified during the physician's appointment, providing greater ease of adoption of the app in the primary care setting; and (3) to enable data transfer to other devices, since we expect that our target population will likely migrate to mobile phones in the following years.

aFib app prototype was delivered in Portuguese. Terminology was adapted to both patients and health professionals according to whom the information was directed to. Language in the educational video, in the pictograms, and in the summarized information about medications was directed to low-literacy patients, whereas language of the risk scores and leaflets was directed to their caregivers. Graphic design was developed to be clear and intuitive, with few but meaningful graphics and a color code to highlight risks and benefits of the treatment. The first version was designed to Android tablets with 10.1-inch screen to improve reading since the majority of patients with AF are elderly and may have vision impairment. Security and privacy were assured through unique ID authentication, and data transfer to central database was done using a Transport Layer Security (TLS) with 128-bit encryption method. A privacy policy was presented at the beginning of data collection with appropriate information, purpose, and user rights. See Multimedia Appendix 1 for main screens of *aFib*.

Three clinical cardiologists, 2 cardiac electrophysiologists, 1 medicine student, and 20 patients evaluated *aFib* in the pilot phase and gave feedback about perceived ease of use, perceived usefulness (two statements with a 5-point Likert scale), relevancy of content, navigation, terminology, interactivity, attractiveness, learnability (through a pre- and posttest questionnaire about the disease and treatment), and conflict about decision process (measured by a decisional conflict scale)

[20]. Written informed consent was obtained from all participants, and the Institutional Ethics Committee approved the study.

After adjustments that were made based on these feedbacks, *aFib* is being currently evaluated in a randomized clinical trial with the target population described, with short- and long-term outcomes previously established (improve knowledge, treatment adherence, and maintenance of adequate levels of anticoagulation and cost-effectiveness of this strategy).

The main challenges in the development process were (1) in the app contents, to summarize information in a way that would maximize knowledge acquisition and maintain patient's attention; (2) in the design, to minimize screens and to translate the percentages of risk in graphic information understandable by low-literacy users; (3) in the technical area, to level the knowledge of the development team in order to permit brainstorming, that is, to provide the developer and the designer with the medical information needed to understand the app context and, at the same time, to provide physicians with the technical information essential for structuring the app.

Results

Key Recommendations

On the basis of this experience, we created a short guide to the development of mHealth apps (Figure 1), suitable for use in other oncoming mHealth apps for use in LMIC.

Figure 1. Processes and recommendations for creating mHealth apps for low-income populations, based on the aFib experience.

Characterize the Problem and the Target User

A solid project starts with understanding who the users are and what problem do the app want to solve. If the subject in question is too broad, try to approach a key problematic aspect, like knowledge gaps, difficult choices, or complex treatments.

An mHealth app may be directed to patients or their relatives, health care professionals, or even to healthy people looking for disease prevention. It is important to understand not only the

socioeconomic background and educational level of the target population, but also their desires and doubts. What is their most pressing issue? Where do they get their information? What benefit of the app will help solve their problem? All these questions must be answered in order to develop a user-centered mHealth app. It is important to think also about the Internet connectivity and multimedia capability of the device in which the app will be accessed. In the United States, low-income groups are now using mobile phones as their primary method for Internet access [21]. In other countries, it might be desirable that the content can be downloaded to be accessed offline. Usability has to be planned foreseeing the worst scenario.

Review the Literature

Citizens from LMIC can have inconsistent access to their health systems, and an mHealth app can be a great opportunity to reach these populations. Thus, it should provide the best available evidence about the problem: guidelines, meta-analysis, systematic reviews, and randomized clinical trials will be the most helpful, with preference to local guidelines. Identify risk scores, outcomes, and the core information to be delivered. The references should be provided in order to aid users to make their own judgment on its reliability.

Ascertain the prevalence, incidence, and other important measures of impact, effect, and association of the problem in the target population. This would help to justify the app contents and/or interventions and establish outcomes.

If the subject had been addressed before by other apps, then identify which knowledge gaps are still blank and how to fill local population needs.

Translate Information to Knowledge

Once the problem has been defined globally and the content is evidence-based, the main challenge is to transform a huge amount of data in best quality and well-presented information, tailored to the user. Low literacy can be a barrier to the adoption of usual solutions. The 4 topics that should be kept in mind to better achieve the goal of transmitting knowledge are discussed below.

Build Easy Navigation

This refers to the way a user navigates throughout the app to complete tasks. If it is expected that the app will be used in a context of frequent interruptions, multitasking, and increased cognitive load, bad navigation may result in errors of attention and attribution [22]. Icons, tab views, and buttons should be easily recognizable [13]. It is possible to reduce cognitive load by creating steps, unifying scores, and gathering information to optimize time and minimize the number of screen switching. Screen size must also be taken into account since the smaller screen of a mobile phone will need more screen switches compared with the larger screen of a tablet.

Stick to the Main Points

There are several ways to reduce the amount of information, but any such reduction is also limited by the potential loss of critical information [22]. Main information must be highlighted, but the app should provide ways to access more complete references (eg, through hyperlinks or information buttons). Although an app is a pull technology, additional reinforcement can be achieved by employing push technology like SMS. Push and pull technology is widely used in LMIC; some examples are the improvement of early infant diagnosis of human immunodeficiency virus (HIV) in Zambia [23] and health education through messages in Benin, Malawi, and Uganda [24]. Personalized messages are seen as the most easily implemented and most effective strategy in changing patient behavior [3].

Invest in Interface Design

This theme refers to the design and layout, including consistency, location of icons, functions on each screen, font, color, density, placement, and images [13]. People learn better from visual information [25]. In a low-literacy scenario, cartoons can be used to simplify the message. The right images can improve comprehension, trigger emotions, and stick in long-term memory, but the incorrect use can deter instructiveness. mHealth users' main complaints about app design are related to visibility (as well as small screen space), hard to read fonts, lack of color coding, and poor graphic displays [26]. An effective visual communication include (1) appropriate and legible typography, (2) use of no more than five colors in the layout, (3) simple, easy to understand, and universal iconography, (4) spare use of callouts to highlight only key information, (5) significant negative space between messages, (6) use of illustration only if it enhances the content, and (7) maintain a logical hierarchy of the contents [27].

Adapt the Terminology

Terminology reflects the user's ability to identify with and understand the language used within the app [13]. Linguistic and cultural customization of health-related contents improve the involvement of low-income populations and the first step of this process is related to the first recommendation of this tutorial, that is, to characterize the target user [28]. Apps aimed at poor literacy populations must adopt health vocabulary that they use routinely. It can also be useful if the correct terminology is mentioned, between parentheses, for example, for learning purposes. Consultants that represent the target user's population should revise all contents in the pilot evaluation. Important questions that can be asked are (1) What was the main idea? (2) Was it easy to read or understand? (3) Would you change any term to improve understanding?

Protect Information

Security and privacy in mHealth apps is a vast subject, and laws regulating these aspects vary widely between countries. A recent review addressed this issue and suggested minimum requirements for developers [29], summarized here:

- The user should be able to control access to their personal health information (PHI) at any moment.
- Authentication must be done with a unique ID.
- Use advanced encryption standard (AES) to encrypt PHI, with a cryptographic key of at least 128 bits.
- Before PHI is collected, present a privacy policy with all appropriate information, including data retention, purpose, and user rights.

- Data transfer should be done with TLS with 128-bit encryption methods or virtual private networks (VPNs).
- Cryptographic methods must be used in securing the body sensor networks for authentication and key distribution.
- In case of a PHI breach, the competent authority and the affected user must be notified as soon as possible (1-3 days) and possible consequences must be relieved.

We strongly recommend a comprehensive review of the laws from the country for which the app is being developed since these minimum requirements can be insufficient in some cases.

A built-in medical-legal disclaimer with the terms of use agreement is of special interest if the app is widely available for download by doctors and patients, to help clarify the publisher's responsibilities and thereby reduce the legal risks associated with the use.

Evaluate Usability and Efficacy

Recent studies about mHealth usability suggest the use of a multimethod approach and standardized methods and tools in mHealth evaluations, which can result in a more comprehensive identification of usability issues, more specific redesign recommendations, and better reproducibility of results across studies. For users, improved mHealth design and usability could result in improved interactions, greater use of mHealth apps, and perhaps even increased adherence to suggested interventions and therapeutic [30].

To date, there is a paucity of published studies on the efficacy of mobile phone apps for health promotion in low-income populations. More research and evaluation is necessary about both internal and external validity and sustained health outcomes [31].

Internal validity of mHealth apps for low-income populations can be threatened by selection bias (eg, participants with sociocultural characteristics that do not represent the target population), instrument changes (eg, version updates of the app), regression toward the mean (eg, in knowledge evaluation of low-literacy participants), between other factors. To improve and standardize evaluation reports of mHealth interventions, a validated framework like CONSORT-EHEALTH [32] or RE-AIM [33] is recommended. The following are the steps that can be followed to validate an app.

Make a Pilot

For formative usability tests, 5-8 users are able to detect 80-85% of usability problems [34]. A pilot study of the app is imperative to adjust design and navigability based on user-centered data.

Test for Short-Term Outcomes

First real-world trial of the app should analyze short-term outcomes, such as knowledge increase, user satisfaction, behavioral changes, and improvements in validated tests, scores, or modifiable risk factors.

Test for Long-Term Outcomes

If the proposed new health care tool can act positively on factors mentioned above, it could possibly improve long-term outcomes as well. The ideal scenario is to test the mHealth app in a randomized trial with preestablished clinical outcomes, and to evaluate cost-effectiveness when compared with existing strategies. Burke et al [2], on its recent review about current science on mHealth, have proposed some interesting questions that future mHealth apps will have to answer: Does the product work best when used in certain settings or among specific patient groups? Does the app potentiate impact when it is combined with other traditional interventions? In what cases can the findings be generalized among similar technologies in the class? Are the effects seen durable? Are there any unintended consequences associated with the device and program in which it is used? [2] We need to embrace the challenge of producing this needed evidence.

Provide Feedback Options

After go-live phase, it is important that users can continue evaluating all of the aforementioned aspects. All app stores have this option, but users can be stimulated to give their opinions and a customer service should be organized to answer main doubts.

Discussion

Principal Findings

Achieving success in health prevention and treatment in LMIC is challenging and require approaches and tools that (1) have proven clinical benefit, (2) can be scaled to reach a global population and (3) are affordable. Mobile technologies provide a potential platform to facilitate these needs [35].

mHealth is empowering individuals to assume a more active role in monitoring and managing their chronic conditions and therapeutic regimens, as well as their health and wellness [2]. But, this new health tool needs to be adapted to local language and reality [6].

This tutorial was based on the experience acquired while developing the app "aFib," and describes processes and recommendations to aid developers who are interested in creating or adapting mHealth apps to low-income populations. A problem-targeted and user-centered strategy appears to be a logical trend to the development of these apps. A comprehensive review of literature must be the base of the project. The best efforts should be made to translate information to knowledge and it should be kept in mind that good navigability, terminology, and interface design can help on this task. Protection of user information is essential, and local laws on the matter should be studied beforehand. Usability and efficacy must always be evaluated in a variety of scenarios.

This tutorial has several limitations. First, the literature about mHealth is increasing quickly and new models are being tested every day to improve the development process, which can soon overwhelm the models we used here. Second, it is likely that a single experience cannot provide insight about every step of this process. Third, other diseases or conditions can present with different challenges related to low-income populations. Finally, the characteristics of low-income populations vary widely between countries, with cultural and social differences that may need distinct adaptations.

Despite these limitations, we believe that it can encourage the development and evaluation of mHealth apps in LMIC. mHealth is a low-cost strategy and appear to be an appreciated, easy-to-use, and promising aid to improve knowledge and engage individuals from LMIC in the management of their illness, supporting healthy behavior change and potentially improving population health.

Conclusions

As mobile technologies become increasingly ubiquitous, apps adapted to local use in low-income populations are needed. This tutorial expects to stimulate the development of mHealth apps for low-income populations, on a scientific base. Future work should address other possible ways to reach this special group and the extent to which this new health resource will affect their health care.

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Authors' Contributions

LS was involved in conception of the research. Review of literature, acquisition, analysis, and interpretation of the data were done by LS, EA, RG, AL, and TL. The application was developed by RM, and designed by MA. LS, EA, RG, RM, MA, AL, and TL wrote the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Main screens of aFib app.

[JPG File, 1MB - mhealth_v5i4e41_app1.jpg]

References

1. Smith A. Pewinternet. 2015. The Smartphone Difference Internet URL: http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/ [accessed 2016-08-15] [WebCite Cache ID 6jmsSPEBM]
2. Burke LE, Ma J, Azar KM, Bennett GG, Peterson ED, Zheng Y, American Heart Association Publications Committee of the Council on Epidemiology and Prevention, Behavior Change Committee of the Council on Cardiometabolic Health, Council on Cardiovascular and Stroke Nursing, Council on Functional Genomics and Translational Biology, Council on Quality of Care and Outcomes Research, and Stroke Council. Current science on consumer use of mobile health for cardiovascular disease prevention: a scientific statement from the American Heart Association. Circulation 2015 Sep 22;132(12):1157-1213. [doi: 10.1161/CIR.0000000000000232] [Medline: 26271892]
3. Research2Guidance. 2016. mHealth App Development Economic 2016 Internet URL: http://research2guidance.com/r2g/r2g-mHealth-App-Developer-Economics-2016.pdf [accessed 2017-03-17] [WebCite Cache ID 6p2GgiLyz]
4. Johnston N, Bodegard J, Jerström S, Åkesson J, Brorsson H, Alfredsson J, et al. Effects of interactive patient smartphone support app on drug adherence and lifestyle changes in myocardial infarction patients: A randomized study. Am Heart J 2016 Aug;178:85-94 [FREE Full text] [doi: 10.1016/j.ahj.2016.05.005] [Medline: 27502855]
5. Chow CK, Redfern J, Hillis GS, Thakkar J, Santo K, Hackett ML, et al. Effect of lifestyle-focused text messaging on risk factor modification in patients with coronary heart disease: a randomized clinical trial. J Am Med Assoc 2015;314(12):1255-1263. [doi: 10.1001/jama.2015.10945] [Medline: 26393848]
6. Royston G, Hagar C, Long L, McMahon D, Pakenham-Walsh N, Wadhwani N, mHIFA Working Group (Mobile Healthcare Information For All). Mobile health-care information for all: a global challenge. Lancet Glob Health 2015 Jul;3(7):e356-e357 [FREE Full text] [doi: 10.1016/S2214-109X(15)00054-6] [Medline: 26087979]
7. Meirelles F. eaesp.fgvsp. 2016. Pesquisa Anual do Uso de TI nas Empresas, GVcia Internet URL: http://eaesp.fgvsp.br/sites/eaesp.fgvsp.br/files/pesti2016gvciappt.pdf [accessed 2017-01-28] [WebCite Cache ID 6nqGu8Fe8]
8. Lip GYH, Tse HF, Lane DA. Atrial fibrillation. Lancet 2012 Feb 18;379(9816):648-661. [doi: 10.1016/S0140-6736(11)61514-6] [Medline: 22166900]
9. Katsnelson M, Koch S, Rundek T. Stroke prevention in atrial fibrillation. J Atr Fibrillation 2010;2(2):790-801.
10. Turakhia MP, Hoang DD, Xu X, Frayne S, Schmitt S, Yang F, et al. Differences and trends in stroke prevention anticoagulation in primary care vs cardiology specialty management of new atrial fibrillation: the Retrospective Evaluation and Assessment of Therapies in AF (TREAT-AF) study. Am Heart J 2013 Jan;165(1):93-101.e1. [doi: 10.1016/j.ahj.2012.10.010] [Medline: 23237139]

11. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC, ACC/AHA Task Force Members. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2014 Dec 02;64(21):e1-76 [FREE Full text] [doi: 10.1016/j.jacc.2014.03.022] [Medline: 24685669]
12. Sjölander M, Eriksson M, Asplund K, Norrving B, Glader E. Socioeconomic inequalities in the prescription of oral anticoagulants in stroke patients with atrial fibrillation. Stroke 2015 Aug;46(8):2220-2225 [FREE Full text] [doi: 10.1161/STROKEAHA.115.009718] [Medline: 26081841]
13. Kirwan M, Duncan MJ, Vandelanotte C, Mummery WK. Design, development, and formative evaluation of a smartphone application for recording and monitoring physical activity levels: the 10,000 Steps “iStepLog”. Health Educ Behav 2013 Apr;40(2):140-151. [doi: 10.1177/1090198112449460] [Medline: 22984196]
14. Leiria TL, Pellanda L, Miglioranza MH, Sant'Anna RT, Becker LS, Magalhães E, et al. Warfarin and emfprocumone: experience of an anticoagulation clinic. Arq Bras Cardiol 2010 Jan;94(1):41-45. [doi: 10.1590/S0066-782X2010000100008]
15. Esmerio FG, Souza EN, Leiria TL, Lunelli R, Moraes MA. Chronic use of oral anticoagulant: implications for the control of adequate levels. Arq Bras Cardiol 2009 Nov;93(5):549-554. [doi: 10.1590/S0066-782X2009001100017]
16. Mohr DC, Schueller SM, Montague E, Burns MN, Rashidi P. The behavioral intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions. J Med Internet Res 2014;16(6):e146 [FREE Full text] [doi: 10.2196/jmir.3077] [Medline: 24905070]
17. Clarkesmith DE, Pattison HM, Lane DA. Educational and behavioural interventions for anticoagulant therapy in patients with atrial fibrillation. Cochrane Database Syst Rev 2013 Jun 04(6):CD008600. [doi: 10.1002/14651858.CD008600.pub2] [Medline: 23736948]
18. Clarkesmith DE, Pattison HM, Lip GY, Lane DA. Educational intervention improves anticoagulation control in atrial fibrillation patients: the TREAT randomised trial. PLoS One 2013;8(9):e74037 [FREE Full text] [doi: 10.1371/journal.pone.0074037] [Medline: 24040156]
19. Eckman MH, Wise RE, Naylor K, Arduser L, Lip GY, Kissela B, et al. Developing an Atrial Fibrillation Guideline Support Tool (AFGuST) for shared decision making. Curr Med Res Opin 2015 Apr;31(4):603-614 [FREE Full text] [doi: 10.1185/03007995.2015.1019608] [Medline: 25690491]
20. O'Connor A. Decisionaid.ohri. User Manual - Decisional Conflict Scale (10 question format) Internet URL: https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf [accessed 2017-01-28] [WebCite Cache ID 6nqIoQFCP]
21. Smith A. Pewinternet. 2013. Smartphone Ownership URL: http://www.pewinternet.org/2013/06/05/smartphone-ownership-2013/ [accessed 2017-01-17] [WebCite Cache ID 6nqHa8ZmD]
22. Varshney U. Mobile health: four emerging themes of research. Decis Support Syst 2014 Oct;66:20-35. [doi: 10.1016/j.dss.2014.06.001]
23. Wheeler E, Copeland C, McNulty T, Caktus Consulting Group. Rapidsms. 2016. Project Mwana URL: https://www.rapidsms.org/projects/project-mwana/ [accessed 2017-01-28] [WebCite Cache ID 6nqHvJ6St]
24. Aker JC, Mbiti IM. Files.ethz. 2010. Mobile Phones and Economic Development in Africa URL: https://www.files.ethz.ch/isn/117279/wp211.pdf [accessed 2017-03-29] [WebCite Cache ID 6pKDDeazN]
25. Burmark L. Visual literacy: learn to see, see to learn. Alexandria, Va: Association for Supervision and Curriculum Development; 2002.
26. Schnall R, Rojas M, Bakken S, Brown W, Carballo-Dieguez A, Carry M, et al. A user-centered model for designing consumer mobile health (mHealth) applications (apps). J Biomed Inform 2016 Apr;60:243-251. [doi: 10.1016/j.jbi.2016.02.002] [Medline: 26903153]
27. Crooks R, Lankow J, Ritchie J. Visage. 2012. A Business Guide To Visual Communication e-book URL: https://visage.co/ [accessed 2017-01-28] [WebCite Cache ID 6nqJWx5dV]
28. Dragan A. Peelregion. 2009. The importance of addressing linguistic ethno-cultural diversity in the delivery of public health services: a literature review URL: https://www.peelregion.ca/health/resources/pdf/adriana.pdf [accessed 2017-02-20] [WebCite Cache ID 6oPMPqJcq]
29. Martínez-Pérez B, de la Torre-Díez I, López-Coronado M. Privacy and security in mobile health apps: a review and recommendations. J Med Syst 2015 Jan;39(1):181. [doi: 10.1007/s10916-014-0181-3] [Medline: 25486895]
30. Georgsson M, Staggers N. An evaluation of patients' experienced usability of a diabetes mHealth system using a multi-method approach. J Biomed Inform 2016 Feb;59:115-129 [FREE Full text] [doi: 10.1016/j.jbi.2015.11.008] [Medline: 26639894]
31. Bernhardt JM, Chaney JD, Chaney BH, Hall AK. New media for health education: a revolution in progress. Health Educ Behav 2013 Apr;40(2):129-132. [doi: 10.1177/1090198113483140] [Medline: 23548787]
32. Eysenbach G, CONSORT-EHEALTH. Improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res 2011;13(4):e126 [FREE Full text] [doi: 10.2196/jmir.1923] [Medline: 22209829]
33. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health 1999 Sep;89(9):1322-1327. [Medline: 10474547]
34. Virzi RA. Refining the test phase of usability evaluation: how many subjects is enough? Hum Factors 1992;34(4):457-468. [doi: 10.1177/001872089203400407]

35. Eapen ZJ, Peterson ED. Can mobile health applications facilitate meaningful behavior change?: time for answers. J Am Med Assoc 2015;314(12):1236-1237. [doi: 10.1001/jama.2015.11067] [Medline: 26393844]

Abbreviations

AES: advanced encryption standard
AF: atrial fibrillation
apps: applications
BITs: behavioral intervention technology
HIV: human immunodeficiency virus
ID: identification
LMIC: low- and medium-income countries
mHealth: mobile health
PHI: personal health information
INR: international normalized ratio
SMS: short message service
TLS: Transport Layer Security
VPN: virtual private network

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Original Paper

Immediate Mood Scaler: Tracking Symptoms of Depression and Anxiety Using a Novel Mobile Mood Scale

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Abstract

Background: Mood disorders are dynamic disorders characterized by multimodal symptoms. Clinical assessment of symptoms is currently limited to relatively sparse, routine clinic visits, requiring retrospective recollection of symptoms present in the weeks preceding the visit. Novel advances in mobile tools now support ecological momentary assessment of mood, conducted frequently using mobile devices, outside the clinical setting. Such mood assessment may help circumvent problems associated with infrequent reporting and better characterize the dynamic presentation of mood symptoms, informing the delivery of novel treatment options.

Objectives: The aim of our study was to validate the Immediate Mood Scaler (IMS), a newly developed, iPad-deliverable 22-item self-report tool designed to capture current mood states.

Methods: A total of 110 individuals completed standardized questionnaires (Patient Health Questionnaire, 9-item [PHQ-9]; generalized anxiety disorder, 7-Item [GAD-7]; and rumination scale) and IMS at baseline. Of the total, 56 completed at least one additional session of IMS, and 17 completed one additional administration of PHQ-9 and GAD-7. We conducted exploratory Principal Axis Factor Analysis to assess dimensionality of IMS, and computed zero-order correlations to investigate associations between IMS and standardized scales. Linear Mixed Model (LMM) was used to assess IMS stability across time and to test predictability of PHQ-9 and GAD-7 score by IMS.

Results: Strong correlations were found between standard mood scales and the IMS at baseline (r=.57-.59, P<.001). A factor analysis revealed a 12-item IMS ("IMS-12") with two factors: a "depression" factor and an "anxiety" factor. IMS-12 depression subscale was more strongly correlated with PHQ-9 than with GAD-7 (z=1.88, P=.03), but the reverse pattern was not found for IMS-12 anxiety subscale. IMS-12 showed less stability over time compared with PHQ-9 and GAD-7 (.65 vs .91), potentially reflecting more sensitivity to mood dynamics. In addition, IMS-12 ratings indicated that individuals with mild to moderate depression had greater mood fluctuations compared with individuals with severe depression (.42 vs .79; P=.04). Finally, IMS-12 significantly contributed to the prediction of subsequent PHQ-9 (beta=1.03, P=.02) and GAD-7 scores (beta =.93, P=.01).

Conclusions: Collectively, these data suggest that the 12-item IMS (IMS-12) is a valid tool to assess momentary mood symptoms related to anxiety and depression. Although IMS-12 shows good correlation with standardized scales, it further captures mood

fluctuations better and significantly adds to the prediction of the scales. Results are discussed in the context of providing continuous symptom quantification that may inform novel treatment options and support personalized treatment plans.

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KEYWORDS

mood disorders; mobile; ecological momentary assessment; depression; anxiety

Introduction

Mood disorders such as anxiety and depression afflict a significant portion of the population and pose a huge burden in total disability-adjusted years among midlife adults [1-5]. Mood disorders are often dynamic disorders, with symptoms showing high interpatient variability, as well as high intrapatient changes over time. However, our ability to accurately characterize day-to-day variation in these symptoms is limited by current standard of care, which is composed primarily of retrospective self-reports and subjective clinical impression, often during infrequent clinical visits [6-10]. Thus, despite their clinical significance, most symptoms are not continuously tracked outside the clinical setting or between treatment sessions [11].

Monitoring patients more frequently outside of the clinical setting, in "the real world" may improve clinical care and help facilitate timely interventions. First, capturing the relationship between mood dynamics and disease profile may pave the way for a better understanding and classification of disease and allow for improved accuracy of diagnosis and personalization of treatment [12,13]. Several recent studies have shown the clinical significance of temporal fluctuations in mood symptoms, noting the dynamic nature of mood characteristics that often go unreported, and the lost potential to better guide treatment planning [9,14-17]. Specifically, variations in positive and negative affect have been linked to the current level of depression, and increased variability in mood ratings predicted future depressive episodes [18-22]. However, there is an ongoing debate as to how mood fluctuations and variability in mood symptoms over time are associated with the severity of disease at onset (see [21] for a recent review), which may be resolved by data collected through consistent mood tracking that should provide better disease classification and ultimately improved personalized diagnosis and treatment.

Second, mobile mood tracking may help eliminate the potential reporting bias which arises when patients are required to retrospectively recall and rate symptoms, often of a distressing nature, that occurred over the past weeks or months [23,24]. Such mood reporting, particularly among those experiencing mood disruptions, is known to be associated with a large number of recall biases and erroneous judgments [25-29], such as "reconstruction" of memories [30,31] or excessive reliance on cognitive heuristics [32,33]. It has further been shown that mood reporting at the time of recall can also bias memory, making mood-congruent information more prone to be reported [34]. Finally, individuals suffering from mood disorder have been shown to have cognitive limitations, such as working memory deficits, which may obscure the utility of such reporting [35-41].

Third, identification of environmental factors relevant to mood symptoms and intervention can lead to personalized and more effective care. In addition to inaccurately captured mood fluctuations and potential biases, standard assessment in the clinic, rather than in the individual's natural ecologically relevant settings, is likely to significantly limit the ability to assess true mood state. Assessing a person's mood in their everyday settings, with further understanding of typical scenarios that influence mood state, may provide better and more complete avenues for treatment, more easily incorporated into day-to-day activities. The fact that more than 75% of patients suffer a depressive episode again within 2 years of treatment [42], which has been partly accounted for by poor continuity of care, further necessitates immediate mood tracking, performed under more ecologically valid conditions and outside of standard care.

Recent advances in mobile "smart" technologies may now facilitate remote tracking and monitoring of patients with mood disorders in their natural environment, and may thus help overcome barriers to treatment success and reporting biases, and ensure better continuity of care [8-10,14,43-45]. As patients with mood disorders are increasingly using mobile technology [10], mobile mood apps offer a convenient ecological momentary assessment mechanism to capture patients' status in real time [8]. Approaches to ecological momentary mood assessment in psychiatric patients have received some research support in studies showing feasibility of use in depression screening using a mobile phone app [7,12,13,17,46], and in patients' capability to fill out questionnaires for quantitative data entry [6,47,48]. Similar results were reported by Torous et al [49], who used a mobile phone app to administer a subset of PHQ-9 questions to capture depressive symptoms in psychiatric outpatients. Others [16,50,51] have also examined the feasibility of daily or weekly short message service (SMS)–based mood ratings and found these ratings to be a valid monitoring strategy for depressed participants. Such studies provide initial promising evidence for the utility of remote momentary assessments, and additional evidence is required in order to better establish the usability of such tools. Notably, although data from some of these studies suggest that daily mood reporting may provide more accurate indicator of longitudinal symptoms [16,47], further understanding of the nature of mood fluctuations captured on a mobile device in ecologically valid setting is necessary and would potentially provide a powerful tool to inform treatment in patients with mood disorders.

This study was designed to assess the utility of a novel mobile mood tracking scale, the Immediate Mood Scaler (IMS), a quick 22-item scale which asks participants to rate mood-related constructs in the moment. IMS was delivered along with

standardized mood-related questionnaires within a single mobile app (the Mobile Mood Tracker), thus allowing us to evaluate its efficacy for accurately characterizing the current level of depression or anxiety (ie, mood) outside the clinic. We further aimed to assess the dynamic range of mood ratings over time, and test the hypothesis that the variability of mood ratings provides additional information in predicting levels of depression and anxiety [52].

Methods

Recruitment and Enrollment

A convenience sample of 110 participants was included in the study and completed the assessments using iPads (see details below). Participants were recruited from three sites: 75 participants were patients at the Epilepsy Monitoring Unit (EMU) of the University of California, San Francisco (UCSF) Medical Center, 24 participants were recruited through the University of California, Berkeley (UCB) Department of Psychology, and 11 participants were recruited through Posit Science (PSC).

Participants at UCSF EMU were recruited as part of broader efforts to examine daily mood fluctuations, while participants were hospitalized for seizure monitoring and probing neural correlates with electroencephalography (EEG) and electrocorticography (ECoG) [53]. These participants were enrolled in the study during their stay at the EMU. UCB participants were recruited through the Research Participant Pool and received course credit for completing the study. PSC participants were recruited through Web-based ads. UCSF EMU patients were consented for research studies, including mood assessment with the app, on a study-provided mini iPad. UCB and PSC participants gave written informed consent before using the app. The study was run under the institutional review board (IRB) approvals from UCSF, UCB, and Western IRB. Participants were not paid for their participation in the study.

Note that although we have two separate subgroups in our sample (considering the PSC and UCB samples to be similar), and that we estimated that they would be quantitatively independent groups per intraclass correlations (ICC), random coefficient models suggested that the cohorts did not observe different associations between variables. Thus, because the correlations between variables were similar across groups, we decided to treat the group as one sample in the analysis.

Study Procedures

Following informed consent, participants were given an iPad mini (Model # A1454, iPad mini WiFi 16GB; Apple, Inc) and were asked to log in to PSC's Mobile Mood Tracker app with a unique password-protected login to complete the tasks (Figure 1). UCSF EMU participants completed the procedure during their hospitalization (in clinic) and UCB or PSC participants completed it in the lab at UC Berkeley or at the PSC offices in San Francisco. Data were saved on a password-protected Health Insurance Portability and Accountability Act (HIPAA)–compliant server, accessible to study investigators only through a Web browser. Study participants completed at least one session (with a variable number of assessments completed, see below). To obtain repeated-use data, 56 of the participants (all EMU patients) agreed to repeat IMS administration at least one more time. Of them, 17 participants also repeated the PHQ-9 and GAD-7 questionnaires a second time. Below is the list of mobile assessments completed by study participants:

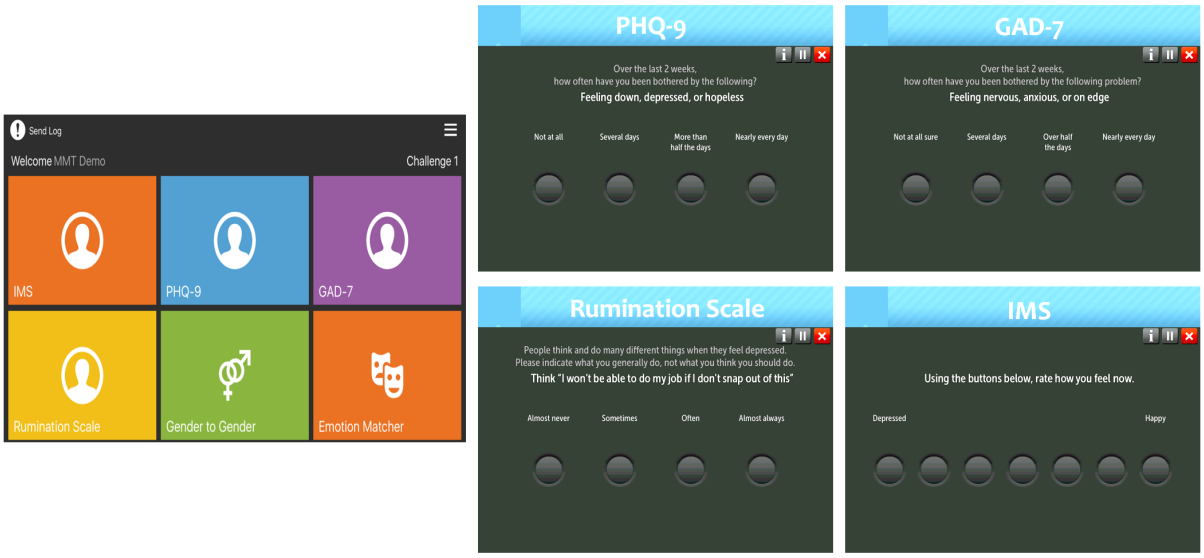
Immediate Mood Scale (IMS)

A novel 22-item measure developed to assess dynamic components of mood. Participants were asked to rate their current mood state on a continuum using 7-point Likert scales (eg, happy-sad, distracted-focused, sleepy-alert, fearful-fearless. For each item, an integer score between 1 and 7 was derived. The total score for this scale is the sum of the scores on all 22 items. To make this scale in-line with the scores derived from the PHQ-9 measure, we then inverted the total score received, such that higher scores reflect more negative mood states. Baseline IMS data were obtained from all 110 participants. A complete list of the 22 IMS items can be found in Multimedia Appendix 1 and a video demo of the IMS can be found in Multimedia Appendix 2.

Patient Health Questionnaire, 9-Item (PHQ-9)

A standardized, validated 9-item self-report questionnaire used to assess DSM-V-TR [55] symptoms of depression experienced in the 2 weeks preceding administration in adults [54]. We used this measure to classify participants into the following categories, per PHQ-9 cut-off scores (total scores range from 0 to 27): minimal depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (20 and over). Baseline PHQ-9 data were obtained from all the 110 participants. PHQ-9 is the most commonly administered self-report tool for depression, has good diagnostic and psychometric properties, and has been shown to be valid across numerous modes of administration [56].

Figure 1. Posit Science's mobile mood tracker app. Left: the app's intro screen on the iPad. The user clicks on any tile to start the assessment. Right: single example items from PHQ-9, GAD-7, Rumination, and IMS are shown. PHQ-9: patient health questionnaire, 9-item. GAD-7: generalized anxiety disorder, 7-item. IMS: Immediate Mood Scaler.



Generalized Anxiety Disorder, 7-Item (GAD-7)

A standardized, validated 7-item self-report questionnaire used to assess symptoms of anxiety experienced in the 2 weeks preceding administration [57]. We used this measure to classify participants in the following categories, per GAD-7 cut-off scores (total scores range from 0 to 21): minimal anxiety (0-4), mild anxiety (5-9), moderate anxiety (10-14), and severe anxiety (15 and over). Baseline GAD-7 data were obtained from 93 of the 110 participants (84.5%) since this scale was added at a later stage. GAD-7 has good reliability and validity metrics.

Ruminative Responses Scale (Rumination)

A standardized, validated 22-item self-report questionnaire used to assess level of rumination experienced in the 2 weeks preceding administration [58]. As this scale was added to app at a later stage of the study, baseline rumination data were obtained from only 64 of the 110 participants (58.1%).

Data Analysis

All statistical analyses were conducted using Stata (StataCorp LP). Sample demographics (age and gender) were analyzed using descriptive statistics, and were compared using independent sample *t* tests with the Welch-Satterthwaite correction (age) and with Pearson chi-square test (gender).

To examine relationship between IMS and standard scales (PHQ-9, GAD-7, rumination) at baseline, we computed zero-order correlations using Pearson *r* to investigate possible associations between PHQ-9, GAD-7, rumination, and IMS. The difference between correlations was examined using the test for comparing elements of a correlation matrix [59], using a Web-based tool [60].

To perform dimensionality reduction and factor analysis of IMS, we conducted an exploratory principal axis factor analysis with Promax rotation on all items comprising the IMS, with the global item removed. We used parallel analysis [61] with 1000 simulations of the raw data to identify the number of factors to retain, and considered factors present if they exceeded the simulated eigenvalue. Internal consistency of the solution was tested using Cronbach's alpha.

To test stability of the total IMS score and subscales across time (repeated observations), we used a linear mixed model (LMM [62]) which allows for repeated observations and tolerates missing data, a common occurrence in repeated-measures designs. Stability was estimated using ICC.

Finally, to test predictability of PHQ-9 and GAD-7 scores by IMS, we conducted an exploratory analysis on the subset of participants that had multiple data points for these scales using LMMs. Due to the small sample size, we used restricted maximum likelihood estimation and applied Satterthwaite degrees of freedom to provide a more conservative test of significance. Predictors in these models were standardized before analysis to facilitate interpretation of the coefficients.

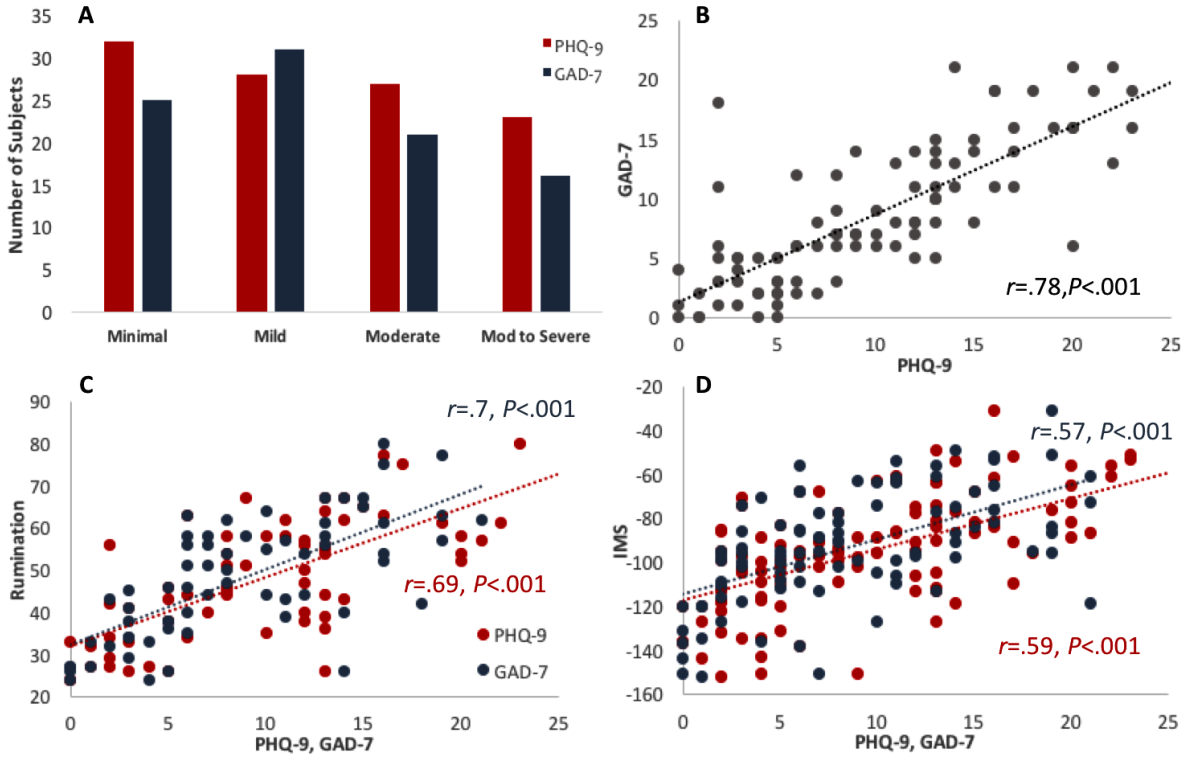
Results

Characterization of Study Sample

Participants' age range was 18-63 years old (average: 34 years, SD 11.8). Of the 110 participants, 64 (58.1%) were female, 32 were classified as having minimal or no depression (PHQ-9 scores of 0-4; mean age 31, SD 11.8), 28 with mild depression (PHQ-9 scores of 5-9; mean age 30, SD 8.3), 27 with moderate depression (PHQ-9 scores of 10-14; mean age 37.3, SD 13.5), 12 with moderately severe depression (PHQ-9 scores of 15-19; mean age 36.2, SD 10.6), and 11 with severe depression (PHQ-9 scores of 20-27; mean age 46.8, SD 6.9). The study sample is depicted in Multimedia Appendix 3 and in Figure 2.

Comparing the two participant groups in our sample (UCSF, and UCB or PSC samples) showed that the two groups differed significantly in age (t_{54}=4.3, P<.001), but not in PHQ-9 (t_{67}=1.8, P=.07) or in gender (χ^2_2=.5, P=.76).

Figure 2. (A) PHQ-9 (red bars) and GAD-7 (blue bars) score distribution. Since the GAD-7 scale only has 4 categories and PHQ-9 has 5 categories, we have included PHQ-9 scores of moderately severe to severe in the "Mod to Severe" category. (B) PHQ-9 individual score correlation with the GAD-7 scale. (C) Correlation between PHQ-9 (red) and GAD-7 (blue) scales and the rumination scale. (D) Correlation between PHQ-9 (red) and GAD-7 (blue) scores with the full IMS score. PHQ-9: patient health questionnaire, 9-item. GAD-7: generalized anxiety disorder, 7-item. IMS: Immediate Mood Scaler.



Correlation Between Measures at Baseline

We examined the correlation between PHQ-9, GAD-7, and rumination scale, as well as the correlation between these scales and IMS. As expected, the standardized depression scale (PHQ-9) was highly correlated with the standardized anxiety scale (GAD-7; r=.78, P<.001; Figure 2), pointing to the frequent comorbidity of depression and anxiety. Furthermore, the PHQ-9 and GAD-7 were both highly correlated with the rumination scale (r=.69 and .70, P<.001 for PHQ-9 and GAD-7, respectively; Figure 2). The IMS total score was highly correlated with PHQ-9 (r=.59, P<.001; n=110) and with GAD-7 (r=.57, P<.001; n=93) scales (Figure 2), as well as with rumination scale (r=.57, P<.001; n=64; data not shown).

Dimensionality Reduction and Factor Analysis for the Immediate Mood Scaler (IMS)

To assess factorial validity and to identify which items needed to be removed from the IMS to provide briefer assessment, we conducted an exploratory principal axis factor analysis. Although our sample size was not ideal for a factor analysis (N=110), the Kaiser-Meyer-Olkin (KMO) [63] measure of sampling adequacy (.91) and Bartlett Test of Sphericity [64] (χ^2_{231}=1560.35, P<.001) indicated that a factor analysis was appropriate for the data. We first identified the number of factors to retain through parallel analysis [61] on the raw data with 1000 simulations. A factor was considered present if it exceeded the simulated eigenvalue. This procedure resulted in three underlying factors, which were applied to the data (see Multimedia Appendix 4). Due to the high comorbidity between anxiety and depression, we used an oblique (Promax) rotation to allow the factors to correlate. Because our goal was to first reduce the number of items in the IMS, we examined the pattern matrix and removed items with low loadings (<.40) or items that loaded on more than one factor. We then subjected the remaining 16 items to the same process as outlined above. This resulted in the same 3-factor solution with a depression subscale, an anxiety subscale, and another, weaker 3-item subscale (q5, q6, and q7) which represented energy level. Because our aim was to identify a brief but reliable instrument, we removed the 3-item energy subscale. This resulted in a clear 2-factor solution with excellent internal consistency for the total scale (Cronbach's alpha=.93) and for the subscales (Cronbach's alpha=.90 and .93 for depression and anxiety, respectively). This brief 12-item measure (IMS-12) has a near-perfect correlation with the full 22-item IMS scale (r=.97, P<.001), indicating inconsequential information loss.

The IMS-12 factor analysis results are summarized in Table 1. Items q3, q8, q9, q10, q11, q12, and q16 load between .64 and .83 on factor 1, which seems to capture depressive states (eg, apathetic vs motivated, pessimistic vs optimistic). Items q18-q22 load between .73 and .84 on factor 2, which captures anxiety (eg, worried vs untroubled, anxious vs peaceful).

Following this exploratory analysis, we derived 3 metrics: (1) IMS-12 total score (the sum of the 12 IMS items), (2) IMS-12 depression subscale (a sum of the items loading on factor 1),

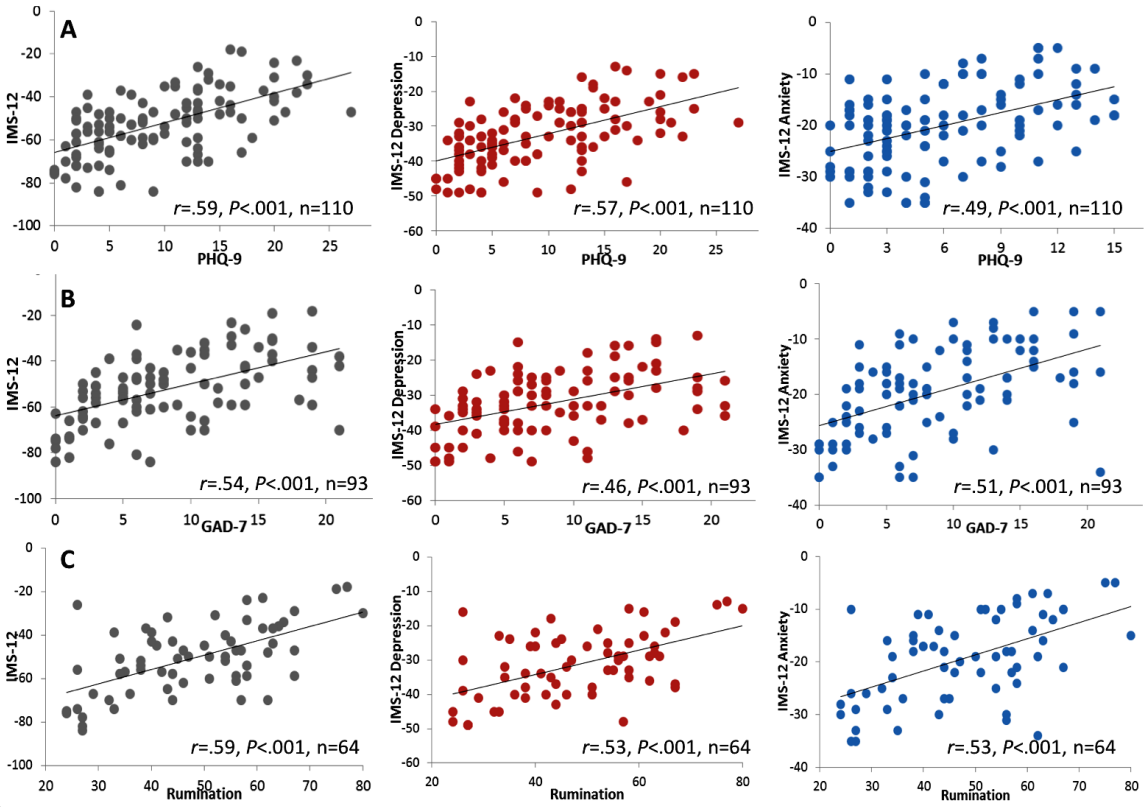
and (3) an IMS-12 anxiety subscale (a sum of the items loading on factor 2).

Table 1. Factor analysis pattern matrix for IMS-12 items.

IMS item			Factor 1 Depression	Factor 2 Anxiety
q3	Worthless	Valuable	*.64* [a]	.13
q8	Pessimistic	Optimistic	*.69*	−.06
q9	Apathetic	Motivated	*.75*	.20
q10	Guilty	Proud	*.69*	.24
q11	Numb	Interested	*.83*	−.01
q12	Withdrawn	Welcoming	*.71*	.16
q16	Hopeless	Hopeful	*.71*	−.15
q18	Tense	Relaxed	.03	*.83*
q19	Worried	Untroubled	.03	*.83*
q20	Fearful	Fearless	.17	*.73*
q21	Anxious	Peaceful	.09	*.84*
q22	Restless	Calm	.01	*.81*

[a]Values are denoted in italics for the factor they loaded more for.

Figure 3. Correlations between IMS-12 and standardized scales. Correlations between IMS-12 total (left, gray), IMS-12 depression (middle, red), and IMS-12 anxiety (right, blue) with PHQ-9 (A; top row), GAD-7 (B; middle row), and rumination (C; bottom row) scales. Pearson r values and number of subjects are shown for each graph. PHQ-9: patient health questionnaire, 9-item. GAD-7: generalized anxiety disorder, 7-item. IMS: Immediate Mood Scaler.



Relation Between Baseline IMS-12 and Baseline Levels of Depression and Anxiety

We next examined whether IMS subscales were correlated with the PHQ-9 and GAD-7 scales. Correlation results are shown in Figure 3 and in Multimedia Appendix 5. The IMS-12, similarly to the full 22-item scale, was highly correlated with PHQ-9 (r=.59, n=110, P<.001) and GAD-7 (r=.54, n=93, P<.001) and rumination (r=.59, n=64, P<.001) scales, proving that the same correlation is maintained even with a scale featuring a subset of the items (left panels of Figure 3). Of note, we found similar

correlations between IMS-16 (with 3 factors) and PHQ-9 and GAD-7 (data not shown).

Similarly, strong correlations were found for IMS-12 depression subscale, which was highly correlated with the PHQ-9 (r=.57, n=110, P<.001), with GAD-7 (r=.46, n=93, P<.001) and with rumination (r=.53, n=64, P<.001). Similarly, the IMS-12 anxiety subscale was highly correlated with PHQ-9 (r=.49, n=110, P<.001), GAD-7 (r=.51, n=93, P<.001) and with rumination (r=.53, n=64, P<.001). Because we hypothesized that IMS-12 depression would have a stronger correlation with the PHQ-9 than with the GAD-7, we tested for the difference in correlations using a one-tailed test of significance. Indeed, the correlation between IMS-12 depression and PHQ-9 was stronger than that of IMS-12 depression and GAD-7 (z=1.88, P=.03; using Steiger test). However, the correlation between IMS-12 anxiety and GAD-7 was as strong as the correlation between IMS-12 and PHQ-9.

Time to Administer Scales

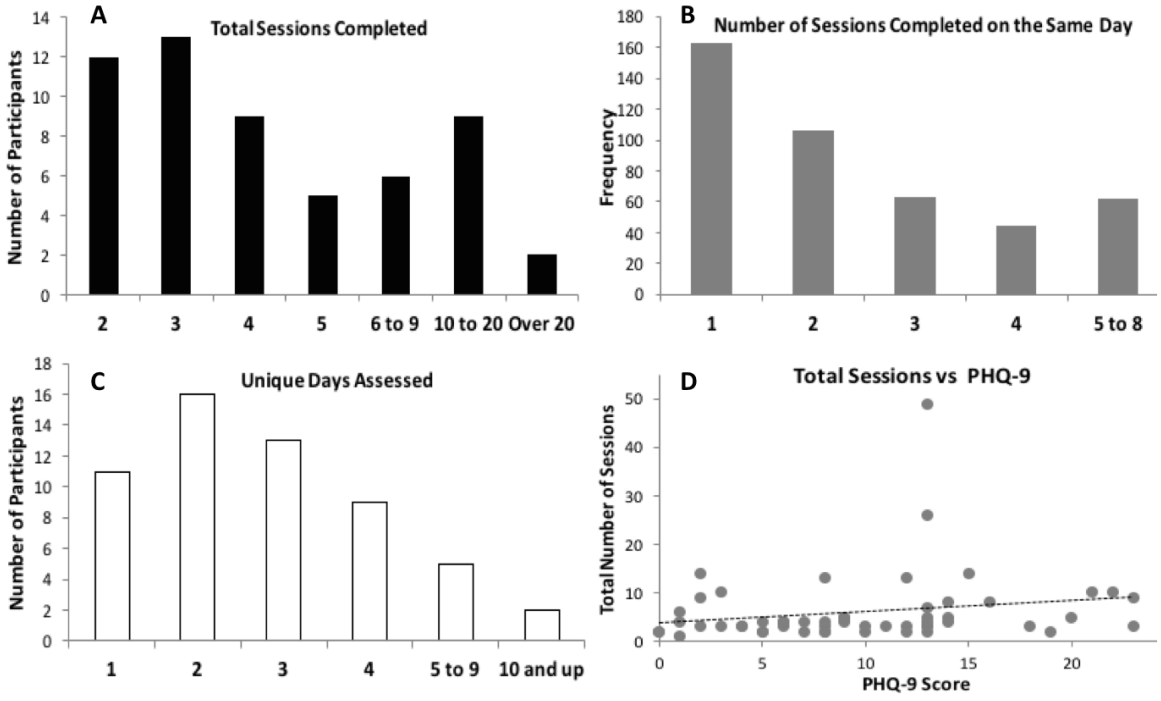
Given our goals of producing an efficient measure of mood, we calculated the average time required to complete each of the assessments. On average, it took participants 12.65 s (SD 8) to complete a PHQ-9 item, 8.35 s (SD 4.8) to complete a GAD-7 item and 6.54 s (SD 3.4) to complete an IMS item. An analysis of variance (ANOVA) with Greenhouse-Geisser correction confirmed that the time to complete an IMS item was significantly shorter than the other scales (n=107; $F_{1.29,137}$=77.7, P<.001).

We further derived the average time it should take to complete the entire scale: PHQ-9 takes, on average, 113.9 s (SD 73.7) to complete, GAD-7 takes 59.5 s (SD 33.5), and IMS-12 takes, on average, 78.4 s (SD 63.8) to complete.

Analyses of Repeated Administration of IMS

A total of 56 participants completed two or more sessions during the course of the study, and had IMS data for all repeated sessions they completed. Participants had a variable number of data points, ranging from 2 to 49 (Figure 4), with most participants having 2 or 3 data points of IMS collected (mean 6.5, SD 7.5; median 4). Most data points were collected on the same day, but some were collected on different days (see Figure 4). Number of data points collected did not correlate with severity of symptoms by baseline PHQ-9 (r=.18, P=.19; Figure 4) or GAD-7 scores (r=.01, P=.93). Out of those 56 participants, 17 also repeated PHQ-9 and GAD-7 a second time.

Figure 4. Repeated IMS data frequency. IMS data was collected within days and across days for 56 participants. (A) A histogram showing the total number of sessions completed by participants. (B) Number of sessions completed on the same day (multiple sessions for participants). (C) A histogram showing the unique days of IMS assessments completed by participants. (D) Total number of sessions completed as a function of baseline PHQ-9 score (r=.18, P=.18). PHQ-9: patient health questionnaire, 9-item. IMS: Immediate Mood Scaler.



Stability of IMS-12 Scores Across Time and for Different Levels of Depression

We examined the stability of the IMS-12 and its subscales, as well as its ability to predict PHQ-9 and GAD-7 scores administered the second time through the use of LMMs and ICC, taking the maximal number of repeated measures per participant. ICC revealed high test stability for both the PHQ-9 and GAD-7 (ICC=.91 for both) and lower test stability for the IMS-12 (ICC=.65), with similar stability for the depression (ICC=.60) and anxiety (ICC=.61) subscales.

To test the hypothesis that participants with mild to moderate depression levels have greater variability in their mood

compared with participants with minimal or severe depression levels, we further examined IMS-12 ICC for different depression levels. Results are summarized in Table 2. Tests for the differences in ICC revealed that individuals with severe depression (PHQ-9 scores of moderately severe to severe) had significantly more consistent mood by the IMS-12 (ie, less fluctuations; ICC=.79) than individuals with mild to moderate depression (ICC=.42; z=2.03, P=.04). Despite a trend for more consistent mood in individuals with minimal depression than those with mild to moderate, there were no other significant differences between groups; however, this may be due in part to sample size.

Table 2. IMS-12 intraclass correlations.

Depression level	N	ICC[a] (95% CI)	Group comparisons	z	P
Minimal	39	.69 (.54 to .81)	Minimal versus mild or moderate	1.53	.12
Mild to moderate	27	.42 (.25 to .61)	Minimal versus moderate severe or severe	.78	.43
Moderately severe to severe	21	.79 (.63 to .89)	Mild to moderate vs moderately severe or severe	2.03	.04

[a]ICC: intraclass correlations.

Predictability of PHQ-9 and GAD-7 by IMS-12

We next asked whether IMS-12 scores predicted PHQ-9 and GAD-7 scores over multiple observations, to determine whether current mood influences self-report ratings of "trait" mood over and above the effects of baseline PHQ-9 and GAD-7.

As noted, there was high test stability in the PHQ-9 and GAD-7, likely a reflection of the instruments' focus on the previous 2 weeks. Although test stability is high in both measures over the course of repeated observations over several days, we hypothesized that fluctuations in mood may account for some of the variability in PHQ-9 and GAD-7 scores. Because few participants completed the PHQ-9 and GAD-7 more than once (n=17), we conducted an exploratory analysis with that subgroup of participants to predict PHQ-9 and GAD-7 scores over repeated observations via LMMs, in which PHQ-9 and GAD-7 were modeled as a function of time. Due to our small sample size, we used restricted maximum likelihood estimation and applied Satterthwaite degrees of freedom [65] to provide a more conservative test of significance. We examined the incremental effects of the IMS-12 by testing a model that included time and baseline PHQ-9 or GAD-7 as predictors, and included IMS-12 as a time-varying predictor, with subsequent observations (time two and beyond) of PHQ-9 or GAD-7 serving as the dependent variables. Predictors were standardized before analysis to facilitate interpretation of the coefficients.

The results of the model are summarized in Table 3. As can be seen in the table, baseline PHQ-9 scores contributed substantially to the prediction of subsequent PHQ-9 scores, and the addition of IMS-12 to the model significantly predicted PHQ-9 scores beyond baseline PHQ-9 status alone (beta =1.03, P=.02). This indicates that the IMS-12 accounts for some of the variability seen in PHQ-9 scores, even when taking into consideration "general" mood. Similar results were seen for GAD-7, with IMS-12 significantly contributing to the prediction of GAD-7 scores, beyond the prediction provided by baseline GAD-7 alone (beta=.91, P=.01).

Table 3. Model variables for the prediction of PHQ-9 and GAD-7 from time, baseline measurements, and IMS-12.

PHQ-9[a] (n=17)					GAD-7[b] (n=17)				
Model	Beta	t	Degrees of freedom	P	Model	Beta	t	Degrees of freedom	P
Time	−.13	−0.48	7.79	.65	Time	−.00	−0.01	5.23	.99
+PHQ-9 baseline	3.68	8.83	16.9	<.001	+GAD-7 baseline	4.47	10.45	18.61	<.001
+IMS-12[c]	1.03	2.5	45.47	.02	+IMS-12	.91	2.6	35.98	.01
Intercept	11.05	9.33	1,12.1	<.001	Intercept	9.79	10.94	13.9	<.001

[a]PHQ-9: Patient Health Questionnaire, 9-item.

[b]GAD-7: generalized anxiety disorder, 7-item.

[c]IMS-12: Immediate Mood Scaler, 12-item.

We examined IMS-12 subscales using the same analytic approach, and found that the IMS-12 anxiety subscale significantly predicted PHQ-9 scores (beta=−.97, $t_{85.25}$=−2.44, P=.02); hhowever, the depression subscale was only near-significant (beta=−.67, $t_{54.19}$=−1.84, P=.07). For GAD-7, the IMS-12 anxiety subscale significantly predicted GAD-7 scores (beta=−.85, $t_{72.97}$=−2.29, P=.03), whereas the IMS-12 depression subscale had a similar, albeit only near-significant, effect (beta=−.61, $t_{47.9}$=−1.98, P=.06). This suggests that IMS-12 anxiety subscale may be a good predictor for both depression and anxiety, whereas the IMS-12 depression subscale does not predict either depression or anxiety to a significant extent. The full model is summarized in Multimedia Appendix 6.

Discussion

Principal Findings

The findings of the study provide initial support for the usefulness of the IMS as a tool to remotely and quickly track mood changes related to depression and anxiety in-the-moment. Specifically, we found that a condensed version of IMS comprised of 12 items, IMS-12, is highly correlated with standard scales of depression and anxiety (PHQ-9, GAD-7, and rumination scale). We further found that repeated administration of the IMS-12 provides significant information regarding the participant's mood state. Specifically, the IMS-12 captured greater variability in mood over time compared with the standard scales of PHQ-9 and GAD-7. Moreover, individuals with moderately severe to severe depression were less variable in IMS-12 over time compared with individuals with mild or moderate depression, indicating greater sensitivity to momentary mood changes especially in the moderate range. Finally, mood fluctuations reflected in repeated IMS-12 administrations significantly accounted for a significant portion of the variability in PHQ-9 and GAD-7 scores, with IMS-12 anxiety subscale better accounting for changes in both PHQ-9 and GAD-7 scores compared with the depression subscale.

The Use of IMS-12 as a Mobile Mood Tracking Tool

The main goal of our study was to assess the usability of IMS-12 as a novel scale that can be used to assess ecologically valid symptoms related to mood disorders. Collectively, the results of our study support the use of an ecological momentary assessment as a tool to assess fluctuations in symptoms related to mood disorders remotely. Specifically, we found that (1) a novel 12-item scale, IMS-12, shows strong correlation with standard scales of depression and anxiety (PHQ-9, GAD-7, and rumination scale), (2) IMS-12 is comprised of 2 unique factors or subscales ("depression" and "anxiety"), with the IMS-12 depression subscale was found to be more correlated with PHQ-9 scores than the anxiety subscale, and (3) an IMS-12 item is, on average, faster to administer than standard scales.

The results of this study show that IMS-12 can be used as a tool to remotely and quickly track mood and mood state fluctuations over time, both observationally and in response to interventions [66]. Of note, patients also reported, in informal interviews at the end of the study, that the fact that IMS had very little text and only required rating on a continuum made it easier to use than traditional scales, which often include longer text and choices between numbered options. These findings are consistent with several recent reports that have shown good feasibility of similar ecological momentary assessment approaches in patients with mood disorder (eg, major depressive disorder) [47,49,67,68]. Other recent studies further reported good correlation between mobile monitoring tools and standard clinical measures, such as the PHQ-9 measure used in our study [16,50,51]. For example, Aguilera et al [50] found that text messages of daily mood ratings, and their weekly averages (but not their variances or 2 week averages), were highly correlated with paper-and-pencil PHQ-9 scores. They, therefore, suggested that daily assessments of mobile mood ratings may provide a more accurate indicator of longitudinal symptoms, given the recency-bias in the PHQ-9 data. Similar results were obtained by Keding and colleagues [51] and Richmond et al [16], who used a single text message to probe mood and report good correlation with PHQ-9, with even better predictive power.

We further show that the overall IMS-12 total score provides a significant addition to the prediction of both depression (as captured by PHQ-9) and anxiety (as captured via GAD-7). Interestingly, the IMS-12 *anxiety* subscale score had better predictive value for both depression and anxiety than the IMS-12 depression subscale score. These results are in line with those found in a recent study by Keding et al [51]. In their study, the authors found that a single mood item predicted the affective component of PHQ-9, but not its somatic component. The comorbidity of anxiety and depression can sometimes make it challenging to dissociate between the two at the daily reporting level. Indeed, some researchers believe that generalized anxiety should not be considered a disorder of its own, and instead could be considered a marker for the severity of depression [69-71]. However, our results provide support to the notion that the short "anxiety subscale" of IMS-12 may have a good predictive value for both anxiety and depression. The results by Kessler et al [72], providing evidence for the difference in risk factors between anxiety and depression, further support this notion. More research is needed to determine whether anxiety-related symptoms have a better predictive value for mood-related illness progression.

The Predictive Value of Fluctuations in Mood-Related Symptoms

A secondary aim of the study was to assess the dynamic range of mood ratings over time, and test the hypothesis that the variability of mood ratings provides additional information in predicting levels of depression and anxiety.

Although highly correlated with baseline PHQ-9 and GAD-7 scores, IMS-12 mood ratings were, not surprisingly, less stable over time. Considering that the PHQ-9 and GAD-7 are designed to measure symptoms spanning the previous 2 weeks, whereas the IMS-12 is designed to capture in-the-moment mood status, the lower stability for the IMS-12 and its subscales suggests that the IMS-12 captures fluctuations in mood as expected. Indeed, variability of mood ratings captured in the IMS-12 total score as a function of PHQ-9 baseline scores revealed differences in performance characteristic of the severity of depression. Specifically, individuals with severe depression showed significantly less mood fluctuation compared with those of individuals with mild to moderate depression. This suggests that variability in mood may be used as an index of the severity of depression, and as such, in response to intervention, subsequent greater mood variability in severely depressed individuals may indicate a positive response to treatment.

Interestingly, although recent research suggests that depressed individuals differ from nonclinical populations in the profile of depressed mood during their daily lives [21], there is still an ongoing debate regarding the nature of this difference in relation to fluctuations in mood and mood-related variables (eg, positive and negative affect) [22]. Specifically, although some studies found that individuals with major depressive disorder also show more variable mood states across time [20,68,73-75], others

reported "emotional inertia" or less fluctuations in mood over time in more significantly depressed individuals [18,19,52,76-78]. The findings from this study are consistent with an emotional inertia account, that is, more depressed individuals show more preservative pattern of affect [77]. Pemberton and Fuller Tyszkiewicz [21] suggest that the seeming contradiction between stability and variability in mood ratings in depressed individuals could be accounted for by the different time frames used in different studies. Thus, individuals may exhibit both stability in mood (in the short-term) and variability in mood when viewed over a longer time frame. It may be that the mood fluctuations in our study capture the "short-term stability" of mood in severely depressed individuals, and that over longer period of time more fluctuations would be evident. In any event, these fluctuations are informative in characterizing level of depression.

The Clinical Significance of In-the-Moment, Remote Ecological Mood Monitoring Assessment

The results of this study support similar findings in the recent literature that have shown the significance of remote, in-the-moment (and real-world) approaches to the evaluation of mood state [12,13,17,48]. The feasibility of this approach is supported by the growing usage of mobile devices by patients with mood disorders [9,10,49] and studies that have shown good compliance with mobile monitoring strategies [47,49,79].

Ecological momentary mood assessment has several clear advantages [15,43]. For example, repeated administration of assessments may increase reliability of interpretation and also reduce measurement errors (or misinterpretations). In the case of our app, the fact that IMS-12 scores are more variable than standard mood questionnaires demonstrate its potential to more accurately capture mood fluctuations to better inform treatment planning (eg, quickly determine response to current treatment or potential to benefit from a new treatment, as well as quickly alarm clinicians in case of significant worsening in a patient's state). IMS-12 can be used to supplement PHQ-9, which has been shown by others to be valid when remotely administered [56], and can be used to assess dynamic processes and changes in mood related to treatments. The fact that PHQ-9 has been shown to reflect a recency effect rather than a 2-week average as it should [50] further stresses the need for a dynamic scale that captures mood "in-the-moment." Mobile mood tracking tools such as the one used here can therefore help circumvent the retrospective recall bias which is often associated with current methods used by clinicians to assess mood [15,80,81].

The use of a mobile app to report mood has several other potential benefits. For example, the anonymity of reporting mood using an app, rather than informing a clinician or caregiver may provide more accurate mood reporting. This notion received some support from a recent study [49], showing more accurate capture of suicidal ideation in patients using an app compared with in-person reporting. In addition, monitoring data continuously collected using such tools may help inform clinicians about the best treatment option based on the subject's mood profile, and may further inform the subjects themselves on mood-related behaviors and tendencies as reflected in their continuous monitoring data, that are not readily apparent to them. As more and more data is accumulated that way, significant advances can be made that inform novel therapeutic avenues.

With the rapid development of novel technologies (eg, mobile devices), tracking health-related measures such as mood becomes feasible and accessible to a growing portion of the population. However, in order for it to become standard of care and facilitate clinical work, rigorous testing and validation should take place. However, despite the fact that momentary tracking tools have been around for quite some time, only few have been experimentally tested and even fewer validated [79]. We believe that this initial validation of a mobile scale such as IMS-12 further promotes the likelihood of this approach to aid in clinical care, and further promotes our understanding into illness dynamic manifestation in an ecologically valid manner. Future studies, using mobile phone versions of IMS-12, are needed in order to establish the utility of a mobile mood-tracking platform as a tool that promotes our understanding of the dynamic nature of mood symptoms in everyday lives, and as a tool to monitor and measure treatment response [15,43,82].

Study Limitations

Our study has several limitations that should be addressed in future research. First, our study sample was a convenience sample, which may have limited generalizability. Second, the sample size with repeated IMS and standardized measures data was small, allowing us to make only exploratory analyses that would need to be confirmed by larger-scale studies. Third, as this study was part of a larger study (with a different research question), we did not collect additional psychiatric data on study participants that may have allowed us to further analyze the data based on participants' history or clinical profile. Finally, data was collected in the lab and clinic, which may limit its interpretation. Follow-up studies should address these limitations and further establish the value of the IMS-12 as a momentary assessment tool for symptoms related to mood disorders.

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Conflicts of Interest

Authors Tom Van Vleet, Bruno Biagianti, and Michael Merzenich are all paid employees of Posit Science, a commercial company which develops the mobile mood tracking app and the IMS in particular. Author Mor Nahum is a paid consultant of Posit Science. None of the other authors have any financial interest in Posit Science.

Multimedia Appendix 1

A complete list of the Immediate Mood Scaler (IMS) items.

[PDF File (Adobe PDF File), 21KB - mhealth_v5i4e44_app1.pdf]

Multimedia Appendix 2

Video demo of the Immediate Mood Scaler (IMS).

[MOV File, 24MB - mhealth_v5i4e44_app2.mov]

Multimedia Appendix 3

Distribution of depression Levels, based on PHQ-9 score at baseline for the entire study population (n=110), for the UCSF participants (n=75), and for the UC Berkeley participants (n=35).

[PDF File (Adobe PDF File), 26KB - mhealth_v5i4e44_app3.pdf]

Multimedia Appendix 4

Parallel Analysis based on 1000 simulations of raw data.

[PDF File (Adobe PDF File), 66KB - mhealth_v5i4e44_app4.pdf]

Multimedia Appendix 5

Correlations (Pearson r) between standardized measures and IMS. IMS: Immediate Mood Scaler.

[PDF File (Adobe PDF File), 26KB - mhealth_v5i4e44_app5.pdf]

Multimedia Appendix 6

Model results using IMS-12 depression and anxiety subscales for depression (PHQ-9; top table) and anxiety (GAD-7; bottom table). IMS: Immediate Mood Scaler. PHQ-9: Patient Health Questionnaire, 9-item.

[PDF File (Adobe PDF File), 44KB - mhealth_v5i4e44_app6.pdf]

References

1. Ferrari AJ, Charlson FJ, Norman RE, Patten SB, Freedman G, Murray CJ, et al. Burden of depressive disorders by country, sex, age, and year: findings from the global burden of disease study 2010. PLoS Med 2013 Nov;10(11):e1001547 [FREE Full text] [doi: 10.1371/journal.pmed.1001547] [Medline: 24223526]
2. Greenberg PE, Kessler RC, Birnbaum HG, Leong SA, Lowe SW, Berglund PA, et al. The economic burden of depression in the United States: how did it change between 1990 and 2000? J Clin Psychiatry 2003 Dec;64(12):1465-1475. [Medline: 14728109]
3. Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry 2005 Jun;62(6):593-602. [doi: 10.1001/archpsyc.62.6.593] [Medline: 15939837]
4. Lopez AD, Mathers CD. Measuring the global burden of disease and epidemiological transitions: 2002-2030. Ann Trop Med Parasitol 2006;100(5-6):481-499. [doi: 10.1179/136485906X97417] [Medline: 16899150]
5. Torres ER. Disability and comorbidity among major depressive disorder and double depression in African-American adults. J Affect Disord 2013 Sep 25;150(3):1230-1233 [FREE Full text] [doi: 10.1016/j.jad.2013.05.089] [Medline: 23809403]
6. Anguera JAJ, Jordan JT, Castaneda D, Gazzaley A, Areán PA. Conducting a fully mobile and randomised clinical trial for depression: access, engagement and expense. BMJ Innov 2016 Jan;2(1):14-21 [FREE Full text] [doi: 10.1136/bmjinnov-2015-000098] [Medline: 27019745]
7. BinDhim NF, Shaman AM, Trevena L, Basyouni MH, Pont LG, Alhawassi TM. Depression screening via a smartphone app: cross-country user characteristics and feasibility. J Am Med Inform Assoc 2015 Jan;22(1):29-34 [FREE Full text] [doi: 10.1136/amiajnl-2014-002840] [Medline: 25326599]

8. Shen N, Levitan M, Johnson A, Bender JL, Hamilton-Page M, Jadad AA, et al. Finding a depression app: a review and content analysis of the depression app marketplace. JMIR Mhealth Uhealth 2015;3(1):e16 [FREE Full text] [doi: 10.2196/mhealth.3713] [Medline: 25689790]
9. Torous J, Chan SR, Yee-Marie TS, Behrens J, Mathew I, Conrad EJ, et al. Patient smartphone ownership and interest in mobile apps to monitor symptoms of mental health conditions: a survey in four geographically distinct psychiatric clinics. JMIR Ment Health 2014;1(1):e5 [FREE Full text] [doi: 10.2196/mental.4004] [Medline: 26543905]
10. Torous J, Friedman R, Keshavan M. Smartphone ownership and interest in mobile applications to monitor symptoms of mental health conditions. JMIR Mhealth Uhealth 2014;2(1):e2 [FREE Full text] [doi: 10.2196/mhealth.2994] [Medline: 25098314]
11. DeRubeis RJ, Hollon SD, Amsterdam JD, Shelton RC, Young PR, Salomon RM, et al. Cognitive therapy vs medications in the treatment of moderate to severe depression. Arch Gen Psychiatry 2005 Apr;62(4):409-416. [doi: 10.1001/archpsyc.62.4.409] [Medline: 15809408]
12. Armey MF, Schatten H, Haradhvala N, Miller I. Ecological momentary assessment (EMA) of depression-related phenomena. Curr Opin Psychol 2015 Aug 01;4:21-25 [FREE Full text] [doi: 10.1016/j.copsyc.2015.01.002] [Medline: 25664334]
13. Schwartz S, Schultz S, Reider A, Saunders EF. Daily mood monitoring of symptoms using smartphones in bipolar disorder: A pilot study assessing the feasibility of ecological momentary assessment. J Affect Disord 2016 Feb;191:88-93. [doi: 10.1016/j.jad.2015.11.013] [Medline: 26655117]
14. Myin-Germeys I, Oorschot M, Collip D, Lataster J, Delespaul P, van OJ. Experience sampling research in psychopathology: opening the black box of daily life. Psychol Med 2009 Sep;39(9):1533-1547. [doi: 10.1017/S0033291708004947] [Medline: 19215626]
15. Wenze SJ, Miller IW. Use of ecological momentary assessment in mood disorders research. Clin Psychol Rev 2010 Aug;30(6):794-804. [doi: 10.1016/j.cpr.2010.06.007] [Medline: 20619520]
16. Richmond SJ, Keding A, Hover M, Gabe R, Cross B, Torgerson D, et al. Feasibility, acceptability and validity of SMS text messaging for measuring change in depression during a randomised controlled trial. BMC Psychiatry 2015 Apr 03;15:68 [FREE Full text] [doi: 10.1186/s12888-015-0456-3] [Medline: 25886377]
17. Moore RC, Depp CA, Wetherell JL, Lenze EJ. Ecological momentary assessment versus standard assessment instruments for measuring mindfulness, depressed mood, and anxiety among older adults. J Psychiatr Res 2016 Apr;75:116-123. [doi: 10.1016/j.jpsychires.2016.01.011] [Medline: 26851494]
18. Kuppens P, Sheeber LB, Yap MB, Whittle S, Simmons JG, Allen NB. Emotional inertia prospectively predicts the onset of depressive disorder in adolescence. Emotion 2012 Apr;12(2):283-289. [doi: 10.1037/a0025046] [Medline: 21988744]
19. Kuppens P, Allen N, Sheeber L. Emotional inertia and psychological maladjustment. Psychol Sci 2010 Jul;21(7):984-991 [FREE Full text] [doi: 10.1177/0956797610372634] [Medline: 20501521]
20. Peeters F, Berkhof J, Delespaul P, Rottenberg J, Nicolson NA. Diurnal mood variation in major depressive disorder. Emotion 2006 Aug;6(3):383-391. [doi: 10.1037/1528-3542.6.3.383] [Medline: 16938080]
21. Pemberton R, Fuller Tyszkiewicz MD. Factors contributing to depressive mood states in everyday life: A systematic review. J Affect Disord 2016 Aug;200:103-110. [doi: 10.1016/j.jad.2016.04.023] [Medline: 27131503]
22. Thompson R, Mata J, Jaeggi S, Buschkuehl M, Jonides J, Gotlib I. The everyday emotional experience of adults with major depressive disorder: Examining emotional instability, inertia, and reactivity. J Abnorm Psychol 2012 Nov;121(4):819-829 [FREE Full text] [doi: 10.1037/a0027978] [Medline: 22708886]
23. Beck A, Ward C, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. Arch Gen Psychiatry 1961;4:561-571.
24. Sharp L, Lipsky M. Screening for depression across the lifespan: a review of measures for use in primary care settings. Am Fam Physician 2002 Sep 15;66(6):1001-1008 [FREE Full text] [Medline: 12358212]
25. Clark L, Chamberlain S, Sahakian B. Neurocognitive mechanisms in depression: implications for treatment. Annu Rev Neurosci 2009;32:57-74. [doi: 10.1146/annurev.neuro.31.060407.125618] [Medline: 19400725]
26. Cutler S, Larsen R, Bunce S. Repressive coping style and the experience and recall of emotion: a naturalistic study of daily affect. J Pers 1996 Jun;64(2):379-405. [Medline: 8656322]
27. Gentzler A, Kerns K. Adult attachment and memory of emotional reactions to negative and positive events. Cogn Emot 2006 Jan;20(1):20-42. [doi: 10.1080/02699930500200407]
28. Safer M, Keuler D. Individual differences in misremembering pre-psychotherapy distress: personality and memory distortion. Emotion 2002 Jun;2(2):162-178. [Medline: 12899189]
29. Takayanagi Y, Spira A, Roth K, Gallo J, Eaton W, Mojtabai R. Accuracy of reports of lifetime mental and physical disorders: results from the Baltimore epidemiological catchment area study. JAMA Psychiatry 2014 Mar;71(3):273-280 [FREE Full text] [doi: 10.1001/jamapsychiatry.2013.3579] [Medline: 24402003]
30. Ghaemi S. Feeling and time: the phenomenology of mood disorders, depressive realism, and existential psychotherapy. Schizophr Bull 2007 Jan;33(1):122-130 [FREE Full text] [doi: 10.1093/schbul/sbl061] [Medline: 17122410]
31. Keinan G, Friedland N, Kahneman D, Roth D. The effect of stress on the suppression of erroneous competing responses. Anxiety Stress Coping 1999;12(4):455-476. [doi: 10.1080/10615809908249321] [Medline: 21777071]

32. Bradburn N, Rips L, Shevell S. Answering autobiographical questions: the impact of memory and inference on surveys. Science 1987 Apr 10;236(4798):157-161. [Medline: 3563494]
33. Elliott R, Zahn R, Deakin J F William, Anderson IM. Affective cognition and its disruption in mood disorders. Neuropsychopharmacology 2011 Jan;36(1):153-182 [FREE Full text] [doi: 10.1038/npp.2010.77] [Medline: 20571485]
34. Kihlstrom J, Eich E, Sandbrand D, Tobias B. Emotion and memory: Implications for self-report (with a critique of retrospective analyses). In: Stone AA, Turkkan JS, Bachrach C, Jobe JB, Kurtzman HS, Cain VS, editors. The science of self-report: Implications for research and practice. Mahwah, NJ: Erlbaum; 2000:81-99.
35. Disner S, Beevers C, Haigh EA, Beck A. Neural mechanisms of the cognitive model of depression. Nat Rev Neurosci 2011 Dec 06;12(8):467-477. [doi: 10.1038/nrn3027] [Medline: 21731066]
36. Etkin A, Schatzberg A. Common abnormalities and disorder-specific compensation during implicit regulation of emotional processing in generalized anxiety and major depressive disorders. Am J Psychiatry 2011 Sep;168(9):968-978. [doi: 10.1176/appi.ajp.2011.10091290] [Medline: 21632648]
37. Gorwood P, Corruble E, Falissard B, Goodwin G. Toxic effects of depression on brain function: impairment of delayed recall and the cumulative length of depressive disorder in a large sample of depressed outpatients. Am J Psychiatry 2008 Jun;165(6):731-739. [doi: 10.1176/appi.ajp.2008.07040574] [Medline: 18381906]
38. Joormann J, Levens S, Gotlib I. Sticky thoughts: depression and rumination are associated with difficulties manipulating emotional material in working memory. Psychol Sci 2011 Aug;22(8):979-983. [doi: 10.1177/0956797611415539] [Medline: 21742932]
39. Kircanski K, Joormann J, Gotlib IH. Cognitive Aspects of Depression. Wiley Interdiscip Rev Cogn Sci 2012;3(3):301-313 [FREE Full text] [Medline: 23240069]
40. Pizzagalli D. Frontocingulate dysfunction in depression: toward biomarkers of treatment response. Neuropsychopharmacology 2011 Jan;36(1):183-206 [FREE Full text] [doi: 10.1038/npp.2010.166] [Medline: 20861828]
41. Porter RJ, Gallagher P, Thompson JM, Young AH. Neurocognitive impairment in drug-free patients with major depressive disorder. Br J Psychiatry 2003 Mar;182:214-220 [FREE Full text] [Medline: 12611784]
42. Katon W, Robinson P, Von KM, Lin E, Bush T, Ludman E, et al. A multifaceted intervention to improve treatment of depression in primary care. Arch Gen Psychiatry 1996 Oct;53(10):924-932. [Medline: 8857869]
43. Ebner-Priemer UW, Trull TJ. Ecological momentary assessment of mood disorders and mood dysregulation. Psychol Assess 2009 Dec;21(4):463-475. [doi: 10.1037/a0017075] [Medline: 19947781]
44. Ben-Zeev D, Scherer E, Wang R, Xie H, Campbell A. Next-generation psychiatric assessment: Using smartphone sensors to monitor behavior and mental health. Psychiatr Rehabil J 2015 Sep;38(3):218-226 [FREE Full text] [doi: 10.1037/prj0000130] [Medline: 25844912]
45. Naslund JA, Aschbrenner KA, Barre LK, Bartels SJ. Feasibility of popular m-health technologies for activity tracking among individuals with serious mental illness. Telemed J E-Health Off J Am Telemed Assoc 2015;21:213-216.
46. Gaynes B, DeVeaugh-Geiss J, Weir S, Gu H, MacPherson C, Schulberg H, et al. Feasibility and diagnostic validity of the M-3 checklist: a brief, self-rated screen for depressive, bipolar, anxiety, and post-traumatic stress disorders in primary care. Ann Fam Med 2010;8(2):160-169 [FREE Full text] [doi: 10.1370/afm.1092] [Medline: 20212303]
47. Pelletier J, Rowe M, François N, Bordeleau J, Lupien S. No personalization without participation: on the active contribution of psychiatric patients to the development of a mobile application for mental health. BMC Med Inform Decis Mak 2013 Jul 27;13:78 [FREE Full text] [doi: 10.1186/1472-6947-13-78] [Medline: 23890085]
48. Solhan MB, Trull T, Jahng S, Wood P. Clinical assessment of affective instability: comparing EMA indices, questionnaire reports, and retrospective recall. Psychol Assess 2009 Sep;21(3):425-436 [FREE Full text] [doi: 10.1037/a0016869] [Medline: 19719353]
49. Torous J, Staples P, Shanahan M, Lin C, Peck P, Keshavan M, et al. Utilizing a personal smartphone custom app to assess the patient health questionnaire-9 (PHQ-9) depressive symptoms in patients with major depressive disorder. JMIR Ment Health 2015;2(1):e8 [FREE Full text] [doi: 10.2196/mental.3889] [Medline: 26543914]
50. Aguilera A, Schueller SM, Leykin Y. Daily mood ratings via text message as a proxy for clinic based depression assessment. J Affect Disord 2015 Apr 01;175:471-474 [FREE Full text] [doi: 10.1016/j.jad.2015.01.033] [Medline: 25679202]
51. Keding A, Böhnke JR, Croudace T, Richmond S, MacPherson H. Validity of single item responses to short message service texts to monitor depression: an mHealth sub-study of the UK ACUDep trial. BMC Med Res Methodol 2015 Jul 30;15:56 [FREE Full text] [doi: 10.1186/s12874-015-0054-6] [Medline: 26224088]
52. Cowdry R, Gardner D, O'Leary KM, Leibenluft E, Rubinow D. Mood variability: a study of four groups. Am J Psychiatry 1991 Nov;148(11):1505-1511. [doi: 10.1176/ajp.148.11.1505] [Medline: 1928464]
53. Kirkby L, Luongo F, Nahum M, Van VT, Lee M, Dawes H, et al. An intrinsic network for mood in the human brain. In: Society for Neuroscience Annual Meeting. 2016 Presented at: Society for Neuroscience Annual Meeting; November 12-16, 2016; San Diego, CA.
54. Kroenke K, Spitzer R, Williams J. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [Medline: 11556941]
55. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th edition. Arlington, VA: American Psychiatric Publishing; 2013.

56. Fann JR, Berry DL, Wolpin S, Austin-Seymour M, Bush N, Halpenny B, et al. Depression screening using the patient health questionnaire-9 administered on a touch screen computer. Psychooncology 2009 Jan;18(1):14-22 [FREE Full text] [doi: 10.1002/pon.1368] [Medline: 18457335]
57. Spitzer R, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006 May 22;166(10):1092-1097. [doi: 10.1001/archinte.166.10.1092] [Medline: 16717171]
58. Treynor W, Gonzalez R, Nolen-Hoeksema S. Rumination Reconsidered: A Psychometric Analysis. Cognit Ther Res 2003;27(3):247-259.
59. Steiger JH. Tests for comparing elements of a correlation matrix. Psychol Bull 1980 Mar;87(2):245-251.
60. Lee IA, Preacher KJ. Quantpsy. 2013. Calculation for the test of the difference between two dependent correlations with one variable in common Computer software URL: http://quantpsy.org/ [accessed 2017-03-03] [WebCite Cache ID 6ogt71I36]
61. Horn JL. A rationale and test for the number of factors in factor analysis. Psychometrika 1965;32:179-185.
62. Singer JD, Willett JB. Applied longitudinal data analysis: Modelling change and event occurrence. Oxford: Oxford University Press; 2003.
63. Kaiser HF. A second-generation little jiffy. Psychometrika 1970;35:401-415.
64. Bartlett M. Properties of sufficiencystatistical tests. Proc R Soc Lond Series A Mathematical and Physical Sciences 1937:268-282.
65. Satterthwaite FE. An approximate distribution of estimates of variance components. Biometrics 1946 Dec;2(6):110-114. [Medline: 20287815]
66. Stark-Inbar A, Van VT, Merzenich M, Nahum M. A novel app for cognitive training to improve and assess mood states in people with Parkinsons disease: an initial efficacy study. 2016 Presented at: Cognitive Neuroscience Society; April, 2016; New York, NY.
67. Husky M, Gindre C, Mazure C, Brebant C, Nolen-Hoeksema S, Sanacora G, et al. Computerized ambulatory monitoring in mood disorders: feasibility, compliance, and reactivity. Psychiatry Res 2010 Jul 30;178(2):440-442. [doi: 10.1016/j.psychres.2010.04.045] [Medline: 20488558]
68. Telford C, McCarthy-Jones S, Corcoran R, Rowse G. Experience sampling methodology studies of depression: the state of the art. Psychol Med 2012 Jun;42(6):1119-1129. [doi: 10.1017/S0033291711002200] [Medline: 22008511]
69. Cloninger C, Martin R, Guze S, Clayton P. The empirical structure of psychiatric comorbidity and its theoretical significance. In: Maser JD, Cloninger CR, editors. Comorbidity of Mood and Anxiety Disorders. Washington, DC: American Psychiatric Press; 1990:439-462.
70. Brown TA, Chorpita BF, Barlow DH. Structural relationships among dimensions of the DSM-IV anxiety and mood disorders and dimensions of negative affect, positive affect, and autonomic arousal. J Abnorm Psychol 1998 May;107(2):179-192. [Medline: 9604548]
71. Boyle MH, Offord DR, Campbell D, Catlin G, Goering P, Lin E, et al. Mental health supplement to the Ontario health survey: methodology. Can J Psychiatry 1996 Nov;41(9):549-558. [doi: 10.1177/070674379604100903] [Medline: 8946077]
72. Kessler RC, Gruber M, Hettema J, Hwang I, Sampson N, Yonkers K. Co-morbid major depression and generalized anxiety disorders in the National Comorbidity Survey follow-up. Psychol Med 2008 Mar;38(3):365-374 [FREE Full text] [doi: 10.1017/S0033291707002012] [Medline: 18047766]
73. Bylsma L, Taylor-Clift A, Rottenberg J. Emotional reactivity to daily events in major and minor depression. J Abnorm Psychol 2011 Feb;120(1):155-167. [doi: 10.1037/a0021662] [Medline: 21319928]
74. Gauvin L, Rejeski W, Norris J. A naturalistic study of the impact of acute physical activity on feeling states and affect in women. Health Psychol 1996 Sep;15(5):391-397. [Medline: 8891718]
75. Maes IH, Delespaul PA, Peters M, White M, van HY, Schruers K, et al. Measuring health-related quality of life by experiences: the experience sampling method. Value Health 2015 Jan;18(1):44-51 [FREE Full text] [doi: 10.1016/j.jval.2014.10.003] [Medline: 25595233]
76. Golier JA, Yehuda R, Schmeidler J, Siever LJ. Variability and severity of depression and anxiety in post traumatic stress disorder and major depressive disorder. Depress Anxiety 2001;13(2):97-100. [Medline: 11301926]
77. Koval P, Kuppens P, Allen N, Sheeber L. Getting stuck in depression: the roles of rumination and emotional inertia. Cogn Emot 2012;26(8):1412-1427. [doi: 10.1080/02699931.2012.667392] [Medline: 22671768]
78. Murray G. Diurnal mood variation in depression: a signal of disturbed circadian function? J Affect Disord 2007 Sep;102(1-3):47-53. [doi: 10.1016/j.jad.2006.12.001] [Medline: 17239958]
79. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. J Med Internet Res 2013;15(11):e247 [FREE Full text] [doi: 10.2196/jmir.2791] [Medline: 24240579]
80. Ben-Zeev D, Granholm E, Cafri G. Symptoms of depression and anxiety mediate the relationship between self-esteem and paranoia. Schizophr Res 2009 Dec;115(2-3):377-378 [FREE Full text] [doi: 10.1016/j.schres.2009.06.009] [Medline: 19584021]
81. Ben-Zeev D, Young M. Accuracy of hospitalized depressed patients' and healthy controls' retrospective symptom reports: an experience sampling study. J Nerv Ment Dis 2010 Apr;198(4):280-285. [doi: 10.1097/NMD.0b013e3181d6141f] [Medline: 20386257]

82. Wichers M. The dynamic nature of depression: a new micro-level perspective of mental disorder that meets current challenges. Psychol Med 2014 May;44(7):1349-1360. [doi: 10.1017/S0033291713001979] [Medline: 23942140]

Abbreviations

ANOVA: analysis of variance
ECoG: electrocorticography
EEG: electroencephalography
EMU: Epilepsy Monitoring Unit
GAD-7: generalized anxiety disorder, 7-item
HIPAA: Health Insurance Portability and Accountability Act
ICC: intraclass correlations
IMS: Immediate Mood Scaler
IRB: institutional review board
KMO: Kaiser-Meyer-Olkin
PHQ-9: Patient Health Questionnaire, 9-item
PSC: Posit Science
SMS: short message service
UC: University of California
UCB: University of California, Berkeley
UCSF: University of California, San Francisco

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Original Paper

Development and Testing of the MyHealthyPregnancy App: A Behavioral Decision Research-Based Tool for Assessing and Communicating Pregnancy Risk

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Abstract

Background: Despite significant advances in medical interventions and health care delivery, preterm births in the United States are on the rise. Existing research has identified important, seemingly simple precautions that could significantly reduce preterm birth risk. However, it has proven difficult to communicate even these simple recommendations to women in need of them. Our objective was to draw on methods from behavioral decision research to develop a personalized smartphone app-based medical communication tool to assess and communicate pregnancy risks related to preterm birth.

Objective: A longitudinal, prospective pilot study was designed to develop an engaging, usable smartphone app that communicates personalized pregnancy risk and gathers risk data, with the goal of decreasing preterm birth rates in a typically hard-to-engage patient population.

Methods: We used semistructured interviews and user testing to develop a smartphone app based on an approach founded in behavioral decision research. For usability evaluation, 16 participants were recruited from the outpatient clinic at a major academic hospital specializing in high-risk pregnancies and provided a smartphone with the preloaded app and a digital weight scale. Through the app, participants were queried daily to assess behavioral risks, mood, and symptomology associated with preterm birth risk. Participants also completed monthly phone interviews to report technical problems and their views on the app's usefulness.

Results: App use was higher among participants at higher risk, as reflected in reporting poorer daily moods (Odds ratio, OR 1.20, 95% CI 0.99-1.47, *P*=.08), being more likely to smoke (OR 4.00, 95% CI 0.93-16.9, *P*=.06), being earlier in their pregnancy (OR 1.07, 95% CI 1.02-1.12, *P*=.005), and having a lower body mass index (OR 1.07, 95% CI 1.00-1.15, *P*=.05). Participant-reported intention to breastfeed increased from baseline to the end of the trial, t15=−2.76, *P*=.01. Participants' attendance at prenatal appointments was 84% compared with the clinic norm of 50%, indicating a conservatively estimated cost savings of ~US $450/patient over 3 months.

Conclusions: Our app is an engaging method for assessing and communicating risk during pregnancy in a typically hard-to-reach population, providing accessible and personalized distant obstetrical care, designed to target preterm birth risk, specifically.

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KEYWORDS

mhealth; pregnancy; premature birth; decision making

Introduction

Preterm birth rates in the United States are on the rise, with approximately 1 of every 10 births occurring prior to 37 weeks of gestation [1]. These rates are also disproportionately high among some sociodemographic groups, reaching 1 in 6 among African-Americans [2], with greater prevalence among families living in poverty, regardless of race [3]. These patient groups are also often the hardest to reach due to limited access to and attendance at routine prenatal care.

The consequences of preterm birth are severe, and its causes are complex. Medical interventions for reducing preterm birth typically address one or a few risk factors in isolation, such as antibiotics for asymptomatic bacteriuria [4], 17-alpha hydroxyprogesterone caproate for a history of previous preterm birth, or cerclage for sonographically short cervix [5,6]. These interventions are also often predicated on medical testing, such as cervical measurement, blood-glucose testing, and serial blood pressure readings, which require both patient engagement and follow up. There are other seemingly simple precautions with potentially significant impact, such as the daily intake of a multivitamin during early pregnancy. However, it has proven difficult for health care providers to communicate even these recommendations effectively enough to secure sustained behavior change [7]. In this study, we demonstrate a behavioral intervention that engages pregnant women, providing them with information about risks related to preterm birth that can be identified without medical testing, as well as a suite of protective actions that they can utilize, with support from their health care providers.

In its Committee Opinion on Effective Patient-Physician Communication, the American College of Obstetricians and Gynecologists emphasizes the critical, important nature of effective and compassionate patient-provider communication, specifically noting the opportunities to provide such support with emerging information technologies [8]. Our intervention follows this strategy, as part of the move to provide patient services via mobile phone [9,10]. This strategy is possible because, even in the lowest income bracket, 86% of American adults own a mobile phone and three-fourths of this population own a smartphone, with similar ownership rates across racial and ethnic groups [11]. Moreover, as of 2015, almost 20% of all smartphone users had downloaded at least one pregnancy app [11]. Thus, in principle, apps offer a unique channel for communicating with patients, both for gathering information from them and for addressing their needs—if they can be engaged with the device and use its contents. Our intervention designs such an app, MyHealthyPregnancy (MHP) , using theory, results, and methods from behavioral decision research to provide personalized risk communication, specifically aimed at pregnant women at risk of not receiving such information due to routinely missing prenatal care. It is developed in collaboration with women from that population and then tested for feasibility in a 3-month trial. Although the ultimate implementation goal is to decrease preterm birth rates when used over the full duration of a pregnancy, here we report on the development process and the ability of the app to engage a hard-to-reach patient population. The results reported here address our preliminary research aims of (1) creating an app to engage an at-risk patient population, (2) increasing their attendance at prenatal care appointments, (3) identifying and communicating risk factors associated with preterm birth outcomes, and (4) encouraging risk-reduction behaviors and health promoting intentions.

Methods

App Development

To create an app to engage our target population, we followed the behavioral decision research paradigm [12-14] consisting of (1) normative research, (2) descriptive research, (3) prescriptive interventions, and (4) evaluation research. First, normative research identifies the need to make informed decisions based on the best available medical knowledge. Second, descriptive research characterizes women's current beliefs, values, and constraints; Third, prescriptive interventions provide better information and reduce barriers to desired actions. Finally, evaluation research assesses the effectiveness of those interventions and the validity of the research upon which they rely, in pretests and a field test. User-centered design, informed by feedback from members of the target audience, was central to the process [15,16].

Semistructured Interviews

Our normative research began by consulting with 4 medical expert informants in the field of maternal-fetal medicine and community informants from a diverse set of group (e.g., churches, non-profit organizations, women's shelters, doula groups), before proceeding with our descriptive work. Descriptive work included in-depth, semistructured interviews with 5 women recruited through a church and a family support center in a neighborhood that met demographic criteria of high-risk pregnancy populations (ie, lower average household income, higher proportion of African-American residents, higher proportion of single marital status mothers).

Experts were questioned about the best ways to assess those preterm birth risks falling within their field of specialty (eg, our intimate partner violence experts were asked about which measures to use to assess IPV, as well as how frequently to measure IPV risk in the target group). Our pregnant participants were asked questions related to the causes of preterm birth risk, structured around the risks identified in the normative phase, as well as about barriers to prenatal care access (eg, "What are some things moms can do to avoid a preterm birth?" and "Has there ever been a time when you couldn't make it to one of your appointments?")

All semistructured interview participants were screened for eligibility (at least 18 years of age, neighborhood resident, currently pregnant, or with a child under the age of 1 year). Participants were interviewed between March and April, 2015. Although the sample size was smaller than typical for descriptive work using this approach [17,18], the issues faced by these women were sufficiently similar that few new ones emerged in succeeding interviews, leading us to move on to secure direct feedback from potential users of the app prototype [19].

We interpreted the interviews based on established medical science and clinical practice (normative analysis), as well as research into decision-making processes (descriptive research). Tables 1 and 2 outline critical preterm birth factors that we identified from the normative and descriptive analyses and the features we incorporated into the app to address each of them. These risk factors were pregnancy history (eg, prior preterm births, neonatal intensive care unit stays for previous births), weight gain trajectory (using the 2009 Institute of Medicine guidelines), smoking, alcohol consumption, illegal drug use, symptoms of preterm labor (eg, vaginal bleeding and fluid loss), intimate partner violence (assessed with the HITS Screening Tool that measures "hurt, insult, threaten, and scream") [20], and depression (assessed with the Edinburgh Postnatal Depression Scale) [21]. This final app content was reviewed by the physician experts in our team for accuracy and potential clinical benefit. Our descriptive interviews revealed that transportation to appointments was a barrier to prenatal care, particularly among low-income patients. To lower this barrier, we incorporated free transportation using Uber into the app's functionality.

Table 1. Behavioral risk factors identified in normative and descriptive research and addressed in the MyHealthyPregnancy app.

Pregnancy risk factor	Common challenge or misperception	Exemplar quote	App-based solution
Nutrition and weight gain	Avoidance of weight measurement Beliefs about nutrition	"I'm really into fitness and workout every day, so it's depressing to me to see how much weight I've gained. So, I actually only weigh myself when I come (to the hospital)." "(The midwives) said I needed to start eating healthy. I just kept eating beef jerky, slushies. I didn't eat bad food. I just ate what pregnant girls want to eat. I said, 'If I'm getting bigger, that means my baby is growing. So, it doesn't matter'."	Daily weight monitoring and feedback on ideal weight trajectory FAQs on appropriate diet
Symptomatic bleeding or fluid loss	Confusion between spotting, miscarrying, and menstruation	"My pregnant sister is kind of nervous because she's actually on her (menstrual) period now, and she doesn't want to (have a miscarriage) again."	Daily symptom assessment with feedback on need for immediate medical care (when appropriate)
Routine prenatal care	Barriers to transportation	"There were plenty of times (I missed appointments). I would normally have to catch a bus...and then I would have to walk up that big, long hill and then make a left...when (my belly) was getting out to here, I was like, 'Ugh, I can't do it anymore'."	Complimentary transportation via Uber
Violence	Fear for personal safety during pregnancy	"(He) shot at me...because I used to date his cousin. He's tried to come after me quite a few times, even after I gave birth."	Diagnostic assessment of intimate partner violence and provision of assistance
Smoking	Perceived safety of smoking during pregnancy	"When you're pregnant, it's better not to stop (smoking) because the baby knows that you're smoking and the baby can go through a nicotine withdrawal."	Routine assessment of smoking and provision of smoking cessation resources
Preterm labor	Unfamiliarity with signs of labor	"My boyfriend, he had me laughing hysterically and I thought I was going into labor. I actually googled 'laughing during pregnancy.'"	Contraction timer and feedback on preterm labor and delivery readiness
Fetal movement		"I always tell myself, 'If I don't feel her in the next hour, I'm going to the hospital'."	Kick counter

Table 2. Pregnancy risk factors noted in literature, but not in these interviews.

Alcohol use	Drug use	Depression	Pregnancy history
Routine assessment of alcohol consumption and provision of smoking cessation resources	Routine assessment of drug use and provision of smoking cessation resource	Mood monitoring with triggered and routine assessment of depression	Baseline assessment of pregnancy history

Risk Assessments and Communication

The MHP app gathered data regarding these risks factors through voluntary daily assessments. Deterministic algorithms then delivered patient-specific risk feedback and recommendations (eg, diet, lifestyle) tailored to individual users. For example, if the app detected a decrease in self-reported cigarette use, it provided encouraging messages in addition to quitting resources.

The app (Figure 1) also provided basic pregnancy education, reminders (eg, appointments), access to information and scheduling resources, and fetal health monitoring aids (fetal movement, "kick," and contraction counters). To spur action, as soon as the app detected high-risk events, such as intimate partner violence, suicidal ideation, or clinical indicators (eg, preterm contractions), it sent real-time alerts to medical staff (Figure 2). Women were then contacted directly and linked quickly to appropriate medical or social services.

Figure 1. Sample screenshots taken from MHP, which was evaluated in proof-of-concept pilot with 16 women. From left: (1) Home screen, (2) frequently asked questions, and (3) appointment scheduling tool.

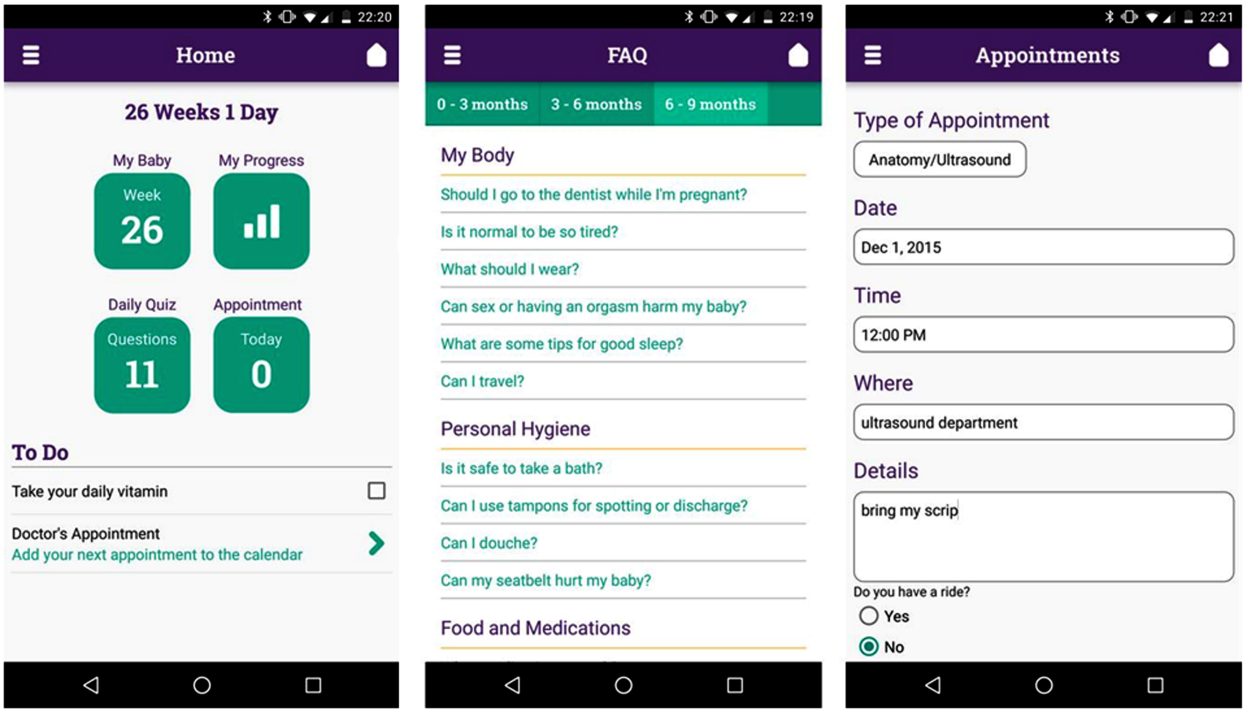
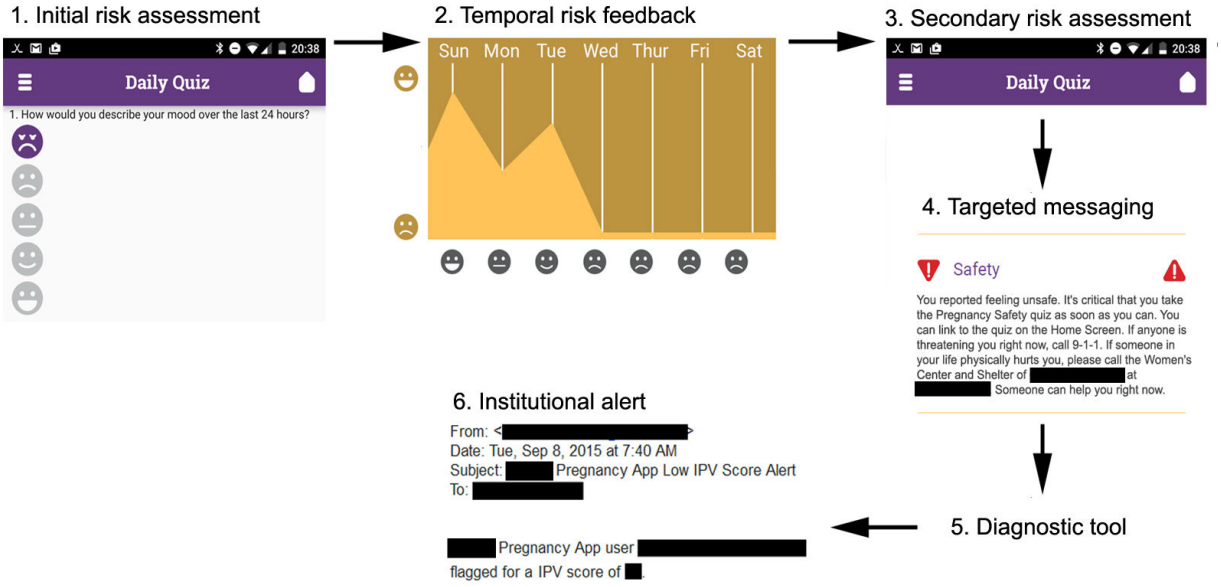


Figure 2. Logic diagram to identify, communicate, and intervene with a specific preterm birth risk (eg, intimate partner violence). From left: (1) user completes daily questionnaire, (2) user receives feedback on risk factor over time, (3) algorithm determines whether additional diagnostic questions are necessary, (4) user receives targeted messaging, (5) user completes validated diagnostic tool, and (6) physician receives real-time alert of intimate partner violence.



Usability Evaluation

Pilot Study

After completing the design and pretesting of the MHP app, we conducted a 3-month proof-of-concept pilot (N=16) to assess its usability by women in all stages of pregnancy. As the app had features targeted to each pregnancy trimester, we aimed to enroll 5 users per pregnancy trimester. Potential participants were identified at routine prenatal appointments at the Magee-Womens Hospital outpatient clinic, which serves patients qualifying for Medicaid. Participants were recruited from August 31 to September 3, 2015. All participants remained in the study for 3 months or until they gave birth.

After providing informed consent and completing a baseline assessment, participants received a digital weight scale and a smartphone preloaded with the MHP app. All participants agreed to complete monthly phone interviews.

The proof-of-concept study was reviewed and approved by the Institutional Review Boards of both the University of Pittsburgh and Carnegie Mellon University. All participants provided written informed consent before participating. Interviewees received US $35 for their time. App pilot participants received US $15 for completing each of 3 telephone interviews over the course of the study and an additional US $25 if they completed each component (interviews and daily quizzes). In addition, participants kept the scale and smartphone.

Measures

Participants completed daily quizzes on the app on a voluntary basis. A baseline quiz assessed baseline preterm birth risk and subsequent daily quizzes assessed the preterm birth risk factors identified in the normative and descriptive research (eg, mood, symptomatic bleeding or fluid loss, weight, and smoking, as detailed in Tables 1 and 2). Patients' responses were used to provide them with risk feedback (eg, weight trajectory contrasted with ideal weight trajectory) and to gather data on factors that can predict preterm birth. Over time, the app used the patient-entered quiz data to prompt for additional diagnostic measures. When algorithms prompted additional diagnostics, such as an intimate partner violence assessment, these were also administered as part of the daily quiz. Engagement was measured by frequency of use of the app, including completion of the daily risk assessment quizzes and additional diagnostic quizzes.

Participants also completed the following measures at baseline in person and at 1, 2, and 3 months by mobile phone:

1. The Perceived Stress Scale [22]: a 10-item inventory measuring how stressful various aspects of their lives are.
2. Behavioral intentions: an inventory with 2 health behaviors (breastfeeding for 6 months postpartum and daily intake of prenatal vitamin during the pregnancy).
3. Usability questions: 2 items regarding the helpfulness of the app and any technical difficulties.

At the final interview, participants who had given birth were also asked to share any information they desired about their birth experience and their use of the app.

Statistical Analyses

Our study was designed to evaluate the usability of the app, under normal conditions of a high-risk pregnancy, with no incentives for use (just for completing our instruments). As a result, our analyses focused on usage data, with suggestive indication of patterns. Given the low statistical power of these preliminary data, we used an alpha level of .1 for statistical significance, treating our analyses as exploratory. We used IBM SPSS Statistics 23.0 and R 3.3.1.

Results

Users

Table 3 summarizes participants' demographics and baseline data. Of 17 participants consented, 16 subsequently enrolled and remained in the study. One participant consented but chose not to enroll due to a time conflict with the enrollment session. Analyses are conducted for all 16 participants.

Table 3. Proof-of-concept pilot self-reported demographics (N=16).

Variable	Median (range) or n (%)
Age (years), mean (SD)	24 (18-35)
Race, n (%)	
African-American	11 (69)
Asian Indian	1 (6)
Hispanic/Latino	1 (6)
Caucasian	1 (6)
Mixed race, other	2 (12)
Income (in US $)	
0-5 k	6 (37)
5-9999 k	2 (12)
15-19,999 k	2 (12)
20-24,999 k	2 (12)
25-29,999 k	1 (6)
30-49,999 k	0
50-69,999 k	0
70,000 k or more	0
Respondent did not know	3 (19)
Education, n (%)	
Less than high school	2 (12)
High school/GED	3 (19)
Some college	9 (56)
2-year college degree (associates)	2 (12)
Bachelor's degree	0
Master's degree	0
Doctorate or professional degree	0
Previous smartphone ownership, n (%)	
Yes	16 (100)
Previously used a pregnancy app, n (%)	
Yes	13 (81)
No	3 (19)
Pregnancy planned? n (%)	
Yes	4 (25)
No	12 (75)
Gestational weeks at enrollment, mean (SD)	24.5 (11-30)
Had a previously very preterm birth? (<32 weeks), n (%)	
Yes	3 (19)
No	13 (81)

Birth outcomes for all 16 participants can be found in Table 4.

Table 4. Birth outcomes for the 16 pilot participants.

Birth outcomes	Frequency
Ongoing Pregnancy	1/16
Gave birth prior to study completion	0/1
Normal gestation (>37 weeks)	13/16
Gave birth before study completion	7/13
Late preterm (34-37 weeks)	2/16
Gave birth before study completion	2/2
Moderate (32-34 weeks) or very preterm (<32 weeks)	0/16
Gave birth before study completion	0/0

Engagement

On average, participants voluntarily logged into the app every 1.5 days to complete daily risk assessments, with the range of assessments completed being 16.7% to 100%. Once logged in, participants visited an average of 5 (SD 1.0) screens (eg, logging an appointment, viewing FAQs). At each monthly follow-up phone interview, participants were asked how helpful the app had been on a scale ranging from 1 (not at all helpful) to 10 (extremely helpful). The mean response at 1, 2, and 3 months was 9.0 (SD 1.15), 9.36 (SD 1.28) and, 9.25 (SD 1.0), respectively, with no difference in perceived helpfulness over time, $F_{1,26}$=1.70, *P*=.20.

In order to capture usage patterns, we characterized each day in terms of whether the woman took a daily quiz on that day (which, as mentioned, occurred on two-thirds of the days). We predicted this dependent variable from baseline data and covariates available when the last quiz was taken, using a generalized mixed logit model with a compound symmetric variance-covariance structure for the errors (ie, varying intercepts per woman), allowing women's responses to have a fixed correlation within person over time.

Table 5 reports the results of these separate, generalized mixed logit models. The strongest relationship was that women used the app more often at earlier weeks of gestation (Odds ratio, OR 1.07, 95% CI 1.02- 1.12, *P*=.005). The app was also used more by women when their daily mood (measured on a 5-point scale) was worse (OR 1.20, 95% CI 0.99-1.47, *P*=.08), when they were self-reported smokers (OR 4.00, 95% CI 0.93 -16.9, *P*=.06), and when they had a lower body mass index (OR 1.07, 95% CI 1.00-1.15, *P*=.05). App use was unrelated to whether women felt their baby move, had a greater weight, or were at a later stage of gestation at intake.

Table 5. Daily and baseline characteristics and their associated odds ratio of missing at least one day of daily quizzes given current levels of these characteristics using a generalized mixed logit model.

Characteristics	Daily/baseline	OR (95% CI)	*P* values	Sample size (quizzes)
Trimester at start	Baseline	0.60 (0.31-1.16)	.13	762
Weeks of pregnancy	Daily	1.07 (1.02-1.12)	.005	762
Daily mood	Daily	1.20 (0.99-1.47)	.07	759
Body mass index	Daily	1.07 (1.00-1.15)	.05	762
Obese (vs normal)	Daily	2.42 (0.98-6.03)	.06	762
Overweight (vs normal)	Daily	1.98 (0.53-7.47)	.31	762
Baby moved	Daily	0.81 (0.46-1.43)	.50	760
Current weight	Daily	1.01 (1.00-1.02)	.27	732
Smoking	Interval determined by baseline response	4.00 (0.93-16.9)	.06	762

Appointment Attendance

Participants had an attendance rate of 84% (63/75) at prenatal appointments, including 3 non-routine appointments for risks surfacing during the pregnancy, compared with 50% for the non-participant clinic population. Attendance was even higher - 89% (31/35 appointments) - among those who scheduled Uber transportation to their appointments through the app. The total cost across patients for providing Uber transportation was US $537.35. The conservatively estimated direct cost of a missed routine appointment provided by the Division Director of Maternal-Fetal Medicine of the hospital system is US $300 per patient. Therefore, the provision of rides suggested an approximate cost savings of US $7,203 for 16 patients over 3 months (~US $450/patient).

Communicating and Assessing Preterm-Birth Related Risk

No participants reported any of the following behavioral risk factors at baseline: intimate partner violence, depression, alcohol use, or illegal drug use. Two participants reported being cigarette smokers. Real-time data collection through the app over the course of 3 months identified 1 case of intimate partner violence, 2 cases of routine smoking, 6 cases of depression scores greater than 10 on the Edinburgh Postnatal Depression Scale, with one participant reporting suicidal thoughts, and 26 cases (2 participants) of illegal drug (marijuana) use. We pre-specified risk markers with potential clinical significance, such that the app electronically notified clinical members of our research team, thereby triggering appropriate clinical interventions. Table 6 tabulates the possible symptoms of preterm birth detected by the app. Algorithms also determined whether participants reporting certain symptoms were given messages that instructed them to call the clinic, go to the hospital, or engage in watchful waiting.

Table 6. Tally of preterm birth risk symptoms reported via the MHP app by trimester.

Symptoms reported	Trimester 1 (n events)	Trimester 2 (n events)	Trimester 3 (n events)	Percent of total events (N=693), n (%)
None	73	332	205	610 (88.0)
Cramping	0	4	32	36 (5.2)
Feeling contraction	1	2	32	35 (5.1)
Abdominal pain	0	2	6	8 (1.2)
Vaginal bleeding	0	1	1	2 (0.3)
Gush or fluid leak	0	0	2	2 (0.3)
Total (N events)	74	341	278	693

Risk-Reduction and Health-Promoting Behavioral Intentions

Breastfeeding

Agreement with the statement “I will try to breastfeed my baby for the first 6 months” increased over the study period. The mean response on a 5-point Likert Scale of agreement at 1, 2, and 3 months, respectively, was 3.63 (SD 1.63), 4.00 (SD 1.30), and 4.06 (SD 1.48). Paired *t*-tests revealed significantly higher intentions to breastfeed compared with those at baseline (mean=3.50, SD 1.41), at both 2 months, t_{13}=−4.16, *P*=.001 and 3 months, t_{15} =−2.76, *P*=.01.

Prenatal Vitamins

Agreement with the statement “How often do you think you will take a prenatal vitamin over the course of this pregnancy” stayed high over the course of the study among all users. The mean response, on a 7-point scale ranging from 1 (I definitely won’t take a prenatal) to 7 (I will take a prenatal vitamin every day without fail), was 6.31 (SD 0.87) at baseline, 5.81 (SD 1.56) at 2 months, and 5.57 (SD 1.99) at 3 months, respectively. These values were not statistically significantly different from one another.

Perceived Stress

Levels of perceived stress decreased from baseline and remained low over the course of the study. The mean response on a 40-point scale, with lower scores indicating less perceived stress, was 16.4 (SD 5.99), 13.1 (SD 5.89), and 15.0 (SD 7.71), at 1, 2, and 3 months, respectively, compared with the mean response of 16.81 (SD 6.06) at baseline.

Qualitative Feedback

Debriefing interview conversations with participants yielded three key insights. (1) They appreciated the risk feedback. (2) Many treated the app as a form of social support, with one participant stating, “(the app) was the only person in my life who asked me how I was doing every day.” (3) All reported wanting a similar app for the early stages of parenting, with one stating, “Please extend the information to after my baby is born (how much to eat, how long they should sleep for). Right now, I’m just asking friends and family...”

Discussion

Principal Findings

A persistent barrier to providing sound care during pregnancy is maintaining contact with women at highest risk. They often have difficulty making appointments. Once they do, health care providers may lack the time needed to learn about their conditions and convey the information most critical to their unique circumstances, especially when culture or socioeconomic differences complicate communication. As a result, health care professionals may fail to provide patients with information in a way that allows them to make informed decisions [23].

One solution to such imperfect patient contact may be virtual care, using mobile phone health apps. Targeting patients through an app poses unique challenges. The app must be engaging and both gather and provide accurate, medically relevant risk information. Although hundreds of pregnancy-related apps, performing a range of functions (from tracking symptoms to hospital bag checklists), exist, few have been developed through a scientific process. To the best of our knowledge, MHP is the first pregnancy app grounded in behavioral decision research that provides and gathers individualized preterm birth-related risk information.

We applied behavioral decision research theory and methods to create a smartphone app that could engage participants who typically face barriers to accessing routine prenatal care. Our

app sought to take advantage of a delivery mode that circumvented the barriers faced by women at high risk by connecting them with the health care system in a way that served their needs for two-way communication. Results from our proof-of-concept trial show a high level of engagement among women recruited from a clinic serving Medicare recipients. Participants were compensated for completing the 4 study surveys, but had no financial incentive for using the app. Nonetheless, they logged on every 1.5 days on average over the course of the pilot study and consulted an average of 5 screens when they did. Moreover, they expressed uniformly high levels of satisfaction with the MHP app, with some describing it in terms such as being a "virtual companion."

Although special caution is needed in considering individual differences with such a small, if intensively observed, sample, the app appeared to be used most consistently (Table 5) by women who might need it most, such as those early in their pregnancy, those with declining mood, and self-reported smokers. The candor and clinical value in their reports can be seen in cases that might otherwise be detected in a less timely manner. There were also individual incidents in which the app provided a vehicle for helping women who reported apparent cases of depression, intimate partner violence, and drug use. In these cases, and others, the app revealed risk information that was not captured at our study baseline or in routine clinical care.

We believe that our app represents an improvement over other pregnancy apps on the market as it reflects two features essential to effective applications. One is a patient-centered design, grounded in discussion with community leaders, formative interviews with individuals drawn from the target populations, and iterative pretesting in its development (in addition to the feedback from the proof-of-concept trial reported here). That sensitivity helped participants to share intimate information about their personal risk. The second feature is being grounded in behavioral decision research, whose theory and methods structured the four essential elements of the development process: normative analysis, with medical experts, providing authoritative, relevant content; descriptive research, with users, informed by the research literature; prescriptive interventions, informed by research on debiasing and risk communication; and evaluation, reported here. Those bodies of research provide a foundation for identifying and addressing misconceptions, such as the mistaken belief that vaginal bleeding is normal during pregnancy. We believe that these features allow us to exploit the technology so that, as our proof-of-concept pilot suggests, the MHP app can communicate and gather sensitive personal health risk information, including the detection of risks, at more frequent intervals than is possible by routine medical care.

We were also successful in increasing access to routine care. By providing Uber rides in real time, we could overcome the barrier posed by lack of transportation for low-income pregnant women who live in inaccessible neighborhoods or have difficulty planning. In addition, increased appointment attendance shows the potential of the MHP app for realizing significant savings to the health care system.

Our app is also designed to address the difficulty that health care providers often experience in communicating even simple recommendations for behavior change [7], especially to women at high risk. It uses language derived from conversations with women drawn from the user population, it acknowledges the practical barriers that they can face in implementing desired behaviors, and it repeats relevant information at frequent intervals. These features allow the app to provide both education and notification, two elements of successful behavioral change. Thus, the app's daily reminders about prenatal vitamin use may have helped to sustain the high level of self-reported intentions observed throughout the study. Breastfeeding intentions also increased significantly over the study, across women in different stages of pregnancy, suggesting the value of repeating an audience-friendly message.

We note that our study was a proof-of-concept observational study, and not a randomized controlled trial (RCT), limiting our ability to infer causality. Next steps include conducting a RCT over the entire pregnancy and evaluating the effects of the MHP app use on behavioral and clinical outcomes, including adverse birth outcomes, in conjunction with other clinical measures of preterm birth precursors. We also note that our volunteer participants were likely drawn from individuals familiar with smartphone apps and looking for support during the pregnancy. Given the proliferation of mobile phone–based health communications, such familiarity should be increasingly common, creating greater opportunity to take advantage of their speed, convenience, low cost, and potential confidentiality. Our MHP pilot results suggest that smartphone apps are a promising step for providing personalized care to at-risk patients who are otherwise hard to reach.

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Conflicts of Interest

Tamar Krishnamurti, Alexander L Davis, and Hyagriv N Simhan have a patent pending for the MyHealthyPregnancy app through Carnegie Mellon University and the University of Pittsburgh. Continuing work on the MyHealthyPregnancy app development is currently funded by a grant awarded to Tamar Krishnamurti from the Henry L. Hillman Foundation. The sponsors had no involvement in any stage of the design, implementation, analysis, or publication of this work.

References

1. Martin JA, Hamilton BE, Osterman MJ. Births in the United States, 2015. NCHS Data Brief 2016 Sep(258):1-8 [FREE Full text] [Medline: 27648876]
2. Martin JA, Hamilton BE, Sutton PD, Ventura SJ, Menacker F, Munson ML. Births: final data for 2003. Natl Vital Stat Rep 2005 Sep 08;54(2):1-116 [FREE Full text] [Medline: 16176060]
3. Martin JA, Hamilton BE, Sutton PD, Ventura SJ, Menacker F, Kirmeyer S. Births: final data for 2004. Natl Vital Stat Rep 2006 Sep 29;55(1):1-101 [FREE Full text] [Medline: 17051727]
4. Smaill FM, Vazquez JC. Antibiotics for asymptomatic bacteriuria in pregnancy. Cochrane Database Syst Rev 2015 Aug 07(8):CD000490. [doi: 10.1002/14651858.CD000490.pub3] [Medline: 26252501]
5. Meis PJ, Klebanoff M, Thom E, Dombrowski MP, Sibai B, Moawad AH, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. N Engl J Med 2003 Jun 12;348(24):2379-2385. [doi: 10.1056/NEJMoa035140] [Medline: 12802023]
6. Berghella V, Rafael TJ, Szychowski JM, Rust OA, Owen J. Cerclage for short cervix on ultrasonography in women with singleton gestations and previous preterm birth: a meta-analysis. Obstet Gynecol 2011 Mar;117(3):663-671. [Medline: 21446209]
7. Nguyen P, Thomas M, Koren G. Predictors of prenatal multivitamin adherence in pregnant women. J Clin Pharmacol 2009;49(6):735-742. [doi: 10.1177/0091270009333487] [Medline: 19386624]
8. American College of Obstetricians and Gynecologists. ACOG. Washington, DC; 2014. Effective Patient-Physician Communication URL: https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co587.pdf?dmc=1&ts=20160204T2009553625
9. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med 2013;10(1):e1001362 [FREE Full text] [doi: 10.1371/journal.pmed.1001362] [Medline: 23349621]
10. Martínez-Pérez B, de la Torre-Díez I, López-Coronado M. Mobile health applications for the most prevalent conditions by the World Health Organization: review and analysis. J Med Internet Res 2013;15(6):e120 [FREE Full text] [doi: 10.2196/jmir.2600] [Medline: 23770578]
11. Pew Research Center. Pewinternet. 2015. The Smartphone Difference URL: http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/ [accessed 2017-03-24] [WebCite Cache ID 6pCJrNURk]
12. Fischhoff B. Judgment and decision making. Wiley Interdiscip Rev Cogn Sci 2010 Sep;1(5):724-735. [doi: 10.1002/wcs.65] [Medline: 26271656]
13. Edwards W. Behavioral decision theory. Annu Rev Psychol 1961;12:473-498. [doi: 10.1146/annurev.ps.12.020161.002353] [Medline: 13725822]
14. Payne JW, Bettman JR, Johnson EJ. Behavioral decision research: a constructive processing perspective. Annu Rev Psychol 1992 Jan;43(1):87-131. [doi: 10.1146/annurev.ps.43.020192.000511]
15. Kujala S. User involvement: a review of the benefits and challenges. Behav Inf Technol 2003 Jan;22(1):1-16. [doi: 10.1080/01449290301782]
16. Gould JD, Lewis C. Designing for usability: key principles and what designers think. Commun ACM 1985;28(3):300-311. [doi: 10.1145/3166.3170]
17. Fowler FJ. Improving Survey Questions: Design and Evaluation. Thousand Oaks, Ca: Sage; 1995.
18. Presser S, Blair J. Survey pretesting: do different methods produce different results. Sociol Methodol 1994;24:73-104. [doi: 10.2307/270979]
19. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. Field Methods 2006 Feb 01;18(1):59-82. [doi: 10.1177/1525822X05279903]
20. Sherin KM, Sinacore JM, Li XQ, Zitter RE, Shakil A. HITS: a short domestic violence screening tool for use in a family practice setting. Fam Med 1998;30(7):508-512 Reproduced with permission of the author: Copyright contact: ksherin@yahoo.com. [Medline: 9669164]
21. Cox JL, Chapman G, Murray D, Jones P. Validation of the Edinburgh Postnatal Depression Scale (EPDS) in non-postnatal women. J Affect Disord 1996 Jul 29;39(3):185-189. [Medline: 8856422]
22. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983 Dec;24(4):385-396. [Medline: 6668417]
23. Street Jr RL, Gordon HS, Ward MM, Krupat E, Kravitz RL. Patient participation in medical consultations: why some patients are more involved than others. Med Care 2005 Oct;43(10):960-969. [Medline: 16166865]

Abbreviations

MHP: MyHealthyPregnancy
IPV: intimate partner violence
RCT: randomized controlled trial

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Original Paper

Technology Use and Preferences for Mobile Phone–Based HIV Prevention and Treatment Among Black Young Men Who Have Sex With Men: Exploratory Research

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Abstract

Background: Black young men who have sex with men (BYMSM) experience higher human immunodeficiency virus (HIV) incidence than their white and Latino counterparts.

Objective: The aim of our study was to understand BYMSM's preferences for mobile phone–based HIV prevention and treatment in order to inform culturally tailored interventions to reduce the spread of HIV and improve HIV treatment outcomes in this population.

Methods: Qualitative focus groups (N=6) with BYMSM aged 18-29 years (N=41; 46%, 19/41 HIV-positive) were conducted to elucidate their preferences for the design and delivery of mobile phone–based HIV prevention and treatment interventions. A modified grounded theory approach to data analysis was undertaken using ATLAS.ti textual analysis software.

Results: Participants preferred holistic health interventions that did not focus exclusively on HIV prevention and treatment. Issues of privacy and confidentiality were paramount. Participants preferred functionality that enables discreet connections to culturally competent health educators and treatment providers who can address the range of health and psychosocial concerns faced by BYMSM.

Conclusions: Mobile phone–based HIV prevention has the potential to increase engagement with HIV prevention and treatment resources among BYMSM. For these approaches to be successful, researchers must include BYMSM in the design and creation of these interventions.

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KEYWORDS

HIV; AIDS; mobile applications; African Americans; men's health; homosexuality; bisexuality; young adult

Introduction

Background and Significance

Although gay, bisexual, and other men who have sex with men (MSM) comprise approximately 2% of the US population, they accounted for 67% of all estimated new human immunodeficiency virus (HIV) infections in 2014 [1]. Black MSM are disproportionately infected with HIV comprising 38% of all HIV diagnoses among gay and bisexual men in 2014, and 78% of diagnoses among all black men in 2014 [2,3]. Black young MSM (BYMSM) between the ages of 13 and 24 years accounted for over half (54%) of new HIV infections among all MSM in that age group [3]. In Los Angeles (LA) County, youth aged 18-29 years constituted 40% of all HIV diagnoses among black men in 2013 [4], and 71% were unaware they were HIV-positive [5]. These data demonstrate that despite current prevention efforts, BYMSM remain disproportionately affected by HIV both nationally and locally.

Previous research indicates that BYMSM face many barriers to HIV testing and treatment [6-8]. In particular, if diagnosed with HIV, BYMSM are less likely to receive appropriate HIV care, be on antiretroviral therapy (ART), or perceive they have access to medication, often due to factors such as economic disadvantage and limited access to culturally appropriate health care [2]. BYMSM also may experience disapproval, discrimination, and homophobia from their families and faith communities and may resist disclosing their sexuality out of fear of rejection [5,7,9]. Such barriers highlight the need to develop tailored HIV prevention and treatment interventions that address the complex structural and psychosocial barriers impacting the health and wellness of BYMSM. Whereas some HIV prevention and treatment interventions target black MSM (ie, Many Men, Many Voices; The Bruthas; MAALES; ES-HIM), few are designed specifically for BYMSM [10-14]. Culturally tailored interventions are especially important when targeting certain subpopulations since varying cultures have been known to espouse different knowledge and attitudes in regards to HIV risk [15]. Nevertheless, previous research demonstrates that culturally appropriate materials can positively impact health behaviors among BYMSM [16].

Mobile Technology, Young Adults, and MSM

Mobile technology, including the Web and mobile phone apps have become important venues for information seeking, communication, and social networking [17]. Young adults aged 18-29 years in the United States represent a digital generation": 83% of this population owned a mobile phone and 97% reported using the Web or email through a mobile device as of January 2014 [17]. Young men who have sex with men (YMSM) also use mobile technology to seek sexual health information and find mobile phone–based HIV prevention interventions acceptable [18-20]. In Los Angeles, 89% of racially or ethnically diverse young MSM mobile phone users accessed the Web to find information about HIV or acquired immune deficiency syndrome (AIDS), whereas 79% used the Web to find an HIV testing location [21].

MSM are also increasingly using geosocial networking (GSN) apps such as Grindr, Jack'd, and Scruff to locate sexual partners, meet friends, and connect to gay communities [22,23]. The use of GSN apps among MSM has been associated with an increased risk for sexually transmitted infections (STIs). A large community-based study by Beymer et al [24] found that MSM in Los Angeles who used GSN apps to meet sexual partners had greater odds of testing positive for gonorrhea and chlamydia compared with those who had not used GSN apps to meet sexual partners. Given the widespread use of technology among young adult populations, the associations between GSN app use and HIV or sexually transmitted infection (STI) risk, and YMSM's willingness to receive HIV prevention information via mobile phone, tailored mobile phone–based prevention and treatment interventions are needed to address HIV-related health disparities among BYMSM [21].

Mobile Technology Interventions and BYMSM

Previous research has demonstrated the need for and effectiveness of technology-based interventions in improving outreach, testing, and linkage to information about and services for HIV among YMSM [25-27]. Although limited, some studies document the outcomes of technology-based interventions targeting BYMSM. For instance, Hightow-Weidman's [16] pilot of HealthMpowerment (HMP), a 4-week, interactive, theory-based Web-based HIV and STI intervention targeting black men in North Carolina (aged 18-30 years) found that participants in the intervention group reported increased intentions to use condoms, as well as engagement in preparatory condom use behaviors, compared with control group participants. HMP also maintained a 90% retention rate at one-month following the intervention and a 78% retention rate at 3 months. A Philadelphia-based, 12-week, text messaging (short message service, SMS) HIV prevention intervention targeting sexually active BYMSM (16-20 years old) who owned a mobile phone, sent 3 weekly HIV prevention-related text messages to intervention group participants, and 3 weekly nutrition-related text messages to control group participants. This study found higher awareness of sexual health among intervention group participants compared with the control group participants at follow-up [28].

The development of mobile phone app interventions for BYMSM has the potential to increase HIV testing and treatment among this high-risk population. Technology-based interventions offer opportunities to engage MSM who are less accessible to researchers and clinicians due to stigma associated with sexual minority identity disclosure, yet who may still engage in high-risk behaviors [29]. This type of intervention is promising because it could be accessed privately by users, helping to circumvent the stigma associated with same sex-sexual behavior or HIV-positive status among some BYMSM [30]. YMSM participating in technology-based HIV prevention interventions and formative research on mobile technology also express satisfaction with and willingness to use mobile phone–based HIV prevention programs [16,21,26]. However, few HIV prevention interventions have been tailored for mobile phone platforms and many fail to attract mobile phone users, receive low user ratings, and are not commonly designed for racially or ethnically diverse populations [2].

Present Study

Given increasing HIV rates among BYMSM, the psychosocial barriers they face related to HIV testing and treatment and their access to and use of mobile phones apps, there is a critical need and opportunity to develop innovative, culturally tailored mobile phone–based HIV prevention strategies for this population. However, little research has qualitatively examined BYMSM's use of apps and preferences for mobile phone–based HIV prevention and treatment, which may be helpful in understanding how to tailor mobile phone–based HIV prevention and treatment efforts for BYMSM. Using qualitative methods, this study sought to elucidate the types and patterns of technology use among a sample of BYMSM in order to better understand their preferences for mobile phone app interventions as a mechanism to promote outreach, HIV testing, and linkage to appropriate HIV and health-related services.

Methods

Participants and Procedures

Data were gathered through focus groups with BYMSM in Los Angeles, California (6 focus groups, 6-8 participants per group, N=41). For this study, we defined youth according to Arnett's (2000) definition of emerging adulthood [31]. Participants were recruited through flyers posted in a range of community-based agencies serving BYMSM throughout LA County. Flyers instructed potential participants to call a central number where they were screened for eligibility. Eligible BYMSM were 18-29 years old; identified as male; identified as black; identified as gay, bisexual, or had had sex with a man in the past 6 months; and had access to a mobile phone. A total of 49 potential participants inquired about the study, 3 were ineligible, and 5 screened eligible but did not attend their scheduled group.

Each focus group lasted 90-120 minutes, was audio-recorded, and conducted in English in private rooms at 2 community-based agencies serving BYMSM in Los Angeles. Prior to the initiation of focus groups participants completed a pre-focus group assessment that asked them to provide information about their demographic characteristics, mobile phone ownership, and social media use. Two trained members of the research team led each focus group and another took notes. Participants were assigned identification numbers, which were used to protect their identities and to track their responses throughout the focus group discussions. Each participant was paid US $20 as an incentive. Study protocols, including informed consent procedures, were approved by the North Campus Institutional Review Board at the University of California, Los Angeles.

Measures

Semistructured focus group methodology was chosen to enable participants to interact with each other in response to a series of a priori questions developed by the research team. This approach was chosen to generate a richness of data not always possible with individual interviews in addition to being a more efficient way of resolving any seemingly conflicting information [32]. Semistructured focus group guides contained a range of questions regarding technology use, health and wellness, access to community resources, experiences on GSN apps, and desired features for mobile phone–based HIV prevention and treatment interventions. Questions were asked in such a way as to allow participants to discuss the positive and negative aspects of the technologies in question.

For this analysis, we focused on the following 2 semistructured interview topics: (1) experiences and impressions of existing mobile apps for gay and bisexual men, and (2) preferences for functions of a mobile phone app for HIV prevention and treatment targeting BYMSM. First, BYMSM were asked about their current experiences with mobile phone apps and the strengths and weaknesses of existing apps. Specifically, we asked which GSN apps participants preferred and the circumstances under which they used these apps. We asked participants to describe preferred features and functions on existing apps. We were particularly interested in what BYMSM might want to see on a new mobile phone app for promoting HIV prevention and treatment. Finally, participants were asked to consider themselves app designers and to suggest layouts, features, functions, and content areas for a new app.

Data Analysis

Audio recordings of the focus groups were transcribed verbatim for analysis by an independent agency and reviewed by the research team for accuracy by listening to the audio recordings and comparing them with the written transcripts. Transcripts were then analyzed using a methodology of "coding consensus, cooccurrence, and comparison" [33]. This methodology relies on iterative coding of focus group transcripts using a priori and emergent codes and team meetings to refine analytic codes and establish interrater reliability. Specifically, the research team reviewed an initial sample of focus group transcripts to identify key themes via in vivo coding, which formed the basis of a formal codebook. The codebook was refined after an iterative coding process and, once finalized, two members of the research team were responsible for coding the interviews separately. Communication between research team members took place after formal coding of all focus groups, for which we used ATLAS.ti textual analysis software [34]. Interrater reliability was calculated by comparing a subset of transcripts and calculating the percent match of a priori codes between the two research assistants. High interrater reliability was achieved (93%). When inconsistencies between coders occurred, a third member of the research team was consulted to discuss and help resolve any inconsistencies. Our analysis focused on the narratives that emerged from discussing the two thematic areas named above (ie, mobile phone app usage patterns and preferences for mobile phone app development).

Analysis was guided by a modified grounded theory approach (ie, theory derived from data and then illustrated by characteristic examples of data) [35]; transcripts were reviewed and memos were written to document initial concepts and to define the boundaries of specific concepts [36]. Field notes and interview transcripts were then independently coded to condense the data into analyzable units. Segments of text ranging from a phrase to several paragraphs were assigned codes based on a priori definitions (ie, from the interview guide) or emergent themes (also known as open coding) [35]. Based on these codes, the computer program ATLAS.ti was used to generate lists of

codes, which were then summarized and entered into data matrices (with the focus group on the column and content area on the row) for comparison across focus groups. Through the process of constant comparison, the codes were further condensed into broad themes [35]. In the reporting of results, pseudonyms were developed for each participant to maintain confidentiality and protect the identities of human subjects.

Results

Descriptive Statistics

The total sample consisted of 41 BYMSM. Participants' ages ranged from 19-29 years; the average age being 26 years. More than three-quarters of the sample identified as gay (31/41). Over half had received some education past high school (56%, 23/41) and an additional 27% (11/41) had graduated college. Participants were stably housed: over half (60%; n=24) rented a house or apartment and nearly two-thirds (65%, 33/41) lived with others. More than three-quarters of the sample had part- or full-time employment (78%, 32/41) and more than a third made less than US $12,000 annually.

Principal Results

The majority of participants used either an Android mobile phone (61%, 25/41) or iPhone (46%, 19/41), which they reported using to communicate most frequently with either friends or romantic partners (59%, 24/41 and 22%, 9/41). The most popular methods of communication via mobile phone were talking (83%, 34/41) and texting (90%, 37/41). Popular social networking sites included Facebook (85%, 34/41), Instagram (85%, 34/41), and Twitter (48%, 19/41). The majority of the sample used social networking apps, with 71% (27/41) reporting daily use. Popular GSN apps for partner seeking included Jack'd (53%, 21/41) and Grindr (18%, 7/41); popular websites for social or sexual networking included Craigslist (38%, 15/41) and Adam4Adam (23%, 9/41). Tables 1 and 2 provide additional information on demographic characteristics and mobile phone and other technology use.

Table 1. Demographic characteristics among BYMSM in Los Angeles, California (N=41).

Characteristic	n (%)
Mean Age (in years)	25.8 (3.1)
Sexual orientation, n (%)[a]	
Heterosexual	1 (3)
Bisexual	7 (18)
Gay or homosexual	31 (78)
Other	1 (3)
Highest educational attainment, n (%)	
High school graduate or less	7 (17)
Some college or trade school training	23 (56)
College graduate or above	11 (27)
Current living situation, n (%)[a]	
Own home or condo	3 (8)
Rent house or apartment	24 (60)
Family member's house	9 (23)
Friend's house, condo, or apartment	1 (3)
Spouse or lover or sexual partner's house, condo, or apartment	1 (3)
Homeless shelter or "safe house"	1 (3)
Other	1 (3)
Currently lives with (check all that apply), n (%)[b]	
Alone, no other person	8 (20)
A spouse or lover	5 (13)
A sexual partner (not spouse)	2 (5)
Other adult family members	12 (30)
Close friends or roommates	14 (35)
Children under the age of 18 years	1 (3)
Other	1 (3)
Main source of income in past 6 months (check all that apply), n (%)[b]	
Employment (part- or full-time)	32 (78)
Food stamps, welfare, disability, unemployment	13 (32)
Other	3 (7)
Money in the last 30 days, n (%)[a]	
Less than US $50 (eg, less than US $600 per annum)	3 (8)
US $51-US $249 (eg, US $600-US $2999 per annum)	4 (10)
US $250-US $499 (eg, US $3000-US $5999 per annum)	8 (20)
US $500-US $999 (eg, US $6000-US $11,999 per annum)	5 (13)
US $1000-US $2999 (eg, US $12,000-US $35,000 per annum)	9 (23)
US $3000-US $4999 (eg, US $36,000-US $59,000 per annum)	5 (13)
US $5000-US $6249 (eg, US $60,000-US $74,999 per annum)	1 (3)
Refused	5 (13)

[a]Percentage may not equal 100 due to rounding.

[b]Response options included check all that apply; percentages will not add to 100.

Table 2. Mobile phone and other technology use characteristics among BYMSM in Los Angeles, California (N=41).

Characteristics	n (%)
Mobile phone type (check all that apply)[a]	
Android	25 (61)
iPhone	19 (46)
Other	1 (2)
Via mobile phone, communicates most with (check all that apply)[a]	
Friends	24 (59)
Spouse or lover	9 (22)
Casual sexual partner	3 (7)
Exchange sexual partner (for sex work)	1 (2)
Roommate	4 (10)
Family of origin	8 (20)
Refused	2 (5)
Uses mobile phone to connect with people by (check all that apply)[a]	
Talking	34 (83)
Texting	37 (90)
Email	28 (68)
Apps	31 (76)
Websites	19 (46)
Other	1 (2)
Other devices used (check all that apply)[a]	
Laptop	29 (73)
Desktop computer	10 (25)
Tablet	15 (38)
Public computer (eg, at a library)	7 (18)
Wearable device (eg, Fitbit, Up Band, Nike Fuel Band)	1 (3)
Social networks used (check all that apply)[a]	
Facebook	34 (85)
Twitter	19 (48)
Instagram	34 (85)
Pinterest	3 (8)
LinkedIn	8 (20)
Google+	11 (28)
Snapchat	5 (13)
MySpace	2 (5)
Dating or hook-up websites currently used (check all that apply)[a]	
Craigslist.org	15 (38)
Gay.com	2 (5)
Adam4Adam.com	9 (23)
Blackgaychat.com	1 (3)
Match.com	1 (3)
Other	7 (18)

Characteristics	n (%)
Dating or hook-up apps currently used (check all that apply)[a]	
Grindr	7 (18)
Jack'd	21 (53)
Other	3 (8)
Frequency of social networking app use to connect with people[b]	
Daily	27 (71)
Weekly	8 (21)
Monthly	1 (3)
Less than once per month	1 (3)
Refused	1 (3)
Typical way of connecting with people in their life (check all that apply)[a]	
In person	24 (60)
By mobile phone (not mobile phone)	6 (15)
By mobile phone	31 (78)
By computer (laptop or desktop)	8 (20)
By tablet	1 (3)

[a]Response options included check all that apply; percentages will not add to 100.

[b]Percentage may not equal 100 due to rounding.

Mobile phone App Usage Patterns

As discussed previously, BYMSM used their mobile phones for varied reasons, including communicating with friends and family, checking emails, engaging with social media, and for personal entertainment. Many engaged in a combination of these activities and found that it made them more "efficient." For example, 29-year-old Darrius used his Android phone to increase his organization and productivity, which he preferred over a regular cellular device:

> *To be efficient in time, like time management. I love Google Now. Navigating purposes, as far as the public transportation, and driving are key for me...And it's like everything on social media and the communication aspects—I can use a regular phone for that, you know what I'm saying? But a mobile phone helps you be efficient.*

Others found that syncing their apps made their lives easier. The integration of multiple apps was important for Alex, a 28-year-old iPhone user:

> *What I like most about the Nike+ Running app is the fact that it integrates with the music that's on my phone, so I'm able to play music as I'm jogging or as I'm running. And then it will adapt—or I can control the music on the go and I don't have to completely go back into iTunes to adjust. It also simultaneously will tell me distance, location, and pace. So I like that it reminds me every so often what my pace is and what I'm doing without me having to think about it.*

When asked why they used their mobile phones and which apps they used most frequently, BYMSM did not mention partner-seeking apps. Whereas this was true across all focus groups, when probed on their use of these apps, almost all BYMSM in the study mentioned using GSN apps such as Grindr, Tinder, and Jack'd. Many mentioned regular use of these apps, while others reported more sporadic use. Some described themselves as "chronic" users. For instance, Marcus, a 23-year-old iPhone user, went so far as to say he was addicted to one:

> *I'm a chronic (GSN app) user. I'm very addicted to (it) at this point. Since I've redownloaded it about 6 months ago, I've accumulated about 480 unread messages and I pick and choose who I want to reply to. Just seeing that number, it does something to my self-esteem that I specifically can't do for myself.*

Interactions on these apps were not always positive, however, and many participants experienced racist or derogatory remarks from other users. Marcus went on to share his negative experiences on a popular partner-seeking app:

> *I would be approached or messaged by Caucasian men and they would make reference to my "big black cock," of which I don't have a picture of anywhere on my profile. I felt like they were putting me in the stereotype of big black men that have these knee-dangling penises and they're just letting everybody suck it. Also one (older) Caucasian man wanted me to be his "slave"...his "bedroom slave." One man was a Latino. He just wanted to tell me I was a nigger and cussed me out in Spanish, called me "mayate"—that's Spanish for a bug.*

In response to and in anticipation of overtly racist interactions, several participants used app features that blocked racist or aggressive users, filtered for their preferences (in order to avoid other users based on race), or created detailed profiles outlining expectations for communication in order to avoid negative conversations. This allowed participants to "filter by race," meaning that they would use the filter function to view only other black men and to structure potential partners on the app to a group of users they thought reflected their own desires and responded to them in a manner that they appreciated.

Julian, a 25-year-old iPhone user, shared:

> *...I have to be honest, you know, I try as much as I can personally to filter through race before I actually meet somebody.*

While filtering and blocking were strategies used by many BYMSM across different apps, specific features of a popular app allowed for users to see who had viewed their profile. This in turn allowed them to see the types of people they attracted and decide with whom to speak. Additionally, many participants commented on the detailed nature of many other users' profiles that stated "what kinds of people they're interested in," allowing them to know if a fruitful conversation was probable. As Jeffrey, a 20-year-old Android user, and Nathan, a 21-year-old Android user, discussed:

> *With who's been viewing you, you can see how many times they usually reply to people, what kinds of people they're interested in, like black, Latino, bears, strictly friends or something like that...who you message and who you talk to.* [Jeffrey]

> *I guess I like how the profile is on (GSN app name) because everything is right there. You have your pictures on one side and then you have all the information about the person on the other side. You can determine if you think you're going to like the person right off the bat because all of the person's qualities or features is right there.* [Nathan]

In general, participants appreciated easily accessible information about potential partners and getting tailored feedback on their app use to facilitate partner seeking and limit negative interactions.

Preferences for Mobile Phone App Development

There was a high degree of support for a mobile phone app for promoting HIV prevention and treatment. However, there was nearly universal agreement that this app should go beyond HIV and address health and wellness more broadly. Many thought that app users should have direct access to trusted doctors and clinicians via an app; yet, participants were torn between whether they should be able to communicate with other users. Some thought that this could be a potential for meeting new friends or even new partners who are also concerned with taking care of their health. Kevin, a 29-year-old Android user commented:

> *This app should have something so you can talk (to) other people who have the app. For example, he may not want to go to the clinic by himself and maybe someone else is going to go, so maybe they can go (together) (sic)...You know, it should be a message board.*

Dejuan, a 20-year-old iPhone user elaborated:

> *I would say direct (messaging) too. You can meet people that have this app, so (that) you know either this person is protected, they know what they're doing, or they're taking care of themself health wise.*

Additionally, participants thought it useful to meet someone who has been through the same issues they might be going through and viewed an app as an opportunity to obtain peer advice rather than strictly medical or professional insight.

Elijah, a 21-year-old iPhone user said:

> *You can actually go to other people for advice. Say, for instance, they already dealt with the problem that you're having, so you can go to them and be like, 'Oh, what did you do? What stuff did you take?' And it can actually help you through it.*

Some expanded on this idea of using an app to meet people with whom they have shared experiences by looking for a "sponsor." Ryan, a 29-year-old iPhone user thought that using a mobile phone app to target BYMSM who are newly HIV-positive would provide an avenue for users to connect with someone who could walk them through the HIV health care process:

> *If you're targeting young, black, African-American males who are just finding out that they are HIV-positive or afraid to deal with the stigma of being HIV-positive, I think it would be great if you were able to click on an app to find a sponsor or someone that would help guide you through the motions. Tell you, 'Let's go find a testing site. I'll walk you through this.*

Conversely, some participants thought that being able to communicate with other users would be a potential breach of the app's confidentiality and strongly opposed communicating with other users on the platform. These participants thought that you should only be able to connect to a local health provider for services or information. Jordan, a 29-year-old Android user elaborated:

> *I agree with only doctors, especially in this lifestyle, you know, people are going to say you've been doing something else. You don't want that on the app because that's going to make people not want to get on the app no more.*

Ryan, a 29-year-old iPhone user, further reflected on the importance of confidentiality:

> *As I said earlier when it comes to apps, everybody knows everybody, knows everybody. And especially when you deal with African-American homosexuals in this environment of West Hollywood...If I choose to go to a testing facility or go somewhere, I'm going to be selective of where I go specifically, so my information doesn't get to someone's friend who knows someone who knows someone, (when) it should be confidential.*

Participants viewed an app as a way to directly connect to a provider privately and confidentially and as a way to avoid automated machines or culturally insensitive HIV health care providers that could taint their experiences of engagement with HIV prevention and care.

Terrance, a 22-year-old iPhone user stated:

> *Just to be able to go through that app to make an appointment. I don't want to have to call; you know what I mean? If I do have to call, then yeah, the number should be on the iPhone, you can click the number and it just directly calls. But on the app, if I'm able to, type, 'Hey, this spot is open, can (I) come in at this time?' it saves me talking to Susie at the front desk and the automated service, which both will piss me off.*

While the majority of participants were excited about the prospect of a new health app geared toward black gay men, they struggled with whether it should be directed only to BYMSM. Citing the many health disparities that exist more generally for men of color, and particularly black men, some thought that the app would be better if it were general in its approach, but allowed for the user to personalize its content. Deshawn, a 28-year-old iPhone user, thought strongly that the app needed to focus on issues outside of HIV and STDs and to be more encompassing to black men's health more generally:

> *Even though we're African American gay men, we're still African American men and we still experience the same health disparities that black men in general experience, but we're so caught up on HIV and STDs that we don't talk about other stuff like diabetes or colon cancer and all these other things. So I think making it broader will not only expose other people to this, but will also expose us to things.*

Furthermore, some participants thought that the app could more broadly cater to the larger black community. Sebastian, a 25-year-old Android user argued:

> *Don't just make it a gay thing...Make sure it's health, period, for black people, because that's the struggle of trying to get black people in health care.*

Despite overall enthusiasm for the creation of an app that would facilitate health and wellness among BYMSM, many participants cited potential barriers to its effectiveness. One such barrier would be if the app were viewed as too "pushy" or forced HIV-related content. Sebastian, contended:

> *Having too much awareness, like having all the ads about HIV and all the ads about health care, sometimes they make you scared to go. You know, like, people try to push religion on you? It makes you feel like—someone trying to push health care on you.*

Other barriers included the accessibility and readability of the information on these apps. For example, participants were concerned about the technical language used on some health websites, such as WebMD. Marcus, a 23-year old iPhone user, stated:

> *Yeah, I've tried WebMD but it wasn't easy for me to use...I think it was the terminology that I didn't understand. When I would click on a certain body part and it'd give me this list of stuff, I'm like, 'What's a tracheal tube?' you know?*

Despite concerns about the use of technical language within the app and fears about privacy and confidentiality, the general consensus among participants was an excitement for the creation of a health app for BYMSM. In order to further refine how an app to promote HIV prevention and treatment for BYMSM might be most successful, participants suggested many features and functions that they would appreciate (see Tables 3 and 4).

Table 3. Content for a health app suggested by BYMSM in Los Angeles, CA (N=41).

Content	Example quotes
Rating and reviews for local clinics and providers	Cedric: "I think a Yelp approach...So I think something like that where you can rate the clinic, where you can rate the provider, and be able to give as detailed or as little of information and feedback..."
Statistics and health news	Dejuan: "I think it should have—you know how they have trending topics, Twitter and all that, it should have statistics and stuff like that too, so people can also be aware as well of other things. Like this many people this, or this many people that. This many people came in this day and got this."
Content on fitness and nutrition	Deshawn: "This may be obvious but I was thinking having the site broken up into clear categories, so mental health versus sexual health versus fitness and nutrition. And then having subcategories under each of those. So from the home page, it's very easy to access whatever specific information you want. You don't have to search through the app to find it."
Other holistic health information not limited to HIV and STDs	Craig: "I think also it would be great to have something that also offers culturally competent mental health services and stuff like that, because beyond just HIV, STD stuff, because there are so many other things that people don't realize that they can have access to resource-wise..."
Localized content about health and up-coming events for BYMSM	Jordan: "Yeah, if you want information, you can login to that app and be like, okay, this is this. Even, it can be different party sites, different clubs going on for the—like, all types of stuff. It's just an app that makes you want to login because you don't know what type of information you're going to get."
Symptom checker	Rohan: "You can have STD information, kind of like how WebMD has it. You can put in symptoms and stuff."

Table 4. Features and functions of a health app suggested by BYMSM in Los Angeles, CA (N=41).

Features and Functions	Example quotes
Direct messaging to clinics and primary care providers	Jaron: "So maybe to be able to be in contact with somebody, like a nurse hotline or something, somebody who could respond to you directly via chat."
User chat and message boards	Kevin: "You know, it should be a message board. Dejuan: I would say direct too. You can meet friends on here but you only meet people that have this app, so you know either this person is protected, they know what they're doing, they're taking care of themself (*sic*) health wise."
Geolocation of testing and care clinic locations	Jeffrey: "Yeah, like the tabs, like different tabs. Because my idea was that it would give updates so that could be one tab is the updates. And then the second tab could be, like, a proximity for where the closest clinics are or something like that. And then another tab could be...whatever else we were coming up with. But different tabs so you can swipe through all your stuff."
Contests and prizes for participating in health games	Nathan: "You can also do—just ask questions about—it can be a random question about, "What is HIV?" and then the first person to answer the question gets movie tickets."
Find a sponsor for newly diagnosed or out-of-care HIV-positive men	Ryan: "When you think about Grindr, Jack'd, and we talk about confidentiality and the good parts about that is picking and choosing who you can deal with and who you want to and you can block people. I think it would be great if you treat the app just like an AA sponsor. If you're targeting young black, African-American males who are just finding out that they are HIV-positive or afraid to deal with the stigma of being HIV-positive, all the above, I think it would be great if you were able to click on an app to find a sponsor or someone that you can disclose confidentiality to that would help guide you through the motions."
Integration with popular dating and relationship apps	Devon: "I think maybe having an app that is cater—we know that as, you know, young black men, everybody's out there having sex. Why not cater to an app that at the forefront is health, where you know that they're having sex, you know what I mean? Instead of something like Jack'd where it's just a sex site. A4A is just a sex site. That it has health advertisement. How about having something that is a health site that you can find somebody that you can have sex with?"

Discussion

Principal Findings

This study was among the first to qualitatively explore BYMSM's preferences for mobile phone–based HIV prevention and treatment. BYMSM continue to be disproportionately impacted by HIV despite existing prevention efforts [2,3,37]. While mobile technologies represent powerful tools to recruit, engage, and deliver HIV prevention and treatment information to young people [38], few studies have effectively harnessed these technologies to reach BYMSM [39]. Our study sought to understand the ways in which BYMSM engage with technology and offer suggestions to researchers and practitioners who seek to use mobile phone apps to engage this population.

BYMSM in our study were avid mobile phone users who relied heavily on apps in their daily lives for productivity, entertainment, information seeking, and meeting sexual partners. These data are consistent with national trends, which suggest that people of color are the fastest growing user base for mobile phones [40], and other research supporting widespread mobile phone use among MSM [41]. The popularity of mobile phones among BYMSM presents a unique opportunity for HIV prevention and treatment intervention researchers and practitioners. However, a recent study by Muessig and colleagues [39] found 55 existing apps for Android or iPhone as of 2012 aimed at HIV prevention and care. The majority of these apps were infrequently downloaded and not highly rated by consumers, raising questions about the relevance of these kinds of apps. It is important to mention that health apps are often available but that the use of these apps may not necessarily be reported in peer-reviewed journals. That said, the data available in the academic literature suggest a potential disconnect between the needs of consumers and the design and functionality of HIV prevention and treatment apps.

BYMSM in our study were interested in an app for health and well-being, not necessarily one targeted exclusively at HIV prevention and care. Privacy and confidentiality were paramount for our participants, who expressed hesitancy about downloading an app onto their mobile phone that might indicate to others that they were HIV-positive or engaging in behavior that could put them at risk for HIV. Other research has highlighted attention to privacy and confidentiality with BYMSM who may be especially vulnerable to stigma and discrimination for engaging in same-sex sexual behaviors [32]. Participants in our study expressed clearly that in order for an app to be trusted among BYMSM, it would need safeguards in place for personal health information. Security breaches are a major barrier for many technology users—this may be especially true among black MSM, where medical mistrust is well documented [42].

Although participants agreed HIV should not be the sole focus of the app, they were strong advocates of being able to access information about HIV prevention and treatment. Participants liked the idea of using GPS to find nearby testing clinics. Furthermore, participants wanted to read reviews of other users' experiences at HIV testing and clinical sites, book appointments, and speak to clinical providers on the Web. These functions are already being incorporated into some apps designed for sexual health. Healthvana, for example, is an HIV and STD testing app that allows users to find nearby clinics, read user reviews, see hours of operation and, in some cases, schedule appointments. Healthvana also enables users to request their test results via the app in order to share those results with

potential sexual partners. The ability of users to communicate directly with HIV health care providers may present challenges in terms of cost and scalability of health apps. The most successful mobile phone interventions to date use low-cost text messaging for appointment and medication adherence [43-45]. However, collaborations with county health departments that enable a peer health educator or nurse practitioner to be "on call" for messaging with app users could be highly effective at engaging users and directing them to appropriate HIV prevention and treatment services.

Many participants liked the idea of incorporating social media into an app and suggested this as a way to build social support networks with others. Some studies have used existing social media platforms, like Facebook, to deliver HIV-prevention interventions for youth [46,47] and for black MSM [48]. Harnessing Online Peer Education (HOPE) is a Facebook-delivered intervention for black and Latino MSM that assigns participants to private Facebook groups facilitated by peer educators who disseminate information about HIV and engage group members in conversations about safer sex behaviors. In a pilot randomized controlled trial in Los Angeles, network ties among users increased over a 12-week period, which was associated with greater requests for HIV home testing kits and lower self-reported HIV risk behaviors [49]. These findings support the integration of social media functionality in mobile phone apps to increase engagement in HIV prevention and treatment.

While social media functionality that enables users to communicate via message board postings as well as instant message may increase interest in app use, it also presents potential challenges. First, a critical mass of users is necessary to entice potential users to join existing networks. Our participants suggested offering incentives to join and engage with the app in addition to partnerships with local businesses to engage the community through advertising and events. Second, some participants were concerned that social media functionality would facilitate sexual partnership formation on the app. Whereas sexual partner seeking via an app designed with health in mind could lead to safer sexual behaviors among users, participants highlighted that there were already many apps designed for this purpose and expressed interest in integration between these apps and a health app for BYMSM. Finally, some participants worried that by enabling users to talk to one another the risk of unwanted disclosures regarding same-sex sexual behaviors or HIV serostatus would be more likely.

Participants were supportive of an app tailored specifically for BYMSM as it had the potential to offer a Web-based space without the overt and covert racism they often experience on other apps. Discrimination and stigma via social media have been reported by BYMSM qualitatively [50], but have rarely been explored in relation to sexual health for this population. Our participants described strategies for mitigating racism, which seemed to have important implications for the construction of sexual networks established via social media. For example, filtering by race in order to avoid overt race-based hostility or sexual objectification may limit the sexual networks of BYMSM. One hypothesis for increasing rates of HIV infection among BYMSM, despite lower reports of behavioral risk factors (eg, unprotected anal intercourse, substance use), focuses on same race sexual networks, where disease transmission risk is higher due to higher HIV prevalence among BYMSM compared with other racial or ethnic groups [37,51]. Further attention to the ways technology influences sexual network structure and composition, including research to elucidate how technology-based sexual networks are formed and maintained among BYMSM, is needed. While an app exclusively for BYMSM has the potential to reinforce sexual partnering by race, a focus on coping with and responding to racism, homophobia, and other forms of oppression on the Web could be useful to BYMSM.

Technology-based HIV intervention research with MSM has recently emerged with promising results [33,38,49]. To our knowledge, only one published study has specifically targeted BYMSM: Hightow-Weidman and colleagues [38] pilot tested a mobile phone optimized intervention called HealthMPowerment.org with 15 young black MSM and transgender women who have sex with men in North Carolina. Although the sample size was too small to detect statistically significant effects, participants described satisfaction with the intervention, which uses gaming theory as a way to engage participants with the app. Upon conclusion of the 4-week trial, participants described how HMP led to changes in sexual risk behaviors, including increased condom use and HIV testing. This early work demonstrates the feasibility and acceptability of app-based HIV prevention interventions and the potential utility of gaming theory as a framework for engaging BYMSM. Participants in our study also suggested the use of incentives to maintain participant engagement but suggested broadening the app framework beyond HIV prevention to incorporate a more holistic conception of health. Our previous work with the House and Ball communities in Los Angeles demonstrates the many other psychosocial concerns facing black MSM: low educational attainment, unemployment, homelessness, stigma, and discrimination [52]. Attention to these concerns within app platforms may improve the engagement and utility of mobile phone apps designed to improve HIV prevention and treatment.

Limitations

This qualitative study focused on the experiences of BYMSM using mobile phones in Los Angeles, California. Selection bias introduced by convenience sampling is a limitation and findings may not be representative of all BYMSM. BYMSM were not asked to provide any identifying information during focus groups; however, participation in a group where others might recognize them or disclose their identity may have prevented some potential participants from volunteering to participate. In order to limit biases introduced during coding and thematic analysis, research assistants wrote statements of reflexivity, which increase objectivity in qualitative research.

In our analyses there did not appear to be differences in app use and app preferences by HIV serostatus. This may be due to the fact that we used the same semistructured interview guide for both HIV-negative and HIV-positive participants. Future studies may want to focus on mobile phone app design related to prevention and treatment separately in order to clarify how to

best leverage technology for HIV prevention versus treatment. While focus group methodology enables interaction between participants, it is difficult to know if the recommendations and preferences that participants shared in a group accurately reflect their actual usage. The rapid pace of technological developments in mobile phones and social media make it difficult for research findings to keep up with usage in the real world. Future studies should pay particular attention to emerging technologies that may be leveraged for HIV prevention and treatment.

Conclusions

As mobile technologies increasingly become tools for the prevention and treatment of HIV, these technologies should be integrated into existing models of care. Researchers would be wise to consider how technology can support BYMSM along the HIV prevention continuum and the HIV care continuum depending on serostatus. Our findings highlight interest in HIV prevention and treatment delivered via apps tailored for BYMSM, but raise significant concerns that must be addressed in order for them to be successful—namely privacy and a singular focus on HIV without attention to the other health and psychosocial issues impacting this population. It is crucial that public health practitioners partner with app developers to create apps that are engaging and provide a range of functions that meet the needs of BYMSM. Our research demonstrates the importance of including BYMSM in the development of these apps to ensure their effectiveness and uptake among this population disproportionately impacted by HIV.

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Conflicts of Interest

None declared.

References

1. CDC. HIV among gay and bisexual men URL: https://www.cdc.gov/hiv/group/msm/ [accessed 2017-01-18] [WebCite Cache ID 6nbIRf6zw]
2. CDC. HIV among African American gay and bisexual men URL: https://www.cdc.gov/hiv/group/msm/bmsm.html [accessed 2017-01-18] [WebCite Cache ID 6nbHFR9A9]
3. CDC. Diagnoses of HIV Infection in the United States and Dependent Areas, 2015. HIV Surveillance Report 2016 Nov;27 HIV diagnosis data are estimates from 50 states, the District of Columbia, and 6 U.S. dependent areas.
4. Publichealth.lacounty. 2014. 2013 Annual HIV Surveillance Report URL: http://publichealth.lacounty.gov/wwwfiles/ph/hae/hiv/2013AnnualSurveillanceReport.pdf [accessed 2017-02-27] [WebCite Cache ID 6ob8yzTKu]
5. Peterson JL, Jones KT. HIV prevention for black men who have sex with men in the United States. Am J Public Health 2009 Jun;99(6):976-980. [doi: 10.2105/AJPH.2008.143214] [Medline: 19372510]
6. Malebranche DJ, Peterson JL, Fullilove RE, Stackhouse RW. Race and sexual identity: perceptions about medical culture and healthcare among Black men who have sex with men. J Natl Med Assoc 2004 Jan;96(1):97-107. [Medline: 14746359]
7. Levy ME, Wilton L, Phillips G, Glick SN, Kuo I, Brewer RA, et al. Understanding structural barriers to accessing HIV testing and prevention services among black men who have sex with men (BMSM) in the United States. AIDS Behav 2014 May;18(5):972-996 [FREE Full text] [doi: 10.1007/s10461-014-0719-x] [Medline: 24531769]
8. Arnold EA, Rebchook GM, Kegeles SM. 'Triply cursed': racism, homophobia and HIV-related stigma are barriers to regular HIV testing, treatment adherence and disclosure among young Black gay men. Cult Health Sex 2014 Jun;16(6):710-722 [FREE Full text] [doi: 10.1080/13691058.2014.905706] [Medline: 24784224]
9. Kraft JM, Beeker C, Stokes JP, Peterson JL. Finding the “community” in community-level HIV/AIDS interventions: formative research with young African American men who have sex with men. Health Educ Behav 2000 Aug;27(4):430-441. [Medline: 10929751]
10. Aliabadi N, Carballo-Dieguez A, Bakken S, Rojas M, Brown W, Carry M, et al. Using the information-motivation-behavioral skills model to guide the development of an HIV prevention smartphone application for high-risk MSM. AIDS Educ Prev 2015 Dec;27(6):522-537. [doi: 10.1521/aeap.2015.27.6.522] [Medline: 26595265]
11. Muessig KE, Pike EC, Fowler B, LeGrand S, Parsons JT, Bull SS, et al. Putting prevention in their pockets: developing mobile phone-based HIV interventions for black men who have sex with men. AIDS Patient Care STDS 2013 Apr;27(4):211-222 [FREE Full text] [doi: 10.1089/apc.2012.0404] [Medline: 23565925]
12. Sullivan PS, Grey JA, Simon RB. Emerging technologies for HIV prevention for MSM: what we have learned, and ways forward. J Acquir Immune Defic Syndr 2013 Jun 1;63(Suppl 1):S102-S107 [FREE Full text] [doi: 10.1097/QAI.0b013e3182949e85] [Medline: 23673879]

13. Levy ME, Watson CC, Wilton L, Criss V, Kuo I, Glick SN, et al. Acceptability of a mobile smartphone application intervention to improve access to HIV prevention and care services for black men who have sex with men in the district of Columbia. Digit Cult Educ 2015;7(2):169-191 [FREE Full text] [Medline: 26594251]
14. Outlaw AY, Naar-King S, Parsons JT, Green-Jones M, Janisse H, Secord E. Using motivational interviewing in HIV field outreach with young African American men who have sex with men: a randomized clinical trial. Am J Public Health 2010 Apr 01;100(Suppl 1):S146-S151. [doi: 10.2105/AJPH.2009.166991] [Medline: 20147689]
15. Wilson BD, Miller RL. Examining strategies for culturally grounded HIV prevention: a review. AIDS Educ Prev 2003 Apr;15(2):184-202. [Medline: 12739794]
16. Hightow-Weidman LB, Fowler B, Kibe J, McCoy R, Pike E, Calabria M, et al. HealthMpowerment.org: development of a theory-based HIV/STI website for young black MSM. AIDS Educ Prev 2011 Feb;23(1):1-12 [FREE Full text] [doi: 10.1521/aeap.2011.23.1.1] [Medline: 21341956]
17. Lenhart A, Purcell K, Smith A, Zickuhr K. Pew Research Center. 2010. Social media & mobile internet use among teens and young adults URL: http://www.pewinternet.org/files/old-media/Files/Reports/2010/PIP_Social_Media_and_Young_Adults_Report_Final_with_toplines.pdf [accessed 2017-01-19] [WebCite Cache ID 6nddOu1JM]
18. Kingdon MJ, Storholm ED, Halkitis PN, Jones DC, Moeller RW, Siconolfi D, et al. Targeting HIV prevention messaging to a new generation of gay, bisexual, and other young men who have sex with men. J Health Commun 2013;18(3):325-342. [doi: 10.1080/10810730.2012.727953] [Medline: 23320963]
19. Kubicek K, Carpineto J, McDavitt B, Weiss G, Iverson EF, Au C, et al. Integrating professional and folk models of HIV risk: YMSM's perceptions of high-risk sex. AIDS Educ Prev 2008 Jun;20(3):220-238 [FREE Full text] [doi: 10.1521/aeap.2008.20.3.220] [Medline: 18558819]
20. Kubicek K, Carpineto J, McDavitt B, Weiss G, Kipke MD. Use and perceptions of the internet for sexual information and partners: a study of young men who have sex with men. Arch Sex Behav 2011 Aug;40(4):803-816 [FREE Full text] [doi: 10.1007/s10508-010-9666-4] [Medline: 20809373]
21. Holloway IW, Rice E, Gibbs J, Winetrobe H, Dunlap S, Rhoades H. Acceptability of smartphone application-based HIV prevention among young men who have sex with men. AIDS Behav 2014 Feb;18(2):285-296 [FREE Full text] [doi: 10.1007/s10461-013-0671-1] [Medline: 24292281]
22. Bauermeister JA, Leslie-Santana M, Johns MM, Pingel E, Eisenberg A. Mr. Right and Mr. Right Now: romantic and casual partner-seeking online among young men who have sex with men. AIDS Behav 2011 Feb;15(2):261-272 [FREE Full text] [doi: 10.1007/s10461-010-9834-5] [Medline: 20953689]
23. Garofalo R, Herrick A, Mustanski BS, Donenberg GR. Tip of the Iceberg: young men who have sex with men, the Internet, and HIV risk. Am J Public Health 2007 Jun;97(6):1113-1117. [doi: 10.2105/AJPH.2005.075630] [Medline: 17463378]
24. Beymer MR, Weiss RE, Bolan RK, Rudy ET, Bourque LB, Rodriguez JP, et al. Sex on demand: geosocial networking phone apps and risk of sexually transmitted infections among a cross-sectional sample of men who have sex with men in Los Angeles County. Sex Transm Infect 2014 Nov;90(7):567-572 [FREE Full text] [doi: 10.1136/sextrans-2013-051494] [Medline: 24926041]
25. Bourne C, Knight V, Guy R, Wand H, Lu H, McNulty A. Short message service reminder intervention doubles sexually transmitted infection/HIV re-testing rates among men who have sex with men. Sex Transm Infect 2011 Apr;87(3):229-231. [doi: 10.1136/sti.2010.048397] [Medline: 21296796]
26. Holloway IW, Cederbaum JA, Ajayi A, Shoptaw S. Where are the young men in HIV prevention efforts? Comments on HIV prevention programs and research from young men who sex with men in Los Angeles county. J Prim Prev 2012 Dec;33(5-6):271-278 [FREE Full text] [doi: 10.1007/s10935-012-0282-z] [Medline: 23132515]
27. Kegeles SM, Hays RB, Coates TJ. The Mpowerment Project: a community-level HIV prevention intervention for young gay men. Am J Public Health 1996 Aug;86(8):1129-1136. [Medline: 8712273]
28. Juzang I, Fortune T, Black S, Wright E, Bull S. A pilot programme using mobile phones for HIV prevention. J Telemed Telecare 2011;17(3):150-153. [doi: 10.1258/jtt.2010.091107] [Medline: 21270049]
29. Harper GW. Sex isn't that simple: culture and context in HIV prevention interventions for gay and bisexual male adolescents. Am Psychol 2007 Nov;62(8):803-819. [doi: 10.1037/0003-066X.62.8.806] [Medline: 18020756]
30. Allison SM, Adams D, Klindera KC, Poteat T, Wolf RC. Innovative uses of communication technology for HIV programming for men who have sex with men and transgender persons. J Int AIDS Soc 2014;17:19041 [FREE Full text] [Medline: 25280864]
31. Arnett JJ. Emerging adulthood: a theory of development from the late teens through the twenties. Am Psychol 2000;55(5):469-480. [Medline: 10842426]
32. Harrell MC, Bradley M. Data collection methods: semi-structured interviews and focus groups. Santa Monica, CA: RAND Corporation; 2009.
33. Willms D, Best J, Taylor D, Gilbert J, Wilson DM, Lindsay E, et al. A systematic approach for using qualitative methods in primary prevention research. Med Anthropol Q 1990;4(4):391-409.
34. ATLAS.ti. 1999. ATLAS.ti URL: http://atlasti.com/ [accessed 2017-02-27] [WebCite Cache ID 6ob9mqwb8]

35. Glaser B, Strauss AL. The discovery of grounded theory: strategies for qualitative research. Chicago, IL: Aldine Publishing Co; 1967.
36. Miles M, Huberman A. Qualitative data analysis: an expanded sourcebook. Thousand Oaks, CA: Sage Publications; 1994.
37. Berry M, Raymond HF, McFarland W. Same race and older partner selection may explain higher HIV prevalence among black men who have sex with men. AIDS 2007 Nov 12;21(17):2349-2350. [doi: 10.1097/QAD.0b013e3282f12f41] [Medline: 18090287]
38. Hightow-Weidman LB, Muessig KE, Pike EC, LeGrand S, Baltierra N, Rucker AJ, et al. HealthMpowerment.org: building community through a mobile-optimized, online health promotion intervention. Health Educ Behav 2015 Aug;42(4):493-499. [doi: 10.1177/1090198114562043] [Medline: 25588932]
39. Muessig KE, Pike EC, Legrand S, Hightow-Weidman LB. Mobile phone applications for the care and prevention of HIV and other sexually transmitted diseases: a review. J Med Internet Res 2013;15(1):e1 [FREE Full text] [doi: 10.2196/jmir.2301] [Medline: 23291245]
40. Anderson M. Pew Research Center.: www.pewresearch.org; 2015 Apr 30. Racial and ethnic differences in how people use mobile technology URL: http://www.pewresearch.org/fact-tank/2015/04/30/racial-and-ethnic-differences-in-how-people-use-mobile-technology/ [accessed 2017-01-19] [WebCite Cache ID 6nddVxwO7]
41. LGBT Market Research and Development Lab. Communitymarketinginc. San Francisco, CA: Community Marketing, INC; 2012. The LGBT Community Survey URL: http://communitymarketinginc.com/wp-content/uploads/2016/01/BisexualCommunitySurvey2012_Final.pdf [accessed 2017-03-02] [WebCite Cache ID 6oehiuTGj]
42. Maulsby C, Millett G, Lindsey K, Kelley R, Johnson K, Montoya D, et al. HIV among black men who have sex with men (MSM) in the United States: a review of the literature. AIDS Behav 2014 Jan;18(1):10-25. [doi: 10.1007/s10461-013-0476-2] [Medline: 23620241]
43. Lester RT, Ritvo P, Mills EJ, Kariri A, Karanja S, Chung MH, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. Lancet 2010 Nov 27;376(9755):1838-1845. [doi: 10.1016/S0140-6736(10)61997-6] [Medline: 21071074]
44. Price H, Waters AM, Mighty D, Nixon J, Burton N, Picket J, et al. Texting appointment reminders reduces 'Did not Attend' rates, is popular with patients and is cost-effective. Int J STD AIDS 2009 Feb;20(2):142-143. [doi: 10.1258/ijsa.2008.008448] [Medline: 19182066]
45. Smillie K, Van Borek N, Abaki J, Pick N, Maan EJ, Friesen K, et al. A qualitative study investigating the use of a mobile phone short message service designed to improve HIV adherence and retention in care in Canada (WelTel BC1). J Assoc Nurses AIDS Care 2014;25(6):614-625 [FREE Full text] [doi: 10.1016/j.jana.2014.01.008] [Medline: 24768442]
46. Bull SS, Breslin LT, Wright EE, Black SR, Levine D, Santelli JS. Case study: an ethics case study of HIV prevention research on Facebook: the Just/Us study. J Pediatr Psychol 2011;36(10):1082-1092 [FREE Full text] [doi: 10.1093/jpepsy/jsq126] [Medline: 21292724]
47. Bull SS, Levine DK, Black SR, Schmiege SJ, Santelli J. Social media-delivered sexual health intervention: a cluster randomized controlled trial. Am J Prev Med 2012 Nov;43(5):467-474 [FREE Full text] [doi: 10.1016/j.amepre.2012.07.022] [Medline: 23079168]
48. Young SD, Szekeres G, Coates T. Sexual risk and HIV prevention behaviours among African-American and Latino MSM social networking users. Int J STD AIDS 2013 Aug;24(8):643-649 [FREE Full text] [doi: 10.1177/0956462413478875] [Medline: 23970575]
49. Young SD, Holloway I, Jaganath D, Rice E, Westmoreland D, Coates T. Project HOPE: online social network changes in an HIV prevention randomized controlled trial for African American and Latino men who have sex with men. Am J Public Health 2014 Sep;104(9):1707-1712. [doi: 10.2105/AJPH.2014.301992] [Medline: 25033137]
50. Paul JP, Ayala G, Choi K. Internet sex ads for MSM and partner selection criteria: the potency of race/ethnicity online. J Sex Res 2010 Nov;47(6):528-538 [FREE Full text] [doi: 10.1080/00224490903244575] [Medline: 21322176]
51. Oster AM, Wiegand RE, Sionean C, Miles IJ, Thomas PE, Melendez-Morales L, et al. Understanding disparities in HIV infection between black and white MSM in the United States. AIDS 2011 May 15;25(8):1103-1112. [doi: 10.1097/QAD.0b013e3283471efa] [Medline: 21505305]
52. Holloway IW, Traube DE, Kubicek K, Supan J, Weiss G, Kipke MD. HIV prevention service utilization in the Los Angeles House and Ball communities: past experiences and recommendations for the future. AIDS Educ Prev 2012 Oct;24(5):431-444 [FREE Full text] [doi: 10.1521/aeap.2012.24.5.431] [Medline: 23016504]

Abbreviations

AIDS: acquired immunodeficiency syndrome
ART: antiretroviral therapy
BYMSM: black young men who have sex with men
CFAR: UCLA Center for AIDS Research
CHIPTS: Center for HIV Identification, Prevention, and Treatment
CSTI: California Specialized Training Institute

GSN: geosocial networking
HIV: human immunodeficiency virus
HMP: HealthMpowerment
HOPE: Harnessing Online Peer Education
LA County: Los Angeles County
MSM: men who have sex with men
NIH: National Institues of Health
NIMH: National Institute of Mental Health
STD: sexually transmitted disease
STI: sexually transmitted infection
YMSM: young men who have sex with men

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Original Paper

Texting and Mobile Phone App Interventions for Improving Adherence to Preventive Behavior in Adolescents: A Systematic Review

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Abstract

Background: Many preventable behaviors contribute to adolescent mortality and morbidity. Non-adherence to preventive measures represents a challenge and has been associated with worse health outcomes in this population. The widespread use of electronic communication technologies by adolescents, particularly the use of text messaging (short message service, SMS) and mobile phones, presents new opportunities to intervene on risk and preventive risk behavior, but little is known about their efficacy.

Objective: This study aimed to systematically evaluate evidence for the efficacy of text messaging and mobile phone app interventions to improve adherence to preventive behavior among adolescents and describe intervention approaches to inform intervention development.

Methods: This review covers literature published between 1995 and 2015. Searches included PubMed, Embase, CENTRAL, PsycINFO, CINAHL, INSPEC, Web of Science, Google Scholar, and additional databases. The search strategy sought articles on text messaging and mobile phone apps combined with adherence or compliance, and adolescents and youth. An additional hand search of related themes in the Journal of Medical Internet Research was also conducted. Two reviewers independently screened titles and abstracts, assessed full-text articles, and extracted data from articles that met inclusion criteria. Included studies reflect original research—experimental or preexperimental designs with text messaging or mobile phone app interventions—targeting adherence to preventive behavior among adolescents (12-24 years old). The preferred reporting items of systematic reviews and meta-analyses (PRISMA) guidelines were followed for reporting results, and findings were critically appraised against the Oxford Centre for Evidence-based Medicine criteria.

Results: Of 1454 records, 19 met inclusion criteria, including text messaging (n=15) and mobile phone apps (n=4). Studies targeted clinic attendance, contraceptive use, oral health, physical activity and weight management, sun protection, human papillomavirus (HPV) vaccination, smoking cessation, and sexual health. Most studies were performed in the United States (47%, 9/19), included younger adolescents (63%, 12/19), and had sample size <100 (63%, 12/19). Although most studies were randomized controlled trials (RCTs; 58%, 11/19), only 5 followed an intent-to-treat analysis. Only 6 of 19 studies (32%) incorporated a theoretical framework in their design. Most studies reported good feasibility with high acceptability and satisfaction. About half of the included studies (42%, 8/19) demonstrated significant improvement in preventive behavior with moderate standardized mean differences. As early efforts in this field to establish feasibility and initial efficacy, most studies were low to moderate in

quality. Studies varied in sample size and methods of preventive behavior adherence or outcome assessment, which prohibited performing a meta-analysis.

Conclusions: Despite the promising feasibility and acceptability of text messaging and mobile phone apps in improving preventive behavior among adolescents, overall findings were modest in terms of efficacy. Further research evaluating the efficacy, effectiveness, and cost-effectiveness of these intervention approaches in promoting preventive behavior among adolescents is needed.

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KEYWORDS

adolescent; text messaging; smartphone; mobile phone; mobile applications; medication adherence; behavior; prevention

Introduction

The burden of morbidity and mortality in adolescents worldwide is increasing [1-3], and the prevention of communicable and noncommunicable diseases, particularly those related to modifiable behavior, has been emphasized as a key component of adolescent health [4]. Many problem behaviors in adolescents, such as tobacco, alcohol, and other drug use; risky driving; and unsafe sex are preventable to a large extent [4], and their associated negative outcomes could be mitigated with preventive interventions. For adolescents, adherence to preventive measures represents a challenge in that the immediate and short-term benefits are often hard to comprehend and the long-term benefits may not be fully appreciated.

Several systematic reviews and meta-analyses have found positive effects of interventions to reduce risk behavior among adolescents and young adults, including tobacco use [5-7], alcohol misuse [8-11], drug use [12,13], risky driving [8], and unsafe sex [14]; as well as interventions to promote health behaviors, such as use of contraception to prevent pregnancy [15-17], human papilloma virus (HPV) vaccination [18], oral health and hygiene [19,20], and nutrition and exercise promotion [21-23]. The widespread use of electronic communication technologies by young people, particularly the use of mobile phones and other mobile devices [24-26], presents new opportunities to intervene on risk and preventive behavior. To our knowledge, no recent systematic reviews have been conducted on the effects of texting (short message service, SMS) and mobile phone apps—the most widely used technologies by young people—to improve prevent risk behavior and promote adherence to preventive health behavior in adolescents. The objective of this review was to systematically evaluate the evidence for the efficacy of texting and mobile phone app interventions in improving adherence to preventive behavior among adolescents and describe intervention approaches used in the included studies that would inform future intervention development.

Methods

Study Design

The protocol for this review was registered with the international prospective register of systematic reviews (PROSPERO; CRD42015025907) [27] and covered literature published between 1995 and 2015 with no language limits. The search strategy looked for all articles on texting, phones, mobile phone apps, and portable software combined with adherence or compliance, and search terms related to child, pediatric, adolescents, and youth. We intentionally used the Boolean search term "OR" instead of "AND" to capture the most comprehensive set of articles possible to which we applied our eligibility criteria. We followed the guidelines for the preferred reporting items for systematic reviews and meta-analyses (PRISMA) in the reporting of evidence across the studies reviewed herein [28]. In brief, a medical librarian conducted the literature search in the following sources: MEDLINE, Embase, CENTRAL, CINAHL, PsycINFO, Web of Science, Center for Review and Dissemination, INSPEC, Proquest Dissertations, Scopus, ClinicalTrials.gov, WHO Clinical Trials, Controlled-Trials.org, IEEE Explore, and Google Scholar (Multimedia Appendix 1). An additional hand search of related themes in the *Journal of Medical Internet Research* was also conducted. Two independent reviewers (SB and LK) assessed abstracts and articles against eligibility criteria and critically appraised the methodological quality using established criteria from the Oxford Centre for Evidence-based Medicine [29]. Disagreements were resolved by discussion or consultation with a colleague, if needed.

Eligibility Criteria

Eligible studies were original research articles that included randomized controlled trials, quasi-experimental studies, or pilot pre-post studies of texting or mobile phone–based apps designed to improve adherence to preventive or prophylactic behavior in adolescents aged 12-24 years [30]. Adherence was defined as "the extent to which a person's behavior coincides with medical or health advice" [31,32]. Therefore, the term "adherence" included both prescribed medications and scheduled clinic appointments [31-33]. To be included in this review, the studies had to report at least one primary or secondary outcome related to adherence to preventive behavior. Studies focused on parents rather than on adolescents, disease monitoring without intervention, or use of other forms of technology (ie, other than mobile phone apps or texting) were excluded.

Data Synthesis

We used a standardized form for data extraction. Data items in the extraction form included the following: first author's name; publication year; country; aim of the study; participants' age and sex; study design and setting; sample size; selection criteria; duration of intervention and follow-up; retention rate; components of study intervention (texting or mobile phone apps) and comparator (if applicable); adherence measures and

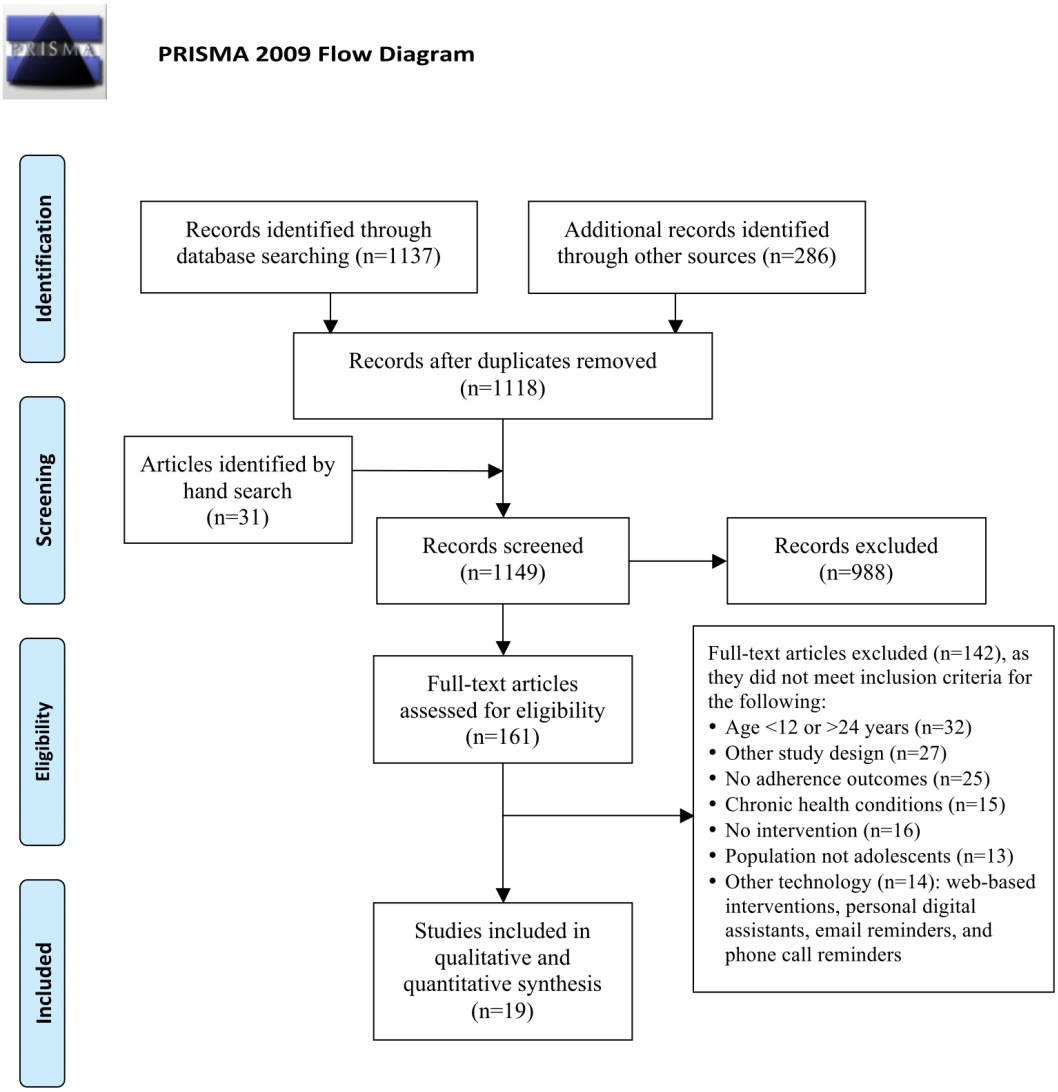
outcomes; other related outcome; and theoretical framework. Data were analyzed and summarized qualitatively and quantitatively. Standardized mean differences (SMD) with 95% CIs were calculated—using means and standard deviations, pre- and postvalues, or frequencies of outcomes—to evaluate the efficacy of texting or mobile phone–based apps in improving adherence to preventive behavior and related outcomes [34]. Data were analyzed using StataCorp (2013, StataCorp LP).

Results

Literature Search

The literature search identified 1454 references (Figure 1), and 161 full articles were retrieved. Nineteen articles met all inclusion criteria [35-53]. Most (n=15) included texting interventions [35-41,43-45,47-49,52,53], and only 4 studies had mobile phone–based app interventions [42,46,50,51]. The primary aim of the interventions was to improve adherence to clinic attendance (primary care, gynecology, mental health) [35,36], contraception use [37-39], oral health and hygiene in orthodontic patients [46,47], physical activity and weight management [48-51], sun-protective measures [52], and HPV vaccination [53]; or to reduce risky behavior, including unsafe sex [40-42], smoking [45], and alcohol misuse [43,44].

Figure 1. Flow of studies through the review according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Description of Included Studies

Table 1 summarizes study characteristics (also see Multimedia Appendix 2). Nine were conducted in the United States [36-41,47,50,53], 3 in Switzerland [35,44,45], 2 in Hong Kong [48,49], and 1 each in Colombia [42], Wales [43], Italy[46], New Zealand [51], and Germany [52]. Most (n=9) were conducted in a clinic setting [35-39,46,47,53], 3 in a university [41-43], 2 in vocational schools [44,45], 1 in secondary schools [48], 1 in an emergency department [40], 1 in a clinic and summer camp [52], 1 in both a clinic and Web-based environment [50], and 1 at participants' home [51]. Most (n=12) enrolled younger adolescents (age ≥12 and < 18 years) [35,36,41,45-53], 6 enrolled older adolescents (age ≥18 and <24 years) [37,38,40,42-44], and 1 reported only an age range of 13-21 years [39]. Fourteen studies indicated regular or mobile phone ownership or access as 1 of the eligibility criteria [35-40,42,44-48,51,52], 2 included patients with mobile phones [41,50], and 3 were not explicitly stated or reported [43,49,53]. Sample size ranged from 26 to 999, with a median of 78 and a mean of 232 participants per study; 12 enrolled < 100 [36,38,40,41,43,46-52], and 7 had ≥100 participants [35,37,39,42,44,52,53]. Participants' race or ethnicity varied: majority were white in 5 [38,44,45,50,51], black in 3 [39-41], Asian in 2 [48,49], Latino in 1 [42], black and Latino in 2 [36,37], and not reported in 6 studies [35,43,46,47,52,53]. Only 6 studies incorporated or were informed by a clear theoretical framework for their intervention effects, including Transtheoretical Model [37], Geser's Sociological Framework [39], Health Belief Model and Information Motivation Behavior Model [40], Health Action Process Approach [45], Stages of Motivational Readiness for Change Model [48], Addiction Treatment Model [50], or utilized specific effective self-regulatory behavior change techniques without an identified theoretical model [51].

Table 1. Summary of included studies focused on improving adherence to preventive measures in adolescents.

Source (country)	Aim of intervention	Study design (setting)	Age in years, (sex)	Group (n)	Tech	Follow-up	Retention rate	Grade
Narring et al [35] (Switzerland)	Improve attendance in clinic	RCT (randomized controlled trial), investigator-blinded (multidisciplinary youth clinic: primary care, gynecological and mental)	Intervention[a]: 17.7 (2.8) (75.9% Female) Control[a]: 17.7 (3) (75.4% Female)	Intervention (469) Control (530)	Text messages	6 months	Intervention: 462 (98.5%) Control: 529 (99.8%)	Moderate
Branson et al[36] (United States)	Improve attendance in mental health clinic	Quasi-experimental pilot study (large hospital mental health clinic)	Intervention[a]: 15.4 (1.3) (58% Female) Control[a]: 14.8 (1.5) (42% Female)	Intervention (24) Control (24)	Text messages	3 months	Intervention: 24 (100%) Historical Control: N/A[d]	Moderate
Castano et al [37] (United States)	Improve continuation of OCPs (oral contraceptive pills)	RCT, investigator-blinded (urban family planning health center)	Intervention[a]: 20.8 (2.5) Control[a]: 20.4 (2.7) All females	Intervention (480) Control (482)	Text messages	6 months	Intervention: 346 (72.1%) Control: 337 (69.9%)	Moderate
Hou et al[38] (United States)	Increase adherence to OCPs	RCT, investigator-blinded (Planned Parenthood League clinic)	Intervention[b]: 22 (18-31) Control[b]: 22 (18-30) All females	Intervention (41) Control (41)	Text messages	3 months	Intervention: 36 (88%) Control: 37 (90%)	Moderate
Trent et al [39] (United States)	Improving Depo-Provera appointment attendance	RCT, nonblinded (large urban academic General Pediatric and Adolescent Medicine Practice)	Intervention[b]: 13-21 Control[b]: 13-21 All females	Intervention (50) Control (50)	Text messages	12 months	Intervention: 33 (66%) Control: 36 (72%)	High
Suffoletto et al [40] (United States)	Reduce sex risk behavior among at-risk young adult F[g] discharged from emergency department	RCT, nonblinded (urban tertiary hospital emergency department)	Intervention[a]: 22 (2) Control[a]: 21 (2) All females	Intervention (23) Control (29)	Text messages	3 months	Intervention: 15 (65%) Control: 21 (72%)	Low
Cornelius et al [41] (United States)	Improve HIV knowledge and attitudes toward condoms among African American adolescents	Pre-post single-arm pilot study (university)	Intervention[a]: 15.4 (1.7) (52.5% Female)	Intervention (40)	Text messages	3 months	Intervention: 36 (90%)	Low
Lopez et al [42] (Colombia)	Provide sexual education and improve knowledge about the sexual risk factors	Pre-post single-arm pilot study (university)	Intervention[a]: 21 (3.6) (53% Female)	Intervention (127)	App	6 months	Intervention: 58 (45.7%)	Very low
Moore et al [43] (Wales)	Reduce future alcohol consumption based on data of past alcohol expenditure	RCT, nonblinded (university)	Student[a]: 22 (3.7) Nonstudent[a]: 38.5 (14.3) Overall (33% Female)	Intervention (40): Student (21); nonstudent (19) Control (38): Student (16); nonstudent (22)	Text messages	2 months	Intervention: Student 20 (95%); nonstudent 18 (95%) Control: Student 14 (88%); nonstudent 22 (100%)	Low

Source (country)	Aim of intervention	Study design (setting)	Age in years, (sex)	Group (n)	Tech	Follow-up	Retention rate	Grade
Haug et al [44] (Switzerland)	Reduce alcohol binge or problem drinking	Pre-post single-arm pilot study (vocational school)	Intervention "participants"[a]: 18.0 (2.4) (24.5% Female) Control "nonparticipants"[a]: 17.8 (1.7) (19.5% Female)	Intervention (364) Control (113)	Text messages	3 months	Intervention: 280 (76.9%) Control: 87 (77.0%)	Moderate
Haug et al [45] (Switzerland)	Increase smoking cessation and reduce cigarettes consumption	Two-arm cluster RCT, assessor-blinded (vocational school)	Intervention[a]: 18.2 (2.4) (48.7% Female) Control[a]: 18.3 (2.2) (55.1% Female)	Intervention (372) Control (383)	Text messages	6 months	Intervention: 287 (77.2%) Control: 272 (71.0%)	High
Zotti et al [46] (Italy)	Improve oral hygiene adherence and oral health	RCT, assessor-blinded (orthodontic clinic in a university hospital)	Intervention[a]: 14.1 (58% Female) Control[a]: 13.6 (58% Female)	App (40) Control (40)	App	12 months	Intervention: 40 (100%) Control: 40 (100%)	Low
Bowen et al [47] (United States)	Improve adherence to oral hygiene and reduce plaque formation	RCT, patient-blinded (orthodontic clinic in a university hospital)	Intervention[a]: 15.5 (60% Female) Control[a]: 14.6 (56% Female)	Intervention (25) Control (25)	Text messages	3 months	Intervention: 19 (76%) Control: 21 (84%)	Low
Lau et al [48] (Hong Kong)	Promote physical activity in school age children	Quasi-experimental (secondary schools)	Intervention[a]: 12.3 (0.9) (68% Female) Control[a]: 13.3 (1.1) (63% Female)	Intervention (38) Control (40)	Text messages	2 months	Intervention: 38 (100%) Control: 40 (100%)	Low
Abraham et al [49] (Hong Kong)	Improve weight management	RCT, investigator-blinded (pediatric obesity clinic of a tertiary care hospital)	Intervention "Internet"[b]: 14.9, 13.7-16.2 (44% Female) Intervention "sLMP"[b]: 14.1, 13.5-15.3 (38% Female) Cnotrol[b]: 14.3, 13.5-16 (38% Female)	Intervention "Internet" (16) Intervention "sLMP" (16) Control (16)	Text messages	6 months	Intervention "Internet": 16 (100%) Intervention "sLMP": 16 (100%) Control: 16 (100%)	Low
Pretlow et al [50] (United States)	Improve weight management	Pre-post single arm pilot study (university hospital clinic and on the Internet)	Intervention[a]: 16 (0.43) (65% Female)	Intervention (43)	App	5 months	Intervention: 27 (63%)	Moderate
Direito et al [51] (New Zealand)	Improve fitness in insufficiently active healthy young people	Three-arm, parallel, RCT, nonblinded (participants home)	Intervention "immersive"[a]: 15.78 (1.11) (53% Female) Intervention "nonimmersive"[a]: 15.69 (1.04) (63% Female) Control[a]: 15.55 (1.32) (56% Female)	Intervention "immersive" (17) Intervention "non immersive" (16) Control (18)	App	2 months	Intervention "immersive": 17 (100%) Intervention "non immersive": 15 (94%) Control: 17/18 (94%)	Moderate
Sachse et al [52] (Germany)	Improve sun-protection knowledge and behavior	Pre-post single-arm pilot study (summer cap/clinic)	Intervention[a]: 16.1 y, 13-22 (27% Female)	Intervention (26)	Text messages	2 months	Intervention: 19 (73%)	Very low

Source (country)	Aim of intervention	Study design (setting)	Age in years, (sex)	Group (n)	Tech	Follow-up	Retention rate	Grade
Matheson et al [53] (United States)	Increase HPV (human papillomavirus) vaccination series completion rate	Pilot Quality Improvement project (urban pediatric clinic)	Intervention[a]: 12 (62% Female) Interested[a,c]: 14 (64% Female) Control[a,c]: 14 (42% Female)	Intervention (37) Interested[c] (43) Control[c] (232)	Text messages	8 months	Intervention: data not reported	Low

[a]Age reported as mean (SD, standard deviation).

[b]Age reported as median (range, minimum-maximum).

[c]Interested group included patients or parents enrolled in the project during their clinic visit who did not complete their opt-in process to receive text message reminders after leaving clinic; historical control included all patients who initiated HPV vaccination series during study period, but were either not offered or declined to participate in the project.

[d]N/A: not applicable.

Studies Methodological Quality

Most (n=11) were RCTs [35,37-40,43.45-47,49,51], 6 pre-post pilot design [41,42,44,50,52,53], and 2 quasi-experimental studies [36,48]. Of the RCTs, 7 were single-blinded—investigator (n=4), assessor (n=2), and patient (n=1) [35,37,38,45-47,49]; 4 nonblinded [39,40,43,51]; and none double-blinded. Overall, the quality of the included studies was low to moderate (Table 1). Details of allocation concealment and study blinding were inadequately reported for most studies. About half of the RCTs (n=5) used intention-to-treat analysis [35,37,38,45,51]. Almost all (n=18) reported retention rates, which differed across studies from <80% in 8 [37,38,40,42,44,45,50,52], ≥80 to <100% in 6 [35,38,41,43,47,51], 100% in 4 [36,46,48,49], and not reported in 1 study [53]. The duration of the interventions ranged from 2 to 12 months as follows: 2-3 months (n=11) [36-38,40,41,43,44,47,48,51,52], 5-8 months (n=6) [35,42,45,49,50,53], and 12 months (n=2) [39,46]. Only 2 studies extended follow-up for 2 [37] and 3 months [45] after the completion of active intervention.

Description of Texting Interventions

Most (n=10) included texting as the only intervention [35-40,43,45,47,53], whereas 5 included additional components [41,44,48,49,52]: in-person training sessions in 2 [41,52], Web-based program in 2 [44,48], Internet-based curriculum in 1 [49], and a facilitator or a coach in 1 study [41]. Texting interventions varied in frequency, message content, and directionality of messages (also see Multimedia Appendix 3). Text reminders for frequent behaviors were sent once daily in 7 [37,38,41,43,45,48,52], and once or twice weekly in 5 studies [40,44,45,47,49]. Appointment reminders were sent at differing frequencies, including 1 day in 2 [35,36] or daily for 3 days before in 1 [39], or 7 days before, after and on the scheduled date in 1 study [53]. Text reminders were customized to the patient's personal preferences in terms of scheduling (ie, day or time) in 5 studies [36-39.53], content in 8 [40,41,43-45,48,49,52], or both in 1 study [35]. Text-reminder directionality was 1-way in 7 [36-38,47,48,52,53] and 2-way in 8 [35,39-41,43-45,49], with emotion icon (emoji) response in 1 [49] and according to a sophisticated tailored algorithm in 3 studies [40,44,45]. All text reminders were sent to adolescents or young adults, not their parents. Text messages were also a tool for education in 7 [37,39,41,47,48,52], positive reinforcement or personalized feedback in 5 [40,44,45,48,49], goal setting in 3 [40,48,49], and addressing barriers in 1 study [48]. Most (n=9) provided incentives or a reward system for patient engagement [36,37,39-41,43-45,48]. One included a virtual friend "Jackie" who was part of all messages to build rapport with participants and provide more social support [48], and none included an explicit motivational approach or targeted social support network.

Description of Mobile Phone App Interventions

In terms of the mobile phone platforms (also see Multimedia Appendix 4), 2 used existing commonly used mobile phone app platforms, "WhatsApp" [46] and "Zombies, Run! 5K Training app" or "Get Running-Couch to 5k app" [51], whereas 2 included apps developed specifically for the study [42,50]. Zotti et al [46] created an anonymous study group "Brush Game" on the app where patients shared 2 photographs of themselves weekly ("selfies"), participated in chat room conversations, shared materials related to oral hygiene, and viewed a weekly ranking of the top 5 participants based on chat room participation and oral hygiene outcomes. In contrast, Direito et al had participants randomized to either an immersive app "Zombies, Run! 5K Training" with a game-themed design embedded with a story where participants were trained to collect supplies and protect a town from zombies, or a nonimmersive app "Get Running-Couch to 5k" [51]. Both apps consisted of a fully automated 8-week training designed to improve fitness and ability to run 5 km, provided information on running and audio instructions on how to perform the training components, and tracked and displayed participant's progress throughout the program; and included the ability to work out with music on the device's library and links to associated websites to interact with other users [51]. Participants were encouraged to use their app 3 times per week and work their way through each of the workouts, but no cointerventions (ie, emails, phone calls, text message) or prompts to use the app were utilized [51]. On the contrary, Lopez et al developed a native app "DoctorChat" as an intervention that allowed participants to submit questions on different sexual and reproductive health issues through their mobile phones, and to receive personalized, accurate, and informative responses from health care professionals and experts

in the field [42]. Moreover, Pretlow et al [50] utilized a multifunction app for weight management, in addition to group meetings and personalized coaching. The app included different capabilities such as progress reports, peer support, coping skills and self-management toolbox, fun activity ideas for distraction, and mentor communication [50].

Intervention Effects on Adherence to Preventive Behavior and Other Outcomes

Most (n=12) reported clinical effects related to adherence to preventive behavior [40-51], 9 measured actual adherence to preventive behaviors [35-40.46,50,53], and 5 described other outcomes as well, including knowledge gain in 3 [41,42,52], motivational readiness in 1 [48], and change in self-management skills in 1 study [50] (also see Multimedia Appendices 5 and 6). Adherence to preventive behavior was evaluated by clinic attendance in 4 [35,36,39,53], self-report of adherence in 3 [37,40,50], self-report and electronic device to monitor adherence in 1 [38], and electronic direct observation of adherence behavior (self-photographs or selfies) in 1 study [46]. All the included studies provided enough information to calculate standardized outcomes (ie, effect sizes *d* or SMDs), except 1 [42]. At the end of the active intervention period, about half (n=8) of the studies reported significant improvement in adherence to preventive behavior and other related outcomes with moderate SMDs [36,37,44-47,52,53]. Table 2 summarizes SMDs for all included studies. Several studies reported findings for efficacy as well as usability and feasibility. Most (n=11) reported high levels of satisfaction and acceptability of study interventions [36-42,48-50,52].

Table 2. Effect sizes for the main outcomes of included studies.

Source (intervention)	Study outcomes	Effect size, *d* (95% CI)[a]
Narring et al [35] (Texting)	Attendance to all clinics	0.15 (–0.03 to 0.33)
	Attendance to primary care clinic	0.06 (–0.16 to 0.27)
	Attendance to gynecological clinic	0.32 (–0.10 to 0.74)
	Attendance to mental health clinic	0.32 (–0.21 to 0.85)
	Attendance to mental health clinic	0.32 (–0.21 to 0.85)
Branson et al [36] (Texting)	Attendance to mental health clinic	0.67 (0.09-1.25)[h]
Castano et al [37] (Texting)	Continued use of OCPs[b] at follow-up: overall	0.23 (0.06-0.40)[h]
	Continued use of OCPs at ≤187 days	0.52 (0.19-0.86)[h]
	Continued use of OCPs at ≥188 days	0.13 (–0.07 to 0.33)
Hou et al [38] (Texting)	Decreased OCP doses miss rate: all participants	0.09 (–0.34 to 0.53)
	Decreased OCP doses miss rate: 3 cycles complete	0.13 (–0.30 to 0.57)
Trent et al [39] (Texting)	Depo-Provera on-time visit attendance: cycle 1	0.29 (–0.19 to 0.77)
	Depo-Provera on-time visit attendance: cycle 2	0.77 (–0.35 to 0.69)
	Depo-Provera on-time visit attendance: cycle 3	0.01 (–0.57 to 0.60)
Suffoletto et al [40] (Texting)	Condom use with last sexual intercourse	0.32 (–0.29 to 0.93)
	Always condom use in last 28 days	0.29 (–0.38 to 0.95)
	Drug or alcohol use before last sex	0.23 (–0.53 to 0.99)
	Any unprotected sex with concurrent alcohol use in last 28 days	0.58 (–0.41 to 1.57)
Cornelius et al [41] (Texting)	HIV knowledge	0.42 (–0.03 to 0.86)
	Attitudes toward condoms	0.08 (–0.36 to 0.52)
	Reduction in risky behavior: intercourse	0.17 (–0.27 to 0.60)
	Reduction in risky behavior: illegal drugs	0.41 (–0.03 to 0.86)
Moore et al [43] (Texting)	Decrease alcohold use in students	0.00 (–0.65 to 0.65)
	Decrease alcohol use in nonstudents	0.13 (–0.48 to 0.75)
Haug et al [44] (Texting)	Reduction in RSOD[c] in persons with ≥1 occasion in the last month	0.22 (0.01- 0.42)[h]
	Reduction in RSOD in persons with >2 occasions in the last month	0.16 (–0.02 to 0.35)
	Reduction in number of standard drinks in a typical week	0.14 (–0.02 to 0.31)
	Reduction in the maximum number of drinks on an RSOD occasion	0.08 (–0.09 to 0.24)
	Reduction in having one or more alcohol-related problems	0.24 (–0.01 to 0.48)
Haug et al [45] (Texting)	7-day smoking abstinence at 6 months: total sample	0.16 (–0.13 to 0.46)
	7-day smoking abstinence at 6 months: occasional smokers	0.25 (–0.21 to 0.71)
	7-day smoking abstinence at 6 months: daily smokers	0.15 (–0.28 to 0.59)
	4-week smoking abstinence at 6 months: total sample	0.08 (–0.31 to 0.47)
	4-week smoking abstinence at 6 months: occasional smokers	0.38 (–0.27 to 1.03)
	4-week smoking abstinence at 6 months: daily smokers	0.39 (–0.21 to 0.98)
	Reduction in cigarette consumption at 6 months: total sample	0.33 (0.16-0.50)[h]
	Reduction in cigarette consumption at 6 months: occasional smokers	0.36 (0.02-0.71)[h]
	Reduction in cigarette consumption at 6 months: daily smokers	0.20 (0.01-0.39)[h]
	Smoking quit attempts at 6 months: total sample	0.17 (–0.02-0.36)

Source (intervention)	Study outcomes	Effect size, *d* (95% CI)[a]
	Smoking quit attempts at 6 months: occasional smokers	1.09 (0.65-1.52)[h]
	Smoking quit attempts at 6 months: daily smokers	0.06 (–0.16 to 0.29)
Zotti et al [46] (App)[d]	Gingival index at 6 months	0.56 (0.12-1.01)[h]
	Gingival index at 9 months	1.04 (0.57-1.51)[h]
	Gingival index at 12 months	1.43 (0.94-1.92)[h]
	Plaque index at 6 months	0.73 (0.28-1.18)[h]
	Plaque index at 9 months	1.50 (1.00-2.00)[h]
	Plaque index at 12 months	1.40 (0.91-1.89)[h]
	Visible white spots at 9 months	0.67 (0.04-1.30)[h]
	Visible white spots at 12 months	0.63 (0.06-1.20)[h]
Bowen et al [47] (Texting)	Plaque coverage reduction at 4 weeks	1.62 (0.98-2.26)[h]
	Plaque coverage reduction at 12 weeks	2.40 (1.67-3.12)[h]
Lau et al [48] (Texting)	Self-report of physical activity	0.31 (–0.14 to 0.76)
Abraham et al [49] (Texting)	Reduction in BMI (body mass index)	0.09 (–0.61 to 0.78)
Pretlow et al [50] (App)[e]	Reduction in percent over-BMI in males	0.17 (–0.55 to 0.88)
	Reduction in percent over-BMI in females	0.08 (–0.44 to 0.61)
Direito et al [51] (App)	Time to complete 1-mile walk or run using an immersive app	–0.238 (–0.9 to 0.43)
	Time to complete 1-mile walk or run using a nonimmersive app	–0.14 (–0.81 to 0.54)
Sachse et al [52] (Texting)	Understanding of the meaning of UV[f]-index	1.49 (0.61-2.37)[h]
	Naming ≥3 of ABCDE (ie, asymmetry, border, color, diameter, and evolution) mnemonic for skin self-exam	1.40 (0.19-2.61)[h]
	Knowing that it takes hours to recognize sunburns	0.51 (–0.24 to 1.26)
Matheson et al [53] (Texting)	HPV[g] vaccine dose 2	1.10 (0.67-1.52)[h]
	HPV vaccine dose 2 on-time	0.46 (0.06-0.86)[h]
	HPV vaccine dose 3	0.70 (0.14-1.27)[h]
	HPV vaccine dose 3 on-time	0.91 (0.24-1.58)[h]

[a]Positive effect size value means improvement in a study outcome, while a negative one means worsening outcome.

[b]OCPs: oral contraceptive pills.

[c]RSOD: risky single-occasion drinking.

[d]Gingival index score (0-3): 0 being normal gingiva and 3 having severe inflammation and edema, with spontaneous bleeding; plaque index score (0-3): 0 being best with no plaques and 3 having plaque covering more than half of the surface; white spots score: (0-3): 0 being no visible white spots and 3 having visible white spots requiring restoration.

[e]Percent over-BMI was calculated as [(BMI – BMI at 50th percentile for age and sex) / BMI at 50th percentile] × 100.

[f]UV: ultraviolet.

[g]HPV: human papillomavirus.

[h]Statistically significant $P<.05$.

Effects on Clinic Attendance

Narring et al found no significant differences in multidisciplinary clinic attendance as a result of text message reminders in comparison to control at 6-month follow-up across all clinics (d=0.15; 95% CI –0.03 to 0.33) or by clinic type; primary care (d=0.06; 95% CI –0.16 to 0.27), gynecology (d=0.32; 95% CI –0.10 to 0.74), or mental health clinics (d=0.32; 95% CI –0.21 to 0.85) [35]. In contrast, Branson et al reported a significant improvement in their mental health clinic attendance rate in the texting intervention group compared with controls at 3-month follow-up (d=0.67; 95% CI 0.09-1.25) [36].

Effects on Contraception

Castano et al found significantly higher oral contraceptive pill (OCP) continuation rates at 6 months (ie, having taken a pill in last 7 days) in texting intervention arm compared with controls (d=0.23; 95% CI 0.06-0.40) [37]. The observed effect of the intervention dissipated over time with the difference in OCP continuation rates significant at 187 days or less (d=0.52; 95% CI 0.19-0.86), but not at 188 days or more (d=0.13; 95% CI –0.07 to 0.33) [37]. In contrast, Hou et al reported no significant differences in average rates of missed OCPs in text intervention group compared with controls, overall (d=0.09; 95% CI –0.34 to 0.53) and in those who completed 3 cycles or 3-month follow-up (d=0.13; 95% CI –0.30 to 0.57) [38]. Similarly, Trent et al found that on-time Depo-Provera (injectable contraceptive) completion rate was not significantly different between text intervention and control groups over 12-month study period in those who completed cycle 1 (d=0.29; 95% CI –0.19 to 0.77), cycle 2 (d=0.77; 95% CI –0.35 to 0.69), or cycle 3 (d=0.01; 95% CI –0.57 to 0.60) [39].

Effects on Risky Behavior

Testing a texting intervention using a sequence of messages to assess and then intervene on risk behavior, Suffoletto et al reported no significant differences between intervention and control groups for condom use at last sexual intercourse (d=0.32; 95% CI –0.29 to 0.93) or proportion of "always condom use" over the past 28 days (d=0.29; 95% CI –0.38 to 0.95) at 3-month follow-up [40]. Additionally, there was no significant difference in observed drug or alcohol use before last sex (d=0.23; 95% CI –0.53 to 0.99) and any unprotected sex with concurrent alcohol use in last 28 days (d=0.58; 95% CI –0.41 to 1.57) [40]. Cornelius et al, in their evaluation of texting intervention among African American adolescents at 3-month follow-up, failed to show a significant improvement in human immunodeficiency virus (HIV) knowledge (d=0.42; 95% CI –0.03 to 0.86), attitudes toward condoms (d=0.08; 95% CI –0.36 to 0.52), and risky behavior related to sexual intercourse (d=0.17; 95% CI –0.27 to 0.60) or illegal drug use (d=0.41; 95% CI –0.03 to 0.86) [41]. In contrast, Lopez at al developed and evaluated a dedicated mobile phone app "DoctorChat" as a tool to provide sexual education [42]. At 6-month follow-up, the authors reported some improvement in participants' knowledge about the sexual risk factors among young adults, but no significant differences in preventive behavior [42].

In an intervention using a single text message summarizing alcohol-related expenses by the participants over the prior month, Moore et al reported no significant reduction in average units of alcohol consumed at follow-up between intervention and control groups among students (d=0; 95% CI –0.65 to 0.65) and nonstudents participants (d=0.13; 95% CI –0.48 to 0.75) [43]. In contrast, Haug et al utilized a combined intervention of automatically generated individually Web-based feedback and text messages tailored for participants' age, sex, and alcohol drinking behavior [44]. At 3-month follow-up, the authors were able to show a significant reduction in the number of risky single-occasion drinking episodes in persons with at least one occasion in the last month (d=0.22; 95% CI 0.01-0.42), but not the number of drinks or alcohol-related problems [44].

In another study, Haug et al evaluated the efficacy of a 2-way text message–based intervention on smoking cessation tailored based on individual smoking behavior and attitudes toward smoking cessation [45]. The authors showed a significant reduction in cigarette consumption (ie, the number of cigarettes smoked) at 6-month follow-up in all participants (d=0.33; 95% CI 0.16-0.50), occasional smokers (d=0.36, 95% CI 0.02-0.71), and daily smokers (d=0.20; 95% CI 0.01-0.39), as well as a significant increase in the number of smoking quit attempts in occasional smokers only (d=1.09; 95% CI 0.65-1.52) [45]. However, there was no significant improvement in either 7-day or 4-week smoking abstinence among study participants [45].

Effects on Oral Health

Zotti et al utilized an existing commonly used mobile phone app platform (WhatsApp) and showed a significant improvement in participants' oral hygiene with lower average gingival index scores in the intervention group compared with controls at 6 months (d=0.56; 95% CI 0.12-1.01), 9 months (d=1.04; 95% CI 0.57-1.51), and 12 months (d=1.43; 95% CI 0.94-1.92) [46]. Intervention participants also had significantly lower plaque index scores at 6 months (d=0.73; 95% CI 0.28-1.18), 9 months (d=1.50; 95% CI 1.00-2.00), and 12 months (d=1.40; 95% CI 0.91-1.89) compared with controls [46]. In addition, the number of visible white spots was lower in the intervention group at 9 months (d=0.67; 95% CI 0.04-1.30) and 12 months (d=0.63; 95% CI 0.06-1.20) compared with controls [46]. However, the frequency of new caries was not significantly different between study groups [46]. Testing a less intensive texting intervention, Bowen et al reported significantly lower average plaque coverage score in the text intervention group compared with controls at 4-week (d=1.62; 95% CI 0.98-2.26); and 12-week follow-up (d=2.40; 95% CI 1.67-3.12) [47].

Effects on Weight Management and Physical Activity

Using a texting reminder approach, Lau et al reported a nonsignificant increase in the average self-report of physical activity scores in the intervention group compared with controls at 2-month follow-up (d=0.31; 95% CI –0.14 to 0.76) [48]. Abraham et al also failed to show any significant changes in body mass index (BMI) at 6-month follow-up in the 3 study groups exposed to a combination of Internet-based educational program and texting intervention versus controls (d=0.09; 95% CI –0.61 to 0.78) [49]. Similarly, testing a multifunction mobile phone app, Pretlow et al reported a nonsignificant improvement in self-management skills and weight loss (% over-BMI) at 5-month follow-up in the intervention group compared with controls, in neither males (d=0.17; 95% CI –0.55 to 0.88) nor females (d=0.08; 95% CI –0.44 to 0.61) [50]. In contrast, Direito et al, in their evaluation of the effect of 2 commercially available fitness apps—immersive app "Zombies, Run!" and nonimmersive app "Get Running-Coach" —on cardiopulmonary fitness among physically inactive adolescents [51] at 2 month follow up, failed to show a significant difference in the time needed to complete 1-mile run or walk using an immersive app (d=0.24; 95% CI –0.43 to 0.9) or nonimmersive app (d=0.14, 95% CI –0.5 to 0.81) compared with the control group.

Effects on Sun-Protective Measures

Sachse et al used a combined approach of a single educational session and texting intervention and reported, at 2-month follow-up, a significant increase in participants' understanding of the meaning of UV-index (d=1.49; 95% CI 0.61-2.37), and their ability to name at least three of the ABCDE mnemonic (ie, asymmetry, border, color, diameter, evolution) for skin self-exam (d=1.40; 95% CI 0.19-2.61), but not in knowing that it takes hours to recognize sunburns (d=0.51; 95% CI –0.24 to 1.26) compared with their baseline [52].

Effects on Vaccination

Using a texting approach, Matheson et al reported significantly higher HPV vaccination series completion rate in intervention group compared with controls for HPV second dose (d=1.10; 95% CI 0.67-1.52), HPV second dose on time (d=0.46; 95% CI 0.06 to 0.86), HPV third dose (d=0.70; 95% CI 0.14-1.27), and HPV third dose on time (d=0.91; 95% CI 0.24-1.58) [53]. Similar significant beneficial effects were seen in the intervention group compared with those who were interested but not enrolled, regarding their completion rates of HPV second dose (d=0.93; 95% CI 0.40-1.46) and HPV third dose (d=1.24; 95% CI 0.05-2.42), but not HPV second dose on time (d=0.46; 95% CI –0.09 to 1.01) or HPV third dose on time (d=1.17; 95% CI –0.03 to 2.36) [53].

Discussion

Principal Findings

Prevention has been emphasized as a key component of adolescent health with evidence that many problem behaviors are amendable to intervention [4] Given the increasing use of communication technologies and mobile devices among young people [24], these media present opportunities for behavioral intervention. However, few studies have attempted to assess the efficacy of these approaches over different preventive behaviors. In this systematic review, we assessed the weight of evidence to date for 2 of the most common mobile technologies used by youth, texting and mobile phone apps, to promote preventive behaviors.

Overall, the evidence was modest, but limited with a small number of studies, relatively small sample sizes, and other methodological considerations, particularly for statistical analysis. We identified only 19 studies that met our pre-set criteria, the vast majority of which were texting interventions. These approaches were used to impact 7 types of behavior (clinic attendance, contraceptive use, risky behavior, oral health, physical activity and weight management, sun protection, HPV vaccination). Most interventions were carried out among younger adolescents and in clinic settings, which indicates the potential of clinical settings to adopt innovative technology-based prevention approaches to address different types of preventive behaviors.

Although texting was used more frequently than mobile phone apps to promote preventive behavior, there were many differences in the timing and content of texting approach. The majority of interventions used customized messages aimed at specific behavioral targets (depending on the preventive behavior of interest) and schedules. More than a simple reminder, texting was used to communicate educational messages, behavioral goals, and reinforce positive behavior. Many studies demonstrated both feasibility and satisfaction with these approaches, which suggests potential for further development.

Overall results for behavior change are modest, with half of interventions reviewed herein demonstrating evidence of efficacy. There was some evidence of efficacy for texting to promote oral contraceptive adherence, specialty clinic attendance, and HPV vaccination. Effects were strongest for oral health and hygiene with both a multifunction app and a texting approach, resulting in significant effects. There was limited evidence of efficacy of either a multifunction app or texting approach on weight management and physical activity; or for texting approach to change sexual risk behavior in the context of substance use. The variability in the observed effects across different behaviors could be due to the level of difficulty and effort required. The challenges and the characteristics associated with certain behaviors would make them easier or harder to influence or change over time. More research is needed to measure the level of difficulty of behavior change in a standardized way and to compare effect sizes across behaviors and intervention approaches.

A recent review of electronic media to promote health or safety behavior change in children (aged ≤18 years) concluded that there is good evidence of efficacy for these approaches [54]. Most studies focused on pre-teen children and utilized computer games and videos. The difference in findings in comparison to our review may be due in part to our focus on adolescents, for whom behaviors may be more difficult to change; our focus on newer technologies, which are still relatively nascent media for health behavior change; and on a wide variety of preventive behaviors, for which there is heterogeneity in approach. Mobile phone approaches, including texting in particular, have been found to be a feasible and potential efficacious medium for increasing levels of health education in adolescents [55]; behavioral targets may be more resistant to change.

Strengths

Our systematic review had a number of strengths. First, in our review, we followed the recommendations for rigorous systematic reviews methodology [28,29,56-58]. Second, we conducted a review with a highly sensitive search strategy guided by a librarian information specialist with no language restrictions to minimize publication bias and identify the largest possible number of relevant studies. Our search also included published systematic reviews, clinical trial registries, and various electronic databases. Third, although our search was limited to studies published since 1995, we identified no eligible studies before 2005, and therefore we believe that the possibility of missing earlier studies is very small. Finally, 2 authors completed the review process independently at all stages of the systematic review.

Limitations

Some potential methodological limitations of our systematic review warrant discussion. First, similar to any other systematic

literature review, although our search criteria were planned to be as comprehensive as possible, the possibility of missing few relevant articles cannot be excluded. Second, to identify the strongest available evidence, we included only articles that were published in peer-reviewed journals, and therefore there could be a publication bias with the tendency to report positive study results [59]. Third, the study sample size and ages, and the definition of adherence to preventive behaviors and other related outcomes varied. These limitations prohibited a meta-analysis from being performed [60]. Fourth, a number of the included studies had relatively small sample sizes and short follow-up period. Finally, the number of the studies that met our predefined criteria was relatively small; however, this is likely the result of the available evidence and published studies in the field.

Conclusions

In conclusion, despite the promising feasibility and acceptability data of texting and mobile phone apps in improving preventive behavior among adolescents, the evidence for actual behavior change is modest, with most studies of relatively low to moderate quality. However, the field of mobile health research is an evolving one with promising results that suggest a potential impact on improving health outcomes, given the growing evidence and the ubiquitous access to mobile technology. The variability in the observed effects across studies could be related to the nature of different behaviors and the heterogeneity of intervention approaches. Further research of these intervention approaches with rigorous research designs is needed to evaluate their efficacy, effectiveness, and cost-effectiveness in promoting preventive behavior among adolescents. These research efforts would be crucial to inform the evidence base on the use of texting and mobile phone apps as tools for behavior change among adolescents.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Updated search strategies.

[PDF File (Adobe PDF File), 157KB - mhealth_v5i4e50_app1.pdf]

Multimedia Appendix 2

Eligibility criteria of the included studies.

[PDF File (Adobe PDF File), 70KB - mhealth_v5i4e50_app2.pdf]

Multimedia Appendix 3

Detailed description of text message interventions.

[PDF File (Adobe PDF File), 169KB - mhealth_v5i4e50_app3.pdf]

Multimedia Appendix 4

Detailed description of mobile phone app interventions.

[PDF File (Adobe PDF File), 41KB - mhealth_v5i4e50_app4.pdf]

Multimedia Appendix 5

Outcomes of text message interventions.

[PDF File (Adobe PDF File), 65KB - mhealth_v5i4e50_app5.pdf]

Multimedia Appendix 6

Outcomes of mobile phone app interventions.

[PDF File (Adobe PDF File), 49KB - mhealth_v5i4e50_app6.pdf]

References

1. Gore FM, Bloem PJ, Patton GC, Ferguson J, Joseph V, Coffey C, et al. Global burden of disease in young people aged 10-24 years: a systematic analysis. Lancet 2011 Jun 18;377(9783):2093-2102. [doi: 10.1016/S0140-6736(11)60512-6] [Medline: 21652063]
2. Mokdad AH, Forouzanfar MH, Daoud F, Mokdad AA, El BC, Moradi-Lakeh M, et al. Global burden of diseases, injuries, and risk factors for young people's health during 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 2016 Jun 11;387(10036):2383-2401. [doi: 10.1016/S0140-6736(16)00648-6] [Medline: 27174305]
3. Patton GC, Coffey C, Sawyer SM, Viner RM, Haller DM, Bose K, et al. Global patterns of mortality in young people: a systematic analysis of population health data. Lancet 2009 Sep 12;374(9693):881-892 [FREE Full text] [doi: 10.1016/S0140-6736(09)60741-8] [Medline: 19748397]
4. Catalano RF, Fagan AA, Gavin LE, Greenberg MT, Irwin CE, Ross DA, Shek Daniel T L. Worldwide application of prevention science in adolescent health. Lancet 2012 Apr 28;379(9826):1653-1664 [FREE Full text] [doi: 10.1016/S0140-6736(12)60238-4] [Medline: 22538180]
5. Curry SJ, Mermelstein RJ, Emery SL, Sporer AK, Berbaum ML, Campbell RT, et al. A national evaluation of community-based youth cessation programs: end of program and twelve-month outcomes. Am J Community Psychol 2013 Mar;51(1-2):15-29. [doi: 10.1007/s10464-012-9496-8] [Medline: 22395364]
6. Patnode CD, O'Connor E, Whitlock EP, Perdue LA, Soh C, Hollis J. Primary care-relevant interventions for tobacco use prevention and cessation in children and adolescents: a systematic evidence review for the U.S. Preventive Services Task Force. Ann Intern Med 2013 Feb 19;158(4):253-260. [doi: 10.7326/0003-4819-158-4-201302190-00580] [Medline: 23229625]
7. Sussman S, Sun P. Youth tobacco use cessation: 2008 update. Tob Induc Dis 2009 Jan 30;5:3 [FREE Full text] [doi: 10.1186/1617-9625-5-3] [Medline: 19183452]
8. Steinka-Fry KT, Tanner-Smith EE, Hennessy EA. Effects of brief alcohol interventions on drinking and driving among youth: a systematic review and meta-analysis. J Addict Prev 2015;3(1) [FREE Full text] [Medline: 26221619]
9. Samson JE, Tanner-Smith EE. Single-session alcohol interventions for heavy drinking college students: a systematic review and meta-analysis. J Stud Alcohol Drugs 2015 Jul;76(4):530-543 [FREE Full text] [Medline: 26098028]
10. Bhochhibhoya A, Hayes L, Branscum P, Taylor L. The use of the internet for prevention of binge drinking among the college population: a systematic review of evidence. Alcohol Alcohol 2015 Sep;50(5):526-535 [FREE Full text] [doi: 10.1093/alcalc/agv047] [Medline: 26047832]
11. Strøm HK, Adolfsen F, Fossum S, Kaiser S, Martinussen M. Effectiveness of school-based preventive interventions on adolescent alcohol use: a meta-analysis of randomized controlled trials. Subst Abuse Treat Prev Policy 2014 Dec 13;9:48 [FREE Full text] [doi: 10.1186/1747-597X-9-48] [Medline: 25495012]
12. Carney T, Myers B. Effectiveness of early interventions for substance-using adolescents: findings from a systematic review and meta-analysis. Subst Abuse Treat Prev Policy 2012 Jun 14;7:25 [FREE Full text] [doi: 10.1186/1747-597X-7-25] [Medline: 22697269]
13. Jensen CD, Cushing CC, Aylward BS, Craig JT, Sorell DM, Steele RG. Effectiveness of motivational interviewing interventions for adolescent substance use behavior change: a meta-analytic review. J Consult Clin Psychol 2011 Aug;79(4):433-440. [doi: 10.1037/a0023992] [Medline: 21728400]
14. Johnson BT, Scott-Sheldon Lori A J, Huedo-Medina TB, Carey MP. Interventions to reduce sexual risk for human immunodeficiency virus in adolescents: a meta-analysis of trials, 1985-2008. Arch Pediatr Adolesc Med 2011 Jan;165(1):77-84 [FREE Full text] [doi: 10.1001/archpediatrics.2010.251] [Medline: 21199984]
15. Halpern V, Lopez LM, Grimes DA, Stockton LL, Gallo MF. Strategies to improve adherence and acceptability of hormonal methods of contraception. Cochrane Database Syst Rev 2013 Oct 26(10):CD004317. [doi: 10.1002/14651858.CD004317.pub4] [Medline: 24163097]
16. Lopez LM, Grey TW, Chen M, Denison J, Stuart G. Behavioral interventions for improving contraceptive use among women living with HIV. Cochrane Database Syst Rev 2016 Aug 09(8):CD010243. [doi: 10.1002/14651858.CD010243.pub3] [Medline: 27505053]
17. Smith C, Gold J, Ngo TD, Sumpter C, Free C. Mobile phone-based interventions for improving contraception use. Cochrane Database Syst Rev 2015;6:CD011159. [doi: 10.1002/14651858.CD011159.pub2] [Medline: 26115146]
18. Walling EB, Benzoni N, Dornfeld J, Bhandari R, Sisk BA, Garbutt J, et al. Interventions to improve HPV vaccine uptake: a systematic review. Pediatrics 2016 Jul;138(1). [doi: 10.1542/peds.2015-3863] [Medline: 27296865]
19. Aljabaa A, McDonald F, Newton JT. A systematic review of randomized controlled trials of interventions to improve adherence among orthodontic patients aged 12 to 18. Angle Orthod 2015 Mar;85(2):305-313. [doi: 10.2319/031214-184.1] [Medline: 25045779]
20. Newton JT, Asimakopoulou K. Managing oral hygiene as a risk factor for periodontal disease: a systematic review of psychological approaches to behaviour change for improved plaque control in periodontal management. J Clin Periodontol 2015 Apr;42 Suppl 16:S36-S46. [doi: 10.1111/jcpe.12356] [Medline: 25639708]

21. Hynynen S, van Stralen MM, Sniehotta FF, Araújo-Soares V, Hardeman W, Chinapaw MJ, et al. A systematic review of school-based interventions targeting physical activity and sedentary behaviour among older adolescents. Int Rev Sport Exerc Psychol 2016 Jan 1;9(1):22-44 [FREE Full text] [doi: 10.1080/1750984X.2015.1081706] [Medline: 26807143]
22. Lavelle HV, Mackay DF, Pell JP. Systematic review and meta-analysis of school-based interventions to reduce body mass index. J Public Health (Oxf) 2012 Aug;34(3):360-369 [FREE Full text] [doi: 10.1093/pubmed/fdr116] [Medline: 22267291]
23. Silveira JA, Taddei JA, Guerra PH, Nobre MR. The effect of participation in school-based nutrition education interventions on body mass index: a meta-analysis of randomized controlled community trials. Prev Med 2013 Mar;56(3-4):237-243. [doi: 10.1016/j.ypmed.2013.01.011] [Medline: 23370048]
24. Lenhart A. Pew Research Center. Teens, Social Media & Technology Overview URL: http://www.pewinternet.org/2015/04/09/teens-social-media-technology-2015/ [accessed 2016-08-07] [WebCite Cache ID 6jaddHT8x]
25. Smith A. Pew Research Center. 2015. U.S. Smartphone Use in 2015 URL: http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/ [accessed 2016-06-10] [WebCite Cache ID 6lInLhY2S]
26. Badawy SM, Thompson AA, Liem RI. Technology access and smartphone app preferences for medication adherence in adolescents and young adults with sickle cell disease. Pediatr Blood Cancer 2016 May;63(5):848-852. [doi: 10.1002/pbc.25905] [Medline: 26844685]
27. Badawy S. CRD. Text messaging and smartphone app interventions to improve adherence in adolescents and young adults: a systematic review and meta-analysis URL: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015025907 [accessed 2016-10-16] [WebCite Cache ID 6lIl7DjVt]
28. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epidemiol 2009 Oct;62(10):1006-1012. [doi: 10.1016/j.jclinepi.2009.06.005] [Medline: 19631508]
29. Howick J. CEBM. 2011. OCEBM Levels of Evidence URL: http://www.cebm.net/index.aspx?o=5653 [accessed 2016-10-16] [WebCite Cache ID 6lIlRJmKV]
30. Department of Child and Adolescent Health and Development. World Health Organization. 2001. The second decade: improving adolescent health and development URL: http://apps.who.int/iris/bitstream/10665/64320/1/WHO_FRH_ADH_98.18_Rev.1.pdf [accessed 2016-10-16] [WebCite Cache ID 6lIlhRvXw]
31. Haynes R. Introduction. In: Haynes RB, Taylor DW, Sackett DL, editors. Compliance in Health Care. Baltimore, MD: Johns Hopkins University Press; 1979:1-7.
32. Christensen A. Patient Adherence to Medical Treatment Regimens. New Haven, CT: Yale University Press; 2004.
33. Sabate E. World Health Organization. Adherence to long-term therapies: evidence for action URL: http://apps.who.int/iris/bitstream/10665/42682/1/9241545992.pdf [accessed 2016-10-16] [WebCite Cache ID 6oKAGcsV7]
34. Lipsey MW, Wilson DB. Practical Meta-Analysis (Applied Social Research Methods). Thousand Oaks, CA: Sage Publications; 2000.
35. Narring F, Junod PN, Dominicé DM, Camparini RN, Humair J, Broers B, et al. Text-messaging to reduce missed appointment in a youth clinic: a randomised controlled trial. J Epidemiol Community Health 2013 Oct;67(10):888-891. [doi: 10.1136/jech-2013-202510] [Medline: 23761412]
36. Branson CE, Clemmey P, Mukherjee P. Text message reminders to improve outpatient therapy attendance among adolescents: a pilot study. Psychol Serv 2013 Aug;10(3):298-303. [doi: 10.1037/a0026693] [Medline: 23937089]
37. Castaño PM, Bynum JY, Andrés R, Lara M, Westhoff C. Effect of daily text messages on oral contraceptive continuation: a randomized controlled trial. Obstet Gynecol 2012 Jan;119(1):14-20. [doi: 10.1097/AOG.0b013e31823d4167] [Medline: 22143257]
38. Hou MY, Hurwitz S, Kavanagh E, Fortin J, Goldberg AB. Using daily text-message reminders to improve adherence with oral contraceptives: a randomized controlled trial. Obstet Gynecol 2010 Sep;116(3):633-640. [doi: 10.1097/AOG.0b013e3181eb6b0f] [Medline: 20733446]
39. Trent M, Thompson C, Tomaszewski K. Text messaging support for urban adolescents and young adults using injectable contraception: outcomes of the depotext pilot trial. J Adolesc Health 2015 Jul;57(1):100-106 [FREE Full text] [doi: 10.1016/j.jadohealth.2015.03.008] [Medline: 26002432]
40. Suffoletto B, Akers A, McGinnis KA, Calabria J, Wiesenfeld HC, Clark DB. A sex risk reduction text-message program for young adult females discharged from the emergency department. J Adolesc Health 2013 Sep;53(3):387-393. [doi: 10.1016/j.jadohealth.2013.04.006] [Medline: 23707402]
41. Cornelius JB, Dmochowski J, Boyer C, St LJ, Lightfoot M, Moore M. Text-messaging-enhanced HIV intervention for African American adolescents: a feasibility study. J Assoc Nurses AIDS Care 2013;24(3):256-267 [FREE Full text] [doi: 10.1016/j.jana.2012.06.005] [Medline: 23122907]
42. Lopez C, Ramirez DC, Valenzuela JI, Arguello A, Saenz JP, Trujillo S, et al. Sexual and reproductive health for young adults in Colombia: teleconsultation using mobile devices. JMIR Mhealth Uhealth 2014 Sep 25;2(3):e38 [FREE Full text] [doi: 10.2196/mhealth.2904] [Medline: 25263432]
43. Moore SC, Crompton K, van GS, van den Bree M, Bunney J, Lydall E. A feasibility study of short message service text messaging as a surveillance tool for alcohol consumption and vehicle for interventions in university students. BMC Public Health 2013;13:1011 [FREE Full text] [doi: 10.1186/1471-2458-13-1011] [Medline: 24160674]

44. Haug S, Schaub MP, Venzin V, Meyer C, John U, Gmel G. A pre-post study on the appropriateness and effectiveness of a Web- and text messaging-based intervention to reduce problem drinking in emerging adults. J Med Internet Res 2013;15(9):e196 [FREE Full text] [doi: 10.2196/jmir.2755] [Medline: 23999406]
45. Haug S, Schaub MP, Venzin V, Meyer C, John U. Efficacy of a text message-based smoking cessation intervention for young people: a cluster randomized controlled trial. J Med Internet Res 2013;15(8):e171 [FREE Full text] [doi: 10.2196/jmir.2636] [Medline: 23956024]
46. Zotti F, Dalessandri D, Salgarello S, Piancino M, Bonetti S, Visconti L, et al. Usefulness of an app in improving oral hygiene compliance in adolescent orthodontic patients. Angle Orthod 2016 Jan;86(1):101-107. [doi: 10.2319/010915-19.1] [Medline: 25799001]
47. Bowen TB, Rinchuse DJ, Zullo T, DeMaria ME. The influence of text messaging on oral hygiene effectiveness. Angle Orthod 2015 Jul;85(4):543-548. [doi: 10.2319/071514-495.1] [Medline: 25343689]
48. Lau EY, Lau PW, Chung P, Ransdell LB, Archer E. Evaluation of an internet-short message service-based intervention for promoting physical activity in Hong Kong Chinese adolescent school children: a pilot study. Cyberpsychol Behav Soc Netw 2012 Aug;15(8):425-434. [doi: 10.1089/cyber.2012.0161] [Medline: 22897473]
49. Abraham AA, Chow W, So H, Yip BH, Li AM, Kumta SM, et al. Lifestyle intervention using an internet-based curriculum with cell phone reminders for obese Chinese teens: a randomized controlled study. PLoS One 2015;10(5):e0125673 [FREE Full text] [doi: 10.1371/journal.pone.0125673] [Medline: 25946465]
50. Pretlow RA, Stock CM, Allison S, Roeger L. Treatment of child/adolescent obesity using the addiction model: a smartphone app pilot study. Child Obes 2015 Jun;11(3):248-259 [FREE Full text] [doi: 10.1089/chi.2014.0124] [Medline: 25760813]
51. Direito A, Jiang Y, Whittaker R, Maddison R. Apps for improving fitness and increasing physical activity among young people: the AIMFIT pragmatic randomized controlled trial. J Med Internet Res 2015;17(8):e210 [FREE Full text] [doi: 10.2196/jmir.4568] [Medline: 26316499]
52. Sachse MM, Böttcher S, Pape L, Wagner G, Mehls O, Klaus G, et al. Face-to-face sun protection training and text messages improve sun protection behaviour in adolescent organ transplant recipients: HIPPOlino feasibility study. Acta Derm Venereol 2016 Mar;96(3):341-345 [FREE Full text] [doi: 10.2340/00015555-2234] [Medline: 26336924]
53. Matheson EC, Derouin A, Gagliano M, Thompson JA, Blood-Siegfried J. Increasing HPV vaccination series completion rates via text message reminders. J Pediatr Health Care 2014;28(4):e35-e39. [doi: 10.1016/j.pedhc.2013.09.001] [Medline: 24200295]
54. Hieftje K, Edelman EJ, Camenga DR, Fiellin LE. Electronic media-based health interventions promoting behavior change in youth: a systematic review. JAMA Pediatr 2013 Jun;167(6):574-580 [FREE Full text] [doi: 10.1001/jamapediatrics.2013.1095] [Medline: 23568703]
55. L'Engle KL, Mangone ER, Parcesepe AM, Agarwal S, Ippoliti NB. Mobile phone interventions for adolescent sexual and reproductive health: a systematic review. Pediatrics 2016 Sep;138(3). [doi: 10.1542/peds.2016-0884] [Medline: 27553221]
56. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011].: The Cochrane Collaboration URL: http://www.cochrane-handbook.org/ [accessed 2016-02-16] [WebCite Cache ID 6lIm75YRF]
57. Centre for Reviews and Dissemination. 2009. Systematic Reviews: CRD's Guidance for Undertaking Reviews in Health Care (Internet) URL: https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf [accessed 2016-10-16] [WebCite Cache ID 6lImTISH8]
58. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev 2015 Jan;4:1 [FREE Full text] [doi: 10.1186/2046-4053-4-1] [Medline: 25554246]
59. Dubben H, Beck-Bornholdt H. Systematic review of publication bias in studies on publication bias. BMJ 2005 Aug 20;331(7514):433-434 [FREE Full text] [doi: 10.1136/bmj.38478.497164.F7] [Medline: 15937056]
60. Bartolucci AA, Hillegass WB. Overview, strengths, and limitations of systematic reviews and meta-analyses. In: Chiappelli F, Caldeira Brant XM, Neagos N, Oluwadara OO, Ramchandani MH, editors. Evidence-Based Practice: Toward Optimizing Clinical Outcomes. Berlin: Springer-Verlag; 2010:17-33.

Abbreviations

BMI: Body Mass Index
ED: Emergency Department
HIV: Human Immunodeficiency Virus
HPV: Human Papillomavirus
OCP: Oral Contraceptive Pills
PRISMA: Preferred Reporting Items of Systematic Reviews and Meta-analyses
RCT: Randomized Controlled Trial
RSOD: Risky Single-occasion Drinking
SD: Standard Deviation

SMD: Standardized Mean Differences
SMS: Short Message Service
STI: Sexually Transmitted Infection
UV: Ultraviolet

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Original Paper

User Interest in Digital Health Technologies to Encourage Physical Activity: Results of a Survey in Students and Staff of a German University

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Abstract

Background: Although the benefits for health of physical activity (PA) are well documented, the majority of the population is unable to implement present recommendations into daily routine. Mobile health (mHealth) apps could help increase the level of PA. However, this is contingent on the interest of potential users.

Objective: The aim of this study was the explorative, nuanced determination of the interest in mHealth apps with respect to PA among students and staff of a university.

Methods: We conducted a Web-based survey from June to July 2015 in which students and employees from the University of Potsdam were asked about their activity level, interest in mHealth fitness apps, chronic diseases, and sociodemographic parameters.

Results: A total of 1217 students (67.30%, 819/1217; female; 26.0 years [SD 4.9]) and 485 employees (67.5%, 327/485; female; 42.7 years [SD 11.7]) participated in the survey. The recommendation for PA (3 times per week) was not met by 70.1% (340/485) of employees and 52.67% (641/1217) of students. Within these groups, 53.2% (341/641 students) and 44.2% (150/340 employees)—independent of age, sex, body mass index (BMI), and level of education or professional qualification—indicated an interest in mHealth fitness apps.

Conclusions: Even in a younger, highly educated population, the majority of respondents reported an insufficient level of PA. About half of them indicated their interest in training support. This suggests that the use of personalized mobile fitness apps may become increasingly significant for a positive change of lifestyle.

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KEYWORDS

physical activity; telemedicine; primary prevention; healthy lifestyle

Introduction

There is considerable evidence that physical activity (PA) has a positive effect on health [1,2]. A sedentary lifestyle, on the other hand, increases the risk of developing cardiovascular, metabolic, or malignant diseases and leads to a reduction in life expectancy [3,4]. According to the World Health Organization (WHO), 150 min per week of moderately intensive endurance

activity is currently recommended as the minimum level for promoting health in adults, both in primary and in secondary and tertiary prevention [5]. Although many individuals are already well aware of the positive effects of PA, a large part of the population does not succeed in continuously implementing the recommendations for increasing PA in their everyday lives [5-7].

The increasingly available mobile health (mHealth) trackers such as wearables or mobile phone apps are usually developed with the motivational aspect in mind and offered to a wide range of potential users. They are an opportunity for improving self-activation and can help overcome implicit barriers for engaging in PA. Over 100,000 of these apps are already available [8]. Many of these apps aim to increase physical capacity and include features such as heart rate monitor, pedometer, activity instructions, and activity monitor [9]. In addition, they often implement behavioral components such as self-check, feedback mechanisms, or social support features, which can help optimize starting and continuing PA [10]. Depending on their content, mHealth apps can support the intention to become physically active or to increase the PA level. Moreover, the transfer into everyday life as well as the long-term maintenance of PA may be ensured. Those phases meet the stages of the transtheoretical model (preparation, action, maintenance) [11]. Concerning the development of model-based, effective apps, the needs of potential users must be considered. However, the basic condition in such apps remains the interest of the target group.

Meta-analyses and systematic reviews that have been conducted were able to prove the effect of mHealth monitors with respect to increasing PA, but according to the authors, long-term randomized controlled trials, especially of larger samples, are lacking thus far [12-14]. Furthermore, the training recommendations that are implemented in most of the apps developed until now are not sufficiently evidence-based [9,10,13,15,16]. Additionally, the majority of mHealth systems are not medical products that are clinically evaluated. Therefore, validity and reliability of these systems cannot be assumed [17-20].

But, due to the potential benefit of mHealth monitors for increasing PA, they are particularly significant for stakeholders in the health care system, especially insurance companies. However, before noncommercial apps are developed by health insurers, the acceptance and general interest of potential users and the special interest in individual features of the systems (eg, providing information, documenting measured values, reminders, and instructions) should be determined.

The aim of this study was the explorative, nuanced determination of the interest in mHealth apps with respect to PA among students and staff of a university.

Methods

Survey Design and Implementation

In the period from June to July 2015, an Web-based survey was conducted among students and staff of the University of Potsdam. The survey mailing list referred to the students and employee database of the University of Potsdam. Mail addresses of all students, scientific and administration employees were included. The cover letter of the survey mail informed potential participants about the content and aim of the survey, their voluntary participation, the required time, and contained a hyperlink that guided participants to the survey. The survey mail was sent once from the administration department of the University of Potsdam. The survey instrument was created in "UP survey," which is a platform of the University of Potsdam offering a toolset based on the software Solutions QUAMP (QUAMP qEducation Software, Sociolutions GmbH Potsdam).

The standardized questionnaire included 35 questions (90 items) about PA, the use of or interest in digital fitness apps, sociodemographic parameters such as age, gender, body mass index (BMI), and level of education, and presence of a chronic disease. PA was assessed by questioning patients about their PA during the last 3 months. The question was specified with the terms PA, sports, or fitness during leisure time that led at least to a low increase of respiratory and heart rate. Nordic walking, ball games, jogging, bicycling, swimming, aerobic, and badminton were cited as examples. All questions about PA in the survey were related to this definition.

Chronic disease was assessed by asking participants if they suffer from a chronic disease or a longer lasting health concern persisting for more than six months.

The arrangement of the questions was the result of an optimization process that took the perspective of the surveyed persons into account along with validity aspects and technical requirements (filter questions). By using filter questions, individual questions could be varied depending on the situation and—for certain subgroups of participants—redundant topics were avoided. Groups that were more and less interested in PA or digital media were thus addressed specifically. Accordingly, the questionnaires included sections of questions for participants who were more and less interested in PA and who were additionally differentiated according to the use of or interest in digital fitness apps.

The study used established terminology that was adapted to the target groups in the study or to the topics of this study. Questions about PA and sociodemographic data were based largely on the health survey of the Robert Koch Institute [6]. Questions about digital activity trackers and health or fitness apps were based on a study of mobile software apps [15].

Survey Functionality and Analysis

The programmed survey was tested several times to ensure its functionality and usability. Using IP-Check, duplicates could be excluded in the analysis. No personal data were collected. Data were anonymously transmitted and descriptively analyzed. The results of the descriptive statistics were presented as percentages for categorical variables and as mean values (standard deviation) for metric variables. Group differences regarding the level of PA (active: ≥3 days/week, less active: 1-2 days/week, inactive: <1 day/week) and the interest in mHealth apps were determined using the chi-square test for categorical variables, the Mann-Whitney *U* test for ordinal variables, and the *t* test for metric variables. The level of

significance was determined as $P<.05$. The statistical analyses were calculated using SPSS (IBM SPSS Statistics for Windows, version 22.0; IBM Corporation).

Results

Study Participants

A total of 18,961 students and 2621 employees of the University of Potsdam were invited to take part in the Web-based survey. After data processing and correction, a total of 1217 data sets for students (6.42%) and 485 data sets for staff (18.50%) were evaluated.

Around one-fifth of the students and one-third of employees reported suffering from a chronic disease; those affected within each group were significantly older than healthy members of the group (students: 26.8 vs 25.7 years, $P=.01$; staff: 46.1 vs 41.0 years, $P=.001$). In addition, 26.05% (317/1217) of participating students and over 43.1% (209/485) of staff were overweight to obese (BMI ≥25 kg/m^2; Table 1).

Table 1. Basic characteristics of study participants.

Characteristics	Students (n=1217)	Staff (n=485)
Age in years, mean (SD)	26.0 (4.9)	42.7 (11.7)
Gender (male, n %)	398 (32.70)	158 (32.5)
High school graduate, n (%)	N/A[a]	416 (85.8)
University degree, n (%)	N/A[a]	357 (73.6)
Chronic disease[b], n (%)	251 (20.62)	145 (29.9)
BMI[c] (kg/m^2), mean (SD)	22.7 (9.5)	24.1 (3.6)
Normal weight, n (%)	900 (74.00)	276 (56.9)
Overweight, n (%)	262 (21.53)	165 (34.0)
Obese, n (%)	55 (4.52)	44 (9.1)
Extent of PA[d], n (%)		
≥1 day/week	1095 (90.00)	397 (81.9)
≥3 days/week	576 (47.33)	145 (29.9)

[a]N/A: not applicable.

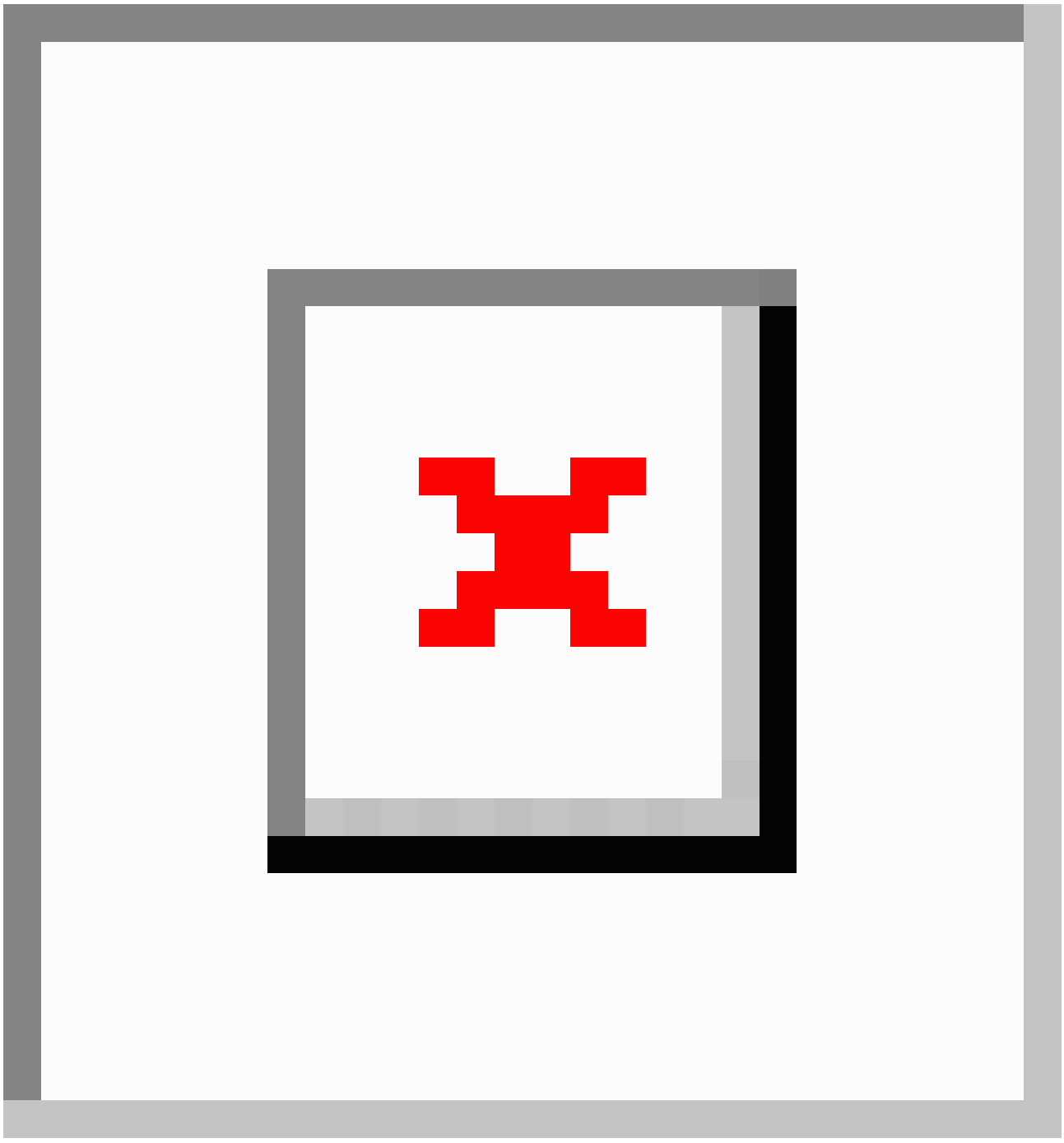
[b]Chronic diseases or long-term health problems lasting at least six months.

[c]Body mass index (BMI) classes: normal weight <25 kg/m², overweight 25 to <30 kg/m², obese ≥30 kg/m².

[d]PA: physical activity.

Some 90.00% (1095/1217) of students and 82% (398/485) of staff engaged in PA at least one day a week; nearly half of the students and one-third of the staff met the WHO's recommendations for PA (≥3 days or 150 min per week). The level of PA was dependent on gender, that is, among the physically active (eg, ≥3 days/week) participants, the percentage of males was higher both for students and for staff than in the respective group of less active (eg, 1-2 days/week) or not active (eg, <1 day/week) participants (students: 38.8 [224/576] vs 27.2% [174/641], $P<.001$; staff: 39.3 [57/145] vs 29.5% [100/340], $P=.04$). Overall, 56.5% (225/398) of the male and 43.3% (355/819) of the female students reported that they engaged in PA at least 3 times a week. Among staff members, 36.7% (58/158) of the men and 27.2% (89/327) of the women met these recommendations for PA. Students who were active in PA were also less often chronically ill than inactive students (17.99 [104/576] vs 23.0% [147/641]; $P=.04$) and an analogous trend was observed among staff members (26.7 [39/145] vs 31.3% [106/340]; $P=.36$). Group differences regarding active or inactive participants in BMI class were identified only for staff members. The physically active staff members had a normal weight more often and were less often obese than inactive employees ($P=.02$; Figure 1, top). Age had no influence on PA in either group of participants.

Figure 1. Physical activity and interest in mobile fitness apps with regard to the body mass index (BMI) class of the university staff surveyed. (Top) BMI and physical activity (≥3 days/week). (Bottom) BMI and the interest in mobile fitness apps to increase physical activity in less active individuals (<3 days/week). BMI is usually expressed in kilogram per square meter (kg/m²).



Interest in Digital Health Technologies

Data on interest in mobile fitness apps to increase PA were collected only for those participants of the study who were not sufficiently active according to the WHO recommendations. It was found that 53.2% (341/641) of the respective students and 44.2% (150/340) of staff indicated interest in the offers independently of age, gender, or BMI class (Figure 1, bottom). However, the interest of staff members appeared to be dependent on the extent of previous PA. Of those interested in mobile fitness apps, 30.0% (45/150) were previously inactive, whereas the percentage of previously inactive individuals in the group of those who were not interested was only 15.3% (29/190; *P*=.003).

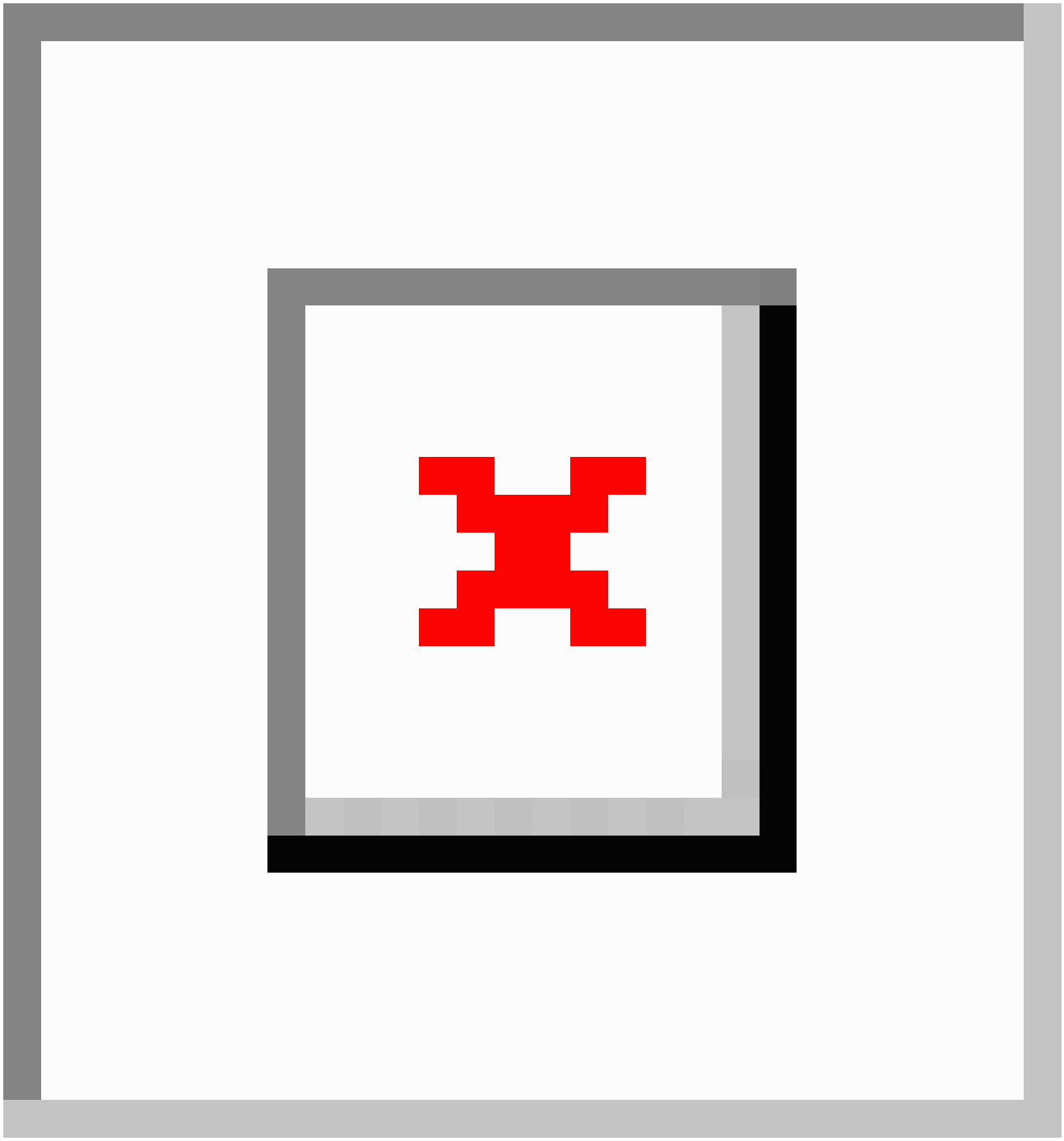
A total of 89.7% (575/641) and 85.6% (291/340), respectively, of previously inactive students and staff expressed willingness to pay at least some of the costs of such a fitness app. In fact, 37.8% (242/641) of these less-active or inactive students and 35.8% (122/340) of staff already use fitness apps.

With respect to individual program functions, the greatest interest of those surveyed was in documenting or managing the measured values, instructions, and feedback (Figure 2). With respect to trust in potential providers of health or fitness apps, the majority of the students and staff surveyed were neutral.

They were most likely to trust their physician (33%, 212/641, and 27%, 92/340, respectively) and the sports club or trainer (38%, 244/641, and 27%, 92/340, respectively).

Questions as to the potential access to data stored by the health or fitness apps were also answered by most participants with "undecided" or "opposed." Here as well, the participants would prefer to allow giving access to their physician (53%, 340/641, of students and 45%, 153/340, of staff) or the sports club or trainer (25%, 160/640, and 12%, 41/340, respectively).

Figure 2. Desired features of mobile fitness apps.



Discussion

Principal Findings

In this survey, the percentage of physically active university members was high, with 90% of students and over 80% of employees. Of these, 57% of the male and 43% of female students and 37% of male and 27% of female staff members met the level of PA of 150 min (or 3 times) a week as recommend by the WHO. Lampert et al [21] confirmed, based on survey data from the Robert Koch Institute from 2009 for the general population, lower percentages of physically active persons, but simultaneously emphasized the key correlation between PA and social status determined by the level of education and income. With this in mind and taking into account the fact that 10% of the students were majoring in a subject related to sports, the high level of PA among the population in

the study is not particularly surprising and is comparable with the results of other internal surveys at universities [22,23].

Around half of the students, who were previously not sufficiently physically active, and one-third of the staff indicated an interest in mHealth apps. Although there was no age dependence within the groups of participants, an age-related dependence of interest in digital solutions may be postulated for the intergroup comparison between students and staff. Recent literature provides extensive evidence that younger individuals in various target groups are more interested in mHealth apps and are more often willing to use such devices [24-26]. There has now been a broad discussion of the problems regarding the acceptance of digital devices among older groups, which focused, for example, on the failure to address the needs of these groups and called for the development of apps specifically for these target and age groups in order to increase user acceptance [27,28].

On the other hand, this study identified only negligible differences between students and staff with respect to potentially interesting functions of mHealth apps. Only "documenting and managing measured values" was named by students (approximately 10%) more often than by staff. Overall, these program functions were among the most important features of a mHealth app for both groups aside from "instructions" and "feedback." This result can most likely be interpreted in view of the current state of technological development and the demand induced by the providers of mHealth apps. Cultural values, such as the current "quantified self" movement, at the center of which is collecting data on various aspects of one's own life to improve self-understanding, may also play a role [29-31].

When differentiating between the previously inactive students and staff members compared with those who got PA once to twice a week, in this survey, the "reminder" function that was of considerably greater interest for the inactive individuals, was especially significant. The reminder feature can be considered a self-check technique and supports adherence. It can be assumed that the inactive individuals are well-aware of their need for PA and thus seek suitable support options to adjust their behavior. Similar behavioral patterns are already known from obesity research [32].

Regarding trust in the providers of health or fitness apps and with respect to access to the values measured by such apps, it was found that the great majority of those surveyed were undecided or opposed. They were most likely to trust their own physician and the sports club or trainer in this respect. The indecision and opposition expressed are plausible in view of the requirements of trustworthy apps expressed in literature. Dennison et al [33], for example, emphasize that potential users' desire confidentiality, expertise of the app providers, and the required transparency regarding the functions of the app and with respect to records of the values measured. Recent studies have shown extensive evidence of general concerns regarding data privacy; here again, some correlation with age and level of education has been postulated in addition to media- and experience-based mistrust [26,34,35].

Willingness to assume the partial or full costs for a mHealth app was generally high among the individuals surveyed who were interested in electronic media, corresponding with a recent study [36]. However, the general willingness expressed in an abstract context does not allow a valid conclusion to be drawn about a concrete decision, which may be more complex and take contextual factors such as the financial burden associated with this purchase into consideration. For example, Dennison et al [33] showed that students expect a health or fitness app to be reasonably priced. Ultimately, the actual willingness to assume the costs of a mHealth app is likely to depend not only on the cost, but also on the anticipated benefit of the concrete app.

Limitations

The response rate for the study was within the usual range for surveys of this kind. Return rates of less than 10% for students and less than 20% for staff were also reported in other studies of PA at universities [22,23]. Nevertheless, it must be assumed that this level of response rates may be associated with a sampling bias. Furthermore, a sampling bias regarding the gender distribution of the investigated population can be assumed. The male proportion among the respondents was approximately 33% both in students and staff members, whereas the proportion of male is higher in the whole population, that is, 42% of all students and 44% of the entire staff of the university in 2015 were male.

The percentage of physically active students is relatively high in this study at 90% and thus comparable with the results of Preuß et al [22], who found around 80% of physically active students at the University of Bonn. It is assumed that the percentage of physically active students at the University of Potsdam was overestimated due to the high percentage of sport science programs. It is assumed that questions about PA are more likely to be answered by individuals interested in sports. This applies analogously to the group of staff members with 82% of physically active individuals, although comparable data are available in literature here as well [23].

This study has an explorative nature; the results presented should therefore not be simply transferred to all students and staff at the University of Potsdam or to other populations (such as to population-based cohorts).

Conclusions

Even in younger groups with a high level of education, the majority of individuals do not meet the level of PA recommended by the WHO. However, around half of the individuals in this group of inactive individuals showed interest in mobile apps to encourage activity, indicating that the personalized and age-group-specific use of mHealth apps for optimizing lifestyle through more PA could become increasingly more important.

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Conflicts of Interest

None declared.

References

1. Held C, Iqbal R, Lear SA, Rosengren A, Islam S, Mathew J, et al. Physical activity levels, ownership of goods promoting sedentary behaviour and risk of myocardial infarction: results of the INTERHEART study. Eur Heart J 2012 Feb;33(4):452-466. [doi: 10.1093/eurheartj/ehr432] [Medline: 22238330]
2. Hills AP, Street SJ, Byrne NM. Physical activity and health: "what is old is new again". Adv Food Nutr Res 2015;75:77-95. [doi: 10.1016/bs.afnr.2015.06.001] [Medline: 26319905]
3. Reiner M, Niermann C, Jekauc D, Woll A. Long-term health benefits of physical activity--a systematic review of longitudinal studies. BMC Public Health 2013;13:813 [FREE Full text] [doi: 10.1186/1471-2458-13-813] [Medline: 24010994]
4. Lee I, Shiroma EJ, Lobelo F, Puska P, Blair SN, Katzmarzyk PT. Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. The Lancet 2012 Jul;380(9838):219-229. [doi: 10.1016/S0140-6736(12)61031-9]
5. Global Recommendations on Physical Activity for Health. Geneva: World Health Organization; 2010.
6. Krug S, Jordan S, Mensink GB, Müters S, Finger J, Lampert T. [Physical activity: results of the German Health Interview and Examination Survey for Adults (DEGS1)]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2013 May;56(5-6):765-771. [doi: 10.1007/s00103-012-1661-6] [Medline: 23703496]
7. Hallal PC, Andersen LB, Bull FC, Guthold R, Haskell W, Ekelund U. Global physical activity levels: surveillance progress, pitfalls, and prospects. The Lancet 2012 Jul;380(9838):247-257. [doi: 10.1016/S0140-6736(12)60646-1]
8. Xu W, Liu Y. mHealthApps: a repository and database of mobile health apps. JMIR Mhealth Uhealth 2015 Mar 18;3(1):e28 [FREE Full text] [doi: 10.2196/mhealth.4026] [Medline: 25786060]
9. Modave F, Bian J, Leavitt T, Bromwell J, Harris III C, Vincent H. Low quality of free coaching apps with respect to the American College of Sports Medicine Guidelines: a review of current mobile apps. JMIR mHealth uHealth 2015 Jul 24;3(3):e77. [doi: 10.2196/mhealth.4669]
10. Payne HE, Lister C, West JH, Bernhardt JM. Behavioral functionality of mobile apps in health interventions: a systematic review of the literature. JMIR Mhealth Uhealth 2015 Feb;3(1):e20 [FREE Full text] [doi: 10.2196/mhealth.3335] [Medline: 25803705]
11. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot 1997 Sep;12(1):38-48. [doi: 10.4278/0890-1171-12.1.38]
12. Fanning J, Mullen SP, McAuley E. Increasing physical activity with mobile devices: a meta-analysis. J Med Internet Res 2012 Nov;14(6):e161 [FREE Full text] [doi: 10.2196/jmir.2171] [Medline: 23171838]
13. Bort-Roig J, Gilson ND, Puig-Ribera A, Contreras RS, Trost SG. Measuring and influencing physical activity with smartphone technology: a systematic review. Sports Med 2014 May;44(5):671-686. [doi: 10.1007/s40279-014-0142-5] [Medline: 24497157]
14. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, et al. Using pedometers to increase physical activity and improve health: a systematic review. JAMA 2007 Nov 21;298(19):2296-2304. [doi: 10.1001/jama.298.19.2296] [Medline: 18029834]
15. Higgins JP. Smartphone applications for patients' health and fitness. Am J Med 2016 Jan;129(1):11-19. [doi: 10.1016/j.amjmed.2015.05.038] [Medline: 26091764]
16. Funk C. Mobile Softwareanwendungen (Apps) im Gesundheitsbereich: Entwicklung, Marktbetrachtung und Endverbrauchermeinung. Stuttgart: ibidem-Verlag; 2013.
17. Lee J, Kim Y, Welk GJ. Validity of consumer-based physical activity monitors. Med Sci Sports Exerc 2014 Sep;46(9):1840-1848. [doi: 10.1249/MSS.0000000000000287] [Medline: 24777201]
18. Evenson KR, Goto MM, Furberg RD. Systematic review of the validity and reliability of consumer-wearable activity trackers. Int J Behav Nutr Phys Act 2015;12(1):159 [FREE Full text] [doi: 10.1186/s12966-015-0314-1] [Medline: 26684758]
19. An H, Jones GC, Kang S, Welk GJ, Lee J. How valid are wearable physical activity trackers for measuring steps? Eur J Sport Sci 2017 Apr;17(3):360-368. [doi: 10.1080/17461391.2016.1255261] [Medline: 27912681]
20. Price K, Bird SR, Lythgo N, Raj IS, Wong JY, Lynch C. Validation of the Fitbit One, Garmin Vivofit and Jawbone UP activity tracker in estimation of energy expenditure during treadmill walking and running. J Med Eng Technol 2017 Apr;41(3):208-215. [doi: 10.1080/03091902.2016.1253795] [Medline: 27919170]
21. Lampert T, Mensink GB, Müters S. [Physical and sporting activity among adults in Germany. Results from the "German Health Update 2009" survey]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2012 Jan;55(1):102-110. [doi: 10.1007/s00103-011-1401-3] [Medline: 22286255]

22. Preuß M, Preuß P, Kuhlmann K, Ponert M, Mehlis K, Beauducel A. Healthy campus bonn – sport- und bewegungsverhalten der studierenden. In: Göring A, Möllenbeck D, editors. Bewegungsorientierte Gesundheitsförderung an Hochschulen. Göttingen: Universitätsverlag; 2015:37-64.
23. Mess F, Gerth D, Hanke J, Rabel M, Walter U. Gesundheitsverhalten und gesundheit bei wissenschaftlichen und nicht-wissenschaftlichen Beschäftigen – ein Vergleich an der Universität Konstanz. In: Göring A, Möllenbeck D, editors. Bewegungsorientierte Gesundheitsförderung an Hochschulen. Göttingen: Universitätsverlag; 2015:115-129.
24. Humble JR, Tolley EA, Krukowski RA, Womack CR, Motley TS, Bailey JE. Use of and interest in mobile health for diabetes self-care in vulnerable populations. J Telemed Telecare 2016 Jan;22(1):32-38. [doi: 10.1177/1357633X15586641] [Medline: 26026179]
25. Torous J, Chan SR, Yee-Marie TS, Behrens J, Mathew I, Conrad EJ, et al. Patient smartphone ownership and interest in mobile apps to monitor symptoms of mental health conditions: a survey in four geographically distinct psychiatric clinics. JMIR Ment Health 2014 Dec;1(1):e5 [FREE Full text] [doi: 10.2196/mental.4004] [Medline: 26543905]
26. Steele GC, Miller D, Kuluski K, Cott C. Tying ehealth tools to patient needs: exploring the use of ehealth for community-dwelling patients with complex chronic disease and disability. JMIR Res Protoc 2014 Nov;3(4):e67 [FREE Full text] [doi: 10.2196/resprot.3500] [Medline: 25428028]
27. Schmid A, Dörfler I, Dany F, Böpple O. Analyse der akzeptanzkriterien für mobile anwendungen im bereich gesundheit in der zielgruppe 50+. In: Technologiegestützte Dienstleistungsinnovation in der Gesundheitswirtschaft. Wiesbaden: Gabler Verlag, Springer Fachmedien; 2012:57-82.
28. Giesecke S, Hull J, Schmidt S, Strese H, Weiß C, Baumgarten D. Statista. 2005. AAL – ambient assisted living: Country Report Germany URL: https://www.statista.com/outlook/283/137/ambient-assisted-living--aal-/germany [accessed 2017-03-17] [WebCite Cache ID 6p27gocG9]
29. Banos O, Bilal AM, Ali KW, Afzal M, Hussain M, Kang BH, et al. The Mining Minds digital health and wellness framework. Biomed Eng Online 2016 Jul 15;15 Suppl 1:76 [FREE Full text] [doi: 10.1186/s12938-016-0179-9] [Medline: 27454608]
30. Fawcett T. Mining the quantified self: personal knowledge discovery as a challenge for data science. Big Data 2015 Dec;3(4):249-266. [doi: 10.1089/big.2015.0049]
31. Gimpel H, Nißen M, Görlitz R. Quantifying the quantified self: a study on the motivation of patients to track their own health. 2013 Dec Presented at: 34th International Conference on Information Systems; 2013; Milan, Italy URL: https://pdfs.semanticscholar.org/7ccb/e2e99078317a8657a2d362cdeb755b323cf4.pdf
32. Meister S, Becker S, Simson U. Digitale gesundheit – unterstützung der adipositastherapie durch digitale technologien. Adipositas – Ursachen, Folgeerkrankungen, Therapie 2016;10:38-42.
33. Dennison L, Morrison L, Conway G, Yardley L. Opportunities and challenges for smartphone applications in supporting health behavior change: qualitative study. J Med Internet Res 2013 Apr;15(4):e86 [FREE Full text] [doi: 10.2196/jmir.2583] [Medline: 23598614]
34. Dehling T, Gao F, Schneider S, Sunyaev A. Exploring the far side of mobile health: information security and privacy of mobile health apps on ios and android. JMIR Mhealth Uhealth 2015 Jan 19;3(1):e8 [FREE Full text] [doi: 10.2196/mhealth.3672] [Medline: 25599627]
35. Illiger K, Hupka M, von JU, Wichelhaus D, Albrecht U. Mobile technologies: expectancy, usage, and acceptance of clinical staff and patients at a university medical center. JMIR Mhealth Uhealth 2014 Oct 21;2(4):e42 [FREE Full text] [doi: 10.2196/mhealth.3799] [Medline: 25338094]
36. Mercer K, Giangregorio L, Schneider E, Chilana P, Li M, Grindrod K. Acceptance of commercially available wearable activity trackers among adults aged over 50 and with chronic illness: a mixed-methods evaluation. JMIR Mhealth Uhealth 2016 Jan 27;4(1):e7 [FREE Full text] [doi: 10.2196/mhealth.4225] [Medline: 26818775]

Abbreviations

BMI: body mass index
mHealth: mobile health
PA: physical activity
UP: University of Potsdam
WHO: World Health Organization

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Original Paper

Use of Fitness and Nutrition Apps: Associations With Body Mass Index, Snacking, and Drinking Habits in Adolescents

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Abstract

Background: Efforts to improve snacking and drinking habits are needed to promote a healthy body mass index (BMI) in adolescents. Although commercial fitness and nutrition mobile phone apps are widely used, little is known regarding their potential to improve health behaviors, especially in adolescents. In addition, evidence on the mechanisms through which such fitness and nutrition apps influence behavior is lacking.

Objectives: This study assessed whether the use of commercial fitness or nutrition apps was associated with a lower BMI and healthier snacking and drinking habits in adolescents. Additionally, it explored if perceived behavioral control to eat healthy; attitudes to eat healthy for the good taste of healthy foods, for overall health or for appearance; social norm on healthy eating and social support to eat healthy mediated the associations between the frequency of use of fitness or nutrition apps and BMI, the healthy snack, and beverage ratio.

Methods: Cross-sectional self-reported data on snack and beverage consumption, healthy eating determinants, and fitness and nutrition app use of adolescents (N=889; mean age 14.7 years, SD 0.8; 54.8% [481/878] boys; 18.1% [145/803] overweight) were collected in a representative sample of 20 schools in Flanders, Belgium. Height and weight were measured by the researchers. The healthy snack ratio and the healthy beverage ratio were calculated as follows: gram healthy snacks or beverages/(gram healthy snacks or beverages+gram unhealthy snacks or beverages)×100. Multilevel regression and structural equation modeling were used to analyze the proposed associations and to explore multiple mediation.

Results: A total of 27.6% (245/889) of the adolescents used fitness, nutrition apps or both. Frequency of using nutrition apps was positively associated with a higher healthy beverage ratio (b=2.96 [1.11], P=.008) and a higher body mass index z-scores (zBMI; b=0.13 [0.05], P=.008. A significant interaction was found between the frequency of using nutrition and for the zBMI (b=−0.03 [0.02], P=.04) and the healthy snack ratio (b=−0.84 [0.37], P=.03). Attitude to eat healthy for appearance mediated both the fitness app use frequency-zBMI ($a \times b$=0.02 [0.01], P=.02) and the nutrition app use frequency-zBMI ($a \times b$=0.04 [0.01], P=.001) associations. No mediation was observed for the associations between the frequency of use of fitness or nutrition apps and the healthy snack or beverage ratio.

Conclusions: Commercial fitness and nutrition apps show some association with healthier eating behaviors and BMI in adolescents. However, effective behavior change techniques should be included to affect key determinants of healthy eating.

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KEYWORDS

mhealth; adolescents; snacks; beverages; body mass index

Introduction

In Flanders, Belgium, 18% of the adolescents between 14 and 16 years are overweight [1]. An unhealthy lifestyle characterized by physical inactivity [2], sedentary behavior [3], and unhealthy eating habits [4], plays an important role in the development of obesity. Typical unhealthy eating habits during adolescence are a low consumption of fruit, vegetables, and dairy products and an overconsumption of energy-dense snacks and sugar- and fat-rich beverages [5-9]. Health promotion programs to improve snack and beverage intakes are needed to promote a healthy body mass index (BMI) in adolescents.

Mobile phone use has significantly increased over the last decades, especially among adolescents and children [10-12]. With this increase, health-related apps have become widely spread [10,13-15]. Currently, 79,298 apps are available in the health and fitness category of iTunes and 75,058 in Google Play [16,17], the two leading app stores in Europe [14]. These apps are usually available in English or Dutch [14]. Among these apps, fitness and nutrition apps are the most popular and are typically used to improve fitness or eating habits [10,13]. Fitness and nutrition apps allow users to monitor their physical activity or food intake, provide information on the nutritional content of specific food items, and give instructions or demo videos for physical exercises [13,18,19]. Adolescents are highly skilled in using mobile phones and apps [20,21]. In 2014, 86% of the adolescents in Flanders owned a mobile phone and on average had 10-20 apps installed on the device [22]. Fitness and nutrition apps may thus be a promising, engaging, and affordable way to promote healthy lifestyle behaviors in adolescents [11,12,23].

Despite their potential for health promotion, little information exists about the use and effectiveness of commercially available fitness and nutrition apps [12,24]. Only a handful of studies, mostly in adults, have investigated the use of such apps and/or their relation with health [10,13,18,25,26]. The use of commercially available fitness apps was found to be associated with higher exercise levels, lower BMI, weight loss, and healthier eating [18,25], whereas the use of nutrition apps has been associated with better diet monitoring and weight loss [27,28]. Among adolescents, no differences in physical fitness were observed between fitness app users and nonusers during a randomized controlled trial [20]. To the best of our knowledge, no studies have investigated the use of existing fitness and nutrition apps and their relation with healthy eating habits and/or a lower BMI in adolescents.

Most existing fitness and nutrition apps for children, adolescents, and adults only contain a few effective behavior change techniques and might therefore have a limited capacity to facilitate behavior change [12,23,24,29]. Nevertheless, these apps are popular and perceived as useful and effective by the users [26]. Better evidence gathered via population-based studies on the usage patterns of such apps, their perceived utilities and benefits, and associations with health behaviors and BMI is needed [10,13,26,30].

To more fully comprehend the possible effects of nutrition and fitness apps on health behaviors, the mechanisms through which such apps influence behavior should also be explored [12,18,29]. Fitness and nutrition apps usually do not alter behavior directly, but they contain specific features that focus on key behavioral determinants [18,19,25,31]. Important intermediate determinants of healthy eating habits in adolescents are attitude to eat healthy, behavioral control, social norm, and social support [9,32-34]. Adolescents' attitude to eat healthy is mainly determined by taste, appearance, and health concerns [35-37]. An assessment of intermediate determinants in adults found that the use of fitness apps was associated with a lower BMI through a higher self-efficacy to exercise and higher levels of exercise [18]. To the best of our knowledge, no study has investigated if commercially available fitness and nutrition apps target and/or positively influence key intermediate determinants of adolescents' eating behaviors and anthropometrics.

This study first aimed to examine the use of fitness and/or nutrition apps and the associations between fitness and/or nutrition app use frequency and BMI, healthy snacking, and drinking habits (healthy snack or beverage ratio) in adolescents. It was expected that app use frequency would be related to a lower BMI and a higher healthy snack and/or beverage ratio. The combined influence of fitness and nutrition apps was also considered, as adolescents might use both fitness and nutrition albeit not always to the same extend [10,13]. Second, this study aimed to explore if the key behavioral determinants to eat healthy mediated the associations between fitness and/or nutrition app use and BMI, the healthy snack or beverage ratio. Perceived behavioral control to eat healthy; attitudes to eat healthy for the good taste of healthy foods, for overall health and for appearance; social norm on healthy eating or social support to eat healthy were examined in this regard. It was hypothesized that more frequent use of these apps would be associated with higher scores for the mentioned determinants, which in turn would be associated with lower BMI and healthier snacking and drinking habits.

Methods

Project

This research was conducted within the context of the Rewarding Healthy Food Choices Project [38], a multidisciplinary project that aims to investigate and improve the nutritional status of children and adolescents. The project

combines rewarding paradigms with learning theory and typical behavior change techniques such as monitoring and goal setting, through novel methods such as serious games and mobile phone apps.

Study Procedure and Participants

Data were collected using a pencil-and-paper survey from September 2013 to December 2013 in 14- to 16-year-old adolescents from 20 schools in Flanders, Belgium. A total of 1210 adolescents were sampled; the detailed sample size calculation and sampling procedure was already described elsewhere [1]. The adolescents completed the survey in the classroom in the presence of two researchers who provided clarification where necessary. Confidentiality and anonymity were assured by the researchers before, during, and after the completion of the survey. Passive consent was obtained from the parents or legal guardians of the sampled adolescents and the adolescents were informed that they could withdraw from the study at any time without explanation. The study protocol was approved by the Ethics Committee of the Ghent University Hospital.

Measures

Demographics

Both sex and date of birth of the participants were recorded. Age was derived by subtracting the date of birth from the date the survey took place. The education type of each adolescent (general or technical or vocational) was obtained from the schools.

Snack and Beverage Intake

Snack and beverage intake were assessed using a food frequency questionnaire (FFQ), which is designed to measure snack and beverage intake of adolescents [39]. The FFQ probes for usual food intake with a reference period of 1 month and comprises two sections: beverages and snacks. The intake of beverages was evaluated over the whole day, as beverages such as soft drinks and fruit juice provide additional calories not only at snack times but also throughout the whole day [40]. The intake of snacks was evaluated in terms of all food items consumed outside (>30 min) of breakfast, lunch, and dinner [41].

Snacks and beverages were classified as either unhealthy or healthy using the UK Ofcom Nutrient Profiling model [42]. This model provides a score that represents the "unhealthiness" of a beverage or food product [42]. Following this scoring system, the snack and beverage items are sport drinks, energy drinks, soft drinks, sweetened milk drinks, crisps, other salty snacks, savory rolls (cheese or sausage) or pizza, other fried snacks, fries, hamburgers, cheese or meat cubes, sandwiches with sweet or savory spread, ice cream, popsicles, breakfast cereals, pudding, mousses, chocolate, candy bars, candy, dry cookies, other cookies, breakfast rolls, and pastries, which were all considered to be unhealthy. Items such as water, fruit or vegetable juice, coffee or tea, milk, milk substitutes, unsweetened yoghurt, sweetened yoghurt, dried fruit, fruit, raw vegetables, nuts and seeds, kebab and pasta cups were considered to be healthy.

For each FFQ category, the daily intake was calculated by multiplying the frequency of consumption with the quantity of consumption per week (g) divided by 7. These daily intakes were then summed to obtain the daily intake of healthy snacks (g), unhealthy snacks (g), unhealthy drinks (mL), and healthy drinks (mL). Subsequently, a healthy snack and a healthy beverage ratio were then calculated. These ratios were calculated as follows: gram healthy snacks or beverages/(gram healthy snacks or beverages + gram unhealthy snacks or beverages)×100. The higher this ratio, the more healthy the snack and beverage intake of the adolescents was.

Fitness and Nutrition App Use

Frequencies of fitness and nutrition app use were assessed with the questions: "How often do you use fitness apps on your mobile phone or tablet?" with examples Nike+Running and Fitness Pall and "How often do you use nutrition apps on your mobile phone or tablet?" with examples Weight Watchers and Calorie Counter. Response categories were (almost) *never*, *a few times a year*, *once a month*, *a few times per month*, *once every week*, *a few times per week*, and *(almost) daily*. The answer format was adapted from a previous study on the change in the frequency of media use among adolescents over time [43]. Response categories were rescaled to represent how many times such an app was used in 1 week. *Never* and *a few times a year* were set to 0, whereas other answer categories were given the following values: *once a month*=0.25 (reflected using the apps once every 4 weeks), *a few times per month*=0.5 (midpoint of the interval), *once every week*=1 (reflected using the apps one day a week), *a few times per week*=3.5 (midpoint of the interval), and *daily*=7 (reflected using the apps every day of the week).

Perceived Behavioral Control, Social Influence, and Attitudes

Perceived behavioral control to eat healthy, social norm of healthy eating, social support to eat healthy, and attitudes to eat healthy for the good taste of healthy foods, for overall health and for appearance were measured via 13 items taken from an existing valid and reliable healthy diet determinants questionnaire (Table 1) [35]. All items were evaluated using a 5-point Likert scale. For the constructs perceived behavioral control to eat healthy and attitude to eat healthy for overall health and for appearance, mean scores ranging from 1 to 5 were computed by averaging the scores of the items used to measure these constructs.

Table 1. Overview used constructs, items, and anchors of the healthy diet determinants questionnaire.

Constructs	Questions	Anchors	Cronbach alpha
Perceived behavioral control (1-5)	Suppose you want to eat healthy...How hard is it for you to eat healthy each day?	1=very hard and 5=not hard at all	.71
	How hard is it for you to eat a healthy diet at your home?		
	How hard is it for you to eat a healthy diet at your school?		
Peer social norm (1-5)	How healthy does your best friend eat?	1=very unhealthy and 5=very unhealthy	N/A[a]
Peer social support (1-5)	How often does your best friend encourage you to eat a healthy diet?	1=not at all and 5=very often	N/A
Attitude toward healthy eating for the good taste of healthy foods (1-5)	A reason or benefit for me to eat healthy is that I like the taste of healthy foods	1=completely disagree and 5=completely agree	N/A
Attitude toward healthy eating for overall health (1-5)	I think healthy eating is important for my overall health	1=completely disagree and 5=completely agree	.79
	A reason or benefit for me to eat healthy is that I feel better eating healthy	1=completely disagree and 5=completely agree	
	A reason or benefit for me to eat healthy is that I stay in good health		
Attitude toward healthy eating for appearance (1-5)	A reason or benefit for me to eat healthy is...that I lose weight	1=completely disagree and 5=completely agree	.79
	A reason or benefit for me to eat healthy is...that I can keep my weight as it is now and do not become overweight	1=completely disagree and 5=completely agree	
	A reason or benefit for me to eat healthy is...that other people admire me		
	A reason or benefit for me to eat healthy is...to have an attractive body		

[a]N/A: not applicable.

Height and Weight

Two trained research assistants measured body height and weight using a standardized protocol [44]. Adolescents were measured without shoes and were allowed to wear light clothing. Body height was measured with a SECA Leicester Portable Stadiometer with an accuracy of 1 mm. Weight was measured with a calibrated electronic scale SECA 861 with an accuracy of 100 g. Age and sex-specific body mass index z-scores (zBMI) were calculated using Flemish 2004 growth reference data [45]. According to the International Obesity Task Force cut-off points, adolescents were classified as either normal weight or overweight [46].

Statistical Analyses

First, descriptive statistics of the sample were computed. Second, associations between the independent variables (fitness and/or nutrition app use frequency) and the dependent variables (zBMI, the healthy snack ratio, and the healthy beverage ratio) were assessed using multilevel linear regression analyses with a three-level structure (adolescents within classes within schools) to account for clustering of the data. Five consecutive models were tested. Model 0 was an intercept-only model without any level 1, level 2, or level 3 predictors; Model 1 was a covariates-only model (gender and education type). Models 2 and 3 evaluated the singular associations of fitness or nutrition app use frequency with the dependent variables by adding the fitness app use frequency or nutrition app use frequency to Model 1. Model 4 examined the independent influence of fitness and nutrition app use frequency by simultaneously adding both fitness app use frequency and nutrition app use frequency to Model 1. Model 5 explored the interplay between fitness and nutrition app use frequency by adding the fitness app use frequency × nutrition app use frequency interaction term to Model 4. When evidence of interaction was found in Model 5, a margins plot was computed to allow easier interpretation. Gender and education type (two dummies) were operationalized as categorical variables with 0=boys or general education. Frequencies of fitness and nutrition app use were treated as continuous predictors. As the intercept- and the covariates-only models (Models 0 and 1) were less relevant to test the postulated hypotheses, only Models 2-5 were presented.

Finally, to assess the mechanisms through which fitness and nutrition apps influence behavior, mediation analyses were executed for each app separately. Mediation of the associations between the independent (zBMI, healthy snack ratio, or healthy beverage ratio) and the dependent variables (fitness app use frequency or nutrition app use frequency) by the healthy diet determinants was explored with multiple mediation models. These models were fitted using multilevel structural equation modeling (MSEM; path analyses) with three levels for each of the app-outcome combinations, resulting in 6 models. Mediation was assessed following Preacher, Zyphur and Zhang [47,48]

for the multilevel 1-1-1 model, using bootstrapped standard errors for the indirect effects (1000 replications). The coefficients shown in "Results" section, however, are the result of single level generalized structural equation modeling (GSEM) as the multilevel models did not provide substantial higher efficiency, based on Akaike information criterion (AIC), and computationally simpler models were thus preferred.

For both the multilevel regression models, as the multiple mediation models associations were controlled for gender and education type, continuous parameters were mean centered, outliers were removed, unstandardized coefficients and their standard errors were displayed, and associations with *P* value <.05 were considered statistically significant. For all models also the log-likelihoods and the log-likelihood tests compared with the null model (intercept only), together with the explained variances compared with the null model were computed. All analyses were conducted using Stata version 13 SE (StataCorp LP).

Results

Descriptives

Of the 1210 selected adolescents, 6% were absent or did not receive parental consent and 2.8% returned a questionnaire of unsatisfactory quality (more than 33% of the questions not completed or straight-lining responses). Only 73% (889/1104) of the adolescents who filled out the survey completed the questions on app use and were considered for the analyses. The mean age of these adolescents was 14.7 years 54.8% (481/878) were male, 18.1% (145/803) overweight or obese, 46.1% (410/889) enrolled in general, 34.7% (308/889) in technical, and 19.2% (171/889) in vocational education (see Table 2). Table 2 also shows the mean and standard deviations (SDs) for the dependent and independent variables. The mean zBMI was 0.28 (SD 1.02), the mean healthy snack ratio 37.16 (SD 25.39), and the mean healthy beverage ratio 72.76 (SD 24.79). Healthy snacks and beverages thus accounted for 37.2% and 72.8%, respectively, of the total snack or beverage intake in adolescents.

Table 2. Characteristics of the participants (n=889), zBMI, snack and beverage intake, perceived behavioral control, social influences, and attitudes.

Characteristics		% or mean (SD[a])
Demographics		
	Overweight	18.1
	Boys	4.8
	General education	46.1
	Technical education	34.7
	Vocational education	19.2
	Age	14.69 (0.81)
App use		
	Use fitness apps	17.6%
	Use nutrition apps	7.6%
	Use both fitness and nutrition apps	1.7%
	Frequency of use of fitness apps (0-7)	0.54 (1.47)
	Frequency of use of nutrition apps (0-7)	0.16 (0.80)
zBMI[b] , healthy snack, and beverage ratio		
	zBMI	0.28 (1.02)
	Healthy snack ratio	37.16 (25.39)
	Healthy beverage ratio	72.67 (24.79)
Healthy eating determinants		
	Perceived behavioral control to eat healthy (1-5)	3.36 (0.82)
	Attitude to eat healthy eating for the good taste of healthy foods (1-5)	3.70 (0.78)
	Attitude to eat healthy for overall health (1-5)	3.70 (0.78)
	Attitude to eat healthy for appearance (1-5)	3.03 (0.90)
	Social norm to eat healthy (1-5)	3.12 (0.84)
	Social support to eat healthy (1-5)	2.11 (0.95)

[a]SD: standard deviation.

[b]zBMI: body mass index z-scores.

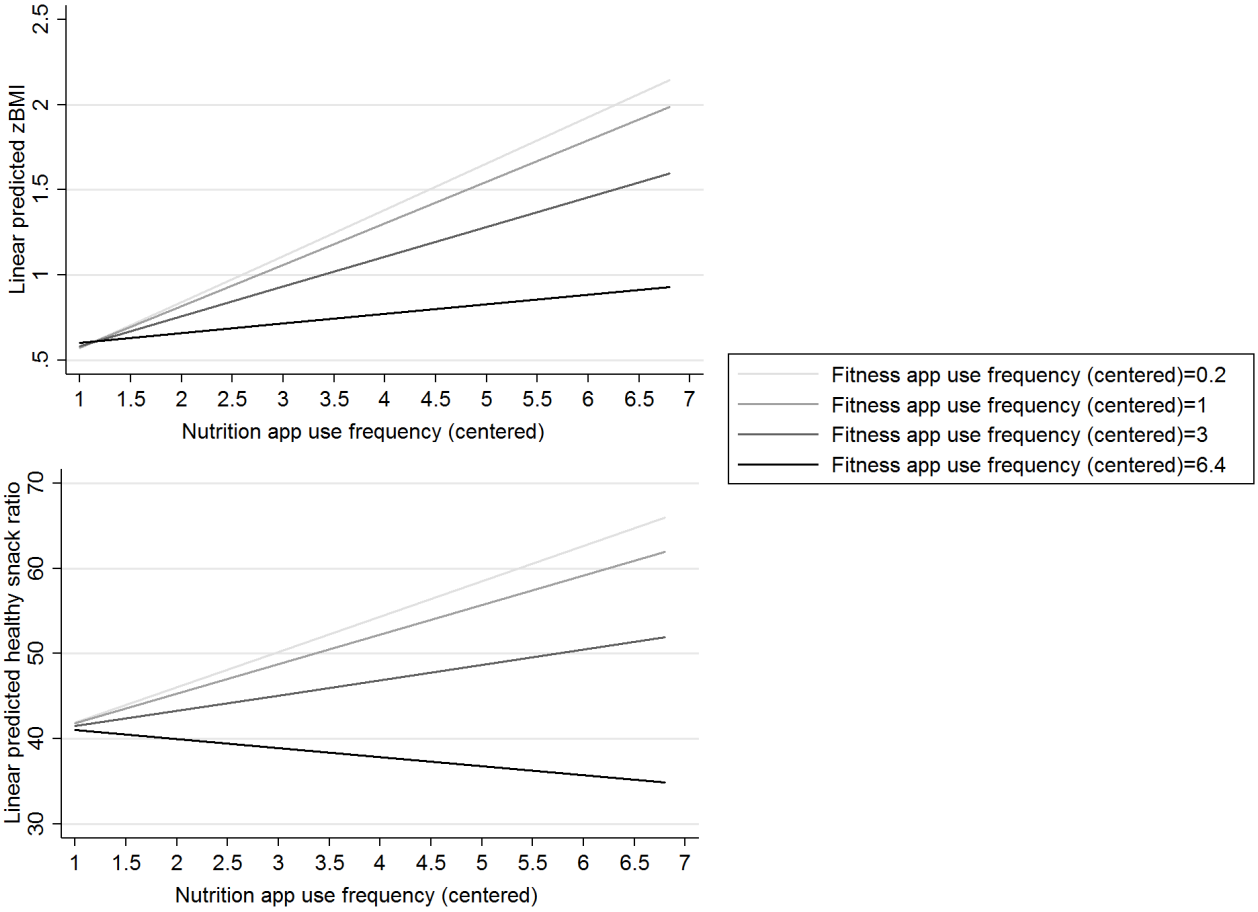
A total of 27.6% (245/889) of the adolescents used fitness and nutrition apps, most of them used fitness apps (17.6%, 167/889). A smaller group used both fitness and nutrition apps (7.6%, 63/889) and merely 3% (15/889) used only nutrition apps. The mean frequency of use is less than once a month for nutrition apps and between a few times per month and every week for fitness apps.

Multilevel Associations

zBMI

Both fitness and nutrition app use frequency were singularly associated with zBMI (see Models 2 and 3 in Multimedia Appendix 1). The more frequent adolescents used fitness apps (*b*=0.07 (0.02), *P*=.001) or nutrition apps (*b*=0.18 (0.03), *P*<.001), the higher the zBMI of the adolescents was. However, when both fitness and nutrition app use frequency were considered simultaneously (Model 4 in Multimedia Appendix 1), only nutrition app use frequency was independently and directly associated with zBMI (*b*=0.16 (0.04), *P*<.001). In addition, a significant interaction between fitness app use frequency and nutrition app use frequency (*b*=−0.03 (0.02), *P*=.04) in relation to zBMI was found (Model 5 Multimedia Appendix 1) in a way that when fitness apps were more frequently used, the association between nutrition app use frequency and zBMI decreased (see margins plot in Figure 1). Model 5 had the lowest log-likelihood and was thus the best fitting model. Together with the covariates, fitness and nutrition app use frequencies explained 7% of the variation in zBMI.

Figure 1. Margins plot zBMI and healthy snack ratio. Analyses controlled for sex and education type.



Healthy Snack Ratio

No significant singular or independent associations between the frequencies of use of fitness or nutrition apps and the healthy snack ratio could be observed (see Models 2-4 in Multimedia Appendix 1). However, there was an interaction of fitness and nutrition app use frequency (*b*=−0.84 (0.37), *P*=.03) with the healthy snack ratio (Model 5 in Multimedia Appendix 1). More specifically, the association between the nutrition app use frequency and the healthy snack ratio was positive at low frequencies of use of fitness apps. At higher frequencies, the association between nutrition app use frequency and the healthy snack ratio was negative (Figure 1). Here also, Model 5 was the best fitting model. The covariates together with the frequencies of use of both fitness and nutrition apps explained 9% of the variation in the healthy snack ratio.

Healthy Beverage Ratio

In contrast to fitness app use frequency, nutrition app use frequency was significantly associated with the healthy beverage ratio (see Models 2-4 in Multimedia Appendix 1). Adolescents who used nutrition apps more often had a higher healthy beverage ratio (*b*=2.96 (1.11), *P*=.008). Also, no significant interaction of fitness app use frequency and nutrition app use frequency was observed (see Model 5 in Multimedia Appendix 1). Model 5 again had the lowest log-likelihood and thus

provided the best fit. Together with the covariates, fitness and nutrition app use frequencies explained 5% of the variation in the healthy beverage ratio.

Multiple Mediation

The multiple mediation analyses indicated that both the fitness and nutrition app use frequencies were positively associated with social support to eat healthy (fitness apps *b*=0.05 [0.02], *P*=.03; nutrition apps *b*=0.10 [0.04], *P*=.01) and attitude to eat healthy for appearance (fitness apps *b*=0.05 [0.02], *P*=.008; nutrition apps *b*=0.14 [0.04], *P*<.001) (see Figures 2-4, top). The higher the app use frequency, the more positive the attitude to eat healthy for appearance and the felt social support. However, only attitude to eat healthy for appearance was found to be a mediator. The attitude to eat healthy for appearance mediated both the fitness app use frequency-zBMI relation (*a* × *b*=0.02 [0.01], *P*=.02) and the nutrition app use frequency-zBMI relation (*a* × *b*=0.04 [0.01], *P*=.001) (see Figure 3 and Tables 3 and 4). The higher the frequencies of use of fitness or nutrition apps, the more positive the attitude to eat healthy for appearance and the higher the zBMI. The associations between the frequencies of use of nutrition or fitness apps and the healthy snack ratio or the healthy beverage ratio were not mediated by any of the proposed mediators. The multiple mediation models explained, respectively, 9%, 11%, and 16% of the variance in zBMI, the healthy snack ratio, and the healthy beverage ratio (see Figures 2-4).

Table 3. Indirect effects multiple mediation with fitness app use frequency.

Mediator	Indirect effect (*a* × *b*)	Bootstrapped SE[a]	*z*	*P*	Normal-based 95% CI
zBMI[b]					
Perceived behavioral control to eat healthy	−0.00	0.00	−0.89	.37	−0.01 to 0.00
Attitude to eat healthy for the good taste of healthy foods	0.00	0.00	0.03	.98	−0.00 to 0.00
Attitude to eat healthy for overall health	0.00	0.00	0.28	.78	−0.00 to 0.00
Attitude to eat healthy for appearance	0.02	0.01	2.28	.02	0.00-0.03
Social norm to eat healthy	0.00	0.00	0.28	.78	−0.01 to 0.01
Social support to eat healthy	0.00	0.00	0.99	.32	−0.00 to 0.01
Total indirect effect	0.02	0.01	2.00	.046	0.00 to 0.03
Healthy snack ratio					
Perceived behavioral control to eat healthy	0.11	0.11	1.01	.31	−0.10 to 0.32
Attitude to eat healthy for the good taste of healthy foods	−0.01	0.05	−0.19	.85	−0.11 to 0.09
Attitude to eat healthy for overall health	0.01	0.04	0.32	.75	−0.07 to 0.10
Attitude to eat healthy for appearance	0.08	0.07	1.07	.29	−0.06 to 0.22
Social norm to eat healthy	−0.00	0.03	−0.06	.96	−0.05 to 0.05
Social support to eat healthy	0.05	0.06	0.81	.42	−0.07 to 0.17
Total indirect effect	0.24	0.18	1.30	.20	−0.12 to 0.60
Healthy beverage ratio					
Perceived behavioral control to eat healthy	0.10	0.10	1.04	.30	−0.09 to 0.30
Attitude to eat healthy for the good taste of healthy foods	0.01	0.04	0.15	.88	−0.07 to 0.08
Attitude to eat healthy for overall health	0.04	0.06	0.62	.54	−0.08 to 0.15
Attitude to eat healthy for appearance	0.09	0.08	1.11	.26	−0.07 to 0.27
Social norm to eat healthy	0.01	0.05	0.24	.81	−0.09 to 0.12
Social support to eat healthy	0.08	0.07	1.24	.22	−0.05 to 0.21
Total indirect effect	0.33	0.17	1.97	.049	0.00 to 0.66

[a]SE: standard error.

[b]zBMI: body mass index z-scores.

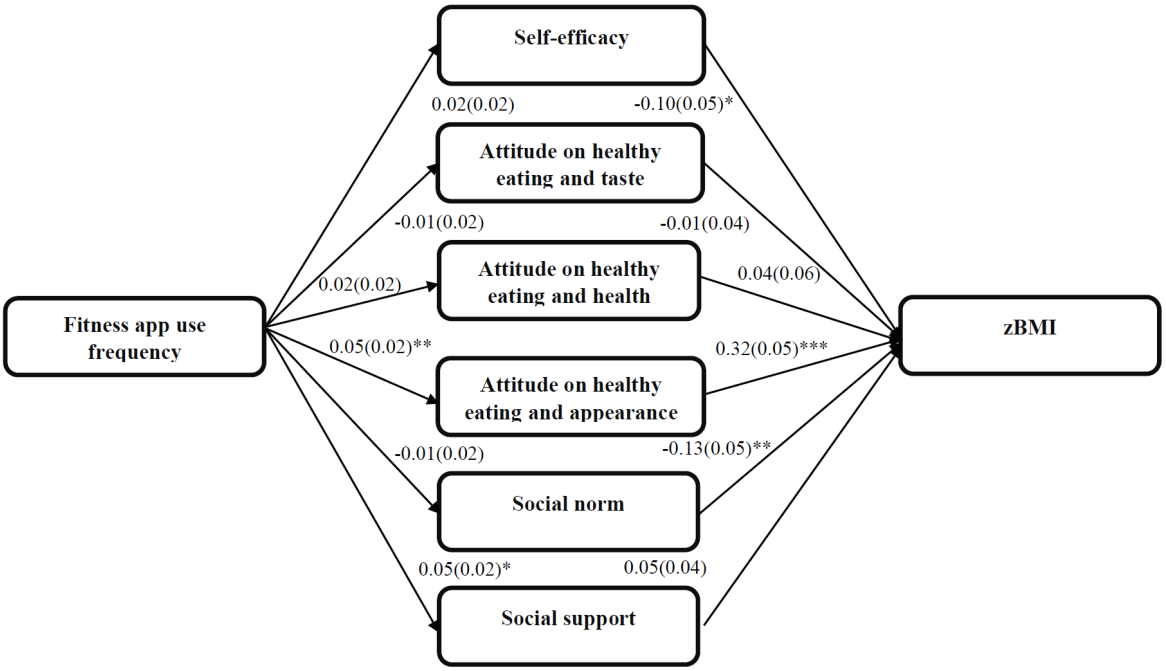
Table 4. Indirect effects multiple mediation with nutrition app use frequency.

Mediator	Indirect effect ($a \times b$)	Bootstrapped SE[a]	z	P	Normal-based 95% CI
zBMI[b]					
Perceived behavioral control to eat healthy	0.00	0.01	0.87	.39	−0.01 to 0.02
Attitude to eat healthy for the good taste of healthy foods	−0.00	0.00	0.05	.69	−0.00 to 0.00
Attitude to eat healthy for overall health	0.00	0.00	0.29	.77	−0.01 to 0.01
Attitude to eat healthy for appearance	0.04	0.01	3.23	.001	0.02 to 0.07
Social norm to eat healthy	0.00	0.00	0.99	.32	−0.00 to 0.01
Social support to eat healthy	0.01	0.01	0.97	.33	−0.01 to 0.02
Total indirect effect	0.06	0.02	3.75	<.001	0.03 to 0.09
Healthy snack ratio					
Perceived behavioral control to eat healthy	−0.26	0.22	−1.17	.24	−0.70 to 0.17
Attitude to eat healthy for the good taste of healthy foods	−0.05	0.12	−0.42	.68	−0.29 to 0.19
Attitude to eat healthy for overall health	0.03	0.10	0.29	.77	−0.16 to 0.22
Attitude to eat healthy for appearance	0.19	0.17	1.12	.26	−0.14 to 0.52
Social norm to eat healthy	−0.01	0.05	−0.18	.85	−0.10 to 0.08
Social support to eat healthy	0.10	0.13	0.73	.46	−0.16 to 0.36
Total indirect effect	−0.01	0.38	0.02	.99	−0.30 to 0.87
Healthy beverage ratio					
Perceived behavioral control to eat healthy	−0.24	0.20	−1.23	.22	−0.63 to 0.15
Attitude to eat healthy for the good taste of healthy foods	0.02	0.08	0.32	.75	−0.14 to 0.19
Attitude to eat healthy for overall health	0.08	0.14	0.56	.58	−0.19 to 0.34
Attitude to eat healthy for appearance	0.20	0.20	1.01	.31	−0.19 to 0.58
Social norm to eat healthy	0.06	0.07	0.91	.37	−0.08 to 0.21
Social support to eat healthy	0.15	0.14	1.12	.26	−0.12 to 0.43
Total indirect effect	0.28	0.35	0.79	.43	−0.41 to 0.96

[a]SE: standard error.

[b]zBMI: body mass index z-scores.

Figure 2. Multiple mediation zBMI. Analyses controlled for sex and education type; * P<.05, ** P <.01, *** P <.001.



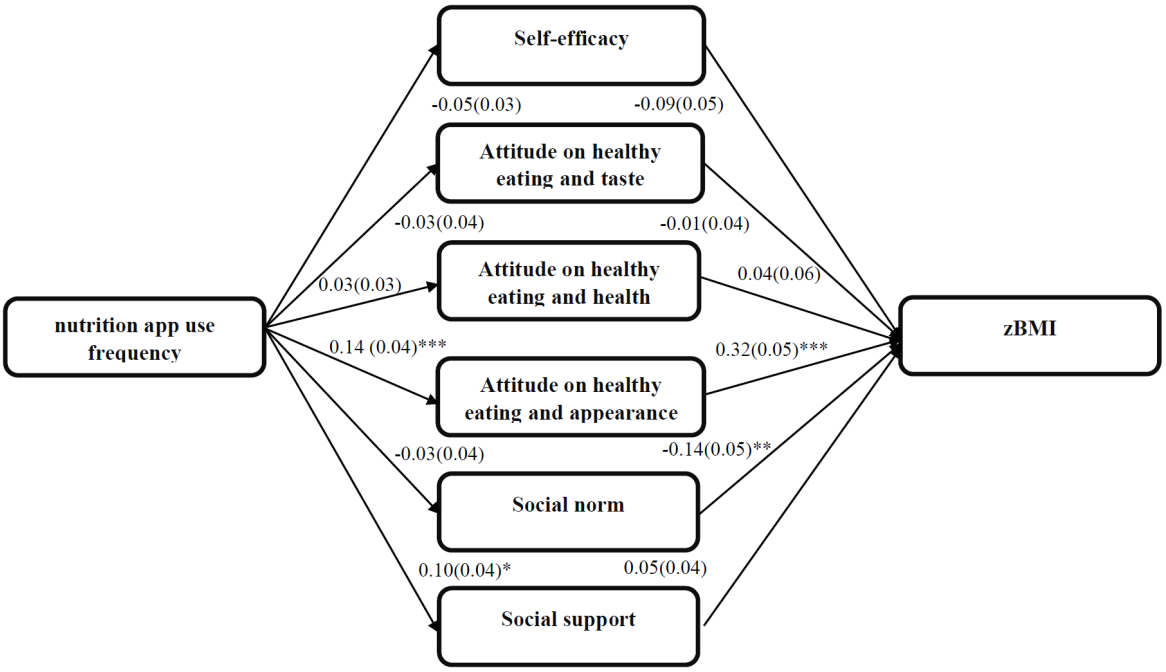
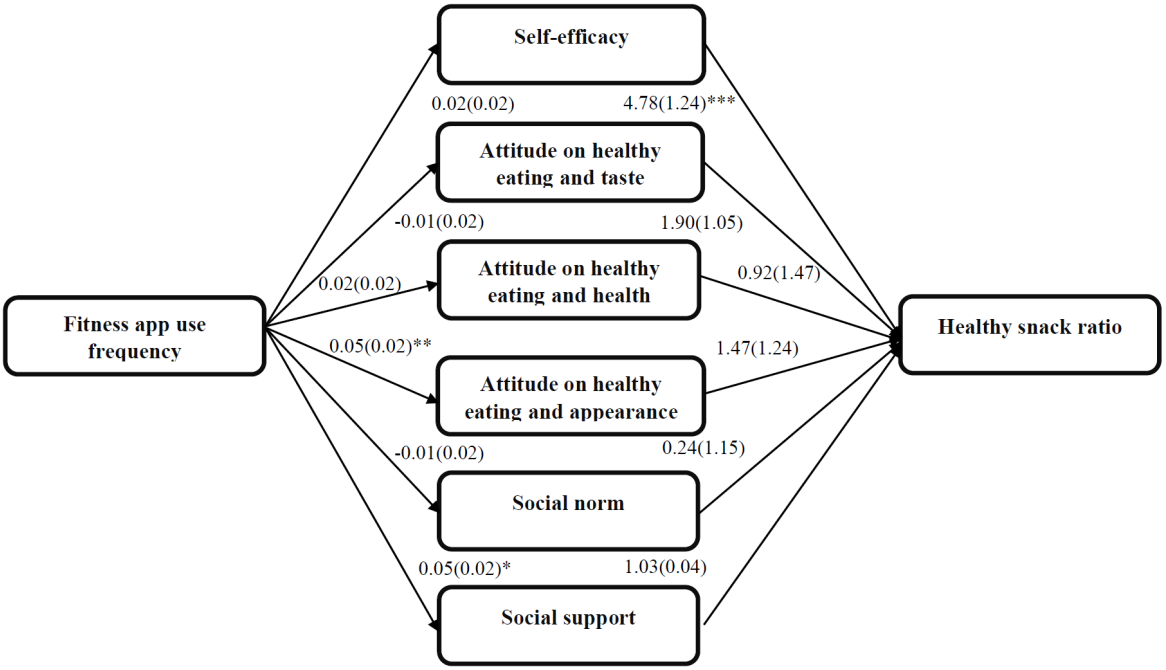


Figure 3. Multiple mediation healthy snack ratio. Analyses controlled for sex and education type; * P <.05, ** P <.01, *** P <.001.



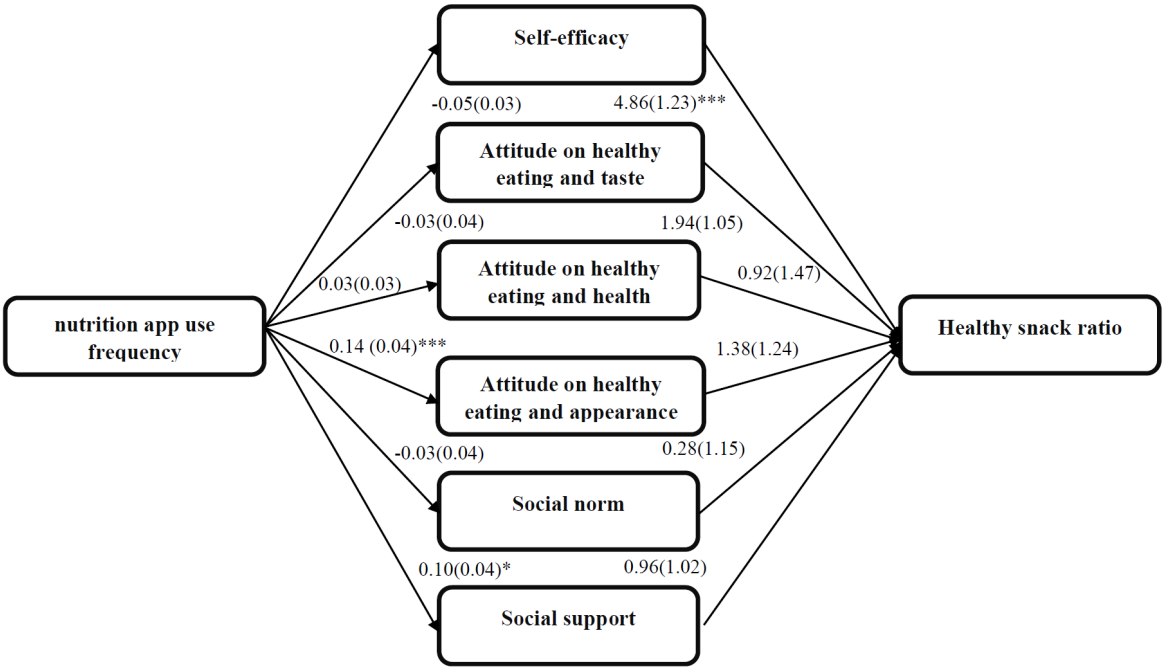
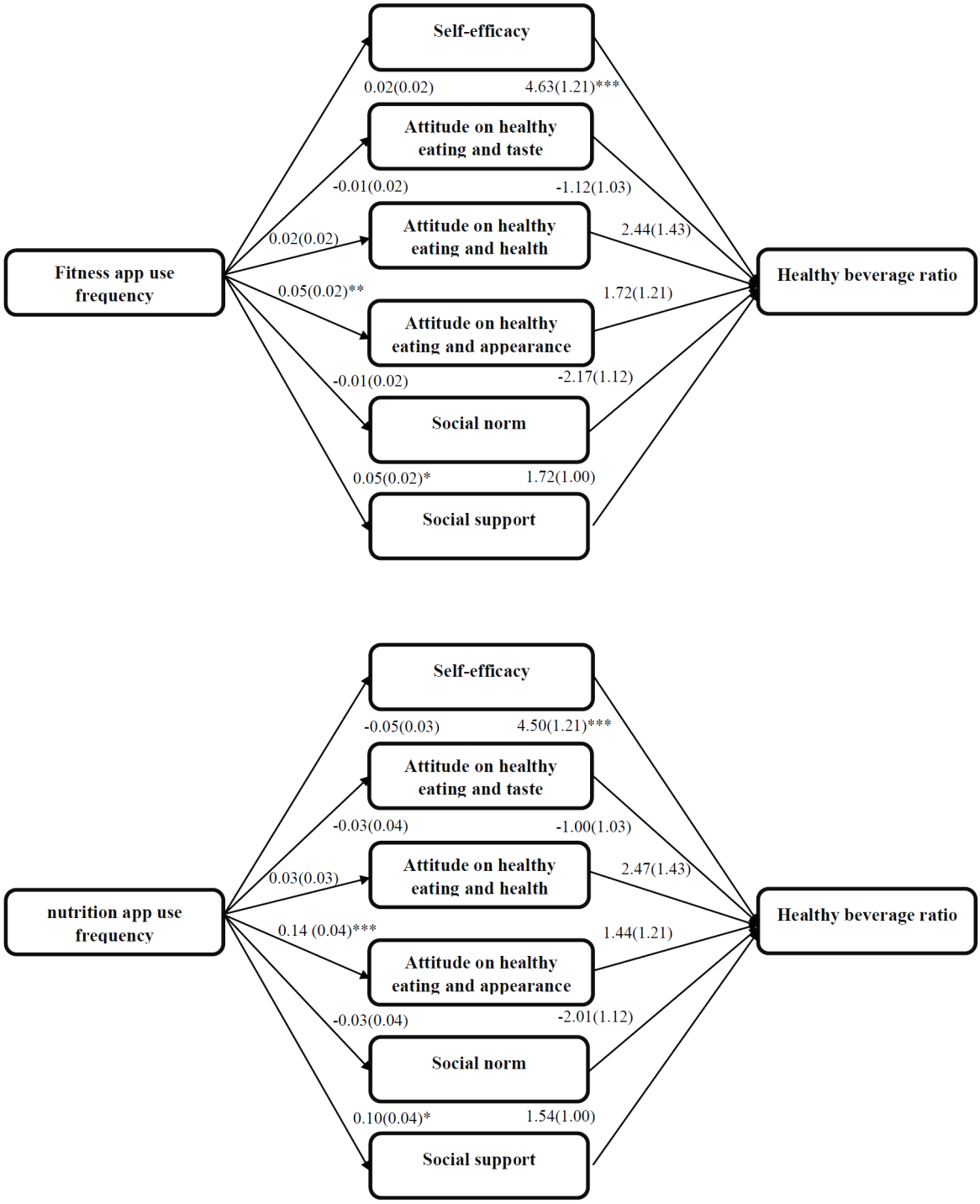


Figure 4. Multiple mediation healthy beverage ratio. Analyses controlled for sex and education type; * P <.05, ** P <.01, *** P <.001.



Discussion

Principal Findings

This study is one of the first to investigate associations, both independent and interactive, between commercial fitness and nutrition app use frequencies and adolescents' snacking and drinking behaviors and BMI. A more frequent use of fitness and nutrition apps was associated with healthier drinking habits and a lower BMI. This study also assessed which determinants mediated the relations between the use of fitness or nutrition apps and BMI, healthy snacking, or healthy drinking habits. Only attitude to eat healthy for appearance was found to be a mediator of the relations between the frequency of use of fitness or nutrition apps and zBMI.

First, a total of 28% of the Flemish adolescents in our sample reported to use fitness or nutrition apps in 2013. The mean frequency of using fitness apps was between a few times per month and every week and less than once a month for nutrition apps. A study conducted in the United States in 2015 found that around 58% of the US adults had downloaded a health app and

that 65% of these also used this app daily [13]. Apart from the country and the timing of the survey, the discrepancy between our results and the 2015 US survey could also be attributed to the surveyed population group. Possibly, adolescents use health apps less frequently when compared with adults. More in-depth research on the motives of adolescents to use health apps will be needed in the future to understand why adolescents might be less inclined to use such app when compared with adults.

Second, a higher use of nutrition apps was independently associated with a higher zBMI. This was unexpected, possibly adolescents using nutrition apps in this study were trying to lose weight. Results confirmed that nutrition app users were indeed more likely to be overweight (36% overweight) in comparison to adolescents who do not use these apps (16% overweight). Using nutrition apps could thus be part of interventions to lose weight. A desire to lose weight was one of the most frequent reasons to download a nutrition app in the United States [13]. Also, the more adolescents used nutrition apps, the more healthy their beverage intake was. No other studies are available to compare these findings with. No significant independent association between fitness apps use frequency and the healthy beverage ratio was found, nor were there significant independent associations observed between fitness or nutrition apps use frequency and the healthy snack ratio. The use of commercial fitness and nutrition apps was thus only weakly associated with healthier snacking and drinking habits in adolescents. This limited influence might be a consequence of their often limited theoretical ground. Our results support the conclusions from reviews and content analyses, which indicated that commercial fitness and nutrition apps tend to lack a thorough theoretical base and therefore might not be effective in promoting good health [14,15,24,29,31].

Third, evidence of an interaction between the frequencies of use of fitness and nutrition apps was found for zBMI and the healthy snack ratio, but not for the healthy beverage ratio. Frequently using both fitness and nutrition apps was associated not only with a lower BMI, but also with a lower healthy snack ratio. The latter finding was unexpected; this could however be a consequence of the perceived higher energy-needs of those adolescents who frequently use fitness apps. These fitness app users might consume more energy-bars that contain large amounts of sugar and/or fat. More research will be needed to further confirm our findings and to explore the existence of such interactive influences for other health behaviors as well. Research on adolescents' motives for using and downloading fitness and/or nutrition apps would also be helpful for a better understanding and explanation of these interactions. Fourth, higher frequencies of fitness and nutrition apps use were associated with a more positive attitude to eat healthy for appearance, which was in turn associated with a higher zBMI. Adolescents with a higher BMI might thus use fitness or nutrition apps to look good or to lose weight. Future research could investigate whether these adolescents show dieting or restrained eating practices and if these practices can (partially) explain the association between nutrition or fitness app use and a higher zBMI. No evidence of mediation was found for the associations between the fitness or nutrition apps use frequency and the healthy snack or beverage ratio. In general, little evidence of mediation was found; current commercially available fitness and nutrition apps seem to influence only a few key determinants of eating behaviors. The apps might hence not incorporate the corresponding behavior change techniques or use these techniques in an effective way. Our findings thereby confirm those from several reviews and content analyses [14,15,24,29,31] that report beneficial influence of commercial fitness and nutrition apps on health is limited by their lack of (effective) behavior change techniques. Apps aimed to change behavior should thus focus more on targeting the key determinants identified in the literature and incorporate the corresponding behavior change techniques in an effective way [12,29].

Strengths and Limitations

The strengths of this study were the use of a representative sample, the objective measurements of height and weight, the use of multilevel regression models and structural equation modeling (SEM) to research the associations and mediations. This study also has some limitations. First, this study considered the use of general fitness and nutrition apps with a 12+ rating. To date, only a few available health apps are specifically developed for adolescents, and adolescents will thus use general health apps. No assessment of the developmental appropriateness of such apps was made. However, such an analysis is warranted given that adolescents have other needs than adults, for example, simpler interfaces and different app features based on differentially identified behavior change techniques compared with adults [12,49,50]. Unfortunately, at present, no coding system and legalities related to age appropriateness of apps for children and adolescents exist within the regulatory framework of the EU [51]. Second, given the cross-sectional nature of this study design, no statements about the causality of the associations found could be made. Experimental research is therefore needed to further examine how nutrition and/or fitness app use influences BMI and eating behaviors or vice versa.. Third, all collected data except the anthropometrics were self-reported and therefore subject to social-desirability bias. Fourth, physical activity and total energy intake were not assessed as this would have increased the participant burden considerably. The survey was already quite lengthy (75 min), which could have increased the chance of poor quality answers at the end of the survey [52]. Three versions of the questionnaire, in which the question were placed in another order, were prepared and administered randomly (except for the demographics, these were always presented first).

Conclusions

A more frequent use of a commercial nutrition app was independently associated with healthier drinking habits in adolescents, but with a higher zBMI. The interactive influence of frequently using both fitness and nutrition apps, on the other hand, was associated with a lower zBMI and less healthy snacking habits. In addition, no evidence of mediation by key determinants was found. Fitness and nutrition apps show some association with healthier eating behaviors in adolescents, but their potential for health promotion could probably be enhanced by incorporating more (effective) behavior change techniques.

Implications and Future Research

The present study was a first attempt to map adolescents' use of commercial health apps and to investigate the relation of using these apps with adolescents' health status in terms of snacking and drinking habits and BMI. Further research is needed to more fully comprehend adolescents' motives for using and downloading such apps. Future research should also continue to explore adolescents' use of commercial nutrition and fitness to determine the possible usefulness of the current fitness and nutrition apps for health promotion among adolescents.

Better understanding of commercial fitness and nutrition app use in adolescents can also guide efforts to develop effective smartphone interventions for healthy lifestyles. In addition to further researching the mechanisms of actions, future studies could also explore what features of commercial apps are deemed effective and liked by adolescents. Evidence from adults [10,13,26,53] in this regard cannot be extended to adolescents, as adolescents have different preferences and need different behavior change techniques than adults [12].

The demand for apps that promote healthy habits is high and these apps are assumed to have a substantial potential for health promotion initiatives. At this point, however, few effective theory-based apps are available on the app market, especially for adolescents. Public health professionals and app developers should collaborate to design more theory-based apps to be used in health promotion and fulfill the needs of the population [29]. Future research should thus focus on developing such apps, by translating and incorporating the already identified effective behavior change techniques into mobile apps and conducting experimental trials to investigate their effectiveness on the behavior of interest and its related determinants [29,31].

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Authors' Contributions

NDC conducted research, conducted the analyses, and wrote the paper. JV conducted research and helped write the paper. WVL conducted research and helped revise the manuscript. LG, LV, CL, KB, SE, SD, LM, JVC, CB, and PK designed research and helped revise the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Associations between zBMI, healthy snack ratio, healthy beverage ratio, and fitness and nutrition app use frequency.

[PDF File (Adobe PDF File), 49KB - mhealth_v5i4e58_app1.pdf]

References

1. De Cock N, Van Lippevelde W, Vervoort L, Vangeel J, Maes L, Eggermont S, et al. Sensitivity to reward is associated with snack and sugar-sweetened beverage consumption in adolescents. Eur J Nutr 2016 Jun;55(4):1623-1632. [doi: 10.1007/s00394-015-0981-3] [Medline: 26163856]
2. Kushner RF, Choi SW. Prevalence of unhealthy lifestyle patterns among overweight and obese adults. Obesity (Silver Spring) 2010 Jun;18(6):1160-1167 [FREE Full text] [doi: 10.1038/oby.2009.376] [Medline: 19875995]
3. Ervin CS, Little RE, Streissguth AP, Beck DE. Alcoholic fathering and its relation to child's intellectual development: a pilot investigation. Alcohol Clin Exp Res 1984;8(4):362-365. [Medline: 6385758]
4. Berkey CS, Rockett HR, Field AE, Gillman MW, Frazier AL, Camargo CA, et al. Activity, dietary intake, and weight changes in a longitudinal study of preadolescent and adolescent boys and girls. Pediatrics 2000 Apr;105(4):E56. [Medline: 10742377]
5. Phillips SM, Bandini LG, Naumova EN, Cyr H, Colclough S, Dietz WH, et al. Energy-dense snack food intake in adolescence: longitudinal relationship to weight and fatness. Obes Res 2004 Mar;12(3):461-472 [FREE Full text] [doi: 10.1038/oby.2004.52] [Medline: 15044663]
6. Nielsen SJ, Popkin BM. Changes in beverage intake between 1977 and 2001. Am J Prev Med 2004 Oct;27(3):205-210. [doi: 10.1016/j.amepre.2004.05.005] [Medline: 15450632]
7. Lasater G, Piernas C, Popkin BM. Beverage patterns and trends among school-aged children in the US, 1989-2008. Nutr J 2011;10:103 [FREE Full text] [doi: 10.1186/1475-2891-10-103] [Medline: 21962086]
8. Davis MM, Gance-Cleveland B, Hassink S, Johnson R, Paradis G, Resnicow K. Recommendations for prevention of childhood obesity. Pediatrics 2007 Dec;120 Suppl 4:S229-S253. [doi: 10.1542/peds.2007-2329E] [Medline: 18055653]

9. Martens MK, van AP, Brug J. Why do adolescents eat what they eat? personal and social environmental predictors of fruit, snack and breakfast consumption among 12-14-year-old Dutch students. Public Health Nutr 2005 Dec;8(8):1258-1265. [Medline: 16372921]
10. Gowin M, Cheney M, Gwin S, Franklin Wann T. Health and fitness app use in college students: a qualitative study. Am J Health Stud 2015 Jul 06;46(4):223-230. [doi: 10.1080/19325037.2015.1044140]
11. Burrows TL, Khambalia AZ, Perry R, Carty D, Hendrie GA, Allman-Farinelli MA, et al. Great 'app-eal' but not there yet: a review of iPhone nutrition applications relevant to child weight management. Nutr Diet 2015 Apr 16;72(4):363-367. [doi: 10.1111/1747-0080.12184]
12. Brannon EE, Cushing CC. A systematic review: is there an app for that? Translational science of pediatric behavior change for physical activity and dietary interventions. J Pediatr Psychol 2015 May;40(4):373-384. [doi: 10.1093/jpepsy/jsu108] [Medline: 25502745]
13. Krebs P, Duncan DT. Health app use among us mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015;3(4):e101 [FREE Full text] [doi: 10.2196/mhealth.4924] [Medline: 26537656]
14. Middelweerd A, Mollee JS, van der Wal CN, Brug J, Te Velde SJ. Apps to promote physical activity among adults: a review and content analysis. Int J Behav Nutr Phys Act 2014;11:97 [FREE Full text] [doi: 10.1186/s12966-014-0097-9] [Medline: 25059981]
15. Azar KM, Lesser LI, Laing BY, Stephens J, Aurora MS, Burke LE, et al. Mobile applications for weight management: theory-based content analysis. Am J Prev Med 2013 Nov;45(5):583-589. [doi: 10.1016/j.amepre.2013.07.005] [Medline: 24139771]
16. AppBrain. Most popular Google Play categories URL: http://www.appbrain.com/stats/android-market-app-categories [accessed 2016-10-05] [WebCite Cache ID 6l1uqCtgZ]
17. Pocketgamer. Categories URL: http://www.pocketgamer.biz/metrics/app-store/categories [accessed 2016-10-05] [WebCite Cache ID 6l1us4yXE]
18. Litman L, Rosen Z, Spierer D, Weinberger-Litman S, Goldschein A, Robinson J. Mobile exercise apps and increased leisure time exercise activity: a moderated mediation analysis of the role of self-efficacy and barriers. J Med Internet Res 2015;17(8):e195 [FREE Full text] [doi: 10.2196/jmir.4142] [Medline: 26276227]
19. Bert F, Giacometti M, Gualano MR, Siliquini R. Smartphones and health promotion: a review of the evidence. J Med Syst 2014 Jan;38(1):9995. [doi: 10.1007/s10916-013-9995-7] [Medline: 24346929]
20. Direito A, Jiang Y, Whittaker R, Maddison R. Apps for improving fitness and increasing physical activity among young people: the AIMFIT pragmatic randomized controlled trial. J Med Internet Res 2015;17(8):e210 [FREE Full text] [doi: 10.2196/jmir.4568] [Medline: 26316499]
21. Kontos E, Blake KD, Chou WS, Prestin A. Predictors of eHealth usage: insights on the digital divide from the health information national trends survey 2012. J Med Internet Res 2014;16(7):e172 [FREE Full text] [doi: 10.2196/jmir.3117] [Medline: 25048379]
22. Apestaartjaren. Onderzoeksrapport apestaartjaren 6 URL: https://www.apestaartjaren.be/onderzoek/apestaartjaren-6 [accessed 2016-10-05] [WebCite Cache ID 6l1vDt16U]
23. Schoffman DE, Turner-McGrievy G, Jones SJ, Wilcox S. Mobile apps for pediatric obesity prevention and treatment, healthy eating, and physical activity promotion: just fun and games? Transl Behav Med 2013 Sep;3(3):320-325 [FREE Full text] [doi: 10.1007/s13142-013-0206-3] [Medline: 24073184]
24. Direito A, Dale LP, Shields E, Dobson R, Whittaker R, Maddison R. Do physical activity and dietary smartphone applications incorporate evidence-based behaviour change techniques? BMC Public Health 2014;14:646 [FREE Full text] [doi: 10.1186/1471-2458-14-646] [Medline: 24965805]
25. Dallinga JM, Mennes M, Alpay L, Bijwaard H, de la Faille-Deutekom MB. App use, physical activity and healthy lifestyle: a cross sectional study. BMC Public Health 2015 Aug;15:833 [FREE Full text] [doi: 10.1186/s12889-015-2165-8] [Medline: 26316060]
26. Wang Q, Egelandsdal B, Amdam GV, Almli VL, Oostindjer M. Diet and physical activity apps: perceived effectiveness by app users. JMIR Mhealth Uhealth 2016;4(2):e33 [FREE Full text] [doi: 10.2196/mhealth.5114] [Medline: 27056639]
27. DiFilippo KN, Huang W, Andrade JE, Chapman-Novakofski KM. The use of mobile apps to improve nutrition outcomes: a systematic literature review. J Telemed Telecare 2015 Jul;21(5):243-253. [doi: 10.1177/1357633X15572203] [Medline: 25680388]
28. Johnston C, Thompson-Felty C. Adherence to daily diet monitoring using one of three commercial diet apps via smart phones was associated with significant weight loss in healthy overweight adults irrespective of the diet app. The FASEB Journal 215;29:597-598 [FREE Full text]
29. Pagoto S, Schneider K, Jojic M, DeBiasse M, Mann D. Evidence-based strategies in weight-loss mobile apps. Am J Prev Med 2013 Nov;45(5):576-582. [doi: 10.1016/j.amepre.2013.04.025] [Medline: 24139770]
30. Wiederhold BK. Behavioral health apps abundant, but evidence-based research nearly nonexistent. Cyberpsychol Behav Soc Netw 2015 Jun;18(6):309-310. [doi: 10.1089/cyber.2015.29001.bkw] [Medline: 26075916]

31. West JH, Hall PC, Hanson CL, Barnes MD, Giraud-Carrier C, Barrett J. There's an app for that: content analysis of paid health and fitness apps. J Med Internet Res 2012 May 14;14(3):e72 [FREE Full text] [doi: 10.2196/jmir.1977] [Medline: 22584372]
32. McClain AD, Chappuis C, Nguyen-Rodriguez ST, Yaroch AL, Spruijt-Metz D. Psychosocial correlates of eating behavior in children and adolescents: a review. Int J Behav Nutr Phys Act 2009;6:54 [FREE Full text] [doi: 10.1186/1479-5868-6-54] [Medline: 19674467]
33. Scaglioni S, Arrizza C, Vecchi F, Tedeschi S. Determinants of children's eating behavior. Am J Clin Nutr 2011 Dec;94(6 Suppl):2006S-2011S [FREE Full text] [doi: 10.3945/ajcn.110.001685] [Medline: 22089441]
34. Pearson N, Ball K, Crawford D. Predictors of changes in adolescents' consumption of fruits, vegetables and energy-dense snacks. Br J Nutr 2011 Mar;105(5):795-803. [doi: 10.1017/S0007114510004290] [Medline: 20969810]
35. Vereecken C, De HS, Maes L, Moreno L, Manios Y, Phillipp K, et al. Reliability and validity of a healthy diet determinants questionnaire for adolescents. Public Health Nutr 2009 Oct;12(10):1830-1838. [doi: 10.1017/S1368980008004655] [Medline: 19195423]
36. Story M, Neumark-Sztainer D, French S. Individual and environmental influences on adolescent eating behaviors. J Am Diet Assoc 2002 Mar;102(3 Suppl):S40-S51. [Medline: 11902388]
37. O'dea JA. Why do kids eat healthful food? perceived benefits of and barriers to healthful eating and physical activity among children and adolescents. J Am Diet Assoc 2003 Apr;103(4):497-501. [doi: 10.1053/jada.2003.50064] [Medline: 12669014]
38. Rewardstudy. URL: http://www.rewardstudy.be/ [accessed 2016-10-05] [WebCite Cache ID 6l1wDxEzu]
39. De Cock N, Van Camp J, Kolsteren P, Lachat C, Huybregts L, Maes L, et al. Development and validation of a quantitative snack and beverage food frequency questionnaire for adolescents. J Hum Nutr Diet 2017;30(2):141-150. [doi: 10.1111/jhn.12411]
40. Malik VS, Schulze MB, Hu FB. Intake of sugar-sweetened beverages and weight gain: a systematic review. Am J Clin Nutr 2006 Aug;84(2):274-288 [FREE Full text] [Medline: 16895873]
41. Rodríguez G, Moreno LA. Is dietary intake able to explain differences in body fatness in children and adolescents? Nutr Metab Cardiovasc Dis 2006 May;16(4):294-301. [doi: 10.1016/j.numecd.2005.08.005] [Medline: 16679222]
42. Departement of public health. 2011. Nutrient Profiling Technical Guidance URL: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216094/dh_123492.pdf [WebCite Cache ID 6hNrjd7x0]
43. Eggermont S. Developmental changes in adolescents' television viewing habits: longitudinal trajectories in a three-wave panel study. J Broadcast Electron 2006 Dec;50(4):742-761. [doi: 10.1207/s15506878jobem5004_10]
44. van Stralen M, te Velde SJ, Singh AS, De Bourdeaudhuij I, Martens MK, van der Sluis M, et al. European energy balance research to prevent excessive weight gain among youth (energy) project: design and methodology of the energy cross-sectional survey. BMC Public Health 2011;11:65 [FREE Full text] [doi: 10.1186/1471-2458-11-65] [Medline: 21281466]
45. Roelants M, Hauspie R, Hoppenbrouwers K. References for growth and pubertal development from birth to 21 years in Flanders, Belgium. Ann Hum Biol 2009;36(6):680-694. [doi: 10.3109/03014460903049074] [Medline: 19919503]
46. Cole TJ, Lobstein T. Extended international (IOTF) body mass index cut-offs for thinness, overweight and obesity. Pediatr Obes 2012 Aug;7(4):284-294. [doi: 10.1111/j.2047-6310.2012.00064.x] [Medline: 22715120]
47. Preacher KJ. Multilevel SEM strategies for evaluating mediation in three-level data. Multivariate Behav Res 2011 Jul 29;46(4):691-731. [doi: 10.1080/00273171.2011.589280] [Medline: 26741527]
48. Preacher KJ, Zyphur MJ, Zhang Z. A general multilevel SEM framework for assessing multilevel mediation. Psychol Methods 2010 Sep;15(3):209-233. [doi: 10.1037/a0020141] [Medline: 20822249]
49. Kenny R, Dooley B, Fitzgerald A. Developing mental health mobile apps: Exploring adolescents' perspectives. Health Informatics J 2016 Jun;22(2):265-275. [doi: 10.1177/1460458214555041] [Medline: 25385165]
50. Schnall R, Okoniewski A, Tiase V, Low A, Rodriguez M, Kaplan S. Using text messaging to assess adolescents' health information needs: an ecological momentary assessment. J Med Internet Res 2013 Mar 06;15(3):e54 [FREE Full text] [doi: 10.2196/jmir.2395] [Medline: 23467200]
51. Europa. mhealth URL: https://ec.europa.eu/digital-single-market/en/mhealth [accessed 2016-10-19] [WebCite Cache ID 6lN4NIWz3]
52. Galesic M, Bosnjak M. Effects of questionnaire length on participation and indicators of response quality in a web survey. Public Opin Q 2009 May 28;73(2):349-360. [doi: 10.1093/poq/nfp031]
53. Serrano KJ, Yu M, Coa KI, Collins LM, Atienza AA. Mining health app data to find more and less successful weight loss subgroups. J Med Internet Res 2016 Jun 14;18(6):e154 [FREE Full text] [doi: 10.2196/jmir.5473] [Medline: 27301853]

Abbreviations

AIC: Akaike information criterion
BMI: body mass index
FFQ: food frequency questionnaire
GSEM: generalized structural equation modeling
MSEM: multilevel structural equation modeling

zBMI: body mass index z-score

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Original Paper

Clickotine, A Personalized Smartphone App for Smoking Cessation: Initial Evaluation

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Abstract

Background: Tobacco smoking is the leading cause of preventable death in the United States, and the annual economic burden attributable to smoking exceeds US $300 billion. Obstacles to smoking cessation include limited access and adherence to effective cessation interventions. Technology can help overcome these obstacles; many smartphone apps have been developed to aid smoking cessation, but few that conform to the US clinical practice guideline (USCPG) have been rigorously tested and reported in the literature. Clickotine is a novel smartphone app for smoking cessation, designed to deliver the essential features of the USCPG and engineered to engage smokers by personalizing intervention components.

Objective: Our objective was to assess the engagement, efficacy, and safety of Clickotine in an initial, single-arm study. Outcomes measured were indicators of engagement with the smartphone app (number of app opens, number of interactions with the Clickotine program, and weeks active with Clickotine), cessation outcomes of 7- and 30-day self-reported abstinence from smoking, and negative health events.

Methods: We recruited US residents between 18 and 65 years of age who owned an iPhone and smoked 5 or more cigarettes daily for the study via online advertising. Respondents were prescreened for eligibility by telephone and, if appropriate, directed to a Web portal to provide informed consent, confirm eligibility, and download the Clickotine app. Participants completed study assessments via the online portal at baseline and after 8 weeks. Data were collected in Amazon S3 with no manual data entry, and access to all data was maximally restrictive, logged, and auditable.

Results: A total of 416 participants downloaded the app and constituted the intention-to-treat (ITT) sample. On average, participants opened the Clickotine app 100.6 times during the 8-week study (median 69), logged 214.4 interactions with the Clickotine program (median 178), and remained engaged with Clickotine for 5.3 weeks (median 5). Among the ITT sample, 45.2% (188/416) reported 7-day abstinence and 26.2% (109/416) reported 30-day abstinence from smoking after 8 weeks. Completer analysis focused on 365 (87.7%) of the 416 enrolled participants who completed the 8-week questionnaire revealed that 51.5% (188/365) of completers reported 7-day abstinence and 29.9% (109/365) reported 30-day abstinence. Few adverse events, mostly consistent with nicotine withdrawal symptoms, were reported and overall no safety signal was detected.

Conclusions: In this initial single-arm trial, Clickotine users appeared to demonstrate encouraging indicators of engagement in terms of the number of app opens, number of program interactions, and continued engagement over time. Clickotine users reported encouraging quit rates while reporting few adverse events. Future research is warranted to assess Clickotine's efficacy in a randomized controlled trial.

Trial Registration: Clinicaltrials.gov NCT02656745; https://clinicaltrials.gov/ct2/show/NCT02656745 (Archived by WebCite at http://www.webcitation.org/6peTT4x60)

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KEYWORDS

smoking cessation; cigarette smoking; tobacco; therapeutics; smartphone

Introduction

The burden of mortality and disease from tobacco use in the United States is extensive. According to the latest report of the Surgeon General regarding the consequences of 50 years of tobacco use in the United States, tobacco smoking is the leading cause of preventable death [1]. Each year the numbers surpass 480,000 deaths; 16 million people live with diseases brought on by smoking; secondhand smoke contributes to the death of more than 41,000 others annually; and approximately 5.6 million children alive today who are younger than 18 years will die prematurely as a result of smoking [2]. It is estimated that 15% of all Americans aged 18 or older smoke tobacco in some form [3], with 9 out of 10 adult cigarette smokers developing a tobacco use disorder before their 18th birthday [4]. Annually, the total economic cost attributable to smoking is now over US $300 billion, with US $170 billion in direct medical costs [5] and US $156 billion in productivity losses [2].

In 2010, approximately 7 out of 10 adult cigarette smokers expressed a desire to quit [6]. However, most quit attempts fail: only 3% to 5% of smokers maintain abstinence up to 1 year after quitting [7]. On the other hand, dissemination and accessibility of proven interventions continue to be limited. For instance, cessation therapies are not always widely accessible and, if they are, they tend to serve only a small population of heavy smokers [7,8]. Furthermore, about 25% of patients looking to stop smoking do not take prescribed medicine as directed [9].

A solution to overcome these obstacles is to develop cessation programs that include effective quit plans with substantial population-level impact and that better ensure long-term adherence. New technologies constitute a promising opportunity to do this at the lowest cost due to high population reach and immediate accessibility [10,11]. A large assessment study in a US cohort found that 76% of smokers own smartphones, meaning smoking cessation apps could be accessible for most smokers and are a worthwhile option to consider [12]. Consequently, in recent years, there has been a proliferation of apps designed to help users quit smoking. In 2013, there were 400 smoking cessation smartphone apps available in the United States, with over 3.2 million downloads in the United States alone [13], but only a small number of these apps [14] appear to follow the US clinical practice guideline (USCPG) on treating tobacco use and dependence [15]. Although the effectiveness of many available smartphone apps for smoking cessation does not appear to have been rigorously tested or reported, efficacy studies of several recently developed apps have been published (for example, apps that deliver Acceptance and Commitment Therapy components [16], or text message-based apps that provide support and interaction [17]). However, a recent review of the content included in smartphone apps for smoking cessation revealed that most of those evaluated did not include behavior change techniques that have been shown to be effective in smoking cessation interventions [18], and most available apps are not customized to users' needs or personal characteristics [19]. Thus, the development of smartphone apps to deliver smoking cessation interventions appears to be warranted, given the demonstrated need for such tools and early evidence that these apps can be efficacious if they are designed to include empirically supported behavior change techniques.

Clickotine is a novel smartphone app, designed and engineered to deliver essential features of the USCPG that are amenable to delivery via an app (advise and encourage to quit; assess willingness to quit and enhance motivation; assist with quit planning and connect with intervention, including advice on pharmacotherapy, connection with counseling and medication treatments, provision of social support, and connection with a quitline; and arrange or provide follow-up) [15]. Through a series of missions and interactions with the app, Clickotine delivers these features, as well as empirically supported smoking cessation intervention components (see App Description section below for a description of the Clickotine program and empirical support). The USCPG also recommends personalizing these features as much as possible to maximize their efficacy. An adaptive proprietary technology platform, Clickometrics, was engineered to enhance engagement by personalizing the smoking cessation intervention components that are delivered. This innovative program is hypothesized to help individuals quit smoking safely and effectively.

In this paper, we report initial results of an 8-week single-arm clinical trial, in which we enrolled 416 participants to assess the engagement and efficacy of Clickotine. Engagement with an app is important to evaluate in preliminary studies, as these interventions will only exert an effect if the users actually use them. High attrition rates are often observed for mobile health apps, potentially limiting their effectiveness [20,21], and discontinuation of smartphone app use is a problem: approximately 26% of app users discontinue after one use, and 74% discontinue by the 10th use [22]. Adherence to smartphone interventions has been shown to predict smoking cessation [23]. It is therefore important to evaluate the engagement with novel smartphone cessation apps in preliminary studies along with efficacy. Indicators of engagement measured in this study were the number of app opens, the number of interactions with the Clickotine program components, and the number of weeks that users remained active with the Clickotine program. In addition to engagement, we also measured preliminary indicators of efficacy, namely 7- and 30-day self-reported point prevalence of abstinence from smoking, after 8 weeks.

Methods

We conducted an 8-week, single-arm clinical trial of Clickotine (Click Therapeutics, Inc, New York, NY, USA). All study procedures were reviewed and approved by Western Institutional

Review Board (IRB) (Puyallup, WA, USA). The trial was registered with clinicaltrials.gov (NCT02656745).

Participants

To be eligible, participants had to be aged 18 to 65 years, smoke at least five cigarettes daily, want to quit smoking in the next 30 days, own an iPhone with iOS 8 or higher capabilities, be willing and able to receive text messages, be able to comprehend the English language, live in the United States, and provide informed consent. The study aimed to include participants who were current daily smokers. We chose the daily cigarette cutoff of 5 to be consistent with other studies of comparable apps (eg, Bricker et al [16]). We also included desire to quit smoking as an inclusion criterion based on other cessation app studies' inclusion criteria (eg, Bricker et al [16]). However, we assumed desire to quit based on participants responding to the digital advertisement, and we asked them about it during the phone screening call although we did not formally measure it.

Recruitment

We recruited potential participants from May to July 2016. Digital advertisements were posted to social media outlets (Facebook, Craigslist, Twitter, Instagram, and Reddit), targeting users who searched for "quit smoking" where possible. Digital advertisements contained IRB-approved copy: "Ready to quit? We're ready to help. If you have an iPhone and want to become smokefree while earning up to $100, we may have a great solution for you." The study director or a study team member under his supervision contacted respondents by telephone to prescreen for eligibility and, if appropriate, directed them to a Web portal for the study. After providing online informed consent and confirming eligibility, participants were sent an email with a secure link to download the app. Providing informed consent and downloading the app constituted enrollment in the study; these respondents constituted the intention-to-treat (ITT) sample for the study.

App Description

Clickotine adheres to the USCPG essential content features for smoking cessation. The USCPG was developed for in-person clinical settings and, as such, not all parts of the guideline will apply for mobile phone apps [14]. In designing the Clickotine program, we followed the parts of the guideline that are appropriate and amenable for inclusion in a digital therapeutic application: advise and encourage to quit; assess willingness to quit and enhance motivation; assist with quit planning and connect with intervention, including counseling and medications, advice on pharmacotherapy, provision of social support, and connection with a quitline; and arrange or provide follow-up. These USCPG features were developed in consideration of empirical support for their efficacy. For advising and encouraging to quit, evidence exists that even brief advice to quit from a counselor or health care provider significantly increases long-term smoking abstinence rates [24]. Support for assessing willingness to quit and enhancing motivation exists, as evidence suggests that a variety of motivational interventions can increase motivation for behavior change, including smoking cessation [25-27]. The effectiveness of encouragement and support as part of smoking cessation treatment (assisting with quit planning and connecting with appropriate interventions) is consistent with the literature regarding the importance of providing a caring, empathic, and understanding context in making health behavior changes [28-30]. Evidence for the effectiveness of arranging and providing follow-up in smoking cessation treatment also exists—the USCPG recommends that assessments within the first week after quitting should be encouraged, as these can minimize relapse in quitters or encourage abstinence in prequitters [31,32].

Clickotine follows these important USCPG guidelines and personalizes these as much as possible via the Clickometrics platform, which is engineered to enhance engagement. Upon downloading the Clickotine app to their iPhone, users are prompted to create a user profile and answer a brief questionnaire on smoking behavior. The users then self-select a quit date between 7 and 21 days after creating their user profile. Based on the chosen quit date, personal characteristics, and smoking characteristics (eg, name, age, sex, location, quit motives, smoking history, and even the desired number of messages per day as indicated by the user), users receive a tailored plan of missions and messages. Within the context of the USCPG features identified above, Clickotine delivers intervention components that have demonstrated efficacy in promoting smoking cessation: controlled breathing [33], personalized messaging [34,35], social engagement [36], encouragement of pharmacotherapy for cessation and of medication adherence [37,38], and digital diversions, including targeted strategies to cope with cravings, withdrawal symptoms, and lapses (such as reviewing positive moments or previous successes in weathering cravings) [39]. Delivery of these components in adherence to the USCPG results in a set of interactions for the user: controlling breathing, using digital diversions, logging cravings, receiving personalized messages, responding to messages, participating with "quit teams," completing missions, logging sentiments and feelings, logging cigarettes smoked, journaling, learning about and using quit aids, and interacting with supporters linked through the app. Table 1 demonstrates the relationship between the USCPG features and the set of interactions experienced by the Clickotine user, and Figure 1 provides representative screenshots of Clickotine interactions. The Clickotine interaction categories do not map 1-to-1 onto the USCPG features, and some interaction categories apply to multiple USCPG features or stages of the Clickotine program. For example, some Clickotine missions are designed to advise and encourage quitting (eg, learn about the health effects of smoking), while others are relevant for assessing willingness and enhancing motivation to quit (eg, exploring the user's quit motives); interacting with supporters is relevant for enhancing motivation to quit in the early stages (eg, connecting with supporters in-app, sharing your desire to quit, and asking for support), as well as being part of cessation intervention in the later stage of the program (eg, updating supporters on progress); and logging cravings or cigarettes smoked can be a mechanism for enhancing motivation to quit and could also be a component of effective intervention. Over the course of a user's quit journey, in-app interactions are emphasized until the quit date, whereas personalized messaging is designed to become the primary engagement modality following the quit date. In general, in this study, we sent a

minimum of 1 personalized message per day to participants as long as they had not deleted the app. If participants responded to a personalized message or completed a mission in response, they were more likely to receive another; thus, participants received different numbers of personalized messages.

Table 1. US clinical practice guideline (USCPG) features and associated Clickotine interaction categories.

Guideline	Clickotine interaction category
Advise and encourage to quit	Complete missions
Assess willingness to quit and enhance motivation	Complete missions
	Log sentiments and feelings
	Participate with "quit teams"
	Interact with supporters
	Log cravings
	Log smokes
Assist with quit planning and connect with intervention	Complete missions
	Control breathing
	Use digital diversions
	Participate with "quit teams"
	Interact with supporters
	Write in a journal
	Learn about and use quit aid
	Receive personalized messages
	Respond to messages
	Log cravings
	Log smokes
Arrange or provide follow-up	Receive personalized messages
	Respond to messages
	Log cravings
	Log smokes
	Log sentiments and feelings

Data Collection

We collected baseline demographic and smoking characteristic data via an online survey for participants who met the eligibility criteria and gave informed consent. We also collected data on smoking behavior, as well as engagement metrics including the number of app opens and interactions with the Clickotine program components in-app after downloading. We administered a Web-based outcome survey 8 weeks after enrollment and, in return for completing the 8-week survey, provided participants with a US $25 Amazon gift certificate. Participants were notified to take the online survey via text message with a link to the survey on day 53 (3 days before reaching 8 weeks after initial consent). Each day thereafter until participants completed the survey, up to 7 days after the target date, they were contacted via text message, email, or phone call. A sample text message is: "Good Morning [name]! Your 8-week survey is ready! Fill it out online to get your first Amazon gift card: http://xxxx." These in-app and online survey data were collected in Amazon Simple Storage Service (Amazon S3; Amazon Web Services, Seattle, WA, USA) with no manual data entry, and access to all data was maximally restrictive, logged, and auditable.

A priori, the study data management plan defined 3 categories of study team members: (1) participant-facing (having some interaction with participants; eg, recruitment or in-app), (2) data team (maintaining the study database), and (3) study leadership (not interacting directly with participants, and not having access to the study database; only conducting analyses on relevant variables provided by the data team after the database lock). This means that access to data was restricted only to the minimum set of actors in the minimal set of use cases needed to complete the study. As per the approved study protocol, no one outside of the designated data team had access to the data and even the data team could not modify it. This procedure follows the principle of least privilege [40]. This was just one of the steps taken to ensure maximal objectivity and transparency in this study conducted by the sponsor. Moreover, the process that wrote the data from users to the database was restricted to write only those files that were relevant to it and had no ability to read data. All app and survey data were stored in an isolated network. All survey data were collected via preprogrammed, automated processes, and all collected data were immediately made immutable and could not be changed by the sponsor. These procedures were approved by an independent IRB and were designed and implemented to minimize potential biases unconsciously introduced by the sponsor, which might have influenced the study data.

Figure 1. Examples of interactions with the Clickotine program (left to right, beginning at top): choose a quit date; log cravings; mission: share quit date with supporters; learn about quit aids; control breathing; receive a personalized message.

Measurements

Baseline Characteristics

We ascertained baseline demographic characteristics (age, sex, race/ethnicity) and smoking characteristics (years smoking, number of cigarettes smoked per day) via questions in the online survey. Baseline nicotine dependence level was measured using the Fagerstr m Test for Nicotine Dependence [41], administered in the online survey upon study enrollment.

Engagement

We measured engagement with the smartphone app in three ways: the number of app opens; the number of interactions with program components beyond app opens (see App Description above); and the number of weeks in which the user remained actively engaged with Clickotine (defined as having at least one interaction with the program in the week, other than passive receipt of a message). App opens is a standard and important metric for measuring engagement with a digital therapeutic, for smoking cessation [42] or other indications. App opens could

be tallied over the course of the entire 8-week study. Clickotine interactions could also be tallied over the entire course of the study, across the categories in total and by category (controlling breathing, using digital diversions, logging cravings, receiving personalized messages, responding to messages, participating with "quit teams," completing missions, logging sentiments and feelings, logging cigarettes smoked, journaling, learning about and using quit aids, and interacting with supporters linked through the app). It was not possible to confirm that a user read a personalized message, so the count for "receiving personalized messages" is the number of personalized messages the user was sent.

Smoking Cessation

To detect a signal for smoking cessation in this short-term trial, the 8-week questionnaire assessed self-reported 7-day and 30-day point prevalence abstinence [43-45]. Self-reported smoking is a standard method for assessing the efficacy of low-intensity interventions [46,47], which we used in this study. Users answered the following question for 7- and 30-day time frames: "Have you smoked (even a puff) in the last [7 or 30] days?"

Medical Monitoring

Negative health events were ascertained via spontaneous report by users in-app and via proactive ascertainment by a focused question in the week-8 questionnaire: "At any point during the study did you experience a negative health event?" All negative health events reported were sent to the medical monitor for evaluation. The medical monitor assessed each event and, when needed in order to comprehensively assess and document reported events, requested additional information from study team members in contact with the participant. All events judged to be clinically significant by the medical monitor were considered to be adverse events. The medical monitor also determined relatedness to Clickotine (possibly related, not related) based on all available information and clinical judgment. The intervention confers minimal risk and, other than referral when appropriate, we delivered no medical intervention.

Data Analysis

We calculated descriptive statistics to estimate engagement with the app and smoking cessation rates. Engagement was quantified in three ways: the number of app opens during the 8-week study, the number of Clickotine program interactions experienced by the user (in total, and for each interaction category), and the number of weeks the user remained actively engaged with Clickotine. We estimated population-level engagement as the mean (SD) values across participants or median (interquartile range) values for instances of nonnormally distributed variables. Smoking abstinence rates were calculated as the proportion of the ITT sample that self-reported not smoking, not even a puff, for at least 7 days and at least 30 days at the 8-week study end point. In this ITT analysis, nonresponders to the 8-week survey were imputed as smokers. This method has been shown to yield potentially biased results, by potentially inflating the proportion of smokers compared with a completer analysis [48]. Despite the potential for bias in smoking cessation trials, this method for ITT analysis is expected for traditional clinical trials and was conducted in this study. However, we also conducted completer analyses on the sample that completed the 8-week outcome survey for comparison with the ITT results.

We conducted post hoc analyses using logistic regression, due to the nonnormal distributions of most of the predictor variables and the dichotomous outcome variables, to explore associations between baseline characteristics and engagement indicators, between baseline characteristics and cessation outcomes, and between engagement indicators and cessation outcomes in this sample. As these were exploratory, hypothesis-generating analyses, we evaluated each independent variable (baseline sex, age, race/ethnicity, nicotine dependence level, years smoked, cigarettes per day, and number of previous quit attempts) as a predictor in a separate model, with app opens, Clickotine interactions, and number of weeks active dichotomized into high/low groups according to median split. We corrected critical *P* values for multiple comparisons familywise (eg, .05/7=.007 for the analyses of 7 baseline predictors of each engagement indicator). Similar models were run with 7-day and 30-day cessation as the binary outcome to explore associations between baseline characteristics and outcomes, with the same *P* value correction (.05/7). Logistic regression analyses were also conducted with app opens, Clickotine interaction counts, and active week counts in separate models as engagement predictors of cessation outcomes, with *P* values corrected for 3 comparisons for each outcome (.05/3=.02). Visual inspection and analyses were conducted using IBM SPSS Statistics for Mac version 24.0 software (IBM Corporation).

Results

Recruitment and Study Enrollment

After 63 days of social media advertising and recruitment, we received 2050 contacts and conducted 617 telephone prescreens of potentially eligible participants. Many of the 2050 respondents did not schedule or respond to the prescreening call. Screening calls were conducted with participants until approximately 600 were completed, which was the target to yield a targeted ITT sample of >400. This resulted in 452 participants invited to provide online informed consent and who were emailed a secure link to download the app. Of these, 416 participants ultimately downloaded the app and constituted the ITT population. Of the 416 participants in the ITT sample, 365 completed the 8-week outcome questionnaire, yielding an 87.7% retention rate. Figure 2 depicts the study flow diagram for this trial.

Figure 2. Study flow diagram. ITT: intention-to-treat.

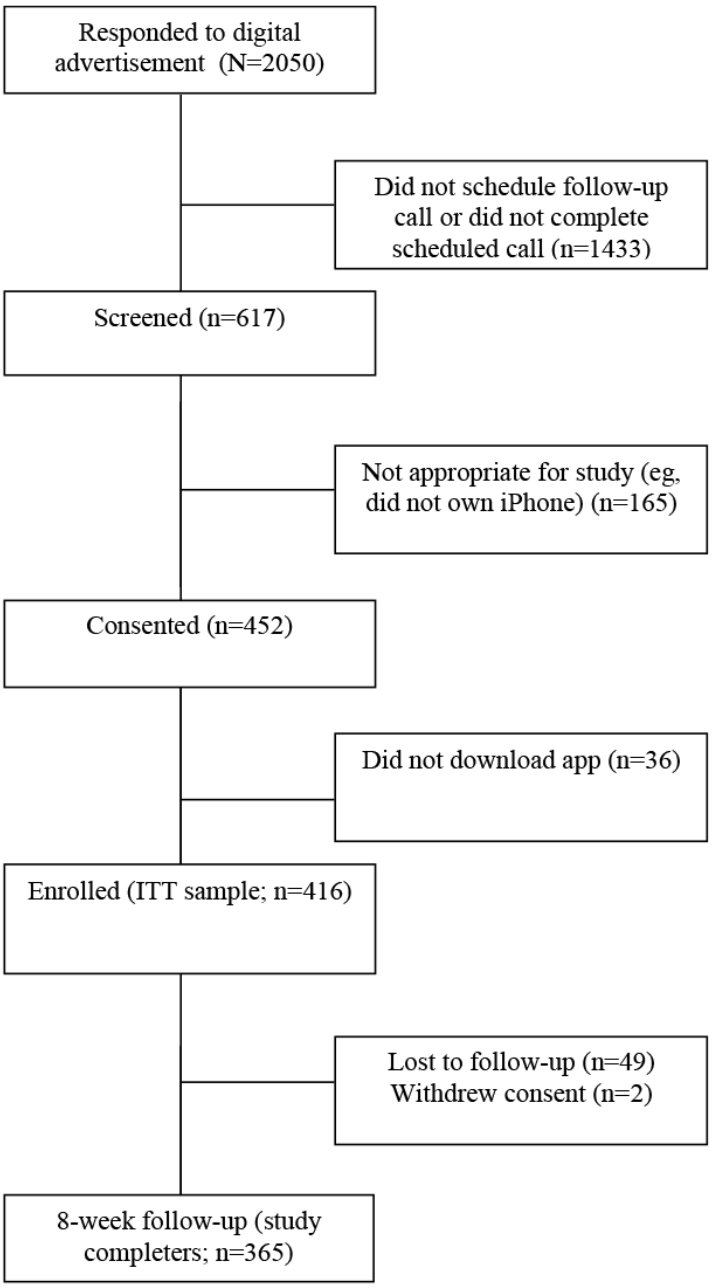

Table 2 provides the demographic and smoking characteristics of the study sample. At baseline, this sample reported a high degree of nicotine dependence: the mean score on the Fagerstr m Test for Nicotine Dependence was 6.1 (SD 2.2), which falls in the high range for nicotine dependence (scores between 6 and 7) [49]. On average, participants had been smoking for 18.1 (SD 10.6) years, and were smoking 16.7 (SD 7.8) cigarettes per day. At baseline, 29 participants (7.0% of the ITT sample) were using a pharmacotherapy smoking cessation aid (nicotine replacement therapy or medication). At study outcome, 66 participants (15.9% of the ITT sample) were using a pharmacotherapy smoking cessation aid (nicotine replacement therapy or medication).

Engagement Indicators

The distributions were significantly nonnormal for app opens (W_{416}=.773, P<.001), Clickotine program interactions (W_{416}=.809, P<.001), and the number of active weeks with Clickotine (W_{416}=.892, P<.001) according to Shapiro-Wilk tests of departure from normality. Table 3 provides the measures of central tendency of these data: mean (SD), range, median, and interquartile range. Table 4 describes the frequency with which users encountered each interaction category, as well as the proportion of program interactions each category represented.

Table 2. Demographic and smoking characteristics of the study sample.

Characteristics	Mean (SD) or n (%)
Demographics	
Age in years, mean (SD)	36 (10.8)
Female, n (%)	247 (59.4)
Race/ethnicity, n (%)	
White	315 (75.7)
Hispanic	37 (8.9)
African American	22 (5.3)
Asian or Pacific Islander	11 (2.6)
Native American	5 (1.2)
Other/no response	26 (6.3)
Smoking characteristics	
Fagerstr m score, mean (SD)	6.1 (2.2)
No. years smoking, mean (SD)	18.1 (10.6)
No. cigarettes per day, mean (SD)	16.7 (7.8)
No. of previous quit attempts in past year, n (%)	
0	88 (21.2)
1	119 (28.6)
>1	166 (39.9)
Did not respond	43 (10.3)

Table 3. Engagement indicators over the 8-week study period.

Indicator	Mean (SD)	Median	Range	Interquartile range
App opens	100.6 (98.2)	69.0	3-780	36.0-134.75
Clickotine program interactions	214.4 (158.4)	178.0	20-1213	110.25-273.0
Weeks active with Clickotine	5.3 (2.4)	5.0	0-8	3.0-8.0

Table 4. Clickotine interactions by category over the 8-week study period.

Interaction category	Mean (SD)	% of total interactions	Median	Range	Interquartile range
Receiving personalized messages	84.06 (44.87)	39.2	79.0	1-372	59-94.75
Logging cigarettes smoked	53.61 (73.78)	25.0	33.0	0-964	12-73
Completing missions	27.83 (22.48)	13.0	23.5	0-114	9-39
Logging cravings	15.09 (26.89)	7.0	5.0	0-224	2-15
Responding to messages	10.16 (24.12)	4.7	3.0	0-337	1-11
Controlling breathing	6.94 (10.49)	3.2	4.0	0-105	2-8
Journaling	4.42 (7.78)	2.1	2.0	0-87	0-5
Participating with quit teams	3.52 (15.21)	1.6	0.0	0-171	0-0
Logging sentiments and feelings	2.66 (6.69)	1.2	0.0	0-76	0-2
Using digital diversions	2.54 (11.90)	1.2	0.0	0-211	0-1
Learning about and using quit aid	1.82 (10.16)	0.9	0.0	0-165	0-1
Interacting with supporters	1.74 (4.04)	0.8	0.0	0-53	0-2
Total	214.4 (158.4)				

Cessation Outcomes

Table 5 summarizes the results of the ITT and completer analyses of cessation outcomes. In the ITT sample (n=416), at the end of the 8-week study period, 45.2% (n=188) of participants reported achieving 7-day abstinence and 26.2% (n=109) of participants achieved 30-day abstinence. Among the 365 study completers, 51.5% (n=188) of participants reported achieving 7-day abstinence and 29.9% (n=109) of participants achieved 30-day abstinence. In this study, participants did not appear to reliably provide the in-app weekly smoking data. Only 47 of the 416 participants (11.3%) provided complete data in the weekly cigarette counts; across all users, only 822 of the 3328 (24.7%) weekly cigarette counts were completed. Thus, we derived smoking status from self-report in the baseline and outcome surveys, and we did not use the in-app smoking data in the analyses of cessation outcomes.

Safety Outcomes

Participants reported 4 negative health events spontaneously, and reported an additional 32 in response to the focused safety question in the 8-week questionnaire. Of these 36 negative health events, 19 were considered clinically significant and documented as adverse events. Of the 19 adverse events, 2 were considered possibly related to Clickotine use in the judgment of the medical monitor (nightmare, depressed mood). The most common adverse events were fatigue (reported by 3 participants) and mood change (reported by 2 participants); no additional adverse events occurred in more than 1 participant.

Associations Between Baseline Characteristics, Engagement Indicators, and Cessation Outcomes

Table 6 provides the results of the logistic regression analyses of baseline characteristics predicting engagement indicators. The only association surviving correction for multiple comparisons was female sex predicting an increased likelihood of being in the high app opens group.

Table 7 provides the results of the logistic regression analyses of baseline characteristics predicting cessation outcomes. Older age and greater number of years smoking appeared to predict a decreased likelihood of reporting 7-day abstinence and 30-day abstinence. Greater number of cigarettes smoked per day predicted a decreased likelihood of reporting 30-day abstinence.

Table 8 provides the results of the logistic regression analyses of engagement indicators predicting cessation outcomes. Greater number of weeks active with Clickotine was associated with an increased likelihood of reporting 7-day and 30-day abstinence.

Table 5. Intention-to-treat (ITT) and completer analysis results for smoking cessation.

Duration of abstinence	ITT analysis (n=416), n (%)	Completer analysis (n=365), n (%)
7 days	188 (45.2)	188 (51.5)
30 days	109 (26.2)	109 (29.9)

Table 6. Logistic regression analyses of baseline predictors of engagement indicators.

Engagement indicators	Age	Sex	Race/ethnicity	Fagerstr m score	Years smoking	Cigarettes per day	Prior quit attempts
Clickotine app opens (high/low according to median split)							
OR[a]	1.018	0.563	1.044	1.071	1.019	1.025	0.990
95% CI	1.00-1.04	0.38-0.84	0.95-1.15	0.98-1.17	1.00-1.04	0.999-1.05	0.90-1.00
P value	.048	.005[b]	.36	.12	.047	.06	.7
Clickotine program interactions (high/low according to median split)							
OR	1.018	0.668	0.990	1.070	1.023	1.026	0.981
95% CI	1.00-1.04	0.45-0.99	0.90-1.09	0.98-1.17	1.00-1.04	1.00-1.05	0.89-1.01
P value	.045	.04	.83	.13	.02	.047	.76
No. weeks active (>0 interactions/week)							
OR	0.997	0.690	1.096	0.932	1.001	0.969	1.004
95% CI	0.98-1.01	0.47-1.02	1.00-1.21	0.86-1.02	0.98-1.02	0.94-1.00	1.00-1.01
P value	.75	.07	.06	.11	.92	.02	.24

[a]OR: odds ratio.

[b]*P*<corrected α (.05/7=.007).

Table 7. Logistic regression analyses of baseline predictors of smoking cessation outcomes.

Cessation outcomes	Age	Sex	Race/ ethnicity	Fagerstr m score	Years smoking	Cigarettes per day	Prior quit attempts
7-day cessation							
OR[a]	0.969	1.415	1.094	0.948	0.965	0.976	0.987
95% CI	0.95-0.99	0.95-2.10	1.00-1.20	0.87-1.03	0.95-0.98	0.95-1.00	0.91-1.10
P value	.001[b]	.08	.06	.23	<.001[b]	.06	.74
30-day cessation							
OR	0.964	1.092	1.020	0.945	0.954	0.954	1.034
95% CI	0.95-0.98	0.70-1.70	0.92-1.13	0.86-1.04	0.93-0.98	0.92-0.99	0.94-1.14
P value	.001[b]	.7	.70	.25	<.001[b]	.005[b]	.37

[a]OR: odds ratio.

[b]*P*<corrected α (.05/7=.007).

Table 8. Logistic regression analyses of engagement indicators predicting smoking cessation outcomes.

Cessation outcomes	App opens	Interaction count	Active weeks
7-day cessation			
OR[a]	1.001	1.001	1.218
95% CI	0.999-1.003	0.999-1.002	1.12-1.33
P value	.27	.25	<.001[b]
30-day cessation			
OR	1.001	1.001	1.283
95% CI	0.998-1.003	0.999-1.002	1.16-1.42
P value	.57	.31	<.001[b]

[a]OR: odds ratio.

[b]*P*<corrected α (05/3=.017).

Discussion

In this initial digital study of Clickotine conducted with no in-person visits, we assessed preliminary indicators of the engagement with and efficacy of Clickotine. We measured engagement using three indicators: number of app opens (median 69), number of Clickotine program interactions experienced by the user (median 178), and the duration of active Clickotine use (number of weeks active; median 5). These engagement indicators suggest that participants were actively using Clickotine during the 8-week study period. Clickotine also appeared to be effective for smoking cessation: 26.2% of participants reported achieving 30-day abstinence after 8 weeks. The most commonly reported adverse events, fatigue and mood change, are expected nicotine withdrawal symptoms [50]. Overall, we detected no safety signal in this study, and we expect no adverse reactions with Clickotine use.

The user experience with Clickotine can be described based on the frequency of the various program interactions a user encountered. In this study, the most frequently encountered feature was receiving personalized messages, which accounted for 39.2% of Clickotine interactions on average. Logging cigarettes smoked was the second most frequent category, accounting for 25% of interactions. Completing missions was the third most frequently encountered category, which accounted for 13% of interactions. For 5 of 12 interaction categories, the median frequency was 0, indicating that roughly half of participants did not encounter this type of interaction during their use of Clickotine. This variability in the interaction categories that participants encountered reinforces the personalized and unique journey on which Clickotine takes each individual user.

We conducted post hoc analyses to explore associations between baseline characteristics, engagement indicators, and cessation outcomes, as some associations have been suggested by previous studies. For example, older age and female sex have been associated with increased engagement with Web-based cessation interventions [51] but have not been found to be associated with use of a smartphone-based smoking cessation app [52]. Heavier smoking has been observed to be associated with use of Web-based interventions and smartphone apps [52,53]. Engagement with smartphone cessation apps, also referred to as adherence, has been shown to predict cessation outcomes [23]. Due to the exploratory, post hoc nature of the logistic regression analyses we conducted in this study, we have interpreted the results with caution to identify associations of

interest for future study without drawing much of a conclusion about these associations in the context of this study. In these analyses, female sex appeared to be associated with increased in-app opens. Older age, greater number of years smoking, and greater number of cigarettes smoked per day appeared to be associated with a decreased likelihood of smoking cessation. Results suggested a possible association between an increase in the number of weeks active with Clickotine and an increased likelihood of smoking cessation. Not enough research has been published on predictors of smartphone app use to make comparisons with our study results but, in comparison with one recent study [52], some of our results are contradictory: female sex appeared to be associated with increased app opens, whereas in the previous study female sex was associated with lower use of certain app features. However, our study also appeared to show a trend toward heavier smoking being associated with increased app use, which would be consistent with the previous study [52]. Nonetheless, these associations will be investigated further in the next randomized controlled trials of Clickotine that are conducted, in which statistical and clinical inference will be possible.

This study was efficiently designed and conducted. No in-person visits occurred, and all but one study interaction (the prescreening phone call) was conducted electronically or in-app. This study design enabled the study sponsor to handle a large number of responders to the digital advertising (2050 responses) and enroll the target sample size (400) in a relatively short time (63 days). The study retention rates were encouraging: 365 of the 416 participants completed the 8-week outcome questionnaire, yielding an 87.7% retention rate in this trial. This rate was higher than the retention rates observed in other cessation trials. In one review of 28 Web-based studies, only 8 demonstrated retention rates greater than 80%, 8 demonstrated 50% to 80%, and 12 demonstrated retention rates lower than 50% [54]. In another review of 11 studies [55], the average attrition rate at last follow-up was 38.2%. Comparisons with these studies must be made with caution, however, as these were Web based, whereas our study was smartphone based; the follow-up periods were variable across studies, and some were longer than the 8-week period of our study; and we compensated participants for their time in our study, whereas participants did not receive compensation in some of the other studies. These factors could yield an inflated retention rate in our sample compared with other studies. In comparison, a recent smartphone-based app study, which included similar compensation for participation and was also a single-arm study, reported a retention rate of 84.8% [42]; another similar study comparing 2 different apps reported a retention rate of 82.8% [16]. These rates are similar to the rate of 87.7% observed in our study and bolster confidence in this value as representative of a digital trial of a smartphone-based smoking cessation app.

We studied Clickotine in isolation in this trial and did not directly compare it with other app-based interventions. Although there are factors that limit the ability to compare across unrelated trials, such as differences in sample characteristics and trial methodologies, descriptive rates of engagement and smoking cessation can provide preliminary indications of comparability. In this study, the outcomes observed for Clickotine numerically exceed those of the most comparable mobile apps that have been clinically tested, such as SmartQuit 2.0 (16.6 app opens in an 8-week study and 11% 30-day abstinence in a completer analysis) [42] and the National Cancer Institute's QuitGuide (15.2 app opens in an 8-week study and 8% 30-day abstinence in ITT analysis) [16]. We propose that components unique to Clickotine may contribute to enhanced engagement and efficacy, including Clickotine's highly personalized features.

Certain limitations of this study warrant further discussion. First, the follow-up period was relatively short; substantial relapse naturally occurs after a 2-month follow-up [56] and only about 3% to 5% of smokers maintain abstinence up to 1 year after quitting [7]. We will continue to observe participants in this study and will report longer-term outcomes separately when available. Nonetheless, this study was consistent with previous smoking cessation studies in reporting 30-day point prevalence abstinence rates. Second, we tested only the iPhone version of the app in this study, as the Android version was not yet fully developed by the time of study launch. Also, the average age of participants in this study (36 years) is younger than is typical for smoking cessation trials. Inclusion of younger, iPhone-only users may limit the generalizability of findings. For example, one cessation app study noted that iOS users demonstrated indicators of greater motivation to quit compared with Android users [57]. Third, this trial relied on self-reported smoking cessation to estimate 30-day point prevalence abstinence. While expert consensus suggests that biochemical verification of abstinence is impractical and unnecessary in studies similar to this one [58], future research will need to address this by implementing biochemical verification of smoking cessation (eg, exhaled carbon monoxide). Fourth, in a study of an intervention conducted by the developer of the intervention, the potential for biases (eg, rater biases, response biases) are noted. Despite efforts to eliminate the opportunity for such biases through the design and implementation of rigorous study procedures, the potential for bias will limit the extent to which our results can be interpreted beyond being preliminary indicators. Fifth, some users (29 at baseline and 66 by study outcome) were using a pharmacotherapy cessation aid during the trial, which could have contributed to the cessation rates observed and limits the ability to attribute cessation solely to Clickotine. To overcome such limitations, a pivotal study of Clickotine should evaluate efficacy and test superiority in a blinded, randomized controlled trial conducted by an independent party; include iPhone and Android versions of the app; include an active comparator arm with an alternative mobile app; feature longer-term follow-up; and ascertain abstinence via biochemical verification.

In summary, the results of this initial evaluation suggest that Clickotine participants engaged with the app and appeared to remain engaged with the app for a majority of the study duration on average, and that Clickotine use may be associated with cessation outcomes. Future research is warranted to evaluate the engagement with and efficacy of Clickotine in more robust clinical trials, and to assess Clickotine's long-term efficacy and safety.

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Conflicts of Interest

All authors have equity interest in or are employed by Click Therapeutics, Inc., which sponsored the trial and the writing of this manuscript, with the exception of SXL. SXL was compensated for medical monitoring services. JRS has equity interest in and is employed by Teva Pharmaceuticals. Click Therapeutics will make the data from this trial available to qualified researchers upon request for independent analysis.

References

1. Centers for Disease Control and Prevention. Smoking & tobacco use fast facts. 2016. URL: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/ [accessed 2017-02-27] [WebCite Cache ID 6ob55B8NG]
2. U.S. Department of Health and Human Services. The health consequences of smoking-50 years of progress: a report of the Surgeon General. 2014. URL: https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm [accessed 2016-12-22] [WebCite Cache ID 6mx6zSRhq]
3. Jamal A, King BA, Neff LJ, Whitmill J, Babb SD, Graffunder CM. Current Cigarette Smoking Among Adults - United States, 2005-2015. MMWR Morb Mortal Wkly Rep 2016 Nov 11;65(44):1205-1211 [FREE Full text] [doi: 10.15585/mmwr.mm6544a2] [Medline: 27832052]
4. U.S. Department of Health and Human Services. Preventing tobacco use among youth and young adults. 2012. URL: https://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/ [accessed 2016-12-22] [WebCite Cache ID 6mx7iGtXx]
5. Xu X, Bishop EE, Kennedy SM, Simpson SA, Pechacek TF. Annual healthcare spending attributable to cigarette smoking: an update. Am J Prev Med 2015 Mar;48(3):326-333 [FREE Full text] [doi: 10.1016/j.amepre.2014.10.012] [Medline: 25498551]
6. Centers for Disease Control and Prevention. Tips From Former Smokers. 2011. Burden of tobacco use in the US URL: http://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html [accessed 2016-12-22] [WebCite Cache ID 6mxAbOriW]
7. Hughes JR, Keely J, Naud S. Shape of the relapse curve and long-term abstinence among untreated smokers. Addiction 2004 Jan;99(1):29-38 [FREE Full text] [Medline: 14678060]
8. Fiore MC, Novotny TE, Pierce JP, Giovino GA, Hatziandreu EJ, Newcomb PA, et al. Methods used to quit smoking in the United States. Do cessation programs help? JAMA 1990;263(20):2760-2765. [Medline: 2271019]
9. DiMatteo MR. Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research. Med Care 2004 Mar;42(3):200-209. [Medline: 15076819]
10. Dediu H. When will the US reach smartphone saturation?. 2013. URL: http://www.asymco.com/2013/10/07/when-will-the-us-reach-smartphone-saturation/ [accessed 2016-12-22] [WebCite Cache ID 6mxB9CAXR]
11. Statista. Smartphone penetration in the United States. 2014. URL: https://www.statista.com/statistics/201183/forecast-of-smartphone-penetration-in-the-us/ [accessed 2016-12-22] [WebCite Cache ID 6mxBPL1Fd]
12. Borrelli B, Bartlett YK, Tooley E, Armitage CJ, Wearden A. Prevalence and frequency of mHealth and eHealth use among US and UK smokers and differences by motivation to quit. J Med Internet Res 2015 Jul 04;17(7):e164 [FREE Full text] [doi: 10.2196/jmir.4420] [Medline: 26149323]
13. Das S, Tonelli M, Ziedonis D. Update on smoking cessation: e-cigarettes, emerging tobacco products trends, and new technology-based interventions. Curr Psychiatry Rep 2016 May;18(5):51. [doi: 10.1007/s11920-016-0681-6] [Medline: 27040275]
14. Abroms LC, Padmanabhan N, Thaweethai L, Phillips T. iPhone apps for smoking cessation: a content analysis. Am J Prev Med 2011 Mar;40(3):279-285 [FREE Full text] [doi: 10.1016/j.amepre.2010.10.032] [Medline: 21335258]
15. Fiore M, Jaén C, Baker T, Bailey W, Benowitz N, Curry S. Clinical practice guideline: treating tobacco use and dependence: 2008 update. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service; 2008. URL: https://bphc.hrsa.gov/buckets/treatingtobacco.pdf [accessed 2017-04-11] [WebCite Cache ID 6peUAJi77]
16. Bricker JB, Mull KE, Kientz JA, Vilardaga R, Mercer LD, Akioka KJ, et al. Randomized, controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy. Drug Alcohol Depend 2014 Oct 1;143:87-94. [doi: 10.1016/j.drugalcdep.2014.07.006] [Medline: 25085225]

17. Buller DB, Borland R, Bettinghaus EP, Shane JH, Zimmerman DE. Randomized trial of a smartphone mobile application compared to text messaging to support smoking cessation. Telemed J E Health 2014 Mar;20(3):206-214 [FREE Full text] [doi: 10.1089/tmj.2013.0169] [Medline: 24350804]
18. Ubhi HK, Michie S, Kotz D, van Schayck OC, Selladurai A, West R. Characterising smoking cessation smartphone applications in terms of behaviour change techniques, engagement and ease-of-use features. Transl Behav Med 2016 Sep;6(3):410-417 [FREE Full text] [doi: 10.1007/s13142-015-0352-x] [Medline: 27528530]
19. Hoeppner BB, Hoeppner SS, Seaboyer L, Schick MR, Wu GW, Bergman BG, et al. How smart are smartphone apps for smoking cessation? A content analysis. Nicotine Tob Res 2016 May;18(5):1025-1031. [doi: 10.1093/ntr/ntv117] [Medline: 26045249]
20. Dulin PL, Gonzalez VM, Campbell K. Results of a pilot test of a self-administered smartphone-based treatment system for alcohol use disorders: usability and early outcomes. Subst Abus 2014;35(2):168-175 [FREE Full text] [doi: 10.1080/08897077.2013.821437] [Medline: 24821354]
21. Becker S, Kribben A, Meister S, Diamantidis CJ, Unger N, Mitchell A. User profiles of a smartphone application to support drug adherence--experiences from the iNephro project. PLoS One 2013;8(10):e78547 [FREE Full text] [doi: 10.1371/journal.pone.0078547] [Medline: 24194946]
22. Consumer Health Information Corporation. Motivating patients to use smartphone health apps. 2011. URL: http://www.consumer-health.com/motivating-patients-to-use-smartphone-health-apps/ [accessed 2017-02-15] [WebCite Cache ID 6oItadf7J]
23. Zeng EY, Heffner JL, Copeland WK, Mull KE, Bricker JB. Get with the program: adherence to a smartphone app for smoking cessation. Addict Behav 2016 Dec;63:120-124. [doi: 10.1016/j.addbeh.2016.07.007] [Medline: 27454354]
24. Bao Y, Duan N, Fox SA. Is some provider advice on smoking cessation better than no advice? An instrumental variable analysis of the 2001 National Health Interview Survey. Health Serv Res 2006 Dec;41(6):2114-2135 [FREE Full text] [doi: 10.1111/j.1475-6773.2006.00592.x] [Medline: 17116112]
25. Brown RA, Ramsey SE, Strong DR, Myers MG, Kahler CW, Lejuez CW, et al. Effects of motivational interviewing on smoking cessation in adolescents with psychiatric disorders. Tob Control 2003 Dec;12 Suppl 4:IV3-I10 [FREE Full text] [Medline: 14645934]
26. Steinberg ML, Ziedonis DM, Krejci JA, Brandon TH. Motivational interviewing with personalized feedback: a brief intervention for motivating smokers with schizophrenia to seek treatment for tobacco dependence. J Consult Clin Psychol 2004 Aug;72(4):723-728. [doi: 10.1037/0022-006X.72.4.723] [Medline: 15301657]
27. Wakefield M, Olver I, Whitford H, Rosenfeld E. Motivational interviewing as a smoking cessation intervention for patients with cancer: randomized controlled trial. Nurs Res 2004;53(6):396-405. [Medline: 15586136]
28. Miller WR. Rediscovering fire: small interventions, large effects. Psychol Addict Behav 2000 Mar;14(1):6-18. [Medline: 10822741]
29. Orlinsky D, Grawe K, Parks B. Process and outcome in psychotherapy. In: Lambert M, editor. Handbook of Psychotherapy and Behavior Change. 5th edition. New York, NY: Wiley; 1994:270-378.
30. Squier RW. A model of empathic understanding and adherence to treatment regimens in practitioner-patient relationships. Soc Sci Med 1990;30(3):325-339. [Medline: 2408150]
31. Kenford SL, Fiore MC, Jorenby DE, Smith SS, Wetter D, Baker TB. Predicting smoking cessation. Who will quit with and without the nicotine patch. JAMA 1994 Feb 23;271(8):589-594. [Medline: 8301790]
32. Brown RA, Lejuez CW, Kahler CW, Strong DR, Zvolensky MJ. Distress tolerance and early smoking lapse. Clin Psychol Rev 2005 Sep;25(6):713-733 [FREE Full text] [doi: 10.1016/j.cpr.2005.05.003] [Medline: 16023275]
33. Shahab L, Sarkar BK, West R. The acute effects of yogic breathing exercises on craving and withdrawal symptoms in abstaining smokers. Psychopharmacology (Berl) 2013 Feb;225(4):875-882. [doi: 10.1007/s00213-012-2876-9] [Medline: 22993051]
34. Free C, Knight R, Robertson S, Whittaker R, Edwards P, Zhou W, et al. Smoking cessation support delivered via mobile phone text messaging (txt2stop): a single-blind, randomised trial. Lancet 2011 Jul 2;378(9785):49-55 [FREE Full text] [doi: 10.1016/S0140-6736(11)60701-0] [Medline: 21722952]
35. Abroms LC, Boal AL, Simmens SJ, Mendel JA, Windsor RA. A randomized trial of Text2Quit: a text messaging program for smoking cessation. Am J Prev Med 2014 Sep;47(3):242-250. [doi: 10.1016/j.amepre.2014.04.010] [Medline: 24913220]
36. Moore S, Teixeira A, Stewart S. Effect of network social capital on the chances of smoking relapse: a two-year follow-up study of urban-dwelling adults. Am J Public Health 2014 Dec;104(12):e72-e76. [doi: 10.2105/AJPH.2014.302239] [Medline: 25320891]
37. McDonald HP, Garg AX, Haynes RB. Interventions to enhance patient adherence to medication prescriptions: scientific review. JAMA 2002 Dec 11;288(22):2868-2879. [Medline: 12472329]
38. Hays JT, Leischow SJ, Lawrence D, Lee TC. Adherence to treatment for tobacco dependence: association with smoking abstinence and predictors of adherence. Nicotine Tob Res 2010 Jun;12(6):574-581. [doi: 10.1093/ntr/ntq047] [Medline: 20457644]
39. Ploderer B, Smith W, Pearce J, Borland R. A mobile app offering distractions and tips to cope with cigarette craving: a qualitative study. JMIR Mhealth Uhealth 2014;2(2):e23 [FREE Full text] [doi: 10.2196/mhealth.3209] [Medline: 25099632]

40. Wikipedia. 2016. Principle of least privilege URL: https://en.wikipedia.org/wiki/Principle_of_least_privilege [accessed 2017-02-16] [WebCite Cache ID 6oJNBHPXd]
41. Heatherton TF, Kozlowski LT, Frecker RC, Fagerström KO. The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. Br J Addict 1991 Sep;86(9):1119-1127. [Medline: 1932883]
42. Bricker JB, Copeland W, Mull KE, Zeng EY, Watson NL, Akioka KJ, et al. Single-arm trial of the second version of an acceptance & commitment therapy smartphone application for smoking cessation. Drug Alcohol Depend 2016 Nov 04;170:37-42. [doi: 10.1016/j.drugalcdep.2016.10.029] [Medline: 27870987]
43. Brunette MF, Gunn W, Alvarez H, Finn PC, Geiger P, Ferron JC, et al. A pre-post pilot study of a brief, web-based intervention to engage disadvantaged smokers into cessation treatment. Addict Sci Clin Pract 2015 Feb 01;10:3 [FREE Full text] [doi: 10.1186/s13722-015-0026-5] [Medline: 25638283]
44. Courtney RJ, Clare P, Boland V, Martire KA, Bonevski B, Hall W, et al. Predictors of retention in a randomised trial of smoking cessation in low-socioeconomic status Australian smokers. Addict Behav 2017 Jan;64:13-20. [doi: 10.1016/j.addbeh.2016.07.019] [Medline: 27533077]
45. Salepci B, Caglayan B, Fidan A, Parmaksiz ET, Kiral N, Comert SS, et al. The effect of pulmonary function testing on the success of smoking cessation. Respir Care 2016 Aug;61(8):1073-1080. [doi: 10.4187/respcare.04490] [Medline: 26932380]
46. Hutton HE, Wilson LM, Apelberg BJ, Tang EA, Odelola O, Bass EB, et al. A systematic review of randomized controlled trials: Web-based interventions for smoking cessation among adolescents, college students, and adults. Nicotine Tob Res 2011 Apr;13(4):227-238. [doi: 10.1093/ntr/ntq252] [Medline: 21350042]
47. Stead LF, Hartmann-Boyce J, Perera R, Lancaster T. Telephone counselling for smoking cessation. Cochrane Database Syst Rev 2013;8:CD002850. [doi: 10.1002/14651858.CD002850.pub3] [Medline: 23934971]
48. Nelson DB, Partin MR, Fu SS, Joseph AM, An LC. Why assigning ongoing tobacco use is not necessarily a conservative approach to handling missing tobacco cessation outcomes. Nicotine Tob Res 2009 Jan;11(1):77-83. [doi: 10.1093/ntr/ntn013] [Medline: 19246444]
49. National Institute on Drug Abuse. NIDA CTN common data elements: Fagerstrom Score. 2016. URL: https://cde.drugabuse.gov/instrument/d7c0b0f5-b865-e4de-e040-bb89ad43202b/module/f7cc1db9-2f13-70d5-e040-bb89ad4345a3/question/f7cc1db9-2f15-70d5-e040-bb89ad4345a3 [accessed 2016-12-22] [WebCite Cache ID 6mxDBXsko]
50. Hughes JR. Effects of abstinence from tobacco: valid symptoms and time course. Nicotine Tob Res 2007 Mar;9(3):315-327. [doi: 10.1080/14622200701188919] [Medline: 17365764]
51. Cobb NK, Graham AL, Bock BC, Papandonatos G, Abrams DB. Initial evaluation of a real-world Internet smoking cessation system. Nicotine Tob Res 2005 Apr;7(2):207-216 [FREE Full text] [doi: 10.1080/14622200500055319] [Medline: 16036277]
52. Zeng EY, Vilardaga R, Heffner JL, Mull KE, Bricker JB. Predictors of utilization of a novel smoking cessation smartphone app. Telemed J E Health 2015 Dec;21(12):998-1004. [doi: 10.1089/tmj.2014.0232] [Medline: 26171733]
53. Wangberg SC, Bergmo TS, Johnsen JK. Adherence in Internet-based interventions. Patient Prefer Adherence 2008;2:57-65 [FREE Full text] [Medline: 19920945]
54. Civljak M, Stead LF, Hartmann-Boyce J, Sheikh A, Car J. Internet-based interventions for smoking cessation. Cochrane Database Syst Rev 2013;7:CD007078. [doi: 10.1002/14651858.CD007078.pub4] [Medline: 23839868]
55. Shahab L, McEwen A. Online support for smoking cessation: a systematic review of the literature. Addiction 2009 Nov;104(11):1792-1804. [doi: 10.1111/j.1360-0443.2009.02710.x] [Medline: 19832783]
56. Hollis JF, McAfee TA, Fellows JL, Zbikowski SM, Stark M, Riedlinger K. The effectiveness and cost effectiveness of telephone counselling and the nicotine patch in a state tobacco quitline. Tob Control 2007 Dec;16 Suppl 1:i53-i59 [FREE Full text] [doi: 10.1136/tc.2006.019794] [Medline: 18048633]
57. Ubhi HK, Kotz D, Michie S, van Schayck OC, West R. A comparison of the characteristics of iOS and Android users of a smoking cessation app. Transl Behav Med 2017 Feb 06. [doi: 10.1007/s13142-016-0455-z] [Medline: 28168609]
58. SRNT Subcommittee on Biochemical Verification. Biochemical verification of tobacco use and cessation. Nicotine Tob Res 2002 May;4(2):149-159. [doi: 10.1080/14622200210123581] [Medline: 12028847]

Abbreviations

IRB: institutional review board
ITT: intention-to-treat
USCPG: US clinical practice guideline

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Original Paper

Development of a Culturally Tailored Text Message Maternal Health Program: TextMATCH

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Abstract

Background: Mobile phones are increasingly being used to deliver health information and health services globally. Mobile health (mHealth) interventions may be well-suited for minority groups with greater barriers to accessing traditional health services. However, little has been written about the process of culturally adapting interventions for multiple ethnic and cultural minorities within a population.

Objective: This study describes the process of developing a culturally tailored text message-based maternal health program (TextMATCH: Text for MATernal and Child Health) for Māori, Pacific, Asian, and South Asian families living in New Zealand. We report on engagement and acceptability of the TextMATCH program.

Methods: Program data was examined to describe engagement with the program 18 months after implementation. Telephone interviews were conducted with a sample of participants who consented to provide feedback on acceptability and relevance of the program.

Results: A total of 1404 participants enrolled in TextMATCH over 18 months, with 18.52% (260) actively opting out at some point (after 0 to 17 months of messages). It was found that 356 (70.9%) of the 502 eligible participants actively switched from the initial pregnancy program to the baby program after delivery. Phone interviews were conducted with 29 participants including 6 who had withdrawn (duration of program from 3 to 16 months). Only 2 participants reported that the program was not useful, with the remainder rating the usefulness of messages positively (average 4.24 out of 5). All participants stated that the messages were relevant, culturally appropriate, and easy to understand. Most were happy with the specific advice and the language options provided.

Conclusions: We have demonstrated the importance of an intensive approach to the development of a culturally adapted and tailored mHealth program for multiple different cultural minority groups within our population.

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KEYWORDS

mHealth; short message service; maternal health; culture; text messages

Introduction

Background

Mobile health (mHealth) is the use of mobile devices, including mobile phones, to deliver health services and information [1]. Due to the high use of mobile phones and the low cost of delivery, this mode of communication appears as an ideal platform for the delivery of health interventions. mHealth interventions are often designed as a means to reach underserved groups like ethnic or cultural minorities. This is justified due to the following reasons: (1) traditional health promotion methods often fail to serve the group in question; (2) the low cost of mHealth interventions make mHealth interventions feasible in low-resource environments; (3) mobile phone use or use of specific capabilities like text messaging or voice calling are common within the group targeted; and (4) mHealth has proven acceptable or effective in other, similar areas, or in feasibility studies [2-8].

Adapting effective mHealth programs for multiple minority populations requires attention to relevant cultural characteristics [2-4,6,9,10]. Cultural adaptation may reflect the nuances of language and cultural practices, so that health messages and services reflect their history, health beliefs and norms, social practices, and political and economic characteristics [10-14].

Some aspects of cultural adaptation that may improve the sustainability and effectiveness of mHealth include the consideration of users' health beliefs and health literacy levels in message development [2,5], and the accommodation of local language and preferences in message content [3]. Cultural adaptation of message content in mHealth interventions has been executed in varying degrees from basic language translation to a sophisticated process of consultation with prospective users and data collection on barriers to services and health.

The process of the cultural adaption of mHealth interventions can be broadly categorized into three categories:

1. Translation only: mHealth intervention where content has been translated into the local language or a language nominated by users.
2. Translation and addressing group-specific barriers: the use of a local or nominated language, alongside content tailored to barriers in accessing services or health information which were faced by the cultural group concerned.
3. Translation and sophisticated adaptation: the use of a local or nominated language, alongside more complex adaptation and development processes, involving members of the target group.

However, there is a paucity of evidence to support the effectiveness and desirability of cultural adaptation practices in mHealth. In instances where perceptions of culturally adapted mHealth interventions have been described, these perceptions are positive [3,4,6,15-18]. A common factor is the lack of investigation of the cultural appropriateness of messages specifically.

One area of mHealth with some published descriptions of cultural adaptation processes is in the field of maternal health. There is growing support for the use of mHealth, including text messaging, in the field of maternal health [19], particularly for the advancement of the millennium development goals to reduce child mortality and improve maternal health in certain populations.

Text4baby in the United States is a free maternal health text message program, which is delivered in English and Spanish, for pregnant women and mothers of babies aged under 1 year. A survey assessed the linguistic appropriateness of the Spanish messages finding that 98.3% of respondents receiving the Spanish messages found the content to be clear and understandable [18]. In addition, Parker et al [20] detailed the translation, back translation, and intelligibility testing of English text messages from the US-based Text4baby intervention, translated into Russian. Expert checks of the messages were used to test the intelligibility of the messages, which informed pregnant women and mothers on how to keep themselves and their baby healthy, according to gestational age [20].

Mobile Alliance for Maternal Action (MAMA) has conducted cultural adaptation of a generic set of MAMA text messages to create new versions including ChatSalud and Mom Connect [21,22]. In Nicaragua, ChatSalud delivered sexual and reproductive health-oriented information to reduce teen pregnancy and the infant and maternal mortality associated with it [21]. In-depth interviews with adolescents who had participated in a pilot study of ChatSalud contributed relevant information about their particular barriers to sexual and reproductive health. Local health experts were also consulted about development of message content, given their experience of the population health threats in the area [21]. In South Africa, Mom Connect text messages collected data from the mother during pregnancy and the first year of the child's life, and delivered age- and stage-specific messages to inform and support pregnant women and mothers [22]. Focus groups with prospective users and consultation with local health experts sought to ensure that the barriers addressed were relevant to the target group. These included intimate partner violence, depression, and persuading partners to use condoms during pregnancy to prevent human immunodeficiency virus (HIV) transmission. These processes resulted in MAMA South Africa message content being provided in six different languages and incorporating user comments and stories [22].

Although these studies have shown the feasibility of cultural adaptation of text messaging programs in maternal health, more evaluation of such interventions is needed to determine their effectiveness [20].

In New Zealand, we have developed TextMATCH (Text for MATernal and Child Health), an educational and supportive text message program for pregnant, new mothers (of infants aged until 2 years), and other family members. This program was funded by the New Zealand Ministry of Health as part of a broader initiative (*Healthy Babies Healthy Futures, HBHF*) targeting the increasing rates of childhood obesity (11% of children aged 2-14 years in New Zealand are reported to be obese) [23]. Targeting interventions to families is seen as vital

in addressing increasing obesity rates. Commencing in pregnancy, maternal and child nutrition and physical activity influence physiology in ways that contribute to disease risk and lay the path for lifelong health.

TextMATCH was designed to cover three specific areas:

- improve women's health during pregnancy and the postnatal period, through promotion of healthy eating and physical activity;
- promote healthy feeding of babies including encouraging and supporting breastfeeding; and
- promote healthy feeding (including the introduction of healthy first foods) and physical activity of children at preschool age.

TextMATCH, and the broader HBHF initiative it is embedded in, have been developed specifically for Māori (the indigenous population of New Zealand), Pacific, Asian, and South Asian families. These are minority groups with particularly high rates of childhood obesity (Māori 19% and Pacific 27%) [23] or with particular needs arising from being new migrants who may not be well-connected to, or have experience with, the New Zealand health system. This paper describes the development and cultural adaptation of TextMATCH specifically for these groups and the feedback on its acceptability to date.

Intervention Development

The development of TextMATCH was guided by our previously developed mHealth Development and Evaluation framework [24], which provides a process to direct the development and testing of mHealth interventions, with a focus on implementation from the beginning, use of behavioral change theory, and involvement of the target population. A summary of the development process can be seen in Figure 1.

A governance group for the broader HBHF initiative, the Roopu Kaitiaki, provided guidance on the primary focus and scope of the program. This group represented a consortium of community-based providers working with the target audience of the program. The target population was defined as pregnant women and mothers of babies aged under 2 years of Māori, Pacific, Asian, and South Asian ethnic communities within two health districts in Auckland, New Zealand. The target population also included their extended families (whānau in Māori) and anyone else who had influence on the health and wellbeing of the pregnant women, babies, mothers, and their preschool children.

The overarching principles agreed were

- education for those with low health literacy;
- targeting those who have relatively low involvement with conventional support networks;
- providing practical tips and suggestions that are relevant to their specific contexts;
- supporting improvements in health nutrition and uptake of appropriate physical activity;
- linking pregnant women or mothers of young children and their families to health and community services as early as possible; and
- using proven behavior change techniques and theories.

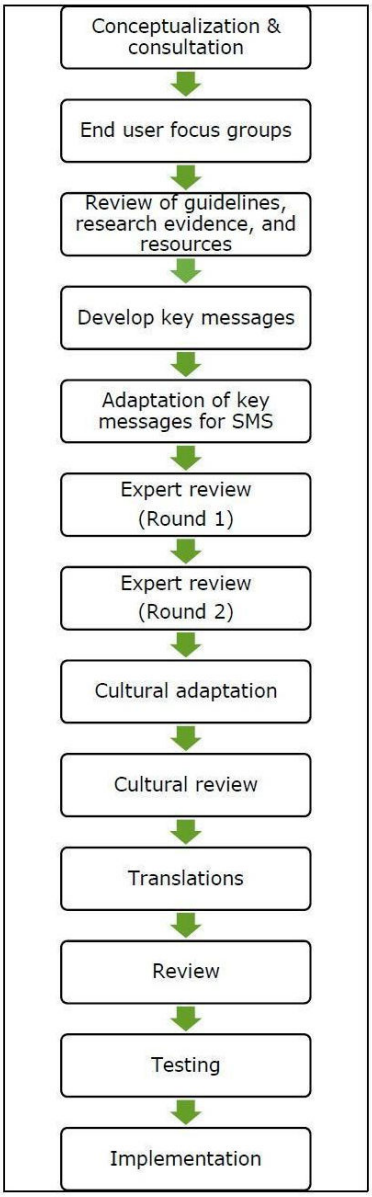
Formative Work

Formative work was conducted to inform development of the program including the design, content, and implementation. This included focus groups with the target audience and a review of the literature, guidelines, and publicly available resources.

The focus groups aimed to determine how the intended audience engaged with technology, how a technology-based health program could benefit them during pregnancy and the first 2 years of their child's life, and to understand cultural norms, traditions, and beliefs around technology and maternal health. A total of 4 culture-specific focus groups were conducted with pregnant women, mothers of children aged under 2 years, and their support people. Participants were identified by the community organizations involved in the wider HBHF initiative. All groups were positive about using technology to support people to eat well and exercise during pregnancy and the first 2 years of a baby's life. Technology preferences differed, with some groups reporting a preference for mobile phone messaging apps (such as WeChat, WhatsApp), whereas others reported nonconsistent mobile phone ownership and a preference for text messaging (short message service, SMS) due to limited data access. Other factors of importance for a mHealth program were being free, accessible on all types of mobile phones, and taking into consideration that phones are sometimes shared among family members. Therefore, in order to ensure greatest reach of the intervention, SMS was agreed on as the mode of delivery. Participants felt strongly that there was benefit to the messages being offered to partners or fathers and other family members, in addition to a pregnant woman or mother.

Consistent across the groups was a preference for New Zealand-based guidance and references, as there was concern that advice in internationally available apps may differ from that in New Zealand. Differences in terminology were identified, as well as culture-specific foods, practices, traditions, and activities, providing rationale for culturally adapted versions of the program. Preferences for languages varied, with all groups recommending an English option and some Asian participants requesting Simplified Chinese and Korean. In addition, consulted health care providers recommended adding Japanese and Te Reo Maori languages. Women in the Pacific Island and Indian focus groups predominately felt that an SMS intervention would be best in English. This was due to wanting the intervention to be in the language they were likely to be communicating with their lead maternal carers (LMCs) in for consistency, as well as a general preference for texting in English.

Figure 1. TextMATCH development process. SMS: short message service.



A review of the current literature, New Zealand guidelines, and resources was undertaken to establish key messages related to nutrition and physical activity for the target population, as well as other relevant areas.

Content Development

Findings from the formative work resulted in the development of key messages for the intervention. The key messages were then adapted into text messages limited to 160 characters. These text messages were sent to a technical advisory group (TAG, including local representatives from midwifery, public health, nutrition, physical activity, Māori health promotion, primary care, and postnatal providers) and revised before being sent to a second panel of experts (obstetrician, pediatrician, and academic experts in nutrition and physical activity) for review to ensure factual correctness. Once the key text messages were confirmed, they were then adapted into 4 cultural versions using the feedback from the formative work. These culturally adapted messages were reviewed and adapted further by the 4 cultural community groups in the consortium. Each cultural version was adapted into 2 versions (total 8 versions); one for mothers and the second one for other family members. Where needed, the messages were then translated into other languages (Te Reo Maori, Chinese, Korean, and Japanese) resulting in 16 different versions of the TextMATCH program (see Table 1 for a breakdown of the different versions). These were reviewed and back-translated by the 4 community groups. The messages underwent a final review before being loaded into the system and tested. Although the development process was linear (Figure 1), if, at later stages in the development process, changes to content were made, the affected content was rereviewed by all levels of reviewers before being translated, rereviewed, and tested.

Versions of the program that were delivered in English included greetings and other key words in the appropriate language (eg, Hindi, Samoan, Tongan, Cook Island Maori, Tuvaluan, and Tokelauan). The messages were also personally tailored by including the participant's name, baby's name, and gender-specific terms for messages after the baby was born (eg, he or him or his). Examples of TextMATCH messages can be seen in Table 2.

Table 1. TextMATCH versions.

Version number	Culture	Language	Relationship to baby
1	Māori	Te Reo	Mother
2	Māori	Te Reo	Other family member
3	Māori	English	Mother
4	Māori	English	Other family member
5	Pacific	English	Mother
6	Pacific	English	Other family member
7	Asian	Chinese	Mother
8	Asian	Chinese	Other family member
9	Asian	Korean	Mother
10	Asian	Korean	Other family member
11	Asian	Japanese	Mother
12	Asian	Japanese	Other family member
13	Asian	English	Mother
14	Asian	English	Other family member
15	South Asian	English	Mother
16	South Asian	English	Other family member

TextMATCH Program

The resulting TextMATCH program is individually tailored and available in 16 different cultural versions and 5 languages (Table 1). A person is referred to TextMATCH using a short referral form with questions to determine their specific TextMATCH program. Once registered, they receive up to 3 free text messages per week delivered to their mobile phone (see Figure 2). The estimated delivery date or baby's birth date determines where in the TextMATCH program participants start. Messages are personalized (with the recipient's name, the baby's name, and gender) and tailored to the gestational age or age of the baby. Messages not only focus on nutrition and physical activity for pregnant women, baby, and wider family, but also cover a range of health topics including immunizations, safety, support services, weight gain, smoking, and emotional encouragement. The program is unidirectional, but if a person is registered during pregnancy they can self-switch to the baby messages, by free texting into the system when their baby is born. People can withdraw from the program by free texting the word "STOP" at any time. The program is provided at no cost to recipients including no cost to send text messages to switch to the baby program, or to withdraw from the program.

The TextMATCH system is automated following registration. Registration requires manual input of the recipient details for the generation of message schedules. In addition, the system is checked daily for unrecognized incoming messages and these are actioned if needed. The ongoing costs of running the program include the Gateway Company shortcode fees and per text message costs, as well as a maximum of 1 hour of person time per week to check the unrecognized incoming messages and manage issues.

Figure 2. TextMATCH system overview. SMS: short message service.

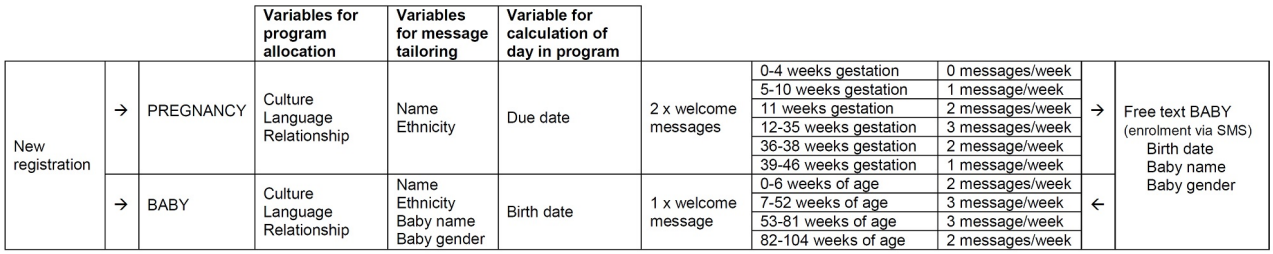


Table 2. A selection of TextMATCH messages.

Example message	Timing	Culture	Relationship to baby
Malo e lelei [firstname]. You are now registered for TextMATCH. We will send you up to 3 messages per week to support you to eat well & be active while pregnant	Registration (during pregnancy)	Pacific-Tongan	Mother
Kia ora [firstname]. Exercise is important for your health & for the mums health during pregnancy, aim for 30 min of activity each day	Pregnancy (14 weeks)	Māori	Other family member
Iron is important to prevent you becoming too tired during pregnancy. Lean red meat, chicken, eggs, bajra flour, cowpea, masoor dal & moth beans contain iron	Pregnancy (23 weeks)	South Asian	Mother
Talofa [firstname]. Keeping active towards the end of pregnancy can be tough but the health benefits make it worth it. Try swimming or a very gentle walk	Pregnancy (36 weeks)	Pacific-Samoan	Mother
Hi [firstname]. Congratulations on the birth of [babyname]. We hope you are enjoying this special & exciting time. Thanks for having TextMATCH on board	Completion of switch to baby program	Asian	Mother
Kia ora [firstname]. Breast milk is the perfect kai for your baby - it's healthy & it's free! Please talk to your midwife if you need help or support	Postnatal (2 weeks)	Māori	Mother
Kia ora. Sounds, smiles, laughter, touch & interaction all help [babyname] to develop. Spending time with [him/her] will help to grow your relationship with [him/her]	Postnatal (17 weeks)	Māori	Other family member
Don't forget to take care of yourself, this includes eating well & getting rest. To be able to look after [babyname] you need to take care of yourself first	Postnatal (22 weeks)	Pacific	Mother
Aim to feed [babyname] a variety of healthy choices in every meal. Try boiling pumpkin or kumara together with spinach or taro leaves for a nutritious option	Postnatal (44 weeks)	Pacific	Other family member
Choose healthy foods for [babyname]. There is no need to add salt, sugar, butter or ghee to [his/her] food. If you want to cancel these messages, reply text STOP	Postnatal (1 year 20 weeks)	South Asian	Mother

Engagement and Acceptability of TextMATCH

TextMATCH went live in August 2014 with people referred to the program by community organizations within two urban health districts in New Zealand. We conducted a study, 18 months post go-live, to assess the engagement and acceptability of the program. The study had two aims:

1. To assess the engagement of participants with the TextMATCH program, including enrollment and disengagement rates.
2. To assess the acceptability of the TextMATCH program, including its cultural appropriateness and relevance, reasons for withdrawal, and to determine ways in which the program could be improved.

Methods

Engagement

Engagement data collected by the content management system was extracted on April 7, 2016. All data was kept private and secure to respect the privacy of all intervention participants. Data collected for the first 18 months was used in this analysis. The data for each participant included program number (indicating cultural group, language, and relationship); month registered; due date month and year; baby birth date and year; whether they switched to the baby program from the pregnancy program; whether they texted "STOP;" their withdrawal date (if applicable); and completion date (if applicable). Descriptive statistics were generated for baseline demographic and clinical characteristics, and measures of engagement with the system. Counts and percentages were reported for categorical variables, along with means and standard deviations for continuous variables.

Acceptability

Phone interviews were conducted between January and March 2016. All study documents and procedures were approved by the New Zealand Health and Disability Ethics Committee (15/CEN/210).

Participants included those who were registered for the TextMATCH program between August 2014 and August 2015, and who had previously agreed to be contacted about their experience with the program. Potential participants were excluded if it was known that they had experienced a miscarriage; their due date fell during the study period; they only spoke Japanese or Korean, as no interviewer was available for these languages. We also excluded those who withdrew from the program by texting "STOP" after receiving less than 2 weeks

of messages, as it was determined that this group would not have received sufficient intervention to provide feedback for this study. To ensure participants with a range of experiences with the program were interviewed, potential participants were split into four categories:

1. those who had received TextMATCH for 6 months or more;
2. those who had received TextMATCH for 3-6 months;
3. those who withdrew from the program by texting "STOP" after receiving a minimum of 2 weeks of messages;
4. those that received TextMATCH during pregnancy but did not self-switch to the baby messages following their baby's birth.

Eligible participants were sent a text message asking if they would be interested in being contacted for an interview. In addition, community providers contacted some eligible participants to invite them to participate, to accommodate those who did not have sufficient credit on their phones to respond, and to ensure adequate numbers. If participants replied "yes," they were called by the research assistant for the interview. Before commencing with the interview, they read the participant information sheet and consent form, and verbal consent was then obtained. Interviews were conducted in English or Chinese based on participant preference. Following informed consent, the researcher then went through the interview schedule with participants covering the following topics:

- General feedback
- Usefulness of the messages
- Appropriateness of the messages, with special attention to the cultural adaptation of messages
- Perceived impacts
- If withdrew: reasons for withdrawal
- If did not self-switch: reasons for not choosing to switch to baby messages
- Suggestions for improvements

The interview data was analyzed and summarized using descriptive quantitative analyses including means, standard deviation and proportions, and qualitative comments analyzed using simple thematic analysis.

Results

Engagement

In the first 18 months of the TextMATCH program, 1404 individuals enrolled and over 98,000 messages were sent by the system. The percentage of participants enrolled in each of the 16 different versions of TextMATCH varied (Table 3). Even though TextMATCH is offered to other family members, 72.44% (1017) of individuals enrolled were mothers—almost three times more than other family members.

Table 3. Enrollment in TextMATCH by version.

Version	Cultural group	Language	Relationship to baby	n (%)
1	Māori	Te Reo	Mother	17 (1.21)
2	Māori	Te Reo	Other family member	8 (0.57)
3	Māori	English	Mother	173 (12.32)
4	Māori	English	Other family member	55 (3.92)
5	Pacific	English	Mother	244 (17.38)
6	Pacific	English	Other family member	39 (2.78)
7	Asian	Chinese	Mother	283 (20.16)
8	Asian	Chinese	Other family member	67 (4.77)
9	Asian	Korean	Mother	51 (3.63)
10	Asian	Korean	Other family member	22 (1.57)
11	Asian	Japanese	Mother	8 (0.57)
12	Asian	Japanese	Other family member	0 (0.00)
13	Asian	English	Mother	19 (1.35)
14	Asian	English	Other family member	14 (1.00)
15	South Asian	English	Mother	222 (15.81)
16	South Asian	English	Other family member	182 (12.96)

Of the 1404 individuals who enrolled in TextMATCH, 260 (18.52%) actively discontinued the program by texting the word "STOP." Discontinuation rates varied between the TextMATCH cultural versions; 14.1% of those registered for the Asian versions of the program (#7-14) texted "STOP," 15.9% of those registered for South Asian versions (#15 and 16), 19.9% of those registered for Pacific versions (#5 and 6), and 29.2% of those registered for Māori versions (#1-4).

For those who texted "STOP," the average duration of messages received was 3.84 months (SD 3.10; range 0-17 months). Of the 502 individuals who were sent text messages prompting them to switch from the pregnancy version of the program to the baby version, 356 (70.9%) fully completed the three text

messages required to switch to the baby program—74.6% of mothers and 59.1% of other family members.

Acceptability

A total of 52 people agreed to be contacted for an interview. Of these, 5 declined to participate, 1 was unable to provide consent, and 17 were unable to be contacted. A total of 29 interviews were completed. Of those who participated, 12 (41%) had received TextMATCH for 6 months or longer, 9 (31%) had received TextMATCH for 3-6 months, 6 (21%) had withdrawn from TextMATCH by texting "STOP," and 2 (7%) had not switched from pregnancy to baby messages.

The mean number of months participants had received TextMATCH messages for was found to be 7 months (range 3-16). Those who had stopped the messages or did not switch over (n=8) received on average 6 months (range 3-9) of messages. A summary of the TextMATCH version that the interview participants had received can be seen in Table 4, and participant's demographic characteristics in Table 5.

Table 4. Interview participants by TextMATCH version.

TextMATCH[a] program #	Description (cultural group, language, relationship)	No. of participants	No. by type of messages received		
			Only pregnancy messages	Only baby messages	Both pregnancy and baby messages
3	Māori, English, mother	4		2	2
5	Pacific, English, mother	5	1	3	1
7	Asian, Chinese, mother	11	3		8
8	Asian, Chinese, other family member	2	1		1
15	South Asian, English, mother	6			6
16	South Asian, English, other family member	1		1	

All but 2 participants (27; 93%) reported that they found the messages personally useful. For those who found it useful, the mean rating on a scale of 1 (a little useful) to 5 (extremely useful) was 4.24 (SD 0.80; range 2-5). Table 6 shows the mean ratings by interview category and TextMATCH cultural version. Many participants commented generally on the usefulness of messages including that TextMATCH provided a timely reminder of information which they previously knew. Participants reported that the messages were also reassuring, encouraging, and motivating. The 2 participants who reported that the messages were not useful had reported finding the content in the messages too basic and therefore not beneficial to them.

Table 5. Characteristics of interview participants (n=29).

Characteristics	Number, n (%)
Gender: Female	26 (90)
Relationship	
Mothers	26 (90)
Other family member(fathers)	3 (10)
Ethnicity	
Māori	5 (17)
Samoan	2 (7)
Niuean	1 (3)
Tuvaluan	1 (3)
Chinese	13 (45)
Indian	4 (14)
Nepalese	2 (7)
Sri Lankan	1 (3)
Mean age (SD[b])	32.6 years (range 23–44)

[a]TextMATCH: Text for MATernal and Child Health.

[b]SD: standard deviation.

Table 6. Mean ratings of usefulness for those reporting the program to be useful (n=27).

Grouping	n	Mean rating (SD[a])	Range
Interview category			
6+ months	11	4.32 (0.64)	3-5
3-6 months	9	4.67 (0.50)	4-5
Withdrew	5	3.20 (0.84)	2-4
Did not switch	2	4.50 (0.71)	4-5
TextMATCH[b] version			
Māori (#1-4)	4	4.00 (0.82)	3-5
Pacific (#5-6)	5	4.20 (0.84)	3-5
Asian (#7-14)	11	4.23 (0.61)	3-5
South Asian (#15-16)	7	4.43 (1.13)	2-5

[a]SD: standard deviation.

[b]TextMATCH: Text for MATernal and Child Health.

All participants responded that the messages were relevant to them, with many commenting that some were more relevant than others (28; 97%). In addition, all study participants reported finding the messages culturally appropriate and easy to understand (29; 100%). Participants provided positive feedback on the personalization of the messages; they enjoyed that the messages included greetings in languages other than English and having their names in the messages.

When asked whether they found the specific food practices and activities mentioned in messages appropriate to them, all but three reported that they were (27; 93%). Reasons why food practices and activities were less relevant to participants included that messages referring to meat were not relevant for vegetarians, and that messages referring to dairy products or to prepreparing and freezing meals were not relevant for many Chinese people.

Table 7. Perceived impacts of TextMATCH.

Impact	Number responded	Response YES: n (%)
Improvements to eating habits	29	18 (62%)
Improvements to family's eating habits	29	16 (55%)
Positive changes to food shopping	29	19 (66%)
Positive impact on exercising	29	15 (52%)
Improvements to knowledge or understanding	29	21 (72%)
Feeling more supported	28	28 (100%)

Participants were also asked if there were any messages that they found irrelevant or inappropriate with only 6 (21%) reporting that there were. Of these, 3 felt that some proportion of messages did not apply to their own pregnancy or child, but many also commented that they were happy to ignore these. Only one respondent felt that these represented a significant proportion of the program, and said that this was because she had a complicated pregnancy and birth.

When asked if they would have preferred the messages to be in a different language, most (25; 89%) responded "no." One participant would have preferred the messages in Hindi, another in Samoan, and one was happy with her Māori cultural messages in the English language but would have preferred more phrases and words in the Te Reo language. A separate question sought participants' suggestions about the provision of messages in other languages. Suggested languages included Samoan (n=5), Hindi (n=5), Tongan (n=1), Niuean (n=1), and Spanish (n=1). Some of those suggesting Pacific languages stated that this would be useful to improve their own Pacific language competency rather than assisting people who did not speak English.

Perceived Impacts

Participants were asked about the impacts that they felt TextMATCH had on themselves, their family, and their baby (see Table 7). A common benefit of the messages appeared to be the reminders and reassurance they provided:

> *(when it's) a stressful time and then you get the message and realize you're not doing too bad.* [Pacific, mother]

Over 50% of participants reported that the program had improved both their eating habits (18; 62%) and exercise (15; 52%). Furthermore, all participants reported feeling supported by messages (28; 100%). Those who felt they had not gained knowledge from the program still found it useful because it made them feel more supported. One mother commented:

> *there's a lot of time in isolation when it's just you and bubba, it's quite nice to receive that message.* [Māori, mother]

A total of 21 (72%) participants reported improvements to their knowledge and understanding. Some participants felt that the program was ideally suited for first-time parents with less baseline knowledge. However, one user stated that:

> *it's quite empowering actually just to get that little bit more information you think you know everything after seven children so it's actually quite cool.* [Māori, mother]

A total of 12 (41%) participants reported that they had family members also receiving the messages. All remarked that it was good for the partners to receive messages, as it put both parents "on the same page" with regard to pregnancy and child care, and many discussed message content. Many mothers also felt that their partners were better able to care for them and the baby as a result of the messages.

All participants (29; 100%) reported that they would recommend the TextMATCH program to others. Reasons included that it provides useful information and tips, uses a medium which is very accessible and unobtrusive, provides valuable reminders, and can benefit the whole family. Respondents also mentioned that messages provided valuable support and encouragement and would be especially useful for first time and younger mothers.

Reasons for Disengagement

There were 6 participants (21%) who had texted in "STOP" to withdraw from the program after an average duration of 6 months of messages (range 4-9 months). Four of these participants reported that they withdrew due to not finding the messages very useful or beneficial, one due to a technical issue, and one reported that they had only wanted the messages during pregnancy and so stopped once their baby was born. There were 2 participants (7%) who had not chosen to switch to the baby messages after completing the pregnancy messages. One reported that they had not realized that they had to text back to sign-up for the baby messages, and the other reported that things were hectic after the baby was born and so they forgot to switch.

Suggestions for Improvements

A total of 20 participants provided suggestions for how the program could be improved. Most commonly, participants suggested that the messages could contain more detailed and specific information on the baby's diet (especially solid foods), recipes, and activities (like where to play outdoors; n=13). Others thought that bidirectional messages to be able to ask about certain aspects of the program would be useful (n=5). Two participants suggested having extra optional message streams for certain maternal health conditions (eg, hypertension or diabetes), areas of interest (eg, diet), or for multiple pregnancies (eg, twins). Other suggestions included information about local events (n=1), the use of other social media like WeChat to enable photo or video messages (n=1), more emotional support for mothers (n=1), changes to the frequency or timing of messages (n=4), and better channels for users to recommend the program to others (n=1).

Discussion

Principal Findings

The process of developing TextMATCH with specific cultural, family, and language versions was extensive and resource-intensive. It involved focus groups and testing directly with the target audience. It also involved considerable input from the community groups working with those families. This resulted in what appears to be a rather simple program to the end-user, but which is actually composed of 16 different versions. The system rules ensuring that the correct version is sent to each participant are based on just a small number of questions. The engagement statistics and feedback from participant interviews have indicated that there is value in this process, with positive responses to the personalization and relevance of the culturally tailored messages. Other benefits of our program include the feelings of support reported by all participants, and the inclusion of other family members receiving the messages.

Some participants reported that some of the messages were not useful for them, inappropriate or irrelevant. This feedback has been taken into consideration and the program is being improved based on their suggestions. Regardless, all those interviewed, even those reporting it not to be of personal use, reported that they would recommend the program to others. Although the program appears to be well-received and perceived to be of benefit, evaluation of its effectiveness has yet to be undertaken and will be necessary to understand if it is impacting on health outcomes.

Feedback from recipients as well as changes in evidence and guidelines mean changes to the content of programs such as TextMATCH need to be made from time to time. In this case, messages are updated using the same process, requiring significant time and input from reviewers before they are loaded into the content management system. This needs to be factored into the ongoing costs of the program.

We believe that it is important that mHealth programs target minority and vulnerable populations, who may have difficulty accessing traditional health services due to a variety of reasons. These reasons can include language, cultural differences, geography, travel, work, or roles caring for others. It is also important to consider the technological infrastructure of a setting, and the power dynamics which determine different groups' access to technologies, and how existing communities and health systems will respond to mHealth [3,7,25].

Limitations

It is important that these findings be interpreted in light of the limitations including the small number of participants interviewed, potential sampling bias in those who agreed to an interview, and unequal samples of cultural groups and interview categories. The overall numbers of people using the Korean or Japanese versions of the program at the time of interviewing were not large and interviews could not be offered in these languages, meaning the results cannot be generalized to those receiving TextMATCH messages in those languages. Further investigation is needed into reasons for disengagement in those

who had withdrawn from TextMATCH within 2 weeks of signing up as this group was not included in the study and could provide valuable insight into engagement.

Conclusions

We have described how mHealth can provide access to health information, motivation, reassurance, and support in simple programs like TextMATCH. It can also link people to existing community programs for appropriate in-person support. It is important that mHealth programs are designed with the involvement of these vulnerable groups in our populations, and that we take the time and extra resources required to ensure that the programs will be relevant and appropriate for the context of their daily lives. This is not simply about translating programs that have been developed for the majority. We have described here an extensive process of developing an intervention with minority populations first. There is no "majority" (pakeha /New Zealand European) version of TextMATCH. This process has begun in collaboration with the community which cares for these families of minority cultural groups and which shares their culture.

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Authors' Contributions

RD and RW designed the study and prepared the manuscript. HB, RC, and AC collected the data. RD, RW, MR, and JM contributed to analysis, and verification of findings. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

References

1. World Health Organization. mHealth: new horizons for health through mobile technologies: second global survey on eHealth URL: http://www.who.int/goe/publications/goe_mhealth_web.pdf [accessed 2015-01-15] [WebCite Cache ID 6VaF4Zrjl]
2. Aggarwal NK. Applying mobile technologies to mental health service delivery in South Asia. Asian J Psychiatr 2012 Sep;5(3):225-230. [doi: 10.1016/j.ajp.2011.12.009] [Medline: 22981050]
3. Aranda-Jan CB, Mohutsiwa-Dibe N, Loukanova S. Systematic review on what works, what does not work and why of implementation of mobile health (mHealth) projects in Africa. BMC Public Health 2014 Feb 21;14:188 [FREE Full text] [doi: 10.1186/1471-2458-14-188] [Medline: 24555733]
4. Arora S, Peters A, Burner E, Lam C. Menchine M: Trial to examine text message? based mHealth in emergency department patients with diabetes (TExT-MED): a randomized controlled trial. Ann Emerg Med 2014;63(6):e746. [Medline: 24225332]
5. Brian R, Ben-Zeev D. Mobile health (mHealth) for mental health in Asia: objectives, strategies, and limitations. Asian J Psychiatr 2014;10:96-100. [Medline: 25042960]
6. Chandra P, Sowmya H, Mehrotra S, Duggal M. 'SMS' for mental health—feasibility and acceptability of using text messages for mental health promotion among young women from urban low income settings in India. Asian J Psychiatr 2014 Oct;11:59-64. [doi: 10.1016/j.ajp.2014.06.008] [Medline: 25453699]
7. Chib A. The promise and peril of mHealth in developing countries. Mobile Media & Communication 2013 Jan;1(1):69-75. [doi: 10.1177/2050157912459502]
8. Chib A, Wilkin H, Hoefman B. Vulnerabilities in mHealth implementation: a Ugandan HIV/AIDS SMS campaign. Glob Health Promot 2013 Mar;20(1 Suppl):26-32. [doi: 10.1177/1757975912462419] [Medline: 23549699]
9. Tamrat T, Kachnowski S. Special delivery: an analysis of mHealth in maternal and newborn health programs and their outcomes around the world. Matern Child Health J 2012 Jul;16(5):1092-1101. [doi: 10.1007/s10995-011-0836-3] [Medline: 21688111]
10. Nimmon L, Poureslami I, Fitzgerald JM. What counts as cultural competency in telehealth interventions? A call for new directions. J Telemed Telecare 2012 Oct;18(7):425-426. [doi: 10.1258/jtt.2012.120517] [Medline: 23104769]

11. Dobson R, Carter K, Cutfield R, Hulme A, Hulme R, McNamara C, et al. Diabetes text-message self-management support program (SMS4BG): a pilot study. JMIR Mhealth Uhealth 2015 Mar 25;3(1):e32 [FREE Full text] [doi: 10.2196/mhealth.3988] [Medline: 25830952]
12. Whittaker R, Merry S, Stasiak K, McDowell H, Doherty I, Shepherd M, et al. MEMO--a mobile phone depression prevention intervention for adolescents: development process and postprogram findings on acceptability from a randomized controlled trial. J Med Internet Res 2012 Jan 24;14(1):e13 [FREE Full text] [doi: 10.2196/jmir.1857] [Medline: 22278284]
13. Bramley D, Riddell T, Whittaker R, Corbett T, Lin R, Wills M, et al. Smoking cessation using mobile phone text messaging is as effective in Maori as non-Maori. N Z Med J 2005 Jun 03;118(1216):U1494. [Medline: 15937529]
14. Whittaker R, Matoff-Stepp S, Meehan J, Kendrick J, Jordan E, Stange P, et al. Text4baby: development and implementation of a national text messaging health information service. Am J Public Health 2012 Dec;102(12):2207-2213. [doi: 10.2105/AJPH.2012.300736] [Medline: 23078509]
15. Osborn C, Mulvaney SA. Development and feasibility of a text messaging and interactive voice response intervention for low-income, diverse adults with type 2 diabetes mellitus. J Diabetes Sci Technol 2013 May 01;7(3):612-622 [FREE Full text] [doi: 10.1177/193229681300700305] [Medline: 23759393]
16. Lau E, Lau PW, Cai B, Archer E. The effects of text message content on the use of an internet-based physical activity intervention in Hong Kong Chinese adolescents. J Health Commun 2015;20(9):1041-1051. [doi: 10.1080/10810730.2015.1018580] [Medline: 25996371]
17. Lau E, Lau PW, Chung P, Ransdell L, Archer E. Evaluation of an internet-short message service-based intervention for promoting physical activity in Hong Kong Chinese adolescent school children: a pilot study. Cyberpsychol Behav Soc Netw 2012 Aug;15(8):425-434. [doi: 10.1089/cyber.2012.0161] [Medline: 22897473]
18. Martinez K, Uekusa S. Csusm. 2013. National survey of Text4baby participants URL: http://www.csusm.edu/anthropology/docsandfiles/Text4baby.pdf [accessed 2017-02-03] [WebCite Cache ID 6nzM2Dda9]
19. Poorman E, Gazmararian J, Parker R, Yang B, Elon L. Use of text messaging for maternal and infant health: a systematic review of the literature. Matern Child Health J 2015 May;19(5):969-989. [doi: 10.1007/s10995-014-1595-8] [Medline: 25081242]
20. Parker R, Dmitrieva E, Frolov S, Gazmararian JA. Text4baby in the United States and Russia: an opportunity for understanding how mHealth affects maternal and child health. J Health Commun 2012;17 Suppl 1:30-36. [doi: 10.1080/10810730.2011.649162] [Medline: 22548596]
21. Mobile Alliance for Maternal Action. Community Spotlight: Chatsalud. Nicaragua; 2014. URL: http://www.mhealthknowledge.org/sites/default/files/Spotlight-Chatsalud.pdf [WebCite Cache ID 6munPR6gK]
22. Mobile Alliance for Maternal Action. Reimagining mobile in South Africa: Lessons from one year. 2014. URL: http://www.mhealthknowledge.org/sites/default/files/Reimagining%20Mobile%20in%20South%20Africa.%20Lessons%20from%20Year%20One.pdf [WebCite Cache ID 6munZy87K]
23. Ministry of Health. 2013. New Zealand health survey: annual update of key findings 2012/13 URL: http://www.health.govt.nz/system/files/documents/publications/new-zealand-health-survey-annual-update-2012-13-dec13-v3.pdf [WebCite Cache ID 6S6jNbn4F]
24. Whittaker R, Merry S, Dorey E, Maddison R. A development and evaluation process for mHealth interventions: examples from New Zealand. J Health Commun 2012;17 Suppl 1:11-21. [doi: 10.1080/10810730.2011.649103] [Medline: 22548594]
25. Källander K, Tibenderana J, Akpogheneta O, Strachan D, Hill Z, Ten AA, et al. Mobile health (mHealth) approaches and lessons for increased performance and retention of community health workers in low- and middle-income countries: a review. J Med Internet Res 2013 Jan 25;15(1):e17 [FREE Full text] [doi: 10.2196/jmir.2130] [Medline: 23353680]

Abbreviations

HBHF: Healthy Babies Healthy Futures
HIV: human immunodeficiency virus
LMC: lead maternal carer
MAMA: Mobile Alliance for Maternal Action
mHealth: mobile health
SD: standard deviation
SMS: short message service
TAG: technical advisory group
TextMATCH: Text for MATernal and Child Health

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Original Paper

Designing Patient-Centered Text Messaging Interventions for Increasing Physical Activity Among Participants With Type 2 Diabetes: Qualitative Results From the Text to Move Intervention

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is a disease affecting approximately 29.1 million people in the United States, and an additional 86 million adults have prediabetes. Diabetes self-management education, a complex health intervention composed of 7 behaviors, is effective at improving self-care behaviors and glycemic control. Studies have employed text messages for education, reminders, and motivational messaging that can serve as "cues to action," aiming to improve glucose monitoring, self-care behaviors, appointment attendance, and medication adherence.

Objectives: The Text to Move (TTM) study was a 6-month 2-parallel group randomized controlled trial of individuals with T2DM to increase physical activity, measured by a pedometer. The intervention arm received text messages twice daily for 6 months that were tailored to the participant's stage of behavior change as defined by the transtheoretical model of behavior change.

Methods: We assessed participants' attitudes regarding their experience with text messaging, focusing on perceived barriers and facilitators, through two focus groups and telephone interviews. All interviews were audiorecorded, transcribed verbatim, coded, and analyzed using a grounded theory approach.

Results: The response rate was 67% (31/46 participants). The average age was 51.4 years and 61% (19/31 participants) were male. The majority of individuals were English speakers and married, had completed at least 12th grade and approximately half of the participants were employed full-time. Overall, participants were satisfied with the TTM program and recalled the text messages as educational, informational, and motivational. Program involvement increased the sense of connection with their health care center. The wearing of pedometers and daily step count information served as motivational reminders and created a sense of accountability through the sentinel effect. However, there was frustration concerning the automation of the text message program, including the repetitiveness, predictability of text time delivery, and lack of customization and interactivity of text message content. Participants recommended personalization of texting frequency as well as more contact time with personnel for a stronger sense of support, including greater surveillance and feedback based on their own results and comparison to other participants.

Conclusions: Participants in a theory-based text messaging intervention identified key facilitators and barriers to program efficacy that should be incorporated into future texting interventions to optimize participant satisfaction and outcomes.

Trial Registration: Clinicaltrials.gov NCT01569243; http://clinicaltrials.gov/ct2/show/NCT01569243 (Archived by Webcite at http://www.webcitation.org/6pfH6yXag)

(JMIR Mhealth Uhealth 2017;5(4):e54) doi:10.2196/mhealth.6666

KEYWORDS

diabetes mellitus, type 2; text messaging; exercise; qualitative research

Introduction

Background

Type 2 diabetes mellitus (T2DM) is a disease affecting approximately 29.1 million people in the United States, and an additional 86 million adults have prediabetes [1]. Diabetes self-management education, a complex health intervention composed of 7 behaviors: (1) blood glucose self-monitoring, (2) taking medications, (3) healthy eating, (4) being active, (5) reducing risks, (6) healthy coping, and (7) problem solving, is effective at improving self-care behaviors and glycemic control [2]. Yet many individuals with T2DM fail to adopt and sustain a more active lifestyle despite its benefit on both health outcomes and quality of life [3-5].

Multiple meta-analyses have demonstrated overall success of mobile-based (mHealth) interventions with text messaging for glucose self-monitoring and glycemic control while results for long-term physical activity improvement among those with T2DM have been mixed [6-8]. However, mHealth is viewed as a promising intervention platform given the ubiquity of cell phones with texting and Internet access capabilities including among racial and ethnic groups and those with low socioeconomic status [9-11]. In fact, a 2015 Pew Research Center survey found that 92% of adults in the United States own a cell phone [12]. Importantly, mobile technologies can be tailored to an individual's health behavior needs thus increasing the likelihood of initiating and maintaining lifestyle change [6]. Furthermore, text message-based studies have been shown to be a low-cost and feasible method of conveying health information because message banks can be predesigned and automatically sent to individuals on a set schedule. Studies have employed text messages for education, reminders, and motivational messaging that can serve as "cues to action," aiming to improve glucose monitoring, self-care behaviors, appointment attendance, and medication adherence [6,13-17]. The Text to Move (TTM) program was a 2-parallel group randomized controlled trial that recruited participants with T2DM from health centers affiliated with a large academic center [18]. All individuals in the study were given an ActiPed+ pedometer—a small, wireless activity sensor—that recorded daily step count, distance traveled, calories burned, and activity time. Daily step counts were uploaded either manually or automatically (via Bluetooth wireless technology) onto a Web-based portal. The per subject, per month cost of TTM was approximately US $30.

Participants in the intervention arm were sent two messages a day for a 6-month period. An interdisciplinary team of physicians and health researchers created a bank of over 1000 text messages; subsequently, a behavioral psychologist grouped messages into the stages of behavior change specified by the transtheoretical model of behavior change [19,20]. The Transtheoretical Model states that behavior change is a nonlinear and dynamic process that involves 6 stages: precontemplation, contemplation, preparation, action, maintenance, and termination [21]. Participants' stage of change was measured at enrollment and reevaluated every month, dictating the content of text messages sent. The messages were designed to provide bite-sized (160-character length) coaching based on daily step count, captured by pedometers, and preset physical activity goals that were agreed upon at the initial visit. The messages aimed to provide support, health education, motivation, and reminders to promote healthy behaviors. The text messages were designed at a 3rd grade reading level and were provided in English or Spanish, according to participant preference. Finally, to optimize engagement, two messages per week were question-based and required a simple response from participants. The TTM study design was first tested for participant acceptance in a 3-week feasibility study with 20 individuals [22].

Purpose of the Study

Behavioral interventions should be theory-driven and take into account a participant's beliefs, preferences, readiness for change, and perceived risks and benefits. Currently, there is a paucity of published studies that assess participants' experiences with text messaging interventions, hindering the development of successful, patient-centered programs. The purpose of this study was to collect participants' feedback from the TTM program in order to ascertain the facilitators and barriers to participant engagement. In addition, we inquired about (1) overall satisfaction and perceived effect of participating in the TTM program, (2) knowledge of and barriers to physical activity, (3) perception of text message frequency, content, style, and impact of texts on physical activity, (4) effect of wearing a pedometer, and (5) barriers to intervention efficacy.

Methods

Recruitment

The study was approved by the Institutional Review Board for the Massachusetts General Hospital and registered at clinicaltrials.gov/ct2/show/NCT01569243. A total of 98 individuals completed the TTM study of which 46 were assigned to the intervention arm and were contacted for poststudy interviews 6 months to 1 year after the study concluded.

Study Procedures

All English-speaking TTM intervention participants were asked to participate in one of two focus groups held at two health care centers where participants were originally recruited. These focus groups spanned 90 min, were conducted in English and employed an in-depth, semi-structured guide (see Multimedia

Appendix 1). Participants were compensated US $40 for attending.

If an individual did not attend a focus group or was Spanish-speaking, they were contacted for a telephone interview. Interviews were conducted either in English or Spanish by one of two trained researchers using an adapted questionnaire from the focus groups (see Multimedia Appendix 2) to facilitate telephone engagement. Interviews lasted at most 45 min and participants received US $25. The interview guide was professionally translated to Spanish and reviewed for accuracy by two native Spanish speakers. Saturation was reached when members of the study team determined participant responses were reoccurring and no new insights or information was being gathered [23,24].

Data Analysis

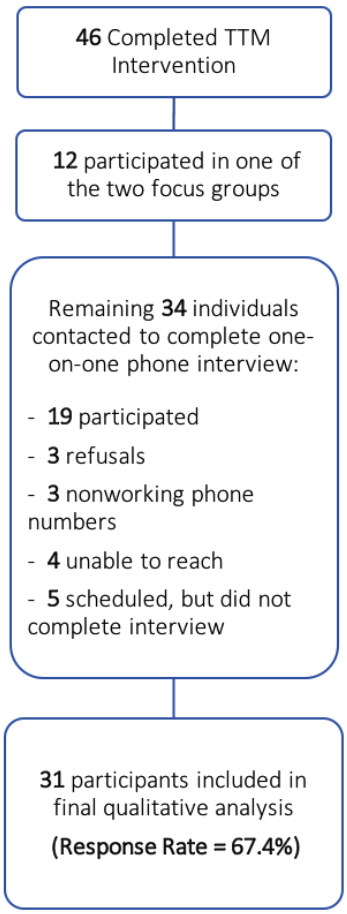
All interviews and focus group sessions were audiorecorded, professionally transcribed verbatim, and then reviewed by team members for accuracy and completeness. Transcripts were analyzed with NVivo 9 (QSR International Pty Ltd, Version 9.2.81.0, 2010). A grounded theory approach was used in data analysis, beginning with two researchers reading three transcripts and identifying main themes [25]. Three additional transcripts were chosen based on richness of text, and four team members read through each transcript, modifying the codes, proposing subthemes, and drawing connections between codes. All four researchers conferred and discussed disagreements with our application of codes, ultimately finalizing a thematic framework through consensus. Using this framework, two researchers double-coded two additional transcripts and compared our results to ensure high intercoder reliability. In asking the same questions in the one-on-one interviews and focus groups, the content was comparable although it was not possible to quantify our results [25].

Results

Participation

Figure 1 shows the recruitment of the 46 participants from the TTM intervention arm to attend a focus group or complete a phone interview 6 months to 1 year after the study concluded. For the focus groups, 38 English speakers were invited, 14 agreed to participate, and 12 individuals attended (7 in the first focus group and 5 in the second). Of the remaining 34 individuals who did not partake in a focus group, 24 agreed to participate in a phone interview and were scheduled, 19 individuals participated, and 4 were conducted in Spanish. In total, 31 of the 46 individuals who completed the TTM intervention participated in either a focus group (n=12) or a one-on-one interview (n=19), yielding an overall response rate of 67% (31/46 participants).

Figure 1. Recruitment of participants from Text to Move (TTM) intervention arm.



Participant Characteristics

Of the 31 participants, 19 were male, and the average age was 51.4 years (see Multimedia Appendix 3 for full demographics table). The majority of individuals were married and English speakers, had completed at least 12th grade or attained a General Education Development (GED; ie, high school equivalency diploma). Approximately half of all participants were employed full-time. Compared with individuals who did not participate, participants in postintervention follow-up sessions were not significantly different in demographic characteristics.

Thematic Analysis

On the basis of English and Spanish interviews, four domains emerged from our analysis: (1) effect of study participation, (2) effect of wearing the pedometer, (3) effect of text messages, and (4) barriers to intervention efficacy. The following are select quotes in conjunction with Textboxes 1-4.

Textbox 1. Domain 1: themes and subthemes with associated quotes.

Effect of participating in Text to Move (TTM)

Increase in daily disease awareness

- *Diabetes is an everyday part of my life. Insulin, pills, of course exercise. I thought (TTM) was awesome, actually. It kind of reminded me every time I got a text.*

Program integrated into daily life

- *I mean, first describing it, it seems like, "Oh this may be a pain," but once it's just like everything else, once you implement it into your lifestyle it becomes second nature and it really wasn't that bad.*

Connections arising from participation

- Increased connection and sense of support from health care team
  - *I did try to do the best that I could, so that the research could open up more doors or more windows to people to get the job done the right way, to help out others.*
  - *For me, (the program) did matter because it means that I was doing something that people were putting the time and money into it. Because even if it would have been that I didn't get anything back, any positive feedback or a reminder, I would have been out. They don't care. So if they don't care, why should I care? But just by receiving those text messages on a daily basis and just seeing on the computer how good I was doing, it just kept giving more encouragement for me to do the right stuff.*
- Ambivalence or no change in connection nor sense of support from the health care team
  - *I wanted to believe that there was actually a person who gave a crap about what my data said. It didn't feel that way.*

Textbox 2. Domain 2: themes and subthemes with associated quotes.

Effect of wearing the pedometer and receiving texts on daily step count

Motivational through viewing step count and related texts

- *I'm very much like you where I need that instant—like I need it right now to show me. So with that (pedometer), when I would go home and see the numbers, that would motivate me, when I saw how close I was...I'd go outside at 11:40 (pm) because I knew I had 20 minutes.*
- *I was challenging myself to do better and to go farther than previous...I knew what I did the day before and was like, "How do I challenge myself to go a little bit farther, to push myself a little bit hard today?"*
- *It was very great to have it working correctly, and synchronized (to the) computer, and you could have the graph to see if you were up by a little, you know, how it worked, or your level, you know, how you were doing. A lot of people are visual. So when you see that visual in front of you, it's very powerful.*

Sentinel effect from using the pedometer and receiving step count information

- *I'd feel guilty if I didn't reach my goal everyday...I felt bad, like I'm not doing my homework.*
- *It made me feel motivated...I would (exercise) because I was afraid they were going to say, "Hey! Get off that sofa!"*

Evangelizing new technology to others not involved in study

- *I told all my friends actually, everybody was asking me, "What's that in your shoes?" Because I put it in my shoes, and I told them that's to make me move (chuckles).*

Textbox 3. Domain 3: themes and subthemes with associated quotes.

Effect of text messages

Text messages as daily reminders

- *I never expected that it was a live person behind. I knew it was kind of like, this is six o'clock. I'm going to get the message, whether it's the same one that I had before. I just knew it was like a tool and a reminder. I did find it like a reminder.*

Text messages as informational or useful for idea generation for increasing physical activity

- *There were some times that, let's say I didn't walk. They would be like, "Try to do this type of exercise"...They would give me an example of what other exercises I could have done or stuff like that. So it opens up your mind to see what other things you can do.*

Textbox 4. Domain 4: themes and subthemes with associated quotes.

Barriers to Text to Move (TTM) intervention efficacy

- Technical issues
- Personal reasons
  - Lack of investment in the study
  - Comorbidities or physical pain prevented exercise
  - Environmental factors
    - *It would have been nice, like if it was raining out, we're all in the same area, "Even though it's raining out, you can still get active."*
- Dislike of automation of text messages
  - Text messages were too repetitive and predictable
    - *I can tell that they were a can of limited messages that were repeating over and over again. It seemed like it was coming out and it was automated, almost like an alarm clock, that would give you a text. I would almost expect it.*
  - Inability to control text frequency
  - Lack of personalization
    - *The text messages, I thought, were too generic. I thought that they should be specifically more to your accomplishments, and not just the general daily thoughts of the people that are programming it.*
    - *(The messages) should specifically target that individual...relating to what you are achieving, or what you're trying to achieve.*
  - Lack of interactivity of text messages
    - *You should be able to voice your opinion, which you can't answer them back when they send you a message. That they should let you do.*
- Limited knowledge of recommended physical activity

Domain 1: Effect of Study Participation

Theme: Increase in Daily Diabetes Awareness

Overall, most respondents reported that participation increased awareness of the daily presence of diabetes in their lives and of their current levels of physical activity.

Theme: Program Integrated into Daily Life

Many participants explained that once they grew accustomed to wearing the pedometer and began to anticipate text messages, the program was incorporated into their daily routine.

Theme: Connections Arising From Participation

Increased Connection and Sense of Support From Health Care Team

Several participants exhibited high relationality within the TTM program, noting that their involvement made them feel as if "someone cared." A focus group participant explained, "It felt like, yea, someone cares what I did today. Even though I have great support from my family, it's my private, personal, little cheerleader." Other respondents relayed feelings of "being a part of a team" during participation in the TTM study.

Furthermore, when asked if and how the program altered participants' views of their clinician or health care center, many described developing a more positive outlook. In fact, approximately one-third of participants reported that it was their

physician who introduced them to the program and encouraged them to enroll. One individual recollected, "If (doctors) mention it to (patients) in the right way, like my doctor did, you'd want to get involved. I believe my doctor's the one who really made me feel comfortable about it."

Ambivalence or No Change in Connection Nor Sense of Support From Health Care Team

Almost half of the participants demonstrated low relationality during the program. In other words, many felt that their involvement in the TTM program was arbitrary and they did not believe that anyone was monitoring their progress. When asked who they perceived to be sending the text messages, a quarter of respondents had no opinion of the sender. They expressed ambivalence when asked how the program impacted their view of their health care center or physician, stating that their health care provider was not aware of their involvement.

Domain 2: Effect of Wearing the Pedometer and Receiving Texts on Daily Step Count

Theme: Motivation Through Viewing Pedometer Step Count and Related Texts

For over half of participants, the pedometer proved to be a motivating tool, as step count was perceived as a tangible and realistic target. One female described, "...I would see my numbers and I'm like, 'I'm so close to this goal.' I would go out in my backyard and just walk in circles just to get to that next level."

Specifically, "seeing the numbers" represented a goal that participants could attain. Many participants described that knowing the previous day's step count provided a measure that could be reached or surpassed the following day. The Web-based portal was generally viewed favorably, as several participants noted that it was helpful to track progress longitudinally and observe patterns of physical activity.

Theme: Sentinel Effect From Using the Pedometer and Receiving Step Count Information

Over half of participants explained that they felt their performance in the TTM program was being monitored closely and thus they felt motivated to improve their levels of physical activity. This awareness of being monitored and the subsequent adjustment of behavior is known as the "sentinel effect." For instance, one individual stated, "The majority of the time I was physically active because I knew I was being monitored, and I was trying to challenge myself."

Theme: Evangelizing New Technology to Others Not Involved in Study

A few individuals were very enthusiastic about sharing the technology with family, friends, and colleagues.

Domain 3: Effect of Receiving the Text Messages

Theme: Text Messages as Daily Reminders

Most participants regarded the text messages as daily reminders about physical activity or a diabetes self-care behavior. This perception of the text messages as a functional tool, rather than a source of motivational or educational information, was very common. For example, a participant described, "It reminded me about taking my medication, it reminded me, 'Yeah, I need to get up and go exercise.' I always thought it would be good for quitting smoking, too."

Theme: Text Messages as Informational and Useful for Idea Generation for Increasing Physical Activity

A few individuals recalled that the texts provided helpful hints on ways to increase physical activity. One participant recounted, "Instead of parking right next to the door at my work, I parked at the very end of the parking lot and walked. It was one of these things, those little reminders, 'don't park so close to your work,' 'don't park so close to the mall entrance,' 'park farther away,' and get in a few more minutes of walking a day."

Domain 4: Barriers to Text to Move (TTM) Intervention Efficacy

Theme: Technical Issues

The most common complaint with the TTM program was malfunctioning of the pedometer or computer software, which led to illogical text messages being sent to participants. Technological issues were a source of frustration with a quarter of respondents. Two participants reported having trouble using their phone keypads to write a text, preventing a response to question-based messages.

Theme: Personal Reasons

Lack of Investment in the Study

Individuals often cited reluctance toward physical activity or diabetes self-management as reasons why TTM was not effective. For instance, a couple of participants revealed that they were not emotionally invested in the program. In discussing the text messages, one man said, "They weren't supportive—they probably would have been supportive if I was willing to do stuff."

Comorbidities or Physical Pain Prevented Exercise

About half of respondents explained that comorbidities or pain prevented physical activity. A few participants wished the text messages had taken into account the physical challenge associated with the transition period between a sedentary and active lifestyle. For example, "I kind of ignored (the text messages) because if I was hurting I would do nothing. I would just not pay attention to it."

Environmental Factors

Many individuals reported that there were external factors inhibiting physical activity such as inclement weather, time constraints, or exhaustion from daily work requirements.

Theme: Dislike of Automation of Text Messages

Text Messages Were Too Repetitive and Predictable

Many participants divulged that the text messaging component became predictable, monotonous, and toward the end of the program they would ignore the texts. One male respondent elaborated, "When they're repetitive, they were nagging because it's like, 'I already read this, I need something new'... it's kind of sad, but at the end of it, it was like really annoying."

Inability to Control Text Frequency

A few participants reported that they became weary of the unchanging frequency and timing of the text messages. Although over half of respondents "felt fine" with the number of the texts messages, a few said that there were too many. Several participants expressed interest in controlling the amount and timing of the messages that they received.

Important to note, whereas a few participants were dissuaded by the automation of the program, others did not mind the consistency of the text messaging system. One man stated, "To me it didn't matter, because when you get a text message it's so impersonal that it doesn't matter who it comes from, where it comes from. As long as it says the right thing." In discussing the amount and regularity of the text messages, one man explained, "I would say no, not annoyed. I like the word 'nagging' better. It was like motherly love."

Lack of Personalization of Text Messages

There was frustration with the lack of personalization of the text messages. Several participants stated that they would be more likely to read the texts if they contained information specific to their health goals or progress. In addition to addressing activity goals, many participants agreed that they would like the text messages to include a personal touch, such as their name.

Lack of Interactivity of Text Messages

The lack of interactivity associated with the text messaging system was another source of dissatisfaction, participants often asserting, "there was no way you can respond."

Theme: Limited Knowledge of Recommended Physical Activity

There was a lack of differentiation between physical activity and exercise. When probed during the one-on-one interview, only 4 participants identified the two as separate constructs. When questioned about the recommended level of physical activity for individuals with T2DM, approximately half of individuals said that they were not aware of the guidelines. A few respondents said that they received information on appropriate activity levels from their physician, whereas others said that they knew that physical activity was important, although they were not sure how much was necessary. When asked the most frequent form of physical activity that they partake in, half of participants replied, "walking," whereas one-third of respondents answered, "use of equipment or weights."

Discussion

Principal Findings

This study reports the perspectives of participants who completed a texting-based physical activity program for individuals with T2DM. TTM was a unique program for three significant reasons: (1) it combined pedometer and text-message components, (2) the text messages were developed based on the transtheoretical model of behavior change, and (3) participants could move between stages of change according to pedometer activity input. There was general participant satisfaction with the program, with over 90% of respondents agreeing that they would recommend the TTM program to a friend with some participants evangelizing the pedometer and TTM to others not involved in study. Yet, several themes reveal sources of frustration among study participants, including a lack of control over program intensity, impersonalization of text messages, and limited feedback from study coordinators. At the same time, we found that participants' views on TTM were impacted both by social influences and personal reasons.

To start, participants varied in their preferences for program intensity stating that they wanted more control over texting frequency. Our finding is consistent with the variable-ratio schedule operant conditioning phenomenon in which a schedule of behavioral learning reinforcement is accomplished through an unpredictable sequence of communication or rewards. This schedule creates a steady and high rate of behavior change compared with a fixed schedule that was used in TTM [26]. Other studies have allowed participants to control the frequency and timing of text messages [6,27]. One texting-based weight loss program was designed to automatically reduce the number of text messages sent to a participant if their response rate was declining, aiming to minimize annoyance [28]. Texting-based interventions should utilize the variable-ratio schedule or permit greater participant autonomy in regulating text frequency in order to reduce texting fatigue and increase the likelihood of engagement.

In addition to the frequency pattern of messages, meta-analyses of technology-based studies suggest that personalization of message content can lead to higher participant retention and engagement [6,7]. Our results corroborate these findings. Tailoring encompasses three domains: personalization, feedback, and content matching (identifying determinants of a given behavior that an individual must focus on to achieve that behavioral outcome [29]). In content matching, potential barriers to physical activity could be identified at enrollment and text content adjusted to incorporate tailored solutions [30,31]. In addition, teaching problem solving techniques has been shown to be an essential component of behavior interventions and could be easily integrated into mHealth programs [29] enhancing participants' self-efficacy and empowerment for long-term behavioral change [32]. TTM respondents recommended that messages could incorporate not only name and gender, but also the participant's behavioral preferences and goals, perceived barriers, previous text responses, and medical status. Through personalizing text messages, participants could feel "coached" as opposed to "hassled," potentially increasing their attention to messages. Importantly, the feasibility of personalization has been demonstrated in several texting-based studies that rely on low-cost computer programming to formulate messages [32,33].

Immediate feedback is also considered a cornerstone of a tailored invention as it is used to validate and encourage participants' progress [34-36]. TTM was characterized by mostly unidirectional, computer-generated communication that many participants found exasperating. However, other participants reported increased connections arising from participation and were very pleased with the program's design. Evidence of high relationality included perceived programmatic or clinical support, being "a part of a team" and the "sentinel effect" (ie,

the tendency for performance to improve when participants become aware that their behavior is being evaluated and believe that meaningful consequences could follow). Our results suggest that through amplifying the "human component" via interactivity, the monotony of automated messaging, often necessary due to feasibility and cost restrictions, could perhaps be overcome. For example, CareSmarts, a successful diabetes behavioral modification intervention, combined computer-generated text messaging with remote nursing support [27]. The interactive nature of the text messages allowed for immediate nurse follow-up if a health problem arose. Although we were unable to correlate relationality with outcomes, previous studies link participant awareness of "someone on the other end" to greater participant activation, retention, higher self-efficacy (ie, an individual's belief that a behavior-specific goal can be achieved), and greater physical improvements, including a larger reduction in HbA1c (glycated hemoglobin) [7,27,35,37-39]. It is important to consider that requiring a response from participants may entail a higher level of mobile phone proficiency. At the same time, expanding the role of program staff may increase social support and subsequently improve diabetes self-management [40]. There is limited evidence that text messages are a sufficient stand-alone tool to engage patients in long-term, complex behavioral change and our findings highlight the value of maintaining human interaction in a technology-based program [41].

Identified themes pertaining to preference for increased relationality align with the unified theory of acceptance and use of technology (UTAUT), which outlines several factors influencing technology adoption: effort expectancy (perceived ease of use of the technology); performance expectancy (perceived usefulness of the technology); and social influences (perceived expectations from others regarding one's personal use of the technology [42]). Effort expectancy is essential to technology adoption and future studies will need to offer varying degrees of continual technical support. Problems with technology was the most frequent complaint among participants and perhaps contributed to disengagement with the program. Our analysis also revealed that performance expectancy and social influence shaped participants' perceptions of the TTM program, particularly if they felt connected to their health care provider and clinic. Prior studies have found that participation over time in mHealth interventions can be improved through regular reminders from clinicians and that there is a patient preference for occasional in-person interaction with physicians [43,44]. mHealth interventions should underscore perceived support from clinical team members and further investigate optimal contact intensity for program success. This is critical when considering the importance of end-user satisfaction in increasing long-term success [45].

Finally, it is important to recognize that T2DM is a multifaceted condition affected by a range of behavioral and physiological processes. The theme describing text messages as reminders, which while useful to many, reveals that TTM may have been too narrow in scope to promote long-term behavioral change. Unlike interventions aimed at achieving smoking cessation or hand washing, programs that seek to increase physical activity levels may require a more comprehensive approach [46,47]. Several texting-based studies that address physical activity along with supplemental behaviors such as diet, tobacco use, and diabetes self-care activities, have demonstrated greater health outcomes and lower attrition rates [48,49]. Other studies involving individuals with T2DM have successfully integrated a glucometer with a mobile device to monitor blood glucose levels [45,50]. There are several behaviors implicated in T2DM outcomes and interventions should reflect this complexity. Prior non-mHealth physical activity behavioral interventions have included additional features that may be of use in mHealth-based studies: (1) goal setting; (2) behavioral contracting; and (3) adjustable physical activity goals that are personalized to a participant's stage of change [49].

Limitations

Despite study strengths, our results should be interpreted with the following limitations. First, interviews were conducted half a year to one year following closeout of the 6-month TTM program. Therefore, recall and social desirability biases may have impacted participant responses to be more favorable than if collected during or immediately after the intervention. However, we are reassured that the data collected during focus groups and one-on-one interviews, though spaced months apart, revealed common themes. Finally, our results may not be generalizable to other settings because our participants were recruited from community health centers aligned within a large, urban academic health center in Massachusetts. Participants were mostly English-speaking and had high levels of educational attainment and employment.

Comparison With Prior Work

Texting-based interventions have the potential to improve diabetes self-management and enhance physical activity in individuals with type 2 diabetes. Future studies should prioritize participant involvement and input in the design of texting features [51]. In addition, enhancing the human connection, via in-person or telephone contact, while also providing personal feedback and problem solving guidance may increase program efficacy, as participants are made to feel accountable and supported during the study. Finally, including supplemental health behaviors in the content of text messages, such as diet and medication adherence, may aid in participant engagement.

Conclusions

Although text messaging represents a scalable and cost-effective method of facilitating communication between patients and their health care team [52], our results suggest that texting should not substitute, but rather supplement clinical support. In all, twice-daily text messages paired with a pedometer device were generally accepted as congruous tools to motivate and monitor physical activity for individuals with type 2 diabetes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Guide for focus group discussions.

[PDF File (Adobe PDF File), 30KB - mhealth_v5i4e54_app1.pdf]

Multimedia Appendix 2

Guide for one-on-one exit interviews.

[PDF File (Adobe PDF File), 48KB - mhealth_v5i4e54_app2.pdf]

Multimedia Appendix 3

Characteristics of participants versus nonparticipants in post-intervention interviews.

[PDF File (Adobe PDF File), 32KB - mhealth_v5i4e54_app3.pdf]

References

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States. Atlanta, GA: US Department of Health and Human Services; 2014.
2. American Diabetes Association. (4) Foundations of care: education, nutrition, physical activity, smoking cessation, psychosocial care, and immunization. Diabetes Care 2015 Jan;38 Suppl:S20-S30. [doi: 10.2337/dc15-S007] [Medline: 25537702]
3. Zhao G, Ford ES, Li C, Mokdad AH. Compliance with physical activity recommendations in US adults with diabetes. Diabet Med 2008 Feb;25(2):221-227. [doi: 10.1111/j.1464-5491.2007.02332.x] [Medline: 18201213]
4. Hayes C, Kriska A. Role of physical activity in diabetes management and prevention. J Am Diet Assoc 2008 Apr;108(4):S19-S23. [doi: 10.1016/j.jada.2008.01.016]
5. Anokye NK, Trueman P, Green C, Pavey TG, Taylor RS. Physical activity and health related quality of life. BMC Public Health 2012 Aug 7;12(1):624. [doi: 10.1186/1471-2458-12-624]
6. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. Epidemiol Rev 2010;32:56-69 [FREE Full text] [doi: 10.1093/epirev/mxq004] [Medline: 20354039]
7. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. Am J Prev Med 2009 Feb;36(2):165-173. [doi: 10.1016/j.amepre.2008.09.040] [Medline: 19135907]
8. Hall AK, Cole-Lewis H, Bernhardt JM. Mobile text messaging for health: a systematic review of reviews. Annu Rev Public Health 2015 Mar 18;36:393-415 [FREE Full text] [doi: 10.1146/annurev-publhealth-031914-122855] [Medline: 25785892]
9. Albright CL, Pruitt L, Castro C, Gonzalez A, Woo S, King AC. Modifying physical activity in a multiethnic sample of low-income women: one-year results from the IMPACT (Increasing Motivation for Physical ACTivity) project. Ann Behav Med 2005 Dec;30(3):191-200. [doi: 10.1207/s15324796abm3003_3] [Medline: 16336070]
10. Price M, Williamson D, McCandless R, Mueller M, Gregoski M, Brunner-Jackson B, et al. Hispanic migrant farm workers' attitudes toward mobile phone-based telehealth for management of chronic health conditions. J Med Internet Res 2013;15(4):e76 [FREE Full text] [doi: 10.2196/jmir.2500] [Medline: 23624105]
11. Anderson M. Pew Research Center. 2015 Oct 29. The demographics of device ownership URL: http://www.pewinternet.org/data-trend/mobile/cell-phone-and-smartphone-ownership-demographics/ [accessed 2016-12-28] [WebCite Cache ID 6n6IlNAw1]
12. Anderson M. Pew Research Center. 2015 Oct 29. Technology Device Ownership: 2015 URL: http://www.pewinternet.org/2015/10/29/technology-device-ownership-2015/ [accessed 2016-12-25] [WebCite Cache ID 6n6IvMNYY]
13. Fry JP, Neff RA. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. J Med Internet Res 2009;11(2):e16 [FREE Full text] [doi: 10.2196/jmir.1138] [Medline: 19632970]
14. Krishna S, Boren SA, Balas EA. Healthcare via cell phones: a systematic review. Telemed J E Health 2009 Apr;15(3):231-240. [doi: 10.1089/tmj.2008.0099] [Medline: 19382860]

15. Kreps GL, Neuhauser L. New directions in eHealth communication: opportunities and challenges. Patient Educ Couns 2010 Mar;78(3):329-336. [doi: 10.1016/j.pec.2010.01.013] [Medline: 20202779]
16. Guy R, Hocking J, Wand H, Stott S, Ali H, Kaldor J. How effective are short message service reminders at increasing clinic attendance? a meta-analysis and systematic review. Health Serv Res 2012 Apr;47(2):614-632 [FREE Full text] [doi: 10.1111/j.1475-6773.2011.01342.x] [Medline: 22091980]
17. Car J, Gurol-Urganci I, de Jongh T, Vodopivec-Jamsek V, Atun R. Mobile phone messaging reminders for attendance at healthcare appointments. Cochrane Database Syst Rev 2012;7:CD007458. [doi: 10.1002/14651858.CD007458.pub2] [Medline: 22786507]
18. Agboola S, Jethwani K, Lopez L, Searl M, O'Keefe S, Kvedar J. Text to move: a randomized controlled trial of a text-messaging program to improve physical activity behaviors in patients with type 2 diabetes mellitus. J Med Internet Res 2016 Nov 18;18(11):e307 [FREE Full text] [doi: 10.2196/jmir.6439] [Medline: 27864165]
19. Prochaska JO, DiClemente CC. The transtheoretical approach: crossing traditional boundaries of therapy. Homewood, IL: Dow Jones-Irwin; 1984.
20. Prochaska JO, Marcus BH. The transtheoretical model: applications to exercise. In: Dishman RK, editor. Advances in exercise adherence. Champaign, Ill: Human Kinetics Publishers; 1994:161-180.
21. Glanz K, Rimer BK. Theory at a glance: a guide for health promotion practice. Washington D.C: National Cancer Institute, National Institutes of Health, Public Health Service, U.S. Dept of Health and Human Services; 1997.
22. Agboola S, Lopez L, O'Keefe S, Kvedar J, Jethwani K. Text to Move randomized controlled trial of personalized text messaging to improve physical activity in a diverse patient population with type 2 diabetes mellitus. Journal MTM 2013 Dec;2(4S):8-8. [doi: 10.7309/jmtm.2.4S.6]
23. Strauss A, Corbin J. Basics of qualitative research: grounded theory procedures and techniques. Newbury Park, Calif: SAGE Publications; 1990.
24. Guest G. How many interviews are enough?: an experiment with data saturation and variability. Field methods 2006 Feb 01;18(1):59-82. [doi: 10.1177/1525822X05279903]
25. Michell L. Combining focus groups and interviews: telling how it is; telling how it feels. In: Barbour RS, Kitzinger J, editors. Developing focus group research: Politics, theory, and practice. London: SAGE Publications Ltd; 1999:36-46.
26. Miltenberger RG. Chapter 4: Reinforcement. In: Behavior Modification: Principles and Procedures, 5th Edition. Belmont, CA: Wadsworth Publishing; 2012:61-86.
27. Nundy S, Mishra A, Hogan P, Lee SM, Solomon MC, Peek ME. How do mobile phone diabetes programs drive behavior change? Evidence from a mixed methods observational cohort study. Diabetes Educ 2014;40(6):806-819 [FREE Full text] [doi: 10.1177/0145721714551992] [Medline: 25278512]
28. Patrick K, Raab F, Adams MA, Dillon L, Zabinski M, Rock CL, et al. A text message-based intervention for weight loss: randomized controlled trial. J Med Internet Res 2009;11(1):e1 [FREE Full text] [doi: 10.2196/jmir.1100] [Medline: 19141433]
29. Hawkins RP, Kreuter M, Resnicow K, Fishbein M, Dijkstra A. Understanding tailoring in communicating about health. Health Educ Res 2008 Jun;23(3):454-466 [FREE Full text] [doi: 10.1093/her/cyn004] [Medline: 18349033]
30. Hurling R, Catt M, Boni MD, Fairley BW, Hurst T, Murray P, et al. Using internet and mobile phone technology to deliver an automated physical activity program: randomized controlled trial. J Med Internet Res 2007;9(2):e7 [FREE Full text] [doi: 10.2196/jmir.9.2.e7] [Medline: 17478409]
31. Dubé M, Valois P, Prud'homme D, Weisnagel SJ, Lavoie C. Physical activity barriers in diabetes: development and validation of a new scale. Diabetes Res Clin Pract 2006 Apr;72(1):20-27. [doi: 10.1016/j.diabres.2005.08.008] [Medline: 16256239]
32. Venkatesh V, Brown SA, Maruping LM, Bala H. Predicting different conceptualizations of system use: the competing roles of behavioral intention, facilitating conditions, and behavioral expectations. MIS Quart 2008;32(3):483-502.
33. Bauer S, de Niet J, Timman R, Kordy H. Enhancement of care through self-monitoring and tailored feedback via text messaging and their use in the treatment of childhood overweight. Patient Educ Couns 2010 Jun;79(3):315-319. [doi: 10.1016/j.pec.2010.03.014] [Medline: 20418046]
34. Tudor-Locke C, Lutes L. Why do pedometers work?: a reflection upon the factors related to successfully increasing physical activity. Sports Med 2009;39(12):981-993. [doi: 10.2165/11319600-000000000-00000] [Medline: 19902981]
35. Fischer HH, Moore SL, Ginosar D, Davidson AJ, Rice-Peterson CM, Durfee MJ, et al. Care by cell phone: text messaging for chronic disease management. Am J Manag Care 2012 Feb;18(2):e42-e47 [FREE Full text] [Medline: 22435883]
36. Fukuoka Y, Lindgren T, Jong S. Qualitative exploration of the acceptability of a mobile phone and pedometer-based physical activity program in a diverse sample of sedentary women. Public Health Nurs 2012;29(3):232-240 [FREE Full text] [doi: 10.1111/j.1525-1446.2011.00997.x] [Medline: 22512424]
37. Quinn CC, Shardell MD, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care 2011 Sep;34(9):1934-1942 [FREE Full text] [doi: 10.2337/dc11-0366] [Medline: 21788632]
38. Cleveringa FG, Gorter KJ, van den Donk M, van Gijsel J, Rutten GE. Computerized decision support systems in primary care for type 2 diabetes patients only improve patients' outcomes when combined with feedback on performance and case

management: a systematic review. Diabetes Technol Ther 2013 Feb;15(2):180-192. [doi: 10.1089/dia.2012.0201] [Medline: 23360424]
39. Saffari M, Ghanizadeh G, Koenig HG. Health education via mobile text messaging for glycemic control in adults with type 2 diabetes: a systematic review and meta-analysis. Prim Care Diabetes 2014 Dec;8(4):275-285. [doi: 10.1016/j.pcd.2014.03.004] [Medline: 24793589]
40. Garay-Sevilla ME, Nava LE, Malacara JM, Huerta R, Díaz de León J, Mena A, et al. Adherence to treatment and social support in patients with non-insulin dependent diabetes mellitus. J Diabetes Complications 1995;9(2):81-86. [Medline: 7599352]
41. Fanning J, Mullen SP, McAuley E. Increasing physical activity with mobile devices: a meta-analysis. J Med Internet Res 2012;14(6):e161 [FREE Full text] [doi: 10.2196/jmir.2171] [Medline: 23171838]
42. Venkatesh V, Morris MG, Davis GB, Davis FD. User acceptance of information technology: toward a unified view. MIS Quart 2003;27(3):425-478.
43. Gerber BS, Solomon MC, Shaffer TL, Quinn MT, Lipton RB. Evaluation of an internet diabetes self-management training program for adolescents and young adults. Diabetes Technol Ther 2007 Feb;9(1):60-67. [doi: 10.1089/dia.2006.0058] [Medline: 17316099]
44. Jenssen BP, Mitra N, Shah A, Wan F, Grande D. Using digital technology to engage and communicate with patients: a survey of patient attitudes. J Gen Intern Med 2016 Jan;31(1):85-92. [doi: 10.1007/s11606-015-3517-x] [Medline: 26385117]
45. El-Gayar O, Timsina P, Nawar N, Eid W. A systematic review of IT for diabetes self-management: are we there yet? Int J Med Inform 2013 Aug;82(8):637-652. [doi: 10.1016/j.ijmedinf.2013.05.006] [Medline: 23792137]
46. Adams J, White M. Why don't stage-based activity promotion interventions work? Health Educ Res 2005 Apr;20(2):237-243 [FREE Full text] [doi: 10.1093/her/cyg105] [Medline: 15253998]
47. Adams J, White M. Are activity promotion interventions based on the transtheoretical model effective? A critical review. Br J Sports Med 2003 Apr;37(2):106-114 [FREE Full text] [Medline: 12663350]
48. Chow CK, Redfern J, Hillis GS, Thakkar J, Santo K, Hackett ML, et al. Effect of lifestyle-focused text messaging on risk factor modification in patients with coronary heart disease: a randomized clinical trial. J Am Med Assoc 2015;314(12):1255-1263. [doi: 10.1001/jama.2015.10945] [Medline: 26393848]
49. Linke SE, Gallo LC, Norman GJ. Attrition and adherence rates of sustained vs. intermittent exercise interventions. Ann Behav Med 2011 Oct;42(2):197-209 [FREE Full text] [doi: 10.1007/s12160-011-9279-8] [Medline: 21604068]
50. Boulé NG, Haddad E, Kenny GP, Wells GA, Sigal RJ. Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. J Am Med Assoc 2001 Sep 12;286(10):1218-1227. [Medline: 11559268]
51. Kandula NR, Khurana NR, Makoul G, Glass S, Baker DW. A community and culture-centered approach to developing effective cardiovascular health messages. J Gen Intern Med 2012 Oct;27(10):1308-1316 [FREE Full text] [doi: 10.1007/s11606-012-2102-9] [Medline: 22584728]
52. Atun RA, Sittampalam SR. Vodafone. Berkshire, UK: Vodafone Group Plc; 2006 Mar 08. A review of the characteristics and benefits of SMS in delivering healthcare URL: https://www.vodafone.com/content/dam/vodafone/about/public_policy/policy_papers/public_policy_series_4.pdf [accessed 2017-03-30] [WebCite Cache ID 6pLwyLo5o]

Abbreviations

GED: General Education Development high school equivalency diploma
.gov: Government Web domain
HbA1c: glycated hemoglobin
mHealth: mobile-based health interventions
T2DM: type 2 diabetes mellitus
TTM: Text to Move
UTAUT: unified theory of acceptance and use of technology
www: World Wide Web

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Original Paper

Design of a Mobile App for Nutrition Education (TreC-LifeStyle) and Formative Evaluation With Families of Overweight Children

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Abstract

Background: Nutrition and diet apps represent today a popular area of mobile health (mHealth), offering the possibility of delivering behavior change (BC) interventions for healthy eating and weight management in a scalable and cost-effective way. However, if commercial apps for pediatric weight management fail to retain users because of a lack of theoretical background and evidence-based content, mHealth apps that are more evidence-based are found less engaging and popular among consumers. Approaching the apps development process from a multidisciplinary and user-centered design (UCD) perspective is likely to help overcome these limitations, raising the chances for an easier adoption and integration of nutrition education apps within primary care interventions.

Objective: The aim of this study was to describe the design and development of the TreC-LifeStyle nutrition education app and the results of a formative evaluation with families.

Methods: The design of the nutrition education intervention was based on a multidisciplinary UCD approach, involving a team of BC experts, working with 2 nutritionists and 3 pediatricians from a primary care center. The app content was derived from evidence-based knowledge founded on the Food Pyramid and Mediterranean Diet guidelines used by pediatricians in primary care. A formative evaluation of the TreC-LifeStyle app involved 6 families of overweight children (aged 7-12 years) self-reporting daily food intake of children for 6 weeks and providing feedback on the user experience with the mHealth intervention. Analysis of the app's usage patterns during the intervention and of participants' feedback informed the refinement of the app design and a tuning of the nutrition education strategies to improve user engagement and compliance with the intervention.

Results: Design sessions with the contribution of pediatricians and nutritionists helped define the nutrition education app and intervention, providing an effective human and virtual coaching approach to raise parents' awareness about children's eating behavior and lifestyle. The 6 families participating in the pilot study found the app usable and showed high compliance with the intervention over the 6 weeks, but analysis of their interaction and feedback showed the need for improving some of the app features related to the BC techniques "monitoring of the behavior" and "information provision."

Conclusions: The UCD and formative evaluation of TreC-LifeStyle show that nutrition education apps are feasible and acceptable solutions to support health promotion interventions in primary care.

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KEYWORDS

mHealth; child; overweight; pediatrics; health behavior; evaluation studies

Introduction

Background

Mobile technology has experienced impressive gains in popularity in recent years [1]. As people typically develop a strong attachment to their mobile devices and frequently keep this technology with them all the times, mobile platforms provide a critical source of information and motivation for engaging users with health interventions and behavior change (BC) [2-3]. Mobile devices increase the potential to promote healthy nutrition behaviors, and today nutrition and diet apps represent the fastest growing field of health promotion apps [4]. Mobile health (mHealth) apps for nutrition education can be suitable solutions to support parents' involvement in childhood weight management interventions provided in primary care, as this is often the families' first point of contact with the health care system [5,6]. The delivery of a primary care intervention by leveraging on digital and mobile support facilitates a higher compliance to it by the target users such as parents, who might have tight daily agendas, difficulties in tracking children's weight-related behaviors over a day per week on paper diaries, and location difficulties [7]. Also, nutrition education apps make it possible to follow up healthy eating interventions long after their completion, a time when relapses are most likely to occur, thus supporting maintenance of healthy behavior in the long-term [8].

Today, a large consensus exists in recommending the development of mHealth interventions as based on evidence, BC theory and taxonomies, as well as on formative evaluation with the target user groups [9,10]. However, still a majority of children weight management apps do not use any recommended strategies or behavioral targets [11], and a few apps specifically target parents or families, which instead play a key role in supporting children's adoption of healthy lifestyles [12,13]. Moreover, recent studies have shown that commercial mHealth apps are more engaging and better appreciated by users with respect to evidence-based mHealth apps [14], but the quality of information provided by commercial mHealth apps is often rated as quite poor [15,16]. This suggests that a thorough user-centered design (UCD) approach informed by theoretical-empirical knowledge, as well as by user engagement principles, is required today to ensure a wide adoption of the mHealth intervention provided [10,17-19].

Involving all relevant stakeholders and target users in the development of such interventions may help improve their effectiveness and acceptability [20,21]. Getting early feedback from end-user populations helps ensure quality and usefulness of content, and the involvement of stakeholders who play a role in providing care to or managing overweight children is the key to inform feasibility and usability of the solutions designed [22].

User-Centered Approach

This study describes how a UCD approach [23] founded on primary care practices and requirements was deployed for developing the TreC-LifeStyle app for nutrition education, and how the validity of the mHealth intervention designed was tested with representatives of the target user group in a formative evaluation.

Methods

mHealth Intervention Design and Development

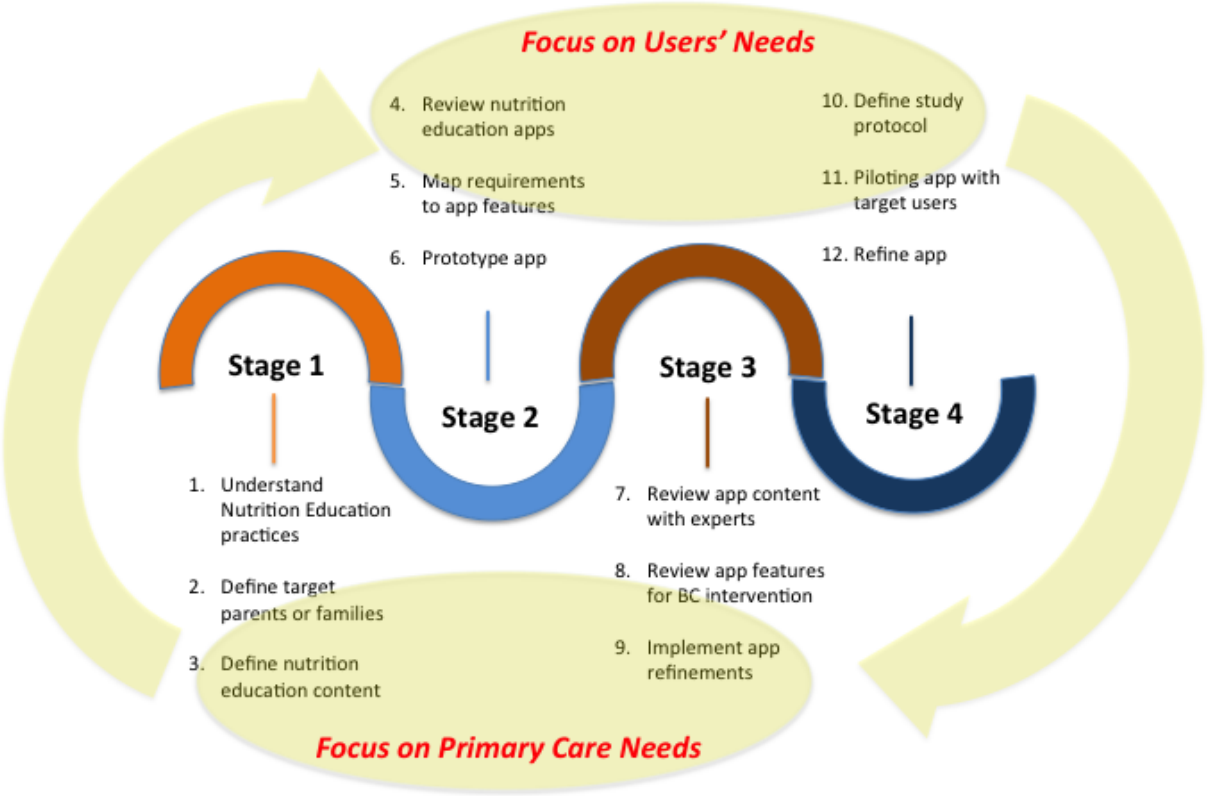
The design and development process of the TreC-LifeStyle mHealth intervention followed four main stages (Figure 1):

1. Collecting requirements from primary care professionals on nutrition education practices, guidelines, and on the typical profiles of parents or families that could most benefit from the intervention
2. Prototyping the app features based on the collected requirements and on a review of nutrition education apps already available in the market
3. Revising the prototyped features with pediatricians and nutritionists with respect to content and BC strategies
4. Deploying the intervention in a formative evaluation study with target families for further refinement of the mHealth app and intervention

In stages 1 and 3, several meetings were held in 2015 among the design team, involving experts in BC interventions, working together with 3 pediatricians and 2 nutritionists from primary care services in the Trento region (Italy). In stage 2, the design team reviewed state-of-the-art features in nutrition education apps available in the market, then mapped the requirements collected with the most appropriate BC techniques proposed by international standards and taxonomies [24]. It also developed a concept for providing the mHealth intervention in the most intuitive way, reducing as much as possible attention thefts by the app for children's food intake reporting and monitoring by parents.

In stage 4, a protocol for the formative evaluation study was prepared by the design team and then deployed for understanding usability and feasibility of the mHealth intervention with target users.

Figure 1. The design and development stages of the mHealth app intervention. BC: behavior change.



Nutrition Education Requirements

In stage 1, pediatricians helped better understand the nutrition education practices and typical interventions provided in pediatrics primary care to prevent children from being overweight [25], as well as the main obstacles met by parents and families in adopting healthy eating behaviors. A main objective for pediatricians is to teach parents how to adhere to the eating guidelines provided by the Mediterranean Diet and the Food Pyramid while educating their children on healthy nutrition and managing them. Parents of overweight or obese children aged 6-12 years often seek support from primary care services, they might be prepared to change, but often fail in putting into practice healthy eating practices. In recent years, pediatricians tend to recommend nutrition education programs based on Therapeutic Patient Education [26] rather than Dietetic Therapy [27], as prescriptive dietary approaches are often perceived as more stigmatizing of individuals' behaviors and were found less acceptable and effective in achieving BC in the short- and long-term [28]. Educational approaches avoid an exclusive focus on children's food intake calories control, but encourage parents to become more aware about their children's lifestyle, including both eating behavior and physical exercise and the complex system of emotional perceptions related to food intake. Accurate, reliable, and personalized monitoring of children's lifestyle is always a challenge during primary care intervention; mHealth apps can improve the delivery of these interventions, helping nutrition education to turn into effective BC, but they need to be enough motivating and engaging to be used by families to achieve the desired objectives.

TreC-LifeStyle App Description

As an output of stage 2, a first prototype of the mHealth app was developed based on a mapping of the requirements collected from primary care experts with nutrition education features most likely to support the desired BC effectively (Table 1).

The mobile app is part of the TreC platform used in the Trento region as a citizen-controlled clinical record system allowing users to manage their own health and facilitating communications with health care professionals and institutions [29,30].

In case of the TreC-LifeStyle solution, pediatricians can access data of their patients (child or parent) from a Web app dashboard (Figure 2) integrated into the TreC platform; they can configure the app intervention for each patient, prescribe it as a nutrition education intervention, and visualize data related to the intervention to inform follow-ups with patients. The TreC-LifeStyle prototype app was developed for Android devices only in this phase, with the plan of implementing both Android and iOS versions of the mobile app after the formative evaluation phase. To ensure confidentiality of the data acquired, the TreC-LifeStyle platform saves data in the local database of the user mobile phone device, in an anonymized format. The

anonymized data are then transferred on to a server by means of rest calls requiring security authentication of level 2 (username and password). This way, the identity of the user-participant is only known by the pediatrician who has prescribed the mHealth intervention.

The target user of the TreC-LifeStyle intervention is the child-parent–dyad in need of overweight or obesity prevention support. In order to minimize possible acceptability concerns related to young children's use (and possible abuse) of the mobile technology, the TreC-LifeStyle app is meant to be installed on the parent's mobile phone and used primarily by the parent as a supporting tool for more precise monitoring of the child's food intake and physical activity during the intervention. To ensure child engagement during the BC intervention, the child is asked to wear a bracelet (synchronized to the mobile app) for automatic tracking of daily steps to be reviewed with the parent on the TreC-LifeStyle home display and for checking the achievement of daily physical activity goals.

Table 1. Mapping of user requirements to TreC-LifeStyle app features and behavioral change techniques.

User requirements	App features	Behavioral change techniques
Time-saving, convenient, intuitive interaction	Food intake dashboard (including recommended portions and quantities), virtual coaching messages	Instruction on how to perform the behavior
Digital tracking of child's food intake over time	Colors of food categories on dashboard, reports of meals and nutrient balance	Monitoring of the behavior
Tracking of compliance with healthy nutrition guidelines	Color or blinking of food boxes on dashboard, color of nutrient bars on reports	Feedback on the behavior, prompt or cues
Automatic tracking of child's physical activity	Daily steps display	Review behavioral goal achievement
Motivation to increase physical activity	Steps label in gold	Rewarding
Memory aid for future food purchases	Shopping list	Information provision

The concept design of TreC-LifeStyle app was based on the following principles:

1. The delivery of evidence-based nutrition education content, compliant with primary care practices, supporting knowledge and adoption of the Mediterranean Diet, Food Pyramid guidelines [31-33], and at least 10 K steps of daily physical activity by children.
2. A low-burden reporting of children's food intake by parents by means of an intuitive food dashboard screen on the app (Figure 3), based on the food categories recommended by international and national guidelines on healthy nutrition [31-33], combined with monitoring, feedback, rewarding, and virtual coaching features proposed by international taxonomies of BC techniques [24].
3. Automatic tracking of children's physical exercise by means of commercial devices like Jawbone and Misfit bracelets integrated with the app's features: The number of daily steps detected from the wearable device is displayed on the home page of the mobile app, close to the display of the calories intake. When the child reaches the goal of 10 K steps per day, the steps label turns to gold to acknowledge the goal achievement.

Children's daily food intake reporting is done by parents who play a key role in children's nutrition management, by selecting food elements on the app dashboard with a few clicks (Figure 3): When correct food elements and portions are selected, the corresponding food box turns green, if food elements and portions exceed the recommended quantities, the box turns red whereas unselected food elements and portions remain gray. Gray boxes go on a blinking mode when the participants have filled in their daily food intake without including sufficient types and quantities of recommended food. This is to prompt the parent participant to align with the guidelines' indications. Colored bars in the app display also help the parent participant to achieve a better balancing of nutrients in children's meals; red bars are shown to indicate excessive quantities consumed in a meal or nutrient (eg, lipids, carbohydrates). The bars' lengths are used to indicate at a glance that different meals have different importance during a day.

Additional monitoring and feedback features (Figure 3) allow the parent participant to (1) monitor the food consumed, in a day or week, (2) visualize calories intake distributed in the principal meals and nutrients through progress bars. Based on personal food intake statistics, the virtual coaching function sends to the user daily reports summarizing deviations versus correct nutrition behavior with respect to the healthy diet guidelines. The virtual coach also sends notifications reporting guidelines for healthy diet adoption during the first 11 days of intervention (1 per day), covering basic topics relevant to nutrition education. Other more detailed information about food properties are available and can be inspected by the user on the app.

The app also provides a simple shopping list feature, allowing a parent participant to mark food to be purchased over a week, with the possibility of changing the family size (Figure 3).

During stage 3, the prototype concept and design were presented to the clinical stakeholders involved in stage 1 who revised both the app content and the BC features.

A main suggestion provided by pediatricians was to keep the overall mHealth intervention within a duration period of 6 weeks, as this is aligned with the typical brief prevention programs delivered in primary care to families to support children's weight management. Clinicians also advised to keep the food intake-reporting task on the app as simple and low demanding as possible for the participants in the initial phase

of familiarization with the mHealth intervention. Based on these suggestions, a basic version of the app (vA) was provided to participants in the first 3 weeks of the intervention, not requiring an exact specification of children's food intake, but a simple reporting of type of food and portions consumed by children. In the following 3 weeks of the intervention, the app automatically upgrades to a more advanced version (vB), where more precise quantities of food intake, dressing of food, and so on can be reported.

Figure 2. The TreC-LifeStyle mobile and Web platform.

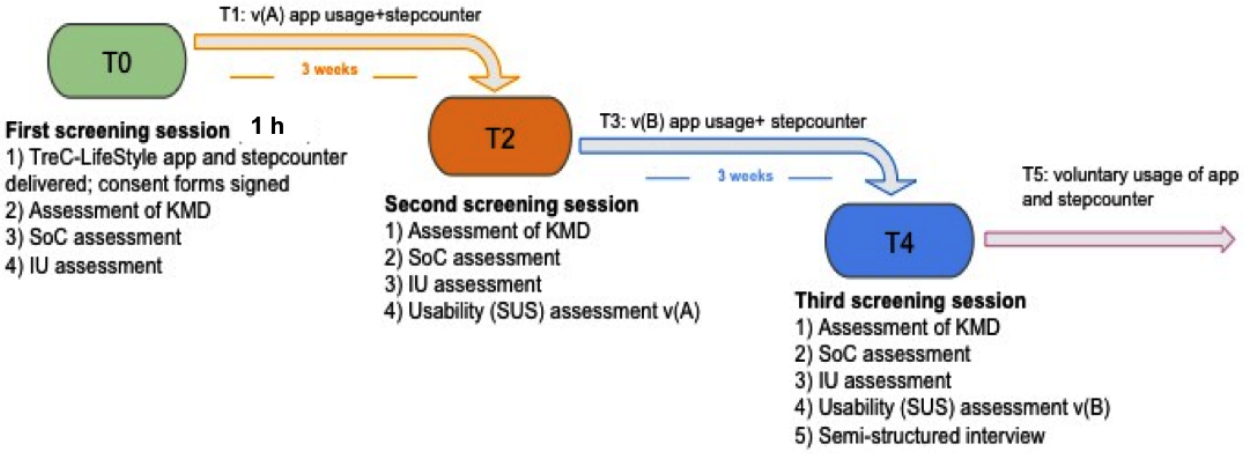
Figure 3. Screenshots of the TreC-LifeStyle app features: food-intake reporting, weekly report, and shopping list.

Formative Evaluation

In stage 4, a protocol for conducting a usability and feasibility study of TreC-LifeStyle was prepared and discussed with the clinical stakeholders to ensure alignment during the pilot. Researchers obtained ethics approval of the study protocol by their Institutional Review Board. As shown in Figure 4, the study involved 3 screening meetings with participants at the primary care offices. At the pilot start, to assess (1) parents' knowledge of the Mediterranean Diet (KMD) guidelines; (2) state of change (SoC) for healthy nutrition-measured by an adapted version of the URICA-short-form scale, based on the 4 readiness to change states of the Transtheoretical Model of Change [34,35]; and (3) intention to use (IU) technology for nutrition education, as well as to train participants on usage of the app and of the activity tracker. After 3 weeks of the app vA usage to assess any change on the screening factors and evaluate parents' perceived usability of the app (System Usability Scale Questionnaire [36]). After 6 weeks from the study start, to assess any change on the screening factors after using vB of the app

and to investigate more in depth the participants' experience with the mHealth intervention in a final semi-structured interview involving both parents and children. Participants were allowed to continue to use TreC-LifeStyle and the activity tracker for the following weeks, on a voluntary basis.

Figure 4. Protocol of the TreC-LifeStyle's formative evaluation conducted in stage 4. vA: version A; vB: version B; KMD: knowledge of the Mediterranean diet; SoC: state of change; IU: intention to use; SUS: system usability scale.



Study Participants

A convenience sample of 6 families attending a pediatric center in the Trentino area for problems related to overweight children was recruited. The group included parents with children aged 7-12 years, classified as overweight (BMI 85th-94th percentile), familiar with the use of mobile phone technology. Families with children already affected by obesity and by motor impairments limiting physical activity were excluded.

Participants were contacted and invited to join the study by phone. If they were interested in participating, an appointment for a recruitment and introduction session was made at the pediatric center. Parent participants provided written informed consent prior to their inclusion in the study.

Data Analysis

Descriptive frequency analyses were conducted on the quantitative data about the use of the TreC-LifeStyle app with respect to the prescribed intervention phases. At the qualitative level, positive, negative, and improvable aspects of the participants' experiences with the TreC-LifeStyle app versions were descriptively coded. Interviews were transcribed verbatim and participants were assigned a numerical indicator (eg, Parent 1=P1). Transcribed data were subjected to an inductive thematic analysis procedure [37], which enabled the researchers to break down the data and identify some core themes that could have relevant implication for the future refinement of the mHealth intervention. Three team members completed the analysis independently. Transcripts were read several times to identify units of meaning in the data. Units of data (quotes) were isolated and similar quotes were grouped together as themes. Data coded within each theme were compared to ensure exclusivity. Themes were placed into 1 of 3 inductively generated groups according to positive feedback, negative feedback, and recommendations for improvements expressed by participants' quotes. These groups were initially created by 1 researcher and then independently verified by 2 other researchers. Themes arising from postintervention interviews were compiled and presented in a tabular form. A meeting among the 3 researchers was finally held to revise the list of themes in the groups and resolve any difference.

Results

Screening Outcomes

The participants group included 6 parents (5 females, 1 male) of 6 overweight children (2 females, 4 males), mean age 9.16 years (SD 2.13). No participant dropout occurred during the prescribed intervention phase (first 6 weeks of app usage).

Parents' KMD was good before the intervention and slightly improved at the end of the intervention (mean score from 12.5 to 12.70 on a total score of 15) with more than 80% of correct responses provided.

It was found that 4 out of 6 parent participants were classified at contemplation SoC before the intervention, but moved to action level after the 6 weeks' intervention (Table 2).

All parent participants expressed a strong IU mobile apps for supporting the acquisition of healthy nutrition and lifestyles by children, both before and after the intervention (average rating was 5 on a 5-point Likert scale).

Usage Patterns and Usability of the TreC-LifeStyle App

During the pilot study, TreC-LifeStyle's app was used by both parents and children in 3 out of the 6 families involved (P2-child aged 10 years, P3-child aged 12 years, and P6-child aged 11 years). In the above three cases, both children and parents shared the food-intake reporting task and used the app during the study.

In other cases, it was the parent participant using the app for food-intake reporting and analyzing feedback, whereas the child wore the activity tracker and checked with the parent the achievement of the activity goal of 10 K steps per day on the app mainly.

The adherence to the mHealth intervention was very high during the first 6 weeks, with a percentage of meals inserted always higher than 90% (mean number of meals inserted per day 2.79), showing that participants kept track of most of their meals and were compliant with the intervention request. This finding also shows a good user acceptance and effectiveness of the BC techniques "instruction on how to perform the behavior," "feedback on the behavior," and "prompt or cues" implemented by means of the food intake dashboard of the app and of the virtual coaching function. In the follow-up phase, when families could use the app on a voluntary basis, 2 participants almost dropped out (P2 and P6) and the other participants lowered interaction with the app considerably (mean number of meals inserted per day 0.44). The follow-up phase occurred during children's summer holidays, and this had a strong impact on families' daily routines and usage patterns (eg, in summer schools children were not allowed to use wearable devices for security reasons).

The frequency of usage of the daily statistics on food intake reported (Table 2), as well as of weekly statistics and of the shopping list feature shows that these app's functionalities were rarely used by parent participants during the study. Therefore, a refinement of the app features supporting the BC techniques "monitoring of the behavior" and "information provision" is required, in order to make these features more engaging and useful from a user's perspective.

Table 2. State of change (SoC), pre-post intervention, daily statistics visualization, percentage of goal achievement (10 K steps per day) in the last 3 weeks of intervention, difference of total deviations from healthy diet in week 1 and week 6 by participants (n=6).

Participant	SoC pre-post intervention	Daily statistics visualization	% of physical activity goal achievement–last 3 weeks of intervention	Difference of total deviations from healthy diet in week 1 and week 6
P1	Maintenance	62	121	0
P2	Contemplation-action	9	133	2
P3	Contemplation-action	9	74	0
P4	Contemplation-action	195	138	1
P5	Maintenance	18	101	−1
P6	Contemplation-action	0	113	−5

The result of children's physical activity tracking was very positive, with most of the children participants reaching, and even overpassing the daily goal of 10 K steps (Table 2). Therefore, we can state that the app features related to the BC techniques "review behavioral goal achievement" and "rewarding" contributed well in supporting children's engagement with the TreC-LifeStyle intervention and their motivation to reach physical activity goals.

By comparing the number of food portion deviations from healthy diet guidelines during week 1 (W1) and week 6 (W6) of the study (beginning and ending weeks of the intervention), we observed that 2 children showed stable behavior, 2 children made a few more deviations, and 2 children made fewer deviations (Table 2). It was noted that the absolute number of deviations per week was not very high in both weeks, which indicates a persisting commitment of participants to comply with the objectives and indications provided by the nutrition education intervention.

Overall, parent participants rated the usability of TreC-LifeStyle app very positively. Both app versions vA and vB were assessed as being at the *best imaginable* level of usability, obtaining SUS mean scores of 95 and 97.92, respectively.

Qualitative Evaluation of the Intervention

Table 3 presents a list of core themes regarding positive, negative, and improvable aspects of the app design reported by participants during the interviews carried out at the end of the mHealth intervention.

Table 3. List of core themes and relative example quotes derived from the qualitative analysis of participants' post-intervention interviews.

Themes groups	Themes	Example quote
Positive feedback	Simplicity of food-intake reporting	*I prefer vB as it is more precise regarding calories...and food quantities...* [Parent, P6]
	Conscious food purchases	*We have changed our habits at the store...we do not care much about special offers anymore.* [Parent, P3]
	Family awareness of dietary choices	*I realized that I used to prepare French fries or fried food too often...* [Parent, P6]
	Influence on meals preparation	*Mom and daddy checked the app to decide what to prepare for lunch and dinner...* [Child, P3]
	Children's goal-driven motivation	*I use the app more if there is the bracelet...I want to achieve the goal 100%...* [Child, P2]
Negative feedback	Difficulties with food portion assessment	*It was not easy sometimes to know the portion of food consumed...* [Parent, P5]
	Poor engagement with secondary app's features	*We did not understand much the functionality "shopping list" so we never used it* [Parent and child, P1]
	Problems with children's use of wearable trackers	*I could not wear the bracelet during some of the sport activities at school, it was forbidden* [Child, P2]
Recommendations for improvement	Visual display of calories intake or burnt	*It would be interesting to have the app showing information about burned calories or intake* [Parent, P4]
	Support to food categorization	*It would be good to get some app's help on categorization of some particular foods, like "polenta"* [Parent, P6]
	Healthy recipes provision	*I would like to receive suggestions on recipes for next meals, as some days it is not easy to find new ideas for meals preparation* [Parent, P5]

All interviewees reported that both the app versions were intuitive to use and valuable as educational tools to deepen their knowledge of healthy nutrition and of the Mediterranean Diet. Most participants expressed a preference for vB over vA, by saying that vA was good enough to get some general knowledge of healthy nutrition, but vB was more precise and allowed a more accurate input of food intake also in terms of quantity.

Some participants also thanked the app intervention, as their family had become more aware about dietary choices over a week, and less influenced by special offers at the store when buying food.

Participants reported being influenced by the feedback provided by the mobile app, which marked the categories of food in red when deviating from a healthy diet. The food categories marked in red were checked every evening, after dinner, affecting decisions about meals to be prepared the day after.

A strong support for motivating the app usage over the intervention was provided by the associated wearable devices used to track the physical activity of children, which triggered participants' interest in monitoring and reflecting over calories' intake versus consumption during the day. Parents reported that children were very interested in monitoring their activity levels and they tried to comply with the 10 K steps per day goal every day, as confirmed also by the activity logs.

Participants found some difficulties in reporting food intake especially with vA, as they could not find out how to specify, approximate, or exact food quantities, as well as the dressing of the food consumed.

Most participants did not use at all or accessed a few times the weekly reports of the monitoring feature and the shopping list feature. It is likely that participants did not find these features particularly useful, which turned out not to contribute much to the user engagement with the app.

Some participants also reported issues with the use of the Jawbone or Misfit devices to be worn by their children during the intervention. For example, during sport activities, children were not allowed to wear the device and this prevented a full synchronization of the physical activity tracking with the diet monitoring features.

Participants were recommended to refine the mobile app by including a visual display of balance between calories intake or burning, which was not provided in the tested app versions. They also asked to facilitate as much as possible the input of some types of food that were less obvious to categorize (eg, corn item under cereals). Moreover, they proposed adding app suggestions on healthy recipes for next meals preparation, in order to consolidate their adoption of the Mediterranean diet in their daily lives.

Discussion

Principal Findings

To our knowledge, this is one of the first studies documenting the UCD of an mHealth app intervention for nutrition education targeting children aged 7-12 years, developed starting from the needs and practices of primary care in pediatrics, also investigating in depth the user compliance and experience with the intervention by 6 families over a period of 6 weeks.

All participants used the app regularly during the intervention period, showing a good compliance of users with the nutrition guidelines and the physical activity goals. Shared usage of the mobile app was observed especially in the families of children aged 10-12 years, so this might further suggest the acceptability and appropriateness of mHealth solutions for this target user group. As this was a pilot study aimed at testing and further improving our mobile app before its larger deployment, we focused on the usability and feasibility of the mHealth intervention, aimed at realizing an effective human and virtual coaching system for nutrition education programs in primary care.

Design of an mHealth Intervention for Obesity Prevention in Pediatric Primary Care

The main difference between our TreC-LifeStyle app and commercial nutrition apps is that it targets families of overweight children attending pediatric primary care programs. Therefore, it is fully integrated with health promotion knowledge and approaches based on clinical evidence and it allows tailoring of the intervention to the specific needs and profile of each participant (eg, configuration of the app based on children's age and weight by the pediatrician before prescription). Beyond supporting a more precise assessment and personalized intervention for obesity prevention in childhood, the TreC-LifeStyle approach has the potential to scale-up to become a useful tool for delivering prevention programs to the target population groups, by leveraging on participants' motivation, knowledge, and self-management skills [38] combined with clinical coaching and support by pediatricians. From a health care perspective, the TreC-LifeStyle platform is an effective cost-benefit solution for collecting data on children's behaviors and lifestyle more reliably, which can be used during primary care visits to inform doctor-patient dialog and facilitate BC goals [39]. This is also aligned with previous research, showing that stand-alone mHealth technologies are unlikely to drive BC, but are most useful when used concurrently with traditional care [40,41].

User Experience of the Mobile App

The analysis of the mobile app usage by participants showed a very high adherence to the intervention over its 6 weeks' duration, with a mean number of meals inserted per day of 2.79. The most frequently used features of the app were the food intake reporting and feedback dashboard, as well as the monitoring of the physical activity levels, that turned out to be also the most appreciated functionalities of the app from the participants' subjective reports. These results are consistent with previous research, which shows the benefit of mHealth apps in supporting participants' self-regulation [42] and an increasing of physical activity [43,44].

However, we observed a considerable drop in the number of daily meals inserted in the app during the follow-up period (mean 0.44), which confirms how food intake recording might impose a high level of burden on users and represent a main challenge if requested out of BC interventions provided by health care providers [45]. A revised version of our mobile app will feature 3 different steps or levels of nutrition education to go through, raising first the user's awareness on categories of food consumed over a week, then on portions, and finally on balance of nutrients. This way the educational support provided by the app and virtual coaching system developed is expected to help the user to deepen their learning of healthy eating behaviors, step by step, unlocking contents at growing levels of detail.

Usability of TreC-LifeStyle was rated as very good by all participants. A positive effect of the intervention was also observed in terms of parent participants' SoC, achieving action or maintenance levels for all participants after the first 3 weeks of the intervention. However, a deeper analysis of participants' comments on their user experience with the app indicated that additional support in defining or inserting food quantities should be provided. Another requested improvement of the app regarded the visual display of the ratio between calories intake and burnt and a possible replacement of the shopping list feature with a more engaging support in recommending recipes preparation compliant with healthy dietary guidelines. It is likely that the design of some app features related to the BC techniques "monitoring of the behavior" and "information provision" was not optimal for ensuring parents' engagement, which is important for BC [46]. In our revised app, the virtual coaching function proactively invites the user to consult the reporting features periodically (eg, in the evening, weekend) and takes into account user's current deviations from healthy guidelines to propose goal settings and suggestions relevant to rebalancing food intake and unhealthy behaviors.

Limitations

There are several limitations in this study. First, developing an mHealth intervention by deploying UCD methodology is rather time- and resource-intensive [9-47]. Some refinements of the features developed need to be implemented before a future large-scale deployment of our app, and going through the different phases of our intervention design took much longer than the typical design time frame of commercial apps for health promotion [48]. Another limitation is that our pilot study involved a small group of participants (parent participants were mainly mothers), which may not reflect the need of other families of overweight children in our target population.

However, to our knowledge, this study is one of the first to assess the usability and feasibility of a mHealth app intervention targeting families of overweight children aged 7-12 years over a 6-weeks' deployment and follow-up period in a primary care setting. Relevant mHealth solutions and evaluation studies are reported in [49,50], but they were targeting families of children or adolescents aged 10-17 years. All our participants used the app frequently over the intervention weeks, reporting positive

effects in terms of children compliance with nutrition and physical activity goals.

TreC-LifeStyle mobile app has the potential of better supporting primary care clinicians in providing effective prevention and health promotion programs related to children's lifestyles, but further improvements of the app in terms of long-term user engagement, nutrition coaching, and food-intake monitoring functions need to be implemented before a next large-scale trial deployment.

Conclusions

TreC-LifeStyle mHealth intervention has the potential to become an effective solution for supporting health promotion and prevention programs for children's weight management in primary care. The UCD and clinically founded methodology used to design the app—which combines healthy lifestyle guidelines, food-intake monitoring and intuitive feedback, as well as Web-based data sharing with pediatricians for evidence-based dialog—is a significant advance over the functionality of current commercially available food journaling apps, and may represent the kind of mHealth interventions best fitting the requirements of primary care practice. Future refinements of the app ensuring user engagement and maintenance of healthy behaviors after the intervention are to be considered and tested further.

Acknowledgments

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Conflicts of Interest

None declared.

References

1. PEW Research Center. PEW research internet project: Device ownership over time URL: http://www.pewinternet.org/fact-sheet/mobile/ [accessed 2017-03-29] [WebCite Cache ID 6pK1CZft9]
2. Google Play. Search android apps URL: https://play.google.com/store/search?q.nutrition&c.apps&hl.en
3. DiFilippo K, Huang EH, Andrade JE, Chapman-Novakofski KM. The use of mobile apps to improve nutrition outcomes: A systematic literature review. J Telemed Telecare 2015 Jul;21(5):243-253. [doi: 10.1177/1357633X15572203] [Medline: 25680388]
4. Bert F, Giacometti M, Gualano MR, Siliquini R. Smartphones and health promotion: a review of the evidence. J Med Syst 2014 Jan;38(1):9995. [doi: 10.1007/s10916-013-9995-7] [Medline: 24346929]
5. Avis JL, Holt NL, Maximova K, van Mierlo T, Fournier R, Padwal R, et al. The development and refinement of an e-health screening, brief intervention, and referral to treatment for parents to prevent childhood obesity in primary care. Telemed J E Health 2016 May;22(5):385-394. [doi: 10.1089/tmj.2015.0128] [Medline: 26451901]
6. Avis J, Bridger T, Buchholz A, Chanoine J, Hadjiyannakis S, Hamilton J, et al. It's like rocket science…only more complex: challenges and experiences related to managing pediatric obesity in Canada. Expert Rev Endocrinol Metab 2014;9(3):223-229.
7. Barlow SE, Ohlemeyer CL. Parent reasons for nonreturn to a pediatric weight management program. Clinical Pediatrics 2006 May 01;45(4):355-360. [doi: 10.1177/000992280604500408]
8. Tate EB, Spruijt-Metz D, O'Reilly G, Jordan-Marsh M, Gotsis M, Pentz MA, et al. mHealth approaches to child obesity prevention: successes, unique challenges, and next directions. Transl Behav Med 2013 Dec;3(4):406-415 [FREE Full text] [doi: 10.1007/s13142-013-0222-3] [Medline: 24294329]
9. Fjeldsoe BS, Miller YD, O'Brien JL, Marshall AL. Iterative development of MobileMums: a physical activity intervention for women with young children. Int J Behav Nutr Phys Act 2012;9:151 [FREE Full text] [doi: 10.1186/1479-5868-9-151] [Medline: 23256730]
10. Curtis K, Lahiri S, Brown KE. Targeting parents for childhood weight management: development of a theory-driven and user-centered healthy eating app. JMIR Mhealth Uhealth 2015 Jun 18;3(2):e69 [FREE Full text] [doi: 10.2196/mhealth.3857] [Medline: 26088692]
11. Schoffman DE, Turner-McGrievy G, Jones SJ, Wilcox S. Mobile apps for pediatric obesity prevention and treatment, healthy eating, and physical activity promotion: just fun and games? Transl Behav Med 2013 Sep;3(3):320-325 [FREE Full text] [doi: 10.1007/s13142-013-0206-3] [Medline: 24073184]
12. Tabacchi G, Giammanco S, La Guardia M, Giammanco M. A review of the literature and a new classification of the early determinants of childhood obesity: from pregnancy to the first years of life. Nutrition Research 2007 Oct;27(10):587-604. [doi: 10.1016/j.nutres.2007.06.001]
13. Birch LL. Child feeding practices and the etiology of obesity. Obesity (Silver Spring) 2006 Mar;14(3):343-344 [FREE Full text] [doi: 10.1038/oby.2006.45] [Medline: 16648602]

14. Pagoto S, Schneider K, Jojic M, DeBiasse M, Mann D. Evidence-based strategies in weight-loss mobile apps. Am J Prev Med 2013 Nov;45(5):576-582. [doi: 10.1016/j.amepre.2013.04.025] [Medline: 24139770]
15. Jeon E, Park HA, Min YH, Kim HY. Analysis of the information quality of korean obesity-management smartphone applications. Healthc Inform Res 2014 Jan;20(1):23-29 [FREE Full text] [doi: 10.4258/hir.2014.20.1.23] [Medline: 24627815]
16. Zhang MW, Ho RC, Hawa R, Sockalingam S. Analysis of the information quality of bariatric surgery smartphone applications using the silberg scale. Obes Surg 2016 Jan;26(1):163-168. [doi: 10.1007/s11695-015-1890-5] [Medline: 26424704]
17. Cafazzo JA, Casselman M, Hamming N, Katzman DK, Palmert MR. Design of an mHealth app for the self-management of adolescent type 1 diabetes: a pilot study. J Med Internet Res 2012 May;14(3):e70 [FREE Full text] [doi: 10.2196/jmir.2058] [Medline: 22564332]
18. Carter MC, Burley VJ, Cade JE. Development of 'My Meal Mate' – A smartphone intervention for weight loss. Nutrition Bulletin 2013 Feb 07;38(1):80-84. [doi: 10.1111/nbu.12016]
19. Hebden L, Cook A, van der Ploeg HP, Allman-Farinelli M. Development of smartphone applications for nutrition and physical activity behavior change. JMIR Res Protoc 2012 Aug;1(2):e9 [FREE Full text] [doi: 10.2196/resprot.2205] [Medline: 23611892]
20. Campbell N, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ 2007 Mar 03;334(7591):455-459 [FREE Full text] [doi: 10.1136/bmj.39108.379965.BE] [Medline: 17332585]
21. Avis J, van MT, Fournier R, Ball G. Lessons Learned From Using Focus Groups to Refine Digital Interventions. JMIR Res Protoc 2015 Jul 31;4(3):e95 [FREE Full text] [doi: 10.2196/resprot.4404] [Medline: 26232313]
22. Burrows T, Hutchesson M, Chai LK, Rollo M, Skinner G, Collins C. Nutrition interventions for prevention and management of childhood obesity: what do parents want from an eHealth program? Nutrients 2015 Dec 15;7(12):10469-10479 [FREE Full text] [doi: 10.3390/nu7125546] [Medline: 26694456]
23. Mummah S, Robinson T, King A, Gardner C, Sutton S. IDEAS (Integrate, Design, Assess, and Share): A framework and toolkit of strategies for the development of more effective digital interventions to change health behavior. J Med Internet Res 2016;18(12):e317. [doi: 10.2196/jmir.5927]
24. Michie S, Richardson M, Johnston M. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013;46:81-95.
25. Barlow SE, Expert C. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. Pediatrics 2007 Dec;120 Suppl 4:S164-S192. [doi: 10.1542/peds.2007-2329C] [Medline: 18055651]
26. Sargent G, Pilotto L, Baur L. Components of primary care interventions to treat childhood overweight and obesity: a systematic review of effect. Obes Rev 2011;12:e219-e235.
27. Pinelli L, Elerdini N, Faith MS, Agnello D, Ambruzzi A, De SM, et al. Childhood obesity: results of a multicenter study of obesity treatment in Italy. J Pediatr Endocrinol Metab 1999;12 Suppl 3:795-799. [Medline: 10626272]
28. Limauro R, Farris E, Gallo P, Cioffi L, Tanas R. Medico e Bambino. 2013. La terapia del bambino sovrappeso e obeso nell'ambulatorio del pediatra di famiglia con l'educazione terapeutica familiare: follow-up di tre anni URL: https://www.medicoebambino.com/?id=1310_667.pdf [accessed 2017-04-06] [WebCite Cache ID 6pWJlCo9g]
29. Eccher C, Piras EM, Stenico M. TreC - a REST-based regional PHR. Stud Health Technol Inform 2011;169:108-112. [Medline: 21893724]
30. Galligioni E, Piras EM, Galvagni M, Eccher C, Caramatti S, Zanolli D, et al. Integrating mHealth in Oncology: experience in the Province of Trento. J Med Internet Res 2015 May 13;17(5):e114 [FREE Full text] [doi: 10.2196/jmir.3743] [Medline: 25972226]
31. Bach-Faig A, Berry EM, Lairon D, Reguant J, Trichopoulou A, Dernini S, Mediterranean Diet Foundation Expert Group. Mediterranean diet pyramid today. Science and cultural updates. Public Health Nutr 2011 Dec;14(12A):2274-2284. [doi: 10.1017/S1368980011002515] [Medline: 22166184]
32. Ghiselli A. SINU. 2014. LARN, Livelli di Assunzione di Riferimento di Nutrienti ed energia per la popolazione italiana URL: http://www.sinu.it/documenti/20121016_LARN_bologna_sintesi_prefinale.pdf [accessed 2017-04-06] [WebCite Cache ID 6pWJz2bv4]
33. Cialfa E. Entecra. 2003. Linee guida per una sana alimentazione italiana URL: http://nut.entecra.it/files/download/linee_guida/lineeguida_intro.pdf [accessed 2017-04-06] [WebCite Cache ID 6pWK4hfZw]
34. Prochaska J, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot 1997;12(1):38-48. [Medline: 10170434]
35. University of Rhode Island. Weight control: stages of change (short form) URL: http://web.uri.edu/cprc/weight-control-stages-of-change-short-form/ [accessed 2017-03-29] [WebCite Cache ID 6pK30EViI]
36. Brooke J. SUS: a retrospective. J Usability Stud 2013;8(2):29-40.
37. Maykut P, Morehouse R. Beginning Qualitative Research: A Philosophic and Practical Guide. London, UK: Falmer Press; 1994.

38. Rusin M, Arsand E, Hartvigsen G. Functionalities and input methods for recording food intake: a systematic review. Int J Med Inform 2013;82(8):653-664. [Medline: 23415822]
39. Højgaard B, Gyrd-Hansen D, Olsen KR, Søgaard J, Sørensen TI. Waist circumference and body mass index as predictors of health care costs. PLoS One 2008 Jul 09;3(7):e2619 [FREE Full text] [doi: 10.1371/journal.pone.0002619] [Medline: 18612430]
40. Patel MS, Asch DA, Volpp KG. Wearable devices as facilitators, not drivers, of health behavior change. JAMA 2015;313:459-460.
41. Jensen C, Duncombe K, Lott M, Hunsaker S, Duraccio K, Woolford S. An evaluation of a smartphone-assisted behavioral weight control intervention for adolescents: pilot study. JMIR Mhealth Uhealth 2016 Aug 23;4(3):e102 [FREE Full text] [doi: 10.2196/mhealth.6034] [Medline: 27554704]
42. Choo S. Development of a weight loss mobile app linked with an accelerometer for use in the clinic: usability, acceptability, and early testing of its impact on the patient-doctor relationship. JMIR mHealth and uHealth 2016;4(1):e24. [doi: 10.2196/mhealth.4546] [Medline: 27032541]
43. Sama PR, Eapen ZJ, Weinfurt KP, Shah BR, Schulman KA. An evaluation of mobile health application tools. JMIR Mhealth Uhealth 2014;2(2):e19 [FREE Full text] [doi: 10.2196/mhealth.3088] [Medline: 25099179]
44. Sharma AM, Kushner RF. A proposed clinical staging system for obesity. Int J Obes (Lond) 2009 Mar;33(3):289-295. [doi: 10.1038/ijo.2009.2] [Medline: 19188927]
45. Spook JE, Paulussen T, Kok G, Van EP. Monitoring dietary intake and physical activity electronically: feasibility, usability, and ecological validity of a mobile-based Ecological Momentary Assessment tool. J Med Internet Res 2013;15(9):e214 [FREE Full text] [doi: 10.2196/jmir.2617] [Medline: 24067298]
46. Thompson L, McCabe R. The effect of clinician-patient alliance and communication on treatment adherence in mental health care: a systematic review. BMC Psychiatry 2012;12:87 [FREE Full text] [doi: 10.1186/1471-244X-12-87] [Medline: 22828119]
47. Whittaker R, Merry S, Dorey E, Maddison R. A development and evaluation process for mHealth interventions: examples from New Zealand. J Health Commun 2012 May;17 Suppl 1:11-21. [doi: 10.1080/10810730.2011.649103] [Medline: 22548594]
48. Pagoto S, Bennett GG. How behavioral science can advance digital health. Transl Behav Med 2013 Sep;3(3):271-276 [FREE Full text] [doi: 10.1007/s13142-013-0234-z] [Medline: 24073178]
49. Xu R, Cvijikj IP, Kowatsch T, Michahelles F, Büchter D, Brogle B, et al. Tell me what to eat – design and evaluation of a mobile companion helping children and their parents to plan nutrition intake. In: Ambient Intelligence. Cham, Switzerlan: Springer; 2014.
50. Mameli C, Brunetti D, Colombo V, Bedogni G, Schneider L, Penagini F, et al. Combined use of a wristband and a smartphone to reduce body weight in obese children: randomized controlled trial. Pediatr Obes 2016 Nov 29 Epub ahead of print. [doi: 10.1111/ijpo.12201] [Medline: 27900849]

Abbreviations

BC: behavior change
eHealth: electronic health
IU: intention to use
mHealth: mobile health
SD: standard deviation
SoC: state of change
SUS: system usability scale
UCD: user-centered design
vA: version A
vB: version B

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Original Paper

Developing a Patient-Centered mHealth App: A Tool for Adolescents With Type 1 Diabetes and Their Parents

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Abstract

Background: Type 1 diabetes (T1D) afflicts approximately 154,000 people under 20 years of age. Three-quarters of adolescents are not achieving glycosylated hemoglobin (HbA1c) targets, which leads to negative health outcomes. Mobile health (mHealth), the use of technology in health, has been used successfully to improve health in many chronic conditions, including diabetes.

Objective: The purpose of this study was to use patient-centered research methods to inform and improve the design and functionality of our T1D app, *MyT1DHero*, and to provide insight for others who are designing a health app for adolescents and parents.

Methods: This study included data from focus groups with participants recruited from the Juvenile Diabetes Research Foundation (JDRF) southeast Michigan's family network. All data collected during the sessions were audio-recorded, transcribed, and coded.

Results: Four key themes were identified: (1) diabetes is unpredictable, (2) negative and frustrated communication, (3) motivations to use an app, and (4) feedback specific to our app.

Conclusions: A patient-centered approach was used to assist in the development of an app for adolescents with T1D. Participants were satisfied with overall app design; customization, interactivity, and tangible rewards were identified as being necessary for continued use. Participants believed the app would help improve the communication between parents and adolescents. Many apps developed in the health context have not used a patient-centered design method or have seen vast improvements in health. This paper offers suggestions to others seeking to develop apps for adolescents and their parents.

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KEYWORDS

mHealth; qualitative research; type 1 diabetes; family

Introduction

Type 1 Diabetes

Type 1 diabetes (T1D) afflicts more than half a million children aged 0-14 years worldwide [1]. Many individuals are diagnosed with T1D at a young age, which requires parents to take responsibility for managing their child's chronic health condition [2]. Proper management includes monitoring multiple daily blood glucose measurements, physical activity, carbohydrate intake, and adjusting insulin doses with the use of multiple daily insulin injections or an insulin pump for basal and bolus insulin delivery [3,4]. Glycemic control is monitored quarterly at medical visits with the glycosylated hemoglobin (HbA1c) test. As children become teenagers, they steadily transition toward self-management, gaining more responsibility for their T1D care, and their parents gradually relinquishing control [5]. This transition period is often difficult because of the complexity of managing T1D in the context of suboptimal communication between the child and parent, often resulting in deleterious health outcomes [6]. Inadequate management during this transition increases the risk of severe hypoglycemia, which can lead to seizures or coma, and ketoacidosis, which can cause neurologic sequelae and even death [7,8]. The long-term consequences of poor diabetes management include cardiovascular disease, stroke, kidney disease, blindness, amputation, and premature death [7-9]. Successful transition is critical to the health and well-being of the teen. Identifying interventions to aid in the transition of care can ultimately increase positive health outcomes and the quality of life for adolescents with T1D [10].

As a result of the complexity of managing T1D, there is often a lack of adherence to proper T1D self-care, resulting in an unsuccessful transition [11]. Approximately 75% of teens are not achieving American Diabetes Association (ADA) HbA1c targets during this transition period [12]. Therefore, identifying and finding solutions to help adolescents attain the knowledge and skills needed to succeed in diabetes management is imperative to increasing positive health outcomes [13]. To ease the transition, interventions that aim to improve productive communication between parents and teens, help build trust and autonomy, and develop problem-solving skills which have demonstrated improved diabetes outcomes [14]. Unfortunately, parent-teen communication is difficult during this transition time, particularly when interactions regarding their diabetes management are often negative [15]. For instance, teens feel their parents are nagging them about their diabetes care [16]. Infusing positive communication into the parent-child relationship is fundamental to the success of this difficult transition [17]. Building trust and autonomy is also important to allow the parent to take a step back from care and give responsibility of disease management to the teen. Finally, problem-solving skills for both the parent and the teen can further improve communication and trust, ultimately improving diabetes outcomes.

mHealth

Mobile health (mHealth), the use of mobile technology in health, has been used in many health contexts, including asthma, pain management, depression, pregnancy, and others for more than a decade and has demonstrated positive outcomes [18-26]. Despite the proliferation of these health apps (over 165,000 available in Google Marketplace and Apple Store), very few have been developed using a patient-centered design [27]. The use of mHealth in diabetes care has been reported as useful in improving trends, but interventions have not been tested over a period of time sufficient to determine long-term engagement [28,29]. A recent study has called for patients to be more engaged in the design and development process [30]. Other studies have explored the wants and needs of an app for people with diabetes. Researchers have found that ease of use, timely and accessible information, and good visual appearance of the technology are all important [31,32]. Building an mHealth intervention using a patient-centered process to increase communication, trust, and autonomy should facilitate the goals of a successful transition to independence and achieving positive health outcomes and quality of life.

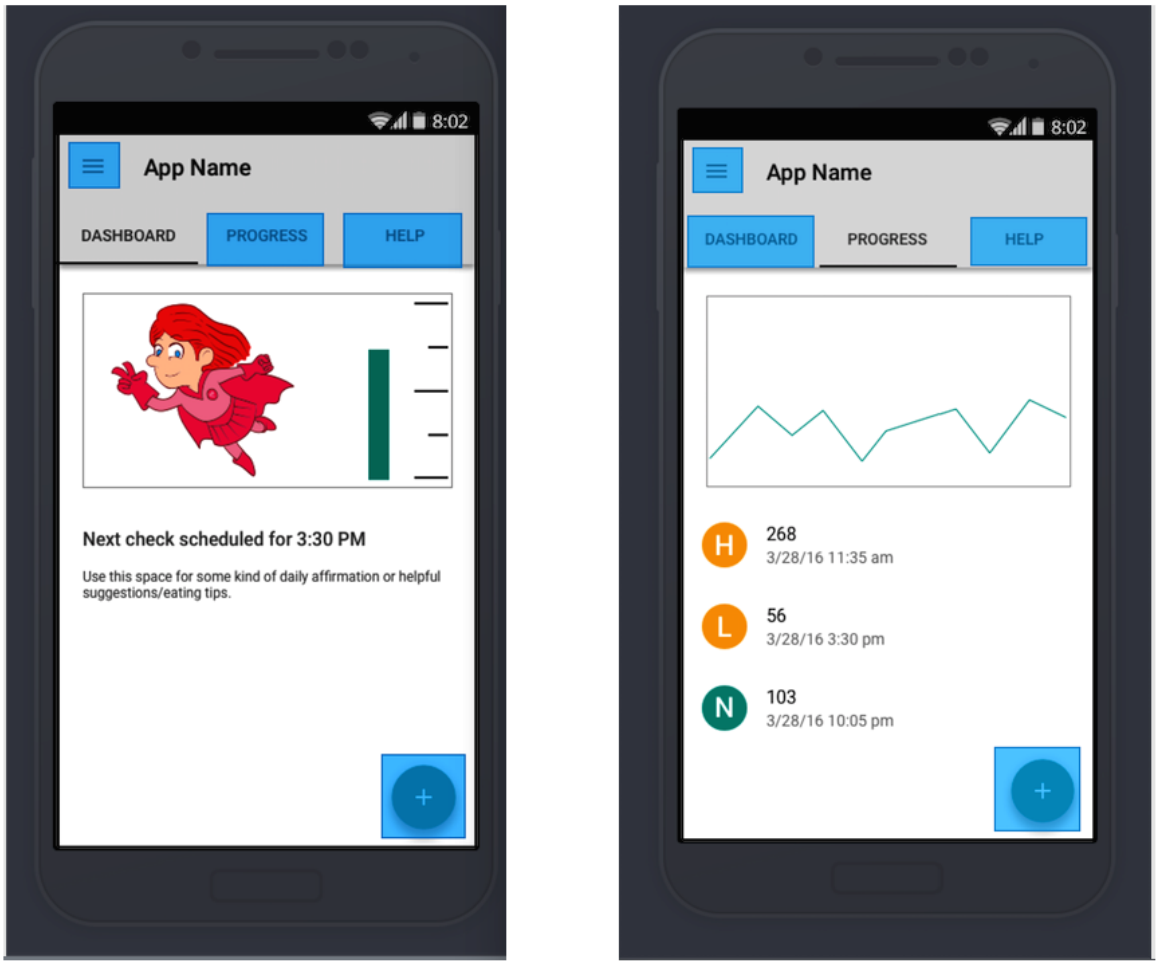
Examining the literature regarding participatory design within T1D and apps, we were unable to find any research that reported including both the parents and the child in the design. Previous research describes working with clinicians and developers [33,34], adults with T1D [35,36], or only the adolescents with T1D (no discussion with the parents) [19]. However, parent-child communication is critical during the transition to self-care and should be of central concern when designing an app for this context. Thus, our study focuses on communication that occurs between the parent and their child surrounding the management of diabetes, as it relates to the development of our app. Our expectation is that an app focused on easing the difficulties of diabetes-specific communication will result in positive health outcomes and better quality of life for both adolescents and their parents [37]. Therefore, we sought to better understand the perspective of both groups and gather feedback regarding our prototype.

The objective of this study was to use patient-centered research methods to inform and improve the design and functionality of our type 1 diabetes app, *MyT1DHero*. Additionally, we hope to provide insight for others who are designing a health app for adolescents and parents. To inform development of the app, we conducted qualitative focus groups to further explore how teens with T1D and their parents communicate about diabetes, what motivates them to use different apps and games, and evaluate their perceptions of our proposed app.

App Description

MyT1DHero is a self-management mobile app that aims to encourage adolescents aged 10-15 years to self-manage their diabetes by recording their blood glucose (BG) values while allowing the parents seamless access to these same values. See Figure 1 for example screenshots of the app. The parent users have a separate login that allows them to access the app and review their child's BG value history from their own phone. The parent and adolescent may also exchange messages via the app that are geared to facilitate positive communication. In addition, the app will have customizable test reminders, BG ranges, and an educational component that provides diabetes information and social support.

Figure 1. App screenshots.



The adolescents will also earn points based on app usage. The accumulated points will allow for the adolescent to purchase "accessories" to customize their avatar, or a virtual character on the app.

Methods

Recruitment and Participants

Participants were recruited via the Juvenile Diabetes Research Foundation (JDRF) southeast Michigan's family network, including Facebook, Twitter, and their email listserv. Inclusion criteria included: the adolescents must: (1) have a T1D diagnosis according to the ADA practice guidelines, (2) be 10-15 years old, (3) have had a diagnosis of T1D for at least six months, and (4) be fluent in English. The parent or guardian must: (1) have an adolescent with T1D who is 10-15 years old and who has had a diagnosis for at least 6 months and (2) be fluent in English. The study was approved by the Michigan State University Institutional Review Board. There were 5 adolescent participants in the focus group aged 10-13 years. The parent focus group had 7 participants, each with a child having a diagnosis of diabetes for 4-6 years. Three of the parents did not have an adolescent participating in the focus group.

Procedure

Figure 2 summarizes the content of the focus group protocol. Parent and adolescent focus groups were conducted separately. The adolescent focus group comprised 5 individuals, which included 4 males with a mean age of 11.6 years old (range 10-13 years), and the adolescents had a diagnosis duration of 4-6 years. The parent focus group comprised 7 individuals and included 6 females. They ranged in age from 35 to 60 years, all white, two had some college, two had a bachelor's degree, and two had master's degrees. The average income based on the participants' zip code was US $80,902.20 (range: US $46,649 to US $112,774). They all resided in southeast Michigan.

Each group consisted of two sections; in the first, participants were asked about their daily diabetes management routine, how their child's diabetes is managed (ie, amount of child responsibility), and overall communication with each other, including how often they communicate, the tone or feel of the communication (eg, positive, happy, nagging), and the channel in which they communicate (eg, phone, text, face-to-face). Gaining the perspectives of both parent and adolescent is key to designing a patient-centered app that fits the context of disease management from the point of view of those directly affected.

Figure 2. Focus group protocol content.

1. Consent
2. Part 1
Adolescent Sample Questions
First, so we can get an idea of how best the app could help you. Will each of you briefly tell me about a typical day managing your diabetes? Do you or your parent log your blood glucose? When do you normally log?
Can you describe a typical conversation with your parent about diabetes?
Parent Sample Questions
Do you or your child log their blood glucose numbers? When do you normally log?
How does your child typically talk to you throughout the day? Texting, phone call, face-to-face? Are the conversations friends, matter-of-fact, stressful? What makes the conversations friendly, matter-of-fact or stressful?
3. App Demonstration
4. Part 2
Adolescent Sample Questions
If your number is below target range, what kind of information or message would you like to get from the app?
What kinds of goals would you like to be able to set for yourself? What would you like to get if you achieve your goals?
Parent Sample Questions
Would you like to be able to see trends of your child's blood glucose? A1c? Fasting blood glucose? Any others?
What types of messages would be encouraging to you in times of stress?

Additionally, we asked about current apps that they used for both diabetes management and for general entertainment. For the second portion of the focus group, the participants were given a demonstration of our app prototype. We asked them general questions about the app, what they liked about it, what they would change, and what would motivate them to use it. The parent focus group lasted for 107 min and the adolescent focus group lasted for 72 min.

Data Analysis

All of the data collected in the focus groups were audio-recorded, transcribed verbatim, and coded using NVivo version 11 (QSR International Pty Ltd) software. Using inductive thematic analysis, part of the team iteratively developed a set of themes that captured the focus group dialog (BH, DH, AH, KM, and MK) [38]. The codes were presented to the whole group for clarification and feedback. Then, two members of the team (KM and MK), coded a random selection of the transcripts to ensure reliability. Once reliability was obtained, each transcript was coded independently by the coders. They then came together to compare and evaluate the codes. Disagreements were resolved through discussion.

Results

Key Themes

Four key themes were identified. These included (1) diabetes is unpredictable, (2) negative and frustrated communication, (3) motivations to use an app, and (4) feedback specific to our app. The following section describes each theme, along with descriptive quotes.

Part 1

This part of the focus group asked participants about how they manage their diabetes and general communication around diabetes. We believe that this is key in understanding how our app could help them in their daily lives.

Diabetes Is Unpredictable

We first asked participants about their personal experience with diabetes and how communication about diabetes occurs between the parent and adolescent. From this line of questioning, two subthemes emerged: (1) Daily care is not an "exact science," and (2) the transition of care increases the unpredictability. When discussing daily diabetes care, the parent participants

discussed at length the importance of having good control of their child's disease. Strategies that were successfully used for glycemic control on one day did not necessarily work another day. One parent stated:

> *There's no exact science to it, it's all a guessing game, and so it gets pretty frustrating.*

Another parent stated:

> *You know, like, it isn't an exact science and sometimes all those numbers that I write down—there's too many factors to play into it.*

A third parent echoed those statements and said:

> *We have six years of paper records...a constant deluge of information. It's information that somebody should be able to use but it doesn't get used because it's not an exact science.*

Because of this unpredictability, parents frequently measure their child's blood glucose level 8 or more times per day and even have to wake up in the middle of the night to check their child. One parent reported:

> *I think we had two episodes of her going almost dangerously low and almost going into shock at night so that definitely sensitized us to be concerned at night. We used to get up two, three times a night and check her.*

Additionally, the parents stated they often worry about their child because they have seen how fast a change in blood glucose can occur. One parent told us:

> *There was no warning or anything (regarding low blood glucose) and I know (it) could just go that fast from (normal)—it does happen quickly.*

The transition of diabetes care from the parent to the adolescent also causes some unpredictability. The adolescents had a good understanding of the required treatment; however, they too expressed feeling overwhelmed with the amount of information to consider and the uncertainty about knowing what to do all the time. One adolescent stated:

> *I do a lot of it (diabetes management), but sometimes I get confused on the carbs, so I have to look it up or have someone to help me out for the day.*

Another followed up:

> *It's hard to do and I don't always know what to do.*

One of the parents commented on this transition saying:

> *They want to be independent and yet they need to be reminded. They forget, almost, that this is their issue. And again, they want to be independent but they want to be boys too.*

Negative and Frustrated Communication

The unpredictable nature of changes in blood glucose often induces parental frustration, which leads to poor quality communication with their child. We noted that when the parent was describing their communication style, they seemingly talked at, rather than with, their child. For instance, one parent said that she says to their daughter:

> *You've got to start taking responsibility for this. It's either going to be you or it's going to me. And I know that you don't want it to me be, so get on track, and start hitting this like you're supposed to. It's trying to get her to think about it.*

Another parent echoed this by saying:

> *You take care of it or I do. And you know what it means when I have to take care of it. It's a lot more nagging.*

One parent said of her child attending a sleepover:

> *My conversation with her was, 'I'll get a phone call or text from you at three a.m., right? Yes, I will. And what will happen if I don't get it? I'll be pounding on the door.' We've had to do that, so that conversation sometimes has been not so good.*

All of the parents said that they knew they were frequently asking their child for blood glucose numbers and about testing.

None of the parents talked about using any strategies to communicate in a positive manner with their child surrounding diabetes management. This is not to say that they are unaware of this issue. When we asked about this, one mom said:

> *They are doing a great job. I mean, just the word thanks. I don't think we say it enough.*

They have good intentions to communicate positively with their child about diabetes, but the need to have their child's blood glucose numbers overshadows any conscious effort at communicating positively.

Part 2

In this section of the focus group, we asked them about their current use of apps to help manage diabetes and what keeps them using technologies. We then conducted a demonstration of our app prototype and gathered feedback.

Use of Apps to Manage Diabetes

None of the parents or the adolescents currently used an app for diabetes management or carb counting. The only technology that the parents used were programs for pump or meter downloads, like Diasend, and they generally only looked at those before attending a doctor's appointment. One parent said:

> *It's like oh crap, we have a doctor's appointment tomorrow. Give me your pump and let me download.*

Another parent said she gives their health care provider their username and password, so they could access their child's information. Parents did, however, express that having these downloads at least once a week would be helpful.

Motivation

Overall, the respondents mentioned three key motivations for the use of a health-tracking app. These motivation themes included customization, interactivity, and tangible rewards.

Customization included being able to put in favorite foods, positive or affirmative messages, glucose ranges, and message

types and times. Customization spurred many ideas of how and why they would use the app. They wanted to be able to enter favorite foods or restaurants to get the nutritional information. One mom said:

> *(I'd) put fruit roll-ups on there because it's not in the (diabetes education) book.*

Another idea included being able to customize some of the messages that the app sent, to both the child and the parent. A mother suggested being able to add in your own reminders. She said:

> *Would it be possible, to type in your own message? Like, say you want to write a Bible verse that's encouraging or uplifting or something like that, or your own motto or something.*

The timing of the testing and the reminders the app set seemed to be a key. One parent stated:

> *What if the reminders—what if you could set whatever time you wanted the reminder to be instead of having them automatic*.

Another parent went on to say:

> *If you (allow a test within) a range...They might not be in a specific space where they can drop everything and test. It does take a minute or two to actually test.*

Interactivity was another motivation suggested by the participants. This refers to not wanting to simply be told information, but to be able to interact with the app in interesting and meaningful ways. For instance, adolescents like the idea of being part of a team. In a popular app-based game that the adolescents played, they worked in teams or clans to defend villages and farms. Thus, they were especially keen on being able to join a team to earn points. One adolescent stated:

> *Everyone who uses the app has a team and the team with the most points wins.*

They also liked the idea of getting individual points in order to get virtual character badges, new "powers" or tools, clothing, and or accessories. One adolescent suggested:

> *If you get a bunch of points, you could have a character with like a hat and sunglasses or something.*

Along with those intrinsic motivations, tangible rewards like earning points redeemable for purchases made at the Apple iStore, Google Marketplace, or Amazon were very popular. For example, a parent said:

> *The Amazon gift card thing—for mine because they are teenagers and are like—Amazon is the best thing.*

One of our adolescents echoed this sentiment stating, "Maybe get points on Amazon." The adolescents were excited about the idea of getting points through the app. One suggested that the more a person opened the app and used the app to enter blood glucose values, the more points would be earned. One adolescent stated that they would also like to be able to redeem the points with their parents.

> *You could use the points for a day of no nagging (from the parents).*

App Feedback

One of the key features of this app was to show parents that their children have tested their blood glucose, but not to show the number immediately. This is designed to increase trust, self-efficacy, and autonomy to help the transition process. We asked both the parents and the adolescents specifically about this feature. All of them said that the parent needs to know the test number immediately. One stated:

> *His numbers are all over the place. You know, I wouldn't feel comfortable with that (not seeing the numbers right away).*

The parents were also aware that they have difficulty in relinquishing control over their child's diabetes care management. For example, one mom said:

> *I mean, it's nice to have a break as a parent but I can't have a break right now.*

The adolescents mostly agreed that the parent should see the number, but more as a way to move the conversation from face-to-face to the app. One adolescent stated:

> *They should be able to see the low and the high, but they don't need to see the regular number. Because they're just like—check their phone, like oh, she's alright.*

Both groups gave positive reviews of the overall app as well as the different features within the app. One mom thought that having the app mediate the communication would be very helpful. Rather than the parent constantly telling the child what to do, the app would remind them to stay on top of their management, allowing more time for the parent to communicate with their child about things other than diabetes. The parents also suggested the use of emojis; one said:

> *I think you could also have emojis that are sad faces or tears or like a heart.*

One of the adolescents repeated this idea stating:

> *I think like maybe if they (parents) could text you an emoji thumbs up that would be good.*

Another said:

> *(The kids) lie because they don't want you to be disappointed, they don't want you to be mad, they don't want you yelling at them. So I think this (the app)—doing it this way would take that whole scenario out of it.*

Discussion

Principal Findings

mHealth used for diabetes management is growing as a method to improve adherence and health outcomes. Using a patient-centered approach, this study sought to understand parent and adolescent perspectives of on-going development of a T1D app. To fully understand how an app could be engaging to both the parent and the child, it was important to understand the environment in which an app would be used. To achieve this goal, we asked parents and adolescents to tell us about how they currently manage the child's diabetes and how they

communicate about the disease. We then showed them a demonstration of our prototype app to obtain their perspectives on the app and additional components they thought the app should have.

These focus groups acknowledge the complexity of disease management and the frustrations in communication for families with an adolescent with T1D. Parents feel the need to remain in control because the day-to-day management of diabetes is very unpredictable. Consistent with other research, the unpredictability fuels some of the frustration that the parent and the adolescent feel and ultimately leads to inadequate communication strategies [23]. Our proposed app is designed to help improve the communication between the parent and their child. The app helps monitor the adolescent's blood glucose and provides positive message prompts to the parent for better communication.

In order for an app to be successful and provide benefit to users, people must actively use it. We asked about different strategies that would keep the users engaged with the app. Customization, interactivity, and tangible rewards were discussed as motivating factors of using the app [37]. This is similar to other studies that have concluded that customization is important to appeal to the needs of various users and that it is imperative to discuss what options should be customizable [39-41]. Having the app be interactive was also stated as a motivation for engaging and using the app. Currently, there is limited interactivity in the downloads of their meter or their pump, which could be one cause of their low usage. Past research has demonstrated that having interactive functions have improved usability and resulted in higher engagement [42-45]. Through these focus groups, we have decided to integrate more interactivity in the app through some of the customization features, as well as through how the parents and child communicate through the app.

Participants also agreed that providing tangible rewards or financial incentives would motivate users to remain engaged with the app. Some research has shown that financial incentives are key motivators in weight loss and smoking cessation [46]. Ethical issues remain related to incentivizing individuals in this manner and what this practice might mean particularly for disadvantaged populations [47]. Additionally, there are issues of long-term sustainability both in terms of the health impacts and how the program would be able to continue to provide those incentives [48]. Because of these issues, we have decided to use some gamification techniques to reward use of the app. The utilization of gamification seeks to encourage users to complete specific tasks within a nongame environment [49-51]. There are several ways to do this, which include giving points every time a user opens the app, and having participants earn badges or points to "buy" items for avatars. Past research has suggested that having an environment that is enjoyable to use can increase health knowledge, efficacy, and adherence to their daily care can improve health outcomes [52-56].

A striking feature from the parent focus group was how parents reported communicating with their child about diabetes. In the current communication cycle, parents often report becoming frustrated and upset with their child, which does not help them learn how to handle the issue in a positive manner [57]. This may lead to the adolescent lying to their parents in hopes of preventing them from becoming frustrated or upset. This leads to further deterioration in the quality of the parent-child communication. In short, the parents talk at their adolescent, commanding them to pay attention to their care rather than working with them to successfully manage diabetes. Therefore, we believe adding problem-solving resources and features to the app would be beneficial. Problem solving, defined by Yeates and colleagues [58], is conceptualized as defining a problem, generating alternative strategies, evaluating outcomes, and selecting a strategy. Some literature has demonstrated positive associations between problem-solving behaviors and improved HbA1c; however more research is needed in this area [59].

An inherent feature of technology is its distance between users. Past research has suggested that "online interaction reduced embarrassment that might be experienced in face-to-face interactions and thus encourages self-disclosure" [60]. There are many studies demonstrating that computer mediated communication enhances self-disclosure [61-62]. This is especially important for adolescents who, developmentally, are often hyper self-aware and self-conscious [62]. As the proposed app will notify parents that their child has measured their blood glucose level, and in some cases report what the blood glucose level is, parents will be able to respond with affirmative preprogrammed messages through the app. We believe that the outcome of app use will change the dynamic of the communication. The adolescent will be more likely to provide true numbers and the parents will have preprogrammed messages with which they can respond, thereby making communication less frustrating and a more honest and constructive exchange.

One of the desirable app features that the adolescents mentioned was to join a team. A growing number of researchers are starting to focus on social interaction in mobile apps. Although fun is the primary reason many use apps, social interaction was reported as the second reason to play games [63]. Using technology in a group leads to greater enjoyment, lower dropout rate, and longer engagement compared with individual play [64]. It has been shown in health and sports studies that most people enjoy playing in a group more than by themselves [65]. Additionally, past research has demonstrated improvement in glycemic control for children with T1D can result from the responsibility of caring for others [66]. Researchers hypothesized that the structured care provided cues that translated to the performance of diabetes self-management behaviors. This suggests that by caring for another, possibly through a team setting, individuals learn to care better for themselves.

Implications for other groups developing an app for children with a chronic disease and their parent include understanding the current communication context that disease management takes place in. As a result of this insight, we were able to add a problem-solving framework into our app. We were also able to understand the importance of having the messages and reminders come from the app and not the parent. Team participation within the app appears to be a way to keep the adolescents engaged and responsible for their own care. Finally,

we learned that some type of reward needs to be added. To achieve this goal, we have added the ability for the adolescent to purchase different accessories for their in-app avatar. Without understanding the communication that currently takes place between the parent and the child, we would have not been able to make these adjustments.

Whereas there are some limitations to this work, the goal was to gain a patient-centered perspective on the app design to date. These focus groups are not representative of all mHealth apps, as ours is specifically for adolescents with T1D and includes their parent. Additionally, our sample size was small. However, we believe that this work provides information that may help others in their app development process. Future studies of this type should include larger samples, including a wider age range of youth.

Conclusions

This app has the potential to provide parents the security they need to start transitioning diabetes management to their children and allowing them to develop the confidence needed for ongoing optimal control of their diabetes. This study used an original app idea and demonstrated a prototype of the app to help guide both the parents' and the adolescents' perspectives to design this patient-centered diabetes app. Overall, the app review was positive and the participants thought it would be useful to aid in the transition to adolescent self-management. Understanding the needs of patients and caregivers will help better inform the development and design of the app. This study also provides others with strategies that can be incorporated into the development of other health apps, including use of a patient-centered design, incorporating interactivity, use of customization, and building teams within the app.

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Conflicts of Interest

None declared.

References

1. Diabetes Atlas. 2015. IDF Diabetes Atlas - 7th Edition URL: http://www.diabetesatlas.org/ [accessed 2017-03-27] [WebCite Cache ID 6pHOgwKZT]
2. Peters A, Laffel L. Diabetes care for emerging adults: recommendations for transition from pediatric to adult diabetes care systems. Diabetes Care 2011;34(11):2477-2485.
3. Downing J, Gleeson HK, Clayton PE, Davis JR, Wales JK, Callery P. Transition in endocrinology: the challenge of maintaining continuity. Clin Endocrinol (Oxf) 2013 Jan;78(1):29-35. [doi: 10.1111/j.1365-2265.2012.04473.x] [Medline: 22734661]
4. Herbert L, Owen V, Pascarella L, Streisand R. Text message interventions for children and adolescents with type 1 diabetes: a systematic review. Diabetes Technol Ther 2013;15(5):362-370.
5. Ersig AL, Tsalikian E, Coffey J, Williams JK. Stressors in teens with type 1 diabetes and their parents: immediate and long-term implications for transition to self-management. J Pediatr Nurs 2016;31(4):390-396.
6. Monaghan M, Hilliard M, Sweenie R, Riekert K. Transition readiness in adolescents and emerging adults with diabetes: the role of patient-provider communication. Curr Diab Rep 2013 Dec;13(6):900-908 [FREE Full text] [doi: 10.1007/s11892-013-0420-x] [Medline: 24014075]
7. American Diabetes Association. 2013. Diabetes Basics: Type 1 URL: http://www.diabetes.org/diabetes-basics/type-1/ [accessed 2017-03-27] [WebCite Cache ID 6pHPYM6MN]
8. JDRF. 2011. Type 1 Diabetes Facts URL: http://jdrf.org/about-jdrf/fact-sheets/type-1-diabetes-facts/ [accessed 2017-03-27] [WebCite Cache ID 6pHPaf43b]
9. NIDDK. 2011. National Diabetes Statistics URL: https://www.niddk.nih.gov/health-information/health-statistics/Pages/default.aspx [accessed 2017-03-27] [WebCite Cache ID 6pHPmbCID]
10. Chen L, Chuang L, Chang C, Wang C, Wang I, Chung Y, et al. Evaluating self-management behaviors of diabetic patients in a telehealthcare program: longitudinal study over 18 months. J Med Internet Res 2013 Dec 09;15(12):e266 [FREE Full text] [doi: 10.2196/jmir.2699] [Medline: 24323283]
11. Hilliard ME, Wu YP, Rausch J, Dolan LM, Hood KK. Predictors of deteriorations in diabetes management and control in adolescents with type 1 diabetes. J Adolesc Health 2013 Jan;52(1):28-34 [FREE Full text] [doi: 10.1016/j.jadohealth.2012.05.009] [Medline: 23260831]
12. Vaala SE, Hood KK, Laffel L, Kumah-Crystal YA, Lybarger CK, Mulvaney SA. Use of commonly available technologies for diabetes information and self-management among adolescents with type 1 diabetes and their parents: a web-based survey study. Interact J Med Res 2015;4(4):e24.

13. Karlsson A, Arman M, Wikblad K. Teenagers with type 1 diabetes--a phenomenological study of the transition towards autonomy in self-management. Int J Nurs Stud 2008 Apr;45(4):562-570. [doi: 10.1016/j.ijnurstu.2006.08.022] [Medline: 17046768]
14. Hanberger L, Ludvigsson J, Nordfeldt S. Use of a web 2.0 portal to improve education and communication in young patients with families: randomized controlled trial. J Med Internet Res 2013 Aug 23;15(8):e175 [FREE Full text] [doi: 10.2196/jmir.2425] [Medline: 23973555]
15. Hanna KM, Juarez B, Lenss SS, Guthrie D. Parent-adolescent communication and support for diabetes management as reported by adolescents with type 1 diabetes. Issues Compr Pediatr Nurs 2003;26(3):145-158. [doi: 10.1080/01460860390223871] [Medline: 12936698]
16. Holtz B, Hershey D, Dunneback J, Cotten S, Holmstrom A, Wood M. Three perspectives on the transition to self-management. 2015 Presented at: 14th Annual Pediatric Research Conference; 2015; Detroit.
17. Kirwan M, Vandelanotte C, Fenning A, Duncan MJ. Diabetes self-management smartphone application for adults with type 1 diabetes: randomized controlled trial. J Med Internet Res 2013 Nov 13;15(11):e235 [FREE Full text] [doi: 10.2196/jmir.2588] [Medline: 24225149]
18. Franklin VL, Greene A, Waller A, Greene SA, Pagliari C. Patients' engagement with “Sweet Talk” - a text messaging support system for young people with diabetes. J Med Internet Res 2008 Jun 30;10(2):e20 [FREE Full text] [doi: 10.2196/jmir.962] [Medline: 18653444]
19. Frøisland DH, Arsand E, Skårderud F. Improving diabetes care for young people with type 1 diabetes through visual learning on mobile phones: mixed-methods study. J Med Internet Res 2012 Aug 06;14(4):e111 [FREE Full text] [doi: 10.2196/jmir.2155] [Medline: 22868871]
20. Mulvaney SA, Anders S, Smith AK, Pittel EJ, Johnson KB. A pilot test of a tailored mobile and web-based diabetes messaging system for adolescents. J Telemed Telecare 2012 Mar;18(2):115-118 [FREE Full text] [doi: 10.1258/jtt.2011.111006] [Medline: 22383802]
21. Holtz B, Whitten P. Managing asthma with mobile phones: a feasibility study. Telemed J E Health 2009;15:907-909.
22. Evans WD, Wallace JL, Snider J. Pilot evaluation of the text4baby mobile health program. BMC Public Health 2012;12(1):1.
23. Ivey JB, Wright A, Dashiff CJ. Finding the balance: adolescents with type 1 diabetes and their parents. J Pediatr Health Care 2009;23(1):10-18.
24. Stinson JN, Jibb LA, Nguyen C, Nathan PC, Maloney AM, Dupuis LL, et al. Development and testing of a multidimensional iPhone pain assessment application for adolescents with cancer. J Med Internet Res 2013 Mar 08;15(3):e51 [FREE Full text] [doi: 10.2196/jmir.2350] [Medline: 23475457]
25. van SA, Cuijpers P, Smits N. Effectiveness of a web-based self-help intervention for symptoms of depression, anxiety, and stress: randomized controlled trial. J Med Internet Res 2008 Mar 25;10(1):e7 [FREE Full text] [doi: 10.2196/jmir.954] [Medline: 18364344]
26. Giménez-Pérez G, Gallach M, Acera E, Prieto A, Carro O, Ortega E, et al. Evaluation of accessibility and use of new communication technologies in patients with type 1 diabetes mellitus. J Med Internet Res 2002 Dec;4(3):E16 [FREE Full text] [doi: 10.2196/jmir.4.3.e16] [Medline: 12554547]
27. The Economist. 2016. Things are looking app URL: http://www.economist.com/news/business/21694523-mobile-health-apps-are-becoming-more-capable-and-potentially-rather-useful-things-are-looking [accessed 2017-03-27] [WebCite Cache ID 6pHQwyEDO]
28. Holtz B, Lauckner C. Diabetes management via mobile phones: a systematic review. Telemed J E Health 2012;18(3):175-184.
29. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. J Med Internet Res 2015;17(2):e52.
30. Peng W, Yuan S, Holtz BE. Exploring the challenges and opportunities of health mobile apps for individuals with type 2 diabetes living in rural communities. Telemed J E Health 2016;22(9):733-738.
31. Årsand E, Frøisland DH, Skrøvseth SO, Chomutare T, Tatara N, Hartvigsen G, et al. Mobile health applications to assist patients with diabetes: lessons learned and design implications. J Diabetes Sci Technol 2012 Sep 01;6(5):1197-1206 [FREE Full text] [doi: 10.1177/193229681200600525] [Medline: 23063047]
32. Fonda SJ, Kedziora RJ, Vigersky RA, Bursell S. Combining iGoogle and personal health records to create a prototype personal health application for diabetes self-management. Telemed J E Health 2010 May;16(4):480-489. [doi: 10.1089/tmj.2009.0122] [Medline: 20455776]
33. Waller A, Franklin V, Pagliari C, Greene S. Participatory design of a text message scheduling system to support young people with diabetes. Health Informatics J 2006 Dec;12(4):304-318. [doi: 10.1177/1460458206070023] [Medline: 17093001]
34. Abidi S, Vallis M, Raza AS, Piccinini-Vallis H, Imran SA. D-WISE: diabetes web-centric information and support environment: conceptual specification and proposed evaluation. Can J Diabetes 2014 Jun;38(3):205-211 [FREE Full text] [doi: 10.1016/j.jcjd.2014.03.006] [Medline: 24909091]
35. Knight BA, McIntyre HD, Hickman IJ, Noud M. Qualitative assessment of user experiences of a novel smart phone application designed to support flexible intensive insulin therapy in type 1 diabetes. BMC Med Inform Decis Mak 2016 Sep 15;16(1):119 [FREE Full text] [doi: 10.1186/s12911-016-0356-6] [Medline: 27629774]

36. Storni C. Design challenges for ubiquitous and personal computing in chronic disease care and patient empowerment: a case study rethinking diabetes self-monitoring. Pers Ubiquit Comput 2014;18(5):1277-1290.
37. Chomutare T, Fernandez-Luque L, Arsand E, Hartvigsen G. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. J Med Internet Res 2011 Sep 22;13(3):e65 [FREE Full text] [doi: 10.2196/jmir.1874] [Medline: 21979293]
38. Smith JA. Qualitative psychology: a practical guide to research method. London: Sage; 2015.
39. Luxton DD. mHealth for mental health: Integrating smartphone technology in behavioral healthcare. Prof Psychol Res Pr 2011;42(6):505.
40. Sama PR, Eapen ZJ, Weinfurt KP, Shah BR, Schulman KA. An evaluation of mobile health application tools. JMIR Mhealth Uhealth 2014 May 01;2(2):e19 [FREE Full text] [doi: 10.2196/mhealth.3088] [Medline: 25099179]
41. Mirkovic J, Kaufman DR, Ruland CM. Supporting cancer patients in illness management: usability evaluation of a mobile app. JMIR Mhealth Uhealth 2014 Aug 13;2(3):e33 [FREE Full text] [doi: 10.2196/mhealth.3359] [Medline: 25119490]
42. Liu C. Status and trends of mobile-health applications for iOS devices: a developer's perspective. J Syst Software 2011;84(11):2022-2033.
43. Guerri JC. A mobile device application applied to low back disorders. Multimed Tools Appl 2009;42(3):317-340.
44. Zhang C, Zhang X, Halstead-Nussloch R. Assessment metrics, challenges, and strategies for mobile health apps. Issues in Information Systems 2014;15(2):59.
45. Danaher BG, Brendryen H, Seeley JR, Tyler MS, Woolley T. From black box to toolbox: outlining device functionality, engagement activities, and the pervasive information architecture of mHealth interventions. Internet Interv 2015 Mar 01;2(1):91-101 [FREE Full text] [doi: 10.1016/j.invent.2015.01.002] [Medline: 25750862]
46. Patel MS, Asch DA, Troxel AB, Fletcher M, Osman-Koss R, Brady J, et al. Premium-based financial incentives did not promote workplace weight loss in a 2013-15 study. Health Aff (Millwood) 2016 Jan;35(1):71-79. [doi: 10.1377/hlthaff.2015.0945] [Medline: 26733703]
47. Lynagh MC, Sanson-Fisher RW, Bonevski B. What's good for the goose is good for the gander. Guiding principles for the use of financial incentives in health behaviour change. Int J Behav Med 2013;20(1):114-120. [Medline: 22094998]
48. Cafazzo JA. Design of an mHealth app for the self-management of adolescent type 1 diabetes: a pilot study. J Med Internet Res 2012;14(3):e70. [Medline: 22564332]
49. Cugelman B. Gamification: what it is and why it matters to digital health behavior change developers. JMIR Serious Games 2013 Dec 12;1(1):e3 [FREE Full text] [doi: 10.2196/games.3139] [Medline: 25658754]
50. Deterding S, Dixon D, Khaled R, Nacke L. From game design elements to gamefulness: defining gamification. In: 15th International Academic MindTrek Conference: Envisioning Future Media Environments. 2011 Presented at: ACM; September 2011; Tampere, Finland p. 9-15.
51. Huotari K, Hamari J. Defining gamification: a service marketing perspective. In: 16th International Academic MindTrek Conference. 2012 Presented at: ACM; October 2012; Tampere, Finland.
52. Zanchi C, Presser LA, Vahey P. Next generation preschool math demo: tablet games for preschool classrooms. In: 12th International Conference on Interaction DesignChildren. 2013 Presented at: ACM; June 2013; New York, NY.
53. Brown SJ, Lieberman DA, Germeny BA, Fan YC, Wilson DM, Pasta DJ. Educational video game for juvenile diabetes: results of a controlled trial. Med Inform (Lond) 1997;22(1):77-89. [Medline: 9183781]
54. Ebrahimpour F. Effect of playing interactive computer game on distress of insulin injection among type 1 diabetic children. Iran J Pediatr 2015;25(3):e427. [Medline: 26199708]
55. Kumar VS, Wentzell KJ, Mikkelsen T, Pentland A, Laffel LM. The DAILY (Daily Automated Intensive Log for Youth) trial: a wireless, portable system to improve adherence and glycemic control in youth with diabetes. Diabetes Technol Ther 2004;6(4):445-453. [Medline: 15320998]
56. Theng YL, Lee JW, Patinadan PV, Foo SS. The use of videogames, gamification, and virtual environments in the self-management of diabetes: a systematic review of evidence. Games Health J 2015 Oct;4(5):352-361. [doi: 10.1089/g4h.2014.0114] [Medline: 26287926]
57. Gammon D, Arsand E, Walseth OA, Andersson N, Jenssen M, Taylor T. Parent-child interaction using a mobile and wireless system for blood glucose monitoring. J Med Internet Res 2005 Nov 21;7(5):e57 [FREE Full text] [doi: 10.2196/jmir.7.5.e57] [Medline: 16403721]
58. Yeates KO, Schultz LH, Selman RL. Bridging the gaps in child-clinical assessment: toward the application of social-cognitive developmental theory. Clin Psychol Rev 1990;10(5):567-588.
59. Hill-Briggs F. Problem solving in diabetes self-management: a model of chronic illness self-management behavior. Ann Behav Med 2003;25(3):182-193.
60. Gunter B. Digital Health: Meeting Patient and Professional Needs Online. Abingdon, UK: Routledge; 2006.
61. Valkenburg PM, Peter J. The effects of instant messaging on the quality of adolescents' existing friendships: A longitudinal study. J Commun 2009;59(1):79-97. [doi: 10.1111/j.1460-2466.2008.01405.x]
62. Valkenburg PM, Peter J. Social consequences of the internet for adolescents a decade of research. Curr Dir Psychol Sci 2009;18(1):1-5 [FREE Full text]

63. Lieberman DA. What can we learn from playing interactive games. In: Playing Video Games Motives, Responses, and Consequences. Abingdon, UK: Routledge; 2006:379-397.
64. Paw MJ, Jacobs WM, Vaessen EP, Titze S, van Mechelen W. The motivation of children to play an active video game. J Sports Sci Med 2008;11(2):163-166.
65. Peng W, Crouse J. Playing in parallel: the effects of multiplayer modes in active video game on motivation and physical exertion. Cyberpsychol Behav Soc Netw 2013 Jun;16(6):423-427. [doi: 10.1089/cyber.2012.0384] [Medline: 23509986]
66. Maranda L, Lau M, Stewart SM, Gupta OT. A novel behavioral intervention in adolescents with type 1 diabetes mellitus improves glycemic control: preliminary results from a pilot randomized control trial. Diabetes Educ 2015 Apr;41(2):224-230 [FREE Full text] [doi: 10.1177/0145721714567235] [Medline: 25614529]

Abbreviations

ADA: American Diabetes Association
HbA1c: glycosylated hemoglobin
JDRF: Juvenile Diabetes Research Foundation
T1D: type 1 diabetes

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Original Paper

Assessing the Medication Adherence App Marketplace From the Health Professional and Consumer Vantage Points

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Abstract

Background: Nonadherence produces considerable health consequences and economic burden to patients and payers. One approach to improve medication nonadherence that has gained interest in recent years is the use of smartphone adherence apps. The development of smartphone adherence apps has increased rapidly since 2012; however, literature evaluating the clinical app and effectiveness of smartphone adherence apps to improve medication adherence is generally lacking.

Objective: The aims of this study were to (1) provide an updated evaluation and comparison of medication adherence apps in the marketplace by assessing the features, functionality, and health literacy (HL) of the highest-ranking adherence apps and (2) indirectly measure the validity of our rating methodology by determining the relationship between our app evaluations and Web-based consumer ratings.

Methods: Two independent reviewers assessed the features and functionality using a 4-domain rating tool of all adherence apps identified based on developer claims. The same reviewers downloaded and tested the 100 highest-ranking apps including an additional domain for assessment of HL. Pearson product correlations were estimated between the consumer ratings and our domain and total scores.

Results: A total of 824 adherence apps were identified; of these, 645 unique apps were evaluated after applying exclusion criteria. The median initial score based on descriptions was 14 (max of 68; range 0-60). As a result, 100 of the highest-scoring unique apps underwent user testing. The median overall user-tested score was 31.5 (max of 73; range 0-60). The majority of the user tested the adherence apps that underwent user testing reported a consumer rating score in their respective online marketplace. The mean consumer rating was 3.93 (SD 0.84). The total user-tested score was positively correlated with consumer ratings (r=.1969, P=.04).

Conclusions: More adherence apps are available in the Web-based marketplace, and the quality of these apps varies considerably. Consumer ratings are positively but weakly correlated with user-testing scores suggesting that our rating tool has some validity but that consumers and clinicians may assess adherence app quality differently.

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KEYWORDS

smartphone; apps; adherence; medication; health literacy

Introduction

Background

Evolution in our health care system and technological advances in recent years have sparked renewed awareness of medication nonadherence; however, it continues to be a problem for our society [1]. Nonadherence produces considerable health consequences and economic burden to patients [2-5]. The repercussions of nonadherence may ultimately impede the appropriate management of common chronic diseases.

Unintentional nonadherence is a category of nonadherence that implies that the patient intends to take their medications, yet fail to do so for reasons such as forgetfulness or thoughtlessness [2]. Numerous strategies aimed at improving unintentional nonadherence have been studied. The use of smartphone medication adherence apps to improve unintentional nonadherence is one innovative approach that has recently gained interest [2,6]. Data suggest the use of or ownership of a smartphone continues to increase. According to the Pew Research Center's Spring 2015 Global Attitudes Survey, an estimated 89% of the US population used the internet or reported owning a smartphone [7]. Estimates in 2015 also revealed that 62% of smartphone owners in the United States used their smartphone to find information about a health condition [8]. Adherence apps must be downloaded and installed using a cellular connection; however, many do not require active internet connections to access information or provide medication reminders. These adherence apps can also combine all of the user's medication-specific material into one source to provide a more efficient way for individuals to participate in their disease management and care [2,6]. Given the proliferation in smartphone use, adherence apps represent a more accessible approach to address unintentional nonadherence in that they are easy to obtain and are available at all times to provide information to patients about their medications.

The development of smartphone adherence apps has increased sharply since 2012. In 2012, there were approximately 160 unique medication adherence apps available [2]. In 2014, the number of adherence apps ballooned to more than 400 [6]. This substantial increase in the adherence app marketplace reflects the high demand for this tool. Literature evaluating the clinical app and effectiveness of smartphone adherence apps to improve medication adherence is generally lacking. Study results indicating that medication reminder systems (eg, short message service [SMS] text messages) can increase medication adherence and may offer promise that adherence apps may also improve adherence [9-11]. A randomized trial conducted in Spain found that an app can improve self-reported adherence, but similar results in the United States have not yet been reported [12]. One study revealed that kidney transplant recipients were interested in using a smartphone app to remind them to take their medications, but they also reported perceived barriers to using these apps (eg, turning the phone off periodically, annoying alarms, an app that is not flexible to work with irregular schedules, and so on) [13]. Currently, a first of its kind randomized controlled trial designed to rigorously evaluate an app's effect on blood pressure and medication adherence is underway [14]. Research also demonstrates lower health literacy (HL) is associated with decreased odds of participating in mobile health (mHealth) interventions for diabetes [15,16]. Although published data regarding efficacy, safety, or clinical outcomes for adherence apps are scarce [14,17], patients are using these apps and many groups of people have positive attitudes toward the use of this type of tool [18]; therefore, health care providers should be able to serve as a resource for patients to help identify an app that may best suit their needs with regard to its adherence features, functionality, and level of HL [2,6].

Previously, our group developed methods to compare adherence apps and identify those that offered a wide range of features that may be the most appropriate to recommend to patients [2,6]. From that work, a searchable online resource (medappfinder.com) was developed to help patients and providers identify and compare adherence apps based on usability, HL, and features that meet their individual needs [6]. The methods and analyses performed to develop these resources were standardized and represented a health care provider viewpoint. Thus, a limitation to these efforts is that patient viewpoints were lacking. Given the number of adherence apps and the rate at which the marketplace expands, directly incorporating patient viewpoints into these assessments is not feasible. However, most apps generally have consumer reviews posted in their online marketplaces. Such consumer reviews for adherence apps represent the viewpoint of the patient or their caregiver. Although these reviews have not been rigorously or systematically analyzed, such an analysis could indirectly provide the patients' viewpoint of a given adherence app.

Objective of the Study

The objective of this study was to (1) provide an updated evaluation and comparison of available medication adherence apps in the marketplace by assessing the features, functionality, and HL of the highest-ranking adherence apps across 5 domains and (2) indirectly measure the validity of our rating methodology by determining the relationship between our app evaluations and online consumer ratings. We hypothesized that consumer ratings and our ratings would be modestly correlated.

Methods

Marketplace Search

In June 2015, an additional Web-based app marketplace (the Microsoft Store [Windows]) and those included in prior analyses (iTunes [iOS], Google Play [Android], Blackberry App World) were analyzed to find all available adherence apps capable of producing medication reminders. The following keywords: alarm, alert, med(s), and pillbox were added to our existing search terms (ie, adherence, compliance, dosage, dose, drug, medication(s), pharm, pharmacy, pill(s), prescription, remind, reminder, Rx, script, take, therapy, treat, and treatment) [2,6]

and used to identify these apps. In addition, "health and diet," "health care services," and "medical guides" categories were used to identify any additional adherence apps that may have not been found using keyword searches. Adherence apps were cataloged using the full name, manufacturer, and operating system (OS). To be included in the analysis, adherence apps had to be available in English and claim to send medication reminders. For adherence apps with both a free or lite and paid or pro version, only the paid or pro versions were recorded, evaluated, and scored for possible user testing, but it was noted if there was also a free version. Since our focus was to rate apps that could be used in a general ambulatory population, apps specific to one type of medication (eg, insulin) or a single disease state (eg, hypertension) were excluded. Apps that were specific to an independent pharmacy and/or required a specific prescription number or insurance type (eg, Humara Pharmacy and NexJ Health Coach) were also excluded from evaluation.

Initial Evaluation and Scoring

Adherence apps were evaluated using previously described processes [2,6], which were developed based on author consensus before adherence app evaluation, and thus, reflects perspectives of the authors (eg, academicians, clinical practitioners, HL specialists, and student pharmacists). This rating system includes 28 features divided into 4 domains: Adherence Attributes, Medication Management, Connectivity, and General Features. It was found that 27 of the 28 features were nominally weighted as previously described from 1 to 3 (1, modest; 2, moderate; and 3, high), based on the authors' views on its relevance and impact in its respective domain [2,6]. To reflect the growing marketplace, the scoring for the feature "Latest Revision Update" was modified from our prior methods. This feature is scored based on the frequency of continued app updates or support by developers. For this analysis, like before, 3 points were awarded if the app had been updated in the 6 months before the analysis, and 2 points were awarded if the app had been updated more than 6 months, but 12 or less months before our analysis. However, an app that had not been updated in more than a year previously received 1 point [6], but in this analysis, this was changed so that an app that had been updated 13-18 months before the review, received 1 point. An app that had not been updated in more than 18 months before this review, received a score of 0. No other scoring modifications were made. Using this rating system, two investigators independently analyzed the developers' claims along with available screenshots of each adherence app in the online marketplace to determine whether an app possessed any of the 28 author-identified features to assign a score. The initial scores based on developers' claims were used to identify the 100 highest ranked unique adherence apps. Those available on multiple platforms (eg, Medisafe, which is available on both iOS and Android), were evaluated separately to identify any differences between the platforms.

User Testing

To compare the developers' claims against the actual quality and functionality, the top 100 highest-ranking unique adherence apps underwent user testing by the same two evaluators using previously described methods [6]. Briefly, adherence apps that could not be installed or set up by at least one researcher due to inefficiencies or malfunctions with the app were excluded from further evaluation (eg, apps that continuously crashed, apps requiring an activation code, and inability set-up reminders despite contacting the app developer). To maintain a total of 100 unique user-tested adherence apps, those excluded from user testing for any reason were replaced with the next highest-ranking unique app based on initial score. Adherence apps available on both iOS and Android were rated for both platforms and given two scores, which were cross-verified and any score discrepancies resolved. The sum of the weighted scores determined an initial score, which was used to rank the adherence apps. Counting multiplatform adherence apps only once, the top 100 highest-ranking apps were then identified for user testing. Apps in the top 100 highest-ranking apps that had not been updated in the last 18 months before review were not retested. Aside from receiving a zero for the feature "Latest Revision Date," these adherence apps received the same initial and user-tested scores as in our previous analysis [6]. Each adherence app was installed using a smartphone or tablet and tested for a minimum of 4 days and a maximum of 7 days using a standardized 6-drug regimen similar to prior analyses (ie, vitamin E, 400 IU once daily; diltiazem, 120 mg twice daily; simvastatin, 40 mg once daily at bedtime; azithromycin, 500 mg once daily for 3 days and then stop; and alendronate, 35 mg once weekly); however, instead of a prednisone taper regimen used in our prior analyses [2,6], the 6th drug used for the standardized regimen was methylnaltrexone, which should be consumed 12 mg every other day. Adherence apps unable to create reminders for a once weekly medication (ie, alendronate) were tested over 4 days, whereas those with this capability were tested over 7 days.

To assess the 28 possible author-identified adherence app features, the two evaluators used the same rating scale used in the initial evaluation with one update to the scoring process. In the initial evaluation, the feature, "Capability of Complex Medication Instructions," was scored dichotomously as "yes" or "no" to reflect the presence or absence of this feature as discerned from the available developers' descriptions and/or screenshots. However, during user testing, this feature was assessed using three possible rating options to reflect the actual performance and the degree to which an app could perform this feature (ie, create reminders for multiple medications and schedules that comprise complex medication instructions). The score given to each app for this feature was based on the number of reminders created for the more complex medication regimens (ie, azithromycin, alendronate, and methylnaltrexone). The maximum score of 3 was awarded when an app could create reminders for all of these medications. If an app was able to create reminders for only two, it received a score of 2. Adherence apps that could only create a reminder for one of these medications were assigned a score of 1. A score of 0 was assigned if an app was unable to create reminders for any of these medications. In these cases, it was decided that assigning a 0 for this feature was preferable to complete exclusion because these adherence apps are still available for potential patients to download. In retaining these adherence apps, this information can be shared with consumers to avoid the possible frustration

had they downloaded based solely on developers' claims and screenshots of apps in the marketplace.

In addition to the 28-feature author-identified rating system, 12 HL-focused attributes were evaluated and scored using a tool endorsed by the Institute of Medicine (IOM) [19] as previously described by Heldenbrand et al [6]. A separate domain was created and each attribute was scored using a Likert scale (1-5) with a maximum of 60 points. To prevent skewing the total user-tested scores, this domain's scores were scaled with one point to be added for each 12-point increment in the HL domain score. The 12 feature's scores were summed with a possible range of 12-60. For example, a HL score of 1-12 had 1 point added to the user-tested score, and a score of 13-24 had 2 points added.

The user-tested scores were calculated using the sum of the four original domains scores (max possible: 68) and the HL domain score (max possible: 5), creating a maximum user-tested score of 73. The user-tested scores, including those for the HL domain, were cross-verified by the two evaluators. Any adherence apps with scoring discrepancies between the two evaluators were reinstalled, and it was confirmed whether or not that adherence app possessed a particular feature. Following cross-verification, each app was given a final user-tested score which was then used to rerank the adherence apps.

To indirectly measure the patients' viewpoint of adherence apps, available consumer ratings and the number of app downloads as of June-July 2015 were obtained from Google Play and iTunes. Pearson product-moment correlations were estimated between consumer ratings, user-testing total scores, and domain scores as a check of the validity of our user rating methodology. Using the obtained consumer ratings, we evaluated correlations between our ratings system based on manufacture claims and consumer ratings. We expected to find medium correlations between consumer ratings and our user domain scores. To classify correlations, we used the empirically based thresholds for correlations of small <0.20; medium (moderate)=0.20-0.30; and large >0.30 [20,21]. Finally, ordinary least square regression models were estimated using consumer ratings as the dependent variable and individual domain scores and individual items as independent variables.

Results

Initial Search

There were 824 adherence apps discovered across the 4 platforms including 378 iOS, 305 Android, 105 Windows, and 36 Blackberry. After applying exclusion criteria, 179 adherence apps were excluded (17 duplicates and 162 specific to a single medication and/or disease state), leaving 645 eligible for evaluation. Of the remaining adherence apps, 71% (461/649) were available on only one platform (208 iOS, 156 Android, 20 Blackberry, and 77 Windows) and 29% (184/634) were available on multiple platforms. Of the 645 adherence apps assessed based on developer claims, the median score was 14 with a mean of 15.5 (SD 9.4) and ranged from 0 to 60 (max possible: 68).

User Testing

From the initial assessment based on developer claims, the top 100 highest-ranking unique adherence apps underwent user testing to assess features and HL resulting in a user-tested score. Due to the multiplatform adherence apps, a total of 144 apps were tested (75 iOS, 62 Android, and 7 Windows). Blackberry adherence apps were excluded due to the lack of devices available to test these apps. During user testing, 34 adherence apps were unable to be installed and/or set up by at least one researcher and were ultimately excluded from further evaluation. The most common issues included apps that continuously crashed despite using multiple devices (eg, iPhone 5, iPhone 6s, and iPad for iOS apps), the need for a specific activation code from a primary care physician and/or pharmacy to set up and use the adherence app, and inability to set up reminders despite contacting the app developer which excluded 5, 11, and 8 apps, respectively. These were replaced by the next 34 highest-ranking adherence apps so that ultimately 100 unique apps were tested and given a user-tested score. The median overall user-tested score was 31.5 and ranged from 0 to 60 (max possible: 73). When compared with initial scores, 32% (46/144) of app scores decreased and 68% (98/144) of scores increased following user testing. Select features from each domain along with their frequencies can be found in Table 1. The overall user-tested score for the domains listed below can be found in Table 2. Table 3 reports the attribute scores of the 13 highest ranked adherence apps.

Table 1. Select adherence app feature frequencies based on user testing (max N=144).

Domain	Feature[a]	Frequency n (%)
Adherence Attributes	Customizable reminders	57 (39.6)
	Refill alerts	67 (46.5)
	Ability to postpone reminder	71 (49.9)
	Specific medication reminders	94 (65.3)
	Medical social networking	18 (12.5)
	Tracks missed or taken doses	88 (61.1)
Medication Management	Medication database	70 (48.6)
	Multiple profiles	69 (46.9)
	Food and drug interactions	15 (10.4)
	Refill from a specific pharmacy	14 (9.7)
Connectivity	Export or share information	93 (64.6)
	Reminders with no connectivity	82 (56.9)
	Cloud storage	81 (56.3)
	Patient Web portal	36 (25)
	Provider Web portal	15 (10.4)
General Features	HIPAA[b] statement	15 (10.4)
	Multiplatform	90 (62.5)
	Multiple language options	30 (20.8)
	Completely free	87 (60)
	Password option	90 (62.5)

[a]Not a comprehensive list of features assessed.

[b]HIPAA: Health Insurance Portability and Accountability Act.

Table 2. Overall user-tested domain scores.

Domain	Median (range)	Max possible
Adherence Attributes	8 (0-21)	21
Medication Management	5 (0-14)	15
Connectivity	5 (0-10)	13
General Features	9 (1-16)	19
Health Literacy	36 (22-49.5)	60
(scaled score)	4 (2-5)	(5)

Table 3. Highest-ranking adherence apps' user-tested domain scores.

Apps	Operating system			Initial score	User-tested score	Adherence attributes	Medication management	Connectivity	General features	Health literacy	User-tested score+HL[a]	Latest revision date[b]
	iOS[c]	A[d]	W[e]	Max: 68	Max: 68	Max: 21	Max: 15	Max: 13	Max: 19	Max: 5	Max: 73	
Medisafe	X	X		47	55	21	10	8	16	5	60	July 2015
Care4Today	X	X		35	49	17	8	10	14	4	53	May 2015
CareZone	X	X		37	47	17	8	10	12	4	51	July 2015
MedPal		X		32	46	21	7	8	10	4	50	December 2013
MyMeds	X	X		38	47	18	9	10	10	3	50	March 2015
CareSync	X	X		30	44	12	10	10	12	4	48	June 2015
Dosecast Premium	X	X		43	44	16	8	8	12	3	47	July 2015
Mango Health	X	X		35	38	14	7	6	11	4	42	May 2015
GenieMD	X	X		35	38	8	13	7	10	3	41	January 2015
MyHealthSaverz	X	X		38	37	13	8	5	11	4	41	March 2015
Pill Reminder by Drugs.com	X			41	38	10	11	7	10	3	41	December 2014
eMedsMate			X	33	36	9	10	8	9	4	40	July 2014
ZibdyHealth		X	X	59	36	5	11	7	15	2	40	June 2015

[a]HL: health literacy.

[b]At the time apps were cataloged (June-July 2015).

[c]iOS: Apple.

[d]A: Android.

[e]W: Windows.

Adherence Attributes

During user testing, 9% (13/144) of adherence apps were unable to reliably send medication reminders although the developers' descriptions and/or available screenshots claimed to have this function, and thus received a 0 for their final user-tested score in this domain.

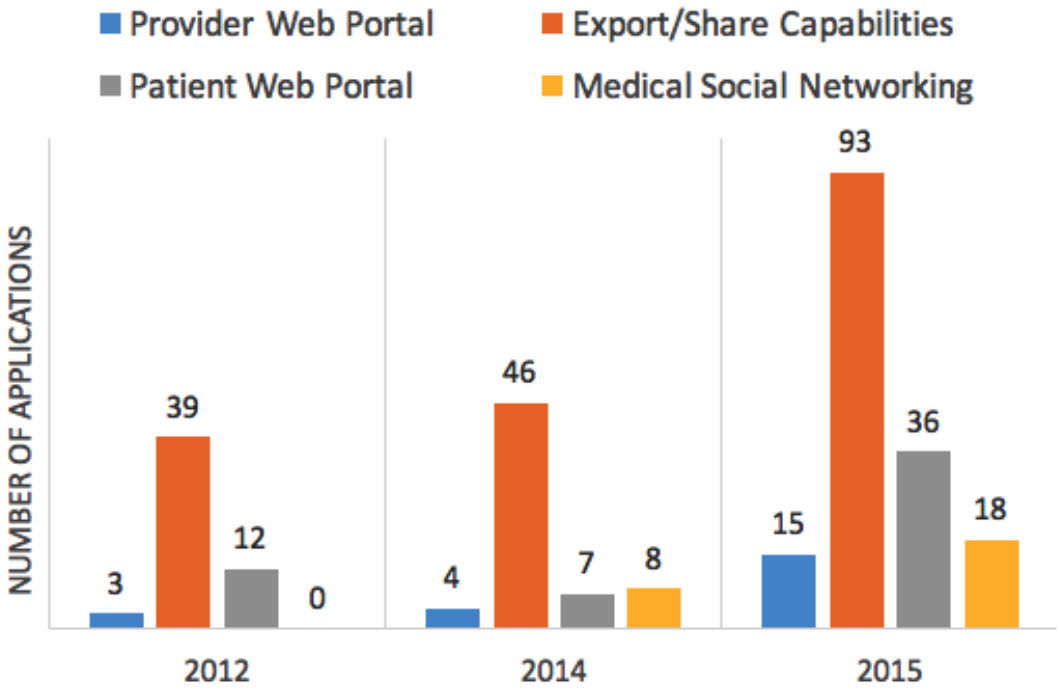
Medication Management

The ability of adherence apps to accurately send reminders on complex medication regimens varied greatly. It was found that 40% (58/144) of adherence apps were able to create reminders for all three medications with complex schedules (ie, azithromycin, alendronate, and methylnaltrexone) and 9% (13/144) were unable to create reminders for any of these medications.

Connectivity

This domain has changed the most since previous medication adherence app studies [2,6] as seen in Figure 1. The number of adherence apps that can export or share information has grown 238% since initial analysis in 2012 (93 vs 39 apps, respectively). Medical social networking, a feature that allows the patient to choose caregivers or providers to actively monitor and participate in the patient's medication adherence, was absent in all apps in 2012 [2], but was present in 13% (18/139) of adherence apps in this analysis.

Figure 1. Changes in advanced connectivity features.



General Features

Of the 57 adherence apps that had a pro or paid version, 60% (34/57) also had a free version. In total, 60% (87/144) were completely free. Adherence app prices ranged from free to US $23.99/year, with the average cost being a one-time purchase fee of US $1. Additionally, some adherence apps were free to download, but required in-app purchases to unlock extra features.

Health Literacy

The plain language feature had a median score of 1, which was the lowest-scoring feature of this domain. Adherence apps were given this score based on the number of words with greater than three syllables (eg, medication, prescription, and interaction). The highest-scoring features were the use of bullets and/or short lists and having adequate white space or little clutter, which both received a median score of 4.

Relationship Between Adherence App Evaluations and Consumer Rating

Of the 645 adherence apps initially evaluated using developer claims, 67% (417/645) had a consumer rating score. The mean consumer rating was 3.54 (SD 1.14) with a minimum rating of 1 and a maximum rating of 5. The total score based on developers' claims was positively and moderately related to consumer ratings (Table 4; r=.2399, P<.001). All domains were significantly positively correlated with consumer ratings, but only the General Features domain had a correlation of at least 0.20.

The majority of the 144 adherence apps that underwent user testing had a consumer rating score. The mean consumer rating was 3.93 (SD 0.84). The total user-tested score was positively and almost moderately correlated with consumer ratings (Table 4; r=.1969, P=.04). Only the Connectivity domain score was significantly and moderately correlated with consumer ratings, whereas the small correlation with the General Features domain score trended toward significance (P=.05). The HL domain score was significant and negatively correlated with consumer ratings (r=−.1942, P=.04).

Because the General Features domain based on user testing and developer claims were positively related to consumer reviews, ordinary least square regressions were estimated between the individual items within the General Features domain and the other domain total scores. The model explained 33% of the variability in consumer ratings of the adherence apps user tested (data not shown). Only one item of the General Features domain, whether the app was free or not, was significantly and positively related to consumer rating (beta=.43, P<.001).

Table 4. Pearson correlation coefficients between consumer ratings and adherence app evaluations based on developers claims and user testing.

Domains	Developers claims N=417	User testing N=144
Adherence Attributes	0.1631 (*P*<.001)	0.0569 (*P*=.55)
Medication Management	0.1302 (*P*<.001)	0.1488 (*P*=.12)
Connectivity	0.1275 (*P*<.001)	0.2362 (*P*=.01)
General Features	0.2575 (*P*<.001)	0.1845 (*P*=.05)
Health Literacy	N/A[a]	−0.1942 (*P*=.04)
Total score	0.2399 (*P*<.001)	0.1969 (*P*=.04)

[a]N/A: not applicable.

Discussion

Principal Findings

There has been a 515% increase in the number of recorded adherence apps since 2012 (160 in 2012 vs 824 in 2015; Figure 2) [2]. The Windows platform, which was added to our analysis in 2015, had 105 adherence apps. This search revealed that 83 of the adherence apps recorded from the summer of 2014 could not be found in 2015. There continues to be extreme variability in the quality and functionality of adherence apps which could decrease the likelihood of consumers finding the best adherence app on their first attempt. Thus, resources that compare and contrast adherence apps for patients and providers (ie, medappfinder.com) could help in determining specific, desired features and help locate the highest-ranking adherence apps containing those selected features (Multimedia Appendices 1-3). Providers should be familiar with several quality adherence apps to recommend to patients as an additional tool for patients to use in addressing medication nonadherence.

Data on the effectiveness of adherence app medication reminder systems for a variety of disease states or specific populations are sparse, and the overall effectiveness of adherence apps for patients with chronic conditions is still unknown [12,22-26]. Therefore, there is a continued need for randomized controlled trials using rigorous research methodologies to establish an evidence-base for effective medication adherence apps.

The positive small to modest correlations between consumer ratings and our methods used to assess adherence apps provide some evidence of the validity of our approach in evaluating adherence apps. We expected to find modest correlations between our ratings and consumer ratings and these were observed empirically in our assessment based on developer's claims and were almost of moderate strength for (*r*=.1969) user testing total scores. Not surprisingly, the General Features domain which assesses the frequency of updates, charges, advertisements, and photos was most strongly correlated with consumer reviews and the strongest individual item associated with consumer reviews was whether or not the adherence app was free of charge. Because there were many more apps with initial scores based on claims (n=417) compared with those with user-testing scores (n=144), the correlations for the user-tested scores bordered on significance while even small correlations for initial scores based on claims were significant. For some of the domain scores, we only found small correlations (*r*<.20), which was lower than anticipated. This may be due to low reliability of consumer ratings described below, possible reliability or validity issues with our approach in assessing the domains, or fundamental differences in how consumers and clinician perceive medication app quality.

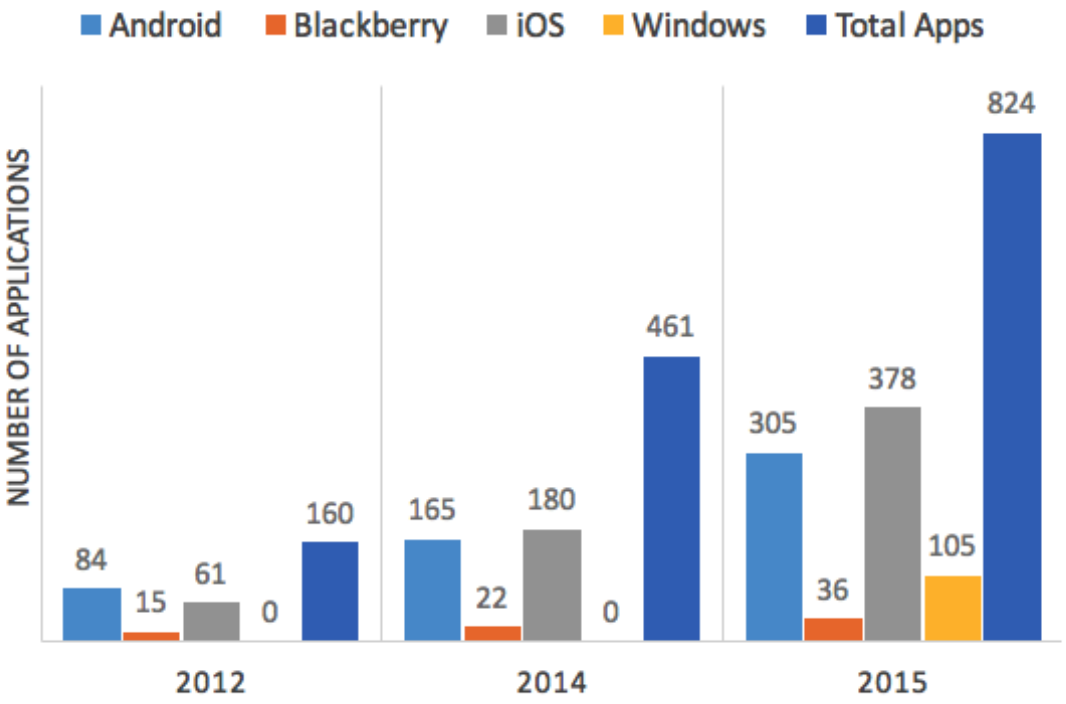
However, the small yet significant negative correlation between our HL assessment and consumer ratings suggests our assessment of HL may need refinement. This disparity requires further investigation. It is possible that the consumer ratings may be measured with error, or perhaps the findings reflect a selection bias of persons who download and take the time to rate and write reviews of adherence apps. Such individuals by virtue of owning a smartphone and downloading the adherence app may have higher educational attainment and higher levels of HL. Consequently, they may be more likely to prefer more sophisticated language and displays than those recommended by IOM best practices, which address the needs of individuals with low HL. In our approach to assessing HL aspects of adherence apps, we adapted the IOM's recommendations for designing health literate mobile apps into a scored scale that was used to evaluate each user-tested adherence app [19]. The scale was applied by two independent evaluators to assess HL and to increase the reliability of our approach. Such selection bias, if present, would result in poorer consumer ratings for adherence apps with simpler designs and features. Alternatively, the consumer rating scores may also not be reliably and validly recorded. Consumer reviews are the mean scores of individual reviews and some apps are reviewed by nearly 100,000 persons and others by less than 5 persons. Further complicating the interpretation of consumer reviews, Android adherence apps include reviews from all app versions, and thus, the reviews incorporate assessments of earlier app versions that may have since been updated and improved. Conversely, iOS adherence app reviews can be limited to the most recent version of the product. To mitigate this discrepancy between platforms, investigators recorded reviews from the iTunes marketplace using the "all versions" option. Considering that updating an adherence app does not guarantee an improvement in the overall product, these differences in reporting of consumer reviews in Web-based marketplaces complicates the analysis.

The top three highest-ranking adherence apps were updated within 1-3 months of data collection. This suggests how these adherence apps (ie, Medisafe, Care4Today, and CareZone) have

kept their services well-run and efficient. These apps are also available on multiple OS's which adds to their convenience. A new OS, Windows, was included and analyzed for this study and two adherence apps with this system were highly ranked initially (ie, eMedsMate and ZibdyHealth); however, after user testing, ZibdyHealth's score dropped due to their Adherence Attributes domain which demonstrates the importance of the user testing portion of this project.

Recent advancement in adherence app connectivity features has increased 238% since our initial evaluation of the app marketplace in 2012 [2]. Medical social networking and the real-time adherence monitoring for both patients and providers are the two features in which notable advancement has been observed since our initial work, particularly among the more advanced adherence apps. Medical social networking allows the patient to choose caregivers or providers to be in their network and receive notifications if the patient misses a dose of their medication. This is especially helpful for the forgetful patient. Real-time adherence monitoring can generate encouraging adherence reports for patients, or be used by providers when assessing the patient's response to medications during clinic visits. Other adherence app technologies that could be promising involve increasing interactivity of the app by offering rewards for desired behaviors with the ultimate goal of promoting habit formation [23,27,28]. This "gamification" and rewards strategy has been used successfully by apps in the mHealth sector for fitness, smoking cessation, and adolescent diabetes self-management [23,24,27,29-32]. Of course, these improvements in connectivity may improve user satisfaction or the value they place on the adherence app, but demonstrating that these advancements in functionality specifically improve medication adherence or patient outcomes will take considerable study.

Figure 2. Changes in the online marketplaces.



Limitations

The following limitations should be considered when interpreting the findings presented herein. As briefly discussed above, consumer ratings introduce potential selection bias, specifically when evaluating how "health-literate" an app is. Such potential is possible, because the demographics and other characteristics of consumers who rate and review adherence apps are unknown. Thus, it is not known if the raters are representative of users who may need adherence apps the most, namely those with poor health outcomes, often related to low HL. Second, the IOM recommendations for designing HL into mobile apps, which were used as rating criteria in this project to assess how "health-literate" the adherence apps are, were only promulgated in 2014. Therefore, it is unknown whether developers are fully aware of these recommendations or the extent to which they have purposefully tried to implement them into their adherence app designs. Although our rating system assesses the inclusion of features consistent with the IOM recommendations, it does not capture when these features were added or how well they address the IOM recommendations. Finally, the attributes and scoring approach reflect the health care provider and research perspectives and not necessarily the consumer or patient perspective. Our ratings, however, were positively correlated with consumer reviews suggesting that our ratings, at least in part, may also be useful to end users.

Conclusions

Medication nonadherence, particularly unintentional nonadherence, continues to complicate the management of those with chronic illnesses. With ongoing proliferation of smartphones and mobile technology, the adherence app marketplace continues to rapidly expand. Past analyses of desirable attributes of adherence apps from a health care provider vantage point correlate with unsolicited consumer reviews of the apps. Although consumer-provided reviews of adherence apps provide an indirect method to assess the patient or caregiver perspective of adherence apps, they do not correlate with standardized health care provider assessments of the "HL" of such apps. Future studies are needed to improve the external validity of the HL assessments of adherence apps.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Medappfinder.com homepage.

[PNG File, 192KB - mhealth_v5i4e45_app1.png]

Multimedia Appendix 2

Medappfinder.com patient app search page.

[PNG File, 86KB - mhealth_v5i4e45_app2.png]

Multimedia Appendix 3

Medappfinder.com provider app search page.

[PNG File, 136KB - mhealth_v5i4e45_app3.png]

References

1. Iihara N, Tsukamoto T, Morita S, Miyoshi C, Takabatake K, Kurosaki Y. Beliefs of chronically ill Japanese patients that lead to intentional non-adherence to medication. J Clin Pharm Ther 2004 Oct;29(5):417-424. [doi: 10.1111/j.1365-2710.2004.00580.x] [Medline: 15482384]
2. Dayer L, Heldenbrand S, Anderson P, Gubbins PO, Martin BC. Smartphone medication adherence apps: potential benefits to patients and providers. J Am Pharm Assoc (2003) 2013;53(2):172-181 [FREE Full text] [doi: 10.1331/JAPhA.2013.12202] [Medline: 23571625]
3. Aitken MS. IMS Health. 2013 Aug 04. Avoidable costs in us healthcare: the $200 billion opportunity from using medicines more responsibly URL: http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Avoidable_Costs_in%20_US_Healthcare/IHII_AvoidableCosts_2013.pdf [accessed 2017-03-31] [WebCite Cache ID 6pNTJ2VZK]
4. Benjamin RM. Medication adherence: helping patients take their medicines as directed. Public Health Rep 2012;127(1):2-3 [FREE Full text] [doi: 10.1177/003335491212700102] [Medline: 22298918]
5. Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005 Aug 4;353(5):487-497. [doi: 10.1056/NEJMra050100] [Medline: 16079372]
6. Heldenbrand S, Martin BC, Gubbins PO, Hadden K, Renna C, Shilling R, et al. Assessment of medication adherence app features, functionality, and health literacy level and the creation of a searchable Web-based adherence app resource for health care professionals and patients. J Am Pharm Assoc (2003) 2016;56(3):293-302. [doi: 10.1016/j.japh.2015.12.014] [Medline: 27067551]
7. Poushter J. Pew Research Center. 2016 Apr 28. Smartphone ownership and internet usage continues to climb in emerging economies URL: http://www.pewglobal.org/files/2016/02/pew_research_center_global_technology_report_final_february_22__2016.pdf [accessed 2017-03-31] [WebCite Cache ID 6pNTSMtZt]
8. Smith A. Pew Research Center. 2016. US Smartphone Use in 2015 URL: http://www.pewinternet.org/files/2015/03/PI_Smartphones_0401151.pdf [accessed 2017-04-10] [WebCite Cache ID 6pc90q3Nz]
9. Lv Y, Zhao H, Liang Z, Dong H, Liu L, Zhang D, et al. A mobile phone short message service improves perceived control of asthma: a randomized controlled trial. Telemed J E Health 2012;18(6):420-426. [doi: 10.1089/tmj.2011.0218]
10. Strandbygaard U, Thomsen S, Backer V. A daily SMS reminder increases adherence to asthma treatment: a three-month follow-up study. Respir Med 2010;104(2):166-171. [doi: 10.1016/j.rmed.2009.10.003]
11. Montes J, Medina E, Gomez-Beneyto M, Maurino J. A short message service (SMS)-based strategy for enhancing adherence to antipsychotic medication in schizophrenia. Psychiatry Res 2012;200(2-3):89-95. [doi: 10.1016/j.psychres.2012.07.034]

12. Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, et al. A Spanish pillbox app for elderly patients taking multiple medications: randomized controlled trial. J Med Internet Res 2014;16(4):e99 [FREE Full text] [doi: 10.2196/jmir.3269] [Medline: 24705022]
13. Israni A, Dean D, Kasel B, Berndt L, Wildebush W, Wang C. Why do patients forget to take immunosuppression medications and miss appointments: can a mobile phone app help? JMIR Public Health Surveill 2016;2(1):e15. [Medline: 27227150]
14. Morawski K, Ghazinouri R, Krumme A, McDonough J, Durfee E, Oley L, et al. Rationale and Design of the Medication adherence Improvement Support App For Engagement - Blood Pressure (MedISAFE-BP) Trial. Am Heart J 2017;186:40-47. [doi: 10.1016/j.ahj.2016.11.007]
15. Nelson L, Mulvaney S, Gebretsadik T, Ho Y, Johnson K, Osborn C. Disparities in the use of a mHealth medication adherence promotion intervention for low-income adults with type 2 diabetes. J Am Med Inform Assoc 2016;23(1):12-18. [Medline: 26186935]
16. Aikens J, Zivin K, Trivedi R, Piette J. Diabetes self-management support using mHealth and enhanced informal caregiving. J Diabetes Complications 2014;28(2):171-176. [Medline: 24374137]
17. Powell A, Torous J, Chan S, Raynor G, Shwarts E, Shanahan M, et al. Interrater reliability of mHealth app rating measures: analysis of top depression and smoking cessation apps. JMIR Mhealth Uhealth 2016;4(1):e15. [Medline: 26863986]
18. Browning R, McGillicuddy J, Treiber F, Taber D. Kidney transplant recipients' attitudes about using mobile health technology for managing and monitoring medication therapy. J Am Pharm Assoc 2016;56(4):450-454. [doi: 10.1016/j.japh.2016.03.017] [Medline: 27450140]
19. Broderick J, Devine T, Langhans E, Lemerise A, Lier S, Harris L. Institute of Medicine of the National Academies. 2014. Designing health literate mobile apps URL: https://health.gov/communication/literacy/BPH-HealthLiterateApps.pdf [accessed 2017-03-31] [WebCite Cache ID 6pNUVdapS]
20. Hemphill J. Interpreting the magnitudes of correlation coefficients. Am Psychol 2003;58(1):78-79. [Medline: 12674822]
21. Gignac GE. Effect size guidelines for individual differences researchers. Pers Individ Dif 2016;102:74-78. [doi: 10.1016/j.paid.2016.06.069]
22. Breland J, Yeh V, Yu J. Adherence to evidence-based guidelines among diabetes self-management apps. Transl Behav Med 2013;3(3):277-286.
23. Cafazzo JA, Casselman M, Hamming N, Katzman DK, Palmert MR. Design of an mHealth app for the self-management of adolescent type 1 diabetes: a pilot study. J Med Internet Res 2012;14(3):e70 [FREE Full text] [doi: 10.2196/jmir.2058] [Medline: 22564332]
24. Abroms L, Padmanabhan N, Thaweethai L, Phillips T. iPhone apps for smoking cessation: a content analysis. Am J Prev Med 2011;40(3):279-285. [Medline: 21335258]
25. Becker S, Kribben A, Meister S, Diamantidis CJ, Unger N, Mitchell A. User profiles of a smartphone application to support drug adherence--experiences from the iNephro project. PLoS One 2013;8(10):e78547 [FREE Full text] [doi: 10.1371/journal.pone.0078547] [Medline: 24194946]
26. Silva J, Mouttham A, El Saddik A. UbiMeds: a mobile application to improve accessibilitysupport medication adherence. In: Proceedings of the 1st ACM SIGMM international workshop on Media studies and implementations that help improving access to disabled users. 2009 Presented at: ACM; October 23, 2009; Beijing, China.
27. Miller AS, Cafazzo JA, Seto E. A game plan: Gamification design principles in mHealth applications for chronic disease management. Health Informatics J 2016 Jun;22(2):184-193. [doi: 10.1177/1460458214537511] [Medline: 24986104]
28. Goyal SJ, Caffazo JA. Mobile phone health apps for diabetes management: current evidencefuture developments. QJM 2013;106(12):1067-1069. [doi: 10.1093/qjmed/hct203]
29. Lyons EJ, Lewis ZH, Mayrsohn BG, Rowland JL. Behavior change techniques implemented in electronic lifestyle activity monitors: a systematic content analysis. J Med Internet Res 2014;16(8):e192 [FREE Full text] [doi: 10.2196/jmir.3469] [Medline: 25131661]
30. Wearing JR, Nollen N, Befort C, Davis AM, Agemy CK. iPhone app adherence to expert-recommended guidelines for pediatric obesity prevention. Child Obes 2014 Apr;10(2):132-144 [FREE Full text] [doi: 10.1089/chi.2013.0084] [Medline: 24655230]
31. Edmunds J, Ntoumanis N, Duda J. Helping your clients and patients take ownership over their exercise: Fostering exercise adoption, adherence, and associated well-being. ACSM's Health Fit J 2009;13(3):20-25. [doi: 10.1249/FIT.0b013e3181a1c2c4]
32. Stawarz K, Cox A, Blandford A. Beyond self-trackingreminders: designing smartphone apps that support habit formation. 2015 Presented at: The 33rd Annual ACM Conference on Human Factors in Computing Systems; April 18-23, 2015; Seoul, Republic of Korea.

Abbreviations

HL: health literacy
IOM: Institute of Medicine
OS: operating system
SMS: short message service

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Original Paper

A Framework for the Study of Complex mHealth Interventions in Diverse Cultural Settings

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Abstract

Background: To facilitate decision-making capacity between options of care under real-life service conditions, clinical trials must be pragmatic to evaluate mobile health (mHealth) interventions under the variable conditions of health care settings with a wide range of participants. The mHealth interventions require changes in the behavior of patients and providers, creating considerable complexity and ambiguity related to causal chains. Process evaluations of the implementation are necessary to shed light on the range of unanticipated effects an intervention may have, what the active ingredients in everyday practice are, how they exert their effect, and how these may vary among recipients or between sites.

Objective: Building on the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth) statement and participatory evaluation theory, we present a framework for the process evaluations for mHealth interventions in multiple cultural settings. We also describe the application of this evaluation framework to the implementation of DREAM-GLOBAL (Diagnosing hypertension—Engaging Action and Management in Getting Lower BP in Indigenous and LMIC [low- and middle-income countries]), a pragmatic randomized controlled trial (RCT), and mHealth intervention designed to improve hypertension management in low-resource environments. We describe the evaluation questions and the data collection processes developed by us.

Methods: Our literature review revealed that there is a significant knowledge gap related to the development of a process evaluation framework for mHealth interventions. We used community-based participatory research (CBPR) methods and formative research data to develop a process evaluation framework nested within a pragmatic RCT.

Results: Four human organizational levels of participants impacted by the mHealth intervention were identified that included patients, providers, community and organizations actors, and health systems and settings. These four levels represent evaluation domains and became the core focus of the evaluation. In addition, primary implementation themes to explore in each of the domains were identified as follows: (1) the major active components of the intervention, (2) technology of the intervention, (3) cultural congruence, (4) task shifting, and (5) unintended consequences. Using the four organizational domains and their interaction with primary implementation themes, we developed detailed evaluation research questions and identified the data or information sources to best answer our questions.

Conclusions: Using DREAM-GLOBAL to illustrate our approach, we succeeded in developing an uncomplicated process evaluation framework for mHealth interventions that provide key information to stakeholders, which can optimize implementation

of a pragmatic trial as well as inform scale up. The human organizational level domains used to focus the primary implementation themes in the DREAM-GLOBAL process evaluation framework are sufficiently supported in our research, and the literature and can serve as a valuable tool for other mHealth process evaluations.

Trial Registration: ClinicalTrials.gov NCT02111226; https://clinicaltrials.gov/ct2/show/NCT02111226 (Archived by WebCite at http://www.webcitation.org/6oxfHXege)

(JMIR Mhealth Uhealth 2017;5(4):e47) doi:10.2196/mhealth.7044

KEYWORDS

mobile health; health care texting; SMS; protocol; process evaluation; process assessment (health care); health services, Indigenous; Tanzania; community-based participatory research; DREAM-GLOBAL

Introduction

Pragmatic RCTs and mHealth Interventions

Explanatory randomized controlled trials (RCTs) are the gold standard for measuring efficacy, the cause and effect relationship in treatment intervention research in medicine, and are instrumental in providing evidence for Clinical Practice Guidelines (CPGs). A key requirement of explanatory RCTs is the stringent standardization of the tested intervention, which (while challenging) is realistic; for example, in pharmaceutical trials that occur in clinical settings where a single variable can be reasonably well controlled. Standardization in explanatory RCTs removes bias and thus results in substantial rigor and strong internal validity; however, in contrast, external validity (ie, the applicability in diverse clinical settings) is often compromised and consequently applying RCT results to populations outside the study's scope can be problematic [1,2].

Health care interventions are typically difficult to standardize because they are complex with long, nonlinear implementation chains that may have unexpected outcomes in disparate settings. Similarly, mobile health (mHealth) interventions usually contain multiple active components that may require changes in the behavior of patients and providers. These behaviors in turn are driven by numerous social, cultural, and environmental factors, thus creating considerable complexity and even ambiguity related to causal chains [3,4]. Therefore, a shortcoming of the robust explanatory RCT methodology is that this approach often falls short of providing answers needed in mHealth interventions and everyday clinical care practice [5]. To facilitate the decision-making capacity between options of care under real-life service conditions, clinical trials must be pragmatic to evaluate an intervention under the variable conditions of health care settings with a wide range of participants [6].

Evaluating and Reporting Pragmatic RCTs of mHealth Interventions

To be truly useful for decision making, pragmatic trials require detailed and standardized reporting with sufficient transparency to communicate what works and what does not work for whom and under what circumstances. The prevailing international standard for reporting trials in general is the CONSORT statement [7], which has been expanded by Zwarenstein and colleagues [6] to reflect the complexity of issues that may impact on pragmatic trials. For Web-based and mHealth interventions, Eysenbach and colleagues have called for further expansion of reporting requirements. They developed the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth) statement to ensure reporting of sufficient detail for replication and theory building specifically to eHealth [8]. The reporting standards are designed to provide important guidance for reporting trials in general, but they do not distinguish specific elements that should be researched during the process of implementation and juxtaposed with outcome research at the end of the trial.

Although the key research outcome of a complex intervention focuses on the effectiveness of the intervention in everyday practice, the process evaluation in contrast assesses how closely the intervention was actually implemented as intended in the study protocol. Process evaluation data explain why a study unexpectedly did not achieve anticipated outcomes or if achieved outcomes are truly a consequence of the intervention. Process evaluations therefore help to distinguish between the reasons for lack of outcome as follows: (1) a consequence of either implementation failure or (2) the failure of the intervention itself. In multisetting studies, the process evaluation also facilitates an examination of differences in outcome and documents program adaptations at various sites. Process evaluations shed light on the range of unanticipated effects an intervention may have, what the active ingredients in everyday practice are, how they exert their effect, and how these may vary among recipients or between sites [9].

Investigating Implementation Factors in Multisetting RCTs

Although standardized reporting of pragmatic trials is crucial to our understanding of how and why complex interventions work, a difficulty related to good reporting is that neither all the active components nor implementation barriers are known before the start of a trial; instead issues are often discovered during the implementation process and may vary between settings, thus requiring an emergent rather than predetermined study of implementation. Consequently, a key opportunity for the discovery and description of the unanticipated active components is the process evaluation. We argue that standardized reporting frameworks for pragmatic RCTs must allow for flexibility to permit investigators to explore emergent processes, once work on the trial has commenced, to ensure rigorous documentation of the evolving and capricious aspects of implementation. Therefore, a process evaluation plan that systematically seeks to document not only the standardized implementation items but also the emergent aspects of

implementation must be a critical piece in the documentation of pragmatic trials, particularly when diverse cultural settings are involved.

Recommendations for the design of process evaluations of complex interventions have been published [9-12]. We maintain, however, that little work has focused on developing theoretical approaches that would help researchers to reduce the complexity of the process evaluation by focusing on those functional components that are most relevant to community stakeholders as well as researchers in mHealth interventions.

Although there can be no single definition of what elements comprise the process evaluation of the implementation of mHealth interventions, we deconstruct the functional components that are most significant to researchers, policy makers and implementation science in this study. Building on the CONSORT-EHEALTH statement and participatory evaluation theory, we present a framework for the process evaluations for mHealth interventions focusing on active components of the intervention in multiple cultural settings. We also describe the application of this evaluation framework to the implementation of DREAM-GLOBAL (Diagnosing hypertension—Engaging Action and Management in Getting Lower BP in Indigenous and LMIC [low- and middle- income countries]), a pragmatic RCT and mHealth intervention designed to improve hypertension management in low-resource environments. In addition, we describe data collection tools and processes that were developed to collect the process evaluation data necessary to inform implementation of the pragmatic RCT and to inform future scale up of DREAM-GLOBAL in various geographic and cultural settings.

Methods

The DREAM-GLOBAL RCT

DREAM-GLOBAL is a pragmatic RCT that can be described as a complex mHealth intervention. It is a research project designed to increase the capacity for affordable, evidence-based, guidelines-driven hypertension management interventions at the patient, provider, and community level by leveraging existing mobile telecommunication technology and task shifting (findings by Yeates K et al, unpublished data, 2016). This study was funded by The Canadian Institutes of Health Research, Grand Challenges Canada, and by the Global Alliance for Chronic Diseases and involves diverse cultural and geographic settings, including Indigenous communities in Canada and the Kilimanjaro region of Tanzania.

The DREAM-GLOBAL mobile technology consisted of health care short messaging services (SMS) texting to support patient hypertension self-management and to facilitate decision support for health care providers. The program theory was informed by the Canadian Hypertension Education Program CPGs drawing on evidence for the prevention of high Blood Pressure (BP) through dietary sodium restriction, BP measurement, education interventions for health care providers and patients, inter-professional care, health systems, and interventions such as automated reminder systems [13,14].

Specifically, the DREAM-GLOBAL RCT was designed to test the effectiveness of mobile phone–based SMS feedback to patients and providers tailored to patients' BP measurements using artificial intelligence. Briefly, in this intervention, nonmedical workers used Bluetooth-enabled BP monitors to record and transmit BP readings from patients with hypertension. Mobile phones were used for storing and transmitting the patient roster and BP readings to a server. The server then sent text messages to the participating patients with their individual results. Study participants were randomized into two groups: one group received a set of cardiovascular health promotion messages and the second group received the same set of messages and additional "active" messages that support self-management by indicating requirement for attendance at medical appointments, rationale for drug therapy, and adherence to medication regimes, and messages directly reflective of their blood pressure readings. In addition, DREAM-GLOBAL closed the loop for sharing of clinical health information among health care providers.

The DREAM-GLOBAL Constructivist Approach to the Process Evaluation

Our review of the RCT reporting and process evaluation literature revealed that there is a significant knowledge gap related to the development of a process evaluation framework that can accommodate the values of community-based participatory research (CBPR) and the importance of acknowledging diverse cultural perspectives and settings. We used a medical anthropology approach to develop a framework reflective of participatory evaluation theory and specifically focused on meeting the information needs of academic and community stakeholders for mHealth interventions in diverse settings. The process evaluation framework was informed by the following 3 main factors:

1. A review of current process evaluation theories applied to complex interventions and established RCT reporting requirements;
2. Formative DREAM-GLOBAL CBPR in diverse cultural settings, including ethnographic notes, research engagement and implementation research notes, and reflective discussion sessions with research and community teams collected during formative research. This data represents a substantial set of qualitative data collected over the period of 1.5 years [15,16];
3. mHealth-specific topics within the context of international, culturally, and geographically diverse low-resource settings [17].

Current Process Evaluation Theories

Various approaches to the evaluation of complex interventions have been described in the literature. Bamberger and colleagues stressed that no single methodology can address all dimensions of complexity and that a careful mapping of complexity dimensions is necessary to design an evaluation [18,19]. They offered a conceptual framework of 5 sources of complexity in the evaluation of interventions as follows: (1) the nature of the program (what does the intervention look like), (2) the context within which the program is embedded, (3) the interactions among the different stakeholders and agencies involved in the

program,(4) the nature of processes of change and causality (how does the program effect change in society and how can change be captured), and (5) the nature of the evaluation process (how to deal with divergent stakeholder interests and incentives, data availability, resources, etc) [20].

In contrast, Damschroder and coworkers conducted a review of the literature and identified 5 major domains for the evaluation of implementation: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. The respective domains are further broken down into a total of 37 subcategories such as cost, policies, implementation climate, stage of change, and engagement [21].

Realist evaluation approaches have also been applied to process evaluations of complex interventions [22]. The realist evaluation questions include: "What works, for whom, in what respects, to what extent, in what contexts, and how?" To answer these questions, realist evaluators tried to identify the underlying mechanisms that explain how the outcomes were caused and the influence of context on the intervention [23]. Although the main realist evaluation questions can be adapted to various projects, there is a lack of consensus and consistency in defining the major domains of "mechanism" and "context." This limited its utility in the development of a concise framework for process evaluations aimed at mHealth interventions, particularly when sources of complexity include culturally and geographically diverse low-resource sites, such as the DREAM-GLOBAL trial [24].

The Medical Research Council's (MRC) guidance report is a framework for process evaluation of complex interventions and builds on the 2008 MRC guidance document for complex interventions, which recognized the importance of process evaluation within trials [11,12]. It builds on three concepts for a process evaluation design namely the description of the intervention, the mechanisms, and the context. These concepts align with realist evaluation theory, although the authors do not recommend specific evaluation theories or approaches. The authors argue for clear descriptions of intervention theory and identification of key implementation process questions and tailoring of the evaluation to the intervention.

While all these frameworks will result in the documentation of important aspects of a process evaluation, there are also serious limitations. For example, although these approaches advocate to examine the setting of the intervention, it is not clear which aspects of the setting evaluators should be focused on. Another limitation specifically associated with realist evaluation approaches is that realist philosophy presupposes that "reality can be experienced and shared by everyone in precisely the same way" [25]. However, in a multicultural context, there is often little knowledge and experience that is shared between the researchers and those who interact with the intervention. It is precisely the lack of a shared culture that makes implementation particularly difficult to predict, unless the differences in how the intervention is experienced in various cultural settings are acknowledged and actively researched. We argue that it is particularly important when dealing with evaluations in multiple cultural settings to use a constructivist approach which acknowledges the knowledge and experience constructed by the individuals and societies. Participatory evaluation theory provides an excellent framework, as this approach incorporates the perspective and lived experience of local stakeholder in all aspects of evaluation. The participatory evaluation approach includes a community-based discovery process of implementation issues that integrates local knowledge and is essential to the development of a good evaluation framework for health interventions designed to work in diverse settings.

We argue that given the complexity of mHealth interventions and the multiple cultural settings of trials such as DREAM-GLOBAL, it would be naive for an evaluator to identify a priori the most important active components of the intervention and related evaluation research questions. Local knowledge and expertise of community stakeholders is urgently needed not only for successful implementation of DREAM-GLOBAL but also to understand implementation barriers and required adaptations. We therefore intentionally moved away from notions of the detached objectivity of a positivistic oriented evaluation which would marginalize local knowledge and emergent understandings. Instead of applying a constructivist evaluation approach, the research team entered the development of the process evaluation as "learners, not claiming to know preordinately what is salient" [26]. The collaborative process, characteristic of constructivist inquiry supported a discovery process informed by dialogue, negotiation, and verification with stakeholders to identify the most relevant evaluation domains related to implementation [26].

Formative Community-Based Participatory Research

CBPR has been defined as "a collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied, representatives of organizations, and researchers in all aspects of the research process to improve health and well-being through taking action, including social change" [27]. CBPR principles have been incorporated into DREAM-GLOBAL. During formative CBPR research for this project, we developed an information gathering and dialogue tool, consisting of the following 3 phases: (1) a community profile tool, (2) an interview guide to facilitate the discussion of strategic topics related to implementation with key stakeholders in the community, and (3) a focus group guide to lead a dialogue on community-specific issues related to the intervention. The methodology has been previously published [15]. A thematic analysis of this qualitative data as well as participant observation data from community visits and team meetings provided initial process evaluation domains and evaluation research questions. We then further compared and contrasted our formative data with the evaluation literature, specifically the MRC guidelines [12] and CONSORT-EHEALTH extension. We ensured that the basic process evaluation domains would address the most important research questions that are meaningful and of immediate importance to community and policy maker stakeholders.

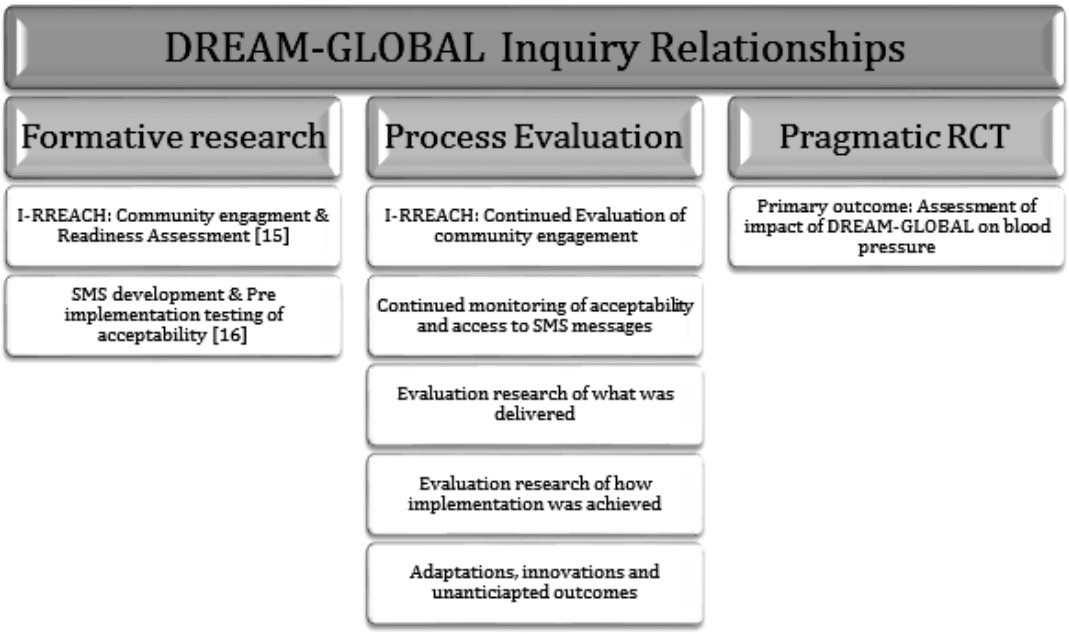
The finalization of the process evaluation domains was facilitated by monthly team discussions and several evaluation

meetings over the period of 12 months where the literature, formative research evidence, ethnographic notes, and stakeholder discussion notes were analyzed, and eventually consensus was reached on the most significant process evaluation domains.

Integration of the Process Evaluation Research Into the DREAM-GLOBAL Trial

The pragmatic trial is designed to test the program theory of DREAM-GLOBAL—to facilitate the control of BP in low-resource environments through evidence-based text messaging, targeting patients, and enabling feedback to health care providers. The formative research was designed to generate technological, cultural, social, and health systems data to determine feasibility and, if necessary, plan for tailoring the implementation for each DREAM-GLOBAL site [15,16]. The process evaluation protocol was nested within the pragmatic trial and followed the formative research before implementation of the trial and preceded outcome research (see Figure 1). The purpose of the process evaluation was primarily to evaluate the process of implementation of the trial; however, it will also generate information that will be valuable for potential posttrial scale up of DREAM-GLOBAL. The objectives of the process evaluation were to examine (1) what was delivered, including the quality (fidelity) and quantity (dose); (2) how delivery of the intervention was achieved; as well as (3) how the mHealth intervention required adaptations or innovations within the context of international, culturally, and geographically diverse low-resource settings [28] and 4) any unanticipated outcomes [12].

Figure 1. DREAM-GLOBAL process evaluation relationship to formative research and trial research (I-RREACH, Intervention and Research Readiness Engagement and Assessment of Community Health Care).



Ethics

The study involved Indigenous people and is built foremost on strong commitment to respectful, CBPR with First Nations communities as partners in research as outlined in the Tri-Council Policy Statement (TCPS 2) [29]. We therefore sought academic ethics review as well as community-based First Nations ethics review for the clinical trial as well as the process evaluation research. Furthermore, the research team also sought formal approval and permission for DREAM-GLOBAL implementation from First Nations decision makers in each of the participating communities after local, in-person presentations. Academic ethics approvals include the following: (1) Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, Kingston, Ontario (DMED-1603-13); (2) Sunnybrook Health Sciences Centre Research Ethics Board, Toronto, Ontario, (#182-2013) and (3) the National Institute for Medical Research Tanzania (NIMR/HQ/R.8a/Vol.IX/1698). Community-based ethics review in First Nations communities included The Cree Board of Health and Social Services of James Bay, Ontario and Manitoulin Anishinaabek Research Review Committee (MARRC), Ontario. The study was also formally approved by decision-making bodies in all participating communities through Band Council Resolutions in participating First Nations.

Trial Status

The implementation of the RCT (ClinicalTrials.gov registration: NCT02111226. 2014) is currently ongoing and is expected to be completed by December 2017. The data analysis had not begun at the time of submission of this protocol.

Results

Organizational Levels of the Process Evaluation

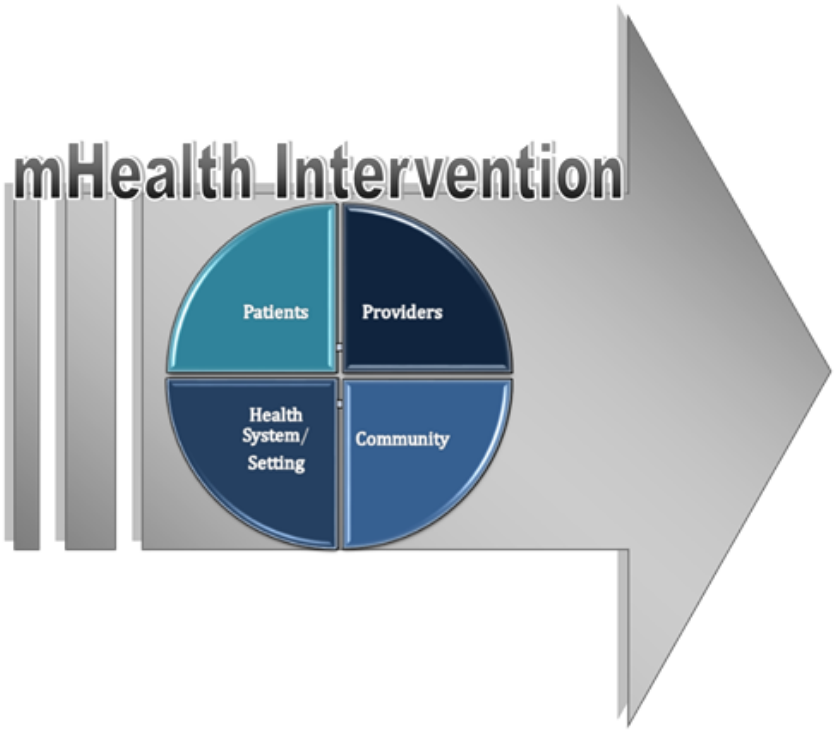
Four human organizational levels of participants impacted by the mHealth intervention were identified in our analysis and included patients, providers, community and organizations actors, and health systems and settings (see Figure 2). These four levels correspond with the organizational evaluation domains (see Textbox 1).

These four organizational levels critically impact on the primary outcome of the mHealth intervention, that is, improvements in BP. The process evaluation framework therefore examines implementation from each of these four organizational perspectives.

Textbox 1. Human organizational levels.

- Patient participants comprise the primary target population of the intervention, in this case people with hypertension are enrolled in the study.
- Provider participants are care and service providers whose work is to some degree altered by the intervention.
- Community and organization members are people whose immediate social environment impacts on the intervention, for example, those who permit the implementation or approve changes in work flow. They may also be decision makers.
- Health system and setting members are people or structures that impact on the implementation at a systems level, such as local and district level decision makers and National health policy makers.

Figure 2. Major factors that interact with the DREAM-GLOBAL mHealth intervention.



Primary Implementation Themes in the Process Evaluation

We thematically reanalyzed qualitative data collected during the formative research and found four primary implementation themes that interact with the four organizational domains described above. The primary implementation themes for each of the organizational domains were (1) identification of the major active component of the intervention (or program theory), (2) the technology of the intervention, (3) cultural congruence, and (4) task shifting. In addition, participant observation research and ongoing collaboration meetings with community stakeholders helped to identify emergent issues and the importance of these issues. We therefore learned the importance of documenting unintended consequences, which became our fifth primary implementation theme.

Development of Evaluation Questions

The interaction between the organizational levels and the primary implementation themes will be explored in this process evaluation. Using the four organizational domains and their interaction with the primary implementation themes, we developed detailed evaluation research questions and the identified data or information sources that we concluded would best answer our questions. The evaluation questions and data sources are presented in Multimedia Appendix 1.

For example, one issue identified as a primary implementation theme in our formative work was the notion of task shifting.

Task shifting in health care is a process where specific tasks are delegated to health care workers who have fewer qualifications but have received competency training [30]. In DREAM-GLOBAL, the task of measuring BP is shifted from a medical to a nonmedical worker. Applying this implementation theme to the four domains of our framework, we developed queries to explore the impact of task shifting on each of the four human organizational levels:

1. Patients have to be comfortable with the task shifting.
2. Nonmedical providers should be confident and willing to take on this new task, and medical providers should be confident on the nonmedical providers to accept that measurements are accurate, in order to act on them
3. The organizational decision makers have to be in a position where they can assign the new tasks.
4. Health system decision makers must support the shift instead of posing barriers (eg, funding or licensing issues).

Discussion

Principal Findings

The DREAM-GLOBAL RCT constitutes a complex mHealth intervention because it is designed to affect change in the behavior of patients, providers, and local systems in order to achieve the primary outcome: lowering BP through management according to CPG. The DREAM-GLOBAL RCT intervenes at multiple points in the care normally provided to patients with hypertension. It combines a chronic care management approach with medical task shifting to community health resource and community health workers in order to ensure hypertension care is delivered according to CPGs, even in low-resource environments such as Indigenous communities in Canada and Tanzania.

Given the complexity of the program, extensive formative research was necessary to understand the local health care system before initiating program implementation. This was necessary for the program to be adapted to patients and providers in diverse cultural contexts and health systems [15]. However, we also realized that some adaptations to optimize integration with existing health services and to minimize undue increased workload and systemic barriers could not be anticipated before implementation and that required an openness to flexibility during the process of implementation. In line with Bumbarger and Perkins [28], we wanted to document the unanticipated issues and distinguish between "innovation" (skilled implementers actively attempting to make an intervention better fit their population or setting) and "drift" (unintentional shortcomings arising from barriers to full implementation) [12].

The research team anticipated the possibility of emerging elements that should be examined in a process that may not have been obvious during implementation planning. The research team preplanned a discovery process through formative and CBPR.

Applicability of the DREAM-GLOBAL Framework to Other mHealth Interventions

The DREAM-GLOBAL pragmatic trial involves several interacting components targeting changes in the patient, provider, health organizations, and health systems, which makes it a complex intervention. This is arguably true for almost all mHealth interventions, and our proposed framework based on human organizational level domains is therefore a useful and a clearly focused framework for process evaluations of complex mHealth interventions.

Our framework chart identified several primary implementation themes related to the intervention that we claim to be explored in process evaluations of mHealth interventions:

Major active components of the intervention: Craig and colleagues discussed for the importance of describing and evaluating how the intervention works by clearly describing how the active ingredients exert their effect. "Only by addressing this kind of question can we build a cumulative understanding of causal mechanisms, design more effective interventions and apply them appropriately across group and setting [10]." We believe that it is necessary to explore active components from the perspective of the four human organizational levels of patients, providers, organizations, and systems.

Technology: Technology is by definition the most integral component of any mHealth intervention and therefore requires close scrutiny in process evaluation at different organizational levels.

Cultural congruence: The importance of the significant additional complexity introduced with the inclusion of diverse cultural settings of implementation has been stressed in the literature [9,11]. With increasing cultural diversity within many regions of the world due to human migration as well as the application of interventions in various settings, a focus on the important role of cultural factors and the arising need for adaptation for cultural congruence is an important emergent area of study of mHealth interventions.

Task shifting: Task shifting is one way to expand the health work force in low-resource countries, and it is a necessary component of mHealth when the interventions require new ways for providers to interact with patients.

Unintended consequences: Many teams have underscored the need for process evaluations to capture unintended consequences and the importance of using a variety of methods to describe these in detail [10,11,31].

Clearly, the primary implementation themes of DREAM-GLOBAL are strongly supported in the literature, which underscores their relevance to process evaluations of mHealth interventions, in general. When the framework is applied to interventions other than DREAM-GLOBAL, additional primary implementation themes could be added by researchers once identified, and added to the framework chart. Evaluation questions within the framework chart should be adapted for each intervention.

Implications for mHealth Interventions in Diverse Cultural Settings

The DREAM-GLOBAL process evaluation protocol provides a framework to document how this intervention was implemented in various Indigenous communities in Canada and rural villages in Tanzania; and if the same intervention was implemented and received in similar ways in different communities or not. Our framework has several strengths related to work in diverse cultural settings.

First, this framework allows for exploration of emergent topics and verification with multiple stakeholder perspectives instead of imposing a rigid linear framework that would have put us at risk of not identifying and analyzing key unanticipated implementation factors. The four human organizational levels (patients, providers, community and organizations, and health systems and settings) can be applied to other mHealth interventions to guide the development of the most salient evaluation research questions. Although implementation themes may vary slightly in other mHealth interventions, following our approach will help to identify the relevant implementation themes.

Second, our collaborative social constructivist I-RREACH approach allowed us to tap into the tacit knowledge of stakeholders by collecting qualitative data through field notes and extensive dialogue and negotiation. Community stakeholders and providers have tacit local knowledge which can support, strengthen and optimize the intervention in the local context; academic team members on the other hand have technical expertise to ensure that essential elements of an intervention are preserved in various settings [15].

Third, CBPR—the research approach employed for DREAM-GLOBAL—is an excellent epistemological fit with a social constructivist evaluation approach. Clearly, CBPR shares the orientation of social constructivist evaluation in that it incorporates and legitimizes multiple value systems, perspectives, and stakeholders and emphasizes the role of dialogue and negotiation and their link to action and improvements. Therefore, as part of the study implementation, the community was involved in shaping how the research would be implemented to provide the maximal benefit for the community and these processes were critically important for the successes of the study.

Fourth, the process evaluation is intended to support the succinct reporting of the DREAM-GLOBAL RCT according to the CONSORT-EHEALTH.

Finally, we found that the formative qualitative research on community engagement and the development of the SMS messages we conducted before implementation of DREAM-GLOBAL [15,16] were also useful in informing the process evaluation. The I-RREACH process was implemented in five Indigenous communities and two rural villages in Tanzania. A total of 135 informants participated in 12 focus groups and 7 interviews. After the sessions were completed, 83 informants participated in an evaluation of the I-RREACH session. During the development of culturally safe SMS messages, a total of 45 informants from 3 Indigenous communities and 1 community in Tanzania participated in four focus groups. This rich formative qualitative research provided deeper understanding of community issues related to the implementation of a hypertension mHealth intervention in our thematic analysis and confirmation for the emerging evaluation domains for the process evaluation protocol.

We acknowledge that an important factor in our approach is that it relies on a collaborative team approach which includes local community experts and a well-functioning interdisciplinary academic team.

Our research supports the notion that process evaluations of complex mHealth interventions cannot be fully designed in advance and instead should employ a framework that allows for emergent research. When an mHealth intervention is to be deployed in multiple cultural settings, our research suggests that a participatory constructivist approach to the development of the process evaluation is necessary to identify relevant evaluation questions that incorporate local knowledge and expertise.

Conclusions

Eysenbach and colleagues stated that the CONSORT-EHEALTH statement is “only the first step and the guideline will be very much a living document in an iterative and ongoing development process” [8]. We have developed from this checklist, to identify items that are well suited to be studied during implantation of an mHealth intervention during the implementation using process evaluation methodologies. We succeeded in creating an uncomplicated approach to the development of a process evaluation framework for mHealth interventions that provide key information to stakeholders, which can optimize implementation of the pragmatic trial and can be used to inform scale up. The human organizational level domains used to focus primary implementation themes in the DREAM-GLOBAL process evaluation framework are sufficiently supported in our research and literature that they can serve as a valuable tool for other mHealth process evaluations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Framework chart with evaluation research questions.

[PDF File (Adobe PDF File), 55KB - mhealth_v5i4e47_app1.pdf]

References

1. Hotopf M. The pragmatic randomised controlled trial. Adv Psychiatr Treat 2002;8(5):326-333. [doi: 10.1192/apt.8.5.326]
2. McAlister FA, van Diepen S, Padwal RS, Johnson JA, Majumdar SR. How evidence-based are the recommendations in evidence-based guidelines? PLoS Med 2007 Aug;4(8):e250 [FREE Full text] [doi: 10.1371/journal.pmed.0040250] [Medline: 17683197]
3. Audrey S, Holliday J, Parry-Langdon N, Campbell R. Meeting the challenges of implementing process evaluation within randomized controlled trials: the example of ASSIST (A Stop Smoking in Schools Trial). Health Educ Res 2006 Jun;21(3):366-377. [doi: 10.1093/her/cyl029] [Medline: 16740670]
4. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. Br Med J 2000 Sep 16;321(7262):694-696 [FREE Full text] [Medline: 10987780]
5. Manchikanti L, Hirsch JA, Smith HS. Evidence-based medicine, systematic reviews, and guidelines in interventional pain management: Part 2: randomized controlled trials. Pain Physician 2008;11(6):717-773 [FREE Full text] [Medline: 19057624]
6. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. Br Med J 2008 Nov 11;337:a2390 [FREE Full text] [Medline: 19001484]
7. CONSORT Transparent Reporting of Trials. Consort-statement. Welcome to the CONSORT Website URL: http://www.consort-statement.org/ [accessed 2016-11-22] [WebCite Cache ID 6mDRDCS1f]
8. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res 2011;13(4):e126 [FREE Full text] [doi: 10.2196/jmir.1923] [Medline: 22209829]
9. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. Br Med J 2008;337:a1655 [FREE Full text] [Medline: 18824488]
10. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. MRC. 2006. Developing and evaluating complex interventions: new guidance URL: https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/ [accessed 2017-03-14] [WebCite Cache ID 6oxZxdcZI]
11. Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. MRC. 2014. Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance URL: https://www.mrc.ac.uk/documents/pdf/mrc-phsrn-process-evaluation-guidance-final/ [accessed 2017-03-14] [WebCite Cache ID 6oxaCOXoN]
12. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. Br Med J 2015;350:h1258 [FREE Full text] [Medline: 25791983]
13. Tobe SW, Touyz RM, Campbell NR, Canadian Hypertension Education Program. The Canadian hypertension education program - a unique Canadian knowledge translation program. Can J Cardiol 2007 May 15;23(7):551-555 [FREE Full text] [Medline: 17534461]
14. Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension. Cochrane Database Syst Rev 2010 Mar 17(3):CD005182. [doi: 10.1002/14651858.CD005182.pub4] [Medline: 20238338]
15. Maar M, Yeates K, Barron M, Hua D, Liu P, Moy LM, et al. I-RREACH: an engagement and assessment tool for improving implementation readiness of researchers, organizations and communities in complex interventions. Implement Sci 2015;10:64 [FREE Full text] [doi: 10.1186/s13012-015-0257-6] [Medline: 25935849]
16. Maar MA, Yeates K, Toth Z, Barron M, Boesch L, Hua-Stewart D, et al. Unpacking the black box: a formative research approach to the development of theory-driven, evidence-based, and culturally safe text messages in mobile health interventions. JMIR Mhealth Uhealth 2016 Jan 22;4(1):e10 [FREE Full text] [doi: 10.2196/mhealth.4994] [Medline: 26800712]
17. W Tobe S, Global Alliance for Chronic Diseases Hypertension Research Teams With the World Hypertension League. The global alliance for chronic diseases supports 15 major studies in hypertension prevention and control in low- and

middle-income countries. J Clin Hypertens (Greenwich) 2016 Jul;18(7):600-605 [FREE Full text] [doi: 10.1111/jch.12835] [Medline: 27251590]
18. Bamberger M, Vaessen J, Raimondo E. Complexity in development evaluation: the framework of the book. In: Bamberger M, Vaessen J, Raimondo E, editors. Dealing with Complexity in Development Evaluation: A Practical Approach. Thousand Oaks, CA: SAGE Publications; 2015.
19. Vaessen J, Raimondo E, Bamberger M. Impact evaluation approaches and complexity. In: Bamberger M, Vaessen J, Raimondo E, editors. Dealing with Complexity in Development Evaluation: A Practical Approach. Thousand Oaks, CA: SAGE Publications; 2015.
20. Raimondo E, Bamberger M, Vaessen J. Introduction. In: Bamberger M, Vaessen L, Raimondo E, editors. Dealing with Complexity in Development Evaluation. Thousand Oaks, CA: SAGE Publications; 2015.
21. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009;4:50 [FREE Full text] [doi: 10.1186/1748-5908-4-50] [Medline: 19664226]
22. Fletcher A, Jamal F, Moore G, Evans RE, Murphy S, Bonell C. Realist complex intervention science: applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions. Evaluation (Lond) 2016 Jul;22(3):286-303 [FREE Full text] [doi: 10.1177/1356389016652743] [Medline: 27478401]
23. Marchal B, Van Belle S, Westhop G. Better Evaluation. Realist evaluation URL: http://betterevaluation.org/approach/realist_evaluation [accessed 2016-11-23] [WebCite Cache ID 6mEzerHeo]
24. Marchal B, Westhorp G, Wong G, Van Belle S, Greenhalgh T, Kegels G, et al. Realist RCTs of complex interventions - an oxymoron. Soc Sci Med 2013 Oct;94:124-128. [doi: 10.1016/j.socscimed.2013.06.025] [Medline: 23850482]
25. Campbell B. Realism versus constructivism: which is a more appropriate theory for addressing the nature of science in science education? EJSE 1998;3(1).
26. Guba E, Lincoln Y. Fourth Generation Evaluation. Newbury Park, CA: SAGE Publications; 1989.
27. Viswanathan M, Ammerman A, Eng E, Gartlehner G, Lohr K, Griffith D, et al. AHRQ. 2004. Community-based participatory research: assessing the evidence URL: http://archive.ahrq.gov/downloads/pub/evidence/pdf/cbpr/cbpr.pdf [WebCite Cache ID 6mF1FA95s]
28. Bumbarger B, Perkins D. After randomised trials: issues related to dissemination of evidence - based interventions. J Child Serv 2008 Apr 12;3(2):55-64. [doi: 10.1108/17466660200800012]
29. Government of Canada. Pre-ethics. 2016. TCPS 2 - Chapter 9: Research involving the first nations, inuit and metis peoples of Canada URL: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/ [accessed 2017-03-14] [WebCite Cache ID 6oxbxKODR]
30. World Health Organization. 2008. Task shifting: rational redistribution of tasks among health workforce teams: global recommendations and guidelines URL: http://www.who.int/healthsystems/TTR-TaskShifting.pdf [accessed 2016-11-23] [WebCite Cache ID 6mF0zFTiI]
31. Grant A, Treweek S, Dreischulte T, Foy R, Guthrie B. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. Trials 2013;14:15 [FREE Full text] [doi: 10.1186/1745-6215-14-15] [Medline: 23311722]

Abbreviations

BP: blood pressure
CBPR: community-based participatory research
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth
CPG: clinical practice guidelines
DREAM-GLOBAL: Diagnosing hypertension—Engaging Action and Management in Getting Lower BP in Indigenous and LMIC
I-RREACH: Intervention and Research Readiness Engagement and Assessment of
LMIC: low- and middle-income countries
mHealth: mobile health
MRC: Medical Research Council
RCT: randomized controlled trial
SMS: short message service

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Original Paper

The Physical Activity Tracker Testing in Youth (P.A.T.T.Y.) Study: Content Analysis and Children's Perceptions

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Abstract

Background: Activity trackers are widely used by adults and several models are now marketed for children.

Objective: The aims of this study were to (1) perform a content analysis of behavioral change techniques (BCTs) used by three commercially available youth-oriented activity trackers and (2) obtain feedback describing children's perception of these devices and the associated websites.

Methods: A content analysis recorded the presence of 36 possible BCTs for the MovBand (MB), Sqord (SQ), and Zamzee (ZZ) activity trackers. In addition, 16 participants (mean age 8.6 years [SD 1.6]; 50% female [8/16]) received all three trackers and were oriented to the devices and websites. Participants were instructed to wear the trackers on 4 consecutive days and spend ≥10 min/day on each website. A cognitive interview and survey were administered when the participant returned the devices. Qualitative data analysis was used to analyze the content of the cognitive interviews. Chi-square analyses were used to determine differences in behavioral monitoring and social interaction features between websites.

Results: The MB, SQ, and ZZ devices or websites included 8, 15, and 14 of the possible 36 BCTs, respectively. All of the websites had a behavioral monitoring feature (charts for tracking activity), but the percentage of participants indicating that they "liked" those features varied by website (MB: 8/16, 50%; SQ: 6/16, 38%; ZZ: 11/16, 69%). Two websites (SQ and ZZ) included an "avatar" that the user could create to represent themselves on the website. Participants reported that they "liked" creating and changing their avatar (SQ: 12/16, 75%, ZZ: 15/16, 94%), which was supported by the qualitative analyses of the cognitive interviews. Most participants (75%) indicated that they would want to wear the devices more if their friends were wearing a tracker. No significant differences were observed between SQ and ZZ devices in regards to liking or use of social support interaction features (P=.21 to .37).

Conclusions: The websites contained several BCTs consistent with previously identified strategies. Children "liked" the social aspects of the websites more than the activity tracking features. Developers of commercial activity trackers for youth may benefit from considering a theoretical perspective during the website design process.

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KEYWORDS

child; physical activity; qualitative research

Introduction

Background

The importance of engaging in daily physical activity (PA) to attenuate the prevalence of preventable chronic disease is well documented. To that end, it is recommended that children and adolescents engage in at least 60 min of moderate-to-vigorous intensity PA every day to maintain or improve health status [1]. However, only 42% of children aged 6-11 years meet this recommendation [2]. To offset the rise of unhealthy trends in youth, new strategies are continually being proposed to modify these unhealthy behaviors.

One of the new approaches being explored is to have youth use trackers to self-manage activity behavior. Previous studies have been successful using pedometers as a tool to promote behavior change [3,4]. Electronic self-monitoring devices, such as fitness trackers, have become very popular with recent reports stating that sales have been more than doubled since 2014 [5]. These devices are targeted at various populations, including children. Consumer activity trackers contain accelerometers and provide measures of activity level to the user with the intent to increase PA behavior. Some studies in adults have shown increases in activity when using a device such as a pedometer or activity tracker [6-8]. However, the capability of these devices to improve behavior relies partially on the device's ability to engage users to encourage and support positive behavior change [9,10].

Using theory to guide interventions designed to change health behaviors in adults and youth is well-supported [11-14]. Theoretical models provide mediating variables that can be assessed to better understand intervention success or failure and allow the research to be replicated or modified in future implementations. To what extent these constructs are incorporated into activity tracker websites remains unclear. In particular, there is a lack of research surrounding these devices when used with children.

With the potential for consumer activity trackers to increase PA, it is important to evaluate the behavioral change techniques (BCTs) that are incorporated into these devices to identify how changes (if any) are produced and how it can be improved. BCTs can be defined as observable and replicable components of behavior change interventions [14]. BCTs can be implemented alone or combined to elicit a specific behavior change in intervention areas such as PA.

Middelweerd et al [15] recently performed a content analysis on mobile apps to promote PA in adults. However, limited research has evaluated the presence of BCTs incorporated into activity trackers, particularly in children. Of the PA tracking devices that are currently marketed to children, only the Zamzee (ZZ) has been evaluated, although the device maker conducted this study [16]. The results of this study suggested that users of the ZZ (54-68%) participated in more moderate to vigorous PA than their control group counterparts (P<.001). Additional independent research is needed to inform the community about how well this device and others incorporate BCTs to stimulate behavior change in this population.

Aims of This Study

The aims of this exploratory study were to (1) perform a content analysis to evaluate the BCTs present in three commercially available youth-oriented activity trackers and (2) to obtain feedback and information describing the children's perception of these devices and the associated websites.

Methods

Participants

Children (N=16; age 8.6 years [SD 1.6]; 50% female) were recruited through posted flyers and word of mouth. Inclusion criteria included age (6-11 years) and no physical or mental disabilities that would interfere with the child's ability to perform PA, understand website navigation, or follow protocol instructions. Children were recruited to reflect the elementary school age range, which appears to be a target demographic for the activity trackers tested in this study. The Institutional Review Board approved this study. Written informed consent was obtained from parents, and assent forms were read to each child before any data collection.

Procedures

Before recruiting participants, a content analysis was completed for each tracker and associated website to identify theory-based BCTs. Following the content analysis, children were recruited to participate in the free-living portion of the study. At an initial visit, each participant was asked to simultaneously wear three commercially available PA trackers on four consecutive days. Children were instructed on use of the trackers, given a brief introduction to each website's features, and provided with instructions on uploading activity tracker data to the websites. Participants were instructed to spend a minimum of 10 min each day on each of the three websites. Parents were provided a log to record the amount of time that the child had spent on each website. After 4 days of wear, children returned all devices and then completed cognitive interviews. Children then completed a survey based on awareness and perception of specific BCTs for each website.

Physical Activity Trackers

This investigation focused on three commercially available devices (Figure 1). The Sqord (SQ: Sqord, Inc, Durham, NC, USA) is a wrist-worn device similar to a watch that lacks a display. The MovBand (MB: MovBand, LLC, Brecksville, OH, USA) is another wrist-worn device that displays the time and "Moves" or "Steps." Finally, the ZZ (a project of HopeLab, Redwood City, CA, USA) is a hip-worn device that uses a built-in clip to attach to a user's waistband, pants pocket, or other location. For this study, the ZZ was clipped to an elastic strap with the device positioned over the child's hip.

Each device used specific terms or language in the corresponding website. Images of the home screen for each device can be seen in Figure 2. Each device tallied points throughout the day and upon syncing the device, points that were accumulated since the last upload would appear for the user to view. For the SQ, the metrics were called "activity points" and "sqoins." If you earned enough "sqoins," you could

purchase items to put in your "backpack" (eg, clothing for website avatar). For the ZZ, the metric was called "pointz," and if you accumulated enough "pointz," you could then earn the more valuable metric of "zamz." Similar to the SQ, the ZZ website had a feature where you could purchase "rewards" when enough zamz were earned. Once the users totaled the minimum number of zamz, they could purchase virtual and actual items (eg, clothing for website avatar, shoelaces); actual items would be mailed to the users. When using the SQ and ZZ websites, the users also had the option to express their feelings by using "thought bubbles" (SQ) and "whamz" or "shoutz" (ZZ). The SQ and ZZ websites also contained an avatar feature in which the user could customize their look. The MB website tracked activity using "moves," steps, and miles.

Figure 1. From left to right, the MovBand (MB), Sqord (SQ), and Zamzee (ZZ) activity trackers.

Figure 2. The home pages of the MovBand (MB), Sqord (SQ), and Zamzee (ZZ) websites.

Behavior Change Techniques

In order to map each device or website onto specific BCTs for promoting PA, we used a previously developed taxonomy for "health and fitness" mobile phone apps [17] that have been recently updated [15]. The taxonomy draws from a number of health behavior theories [18], theory of reasoned action [19] and theory of planned behavior [20], and combines similar theoretical constructs into 16 broad categories with 93 specific BCTs listed within the broader categories. A total of 36 specific BCTs were included for this project, since not all techniques in the full taxonomy applied to children and/or PA promotion. Using our list of 36 BCTs, two researchers assessed the presence of each BCT for each website or device (product) and noted where this BCT was evident. After the independent content analyses, the two researchers conferred and resolved any discrepancies.

Cognitive Interviews and Survey

To assess the children's ability to navigate the websites, we used a combination of semi-structured cognitive interviews during website navigation and structured survey responses to gauge the comprehension of website features. The cognitive interviews used a "talk aloud" technique where participants navigated each device website while talking aloud about their understanding of the display, their likes or dislikes about the format, and their understanding of how to navigate the website. The order of which websites were presented to the child during each interview was random. The interviews were video- and audiotaped to provide an accurate account of each participant's experience. Videotaping was conducted with a digital video camera pointing over the child's shoulder so that the child's face was not seen. The audiotape from each session was transcribed.

After the interview, participants also completed a survey to provide feedback about specific website features and their experience using the devices. To ensure comprehension, all questions and response options were read out loud to all participants and researchers marked their responses on the survey. PA was defined for the child as, "any play, game, sport, or exercise that gets you moving and breathing harder," before answering any questions.

Participants answered questions about their usage (5 questions) and enjoyment of (4 questions) specific website features. When asking about usage of specific features, children chose from the options "never," "a little," or "a lot." For example, one question asking about a SQ specific feature was, "How often did you interact with other people on the Sqord website (high fives, squaks)?" In order to gauge the degree to which a participant enjoyed specific features of the device, they were asked 4

questions for each website; “Tell us how much you liked these features from the Sqord website: (1) Track your PA, (2) Find out about other activities and games, (3) squaks or high fives, and (4) Creating and changing your avatar.” Similar questions were asked for the MB (no avatar) and ZZ website features. Response options included, “disliked,” “okay,” “liked,” or “I don’t know.” We also assessed the participant’s experience as a whole, not related to a specific device, using five additional questions.

Statistical Analyses

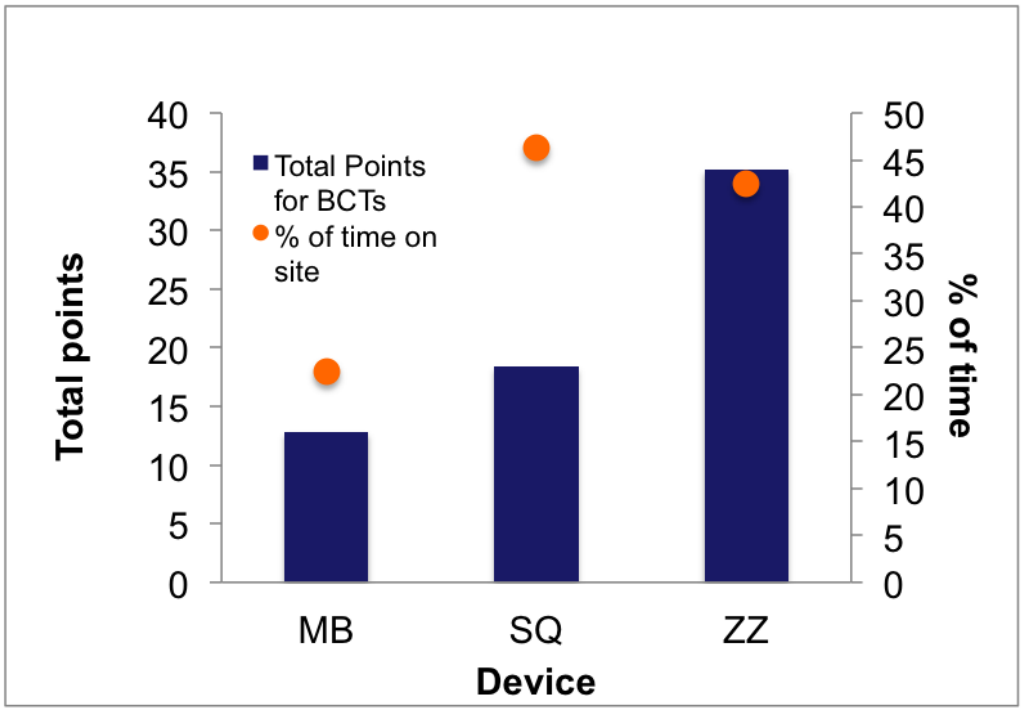
The degree to which each BCT was incorporated into the design of the product was assessed by noting the number of times the BCT category was marked for the device and/or website (assigned 1 point for each subcategory). Also, BCTs that were visible on the home page of the device website or on the tracker itself (eg, display on MB) were assigned an additional point (2 points total) since they would be most visible to the users. The points for each BCT were summed for each product to quantify its overall presence and total scores were compared. Qualitative data analysis was conducted using NVivo 10.0 software (QSR International, Victoria, Australia) to identify common themes mentioned during the cognitive interviews. The transcripts of each cognitive interview were uploaded to NVivo, and one researcher created specific nodes to identify common themes and categories to organize and refine the data. Direct quotes (deidentified) were extracted from the transcriptions to represent general themes. Responses to survey questions were analyzed using descriptive statistics and chi-square analyses (significance was set at $P<.05$). Quantitative data were analyzed using Stata 13.1 (StataCorp LP, College Station, TX, USA).

Results

Behavior Change Techniques

Of the possible 36 BCTs, the MB, SQ, and ZZ websites included 8, 15, and 14 techniques, respectively (Multimedia Appendix 1). When total points were adjusted for location on the device and/or website, the MB, SQ, and ZZ scored 16, 23, and 44 points, respectively. Although the participants spent slightly more time on the SQ website during the cognitive interviews, the ZZ website scored the highest total points in regard to presence of BCTs (Figure 3). There were constructs from the taxonomy that were not represented by any of the devices or their associated websites including natural consequences (information about health consequences), repetition and substitution (forming new habits), comparison of outcomes (to a credible source), and antecedents (adding and removing objects to the environment).

Figure 3. Summary data from behavioral change technique (BCT) scores adjusted for location on the device or website (points) and cognitive interviews (% of time on each site). MB: Movband; SQ: Sqord; ZZ: Zamzee.



Website Social Support Features

Two websites (SQ and ZZ) contained several social support features, including an avatar that the user could create to represent themselves on the website. No significant differences were observed in the participants’ reactions to the social support features provided by the SQ and ZZ ($P=.21$ to $.37$; Table 1). Participants reported that they “liked” creating and changing their avatar (SQ: 12/15, 75%; ZZ: 15/16, 94%). Approximately 17% of the cognitive interview time was in reference to the social support features (eg, avatar, clubhouse, high fives, shoutz,

squaks), with the avatar being the most popular feature among the participants.

> *I like how you can "like" things because then it makes me feel good when people like my stuff because it makes me feel happy.* [Girl, Age 10, ZZ website]
>
> *I like the ones (websites) where you get to do a lot of activities.* [Boy, Age 9, SQ and ZZ websites]

Additionally, the social interactions that took place on the website were an area of interest for some of the participants.

> *I like finding people. And I like looking at how much points I have and they have.* [Boy, Age 6, ZZ website]

All of the websites featured BCTs associated with goals and planning, feedback and monitoring, comparison of behavior, and self-belief. Related to these constructs, 17% of the interviews contained speech on self-monitoring techniques including activity charts or points, medals, "moves" or steps or miles, "sqoins," "zamz," and minutes in the "zamzone." All of the websites had a behavioral monitoring feature(s) (eg, charts for tracking activity), but the percentage of participants who indicated "liking" that feature varied by website (MB: 8/16, 50%; SQ: 6/16, 38%; ZZ: 11/16, 69%).

> *I really like that, um, you get rewards. That's pretty awesome. I like all the rewards. I like everything, but I think they could make the challenges a bit more clear, like of what you're supposed to do.* [Girl, Age 9, ZZ website]

It was apparent that age and maturity modified the participant's perceptions of the devices or websites as well as their ability to navigate the websites on their own. Most of the participants first navigated to a feature that was located on the home page (MB: 16/16, 100%; SQ: 10/16, 63%; ZZ: 14/16, 88%). Many of the younger children were unfamiliar with using a computer and relied on their parent for guidance. Some aspects of the websites were unclear to a few of the participants and may have hindered the impact of certain BCTs.

> *I sometimes look at the challenges but I don't really know what they are.* [Boy, Age 7, ZZ website]
>
> *I don't really know how to get Sqoins and so it's really, really confusing how to get sqoins and stuff because, I mean, I did the exercise.* [Girl, Age 10, SQ website]
>
> *And the thing that I didn't like about this one was that it wasn't clear and I still don't know how you get Zamz, which are like the money* [Girl, Age 10, ZZ website]

On average, 18% of the total interview time was spent on the MB site and its features. The participants spent significantly more time on the SQ and ZZ websites (37% and 34%, respectively). The remaining interview time was spent between websites or additional unrelated commentary. No social support features were observed for the MB and when talking about the MB website, most of the participants mentioned that they did not find the website interesting.

> *This one I thought was the least interesting because you could barely do anything.* [Girl, Age 10, MB website]
>
> *The MovBand I didn't really like it because you couldn't really do anything active, you just look at it which wasn't really fun to me. It did have one advantage which was seeing if you're average or not average.* [Boy, Age 9, MB website]
>
> *That was my favorite watch, but least favorite website.* [Boy, Age 10, MB website]

Table 1. Survey responses (percent) related to social support website features for the Sqord and Zamzee. The MovBand contained no social support features and therefore was not included is these analyses.

Social support website feature	Sqord	Zamzee
Avatar (*P* =.21)		
Disliked	6	0
Okay	0	0
Liked	75	94
I don't know[a]	19	6
Social interaction (*P* =.37)	(squaks, high fives)	(shoutz)
Disliked	6	0
Okay	13	25
Liked	38	38
I don't know[a]	44	37
Frequency of interaction with other users (*P* =.34)		
Never	50	38
A little	12	37
A lot	38	25

[a]The response option "I don't know" was not included in the chi-square analyses.

However, a few participants noted the simplicity of the site made it easy to navigate and understand.

> *This was my favorite because it was kind of easy to understand. It wasn't confusing at all.* [Boy, Age 9, MB website]

When asked if the monitor and website "made me more physically active," a majority of the participants answered "yes" (MB: 12/16, 75%; SQ: 12/16, 75%; ZZ: 15/16, 94%). When asked about their activity level during the four days of tracker wear, 7 of the 16 participants (44%) reported that they were "more active than usual" and 9 of the 16 participants (56%) claimed that their activity level was "about the same as usual." Participants also claimed that wearing the monitors during the 4-day study period made them spend more time on the computer (11/16, 69%); therefore, increasing screen time during the study period. Additionally, 69% (11/16) of users said that wearing the monitors made them "enjoy PA more." Finally, each participant was asked, "If your friends were also wearing these devices, would that make you want to wear them more or less?" and 75% (12/16) responded that they would want to wear them more.

Discussion

Principal Findings

The aims of this study were to (1) perform a content analysis to evaluate the BCTs present in three commercially available activity trackers marketed to children and (2) obtain information on the children's perceptions of these devices and the associated websites using quantitative and qualitative analyses. When the presence of BCTs was summed from each device or website combination, all three devices exhibited less than 50% of the highest possible score (8, 15, and 14 out of a total 36 possible BCTs). Compared with the MB, the SQ and ZZ websites are more child-centric and also utilized more of the BCTs from the taxonomy [11,17]. In addition, children liked the SQ and ZZ websites more than the MB website.

The website layout and design seemed to have an effect on the children's perceptions of the device. This could possibly be explained by the design of the SQ and ZZ websites being colorful, bright, and "child-friendly." The MB website was relatively straightforward and monochromatic. Although such a design esthetic may be appealing to adults, it could potentially decrease a child's interest in using the tracker (Figure 2). It would seem ideal to develop a website that was stimulating enough to encourage consistent use of the tracker while not so engrossing that the child would then spend excess time in front of a screen.

It was apparent that in this study the older children were more comfortable navigating the websites independently, whereas the younger children relied on their parents or guardians for guidance and assistance. Because these devices are marketed as child-friendly, the website design should be appropriate for the user demographics. The SQ and ZZ websites included several links within each page and multiple tabs along the top of the screen that some children did not easily access. A simple and direct navigation platform that targets the most important aspects of the website's features according to successful BCTs would be beneficial, particularly for children.

The participants enjoyed playing with the avatar feature on the SQ and ZZ sites and spent a considerable portion of their interview talking about this specific feature. However, if the goal of these devices is to increase PA, the primary focus should perhaps be on the activity charts and portions of the website devoted to increasing PA and attempting to also comply with

screen time guidelines of less than 2 h/day [21]. One recommendation is to allow user access for an allotted amount of time each day in an effort to support engagement in real-world physical activities [22].

It is recommended that child-centric activity tracker websites be developed in an effort to target BCTs, especially if being used as an intervention tool. Placing essential features on the home page would attract the attention of the users (eg, activity charts). We recognize that incorporating all areas of the taxonomy would pose a challenge to website developers by specifically providing information about why children should engage in PA (natural consequences) and how to make PA part of daily life (repetition and substitution) may be important techniques in promoting behavior change in youth. However, it is not clear that embedding these areas of the taxonomy would actually be appropriate for this age group because of the inability for children to understand such higher level thinking. Natural consequences and repetition or substitution were two of the areas not represented in the content analysis for any of the websites. The recently developed video game "Escape from Diab" [23] incorporated the use of several other theoretical frameworks such as self-determination theory [24] and behavioral inoculation [25] to determine mediators and behavior change processes. Behavioral scientists and website designers worked together to create a video game that would be entertaining and theoretically sound. This type of collaboration should be replicated when attempting to change behavior with the use of technology.

Limitations

One limitation to this study is the small, relatively active, and nondiverse participants (100% Caucasian). An additional limitation is that we did not collect socioeconomic data for our participants. The participants wore the devices independently from each other, so we do not have data regarding the use of the devices in classrooms or other group settings. The children's perceptions of the monitors and websites were likely affected by the length of time they spent exploring the features of the devices and their corresponding websites. Children were instructed to spend a minimum of 10 min/day using each website; however, even with parental involvement, we were not able to obtain accurate estimates of website exposure on each of the 4 days despite asking the parents to provide a written log. In addition, our participants wore all three trackers concurrently and this could have affected their use of the trackers and interaction time with the websites. Additional research should test tracker and website usage for each of these devices separately.

It should be noted that all of these devices can be used in a group setting by establishing groups or teams through the website. For this project, we explored our aims from the standpoint of a single user, rather than a team or classroom group. According to the survey results, 75% of the participants indicated that they would want to wear the devices more if their friends were also using them. Therefore, utilizing the "group" features of the websites may encourage the use of these activity trackers more regularly in this population. Since we did not use these features on the devices, we do not know if using these features would have influenced the children's perceptions of the devices and websites. In addition to not using the group features, the MB website was not seen as visually appealing for the children in this study compared with the others (Figure 2). Future research should explore the use of this feature for each of the devices.

A growing number of studies have examined the use of activity trackers and mobile device apps for stimulating behavior change in adults [6-10,16], but there is a lack of information regarding use of these trackers in younger populations. To our knowledge, this is the first independent research to assess the BCTs in these child-oriented devices in combination with a cognitive interview where we received feedback from the users about their experience with these devices and websites. Although there are far fewer devices specifically targeted to children, the potential exists for manufacturers of adult activity trackers to expand their current offerings to include a child-focused device with a youth version of their existing Web and mobile app content. Therefore, using such devices in school- or group-based interventions would be a logical next step. The use of a criterion measure (such as a research-grade accelerometer) to assess the validity and effectiveness of the activity trackers to increase PA is also recommended. Our results indicate room for expansion in theory-based Web content and changes to website layout so that children are more directly exposed to important and potentially effective BCTs.

Conclusions

This paper provides the first in-depth content analysis of three child-oriented activity trackers and children's perceptions of the devices and websites. A growing number of studies have examined the use of activity trackers and mobile device apps for stimulating behavior change in adults, but there is a lack of information regarding use of these trackers in younger populations. Because young children lack the ability to understand abstract concepts or report feelings on surveys, additional techniques were needed to explore the affective responses of young children. The cognitive interviews with a structured qualitative analysis along with the quantitative survey data provide an innovative mixed-methods analysis that deepens our understanding of the children's affective responses to the devices. With the popularity of the many adult activity trackers and several youth-oriented trackers currently being used in a variety of settings, it is anticipated that manufacturers of adult activity trackers will expand their current offerings to include a child-focused device based on their existing Web and mobile app content. The findings from this study suggest that the trackers or websites that displayed more behavioral constructs were more appealing to the child. However, further research is warranted to explore how the behavior change theoretical constructs are presented on these devices or websites and how these constructs change with long-term use and whether they facilitate healthy behavior change.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Behavior change techniques for activity tracker systems (includes device and website).

[PDF File (Adobe PDF File), 71KB - mhealth_v5i4e55_app1.pdf]

References

1. U.S. Department of Health and Human Services. CDC. 2003. Youth Risk Behavior Surveillance - United States. Morbidity and Mortality Weekly Report, 53(SS-2) URL: https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5302a1.htm [accessed 2017-04-13] [WebCite Cache ID 6pgi81XaZ]
2. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. Med Sci Sports Exerc 2008 Jan;40(1):181-188. [doi: 10.1249/mss.0b013e31815a51b3] [Medline: 18091006]
3. Zizzi S, Vitullo E, Rye J, O'Hara-Tompkins N, Abildso C, Fisher B, et al. Impact of a three-week pedometer intervention on high school students' daily step counts and perceptions of physical activity. Am J Health Educ 2006;37(1):35-40. [doi: 10.1080/19325037.2006.10598875]
4. Duncan M, Birch S, Woodfield L. Efficacy of an integrated school curriculum pedometer intervention to enhance physical activity and to reduce weight status in children. Eur Phy Educ Rev 2012;18(3):396-407. [doi: 10.1177/1356336X12450799]
5. Tractica. 2015. The Wearable Devices Market is Poised for Expansion into Smart Clothing and Body Sensors URL: https://www.tractica.com/newsroom/press-releases/the-wearable-devices-market-is-poised-for-expansion-into-smart-clothing-and-body-sensors/ [accessed 2017-03-20] [WebCite Cache ID 6p6mCcJhL]
6. Chan CB, Ryan DA, Tudor-Locke C. Health benefits of a pedometer-based physical activity intervention in sedentary workers. Prev Med 2004 Dec;39(6):1215-1222. [doi: 10.1016/j.ypmed.2004.04.053] [Medline: 15539058]
7. Araiza P, Hewes H, Gashetewa C, Vella CA, Burge MR. Efficacy of a pedometer-based physical activity program on parameters of diabetes control in type 2 diabetes mellitus. Metabolism 2006 Oct;55(10):1382-1387. [doi: 10.1016/j.metabol.2006.06.009] [Medline: 16979410]
8. Hultquist CN, Albright C, Thompson DL. Comparison of walking recommendations in previously inactive women. Med Sci Sports Exerc 2005 Apr;37(4):676-683. [Medline: 15809569]
9. Breton ER, Fuemmeler BF, Abroms LC. Weight loss-there is an app for that! But does it adhere to evidence-informed practices? Transl Behav Med 2011 Dec;1(4):523-529 [FREE Full text] [doi: 10.1007/s13142-011-0076-5] [Medline: 24073074]
10. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R. Health behavior models in the age of mobile interventions: are our theories up to the task? Transl Behav Med 2011 Mar;1(1):53-71 [FREE Full text] [doi: 10.1007/s13142-011-0021-7] [Medline: 21796270]
11. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol 2008 May;27(3):379-387. [doi: 10.1037/0278-6133.27.3.379] [Medline: 18624603]
12. Cowan LT, Van Wagenen SA, Brown BA, Hedin RJ, Seino-Stephan Y, Hall PC, et al. Apps of steel: are exercise apps providing consumers with realistic expectations?: a content analysis of exercise apps for presence of behavior change theory. Health Educ Behav 2013 Apr;40(2):133-139. [doi: 10.1177/1090198112452126] [Medline: 22991048]
13. Noar SM, Mehrotra P. Toward a new methodological paradigm for testing theories of health behavior and health behavior change. Patient Educ Couns 2011 Mar;82(3):468-474. [doi: 10.1016/j.pec.2010.11.016] [Medline: 21185144]
14. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. J Med Internet Res 2010;12(1):e4 [FREE Full text] [doi: 10.2196/jmir.1376] [Medline: 20164043]
15. Middelweerd A, Mollee JS, van der Wal CN, Brug J, Te Velde SJ. Apps to promote physical activity among adults: a review and content analysis. Int J Behav Nutr Phys Act 2014;11:97 [FREE Full text] [doi: 10.1186/s12966-014-0097-9] [Medline: 25059981]
16. Guthrie N, Bradlyn A, Thompson SK, Yen S, Haritatos J, Dillon F, et al. Development of an accelerometer-linked online intervention system to promote physical activity in adolescents. PLoS One 2015;10(5):e0128639 [FREE Full text] [doi: 10.1371/journal.pone.0128639] [Medline: 26010359]
17. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013 Aug;46(1):81-95. [doi: 10.1007/s12160-013-9486-6] [Medline: 23512568]
18. Bandura A. Social cognitive theory: an agentic perspective. Annu Rev Psychol 2001;52:1-26. [doi: 10.1146/annurev.psych.52.1.1] [Medline: 11148297]

19. Ajzen I. In: Fishbein M, editor. Understanding attitudes and predicting social behavior. Englewood Cliffs, NJ: Prentice Hall; 1980.
20. Ajzen I. From intentions to actions: A theory of planned behavior. In: Action Control: From Cognition to Behavior. Berlin Heidelberg: Springer; 1985:11-39.
21. American Academy of Pediatrics. Committee on Public Education. American Academy of Pediatrics: Children, adolescents, and television. Pediatrics 2001 Feb;107(2):423-426. [Medline: 11158483]
22. Baranowski T, Simons-Morton B, Hooks P, Henske J, Tiernan K, Dunn JK, et al. A center-based program for exercise change among black-American families. Health Educ Q 1990;17(2):179-196. [Medline: 2347694]
23. Thompson D, Baranowski T, Buday R, Baranowski J, Thompson V, Jago R, et al. Serious video games for health how behavioral science guided the development of a serious video game. Simul Gaming 2010 Aug 1;41(4):587-606 [FREE Full text] [doi: 10.1177/1046878108328087] [Medline: 20711522]
24. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. Am Psychol 2000 Jan;55(1):68-78. [Medline: 11392867]
25. McGuire WJ WJ, Papageorgis D. The relative efficacy of various types of prior belief-defense in producing immunity against persuasion. J Abnorm Soc Psychol 1961;62:327-337. [Medline: 13773992]

Abbreviations

BCT: behavior change technique
MB: MovBand
PA: physical activity
SQ: Sqord
ZZ: Zamzee

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