JMIR Formative Research

Impact Factor (2023): 2.0
Volume 3 (2019), Issue 2 ISSN 2561-326X Editor in Chief: Amaryllis Mavragani, PhDc

Contents

Original Papers

Review

Original Paper

Using Text Messaging, Social Media, and Interviews to Understand What Pregnant Youth Think About Weight Gain During Pregnancy

Melissa DeJonckheere[1], PhD; Lauren P Nichols[1], MPH; VG Vinod Vydiswaran[2,3], PhD; Xinyan Zhao[3], MS; Kevyn Collins-Thompson[3], PhD; Kenneth Resnicow[4], PhD; Tammy Chang[1,5], MD, MPH, MS

[1]Department of Family Medicine, University of Michigan, Ann Arbor, MI, United States

[2]Department of Learning Health Sciences, University of Michigan, Ann Arbor, MI, United States

[3]School of Information, University of Michigan, Ann Arbor, MI, United States

[4]School of Public Health, University of Michigan, Ann Arbor, MI, United States

[5]Institute for Healthcare Policy and Innovation, University of Michigan, Ann Arbor, MI, United States

Corresponding Author:
Melissa DeJonckheere, PhD
Department of Family Medicine
University of Michigan
1018 Fuller St
Ann Arbor, MI, 48104
United States
Phone: 1 (734) 998 7120
Email: mjdejonckheere@gmail.com

Abstract

Background: The majority of pregnant youth gain more weight than recommended by the National Academy of Medicine guidelines. Excess weight gain during pregnancy increases the risk of dangerous complications during delivery, including operative delivery and stillbirth, and contributes to the risk of long-term obesity in both mother and child. Little is known regarding youth's perceptions of and knowledge about weight gain during pregnancy.

Objective: The aim of this study was to describe the feasibility and acceptability of 3 novel data collection and analysis strategies for use with youth (social media posts, text message surveys, and semistructured interviews) to explore their experiences during pregnancy. The mixed-methods analysis included natural language processing and thematic analysis.

Methods: To demonstrate the feasibility and acceptability of this novel approach, we used descriptive statistics and thematic qualitative analysis to characterize participation and engagement in the study.

Results: Recruitment of 54 pregnant women aged between 16 and 24 years occurred from April 2016 to September 2016. All participants completed at least 1 phase of the study. Semistructured interviews had the highest rate of completion, yet all 3 strategies were feasible and acceptable to pregnant youth.

Conclusions: This study has described a novel youth-centered strategy of triangulating 3 sources of mixed-methods data to gain a deeper understanding of a health behavior phenomenon among an at-risk population of youth.

(JMIR Form Res 2019;3(2):e11397) doi:10.2196/11397

KEYWORDS

methods; adolescents; weight gain; pregnancy; text messaging; social media; natural language processing

Introduction

Background

Excess weight gain during pregnancy is a serious health concern affecting the majority of US youth who become pregnant [1-3], increasing the risk of dangerous complications during delivery and contributing to the risk of long-term obesity in both mother and child [4-7]. The risk of excess weight gain during pregnancy is especially high for overweight or obese youth, a population that continues to increase in the United States [1,2,8]. Given that more than one-third of US youth (aged between 12 and 19 years) are overweight or obese, and 71% of youth have had at least 1 sexual encounter by age 19 years, a large proportion of US overweight and obese youth are at risk [8-14]. The risk of excess weight gain is even more significant for low income and

racial or ethnic minorities in the United States who have the highest rates of adolescent pregnancy and face significant barriers to nutrition and physical activity during pregnancy [15-19].

Healthy lifestyle interventions have been shown to promote healthy pregnancy weight gain in adults, which can decrease long- and short-term morbidity [20-26]. However, there is a significant gap in our understanding of youth's perceptions of and knowledge about weight gain during pregnancy. Given this gap, current interventions cannot be adequately tailored to the distinct needs and preferences of pregnant youth and, consequently, may not be as effective [27].

Conceptual Framework

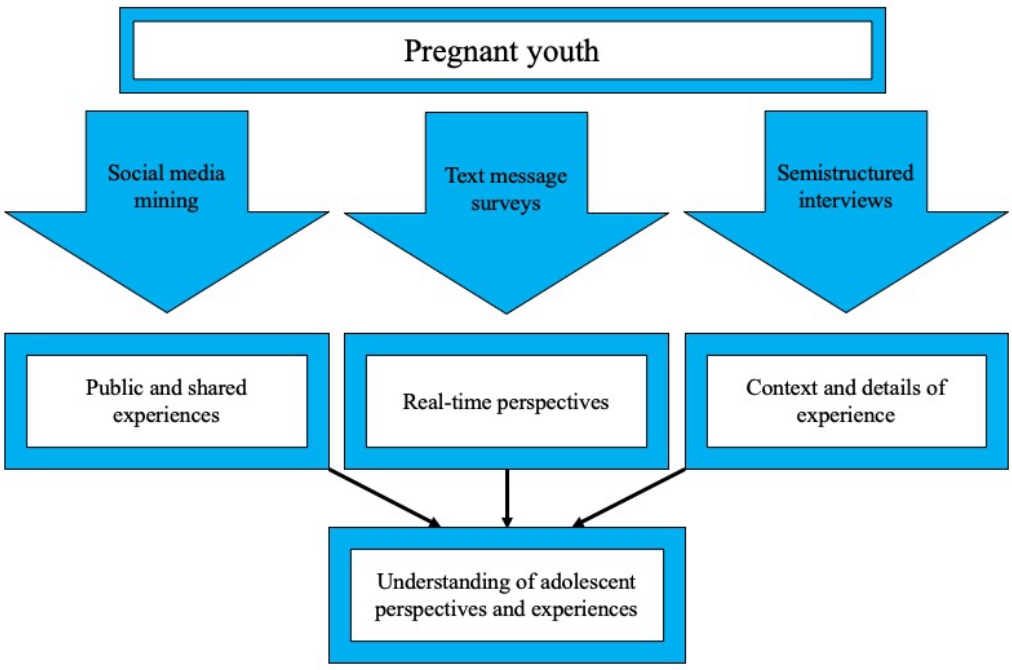
To understand the needs and preferences of pregnant youth, research approaches that appropriately respond to the unique circumstances of adolescence and young adulthood are needed. Many survey measures are not validated or tested among youth [28], whereas those that are are developed or fielded among school or college-based samples. To address these concerns, we have proposed a novel strategy of integrating 3 data sources that may be acceptable and accessible to high-risk youth to develop instruments or to tailor interventions: social media, text messaging, and interviews. Each data collection approach provides a unique perspective on youth behavior and experiences (see Figure 1).

Use of social media on the Web is pervasive and central to the way youth orient themselves to the world and others. With an increasing amount of time spent engaging on social media sites, much of the social and emotional development of youth is occurring on the Web. Regardless of race or socioeconomic status, nearly all youth (>80%) in the United States use social media on the Web with the majority spending several hours per day on the Web [29]. As a result, there is growing interest in social media content for influencing and understanding youth behavior [30-33]. Social media data are increasingly being used by adolescent health researchers, though studies predominantly are observational and reliant on public profiles [34-37]. Examining the social media posts of youth may improve our understanding of their beliefs and behaviors by capturing their *in vivo*, or organic, experiences that they choose to share with their social network. When analyzed using natural language processing (NLP), large amounts of text data (eg, months of Web posts) can be quickly processed and interpreted.

Text messaging is used by nearly all youth aged between 18 and 24 (97%) years and is central to their communication and relational experiences. Text messaging is the preferred form of communication among some subgroups of the population owing to its convenience and efficiency, including African American and Latino youth, individuals with lower educational attainment, and those with a lower income level [29,38,39]. When used in research, text messaging is the preferred mode of data collection among low-income communities [40,41] and results in more accurate data than other types of data collection such as in-person interviews, questionnaires, and in-person observation [42,43]. Although predominantly used to deliver information in research (eg, educational or behavioral interventions), studies are beginning to demonstrate the feasibility and acceptability of text messaging for data collection in youth populations [44]. Data collection via text messaging will allow researchers to gather real-time, immediate feedback rather than relying on recall.

Although both social media and text messaging capture essential aspects of youth experiences, it may be difficult to probe for a deeper understanding of participant experiences using these data collection tools. Qualitative semistructured interviews can complement social media and text messaging data by providing more in-depth context on the thoughts and beliefs of youth.

Figure 1. Conceptual framework of study design.



Interviews allow researchers to probe for more detail when key topics are mentioned, ask for clarification, or explore divergent responses. Interviews have frequently been used with high-risk and marginalized populations, including minority and immigrant youth [45] and pregnant youth [46]. To our knowledge, this traditional method of data collection has not been used with pregnant youth to elicit their understanding or perspectives related to weight gain during pregnancy. Together, social media, text messaging, and semistructured interviews can provide different perspectives into the experiences of youth.

Objectives

In this study, we have presented an integrated methodological approach to understand youth perspectives and behavior related to weight gain during pregnancy. For the purpose of this study, we use *youth* to indicate adolescents and emerging adults within the 15 to 24 age range. We integrated multiple sources of data (social media posts, text message surveys, and semistructured interviews) to capture the complexities of youth experiences more fully. The ultimate goal of this study was to examine the feasibility and acceptability of integrating multiple youth-centered methods to inform the development of interventions to reduce excess weight gain. Our guiding research question was as follows: How do pregnant youth engage with social media mining, text message surveys, and semistructured interviews to provide insight into their experiences with weight gain during pregnancy?

Methods

Overview

The Healthy Pregnancy Project was designed to understand the perspectives of low-income youth during pregnancy to develop a tailored intervention to reduce excessive weight gain. To develop a tailored intervention that is responsive to the needs of pregnant youth, we collected information via youth-friendly methods including mining social media and text message surveys. The Institutional Review Board of the University of Michigan Medical School approved this study (HUM00104989).

Setting

Participants were recruited from 2 low-income urban primary care clinics in Southeastern Michigan. These 2 clinics serve over 70% of the pregnant youth in the county.

Participants

Eligible participants were youth aged between 14 and 24 years with a healthy singleton pregnancy at the time of recruitment, a gestational age of less than 24 weeks, an ability to read and speak English, and a cell phone with text messaging capabilities.

Recruitment

Study staff reviewed clinic schedules and electronic medical records daily to identify participants that appeared to meet the inclusion criteria (eg, age, singleton pregnancy, and gestational age). Participants were recruited before or after regular medical appointments at either of the 2 clinics (see Figure 2 for recruitment and study process) to decrease the burden for both patients and providers. Study staff confirmed eligibility, explained the study requirements, and answered questions from participants. Participants were informed that the study was called *Healthy Pregnancy Project* and the purpose was to learn more about young adults' beliefs and knowledge about weight gain during pregnancy.

Written consent or assent was obtained for all participants. If the participant was aged under 18 years, written assent was obtained from the participant and verbal consent was obtained from the participants' parent or guardian. As minors may seek care without the permission of their parents or guardians at these clinics, pregnant youth who wished to maintain confidentiality from their parents or guardians regarding their pregnancy were excluded from the study. If the youth required care from high-risk obstetrical providers during the course of their pregnancy, they were unenrolled but received incentives for all completed study components. All participants were able to opt out of any study component other than the demographic survey completed upon enrollment. For example, they were able to only participate in the text message survey or only social media mining.

Healthy Pregnancy Project Data Collection

Visit 1 (First Trimester or Early Second Trimester): Recruitment Visit and Demographic Data

Demographic Survey

After being consented, participants completed a demographic survey that collected contact information (cell phone number), demographics (eg, race, education status, and family characteristics) and medical information (eg, body mass index and due date) on a tablet using Qualtrics Survey Software (Qualtrics, Provo, UT) (see Multimedia Appendix 1 for demographic survey items). Questions were adopted from validated surveys when available. Participants aged under 18 years were asked to complete an adolescent socioeconomic status measure [47], whereas participants over the age of 18 years were asked to report their annual household income and household size.

Social Media Mining

We mined participants' social media data, to be analyzed via NLP, to elicit a more complete and unfiltered version of participant *in vivo* experiences. Participants were asked to consent to mining of their social media accounts at 2 points: during the recruitment visit (generally, first trimester) and during the third trimester. Study staff performed a single download of the text posted on Facebook (up to the past year), the text posted on Twitter (up to 3200 tweets), or the text and images posted on Instagram (up to 50 previous posts) at each time point. The downloaded file included a timestamp and the raw text from the original comments and posts. Participants logged into their accounts, and data were extracted using the corresponding platform's query application programming interface (API). On the API platform, we sent requests to participants' accounts for access to their posted messages. Only after participants authorized our requests could we obtain access to the data. When the data collection procedure was completed, participants turned the accounts into private status to prevent any incidental unauthorized data collection. After extraction, participants

signed out of their accounts. Between visits and after completion of the study, the staff did not have access to participants' social media accounts. To protect the anonymity of comments of others on the Web that may be observed during social media mining, only comments and posts made by consented participants were downloaded. We did not record *likes*, *shares*, or other information available within their social media content. No identifying data were recorded from nonconsented individuals.

Participants were reminded of future communications with the Healthy Pregnancy Project research staff: (1) text message surveys for 8 weeks and (2) a follow-up interview and social media mining during their third trimester. Participants provided a short message service–capable phone number to complete the text message surveys.

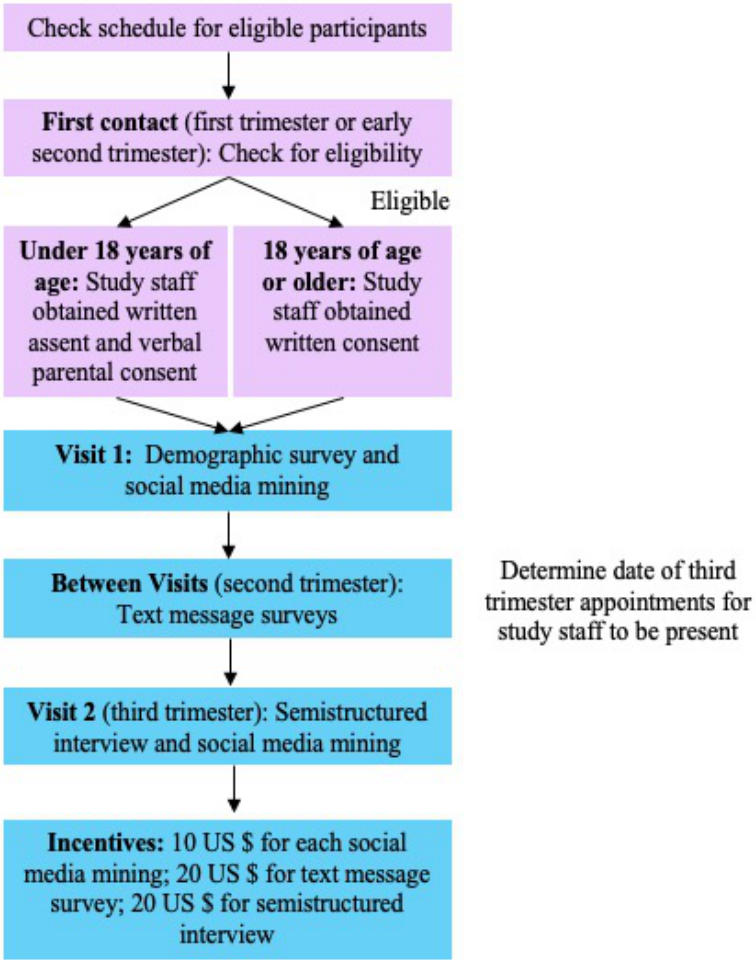
Between Visits

Text Message Surveys

We used text messages to ask questions about young pregnant women's real-time experiences during pregnancy. On the basis of previous work with text message surveys [40,41], the surveys were designed to be low cognitive burden, to which participants could quickly respond. The questions were developed by the research team to be youth friendly by using a conversational tone, asking short closed- and open-ended questions, and including supportive and empowering messages. For example, "Pregnancy is a time of a lot of changes in your body. Tell us how you feel about these changes. We want to hear the good and the bad!" Questions probed for youth knowledge and behaviors around diet, exercise, body image, and health during pregnancy (see Multimedia Appendix 2 for text message survey items). Some messages included multipart questions on the same topic (eg, identifying unhealthy behaviors and then describing barriers). Participants began to receive text message surveys during the second trimester to align with the period in which many women gain the most weight when pregnant [48]. Therefore, participants began and ended text message surveys asynchronously, beginning at 20 weeks gestation and continuing weekly for 8 weeks.

The text message survey questions were sent through an automated secure texting platform that met the Health Insurance Portability and Accountability Act requirements. Participants responded directly to the questions via text message at their convenience. Responses were stored in a secure server until they were downloaded for analysis at completion of the study. Before the Week 1 survey, participants received a tutorial that explained the process, including how to skip questions and how to stop receiving messages at any time. Participants were sent each weekly poll up to 2 times if they did not fully complete the poll the first time. Weekly polls were also resent if study staff learned that the participant's phone number changed.

Figure 2. Recruitment and study process.



Visit 2 (Third Trimester): Semistructured Interview and Social Media Mining

Semistructured Interview

Using a semistructured interview guide consisting of predominantly open-ended questions, we elicited the participants' knowledge, beliefs, and perspectives regarding weight gain during pregnancy. Research staff regularly reviewed electronic medical records for enrolled participants to identify upcoming visits in the third trimester. The staff then contacted participants via phone the night before an appointment to confirm that the participant had time to meet for a 30-minute one-on-one interview before or after the scheduled visit. Research staff trained in qualitative interviewing (postdoctoral research fellow, project coordinator, and medical students) met with participants in a private exam room before or after their perinatal visit. The semistructured interview guide was designed to allow for follow-up and probing questions to clarify participant responses or add detail. Interviews were audio-recorded, and the audio files were uploaded to a secure Web folder.

The interview guide included the following domains: knowledge about eating and drinking during pregnancy, weight gain during pregnancy, barriers to healthy eating and exercise, and behaviors related to eating, cooking, and exercise (see Multimedia Appendix 3 for the interview guide).

Interviews also explored participant experiences with the text message surveys, including acceptability and preferences. Interviews were performed during the third trimester of pregnancy so that participants had more personal experiences with pregnancy-related weight gain and had an opportunity to complete all text message surveys. When available, interviewers used the mined social media data (see the Natural Language Processing of Social Media Data section) from the first visit and text message survey responses to supplement the interview guide. For example, interviews would reference posts made on social media related to their pregnancy, weight gain, eating, exercise, or body image and ask participants to expand upon their statements or explain any contradictions.

Social Media Mining

During this visit, participants with social media accounts logged into their accounts again to allow research staff to download the recent posts from Facebook, Twitter, or Instagram. Files were saved to a secure Web folder. Participants would then log off their accounts, and the study staff would no longer have access.

Chart Review

Participants' electronic medical records were reviewed to verify gestational age, identify the date that the pregnancy was confirmed by medical personnel, and record weight gain.

Incentives

Participants were compensated for each completed study component for a total of up to US $60: US $10 for each social media mining; US $2 per week for text message survey responses; US $4 bonus for completing all 8 weeks of text message surveys; and US $20 for completing the semistructured interview during the third trimester.

Healthy Pregnancy Project Data Analysis

Baseline Survey

After study completion, participant responses were downloaded from the data management software as a comma-separated value (CSV) file. We used descriptive statistics to describe participant demographics, including race, ethnicity, median household income, and educational attainment.

Text Message Surveys

Text message survey responses were downloaded from the texting platform as a CSV file. Data were analyzed using an inductive approach adapted from grounded theory principles. First, all open-ended survey responses were compiled and read by the research team to gain a holistic sense of the data. Second, 2 members of the research team applied descriptive codes to full text message responses or segments of text to represent the central concept. Finally, preliminary categories were created by grouping text message responses (or phrases from text messages) into groups of similar concepts. The descriptive codes and categories were compiled into a codebook that was used when analyzing subsequent transcripts. Subsequent text messages were independently analyzed using the emergent codebook. Using an iterative process, the research team met periodically to identify new codes, modify the codebook, and resolve differences. Codes were organized into themes. Response rates were also calculated to understand participant engagement with text messaging during pregnancy. Data management and analysis were supported by MAXQDA12 qualitative data analysis software (VERBI GmbH; Berlin, Germany).

Semistructured Interviews

Audio recordings of one-on-one interviews were transcribed professionally and reviewed by the research team for errors. Data analysis was conducted using a process similar to the strategy for analyzing the text message survey responses detailed above. During the initial analysis phase, preliminary descriptive codes were created inductively from phrases of similar meaning from the first 2 interviews. Descriptive codes were used to build a codebook that was modified as analysis progressed. Subsequent transcripts were analyzed line-by-line by at least 2 qualitative researchers using the emerging coding scheme. Coders met periodically to identify new codes and arbitrate differences and create a final coding scheme. After all transcripts were coded, the codes were condensed into categories that represented emergent themes. Data management and analysis were supported by MAXQDA12.

Natural Language Processing of Social Media Data

Social media data were analyzed through NLP approaches to understand youth knowledge, beliefs, and social norms regarding weight gain during pregnancy. NLP is an approach to text analysis that allows researchers to review large amounts of free-text data and can augment traditional qualitative data collection and analysis. First, we created a list of keywords and phrases related to the following domains: pregnancy, weight

gain, eating, exercise, body image, and stress. We augmented these words with synonyms and related words from linguistic resources such as WordNet [49] and the Linguistic Inquire and Word Count [50]. For example, to search for content related to pregnancy, we included words related to pregnancy and baby. For content related to weight gain, we included weight, pounds, diet, eat, belly, tummy, skinny, and other common diet- and weight-specific words. We preprocessed and tokenized the text posts and normalized morphological variants (babies vs baby and pregnancy vs pregnant). We searched for this expanded list of words and phrases of interest in the collection of social media posts on the Web made by participants on Facebook, Instagram, or Twitter. The relevant posts were compiled for each participant and analyzed using a traditional qualitative approach. The content that was posted before the participant's date of conception was separated from the content posted after the participant was pregnant to allow for comparison.

In addition, the results of the NLP analysis were used to augment data collection during the one-on-one interviews. The compiled lists of relevant responses (related to pregnancy, weight gain, eating, exercise, body image, and stress) were used in 3 primary ways: (1) to initiate participant responses about a particular topic; (2) to provide context for participants to expand on a particular topic; or (3) to validate previous responses with additional evidence.

Assessment of Acceptability and Feasibility of Methods

We calculated response rates for each data collection strategy (social media mining, text message surveys, and interviews). During the semistructured interview, the final component of data collection, participants were asked questions related to the participation process. Participants reflected on their participation (or limited participation) in the text message surveys and social media mining. Responses were analyzed using a qualitative thematic approach, as described above, focusing on the Healthy Pregnancy Project process.

Results

Participants

In total, 54 participants were enrolled in the study; 5 participants were later withdrawn for having high-risk pregnancies (eg, premature delivery and short cervix) and 3 were excluded after changing medical providers. In total, 46 participants completed at least 1 data collection component (social media mining, text messaging, or interview) of the study (see Table 1 for participant demographics) and were included in the qualitative evaluation presented here.

Social Media Mining

We mined social media data from at least 1 platform for 39 participants (85%; see Table 2). The majority of participants provided access to their social media data available on Facebook (n=33 in the first trimester and n=37 in the third trimester) rather than Instagram (n=7 in the first trimester and n=0 in the third trimester) or Twitter (n=2 in the first trimester and n=1 in the third trimester). Participants who did not complete this component of the study either did not have any social media account (n=2), could not remember the correct log in information (n=2 during the first trimester and n=1 during the third trimester), or were unable to provide data because the mining process failed when attempted by the study staff (n=4 during the first trimester and n=1 during the third trimester). In all, 2 participants declined to participate at both time points, and a reason was not provided.

The mined social media data were used in 2 ways. First, analyzed social media content was used in semistructured interviewing when available. Using this content as an elicitation tool added to semistructured interviews by prompting participants to provide greater context and depth in their responses, validating previous responses, finding new and missing themes, and supporting participants in discussing personal and sensitive topics.

Table 1. Participant demographics.

Demographics	Statistics
Age (years), mean (SD)	21.2 (2.2)
Income (US $)	
Median household income	7200
Race, n (%)	
Non-Hispanic black	22 (48)
Non-Hispanic white	13 (28)
Hispanic or Latino	5 (11)
Mixed race	5 (11)
Other	1 (2)
Educational status, n (%)	
Some high school	12 (26)
High school graduate	21 (46)
Some postsecondary education	13 (28)

Second, social media content was compared before and after each participant's conception date to identify changes in perspectives and behaviors following pregnancy. For example, Oram et al [51] examined youth perspectives toward substance use shared on Facebook in the year before pregnancy and during pregnancy. This analysis allowed us to gain insight into shifts in behavior as a result of pregnancy and opportunities to reduce substance use in this population.

Text Message Surveys

In total, 34 of the participants (74%) responded to at least 1 week of survey questions. Response rates were over 50% for each of the 9 weeks (see Table 3). In all, 10 of 46 participants (24%) completed the text message surveys for all weeks, including the tutorial.

Text message data were used to understand recent and current thoughts, beliefs, and behaviors that youth were engaging in during pregnancy. The data provided quick snapshots into the daily experiences of the participants. Unexpectedly, some participants viewed the text message surveys as a form of informational and social support.

Participants were asked to reflect on the text message surveys as part of the semistructured interview. Thematic analysis revealed a variety of factors supporting engagement with the text message surveys (eg, convenience and ease of use, reminder of healthy behaviors, and social support) and a few barriers to engagement (eg, one-way communication, phone-related barriers, time, and schedule conflicts). Themes and representative quotes depicting the acceptability of text message surveys are summarized in Textbox 1.

Table 2. Social media mining response rate by platform.

Visit	Facebook mined, n (%)	Instagram mined, n (%)	Twitter mined, n (%)
Visit 1: first trimester	33 (72)	7 (15)	2 (4)
Visit 2: third trimester	37 (80)	0 (0)	1 (2)

Table 3. Response rate for text message surveys.

Timepoint	Response rate upon completion, n (%)
Tutorial	23 (50)
Week 1	25 (54)
Week 2	27 (59)
Week 3	25 (54)
Week 4	24 (52)
Week 5	24 (52)
Week 6	26 (57)
Week 7	24 (52)
Week 8	25 (54)
All weeks	10 (22)

Textbox 1. Themes and representative quotes related to the acceptability of text message surveys.

Factors supporting engagement:

- Convenience and ease of use

I'm always on my phone, so when they popped up, it was easy to respond. It really wouldn't have mattered what time you sent them, 'cause I still would have responded. [Participant 56, age 19]

I think that's as easy as it can get with it being a text. [Participant 29, age 20]

I think that was a brilliant idea because any other way would be like probably inconvenient for some people. [Participant 12, age 22]

I did reply late to one of 'em 'cause I was at work and I can't have my phone on the floor when I'm at work, so, I did have to wait 'til I got off work to reply. [Participant 47, age 17]

- Reminder of healthy behavior

I don't mind getting a text. If it's going to help me learn and I can share it with somebody else. I'm willing to always have new information on something. If I'm interested in it, I wouldn't mind getting information on it. [Participant 53, age 24]

It was actually something that was good when they asked me type of questions like that, because sometimes when they would text me like, well, what do you like to eat, I would text them back and tell them, and then I want to go get it because they reminded me of it. Like I want that right now! [Participant 56, age 19]

I really wasn't reflecting on my pregnancy that much. But when the questions came, I'm like, dang! I should really start thinking about this. Like, dang, do I even eat anything healthy? [Participant 47, age 17]

- Social support

You have your doctors when you're pregnant and that's when everybody's telling you, you know, be healthy and they're checking in on you and stuff like that. But other than that, it's kind of like a dead zone for people being concerned about their health. So it's probably good for people to have that little bit of a reminder every now and again that they want to know what you're thinking about. People are always happy for you that you're pregnant and they're congratulating you and stuff like that, and when you're around, they, you know, they ask about it, but when you're not, it's like everybody got their own lives. They're not really checking in on you as much as you might like need it. [Participant 28, age 20]

It was nice, especially because I was going through that hard time with my mom and everything, so just the text messages just asking how I was doing every week was kind of like a positive thing to look forward to. [Participant 23, age 21]

When you're pregnant, you kinda lose a lot of friends, so getting that text is kinda reassuring. It's not like a friend, but it's, like, you know somebody is listening to you. Like, you can just tell somebody how you feel. It's like a virtual friend. They just talk to you. [Participant 41, age 19]

It was fun. Sometimes that was the only person that was texting me. [Participant 19, age 16]

It kept me comforted. Some of their questions would make me feel like, "Oh, okay, maybe I'm just overreacting with this." It was...I would say, it was helpful with the questions to keep coming. For me, it would keep my mind off of other things that worry me about the baby and be able to keep up with the questions and answers. [Participant 44, age 24]

Barriers to engagement:

- One-way communication

I mean, I don't really know how to put it. They weren't bad. It was actually nice to have someone check up on you and see how your pregnancy's going or whatever. I'm like, is this really the lady that I met up with, checking on me? Or is it like, not a spam, but a…something like that? Honestly, I didn't think it was real. I mean, I knew it was real obviously because I knew I had signed up for it and I knew she told me I would be getting them. But is this really the lady? But I didn't want that to be my response; is this the lady I met or is this, you know? [Participant 46, age 24]

The text messages were kind of bothering because they were fake. I could've typed back 7QM and it would've sent me the same thing. I'm saying, I actually could've typed in anything. I could've handed [my son] the phone and typed in something... And it would've sent me the same thing. I didn't like how it was robotic. [Participant 48, age 22]

It would've been nice to be able to ask a question. I didn't really understand it. I was trying to text it back, but I didn't get the response I was looking for, so I'm like, "Oh, okay, well maybe I just gotta wait until they text me back then. So that would be nice, if I would have questions." [Participant 44, age 24]

I was like is this a machine or can you really talk? I was like lonely, and I was tired. Like or when you asked that question about how are you feeling? I'd spill my heart out and it would say [in response], well, thank you for participating. [Participant 15, age 24]

- Phone-related barriers

It's like it'd come to my phone and then if I don't have service in that area, I'll reply back, and it don't go. [Participant 18, age 23]

I don't have a phone, it just got cut off. [Participant 14, age 18]

There was one time my phone was off and you guys had texted me and I couldn't text back. I don't think I was able to text for like a week. [Participant 48, age 22]

- Time and schedule conflicts

I think I sometimes I would try to and then I would forget, cuz there's sometimes I wanna say more than what I'm gonna say at that time that I have. I just forget to go back to it. [Participant 29, age 20]

> *They came when I was asleep. I think they came every Friday, but I work afternoons. They did come before I went to work, but I would sleep until I go back to work the next day. Working a 10-hour shift is not easy.* [Participant 46, age 24]

Semistructured Interviews

In total, 43 of the 46 participants (94%) were interviewed in person during their third trimester, before or after an appointment at the primary care clinic. Interviews ranged from 10:53 to 30:02 minutes, with an average length of 19:39 minutes. Participants discussed several domains including perceived stress; knowledge about weight gain, eating, and exercise; attitudes about weight gain, eating, and exercise; behaviors related to weight gain, eating, and exercise; and experiences while participating in the study. A full description of the qualitative results will be presented in subsequent studies.

Interview data were used to gain in-depth descriptions of participant beliefs and behaviors. Unlike in the text message surveys, the interviews included follow-up and clarifying questions. The interviewer was able to *follow* the participant to explore topics that emerged during the interview. An unexpected theme, for example, was the lack of social support experienced by many of the participants. Although participants were not explicitly asked about social support, they frequently discussed the role of others in their health behaviors during pregnancy. As a result, interviews played an essential role in identifying new themes that did not emerge from other data sources.

Discussion

Principal Findings

This study has demonstrated the potential integration of 3 data collection techniques with pregnant youth. Although independently providing one lens into youth perspectives, the integration of the 3 data sources provides a more complete picture of participant experiences.

Overall, 72% to 76% of participants provided their Facebook data, whereas only 2 participants provided their Twitter data and 7 participants provided Instagram posts. With all 3 platforms, participants who did not complete this component indicated that they did not use these social media platforms or that they could not remember their login information. Our participation rates are similar to the expected prevalence of Facebook use among this population [38]. Future studies that employ social media mining should consider the platforms that are typically used among their target population and how social media use may influence participation rates.

A majority of participants responded to at least 1 week of text message surveys, though engagement varied throughout the duration of the study. Text messaging may be a cost-effective means of communicating with youth participants to collect real-time data, inform intervention development, or investigate processes before, during, and after intervention studies. For the participants in this study, text message surveys were an acceptable modality that had an unexpected outcome of making youth feel supported and connected to others. Collecting survey data via text message allowed participants to control the time of day and space where they participated in the survey.

Text message surveys also present several challenges. Our findings revealed that many youths would have preferred 2-way communication and tailored messaging to engage them each week. Some participants found the language of the texts repetitive, whereas others indicated that the content felt too standardized. Our results also demonstrated that participants varied in their preferences for the frequency, timing, and language of text messages received. Tailoring the frequency, timing, and content of messages may increase acceptability and engagement for participants who were less responsive in the text message surveys, though that may limit the ability to scale text message surveys to larger populations owing to the amount of staff and resources required.

Despite participants having access to a cell phone at the time of enrollment, continued access and regular use of cell phones varied. Several participants reported that they did not participate in the text message surveys owing to a change in cell phone number, poor service, or cell phone plan limits on text messaging. Similar problems were observed with surveys administered via phone or through Web platforms, and innovative strategies to enroll and sustain participation among low-income communities should be addressed in future research [52].

The semistructured interviews had the highest participation rates among all components of the study. As the youth were interviewed before or after an existing, regularly scheduled perinatal visit with their primary care physician, we were able to reduce the time burden to participation. Interviews were conducted in a familiar setting, which may have helped in developing trust and encouraging participation [53]. As the research was supported by the 2 clinical sites, the medical staff served as gatekeepers [54] and facilitated interactions between the research staff and participants. Face-to-face contact may play an important role in engaging pregnant youth who are often balancing many responsibilities. In addition, semistructured interviews allowed for more in-depth exploration of study topics. Interviewers could ask follow-up questions, probe for more information, and use content from social media mining and text message surveys to elicit further details.

All 3 components of the study provided a different lens through which we were able to investigate gestational weight gain among pregnant youth. Through social media mining, we gained access to public beliefs and statements about pregnancy, weight gain, body image, and eating in the months when the women were pregnant. The text message surveys provided real-time descriptions of these same domains, allowing participants to reflect upon their recent experiences and express personal details or opinions they may not want to share with their social network. Finally, the semistructured interviews produced in-depth narratives of participant experiences over the course of the pregnancy. Interviews allowed the research team to ask

follow-up and probing questions that clarified statements and added to our understanding of their lived experiences. Together, the combination of these 3 methods produced a more complete picture of weight gain during pregnancy among an at-risk population of low-income youth.

Limitations and Future Directions

There were several limitations to this study. First, recruiting and retaining youth in research is difficult [21,55]. Pregnancy is also a turbulent and stressful time, which could make study components feel burdensome. The study population may seek care late into pregnancy, making it difficult to complete the study components before their due date. We tried to reduce the burden experienced by the participants by approaching them before or after their regularly scheduled clinic visits. In addition, we minimized the time spent with participants and aimed for all visits to last less than 30 minutes.

Second, using text messaging to collect survey data is a potential limitation. Study participants may have difficulty paying cell phone bills, which may result in their cell phone number changing or service ending during the study. This could result in them not receiving the text messaging questions part way into the study. To overcome this barrier, we provided all participants with a notecard that had our contact information so that they could call, text, or email if their phone number changed during the study. We were also unable to verify that the text message responses received were from the participant themselves or from someone using the participant's phone.

Third, although no participants expressed this concern, potential future participants may have privacy concerns about answering sensitive questions over text message or providing access to their social media accounts. To address this concern, we ensured that the texting platform used for this study was usable and secure through extensive pilot testing with a similar population. Participants were allowed to consent to individual components of the study, so interviews could be done without either text message surveys or social media mining.

Finally, some participants described the text message surveys as a source of social support. As the intention of our study was to collect data about participant experiences and not to intervene, there is potential bias in the responses of the pregnant youth. Studies employing text message surveys with youth will want to consider the potential influence that text messaging may have on participant responses.

Conclusions

Despite these limitations, we demonstrated the feasibility and acceptability of these data collection methods among at-risk pregnant teens in low-income settings. Moderate response rates to the text message surveys and willingness to provide access to social media accounts indicate that participants were comfortable sharing data through these developing modalities.

Acknowledgments

This study was supported by the National Institute of Child Health and Human Development of the National Institutes of Health (award number: 1K23HD08352701A1).

Conflicts of Interest

None declared.

Multimedia Appendix 1

MyVoice demographic survey completed upon enrollment.

[PDF File (Adobe PDF File), 142KB - formative_v3i2e11397_app1.pdf]

Multimedia Appendix 2

Text message surveys by week.

[PDF File (Adobe PDF File), 144KB - formative_v3i2e11397_app2.pdf]

Multimedia Appendix 3

Semistructured interview guide.

[PDF File (Adobe PDF File), 132KB - formative_v3i2e11397_app3.pdf]

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Abbreviations

API: application programming interface
CSV: comma-separated value
NLP: natural language processing

Edited by G Eysenbach; submitted 25.06.18; peer-reviewed by J Most, M Waring; comments to author 07.10.18; revised version received 30.11.18; accepted 27.01.19; published 01.04.19.

Please cite as:
DeJonckheere M, Nichols LP, Vydiswaran VGV, Zhao X, Collins-Thompson K, Resnicow K, Chang T
Using Text Messaging, Social Media, and Interviews to Understand What Pregnant Youth Think About Weight Gain During Pregnancy
JMIR Form Res 2019;3(2):e11397
URL: https://formative.jmir.org/2019/2/e11397/
doi:10.2196/11397
PMID:30932869

Original Paper

Developing a Data Dashboard Framework for Population Health Surveillance: Widening Access to Clinical Trial Findings

David Concannon[1*], BArch, MSc; Kobus Herbst[2], MBChB, MSc; Ed Manley[1*], BSc, MSc, MRes, PhD

[1]Centre for Advanced Spatial Analysis, University College London, London, United Kingdom

[2]Africa Health Research Institute, Durban, South Africa

[*]these authors contributed equally

Corresponding Author:
Ed Manley, BSc, MSc, MRes, PhD
Centre for Advanced Spatial Analysis
University College London
Gower Street
London,
United Kingdom
Phone: 44 02031083884
Email: ed.manley@ucl.ac.uk

Abstract

Background: Population surveillance sites generate many datasets relevant to disease surveillance. However, there is a risk that these data are underutilized because of the volumes of data gathered and the lack of means to quickly disseminate analysis. Data visualization offers a means to quickly disseminate, understand, and interpret datasets, facilitating evidence-driven decision making through increased access to information.

Objectives: This paper describes the development and evaluation of a framework for data dashboard design, to visualize datasets produced at a demographic health surveillance site. The aim of this research was to produce a comprehensive, reusable, and scalable dashboard design framework to fit the unique requirements of the context.

Methods: The framework was developed and implemented at a demographic surveillance platform at the Africa Health Research Institute, in KwaZulu-Natal, South Africa. This context represents an exemplar implementation for the use of data dashboards within a population health-monitoring setting. Before the full launch, an evaluation study was undertaken to assess the effectiveness of the dashboard framework as a data communication and decision-making tool. The evaluation included a quantitative task evaluation to assess usability and a qualitative questionnaire exploring the attitudes to the use of dashboards.

Results: The evaluation participants were drawn from a diverse group of users working at the site (n=20), comprising of community members, nurses, scientific and operational staff. Evaluation demonstrated high usability for the dashboard across user groups, with scientific and operational staff having minimal issues in completing tasks. There were notable differences in the efficiency of task completion among user groups, indicating varying familiarity with data visualization. The majority of users felt that the dashboards provided a clear understanding of the datasets presented and had a positive attitude to their increased use.

Conclusions: Overall, this exploratory study indicates the viability of the data dashboard framework in communicating data trends within population surveillance setting. The usability differences among the user groups discovered during the evaluation demonstrate the need for the user-led design of dashboards in this context, addressing heterogeneous computer and visualization literacy present among the diverse potential users present in such settings. The questionnaire highlighted the enthusiasm for increased access to datasets from all stakeholders highlighting the potential of dashboards in this context.

(JMIR Form Res 2019;3(2):e11342) doi:10.2196/11342

KEYWORDS

data visualization; data dashboards; health and demographic surveillance; sub-Saharan Africa; treatment as prevention; clinical trials; demographics; real-time; data literacy

Introduction

Demographic surveillance, the process of monitoring births, deaths, causes of deaths, and migration in a population over time is 1 of the cornerstones of public health research [1,2]. The availability of detailed data on these population statistics is essential to the planning, implementation, and evaluation of any public health intervention [3]. The lack of vital information presents significant challenges for the use of an evidence-based decision making process for public health interventions [4]. Health and Demographic Surveillance Systems (HDSSs) comprise the continuous monitoring of demographic and health characteristics of a population living in a well-defined geographic area [5]. The goal of an HDSS is to generate high-quality longitudinal datasets to capture the demographic and health changes of the set population [6]. The production of large and complex datasets required to monitor disease burden poses many challenges on the public health community to explore, analyze, and extract valuable information to make timely decisions [7]. The World Health Organization has cited the accumulation of unanalyzed data as a challenge facing HDSS sites [3]. AbouZahr et al [8] suggest that because of the vast quantities of data produced by health information systems, the information overload at higher levels is such that datasets are, in practice, seldom used effectively for decision making. For decision makers, it is essential to rapidly extract relevant information from the flood of data [9]. Without the timely analysis of these datasets, there is a decrease in their value as a tool to monitor disease trends [10]. The intelligent implementation of information visualization has been employed in public health and could offer a means to increase the use of datasets at HDSSs.

Information visualization offers a means to disseminate information promptly and increase its visibility among stakeholders. Card et al [11] defined data visualization as the use of visuals to *amplify cognition* to aid task completion. The use of visualization acts as an intermediate step in converting data into information. Visualization tools exploit human visual and spatial skills by using interactive visual representations of data. Visualization can aid decision making, helping the user build accurate mental models that can leverage cognitive skills [12-15]. Research in cognitive capacity demonstrates that humans can process more information presented graphically than in text [16,17]. Keim [9] states that the key benefits provided by visuals are that they act as a frame or a temporary storage area for human cognitive processes.

La Valle [18] highlighted visualization as a useful tool for gaining insight into large and complex datasets. Longitudinal datasets produced by HDSSs are typically multivariate, complex, with varying levels of granularity [17], and thus may represent suitable datasets for the use of visualization tools. Datasets produced at HDSS sites are typically accessible only in formats that do not allow for the rapid extraction and analysis of salient information. The role that surveillance data produced at HDSSs can play in planning new health interventions can be diminished if the data are not communicated in a timely and understandable manner [19]. Given the multiple data sources collected in HDSSs and the variety of potential users, a dashboard is an excellent vehicle for visualization in this context. Few [20] describes dashboards as a consolidated visual display of pertinent information, arranged so the entire operation of an observed system can be monitored and understood at a glance. Wexler et al [21] give a broad definition as “a visual display of data used to monitor conditions and/or facilitate understanding”.

Dashboards typically comprise a combination of different visualization methods; the commonality is that they draw from multiple data sources to facilitate timely understanding [22]. Carroll’s [23] review of the impact of visualization tools on epidemiology highlighted the richness of the information offered by visualization for communication, and decision making is counterbalanced by difficulties in displaying and interpreting these datasets.

Although there is little evidence in the literature of dashboard implementations at HDSS sites, there is a variety of examples relating more generally to public health monitoring. Cheng [19] developed a Web-based interface to share Hong Kong’s flu surveillance data. The design is based on public health websites and dashboard design guidelines. Cheng emphasizes the need to develop a framework with standard datasets to include multiple sources and to visualize the various diseases. Sopan et al [24] built the community health map to share public health data among a variety of different users, for example, policy makers, journalists, and the public. The dashboard focused on the ability to compare different datasets and indicators, including the spatial visualization of data. The results from the pilot suggested a comprehensive visualization interface could lead to better informed decision making. Kostkova et al [25] developed the *medi+board* to coalesce multiple disease surveillance datasets promptly. This study emphasized the role of modularly in design to allow the timely deployment of dashboards. The lessons from these examples have been incorporated into the design of our dashboard framework.

This paper presents the development and evaluation of a design framework for the implementation of a data dashboard within an HDSS context. The paper proceeds by outlining the structure and design rationale behind the framework, with a focus on its implementation within a specific HDSS context. Following this, an evaluation is described, which outlines the implementation of its use within a specific trial context, revealing promising findings concerning task completion, usability, and sentiment. The contributions of this study are guidelines for designing visualization systems for HDSS sites and identifying their information needs and the development of a framework to reflect the needs of the diverse users. The research identifies the challenges of different users in dashboard design and offers suggestions on how to account for this in future systems.

Methods

Stages of Data Dashboard Development

The development of a data exploration dashboard framework requires a range of implementation decisions. These factors involve elements of data design, user interaction, and the study setting of the dashboard design, all of which contribute to the potential success of the dashboard. The outline framework

described below relates to the design and implementation of a dashboard within a population health–monitoring setting. In developing a dashboard in this context, there are 5 core considerations:

1. Study setting (description of the development context of the framework) informs how interaction with the dashboard takes place, informs about information requirements, and informs about privacy and confidentiality concerns.
2. Dashboard purpose and concept comprise specification of the purpose of the dashboard, including the context, target user group, and the expected objectives of users of the dashboard.
3. User Interaction and flow specify the intended process of user interaction with the dashboard interface, including the expected user *flow* through the dashboard structure, to gain insight.
4. Data selection and visualization design cover the design and construction of the data visualization, including how the key attributes are selected, their location within the dashboard, and their extraction from the underlying database.
5. Framework architecture covers technical aspects of dashboard framework, including input data structures and interfaces.

In the following section, the execution and design considerations involved in the development of a dashboard framework for HDSS sites are described.

Study Setting

The setting of this study is the Africa Health Research Institute (AHRI) in KwaZulu-Natal, South Africa (SA). AHRI's field site operates as an HDSS, generating high-quality longitudinal datasets to capture the demographic and health changes brought about by the HIV epidemic and evaluate interventions to mitigate their impact [6]. The broad objectives of the dashboard trial were to increase access to information for staff and community members to AHRI's Somkhele field site, providing a real-time picture of data collection operations and insight into the variety of major trials and surveys ongoing within the region. The variety and velocity of data collection at AHRI means that this setting was similar to other HDSS contexts. In this context, the dashboard framework was implemented for a monitoring Treatment as Prevention (TasP) trial for sociodemographic analysis and intervention cascade progression. In this study, the primary focus will be upon the TasP implementation.

Within this setting, the dashboards would be displayed on 3 large touch screens within the research center. Placing of the dashboards in public areas hoped to encourage collaborative use, visibility, and discussion of datasets, and it could provide a means to explain the work of the institute field site to visitors.

Dashboard Purpose and Concept

The purpose of the AHRI data dashboard was to provide users with the opportunity to access information about studies at the site and provide a building block for the development of a framework, increasing the visibility and access to the datasets produced at the sites. The dashboard would give a clear and concise overview of the information collected in an understandable and accessible format while ensuring the anonymity of the participants. A diverse range of users would use the dashboards, yet a dashboard cannot be created to fit every user persona. The aim was to design a dashboard, which anyone working at a site could feel comfortable using to explore core datasets in the context of a specific study, for example, community members, field workers, medical staff and resident scientists, and visiting researchers. This design would enable users to either review overall progress or to drill down into analysis depending on their needs.

In achieving these objectives, the dashboard interface would be required to meet the following design criteria:

- Provide a monitor of key performance indicators (KPIs)
- Enable spatial interrogation of datasets in relation to KPIs to identify trends
- Allow for switching from a global to local view in relation to these indicators
- Drill down to the local regions of the map to explore datasets in greater detail

On the basis of these needs, we developed a 2-stage dashboard comprising an overview page and analysis page. The overview page would provide a global picture of the study in question and would feature a display of the key indicators relating to the progress of the trial and an interactive map to display these indicators to allow rapid identification of trends. Interaction with the overview page would enable users to filter data by indicator and act as a jumping-off point to the analysis page. The analysis page would focus on a selected subdivision within the study site, allowing users to compare the performance of a region to the global area and augment their analysis with the typical datasets produced at an HDSS.

User Interaction and Flow

The global performance of indicators is the starting point for the users' interaction with a dashboard, a set of anchors to guide their exploration of the datasets displayed and to compare performance at the global and local level. The design of the dashboard was based on Shneiderman's [26] principles of visual information seeking mantra *overview first, zoom and filter, and details on demand*. The overview component of the dashboard is the display of the global indicators combined with the spatial overview provided by the map. The user can filter data by changing the map display by indicator. The map provides a means to zoom to areas of interest on the basis of spatial patterns of variance. Selecting a map region allows the user to access the details for that specific region.

Data Selection and Visualization Design

A successful dashboard provides an overall picture of the datasets represented with a key objective in mind. In this context, there are a variety of indicators that can reflect the health of a population, for example, child mortality, life expectancy [10]. For the TasP dashboard, for example, the indicators chosen were aligned with the United Nations Programme on HIV/AIDS 90/90/90 targets across the study region (described in Table 1).

Framing data exploration through indicators allows the user to keep the global in mind while exploring details. The dashboard's exploratory hierarchy of datasets is the global view of KPIs than viewing the KPIs at a local level. This flow allows the user to view the global and the local together and make comparisons between both scales, gaining insight into relative local performance and identifying emerging trends quickly and clearly (see Figure 1). Users could directly compare the local performance of a map region with all global indicators and interrogate factors that could influence the rate of the KPIs with the help of explanatory datasets such as demographic data. The user can display explanatory datasets normalized by the region's total population or normalized by population relating to the indicator (eg, HIV-positive individuals).

The Map Interface

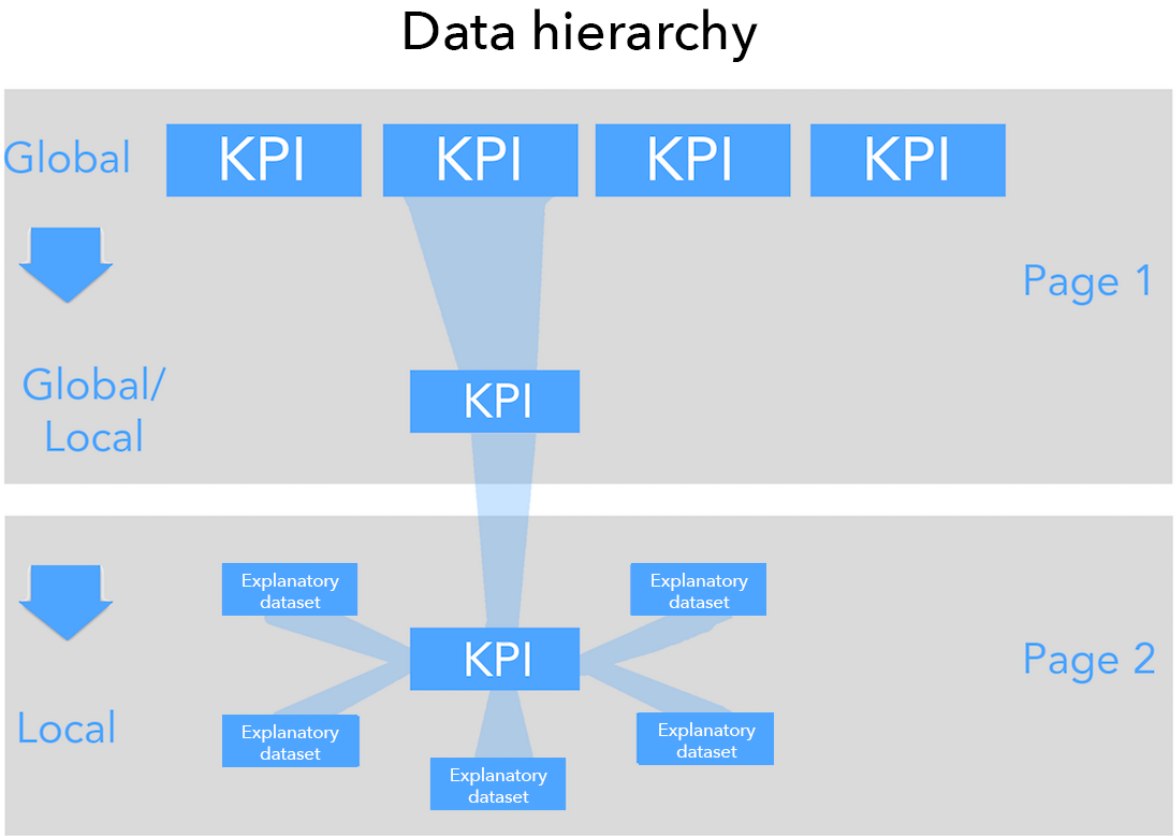
The overview page was designed to fulfill the function of a traditional dashboard by providing the user with access to the most salient information relating to the subject matter while encouraging a detailed exploration of the datasets. The design intention was to provide the user with an overview of the progress of the study to the KPIs, to review a spatial representation of indicator performance, and provide the means to compare the global performance with the local. Once a region had been selected, the user could move to the analysis page, which would focus on local performance with the aid of explanatory variables and the use of comparative visualizations.

Table 1. Summary of selected key performance indicators and data types.

Indicator	Type	Description
Trial participants	Number	The number of individuals enrolled in the Treatment as Prevention trial
HIV prevalence rate	Ratio	The percentage of individuals known to be HIV positive
HIV-positive individuals who know their status/individuals known to be positive	Ratio	The percentage of HIV-positive individuals who know their status/the number of individuals known to be positive
HIV-positive individuals on antiretroviral treatment ART[a]/diagnosed individuals	Ratio	The percentage of HIV-positive individuals on ART
Individuals who are virally suppressed/individuals on ART	Ratio	The percentage of individuals who are virally suppressed

[a]ART: antiretroviral treatment.

Figure 1. User interaction flow between global and local. This image shows the interaction of key performance indicators (KPIs) at the global and local scales, allowing the user to explore the broad spatial trends in the indicator at the global scale, before drilling down into the finer scale spatial variation and associations at the local.



Following Shneiderman's visual information seeking mantra [26], the map page presents an overview of the datasets with the ability to filter according to the KPIs and access local region performance details by using these features to guide the user to the analysis page. The dashboard updates daily from the trial databases, allowing the user to explore the shifting patterns of the study's progress.

The overview pages comprise 3 areas of information display (see Figure 2): (1) map, (2) global performance of indicators, and (3) local performance of indicators in a selected region.

The focus of the overview page was the map display (indicated with point 1 in Figure 2). The map provided a spatial view of the study performance through graduated symbols and acted as a vector for the exploration of local regions. Furthermore, one of the weaknesses in the trial's oversight protocol was the lack of a method to observe spatial variation in the progress of the trial without the generation of geographic information system maps, a time-consuming process. The map would be at the center of the dashboard interface and would drive exploration of trial datasets. The map allows a simultaneous overview of global trends and local variation in the observed attribute. The interface also allows the user to view trial results in relation to local infrastructure, for example, roads and clinics. Spatial data are displayed using a binning technique that divides the trial area into a grid of uniform hexagons. Binning is a means of converting point data into a regular grid of polygons. Each element of the grid represents the aggregation of the points that fall within it. The result is a uniform representation of the trial region, and it allows simple, clear visualization of the datasets, aided by quantification of the map using color breaks. The most pressing concern was to ensure the privacy of the trial's participants. Privacy was the primary driver for choosing a binning technique as participants were aggregated to a hex, resulting in the highest granularity level of the data being the hex, with all local data displayed in relation to the performance of the hexagon region rather than the individual. The use of a grid acted as a means of distortion that prevented users from directly identifying individual homesteads. The use of a universal grid representing the HDSS region allows for the easy visualization of spatial data within the dashboard framework. Spatial data are aggregated to the hex, and hexes containing no data are not displayed, allowing for comparison across dashboards and providing a method that could be replicated at different sites. A downside of this method is that the grid sections display geographically equal areas rather the population density (eg, skewed toward urbanized areas). A solution was to add a layer that represents population density. Using methods such as size distortion would require the grid to be redrawn for each dashboard, which was not deemed feasible.

The graduated color map is used to identify areas of interest and detect spatial autocorrelation within the trial region. The use of a binning technique also related to practical concerns to create regions to capture local performance and acted as a point of interaction to trigger events on the dashboard. When a hexagon is selected, information relating to indicator performance and the number of trial participants residing in that region is displayed. A button on the information window allows the user to view this region in greater detail on the analysis page. Interacting with a map hexagon also triggers the display of KPIs for the selected region in the page footer. The global performance of indicators is displayed in the left-hand sidebar (point 3 in Figure 2). The sidebar displayed the KPIs in the form of donut charts with the percentage figure contained inside. When an indicator chart interacted with the map display, it would update relating to that indicator, whereas the bottom bar would update to display supplementary information on the selected indicator. Donut charts were selected instead of bar charts, as the visualization allowed for the large display of the percentage behind the chart as trial staff requested the prominent display of targets.

The page footer (point 3 in Figure 2) allows direct comparison between the local indicators and the global, in the left sidebar (see Figure 3). This design was to allow the user to consistently frame the global and local together without overloading them with information. Indicators were displayed using horizontal bar charts and contained an information button to display how the selected map indicator was calculated, and also contained a button that moved the user to the analysis page to explore the KPIs in greater detail with the aid of explanatory datasets.

Analysis Page

The analysis page provides a detailed view of the performance of indicators at a local scale, the *details on demand* of Sneiderman's mantra [26]. The design intention was to view explanatory datasets in relation to the total population resident in each region and to add or remove population data relating to the KPIs. The analysis page allows users to view data relating to HIV status, gender, age group, education, relationship, and economic status. The analysis page facilitates exploration of datasets by allowing the user to explore the demographic differences of the trial participants relating to each indicator. For example, users could compare the education level of HIV-positive individuals who have linked to care with those who have not linked to care. The analysis page allows for in-depth exploration and discussion of the datasets among users.

The analysis page comprised 4 areas of information (Figure 4):

1. Explanatory variables
2. Global and local comparison
3. Chart selection, mini map, and global information display
4. Key numbers relating to a region

Figure 2. Landing page of the dashboard. This image shows the interactive front page of the dashboard, displaying the global view of 1 indicator within the map (marked 1), measures of key performance indicators (KPIs) at the selected local region at the bottom of the screen (marked 2), and global KPI measures on the left (marked 3). Data are updated in real-time. The user is invited to manipulate the map and change selected regions through click or touch. The Breakdown Page button leads to a more detailed exploration of KPI measures and related factors within the Analysis page.

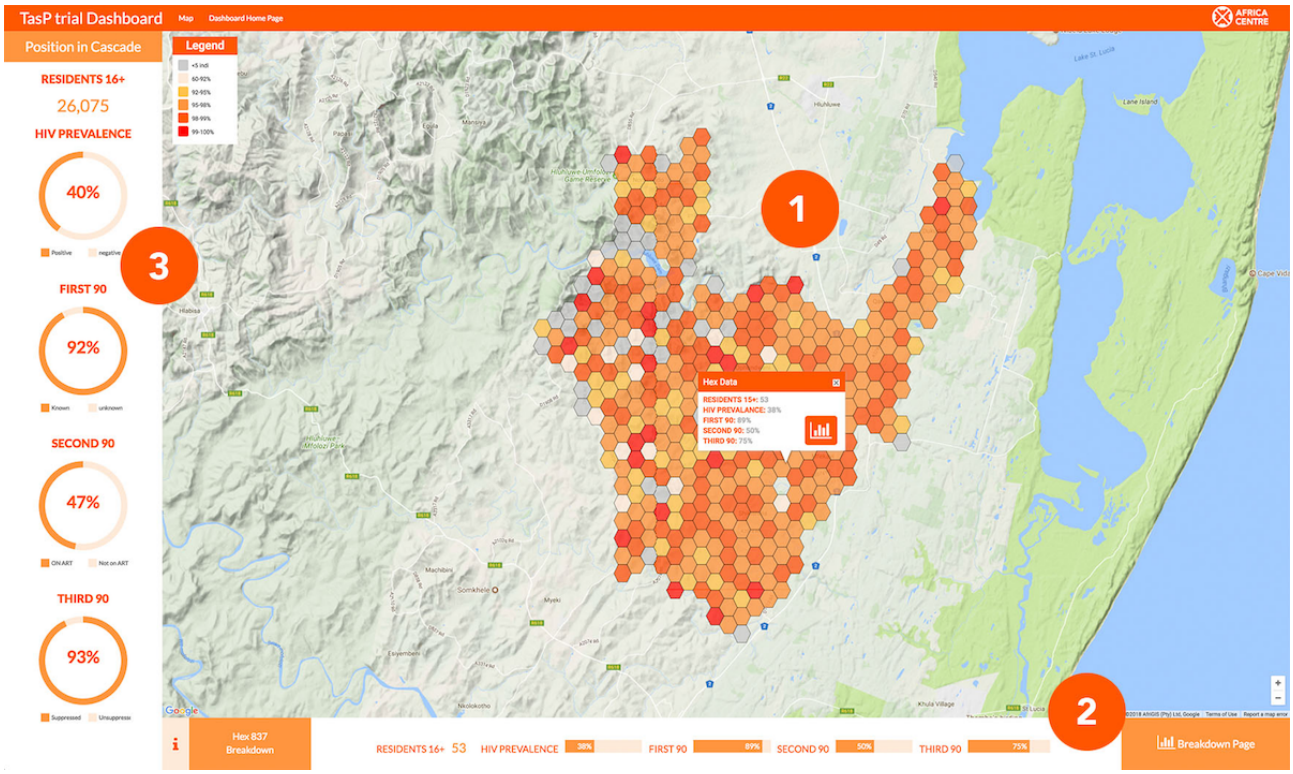


Figure 3. Points of comparison. This image highlights the points of interaction between global and local indicators, showing the points where a user is able to directly compare local and global measures of key performance indicators.

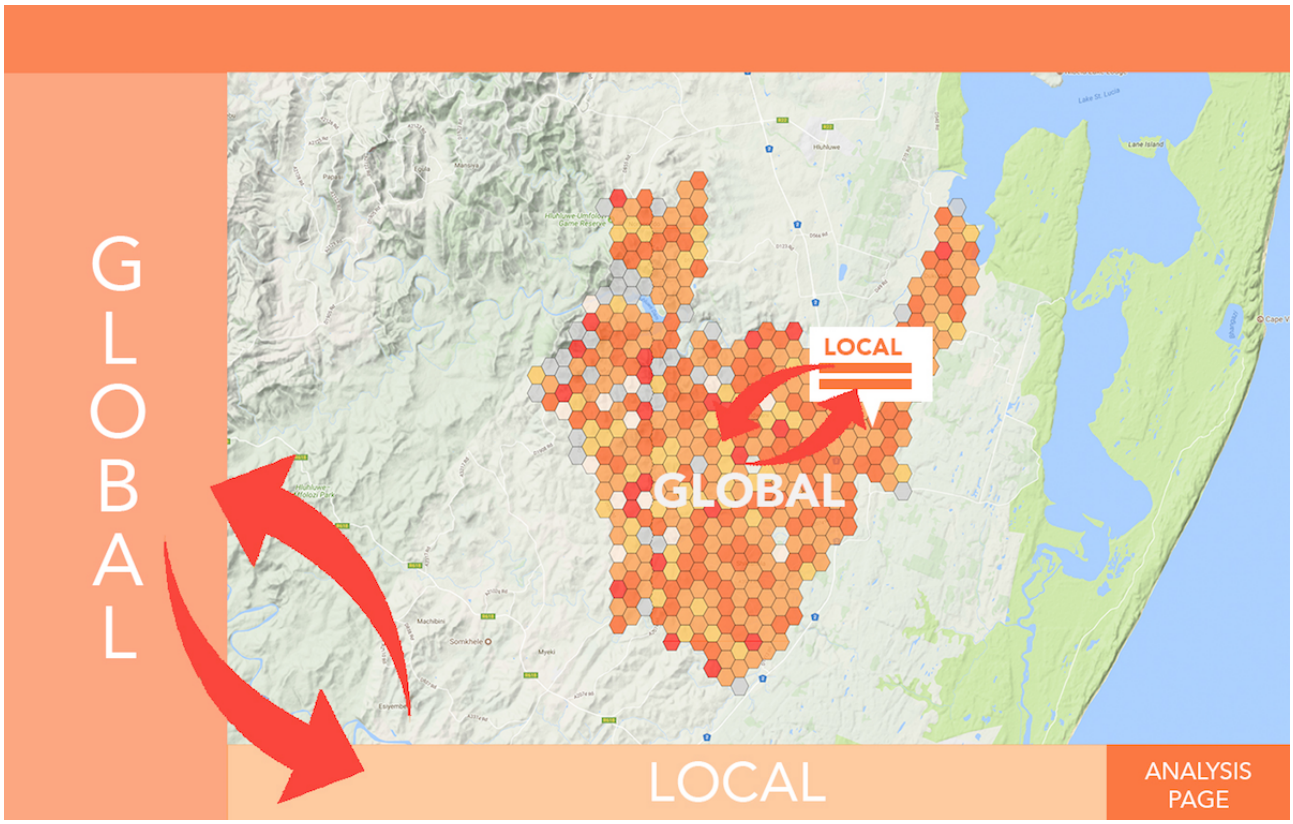
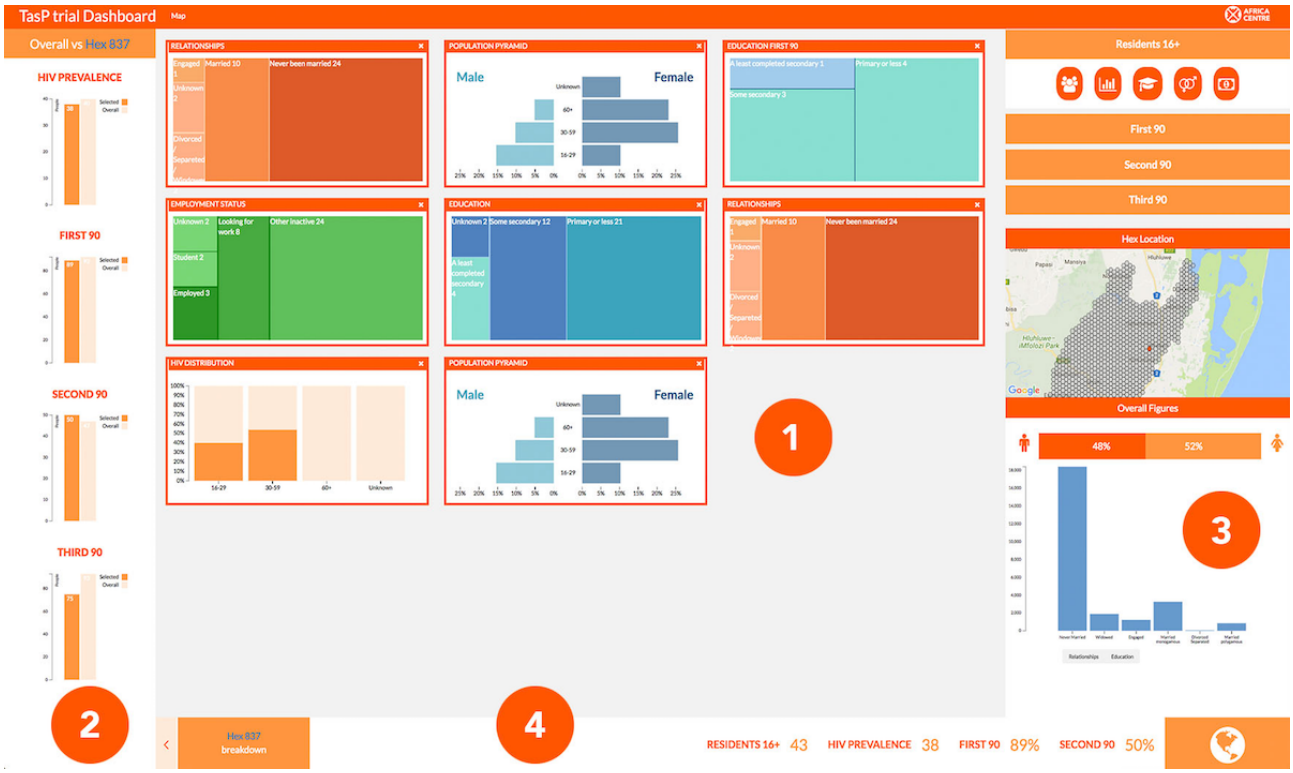


Figure 4. Analysis page. This figure shows the analysis page for a local region selected through the global map page. The page introduces a range of potential explanatory attributes that can be measured against key performance indicators to help develop hypotheses for future studies. Users are able to add and remove visualizations through interactive functionality.



The focus of the analysis page is the explanatory variables section (point 1 in Figure 4). Within this window, charts are displayed in modules that can be added or removed through interaction with the interface. The user can use a set of charts displaying explanatory datasets relating to all trial participants in the local region. The charts are as follows:

1. A population pyramid
2. A normalized stacked bar chart displaying HIV rates by age group
3. A treemap displaying education levels
4. A treemap displaying relationship status
5. A treemap displaying employment levels

Treemaps were chosen over bar charts as users preferred them, and they allowed for a more precise display of labels relating to data. The user can add the charts display population data in relation to each indicator to explore the differences among participants at different stages of the HIV treatment cascade, allowing the user to compare different outcomes directly. We used multiple visualization methods to exploit their differing strengths to enhance the users' data exploration and engagement. Additional chart types alongside those listed above were pie, bar charts, and scatter plots.

The left-hand sidebar (point 2 in Figure 4) displays the KPIs in the local region to the global using bar charts, as with the design of the map page allowing the users to keep global and local in their mind while exploring. The right-hand sidebar (point 3 in Figure 4) acts as the control panel for the visualization portal. The user can select charts to add to the center display relating to an indicator. Icons related to the dataset represent chart choices. The sidebar includes a mini-map, highlighting the selected region and a bar chart displaying the global proportional relationships of education, relationship status, and economic status within the trial. This bar at the bottom of the page (point 4 in Figure 4) displays key figures relating to a region, such as a gender breakdown, HIV prevalence, and KPIs.

Framework Architecture

The data dashboard was designed to inform the development of a framework. The framework was designed as a modular system to allow for the creation of dashboards by the research data management team at the site. The framework aimed to allow the development of dashboards as new datasets are produced. The aim was to develop new chart options as needed. This modularization comprised 3 components and the retention of these components for each new study.

1. Standard inputs for the dashboard frontend
2. Standard architecture for the inclusion of new datasets into the dashboard
3. Standard dataset formats for the generation of data visualizations

All dashboards run from a Web server within AHRI's database architecture. Each dashboard is contained within a folder on the Web server, and adding a new folder to the dashboard Web server generates a new dashboard. The dashboards are displayed through a Web browser, and dashboards can be accessed through the dashboard homepage files on the Web server and can be edited by accessing the dashboard folder on the shared drive. The dashboard works as a typical website, and each folder contains index.html, analysis.html, and folders for Cascading Style Sheets (CSS), JavaScript (JS), and datasets. Data managers have access to the folders to edit the dashboard setup for new

iterations and troubleshoot errors when they occur. The research data management team was trained on the system through training workshops.

Ethics Approval and Consent to Participate

Ethics approval was granted for this study by the University of KwaZulu-Natal Biomedical Research Ethics Committee, reference BE497/16. Informed consent to participate in the study was obtained from all participants.

Results

Evaluation Design

An evaluation of the dashboard framework design was undertaken using the TasP trial dashboard implementation. This data dashboard was evaluated by assessing its usability with 20 users. The site had 100 workers, and the aim was to engage a broad range of potential users. Participants were selected from people working at AHRI, representative of different groups who would use dashboards to gain insight from AHRI datasets. These groups chosen were as follows.

- Scientific staff: primarily medics, health care specialists, and researchers. Staff that would use dashboards to explore data from a research perspective, easing their access to data.
- Operational staff: those ensuring continued operation of AHRI, focusing on data collection and quality. Staff that would use the dashboards to monitor the progress of data collection in studies.
- Nursing staff: those involved in providing health services in the area. Nurses would use the dashboard to monitor how the data they collect are used and keep up to date with the studies they were involved.
- Community Advisory Board (CAB) members: The CAB comprises members of the local community who are consulted and who advise researchers on the implementations of studies. The dashboards allow the CAB to explore the data collected about the community, supporting the group role in improving public understanding and maintaining accountability.

In total, 5 members of each group were randomly selected.

To assess the usability of the dashboards, the users performed a benchmark task evaluation comprising 5 tasks (each incorporating 2 subtasks) of increasing difficulty, requiring the user to extract information using the dashboards. During benchmark task evaluations, participants use visualizations to perform tasks to extract information, measuring targeted metrics [27,28]. The time taken and accuracy of the user responses for the tasks were recorded to evaluate the dashboard's usability. The use of a task evaluation can identify possible shortcomings in the representation of data within a visualization system [29]. The task completion component of the evaluation was filmed with the permission of the participants to ascertain the timing of task completion. The tasks undertaken by participants are provided in Multimedia Appendix 1.

Alongside benchmarking, users were also asked to self-evaluate their knowledge of the TasP trial and their level of computer literacy. Participants were also asked to complete a questionnaire using a Likert scale to assess their attitude toward the dashboard, covering the design of the interface, information presentation, and attitudes toward the future use of dashboards within AHRI. The questionnaire is provided in Multimedia Appendix 2.

Evaluation Results

The results of the evaluation can be broken down into 3 parts: self-evaluation, task evaluation, and the questionnaire.

Self-Evaluation

The self-evaluation asked the users to give their level of computer literacy, awareness of the TasP trial, and the dashboard project (see Table 2). Overall, the CAB and nursing staff reported lower levels of computer literacy than the operational and scientific staff, although knowledge of the TasP trial and the dashboard projects varied within groups, with the nursing staff reporting the highest knowledge of the trial, which was expected as the nurses were involved in the clinical component of the TasP trial.

Task Completion

The results of the task component of the evaluation are provided in Figure 5. The results of the task completion were mostly positive. Except for the second part of the final task, a majority of participants were able to complete the tasks successfully; in the majority of tasks, there was a greater than 70% (14/20) correct completion rate.

The issue with the final task, which involved comparing data from multiple sources, may highlight a design weakness where data must be compared across separate charts rather than as different series within a single chart. Within these results, there was a great deal of variation within the subgroup performance, with the scientific and operational staff performing better in task completion than the CAB and nursing groups. Figure 5 outlines the differences between participant groups.

Overall the time taken to complete tasks increased with the increasing complexity of each task. On an average, users spent more time on tasks where their answer was incorrect. The scientific and operational staff were generally quicker to answer questions, and more often correct, than the CAB and nursing staff. Through one-way analysis of variance, a significant difference in time taken to complete tasks was found between scientific and nursing staff but not among other groups (Figure 6). These results may be influenced by lower computer literacy on the part of the nursing and CAB participants as self-reported. Therefore, they indicate that there are further steps to go to maximize accessibility across all interested groups.

User Questionnaire

The questionnaire comprised 11 questions divided to cover 4 topic areas, the insight provided by the dashboard, the dashboard interface, the future use of the dashboards at the AHRI, and questions allowing users to comment on the dashboards and how they could be improved to provide greater clarity of information. The first 8 questions employed a Likert scale, the last 3 allowed participants to comment on their experience of the dashboard and their thoughts on their future use.

Table 2. Responses to self-evaluation of computer literacy from different participant groups.

Participant group	Very low, n	Low, n	Medium, n	High, n	Very high, n
Community advisory board					
Level of computer literacy	0	2	3	0	0
Knowledge of the TasP[a] trial	0	3	2	0	0
Awareness of the dashboard project	0	1	3	0	1
Nursing staff					
Level of computer literacy	0	2	3	0	0
Knowledge of the TasP trial	0	0	1	4	0
Awareness of the dashboard project	0	2	2	1	0
Operational staff					
Level of computer literacy	0	0	2	2	1
Knowledge of the TasP trial	0	1	2	2	0
Awareness of the dashboard project	1	4	0	1	0
Scientific staff					
Level of computer literacy	0	0	0	5	0
Knowledge of the TasP trial	0	0	3	2	0
Awareness of the dashboard project	0	4	1	0	0

[a]TasP: Treatment as Prevention.

Figure 5. Task completion rates, by group. This figure shows how different groups of participants performed during the evaluation study. CAB: Community Advisory Board.

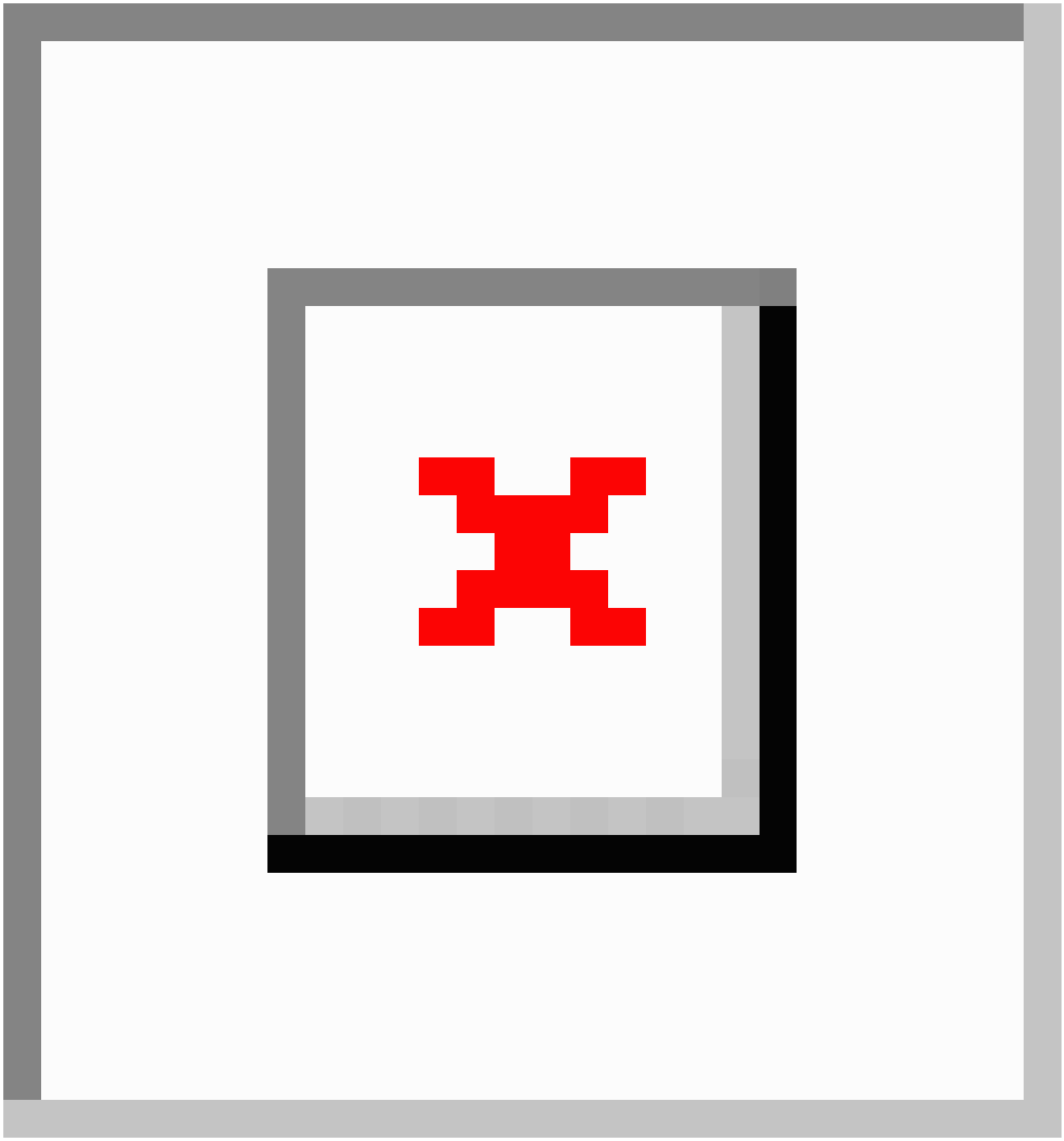
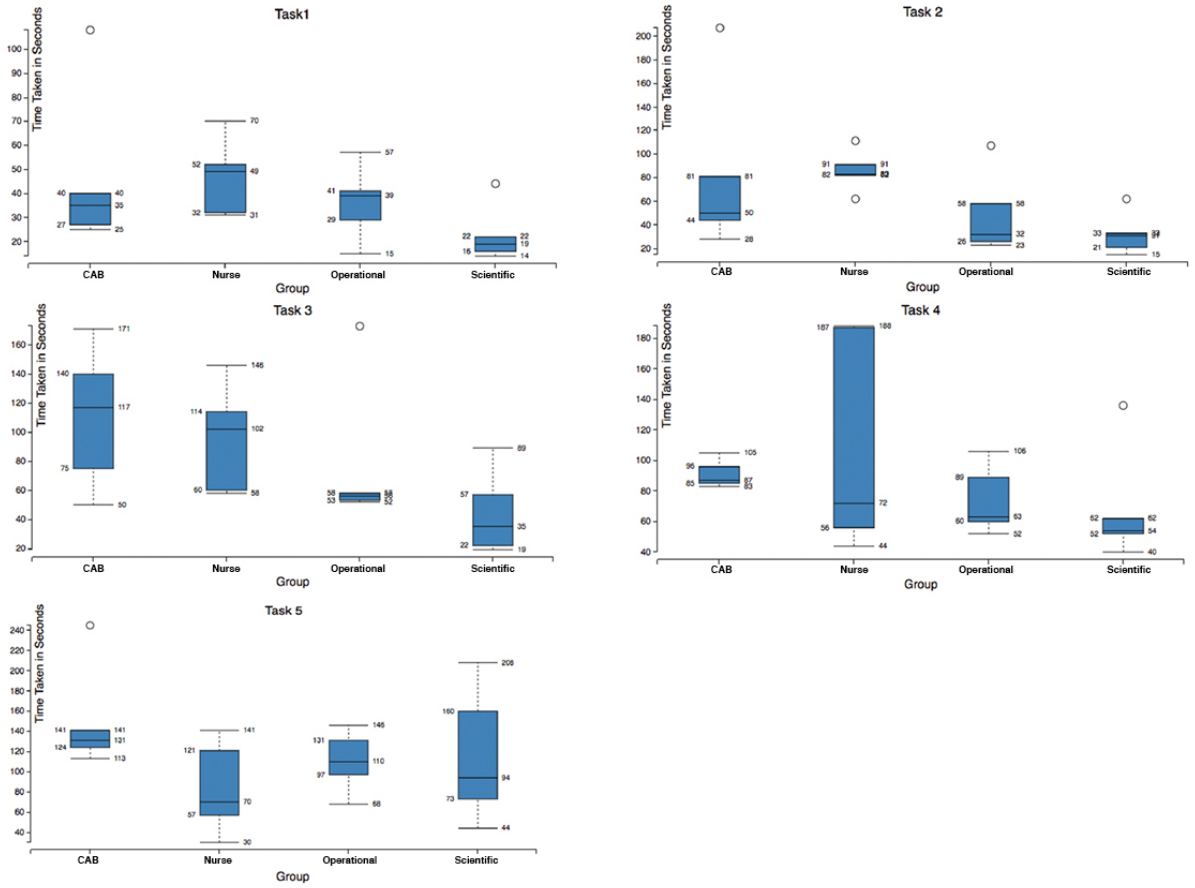


Figure 6. Variance in time taken to complete tasks, by group. This image provides detail on the time taken by each group to complete tasks during the evaluation study. As can be seen, the Community Advisory Board and nursing groups generally took longer to complete tasks than operational and scientific staff, indicating that more work is required around ensuring the dashboard is accessible to all user groups.



Of the users, 80% (16/20) felt that dashboards provided them with a detailed understanding of HIV prevalence and treatment in the TasP trial region, with 5 participants strongly agreeing with the statement and 11 agreeing with the statement. In relation to the questions about the design of the dashboard here, the results were mostly positive, with the majority (60%, 12/20) of users commenting that the terms used in the dashboard aided in the understanding of the data presented, the dashboard was easy to navigate, and the charts were easy to understand. However, the CAB staff and operational staff had a more positive view of the design of the dashboards than the nursing or scientific staff. These differences were also seen in the comments made relating to design and use of dashboards. A member of the nursing staff commented as follows:

> *It must be used by scientists only, not everyone is familiar with use of graphs and percentages when analysing data.* [Nursing staff member]

A member of the scientific staff made a similar comment on the presentation of data relating to ability to understand data visualization:

> *For scientific staff the dashboard is user friendly, for the broader AHRI community, it might not be, particularly for TasP staff, the language and graphs used might not be easy to understand and follow.* [Scientific staff member]

Through the questionnaire, 95% (19/20) of users agreed that the dashboards were a useful tool for providing information on the studies taking place at the center and that the dashboard should be used more widely as a tool for explaining results of the trials:

> *Every staff member should be able to use the dashboard for information purposes.* [Operational staff member]

> *I think there is enough information in this data dashboard because it is very expansive and could help us to understand easily any information that we need. And would help us to gain more information and if you don't understand something it is easy for to go to the data dashboard to punch in that information and gain more knowledge.* [CAB member]

Discussion

Principal Findings

In this study, we outlined a framework for the development of a data dashboard for exploiting real-time data within the context of a population health surveillance site, and a mixed-method evaluation demonstrated the frameworks usability. Population health is like many other health disciplines in experiencing a significant increase in the amount of data created at field sites. This increase is driven by new and more efficient data collection

systems and techniques, such as mobile and Web platforms and integration of datasets from different sites and studies. The potential of such data could be negated and restricted without a visualization system to disseminate datasets in a manner suitable to a varied set of audiences. These interfaces allow for the rapid detection of emerging health trends, highlighting of outliers, and emerging clusters of activity. Once in place, fewer resources are needed to maintain a real-time monitoring system than is required for the creation of ad hoc analyses. The data dashboard design framework presented here is more widely applicable to other HDSS contexts, where similar challenges are being faced.

The dashboard evaluation demonstrated the potential of the dashboards as a method to explain the ongoing progress of research trials to staff and stakeholders at AHRI. The results of the questionnaire also demonstrated a very positive attitude toward their future use within AHRI across all groups studied, demonstrating that there is enthusiasm for not only the increased visibility of data but also the increased use of data visualization as a means to disseminate datasets.

AHRI is typical of an HDSS site. The success of and enthusiasm for the dashboards speaks to the potential for implementation at other sites. Projects such as the South African Population Research Infrastructure Network, a system of HDSS sites, highlight the importance of data sharing to improve population health outcomes. A standard framework of visualization only aids the cause of sharing and understanding. The results of the evaluation demonstrate the potential for a visualization platform to provide an exploratory interface for users to interrogate multiple data sources, develop insights, and form new research hypotheses within this context. Furthermore, the interface presents an opportunity for collaborations among researchers, through shared data exploration. It also allows stakeholders and community members to see how the data collected in their community are being employed to further research and benefit the community at a large scale. Increasing the visibility of data for community members increases transparency and encourages active participants in ongoing studies. The evaluation demonstrated that although the majority of all groups had positive attitudes toward the increased visibility of data, it is crucial to note variation among groups concerning data needs and user ability.

Conclusions

The study outlined the design and development of a framework for dashboard design within the context of population health surveillance. The work done thus far can serve as a template for further development. However, further developments in the design and design process are future areas for exploration. The platform could be further developed to allow for increased flexibility in the types of data visualization available and expansion to other sites and contexts. However, it is clear that a more significant step lies in opening up the dashboard to a broader variety of users. Within the current design process, users consulted informally throughout the project, and there would be advantages in exploring user data needs through a user-led process during later iterations. The evaluation demonstrated that users spent more time on a task when they did not complete the task. These results highlight a need to research how different users interact with the same dashboard. The results highlight the need to understand data visualization literacy in the development of platforms for diverse user group and the need to understand the differing information needs of end users. When we talk about dashboards, we often speak about diverse user groups, yet research has shown that the performance of users can differ substantially despite adhering to good design practice. The potential of dashboards to promote the sharing of information and collaboration among diverse users is diminished if we do not consider literacy in design and build user adaptability into future systems.

Acknowledgments

The authors acknowledge the contributions of Siyabonga Nxumalo for running the evaluation at AHRI, Steven Gray for providing technical assistance on the development of the dashboards, and Dickman Gareta, Jaco Dreyer, and the research data management team at AHRI for all their assistance throughout the development process. The authors thank the AHRI for hosting the study, particularly the participants who gave their time to take part in the evaluation. The authors are further grateful to Professor Rachel McKendry for her continued generous support of this work. The authors would also like to thank Maureen Nomsa Hlongwane for her support and friendship through our time in SA; she is dearly missed. This project was funded under the i-sense (EPSRC IRC [Engineering and Physical Sciences Research Council Interdisciplinary Research Collaboration Early-Warning Sensing Systems for Infectious Disease] project (EP/K031953/1).

Authors' Contributions

The project was conceived and designed by EM, KH, and DC. The technical development of the data dashboard was undertaken by DC. The dashboard evaluation was designed and executed by DC, KH, and EM. The evaluation analysis was carried out by DC. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Evaluation tasks.

[PDF File (Adobe PDF File), 38KB - formative_v3i2e11342_app1.pdf]

Multimedia Appendix 2

User questionnaire.

[PDF File (Adobe PDF File), 48KB - formative_v3i2e11342_app2.pdf]

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Abbreviations

AHRI: Africa Health Research Institute
CAB: Community Advisory Board
HDSS: Health and Demographic Surveillance System
KPI: key performance indicator
SA: South Africa
TasP: Treatment as Prevention

Edited by T Sanchez; submitted 19.06.18; peer-reviewed by D Borland, S Al-Hajj; comments to author 21.09.18; revised version received 20.12.18; accepted 18.01.19; published 04.04.19.

Please cite as:
Concannon D, Herbst K, Manley E
Developing a Data Dashboard Framework for Population Health Surveillance: Widening Access to Clinical Trial Findings
JMIR Form Res 2019;3(2):e11342
URL: https://formative.jmir.org/2019/2/e11342/
doi:10.2196/11342
PMID:30946016

Original Paper

A Pilot Randomized Controlled Trial of a Digital Intervention Aimed at Improving Food Purchasing Behavior: The Front-of-Pack Food Labels Impact on Consumer Choice Study

Richard A Harrington[1], PhD; Peter Scarborough[1], DPhil; Charo Hodgkins[2], PhD; Monique M Raats[2], PhD; Gill Cowburn[1], DPhil; Moira Dean[3], PhD; Aiden Doherty[4], PhD; Charlie Foster[5], PhD; Edmund Juszczak[6], CStat, CSci; Cliona Ni Mhurchu[7], PhD; Naomi Winstone[8], PhD; Richard Shepherd[2], PhD; Lada Timotijevic[2], PhD; Mike Rayner[1], DPhil

[1]Centre on Population Approaches for Non-Communicable Disease Prevention, Nuffield Department of Population Health, University of Oxford, Oxford, United Kingdom

[2]Food, Consumer Behaviour and Health Research Centre, Faculty of Health & Medical Sciences, University of Surrey, Guildford, United Kingdom

[3]Institute for Global Food Security, School of Biological Sciences, Queen's University Belfast, Belfast, United Kingdom

[4]Big Data Institute, Nuffield Department of Population Health, University of Oxford, Oxford, United Kingdom

[5]Centre for Exercise, Nutrition and Health Sciences, School for Policy Studies, University of Bristol, Bristol, United Kingdom

[6]National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, United Kingdom

[7]National Institute for Health Innovation, School of Population Health, University of Auckland, Auckland, New Zealand

[8]Department of Higher Education, University of Surrey, Guildford, United Kingdom

Corresponding Author:
Peter Scarborough, DPhil
Centre on Population Approaches for Non-Communicable Disease Prevention
Nuffield Department of Population Health
University of Oxford
Old Road Campus
Headington
Oxford, OX3 7LF
United Kingdom
Phone: 44 1865289248
Fax: 44 1685289800
Email: peter.scarborough@dph.ox.ac.uk

Abstract

Background: Most food in the United Kingdom is purchased in supermarkets, and many of these purchases are routinely tracked through supermarket loyalty card data. Using such data may be an effective way to develop remote public health interventions and to measure objectively their effectiveness at changing food purchasing behavior.

Objective: The Front-of-pack food Labels: Impact on Consumer Choice (FLICC) study is a pilot randomized controlled trial of a digital behavior change intervention. This pilot trial aimed to collect data on recruitment and retention rates and to provide estimates of effect sizes for the primary outcome (healthiness of ready meals and pizzas purchased) to inform a larger trial.

Methods: The intervention consisted of a website where participants could access tailored feedback on previous purchases of ready meals and pizzas, set goals for behavior change, and model and practice the recommended healthy shopping behavior using traffic light labels. The control consisted of Web-based information on traffic light labeling. Participants were recruited via email from a list of loyalty card holders held by the participating supermarket. All food and drink purchases for the participants for the 6 months before recruitment, during the 6-week intervention period, and during a 12-week washout period were transferred to the research team by the participating supermarket. Healthiness of ready meals and pizzas was measured using a predeveloped scale based solely on the traffic light colors on the foods. Questionnaires were completed at recruitment, end of the intervention, and end of washout to estimate the effect of the intervention on variables that mediate behavior change (eg, belief and intention formation).

Results: We recruited 496 participants from an initial email to 50,000 people. Only 3 people withdrew from the study, and purchase data were received for all other participants. A total of 208 participants completed all 3 questionnaires. There was no difference in the healthiness of purchased ready meals and pizzas between the intervention and control arms either during the intervention period (*P*=.32) or at washout (*P*=.59).

Conclusions: Although the FLICC study did not find evidence of an impact of the intervention on food purchasing behavior, the unique methods used in this pilot trial are informative for future studies that plan to use supermarket loyalty card data in collaboration with supermarket partners. The experience of the trial showcases the possibilities and challenges associated with the use of loyalty card data in public health research.

Trial Registration: ISRCTN Registry ISRCTN19316955; http://www.isrctn.com/ISRCTN19316955 (Archived by WebCite at http://www.webcitation.org/76IVZ9WjK)

International Registered Report Identifier (IRRID): RR2-10.1186/s40814-015-0015-1

(JMIR Form Res 2019;3(2):e9910) doi:10.2196/formative.9910

KEYWORDS

diet; randomized controlled trial

Introduction

Background

Poor diet is a major risk factor for noncommunicable diseases (NCDs) in the United Kingdom, responsible for more than 10% of all morbidity and mortality [1]. Food purchasing precedes and affects food consumption, which makes food purchasing environments a prime setting for intervention studies aimed at improving diet and nutrition. In the United Kingdom, most food shopping is conducted in supermarkets [2], and supermarket purchases have been shown to correlate well with food and nutrient consumption [3].

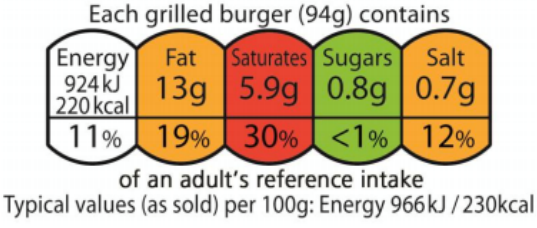
Front of pack (FOP) nutrition labeling on food packaging has been used in the United Kingdom since the mid-2000s [4]. In October 2012, traffic light labeling of nutrients was recommended by the UK Government for FOP labeling [5], and it is currently being used by many UK manufacturers and retailers. Traffic light labeling involves a color-coded assessment (green for low, amber for medium, and red for high) of the level of total fat, saturated fat, sugar, and salt (see Figure 1 [6]).

Supermarket loyalty card data are a potential source of "big data" that could allow for remote, objective monitoring of food purchasing behavior, enabling interventions aimed at improving the healthiness of food purchases that could be delivered at scale to a large population as they require no additional burden beyond continued use of loyalty cards during routine food purchasing. However, loyalty card data are owned by the supermarket industry, and little is known about the feasibility of using such data for the development of public health interventions that incorporate tailored feedback on previous purchases. This is because loyalty card data are commercially sensitive and consumers have privacy concerns over the handling of loyalty card data [7]; as such, it is typically difficult to access. Therefore, the use of such data is rare in the evaluation of public health interventions [8-11].

This study reports on a pilot 2-arm equal allocation parallel randomized controlled trial (RCT) of a digital intervention that incorporated a number of behavior change techniques. The intervention consists of a password-protected website where users can access tailored feedback on previous purchases of ready meals and pizzas, set goals for behavior change, and model and practice the recommended healthy shopping behavior. A theoretical approach based on selection of the most relevant behavior change mechanisms was adopted rather than utilization of an entire theoretical framework, as it has been suggested that this is an optimal approach in a food context [12]. The intervention was aimed at increasing the use of traffic light labeling to encourage healthier purchase decisions when purchasing ready meals and pizzas, thereby leading to purchases lower in total fat, saturated fat, sugar, and salt. Design of the intervention was based on reviews of behavior change literature, and previous research has shown that remotely delivered interventions that provide tailored feedback on previous behavior can improve dietary behavior [13].

The pilot trial was part of the Front-of-pack food Labels: Impact on Consumer Choice (FLICC) project. The protocol for the pilot trial has been previously published and includes a detailed description of development of the intervention design and content [14], and the pilot trial was registered at the ISRCTN registry (ISRCTN19316955).

Figure 1. Example of the type of front of pack labeling recommended by the UK Government for a packet of 4 beef burgers, containing numeric information, percentage of reference intakes, and traffic light color coding.



Objectives

The objectives of the trial were to assess the feasibility of a full RCT by measuring recruitment, retention, and data completion rates of participants, producing estimates for the potential effect size of the intervention on healthiness of purchased own-brand ready meals and pizzas—the primary outcome measure, and producing estimates for the potential effect size of the intervention on all food purchases, purchases of fruit and vegetables, and psychosocial variables associated with label use—secondary outcome measures.

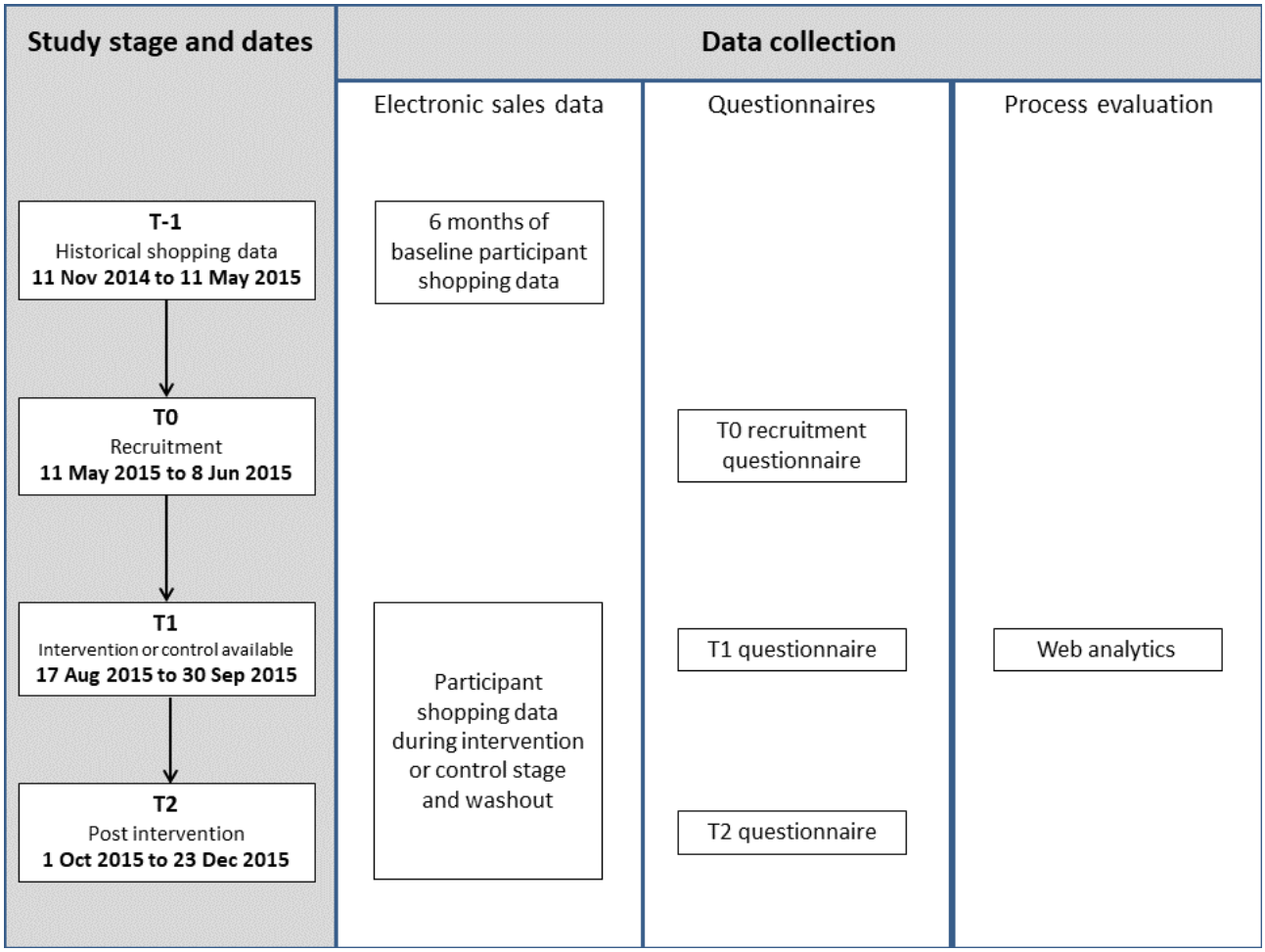
Our hypotheses were that the intervention would increase the healthiness of purchased ready meals and pizzas, while not affecting the total amount of ready meals and pizzas purchased, nor affecting purchasing behavior in other food categories. We hypothesized that the intervention would operate by impacting on mechanisms affecting beliefs and behavioral intention formation as well as those associated with planning and goal setting and the adoption and maintenance of the behavior of interest, namely, traffic light labeling use during purchases of ready meals and pizzas. Due to constraints in the availability of data and the fact that not all branded products contain traffic light labels, we limited our analyses to supermarket's own-brand products only. We hypothesized that the majority of ready meal and pizza purchases would be own-brand products, and so, restricting analyses to these product lines would have limited effect on results.

Methods

Data collection for the FLICC pilot trial took place over 58 weeks from November 11, 2014, to December 23, 2015. The data collected comprised food purchase data obtained from the supermarket loyalty card database and self-completion participant questionnaire data. The trial was split into 4 distinct time periods: 26 weeks of baseline historical shopping data (T-1), 4 weeks of recruitment (T0), 6 weeks of intervention (T1), and 12 weeks of follow-up without intervention (T2). A further 10 weeks between the end of T0 and the start of T1 were used to request, receive, and process the shopping history data for use in the intervention. The trial stages and types of data collected at each point are shown in Figure 2.

The primary focus of this trial was purchases of own-brand ready meals and pizzas. These food categories were chosen because they are highly likely to carry traffic light labeling in the participating supermarket; there is considerable nutritional variation in these food categories, allowing participants scope for buying healthier products; and ready meals and pizzas represent a large and growing proportion of food sales in the United Kingdom [14,15].

Figure 2. Outline of trial calendar, illustrating data collected at each stage.



Ethical Approval

Ethics was granted by the University of Oxford Central University Research Ethics Committee (SSD/CUREC1/14-008) and the University of Surrey Ethics Committee (EC/2014/153/FAHS).

Recruitment

To be eligible for the FLICC pilot trial, individuals needed to be UK residents, have had a loyalty card with the participating supermarket for at least 6 months at recruitment, be older than 18 years, do most of their shopping at stores larger than 8000 square feet (this criterion was to ensure that participants would have access to a large supply of own-brand ready meals and pizzas), be the primary food shopper for their household, not be planning to leave the United Kingdom for longer than 3 weeks during the study period, and have purchased at least 10 ready meals and pizzas in the previous 6 months (self-reported).

On the basis of a power calculation shown in the protocol [14], we aimed to recruit 1300 participants by email from a loyalty card database of the participating supermarket, using a passive approach—a recruitment method that requires a potential participant to make the first contact with the study following an invitation [16]. The supermarket chain emailed 50,000 cardholders selected at random in batches of 3000 from the whole population of cardholders, after filtering to exclude individuals who would not meet the first 4 inclusion criteria. The recruitment email included information on the trial and a link to a FLICC registration website, where participants were screened for the remaining 3 eligibility criteria, provided extra information for allocation through block randomization, and gave informed consent for participation in the trial.

Allocation

Block randomization was used to allocate individuals to the intervention or control arm, stratifying by sex and whether or not participants had dependent children. Participants were told the study was about the influence of traffic light labels on purchasing decisions but not informed whether they were in the intervention or control arm. A total of 2 researchers (RAH and PS) implemented the randomization and had access to the list of control and intervention participants during the study.

Intervention

A full description of the intervention is provided in the published trial protocol [14]; however, a summary of the key components is given in Table 1. A theoretical approach based on the selection of the most relevant behavior change mechanisms was adopted [12,17], and the intervention contains both passive components (information delivery via the Web application) and interactive components (participant is encouraged to engage with the Web application). The passive and interactive elements of the intervention are highlighted in Table 1. Overall, the intervention was designed to help people make intracategory decisions (eg, to compare pizza A and pizza B) and by focusing only on the use of the traffic light element (ie, colors) of the nutrition label.

Participants in each arm were sent an email containing a URL to a password-protected Web application, which remained open for 6 weeks (T1). The control group received a subset of the digital intervention: information on the importance of healthy eating, a description of traffic light labeling, and the message "Green is better than amber but amber is better than red!" Screenshots of the intervention are available from the Centre on Population Approaches for NCD Prevention website [18] or by request to the corresponding author.

Data Collection

Data on food purchases by the participants were collected by the participating supermarket's loyalty card system. Data on all foods and drinks purchased (while using the loyalty card) by the participants in any store across the United Kingdom during the T-1 period were transferred by the participating supermarket to the research team after recruitment had closed. A second transfer of equivalent data covering the periods T1 and T2 was conducted after the study had finished. Where participants withdrew from the study, food purchase data were transferred only up to the withdrawal date, and their questionnaire data were not included for secondary outcome analyses.

The participating supermarket also provided data on the nutritional quality of all own-brand food products currently on sale at 2 time points (before recruitment and after the study had completed), which were used to derive traffic light labels and to calculate outcome measures. Nutrition data for own-brand products found in the shopping history data that were not present in the supermarket nutrition dataset were extracted from the Brandbank database [19].

Demographic (age, sex, ethnicity, educational status, and household size) and socioeconomic (income and job classification) data were collected in the first of 3 Web-based questionnaires delivered at recruitment (T0). Psychosocial variables were collected at T0 and at the end of T1 and T2. In addition, Web analytics were collected to provide data on participants' engagement with the intervention. A single reminder was sent out for completion of the second and third questionnaires, which were incentivized by a £10 online gift voucher.

Measures

This pilot trial collected data on recruitment and retention rates and estimates of effect size for the primary and secondary outcome variables. The primary outcome measure for this trial was the healthiness of own-brand ready meals and pizzas that had traffic light labeling measured at both T1 and T2, where "healthiness" of each item was calculated from a combination of the information provided on the traffic light label. The score ranges from 0 (for 4 red lights) to 1 (for 4 green lights). Foods are awarded 0.15 points for each amber light and 0.25 points for each green light. The weighting for the different colors was derived from a choice experiment [20] where participants were asked to decide between the healthiness of 2 foods based purely on the traffic light label information, thereby revealing the different prominence awarded to each color in the decision-making process.

Table 1. Intervention components.

Behavior change techniques	Intervention components	Behavioral mechanisms impacted
Provide information on consequences of behavior to the individual	The risks of eating a diet high in fat, saturated fat, salt, and sugar and the prominence of these nutrients in ready meals and pizzas are reported (passive)[a]. Personalized feedback on the traffic light profile of the 6 months of ready meals and pizzas purchased by the participant in T1 study period are delivered. Participants are presented with an infographic summarizing the 6 months of data and are able to interrogate the previous data in simple tables, with comparisons made with other available products (interactive).	Mechanisms affecting belief formation and cognitive mechanisms: attention bias, optimistic bias
Provide instruction (how to perform the behavior)	A description is provided of the traffic light labeling that the participants will find in the participating supermarket and what the traffic light colors mean (passive)[a].	Mechanisms of intention formation: outcome expectancies, (action) self-efficacy, and perceived behavioral control; heuristics
Provide information about the traffic light label	Information about the traffic light label profile of a selection of the ready meals and pizzas that are available from the participating supermarket is provided in a tabular form that the participant can interrogate. Designed to highlight the potential for nutritional improvement within the ready meals and pizzas categories (interactive).	
Goal setting	The following outcome goal is provided: "Use traffic light labels when you are shopping in (participating supermarket) for ready meals and pizzas. Compare the traffic light labels between products and try to buy healthier ready meals and pizzas than you would normally. You can do this by reducing the number of red lights on the label and increasing the number of green lights on the label" (passive).	Planning and goal setting
Modeling the behavior	A short video showing individuals performing the behavior in a real store will be provided (passive).	Mechanisms of intention formation: Outcome expectancies and (Action) self-efficacy; perceived behavioral control
Prompt practice	An experiential task is provided, which allows participants to increase their self-efficacy in using traffic light food labels. This consists of multiple-choice tests asking participants to choose healthier versions of ready meals or pizzas with and without traffic light information provided. The intention is to demonstrate that the traffic light information can make these decisions easier to make (interactive).	Mechanisms of intention formation: (Action) self-efficacy; perceived behavioral control
Action planning	Participant is encouraged to plan when and where they will perform the desired behavior via the development of intention statements which they then enter into the Web application (interactive).	Planning and goal setting

[a]This element is provided to participants in both the intervention and the control arm.

In a sample of 406 ready meals and pizzas from the participating supermarket collected in November 2013, the healthiness score was reasonably normally distributed with a mean of 0.63 and SD of 0.21. Foods with scores of 0 and 1 were identified in the sample, demonstrating that the full range of the score was used.

The secondary outcome measures were as follows:

1. The number of ready meals and pizzas purchased in T1/T2
2. Expenditure (measured in £) on ready meals and pizzas purchased in T1/T2
3. The total amount (measured in grams) of fat, saturated fat, sugar, and salt in ready meals and pizzas purchased in T1/T2
4. Expenditure (measured in £) on all foods purchased in T1/T2
5. Expenditure (measured in £) on fruit and vegetables purchased in T1/T2
6. Psychosocial variables including "Stage model of health awareness" [21,22], "Perceived intake," "Perceived need to change," "Expectation and Intention" [23], and "Potential barriers to labelling use" [24-26] measured in T1/T2.

These psychosocial variables were selected to measure the effectiveness of the mechanisms we employed in the intervention design (Table 2) in terms of their potential to shift participants to using traffic light labeling (stage model of health awareness) by impacting on belief formation (perceived intake and perceived need to change), intention formation, and expectation. Potential barriers to labeling use were also measured.

Table 2. Psychosocial variables questions and response options.

Variable	Intervention text	Response
Stage model of health awareness adapted from Weinstein & Sandman and Renner & Schwarzer [21,22]	Thinking about the color-coded nutrition labels often referred to as "traffic light labels," which can be found on the front of food packaging, please select 1 of the following statements which most applies to you.	(1) I have never thought about using Traffic Light Labels when I shop. (2) I have thought about using Traffic Light Labels when I shop but I don't need to do anything. (3) I have thought about using Traffic Light Labels when I shop but I am still undecided. (4) I have already planned to use Traffic Light Labels when I shop but I haven't done anything yet. (5) I am using Traffic Light Labels when I shop and intend to continue doing so in future.
Perceived intake adapted from Raats et al [23]	Thinking about the number of reds on the traffic light labels of the ready meals/pizzas that you typically purchase, how low or high do you think this is?	(1) Extremely low-(7) extremely high
Perceived need to change adapted from Raats et al [23]	To what extent do you feel that you need to use traffic light labels over the next 6 weeks to help you choose ready meals/pizzas that are healthier?	(1) Definitely do not need to-(7) definitely need to
Expectation adapted from Raats et al [23]	How likely/unlikely is it that you will use traffic light labels over the next 6 weeks to help you choose ready meals/pizzas that are healthier?	(1) Extremely unlikely-(7) extremely likely
Intention adapted from Raats et al [23]	I intend to use traffic light labels over the next 6 weeks to help me choose healthier ready meals/pizzas?	(1) Definitely do not-(7) definitely do
Potential barriers to labeling use informed by Cowburn, Cowburn & Stockley and Grunert & Wills [24-26]	In my opinion traffic light labelling...is confusing to use; is truthful; is accurate; is hard to understand; is interesting to use; means you have to do math; means you need to know a lot about nutrition.	(1) Strongly disagree-(7) strongly agree

Statistical Analysis

All analyses were conducted in accordance with a predetermined statistical analysis plan, available from the Centre on Population Approaches for NCD Prevention website [18] or by request to the corresponding author. For normally distributed outcomes, analysis of covariance was used to assess differences between intervention and control arms at periods T1 and T2, adjusted for sex, whether or not the participants had dependent children, and measures collected in T-1 using the following model proposed by Vickers and Altman [27], illustrated by the primary outcome analysis at T1, where beta are regression coefficients, ε is an error term, and "group" refers to allocation to intervention or control:

$$\text{Healthiness}_{T1} = \beta_0 + \beta_1 * \text{Sex} + \beta_2 * \text{Dependents} + \beta_3 * \text{Healthiness}_{T-1} + \beta_4 * \text{Group} + \varepsilon$$

Where not normally distributed, differences were assessed using Mann-Whitney *U* tests not adjusted for sex, dependent children, or measures collected at T-1. Predetermined subgroup analyses of the primary outcome measure were conducted, stratified by socioeconomic status based on job classification (National Statistics Socio-economic Classification (NS-SEC) 1 or 2 vs 3 to 5) using a standard UK definition [28].

Within this study, missing outcome data (MOD) occurred for a number of reasons. For both the sales data and questionnaire data, MOD were generated by participants withdrawing post randomization. For the questionnaire data, MOD were generated by failure to complete some or all of the questions within a questionnaire. The primary outcome variable (average healthiness of ready meals and pizzas purchased in T-1, T1, and T2) included MOD if the participant did not purchase any own-brand ready meals or pizzas using their loyalty card in any of the 3 study phases. A systematic review of methods used to cope with MOD in intention-to-treat analyses demonstrated that there is no consensus toward a preferred approach, with arguments for restricting to complete case analysis and for imputation of missing data [29]. For the FLICC study, we dealt with MOD in the sales data by employing imputation techniques (multiple imputation for the primary outcome variable and single imputation for the secondary outcome variables). The imputation method used regression analysis with sex and dependent children as predictor variables as these were used in the block allocation, so there was no chance of missing data. The imputation datasets were all observations within T-1 for MOD at T-1 and equivalent for periods T1 and T2. We assessed the nature of the MOD from the primary outcome variable by conducting chi-square tests of the presence of missing data at any of the 3 study periods with sex and dependent children. For the questionnaire data, where retention rates were expected to be lower, we conducted analysis on a complete case basis (defined as being participants that provided electronic sales data and questionnaire data at all time points) as predetermined by our statistical analysis plan.

Results

Results to Predetermined Analyses

Of the 50,000 loyalty cardholders who received invitation emails, 869 clicked the link to the FLICC recruitment website. Of these, 496 were eligible and completed the consent process. These figures are illustrated in the flowchart in Multimedia Appendix 1. Our passive recruitment method recruited approximately 1% (496/50000) of the participant pool.

Table 3. Recruitment, retention, and data completeness by sex, dependents, socioeconomic status, ethnicity, age, educational status, general health interest, and dietary considerations because of health status.

Characteristic	Intervention group (n=246), n (%)	Control group (n=250), n (%)	Participants with complete[a] data (n=208), n (%)	Participants with incomplete data (n=288), n (%)	*P* value[b]
Sex					
Male	82 (33.3)	81 (32.4)	70 (33.7)	93 (32.3)	.89
Female	164 (66.7)	169 (67.6)	138 (66.3)	195 (67.7)	.89
Dependent children					
Yes	80 (32.5)	80 (32.0)	62 (29.8)	98 (34.0)	.33
No	166 (67.5)	170 (68.0)	146 (70.2)	190 (66.0)	.33
Socioeconomic status					
Managerial and professional occupations	140 (56.9)	135 (54.0)	149 (71.6)	126 (43.8)	.40
Intermediate occupations	15 (6.1)	10 (4.0)	10 (4.8)	15 (5.2)	.40
Small employers and own account workers	14 (5.7)	19 (7.6)	16 (7.7)	17 (5.9)	.40
Lower supervisory and technical operations	9 (3.7)	9 (3.6)	7 (3.4)	11 (3.8)	.40
Semiroutine and routine occupations	20 (8.1)	21 (8.4)	24 (11.5)	17 (5.9)	.40
Undisclosed or missing data	48 (19.5)	56 (22.4)	2 (1.0)	102 (35.4)	.40
Ethnicity					
White	192 (78.0)	188 (75.2)	198 (95.2)	182 (63.2)	.62
Mixed/multiple ethnic groups	1 (0.4)	0 (0)	1 (0.5)	0 (0)	.62
Asian/Asian British	0 (0)	3 (1.2)	2 (1.0)	1 (0.3)	.62
Black/African/Caribbean/Black British	1 (0.4)	2 (0.8)	1 (0.5)	2 (0.7)	.62
Other ethnic group	1 (0.4)	0 (0)	1 (0.5)	0 (0)	.62
Undisclosed or missing data	51 (20.7)	57 (22.8)	5 (2.4)	103 (35.8)	.62
Age (years)					
18-25	5 (2.0)	5 (2.0)	4 (1.9)	6 (2.1%)	.78
26-35	24 (9.7)	16 (6.4)	26 (12.5)	14 (4.9)	.78
36-45	41 (16.7)	45 (18.0)	45 (21.6)	41 (14.2)	.78
46-55	62 (25.2)	50 (20.0)	59 (28.4)	53 (18.4)	.78
56-65	37 (15.0)	54 (21.6)	48 (23.1)	43 (14.9)	.78
66-75	24 (9.7)	21 (8.4)	21 (10.1)	24 (8.3)	.78
76+	5 (2.0)	4 (1.6)	4 (1.9)	5 (1.7)	.78
Undisclosed or missing data	48 (19.5)	55 (22.0)	1 (0.5)	102 (35.4)	.78
Educational status[c]					
(1)	6 (2.4)	4 (1.6)	6 (2.9)	4 (1.4)	.51[f]
(2)	14 (5.7)	6 (2.4)	8 (3.8)	12 (4.2)	.51[f]
(3)	27 (11.0)	25 (10.0)	25 (12.0)	27 (9.4)	.51[f]
(4)	0 (0)	1 (0.4)	0 (0)	1 (0.3)	.51[f]
(5)	38 (15.5)	38 (15.2)	46 (22.1)	30 (10.4)	.51[f]
(6)	65 (26.4)	74 (29.6)	74 (35.6)	65 (22.6)	.51[f]
(7)	41 (16.7)	46 (18.4)	45 (21.6)	42 (14.6)	.51[f]
(8)	6 (2.4)	2 (0.8)	2 (1.0)	6 (2.1)	.51[f]

Characteristic	Intervention group (n=246), n (%)	Control group (n=250), n (%)	Participants with complete[a] data (n=208), n (%)	Participants with incomplete data (n=288), n (%)	*P* value[b]
(9) Undisclosed or missing	49 (19.9)	54 (21.6)	2 (1.0)	101 (35.1)	.51[f]
General health interest[d]					
Low health interest	17 (6.9)	18 (7.2)	20 (9.6)	15 (5.2)	.42
High health interest	189 (76.8)	187 (74.8)	188 (90.4)	188 (65.3)	.42
Missing data	40 (16.3)	45 (18.0)	0 (0)	85 (29.5)	.42
Dietary considerations because of health status[e]					
Coronary heart disease/high blood pressure					
Yes	64 (26.0	72 (28.8)	66 (31.7)	70 (24.3)	.55
No	142 (57.7)	133 (53.2)	142 (68.3)	133 (46.2)	.55
Missing data	40 (16.3)	45 (18.0)	0 (0)	85 (29.5)	.55
Weight management/obesity					
Yes	96 (39.0)	105 (42.0)	101 (48.6)	100 (34.7)	.89
No	110 (44.7)	100 (40.0)	107 (51.4)	103 (35.8)	.89
Missing data	40 (16.3)	45 (18.0)	0 (0)	85 (29.5)	.89
Type 2 diabetes					
Yes	27 (10.9)	30 (12.0)	30 (14.4)	27 (9.4)	.74
No	179 (72.8)	175 (70.0)	178 (85.6)	176 (61.1)	.74
Missing data	40 (16.3)	45 (18)	0 (0)	85 (29.5)	.74

[a]"Participants with complete data" refers to all participants for which a complete set of electronic sales data and questionnaire data at 3 time points is available. Some missing data still arise from within the questionnaire data where participants chose not to respond to a particular question. For all variables, the difference was assessed excluding missing data.

[b]Difference between complete versus incomplete data participants. Difference is assessed with Pearson chi-square test excluding missing data.

[c](1) No qualifications; (2) 1-4 O levels /certificate of secondary education (CSE)/general certificate of secondary education (GCSEs; any grades), entry level, foundation diploma, national vocational qualification (NVQ) level 1, foundation general national vocational qualification (GNVQ), basic/essential skills; (3) 5 or more O level (passes)/CSEs (grade 1)/GCSEs (grades A*-C), school certificate, 1 A level/2 to 3 advanced subsidiary levels/Victorian Certificate of Education (VCEs), intermediate/higher diploma, intermediate diploma, NVQ level 2, intermediate GNVQ, City and Guilds Craft, BTEC first/general diploma, Royal Society of Arts (RSA) diploma; (4) apprenticeship; (5) 2 or more A levels/VCEs, 4 or more AS Levels, higher school certificate, progression/advanced diploma, NVQ Level 3—advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC, National, RSA advanced diploma; (6) degree (eg, BA and BSc), higher degree (eg, MA, PhD, and PGCE), NVQ Level 4-5, HNC, HND, RSA higher diploma, BTEC higher level, foundation degree; (7) professional qualifications (eg, teaching, nursing, and accountancy); (8) other: vocational/work-related qualifications, qualifications gained outside the United Kingdom; and (9) undisclosed or missing.

[d]General health interest [30].

[e]Dietary considerations due to health status: "When buying food for yourself or your family do you have to consider dietary requirements relating to any of the following? Coronary Heart disease/High blood pressure; Weight management/Obesity; Type 2 Diabetes." Response options Yes/No.

[f]Chi-square test performed on combined groups to avoid low numbers in cells.

Of the recruited participants, 3 withdrew without reason after randomization but before the T1 period commenced—complete purchase data were collected for all other participants. The completion rates for the recruitment (T0), second (T1), and third (T2) questionnaires were 79% (394/496), 54% (270/496), and 63% (313/496), respectively. A chi-square test showed no evidence of difference in provision of complete data by allocation group. Of the 496 recruited participants, 208 (42%) provided complete data (ie, completed all 3 questionnaires and allowed transferal of purchasing data for the complete study period). The majority of the participants were older than 46 years, white, female, with no dependent children, and were in high socioeconomic groups (NS-SEC 1 or 2; Table 3). More than three-quarters of the sample reported a high interest in health using a predefined measure [30].

During the intervention period, 438 ready meals and pizzas were available to purchase through the participating supermarket. A total of 317 (72.4%) of the products were supermarket own-brand and 121 (27.6%) were branded products. Of 10,416 ready meal and pizza purchases used in the analyses, 8263 (79.3%) were supermarket own-brand and 2153 (20.7%) were branded products.

In all 3 data collection periods, there were high levels of MOD for both control and intervention groups for the primary outcome (average healthiness of traffic light and ready meals), indicating zero recorded purchases of own brand ready meals and pizzas

(Table 4). Assessments of the association between the presence of MOD and the 2-block randomization variables (sex and dependent children) showed no evidence of association (P>.2 in all cases), suggesting that the MOD were missing completely at random. The results for the primary outcome showed no difference between intervention and control groups during periods T1 (P=.32) and T2 (P=.59). Predetermined subgroup analyses stratified by socioeconomic status also did not find any differences between intervention and control groups (Multimedia Appendix 1). Exploratory analyses did not find a significant interaction between allocation group and socioeconomic status.

The difference between the control and intervention arms for the food purchasing secondary outcome measures are shown in Table 5 and reveal no evidence that the intervention changed purchasing behavior. In terms of the psychosocial secondary outcome measures (Table 6), these similarly demonstrate no difference between intervention and control groups for the effect of the intervention.

In the context of the lack of an observed effect in the primary outcome for this intervention, it is interesting to note that just over half the participants in the intervention arm (54%) logged onto the FLICC website (as measured by Web analytics) during the study period, and therefore, many participants did not receive or engage with the intervention material at all. Similar levels of engagement were observed in the control arms (48%). In terms of some of the key elements of the intervention content reported in Table 7, in all cases, less than half the intervention arm participants engaged with these.

Post Hoc Results

A complete case analysis of the primary outcome variable, where participants are only included if they purchased at least one ready meal or pizza in both the baseline and either intervention period (n=213) or washout period (n=266), showed a significant increase in the healthiness of food purchases in the intervention group of 0.04 (P=.03)—roughly equivalent to switching 1 red light for 1 amber light for every 3 ready meals or pizzas purchased. There was no difference between intervention and control groups at washout in the complete case analysis.

Table 4. Primary outcome measure results—healthiness of ready meals and pizzas purchased by intervention and control arms in 3 study phases. Healthiness score range between 0 and 1, with a higher score indicating healthier food purchases (n=496).

Allocation group, followed by different definitions of missing data	Average healthiness of traffic lights for ready meals and pizzas[a], T-1		Average healthiness of traffic lights for ready meals and pizzas[a], T1		Average healthiness of traffic lights for ready meals and pizzas[a], T2	
	Mean (SE)	*P* value	Mean (SE)	*P* value	Mean (SE)	*P* value
Control	0.561 (0.008)	.12	0.561 (0.009)	.32	0.557 (0.010)	.59
Intervention	0.582 (0.008)	.12	0.581 (0.010)	.32	0.555 (0.009)	.59
Missing data because of zero purchases of ready meals and pizza[b], n (%)	111 (22.4)	—[c]	258 (52.0)	—	196 (39.5)	—
Missing data because of withdrawal[b], n (%)	0 (0)	—	3 (0.6)	—	3 (0.6)	—

[a]Results of analysis of covariance comparing intervention and control adjusted for sex and dependent children at T-1 and sex, dependent children, and healthiness of ready meals and pizzas purchased at T-1 at other time points.

[b]Multiple imputation using stochastic regression with sex and dependent children as predictors was used to replace missing data in analyses.

[c]Not applicable.

Table 5. Secondary outcome measure results with purchase data using multiple imputation for missing data (3 cases for all variables because of participant withdrawal; n=496).

Variable	T-1		T1		T2	
	Mean (SE)	*P* value	Mean (SE)	*P* value	Mean (SE)	*P* value
Number of ready meals/pizzas purchased (items per week)[a]						
Control	0.32 (0.03)	.81	0.32 (0.04)	.97	0.32 (0.04)	.57
Intervention	0.37 (0.04)	.81	0.34 (0.05)	.97	0.32 (0.03)	.57
Amount (£) of ready meals/pizzas purchased[a]						
Control	0.85 (0.09)	.99	0.84 (0.10)	.73	0.77 (0.09)	.52
Intervention	0.93 (0.10)	.99	0.88 (0.12)	.73	0.84 (0.09)	.52
Total fat (gram) purchased per week[a]						
Control	8.09 (0.71)	.81	7.98 (0.88)	.75	7.81 (0.89)	.51
Intervention	9.15 (0.84)	.81	7.83 (0.96)	.75	8.03 (0.79)	.51
Saturated fat (gram) purchased per week[a]						
Control	3.40 (0.31)	.91	3.37 (0.38)	.62	3.26 (0.40)	.49
Intervention	3.86 (0.37)	.91	3.18 (0.41)	.62	3.37 (0.35)	.49
Total sugar (gram) purchased per week[a]						
Control	3.27 (0.30)	.90	3.31 (0.37)	.82	3.33 (0.37)	.56
Intervention	3.56 (0.31)	.90	3.29 (0.42)	.82	3.19 (0.31)	.56
Salt (gram) purchased per week[a]						
Control	0.80 (0.07)	.91	0.77 (0.09)	.98	0.78 (0.09)	.55
Intervention	0.89 (0.09)	.91	0.80 (0.10)	.98	0.79 (0.08)	.55
Amount (£) of fruit and vegetables purchased[a]						
Control	2.16 (0.19)	.21	2.00 (0.20)	.21	1.64 (0.14)	.24
Intervention	2.09 (0.22)	.21	1.82 (0.20)	.21	1.64 (0.19)	.24
Amount (£) of all food purchased						
Control	18.99 (1.37)	.60	17.49 (1.34)	.43	17.45 (1.29)	.41
Intervention	19.03 (1.38)	.60	17.23 (1.37)	.43	16.57 (1.35)	.41

[a]*P* values for difference between control and intervention adjusted for sex, dependent children, and results at T-1 using analysis of covariance or from unadjusted Mann-Whitney *U* test for non-normally distributed variables.

Table 6. Secondary outcome measure results for psychosocial variables for participants (n=208) with complete data (ie, all participants for which a complete set of electronic sales data and questionnaire data at 3 time points is available. Some missing data still arise from within the questionnaire data where participants chose not to respond to a particular question).

Psychosocial variable	T0		T1		T2	
	Mean (SE)	*P* value	Mean (SE)	*P* value	Mean (SE)	*P* value
Stage model of health awareness [21,22]						
Control	3.62 (0.16)	.53	4.22 (0.13)	.14	4.47 (0.11)	.78
Intervention	3.81 (0.14)	.53	4.39 (0.12)	.14	4.50 (0.10)	.78
Perceived intake[a] [23]						
Control	4.92 (0.12)	.90	4.75 (0.13)	.99	4.82 (0.15)	.97
Intervention	4.92 (0.10)	.90	4.74 (0.13)	.99	4.81 (0.14)	.97
Perceived need to change [23]						
Control	5.27 (0.14)	.70	5.18 (0.16)	.47	5.25 (0.15)	.09
Intervention	5.16 (0.15)	.70	5.05 (0.15)	.47	4.92 (0.15)	.09
Expectation [23]						
Control	5.42 (0.14)	.44	5.14 (0.16)	.55	5.53 (0.16)	.36
Intervention	5.30 (0.14)	.44	5.33 (0.13)	.55	5.41 (0.15)	.36
Intention [23]						
Control	5.68 (0.15)	.05	5.17 (0.18)	.92	5.54 (0.15)	.32
Intervention	5.33 (0.14)	.05	5.32 (0.15)	.92	5.35 (0.15)	.32
Potential barriers to labeling use [24-26]						
Confusing to use						
Control	2.33 (0.13)	.89	2.10 (0.12)	.78	1.98 (0.11)	.97
Intervention	2.29 (0.10)	.89	2.07 (0.12)	.78	1.99 (0.11)	.97
Truthful						
Control	5.25 (0.12)	.21	5.32 (0.12)	.43	5.40 (0.11)	.33
Intervention	5.03 (0.11)	.21	5.25 (0.11)	.43	5.24 (0.11)	.33
Accurate						
Control	5.01 (0.13)	.25	5.19 (0.13)	.42	5.34 (0.11)	.31
Intervention	4.89 (0.10)	.25	5.14 (0.10)	.42	5.18 (0.11)	.31
Hard to understand						
Control	2.01 (0.12)	.08	2.02 (0.13)	.62	1.85 (0.10)	.41
Intervention	2.20 (0.11)	.08	1.83 (0.09)	.62	1.96 (0.10)	.41
Interesting to use						
Control	5.10 (0.12)	.66	4.98 (0.14)	.79	5.03 (0.13)	.73
Intervention	4.94 (0.13)	.66	5.01 (0.11)	.79	4.92 (0.14)	.73
Means you have to do maths						
Control	2.10 (0.13)	.89	2.16 (0.14)	.63	2.03 (0.12)	.66
Intervention	2.07 (0.12)	.89	1.98 (0.11)	.63	2.10 (0.12)	.66
Means you need to know a lot about nutrition						
Control	2.62 (0.16)	.24	2.51 (0.15)	.22	2.26 (0.14)	.27
Intervention	2.76 (0.14)	.24	2.18 (0.11)	.22	2.40 (0.13)	.27

[a]Differences assessed between control and intervention adjusted for sex and dependent children using repeated measures analysis of variance; all other differences are assessed by unadjusted Mann-Whitney U test for non-normally distributed variables.

Table 7. Participant engagement with the intervention measured by Web analytics (excluding withdrawn participants).

Activity	Randomized sample (n=493), n (%)	Control arm (n=248), n (%)	Intervention arm (n=245), n (%)
Logged onto FLICC[a] website	251 (50.6)	120 (48.4)	131 (53.5)
Watched video	—[b]	—	78 (31.8)
Using traffic lights/experiential task page	—	—	101 (41.2)
FLICC task and aims	—	—	122 (49.8)
Set their own goal	—	—	89 (36.3)

[a]FLICC: Front-of-pack food Labels: Impact on Consumer Choice.

[b]Not applicable.

Discussion

Principal Findings

The FLICC pilot trial was an example of a partnership between academia and the supermarket industry to allow for a randomized trial of a behavior change intervention that utilized supermarket loyalty card data for(1) recruitment, (2) provision of tailored feedback on previous purchases, and (3) objective and remote measurement of participant food purchases. The pilot study showed that remote delivery of dietary studies across wide populations allows for speedy recruitment (albeit recruiting only 1% of the participant pool), that measurement of outcomes using loyalty cards can lead to very high retention rates, but that engagement with remotely delivered digital behavior change interventions can be low. The trial did not provide evidence to suggest this specific intervention would be effective at changing purchasing behavior, but the process of conducting the trial has revealed much information about using supermarket loyalty card data for both the delivery of public health interventions and for trials of their effectiveness—issues that are growing in relevance [31-33].

Supermarket loyalty card data provide benefits to public health research; however, the use of such data is rare in the evaluation of public health interventions [8-11]. This study revealed both benefits and limitations attached to the use of loyalty card data. The benefits include high retention rates and the potential to recruit quickly from a wide population. Limitations include generic problems with drawing conclusions about consumption from purchase data (discussed below) and specific issues associated with data sharing between academia and the supermarket industry. Loyalty card data are commercially sensitive, and supermarkets have a duty to ensure that individual-level data are handled with an appropriate level of security as consumers have privacy concerns over the handling of loyalty card data [7]. Recruiting from a loyalty card database means we had little control over recruitment methods, and a low participation rate may not have resulted in a representative sample. These issues are discussed here to highlight practical issues that researchers will need to consider if pursuing similar arrangements in the future. In the case of the FLICC study, the agreement of terms and conditions for transferal of data and the subsequent signing of contracts took over 12 months, and this was far longer than anticipated by either party. This caused significant amendments to the planned timetable for the study. For practical reasons, the participating supermarket was only able to provide us with 2 data extracts over the course of the project, which precluded us from providing participants with multiple updates on their shopping history as the trial progressed. For such collaborative studies to achieve the most success in the future, we advise that at an early stage, all collaborative partners develop an understanding of what can and cannot be delivered by the collaboration. We are grateful that the participating supermarket remained flexible to our needs throughout the research process, without which this study would not have been possible.

The main strengths of our study are the strong internal validity associated with the RCT design, the remote nature of the delivery of the intervention and collection of data (allowing for scalability of an intervention if shown to be effective), and the use of the supermarket loyalty card dataset for recruitment, which allowed quick and efficient recruitment of a large number of participants. The pilot study was able to answer questions about the practicality and feasibility of conducting trials in a supermarket setting in partnership with a supermarket chain, highlighting both the advantages and disadvantages of such a partnership while providing evidence on essential study features that could not have been known in advance. Of the examples, 1 includes the average amount of food purchasing that was recorded by study participants. In the FLICC study, the average amount of money spent on food captured by the loyalty cards was less than £20 per week, whereas the average amount of money spent on food and nonalcoholic drinks in the United Kingdom is £56.80 per household per week [2], which suggests that purchases in our study were a subset of all food purchases made by the participants. This has implications for whether our outcome measures truly reflect consumption behavior. Supermarket loyalty cards can only measure food purchases when a loyalty card is used, which may not be at every occasion that participants visit the supermarket. They also restrict the range of a study to include purchases in 1 supermarket chain only, which may not reflect shopping behavior in many people who regularly frequent more than 1 supermarket chain. They may also be shared by friends and family, so may not collect data from the individual recruited to the study [34]. Although only own-brand ready meal and pizza purchases were included for our analyses and some other branded products may have traffic light labels, we have shown that 79.3% of all purchases were of own-brand products, and thus, we have captured the vast majority of relevant purchasing behavior.

Another limitation was the amount of MOD for the primary outcome variable, which was a result of participants' loyalty card data showing zero purchases of own-brand ready meals or pizzas in T1 and/or T2 (despite participants' self-reporting at recruitment that they were frequent purchasers of these products). Ideally, we would have filtered the recruitment email so that only individuals who have shown frequent purchases of own-brand ready meal and pizzas in their loyalty card data were contacted to take part in the study—unfortunately this was not possible, as the recruitment email was delivered by a market research company aligned with the participating supermarket who had access to geographic and demographic data on loyalty card holders but not on previous purchases. Our screening question at recruitment was "Thinking about the last 6 months, on average have you purchased either Ready Meals or Pizzas at least twice per month? (It doesn't matter if the Ready Meals or Pizzas were for you or for other members of your household)." However, 22% of the recruited participants did not have any records of own-brand ready meal or pizza purchases on their loyalty card data from the previous 6 months (T-1). This was a far higher percentage than we anticipated and increased to 52% during the intervention period (T1). Our predetermined statistical analysis plan stated that we would conduct analyses with imputation for the primary outcome variable but because of the amount of MOD, the imputation effectively overwhelms the analysis.

We measured engagement with our digital intervention using Web analytic tools. Similar methods are now regularly used to measure the engagement of participants with Web-based interventions [35]. We found that overall engagement with the intervention was low but at a similar level (50%) found in a systematic review of use of Web-based behavior change interventions [36]. Other studies have found that engagement with digital interventions can be boosted by telephone-based coaching [37] or professional support [38]; however, this would affect the potential reach of such an intervention delivered at scale. Provision of frequent updates of the intervention, which was not possible in our study because of the data-sharing relationship with the participating supermarket, has also been shown to increase engagement with digital behavior change interventions [38,39].

Other trials have investigated the impact of remotely delivered tailored feedback on dietary behavior and found more encouraging results. Alexander et al [40] conducted an RCT of 2540 participants, where arms 2 and 3 received a website with tailored feedback on previous diet compared with a control of a nontailored dietary advice website, and found that the intervention increased consumption of fruit and vegetables reported in a food frequency questionnaire by 2.7 and 2.8 portions per day, respectively, compared with 2.3 portions per day for the control group (P=.177 for arm 2, P=.050 for arm 3). Huang et al [41] found that a website that provided tailored advice resulted in a reduction in saturated fat of 0.66% of food energy in food purchases from an online supermarket compared with a control of nontailored advice (P<.001), in a randomized trial of 497 participants. Tapper et al [42] found an increase in fruit and vegetable consumption reported in a food frequency questionnaire in intervention compared with control group (P=.08) in an RCT of a website providing tailored dietary feedback with 100 participants. The interventions studied in these trials were more intensive and required a larger time commitment from participants than the intervention in the FLICC study. A recent randomized trial of a phone app that provides feedback on potential food purchases (suggesting switches for lower salt products) found a significant reduction of salt in food purchases of 0.3 g/MJ (95% CI 0.03-0.58) in a study of 66 adults with diagnosed cardiovascular disease [43], suggesting feedback on nutritional content of foods combined with proposed alternatives could be an effective mechanism for improving diets.

Conclusions

Although the FLICC study did not find evidence of an impact of the intervention on food purchasing behavior, the unique methods used in this pilot trial are informative for future studies that plan to use supermarket loyalty card data in collaboration with supermarket partners. The experience of the trial showcases the possibilities and challenges associated with the use of loyalty card data in public health research.

Acknowledgments

This trial was funded by the National Prevention Research Initiative phase IV (MR/J000256/1). No funding or related academic support was received from the participating supermarket throughout the research project. RAH and PS are supported by the NIHR Biomedical Research Centre, Oxford. PS is supported by a BHF Intermediate Basic Science Research Fellowship (FS/15/34/31656). MR is supported by the British Heart Foundation (grant number: 006/PSS/CORE/2016/ OXFORD). AD is supported by the British Heart Foundation Centre of Research Excellence at Oxford (RE/13/1/30181).

Conflicts of Interest

MMR, CEH, LT, RS, and NW's research center has provided consultancy to and received travel funds to present research results from organizations supported by food and drinks companies. The other authors declare that they have no competing interests. Due to nondisclosure agreements with the participating supermarket, not all of the research materials supporting this publication can be made accessible to other researchers. Please contact the corresponding author for more information.

Multimedia Appendix 1

Study participant flowchart and results of prespecified subanalysis by socioeconomic status.

[PDF File (Adobe PDF File), 98KB - formative_v3i2e9910_app1.pdf]

Multimedia Appendix 2

CONSORT 2010 checklist for the FLICC study.

[PDF File (Adobe PDF File), 136KB - formative_v3i2e9910_app2.pdf]

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Abbreviations

FLICC: Front-of-pack food Labels: Impact on Consumer Choice
FOP: front of pack
MOD: missing outcome data
NCD: noncommunicable disease
NS-SEC: National Statistics Socio-economic Classification
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 23.01.18; peer-reviewed by A Grunseit, A Booth; comments to author 11.07.18; revised version received 05.12.18; accepted 30.12.18; published 08.04.19.

Please cite as:
Harrington RA, Scarborough P, Hodgkins C, Raats MM, Cowburn G, Dean M, Doherty A, Foster C, Juszczak E, Ni Mhurchu C, Winstone N, Shepherd R, Timotijevic L, Rayner M
A Pilot Randomized Controlled Trial of a Digital Intervention Aimed at Improving Food Purchasing Behavior: The Front-of-Pack Food Labels Impact on Consumer Choice Study
JMIR Form Res 2019;3(2):e9910
URL: http://formative.jmir.org/2019/2/e9910/
doi:10.2196/formative.9910
PMID:30958277

Original Paper

Development of a Smartphone App for Informal Carers of People With Cancer: Processes and Learnings

Natalie Heynsbergh[1*], BNurs (Hons); Leila Heckel[1*], PhD; Mari Botti[1,2*], PhD; Seung Chul O[3*], MMM; Patricia M Livingston[4*], BA (Hons), PhD

[1]School of Nursing and Midwifery, Faculty of Health, Geelong, Australia

[2]Epworth HealthCare, Melbourne, Australia

[3]School of Psychology, Faculty of Health, Deakin University, Geelong, Australia

[4]Faculty of Health, Deakin University, Geelong, Australia

[*]all authors contributed equally

Corresponding Author:
Natalie Heynsbergh, BNurs (Hons)
School of Nursing and Midwifery
Faculty of Health
Deakin University
Geelong,
Australia
Phone: 61 392446333
Email: n.heynsbergh@deakin.edu.au

Abstract

Background: There are few support systems available to informal carers who provide care to cancer patients. Smartphone apps have the capacity to reach large audiences and can provide information and support at a time convenient to carers.

Objective: The aim of this study was to design a smartphone app prototype for carers of adults with cancer.

Methods: A multiple-method design was used to develop a smartphone app. Current and past carers of people with any type of cancer were recruited from a public hospital, a private hospital, and a carer organization, who participated in either a focus group or phone interview. Carers answered questions about items to include in an app to address supportive care needs identified. Using carers' feedback, a smartphone app was designed and tested. Beta testing was conducted using a convenience sample of participants who completed scenarios to inform the app's design, functionality, and usability. Scenarios were timed and marked as complete or incomplete. Participants completed a questionnaire about the usability of the app. Beta testing occurred in 2 stages—a paper-based version of the app and an app-based test using the participants' preferred device. Alpha testing was completed internally to ensure the functionality of the app. Data were collected between May 2016 and August 2017.

Results: A total of 33 carers participated in phone interviews and 12 in focus groups; their average age was 55 (SD 14) years, and 60% (27/45) were female. The majority of carers (76%, 25/33) had a positive attitude toward using smartphone apps. Carers noted that smartphone technology might improve their ability to seek information and support in managing their own health as well as the care needs of the person with cancer. Carers requested a variety of information and resources to be included in the app. Paper-based testing included the following: participants (N=10) were aged above 30 years (30%, 3/10), 30 to 49 years (30%, 3/10), and 50 years or above (40%, 4/10), and 60% (6/10) were male. Participants found the app user-friendly and pleasing in appearance. App-based testing included the following: participants (N=10) were aged above 30 years (20%, 2/10), 30 to 49 years (30%, 3/10), and 50 years or above (50%, 5/10), and 50% (5/10) were male. Participants reported the app to be user-friendly and easy to navigate. The majority (60%, 6/10) of participants were unable to create a shortcut icon to add the app to the home screen of their phone.

Conclusions: Carers highlighted the needed information and support to assist them during the caring period; they also reported having a positive attitude toward smartphone apps. The Carer Guide App is currently undergoing a pilot study to further test usability among carers of people with 1 cancer type.

(JMIR Form Res 2019;3(2):e10990) doi:10.2196/10990

KEYWORDS

cancer; carer; smartphone; mobile applications; technology

Introduction

Background

Cancer is a significant issue worldwide with over 14 million people diagnosed in 2012 [1] and is estimated to account for 9.6 million deaths in 2018 [2]. Globally, US $1.16 trillion are spent on cancer every year [2]. The financial burden on health care systems has resulted in quicker discharge times for patients and increased the need for care to continue in the community [3]. In Australia, there are approximately 2.7 million informal carers who are not paid for the care they provide [4]. Informal carers are often family members who may have limited awareness and understanding about the disease to sufficiently meet the care needs of individuals [5]. As a result, physical, mental, social, and financial burdens are common among carers resulting in negative health outcomes and poor well-being [6].

Carers often neglect their own needs while looking after someone with cancer [7,8]. Face-to-face support through local medical and counseling services can be costly, time consuming, and inaccessible to carers who are unable to leave care recipients alone or live in remote areas [9]. Technology may provide a solution in addressing the needs of many carers.

Technology-based tools allow large audiences to have access to information and support networks when addressing specific health needs [10]. Smartphone apps allow individuals to access information and support at a suitable time when needed and in the privacy and comfort of their own home [9,10]. Recent trends have shown increasing availability of 4G internet connection worldwide [11], and by 2020, 70% of the population is expected to own smartphones [12]. Although these figures suggest that smartphone and roaming internet access is common, individuals use technology in varying ways; therefore, it is important to assess carers' attitudes toward digital technology as a supportive tool. Existing cancer information and support helplines are not widely recognized or used among people affected by cancer, and carers only account for approximately 20% of people who initiate contact [13,14]. Web-based interventions have been found to be appropriate for use among carers and are accessible to a larger number of people [15]; however, they are not always available through smart devices, and this can limit carers' ability to access support in times of need [16]. Previous studies have shown positive results for the use of smartphone apps across different circumstances including self-management of cancer [17,18], for carers of pediatric illness [19,20], and for children with cancer [21]. However, there have been no studies assessing the use of smartphone apps among adult carers providing care to another adult with cancer [15].

Theoretical Frameworks

This research was guided by 2 theoretical frameworks. The theory of planned behavior (TPB) and the unified theory of acceptance and use of technology (UTAUT). TPB applies 3 concepts—behavioral beliefs, normative beliefs, and control beliefs for understanding social and personal reasons for using technology [22].

The concept "facilitating conditions" within UTAUT measures external factors contributing to technology use such as the ownership of a smartphone device and internet connectivity [23].

User-Centered Design

User centered design (UCD) is a philosophy to guide the design of interventions to meet needs, preferences, and characteristics of users, using a lifecycle process of context, requirements, design, and evaluation [24,25]. UCD has been used to develop technology-based interventions among a variety of populations [26-28].

Aim

The aim of this study was to design a smartphone app prototype for carers of adults with cancer.

Methods

Study Design

This study comprised a multiple-methods design to inform development of the app and included the following 3 sequential phases: (1) focus groups and phone interviews with present and past adult carers to assess their information and supportive care needs as well as their attitudes toward smartphone technology, including existing barriers affecting technology uptake; (2) smartphone app design, content development, and app programming; and (3) alpha and beta testing and user testing of the app. Findings from phase 1 informed the design of the app and its content. Data were collected between May 2016 and August 2017. Ethics approval was obtained from Deakin University Human Research Ethics Committee, from 2016 to 2018.

Context of Use

The context of carers of people with cancer and their needs from a smartphone app were identified in phase 1 via focus groups and interviews. TPB and UTAUT guided the development of the app in terms of its structure and function (eg, font size and navigation) and accessibility to carers' with varying skills and confidence in using smartphone apps. The design phase was completed by combining these results. Evaluation occurred during alpha and beta testing through paper-based and app-based user testing. Between paper-based and app-based testing, the needs of participants were identified, and the design solutions to match these needs were performed and evaluated in line with the UCD methodology.

Specify Requirements: Integration of Theoretical Frameworks

TPB and UTAUT were incorporated into the development of the smartphone app across the different stages. See Table 1 for an outline of how the frameworks were applied to support development of the app.

Table 1. Theoretical frameworks and how they were used to support Carer Guide App development.

Framework, concept	Description	Relevance to app development
Theory of planned behavior (TPB)		
Behavioral beliefs	Attitudes toward using smartphone apps	Participants were asked about their attitudes toward using smartphone apps during focus groups and interviews. Participants in phone interviews responded with positive, neutral, or negative attitude toward smartphone apps. The overall group consensus was reached in focus groups.
Normative beliefs	People who may facilitate or create a barrier toward smartphone app use	Participants in phone interviews provided information about who would facilitate their use of a smartphone app, for example, health care professionals, family, or friends. The overall group consensus was reached in focus groups.
Control beliefs	Confidence in using smartphone apps	Participants were asked about their confidence in using smartphone apps during focus groups and interviews and user testing during development. Participants in phone interviews responded with very confident, moderately confident, or novice. The overall group consensus was reached in focus groups.
Unified theory of acceptance and use of technology (UTAUT)		
Facilitating conditions	External factors that may be a barrier to using smartphone apps	Measured during focus groups and phone interviews, participants gave information about factors that affected their likelihood of using smartphone apps, for example, smartphone ownership.

Creating Design Solution

Phase 1: Focus Groups and Phone Interviews

To develop a smartphone app that was responsive to carers and specific to their needs, focus groups and phone interviews were conducted with current and past adult carers looking after another adult with cancer of all types and stages. Carers were invited to participate if they were older than 18 years and able to speak English sufficient to participate in the group discussion. Questions explored the attitudes (behavioral beliefs), facilitating influences (social norms), confidence (control beliefs), facilitating conditions affecting smartphone app use, and the content desired in a smartphone app to address carers' needs. Demographic data including age, gender, relationship to patient, highest level of education, and living situation were collected. The majority of participants (80%, 36/45) provided information about the type of cancer their family member or friend was diagnosed with. Recruitment continued until saturation of data occurred; overall, 45 carers were recruited (12 into focus groups and 33 into phone interviews).

Phase 2: Design, Content Development, and Programming of the App

The smartphone app, referred to as the Carer Guide App, was designed to support carers of people with cancer based on Shneiderman's "Eight Golden Rules of Interface Design." The content and high-level user experience were informed by the findings of phase 1 of the project. The Carer Guide App was designed and developed by e-Resource developers at Deakin University and built using a hybrid Web-based structure, incorporating technologies including—Adobe Illustrator CC, Adobe Photoshop CC, HTML 5, CSS 3, JavaScript, JQuery, Ajax, PHP, and MySQL (Oracle). Email notifications to users were triggered by a time-based scheduler (known as a cron job) in a Unix-like computer operating system. A hybrid Web-based structure was chosen over that of a native app as it significantly reduced time required in the development stage of the project, including programming, updating functionality, and content revision. Further, the structure that was chosen did not require distribution through either the App Store or Google Play. This saved time in deployment as the often-lengthy review processes of those distribution channels were bypassed. The chosen structure allowed development of the app, which was accessible on a wider range of devices. The app was accessed at a URL address through any current generation mainstream internet browser. The app contained both static and dynamic content accessible through a primarily iconized navigation system. The text in the app contained links to both external websites and built-in interactive functionality to maximize user experience. Security of sensitive information provided by users was a priority, enhanced by features such as personalized secure log-ins and encrypted data. The Carer Guide App took 3 months to develop including user testing and alpha and beta testing. Figure 1 outlines the stages of the app development process.

Phase 3: Evaluate Designs—Testing of the App

Paper-Based User Acceptance Test

A convenience sample of 10 adults was recruited to test a paper-based version of the Carer Guide App before the development of the prototype. Paper-based testing was conducted to assess the visual elements of the app and initial content layout and navigation. This was achieved using printed screenshots of the app. Figure 2 presents an example of screenshots used—screen 1 was the log-in page, screen 2 was the main menu, and screen 3 was the relevant information page.

During UAT, participants were asked to complete scenarios in which they had to navigate the app to locate information, for example, "You require information about financial aid, where would you go to learn about benefits you are entitled to?" Participants also completed a questionnaire including information about—their gender, age, confidence in using apps (control beliefs), usability of the app, and comments for improvement.

Figure 1. Development stages of the Carer Guide App. UAT: user acceptance test; UX: user experience testing.

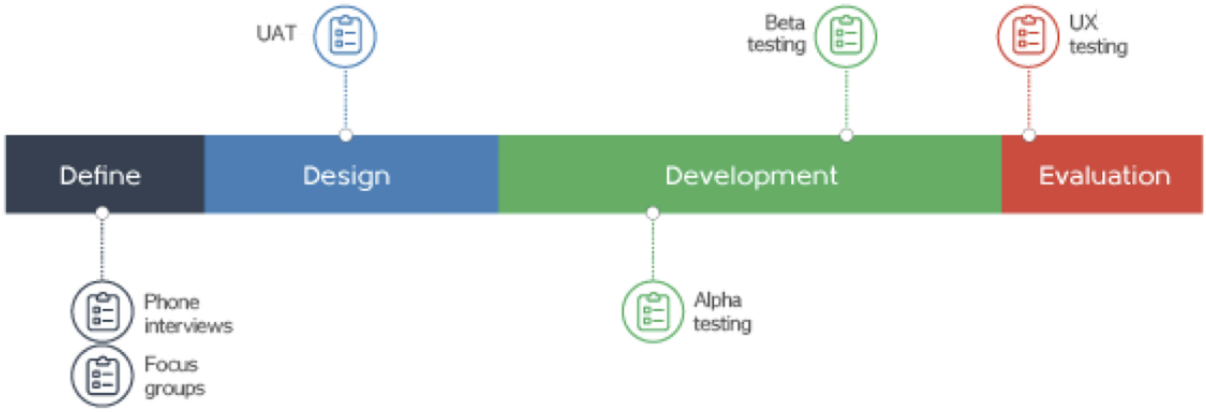
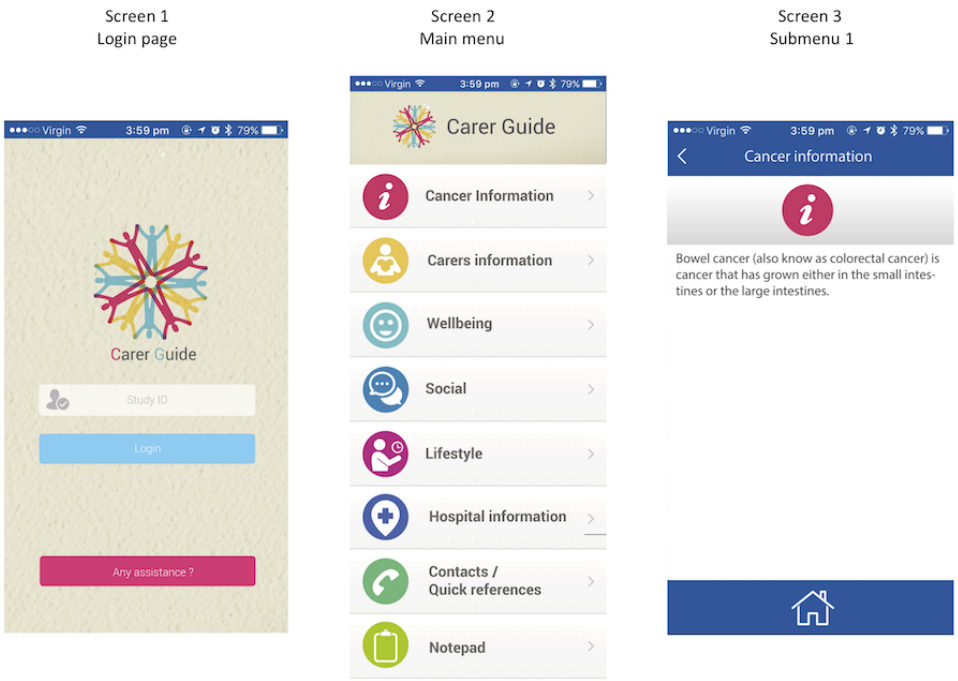


Figure 2. Screenshots of the Carer Guide App used in the paper-based user test.



Alpha and Beta Testing

The Carer Guide App underwent several rounds of internal testing known as alpha and beta testing [29]. Alpha testing was used to assess the input and output of the functions of the app and was performed by the developer while building the structure of the app [29]. Beta testing assessed the complete function and applicability of the app using a smartphone interface among test participants [29]. Google Analytics was linked to the Carer Guide App to collect usage information on—the number and length of sessions, device used, and frequency of pages visited from each participant.

Beta Testing: App-Based User Testing

A second convenience sample of 10 adults was recruited to test the first prototype version of the Carer Guide App. Test participants were asked to complete scenarios in which they had to download the app, create a shortcut icon, log into the app, navigate to locate information, access hyperlinks and phone numbers, and navigate through website browsers. Participants also completed a questionnaire including information about their gender, age, confidence in using apps (control beliefs), functionality of the app, and comments for improvement.

Data Analysis

Focus Groups and Phone Interviews

Data from focus groups and phone interviews were transcribed and coded. A qualitative descriptive approach was used to analyze data [30], and the full analysis procedure has been described in more detail elsewhere [31]. Items suggested by carers to be included into a smartphone app were organized into common categories, for example, information about cancer treatment and information about side effects were grouped together under "cancer information." The frequency of suggestions for app content from carers participating in phone interviews was tallied. Focus group data were analyzed by general group consensus where carers discussed and agreed on concepts; items suggested to be included in the app were organized into the same categories as phone interviews. Data were coded and analyzed using the NVivo (QSR International) software.

To assess theoretical framework measures, the frequency of responses from carers in phone interviews was tallied. Data from focus groups were analyzed by overall group consensus. Data were analyzed using IBM SPSS software.

User Acceptance Test and User Experience Testing

In UAT testing, usability of the app was measured on a Likert scale where 1 meant strongly disagree and 5 meant strongly agree. In UX testing, a similar scale was used to assess functionality of the Carer Guide App. Agree and strongly agree responses were then tallied.

Scenarios were timed and organized into 2 groups: those taking less than 20 seconds to complete, and those taking longer than 20 seconds to complete. This was determined to be an appropriate cut-off time as Web users often only stay on pages for 10 to 20 seconds when seeking information [32]. To ensure the organization of information was relevant, 20 seconds was deemed an appropriate amount of time to navigate and locate information.

In each round of user testing, participants described their level of confidence in using smartphone apps by selecting 1 of 3 options—very confident, moderately confident, or not confident. Responses were then tallied. Data were analyzed using the SPSS software.

Results

Focus Groups and Phone Interviews

The majority of carers were female (60%, 27/45), a spouse (64% 29/45), living with the person receiving cancer treatment (87%, 39/45), held a university degree (47%, 21/45), and caring for someone with breast cancer (30%, 11/45). Carers age ranged from 21-80 years (SD 14) with mean age of 55 years. See Table 2 for full demographic information.

Table 2. Demographic characteristics of carers.

Carer characteristics	Frequency n (%)
Female	27 (60)
Carers relationship to patient	
Spouse	29 (64)
Parent	13 (29)
Other (relative or friend)	3 (7)
Lives with patient	39 (87)
Highest education level	
Primary school	1 (2)
High school	9 (20)
Certificate or Diploma	7 (16)
University degree	21 (47)
Other	6 (13)
Patients' cancer diagnosis as reported by carers	
Breast	11 (30)
Lymphoma or non-Hodgkin's lymphoma	7 (19)
Pancreas	3 (8)
Leukemia	3 (8)
Liver	2 (6)
Lung	2 (6)
Colorectal	2 (6)
Other (eg, brain, prostate, stomach, multiple myeloma, bone, and neck)	69 (17)

Carers provided varied ideas for content that could be included in the app. Overall, carers reported a need for more cancer-related information, links to support services and social networks, case studies, interventions to manage symptoms at home, information on how to identify serious side effects, and when to escalate care, on hospital-specific navigation, and resources to manage their own needs. Resources mentioned included—calendar with symptom tracking, reminders for appointments and medications, notepad, contacts, a search function, and the ability to synchronize the app with other phone functions. Carers specified that the app should have information specific to their needs and the use of push notifications was regarded as beneficial because the app would be perceived as less impersonal.

Some carers felt that more than 1 person could facilitate their use of a smartphone app. Overall, 15% (5/33) carers would not be influenced by others to use an app and were more likely to prefer using the computer or talking face-to-face with a health care professional. Refer to Table 3 for a full summary of results related to theoretical frameworks and their implementation into practice.

Design, Content, and Technical Development

Results from phase 1 indicated that carers required the app to be specific to their information and support needs. Initial development decisions included—app name, color scheme, logo and icon pictures, and the layout structure. To ease navigation, similar content materials were grouped together under 1 main category; this is shown in Figure 3.

Testing of the Carer Guide App

User Acceptance Test

The sample of 10 included past carers, noncarers, and a medical professional on an oncology ward. Participants' age ranged above 30 years (30%, 3/10), 30 to 49 years (30%, 3/10), and 50 years or above (40%, 3/10); 60% (6/10) were male. Confidence in using smartphone apps is outlined in Table 2.

Table 3. Results related to theoretical framework concepts and their implementation into practice.

Framework	Focus groups and phone interviews	User acceptance test	User experience testing	Implementation into practice
Behavioral beliefs	Focus group consensus was positive toward smartphone app use. Overall, 76% (25/33) participants from phone interviews had a positive attitude toward using smartphone apps.	—[a]	—	A smartphone app may be an appropriate way to deliver information and support to carers. Carers' attitudes toward the Carer Guide App in particular need further assessment to provide more information about the suitability of a supporting smartphone app.
Normative beliefs	Participants in phone interviews felt smartphone apps could be facilitated by the following: health care professionals (79%, 26/33); social networks (21%, 7/33); anyone (9%, 3/33); cancer organizations (6%, 2/33); others in the same situation (6%, 2/33). app store listings (3%, 1/3).	—	—	Dissemination of a smartphone app may best be supported by health care professionals. This needs more investigation.
Control beliefs	Overall, participants in focus groups were confident in using smartphone apps. In phone interviews, 82% (27/33) participants were confident with using smartphone apps. Participants with lower confidence were infrequent or nonusers.	Overall, 60% (6/10) participants were very confident in using smartphone apps, 30% (3/10) were moderately confident, and 10% (1/10) were novice.	Overall, 50% (5/10) participants were very confident in using smartphone apps, and 50% (5/10) were moderately confident. Participants stated instructions or a guide to using the Carer Guide App would improve their confidence.	Video instructions were developed to aid carers using the Carer Guide App.
Facilitating conditions	Overall, 9% (3/33) participants in phone interviews noted barriers to smartphone app use included not owning a smartphone, not using smartphone apps, and not having adequate internet connection at home. The overall consensus from focus groups identified lack of smartphone ownership as a barrier; this was among a minority.	—	—	A smartphone app may be a relevant way to deliver information and provide support to carers as the majority of the sample experienced no impact of facilitating conditions. Facilitating conditions are likely to reduce as more people continue to use smartphones.

[a]These concepts were not measured during this phase of development.

Figure 3. Initial structure of the Carer Guide App.

Main menu	Submenu 1	Submenu 2
Cancer information	Information on cancer type	
	Survival and cancer trends	
	Treatment	Treatment plan Side effects Practical aspects of caring
	Medical terminology	
	Home management	Day-to-day management Diet and nutrition When to go to hospital
Carer information	Impact of caring on carers	
Wellbeing	Mindfulness Where to get support Counseling	
Social	Phone contacts Face-to-face groups Facebook	
Lifestyle	*Physical wellbeing*	Exercise Support
	Diet and nutrition	
	Financial aid	Financial assistance
Hospital Information	Healthcare facility 1 Healthcare facility 2	
Contacts and quick references		
Notepad		

Overall, the appearance and layout of the Carer Guide App were considered favorable; however, there was some confusion between 2 icons, *Lifestyle* and *Wellbeing*. Of the 16 tasks, 13 were completed successfully by 100% of the participants. The 3 tasks not completed by all participants included—finding financial aid (60%, 6/10 completed), seeking counseling sessions (90%, 9/10 completed), and seeking peer support (90%, 9/10 completed). These 3 topics related to the app icons— *Lifestyle*, *Wellbeing*, and *Social*. The time taken by participants to complete 5 scenarios was as follows—finding financial aid (66.5 seconds), counseling sessions (36.8 seconds), seeking peer support (26.1 seconds), finding carer resources (29.7 seconds), and saving and exiting the notepad (26 seconds).

Overall, the Carer Guide App's features and functionalities were satisfied by the testing group. Out of a score of 5, participants found the app was easy to navigate and visually appealing (5 out of 5). The icon pictures were also relevant to information on the individual pages. Participants were asked for suggestions to make the app more user-friendly; participants suggested changing the iconized navigation titles, rearranging the layout of contents, and having the capabilities to synchronize app content with other phone functions.

The following UAT changes were incorporated to improve the appearance and usability of the Carer Guide App:

1. The icons *Lifestyle* and *Wellbeing* were merged. Icon name— *Wellbeing*. Icon picture—smiley face. Icon contents—physical well-being, diet and nutrition, counseling, and mindfulness activities.
2. A separate financial aid icon was created. Icon name—*Financial and legal*. Icon picture—dollar symbol.
3. The icon *Social* was renamed to specify that it relates more to connecting with others rather than social issues, for example, social work. Icon name— *My social network*.
4. The icon *Contact/quick references* was renamed to reduce ambiguity. Icon name— *Contacts*.

Figure 4. Modified structure of the Carer Guide App.

Main menu	Submenu and information screen
Cancer information	Information on type of cancer Survival and cancer trends Treatment plan Side effects Practical aspects of cancer Medical terminology Daily management Diet and nutrition When to go to hospital
Carer information	Impact of caring on carers
Wellbeing	Mindfulness Where to get support (eg referrals to counselling and helplines) Counseling Exercise Diet and nutrition Physical wellbeing
My social network	Phone contact Face-to-face social groups Facebook
Financial aid	Financial assistance for carers Legal assistance
Hospital Information	Hospital A Hospital B Hospital C Hospital D Hospital E
Contacts	
Notepad	
Medical terminology	

Following UAT, the layout of the main menu and submenus were modified and are displayed in Figure 4. Submenus 1 and 2 were condensed after consultation with the app developer to reduce the number of screens participants would have to search through to find the information required. During this process, *Medical Terminology* was included in both the main menu and the *Cancer Information* submenu. This was done as the content was relevant for inclusion in *Cancer Information*, but because of the volume of information in this section, it may have required additional time to access. To enhance usability, *Medical Terminology* was included in the main menu of the Carer Guide App for quick reference use.

User Experience Testing

An equal number of females (n=5) and males (n=5) tested the app. Participants were younger than 30 (30%, 3/10), 30 to 49 years (20%, 2/10), and 50 years or above (50%, 5/10). The sample included past carers and noncarers. Android operating systems were used by 30% (3/10) of people, and iPhone operating system (iOS) was used by 70% (7/10). Confidence in using apps is outlined in Table 2.

Of the 23 tasks, 18 were completed by 100% of participants. Completion rates for the following 5 tasks were lower: creating a shortcut icon (40%, 4/10 completed), finding peer support (90%, 9/10 completed), adding a new contact (90%, 9/10 completed), returning to the Carer Guide App window after visiting an external website (90%, 9/10 completed), and clicking on an external number to make a call (90%. 9/10 completed). Overall, 4 of these tasks related to system factors and 1 related to misunderstanding of content.

On average, participants completed the majority of tasks (18 out of 23 tasks) in less than 20 seconds. Overall, 5 tasks took participants on average greater than 20 seconds to complete; this included downloading the app (31.8 seconds), creating a shortcut icon (23 seconds), finding symptom management (46.5 seconds), finding benefits and payments (20.7 seconds), and seeking peer support groups (29.3 seconds).

Participants rated the app as easy to use, and the phone numbers were clear and easy to recognize and access (4.7 out of 5 for each aspect). Ease of accessing the app after visiting an external website was scored 4.1 out of 5. The highest usability factors of the app were awareness of external website links and ease of accessing external links; these scored 4.9 out of 5, and corresponding tasks were completed by 100% (10/10) of participants. Ease of creating a shortcut icon was the lowest scoring aspect (3.6 out of 5), as most participants (60%, 6/10) were unable to complete this task. Of the 6 participants who

could not create the app icon shortcut, 2 still rated it 3 out of 5 as they stated it was easy to do once shown.

The Carer Guide App was tested on both Android and iOS devices to assess any variation in the performance of the app. During testing, it was noted that there were differences between the operating systems. On Android devices, problems encountered included not being able to find the shortcut icon once created, internet and phone links not connecting to external sites or numbers, and the "Add" button in the contact menu did not appear. On iOS devices, icon pictures were enlarged, and pictures appeared in incorrect menus. These errors were not present among all iOS versions. Android errors occurred for 2 participants, and iOS errors occurred for 1 participant.

Comments for improvement included instructions to create a shortcut icon and improvements in system factors, for example, working links and phone numbers. Individual participants requested changes to iconized navigation titles, layout such as having items in menu format, and the ability to synchronize app features to phone features.

On the basis of these test results, the following steps were taken to improve the Carer Guide App:

1. Confirm all links, pictures, and buttons are correct and working in all operating systems.
2. Inclusion of instructional downloading and navigation videos for both iOS and Android operating systems, comprising information on how to create the shortcut icon, how to navigate between different browsers, how to close browsers, highlight weblinks and phone numbers, and how to use them.

Discussion

Principal Findings

Caring for someone with cancer can be stressful, and information and support are not easily available [33,34]. The Carer Guide App was developed to support carers while caring for someone with cancer. Carers may be reluctant to communicate their own needs and struggle to find information that is specific to their own situation [35]. The Carer Guide App provides a means for carers to access information and support anywhere within their internet connection capabilities and allows carers privacy in addressing their needs [9].

The development followed a co-design process, which sought involvement from stakeholders throughout the design and creation phase of development [36]. Involving carers in the creation of the Carer Guide App enabled the content to be designed specifically for carers' needs. The sample was a heterogeneous group, with participants caring for people with different types of cancer, of different ages, and various stages of caring including new, ongoing, recurrent, or past carers. This allowed the Carer Guide App to be designed to address the needs of carers from a variety of clinical, demographic, and social perspectives. Involvement of stakeholders in the development of technology-based interventions is an important part of UCD to ensure systems match users' needs [25]. Using interviews to learn about stakeholders needs have been used among a variety of different groups including people with mental illness [37], among parents and teenagers with asthma [38], and for improving physical activity among people with chronic illnesses [39]. These studies found similar results, suggesting that intervention content should be highly relevant to stakeholders' needs, and in an easy-to-use format [37,38]. During user testing, inclusion of noncarers was important as not all people have previous experience with cancer before becoming a carer. This allowed the Carer Guide App to be tested among people with no previous knowledge of how to address cancer-related needs. Both the UAT and the UX testing showed that participants found the appearance of the Carer Guide App favorable. Issues with navigation during UAT were amended, and participants in the UX test were more easily able to navigate the Carer Guide App. Results from the UX test highlighted the need for specific instructions to accompany the Carer Guide App. UX has been used in the literature to capture design and navigation flaws before larger trials or integration into practice [18]. Tying in with the theoretical frameworks, the Carer Guide App was used successfully among people with varying levels of confidence. Feedback during phases 1 and 3 demonstrated participants' positive attitudes toward the development of the Carer Guide App. Factors potentially affecting Carer Guide App usage included recommendations from health care professionals to use the app. The influence of health care professionals on carers' information-seeking behavior is consistent with findings from previous research [40-42] and highlights the need to involve staff working in oncology settings in the implementation process for new interventions or services. Barriers to using apps included not having access to a smartphone or the internet; however, this only affected 9% (3/33) of this sample. Furthermore, smartphone ownership is expected to increase over time, suggesting smartphone apps are a relevant way to deliver resources to carers [12].

The concepts from the theoretical frameworks were easy to measure and relevant to the development process and could be implemented in any stage of the project. Findings from the theoretical framework provided the study with baseline results about the appropriateness of a smartphone app for carers of people with cancer and highlighted potential dissemination methods, for example, health care professionals to guide future research.

Challenges Encountered

Although participants were engaged during the development of the Carer Guide App, it was not possible to meet the requests of all carers. For example, requests to include interactive features may affect the overall usability for carers who may be less confident in using apps. As a result, interactive features such as discussion boards and symptoms trackers were not created in this version of the app, and synchronizing features were not included in the app.

A second challenge was creating the app within the time frame of the research project. The Carer Guide App was developed as a Web-based app. Although Web-based apps are quicker to develop and launch and easier to modify, it required a different approach to downloading the app. Using the Web-based app, participants were required to create a shortcut icon and navigate

through browser windows when external links were accessed from the Carer Guide App. These factors required testing during the UX test to assess whether participants could understand and navigate these factors and identified the need to develop video instructions for carers to assist them in completing these tasks. However, development of a Web-based app allowed secondary analyses to occur to assess which devices carers used on the Carer Guide App, for example, a phone, tablet, or computer; this may allow for an in-depth analysis about the applicability and acceptance of smartphone apps among carers.

Strengths of the Study

To the researchers' knowledge, this app is the first of its kind as carers guided its development, including the content, visual presentation, and layout. This research used a co-design process by involving carers (as stakeholders) during each phase of development and seeking user feedback to improve system functionality. This approach may be useful for future research to guide the development of novel interventions. Another strength of this research was the inclusion of current carers of a variety of cancer types and stages as well as past carers during focus groups and phone interviews. This enabled the content of the app to be created to meet the needs of carers across the illness trajectory.

Limitations

This study has several limitations including the collection of information from carers living in metropolitan areas only, who spoke English. This may have resulted in the development of an app that is not appropriate for carers living in rural and remote areas or who speak a primary language other than English, as they may experience different needs. The Carer Guide App was not designed to synchronize to other phone functions because of the need to incorporate additional security measures. Not synchronizing the Carer Guide App to phone functions decreased the need for security passwords to access the app; this reduced any burden of having to remember passwords in times of stress by recipients.

Interactive features such as symptom tracking and calendars were not incorporated into this version of the Carer Guide App as they required an extended amount of time to create and test. When developing interventions with interactive features or the ability to synchronize to other phone functions, future researchers should consider the development time frame of their intervention, including the time needed to launch apps through Google Play and the App store.

Recommendations for Future Research

Future research is needed to assess the applicability of apps for carers living in rural and remote areas and those whose primary language is not English. These groups of people may experience different needs and therefore require other information and services within an app.

Next Steps

On the basis of the development of the Carer Guide App outlined in this study, a pilot study is assessing the feasibility, usability, and acceptability among carers looking after people with 1 type of cancer. Findings from the pilot study will complete the UCD process by providing information about the suitability of the Carer Guide App among this population.

Conclusions

In conclusion, carers require information and support during the caring period. A smartphone app may provide 1 solution to address these needs. A pilot study is currently underway to test the feasibility, usability, and acceptability of the Carer Guide App.

Acknowledgments

This research was supported by scholarships from the School of Nursing and Midwifery, Deakin University, and the Eastern Health Foundation.

Conflicts of Interest

None declared.

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Abbreviations

iOS: iPhone operating system
TPB: theory of planned behavior
UAT: user acceptance test
UCD: user-centered design
UTAUT: unified theory of acceptance and use of technology
UX: user experience testing

Edited by G Eysenbach; submitted 08.05.18; peer-reviewed by L Gutierrez-Puertas, YF Tsai, J Mirkovic; comments to author 01.09.18; revised version received 19.10.18; accepted 30.12.18; published 11.04.19.

Please cite as:
Heynsbergh N, Heckel L, Botti M, O SC, Livingston PM
Development of a Smartphone App for Informal Carers of People With Cancer: Processes and Learnings
JMIR Form Res 2019;3(2):e10990
URL: http://formative.jmir.org/2019/2/e10990/
doi:10.2196/10990
PMID:30973346

Original Paper

AO Patient Outcomes Center: Design, Implementation, and Evaluation of a Software Application for the Collection of Patient-Reported Outcome Measures in Orthopedic Outpatient Clinics

Nan E Rothrock[1], PhD; Michael Bass[1], MS; Andrea Blumenthal[2], PhD; Richard C Gershon[1], PhD; Beate Hanson[3], MD; Alexander Joeris[2], MD; Aaron Kaat[1], PhD; Suzanne Morrison[4], MPH; Robert V O'Toole[5], MD; Shalini Patel[1], BS; Michael Stover[6], MD; Michael J Weaver[4], MD; Raymond White[7], MD; Maria Varela Diaz[1], MS; Mark S Vrahas[8], MD

[1]Department of Medical Social Sciences, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

[2]AO Clinical Investigation and Documentation, AO Foundation, Duebendorf, Switzerland

[3]Department of Health Services, University of Washington, Seattle, WA, United States

[4]Partners eCare, Partners HealthCare, Boston, MA, United States

[5]Department of Orthopaedics, University of Maryland School of Medicine, Baltimore, MD, United States

[6]Department of Orthopaedic Surgery, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

[7]Orthopaedic Surgery, Maine Medical Center, Portland, ME, United States

[8]Department of Orthopaedics, Cedars Sinai Health System, Los Angeles, CA, United States

Corresponding Author:
Nan E Rothrock, PhD
Department of Medical Social Sciences
Feinberg School of Medicine
Northwestern University
625 North Michigan Avenue, Suite 2700
Chicago, IL, 60611
United States
Phone: 1 312 503 3514
Fax: 1 312 503 4800
Email: n-rothrock@northwestern.edu

Abstract

Background: Patient-reported outcomes are increasingly utilized in routine orthopedic clinical care. Computer adaptive tests (CATs) from the Patient-Reported Outcomes Measurement Information System (PROMIS) offer a brief and precise assessment that is well suited for collection within busy clinical environments. However, software apps that support the administration and scoring of CATs, provide immediate access to patient-reported outcome (PRO) scores, and minimize clinician burden are not widely available.

Objective: Our objective was to design, implement, and test the feasibility and usability of a Web-based system for collecting CATs in orthopedic clinics.

Methods: AO Patient Outcomes Center (AOPOC) was subjected to 2 rounds of testing. Alpha testing was conducted in 3 orthopedic clinics to evaluate ease of use and feasibility of integration in clinics. Patients completed an assessment of PROMIS CATs and a usability survey. Clinicians participated in a brief semistructured interview. Beta-phase testing evaluated system performance through load testing and usability of the updated version of AOPOC. In both rounds of testing, user satisfaction, bugs, change requests, and performance of PROMIS CATs were captured.

Results: Patient feedback supported the ease of use in completing an assessment in AOPOC. Across both phases of testing, clinicians rated AOPOC as easy to use but noted difficulties in integrating a Web-based software application within their clinics. PROMIS CATs performed well; the default assessment of 2 CATs was completed quickly (mean 9.5 items) with a satisfactory range of measurement.

Conclusion: AOPOC was demonstrated to be an easy-to-learn and easy-to-use software application for patients and clinicians that can be integrated into orthopedic clinical care. The workflow disruption in integrating any type of PRO collection must be addressed if patients' voices are to be better integrated in clinical care.

(JMIR Form Res 2019;3(2):e10880) doi:10.2196/10880

KEYWORDS

orthopedics; patient reported outcome measures; tablet computers

Introduction

There is an increasing demand to utilize patient-reported outcomes (PROs) in clinical care for a variety of aims. PROs that measure symptoms (eg, depression) and disability (eg, physical function) can be utilized to monitor response to treatment, detect unrecognized problems, improve patient and provider communication, and possibly improve health outcomes [1,2]. PROs are particularly important within orthopedics as treatment is often initiated to improve a patient's physical function and reduce pain. Quantification of the patient's perspective can be utilized in treatment decision-making such as when the patient's pain and disability have progressed enough to consider joint replacement and to help judge the success of treatment [3]. Payers have also introduced PROs as a method for assessing health care quality (PRO Performance Measures) rather than only utilizing measures that evaluate the process of care [4-6]. For example, the Centers for Medicaid and Medicare Services now include submission of PRO data for total hip and total knee replacement reimbursement as part of their Comprehensive Care for Joint Replacement Payment Model [7]. It is hoped that using PRO Performance Measures will alter the definition of health care quality to include the function and symptom burden of patients [8].

To improve measurement precision, efficiency, applicability, and interpretability, the National Institutes of Health invested in the development and validation of the Patient-Reported Outcomes Measurement Information System (PROMIS), a collection of PRO measures that assesses important domains of self-reported health. PROMIS measures include computer adaptive tests (CATs)—a tailored administration in which questions are selected dynamically on the basis of past responses using the most informative question for that respondent's specific level of function or symptom severity. This offers rapid assessment with high measurement precision across a wide range of functional abilities and symptom severities. CATs are particularly suited for integration in clinical care as there is little time in the clinic workflow for assessment and a need for highly precise measures when evaluating individual patient data [9].

Our aim was to develop a software application that enables the administration and scoring of PROMIS CATs and other relevant PROs in the clinical routine across diverse orthopedic clinics. Specifically, we hypothesized that (1) we could develop a software application that is easy to learn and easy to use for clinicians and patients, (2) AO Patient Outcomes Center (AOPOC) is feasible for integration into orthopedic clinics, and (3) PROMIS CATs provide rapid and precise quantification of symptoms and function across a wide range of patients.

Methods

AO Patient Outcomes Center Design

Design Principles

AOPOC followed 5 design principles: (1) a primary focus on in-clinic data collection for use in the clinical encounter, including display of longitudinal PRO data for an individual patient, (2) a common assessment battery of PROMIS CATs for all patients, (3) the capability to add other patient- and clinician-reported measures to the assessment, (4) an easy-to-learn and easy-to-use interface that imposes minimal burden on surgeons, and (5) the ability to export data for a group of patients for research analyses.

Description of AO Patient Outcomes Center

AOPOC is a Web-based software application to collect PROs in orthopedic clinics. A clinician is able to establish 1 or more *Patient Groups* (Figure 1). Assessment content can be tailored by the clinician for each Patient Group. For example, clinicians may utilize different PROs for individuals receiving total hip replacement versus an elbow injury. A library of high-quality PROs used in orthopedic care is available (Figure 2), as are numerous clinician-provided variables such as fracture classification code, mechanism of injury, and body mass index. All Patient Groups include the PROMIS CATs for Pain Interference and Physical Function. A patient is registered in AOPOC with full name, date of birth, and is assigned to 1 or more Patient Groups. The interface for the patient to complete the assessment is a simple design maximized for viewing on an iPad (Figure 3). Each CAT is scored in real time and displayed in a longitudinal graph along with the questions and responses from the most recent assessment (Figure 4). This report is available as a PDF to share with a patient or manually added to an electronic health record (EHR). Data from a Patient Group can be exported. They include raw response data, PROMIS measure scores, time and date of a patient's responses, and response time. Optionally, multiple consent forms can be included to facilitate the use of AOPOC in research data collection.

A clinician can give access to a Patient Group to other clinical users who belong to the same organization. For example, a surgeon can establish a Trauma Patient Group and give access to fellows, front desk staff, and a physician assistant. Each member of the team has a unique log-in ID and password and is assigned a level of access to determine whether or not he or she can register patients, modify the assessment content, export data, or carry out other actions.

Figure 1. AO Patient Outcomes Center (AOPOC) homepage.

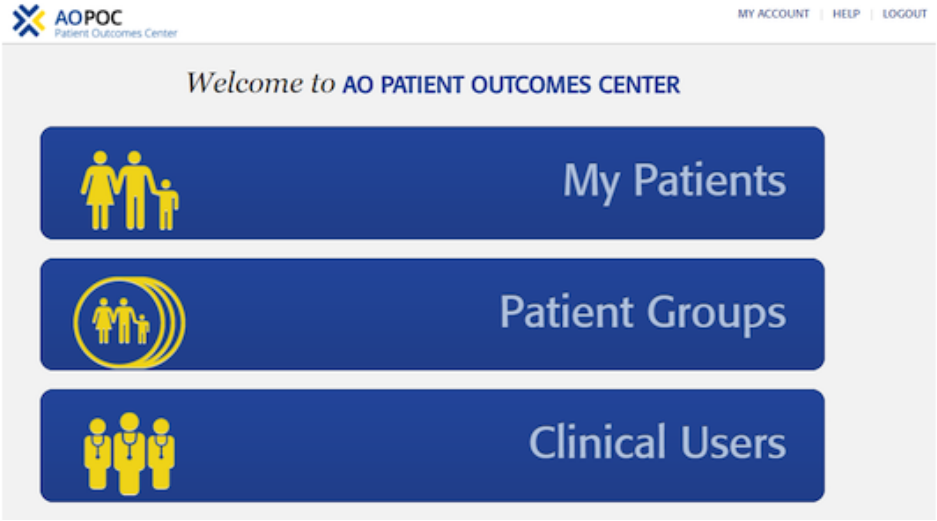


Figure 2. Portion of AO Patient Outcomes Center patient-reported outcomes library. MFA: Musculoskeletal Function Assessment; PROMIS: Patient-Reported Outcomes Measurement Information System.

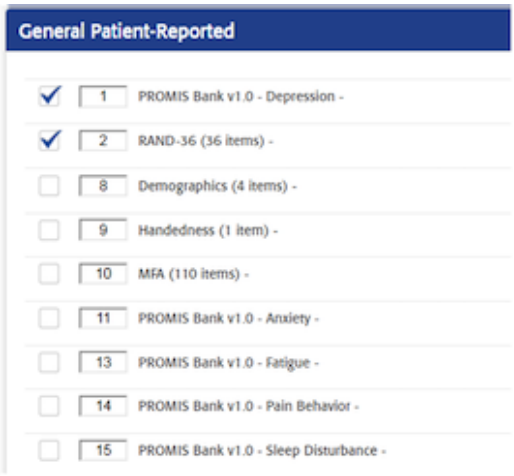


Figure 3. AO Patient Outcomes Center patient interface.

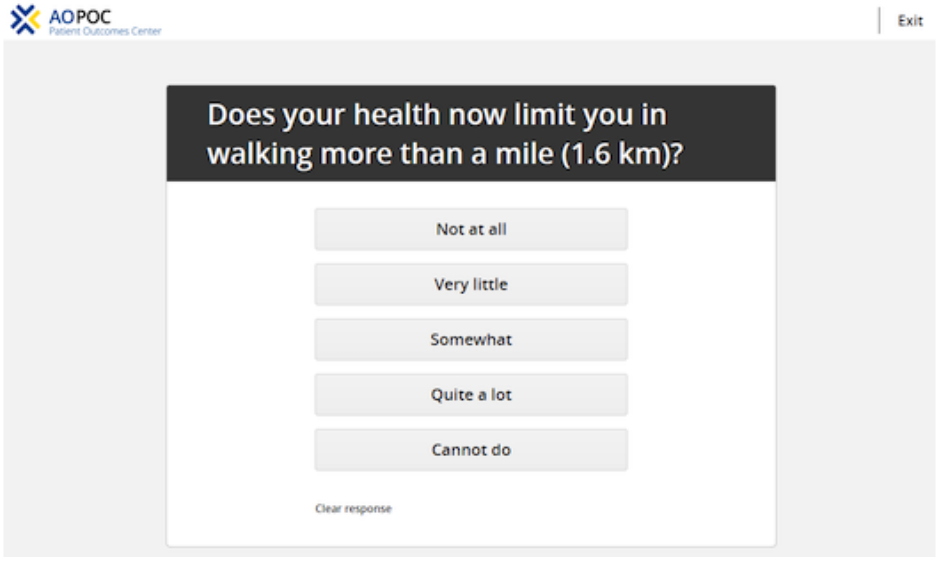
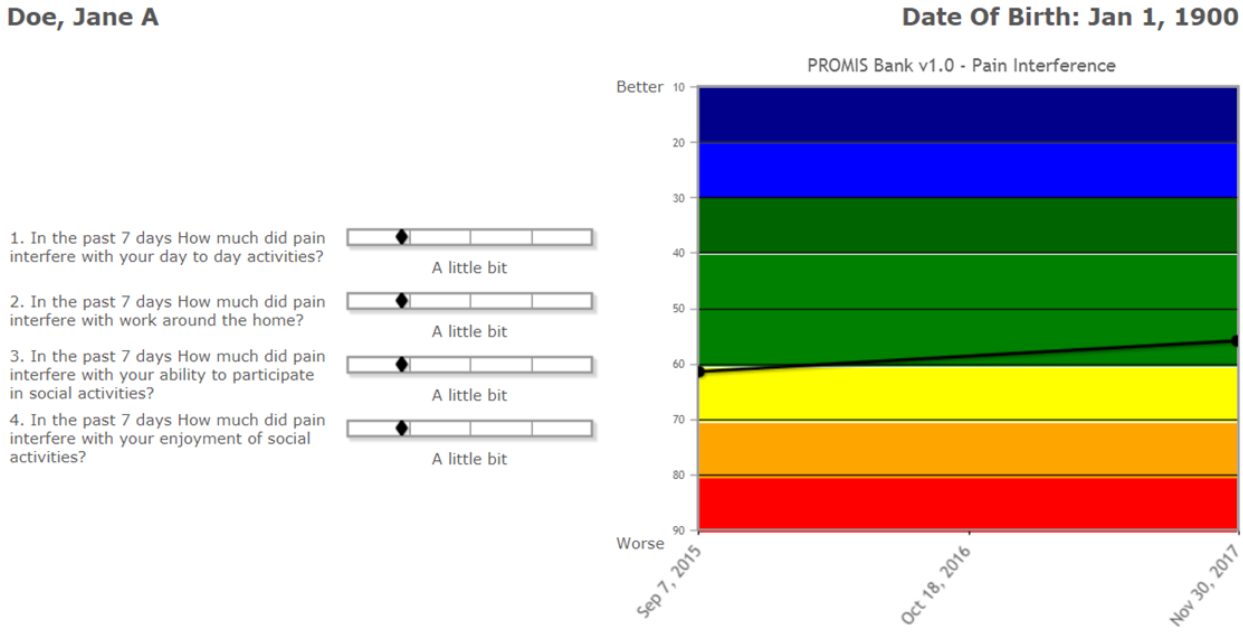


Figure 4. Portion of AO Patient Outcomes Center patient-reported outcomes report. PROMIS: Patient-Reported Outcomes Measurement Information System.



Default Patient-Reported Outcome Battery

The default assessment includes 2 PROMIS CATs. A minimum of 4 and a maximum of 12 questions are administered per CAT. PROMIS T-scores have a mean of 50 (SD 10) in the US general population.

Patient-Reported Outcomes Measurement Information System v1.0 Pain Interference Computer Adaptive Test

Consequences of pain on the relevant aspects of one's life are measured, including the extent to which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities. Higher scores indicate more difficulties from pain.

Patient-Reported Outcomes Measurement Information System v1.2 Physical Function Computer Adaptive Test

Self-reported capability of physical activities including upper extremities, lower extremities, and central regions (neck, back), as well as instrumental activities of daily living, such as running errands are measured. The initial version of AOPOC utilized PROMIS CATs for Mobility (v1.2) and Upper Extremity Function (v1.2) instead of the single PROMIS Physical Function CAT.

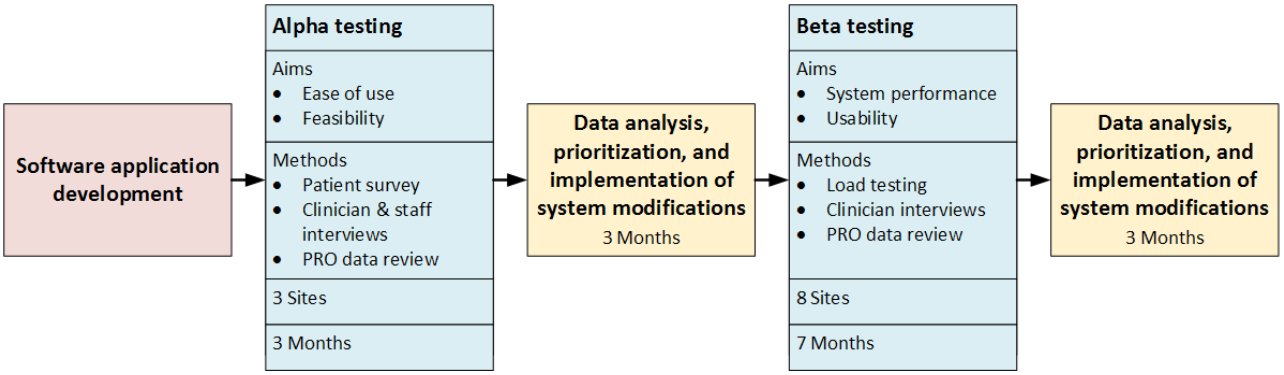
AO Patient Outcomes Center Development

To develop the application, we utilized a modified Agile methodology [10-12] that enabled iterative development with continuous feedback. A multidisciplinary team of orthopedic trauma surgeons, clinic staff, and PRO scientists compiled requirements and constructed use cases that included features' functionality, terminology, navigation, and user interface. Software development, quality assurance (QA) testing, and user acceptance testing (UAT) were completed. When all test cases passed QA, AOPOC was made available in a Web-based production environment.

Evaluation

AOPOC was evaluated in multiple waves of testing (see Figure 5). This included alpha testing for ease of use and feasibility and beta testing for system performance and usability.

Figure 5. Stages of AO Patient Outcomes Center evaluation. PRO: Patient-Reported Outcomes.



Alpha-Phase Testing

Alpha-phase testing was conducted to test ease of use and feasibility in integrating AOPOC in orthopedic clinics. Data were collected from both patients and clinic staff at 3 orthopedic trauma clinics in US academic medical centers associated with a surgeon in the project team. Each site's Institutional Review Board determined that the project did not meet the criteria to be considered human subjects research.

Patients

The site lead identified the patient population for alpha testing (eg, single surgeon's patients, specific clinic's patients). Adult, English-speaking patients were eligible to participate. Participants were asked to complete a battery of PROs selected by his or her surgeon. Following the PROs, an 11-item usability survey comprising questions related to past computer use experience, comfort using the data collection device (eg, tablet computer), and satisfaction with the user interface was administered. Ease-of-use questions had 4 response options (0=Not at all, 1=A little bit, 2=Somewhat, 3=Quite a bit). User-interface questions utilized 5 response options (4=Excellent, 3=Very good, 2=Good, 1=Fair, 0=Poor).

Clinic Staff

After 3 to 9 weeks of AOPOC experience, the site lead identified staff including surgeons, other clinicians, and administrative personnel (eg, front desk staff) who interacted with AOPOC on more than 1 occasion. All were invited via email to participate in a 20-min semistructured interview by phone. The interview included open-ended questions targeting specific features of AOPOC including the following: (1) completing the application for implementing AOPOC at his or her site, (2) establishing the assessment content for specific patients (Patient Group set up), (3) enrolling clinical users, (4) registering patients, (5) having patients complete the assessment, and (6) accessing patient data. Multiple-choice questions assessing the ease of use of specific features, system usefulness, and degree of disruption to clinic workflow were also administered. Questions used a 5-point scale ranging from 1 (Not at all) to 5 (Very). The interview script was modular so that interviewees were only asked about those portions of AOPOC which they utilized. All issues, requested modifications, and responses to multiple-choice items were recorded in a database. In addition, communication with the AOPOC support desk was used to identify areas of confusion or errors as well as requested system modifications. This feedback was added to the database. Throughout alpha testing, bugs (instances when AOPOC was not functioning as it should) were distinguished from change requests (eg, modification to improve usability or expand system capabilities). Bugs were resolved by a software developer immediately. Following prioritization by the project team, high-priority change requests were implemented using the same software development protocol (eg, QA, UAT).

Beta-Phase Testing

The aim of beta-phase testing was to prepare for the public release of AOPOC. It included load testing to quantify and improve system performance, usability testing to again evaluate ease of learning, and using an updated version of AOPOC.

Load Testing

To determine AOPOC performance capabilities, a test harness was developed that ran scripts which simulated common use cases identified by the business analyst and informatics project manager. With this test harness, load testing was conducted by generating a simulated load for a typical AOPOC use case of registering a patient and administration of the default PRO assessment battery. The load testing gradually increased the number of simultaneous patients, starting with 100 and increasing until the system started to return timeout errors caused by server requests exceeding the defined default response time (90 sec). Rounds of testing were conducted to identify server settings that maximized performance, identified bottlenecks (area within the software application that slowed overall performance because of concurrency), and reevaluated performance after modifications were implemented. A benchmark to double-simulated patients was established.

Usability

Surgeon members of AO Trauma, a nonprofit international organization of clinicians and researchers aimed at fostering and improving medical care for musculoskeletal trauma, were surveyed about their interest in serving as an AOPOC beta-test site. The project team reviewed 66 interested orthopedic clinics to identify representatives from specific types of clinics (eg, academic medical center, community hospital practice) and invited a diverse group of 36 sites to participate with a goal of enrolling 20. After 6 months, 16 sites had completed enrollment. Similar to alpha testing, usability feedback was collected in multiple ways. First, data were extracted from AOPOC to evaluate clinicians' ability to tailor assessment content and patient response burden with PROMIS CATs. Second, interactions with clinical users including emails and calls to the AOPOC support desk and questions, comments, or difficulties during demonstrations were used to identify bugs as well as areas of confusion and errors. Third, beta-site leaders identified active AOPOC users at their sites to participate in a 20-min semistructured interview by phone. Interviews utilized the same modular guide as alpha testing. All issues, requested modifications, and responses to multiple-choice items were recorded in a database. Again, bugs were identified throughout beta testing and resolved immediately. Following prioritization by the project team, all high-priority change requests that fit within the available resources were implemented using the same software development protocol (eg, QA, UAT).

Analytic Plan

Alpha-Phase Patient-Level Data

All patient-level data were exported from AOPOC by a software developer and deidentified by a data manager following a standardized protocol. To evaluate measurement performance, score distributions and mean PROMIS scores were calculated for each PROMIS CAT. Completion time was evaluated with frequency distributions for the number of items administered and time to complete each CAT. Frequency distributions and means for individual usability survey items were calculated.

Alpha-Phase Clinician-Level Data

The database of user feedback was reviewed, and redundant entries combined noting the number of users reporting the same issue. If required, additional clarification was sought from the source. All change requests were prioritized for implementation using a Must, Should, Could, or Would rating. Each change request was categorized as a Must (a mandatory change for the intended functionality of AOPOC), Should (a high-priority and desirable change that is not mandatory), Could (a change that would improve AOPOC but is not critical to its success), or Would (a change that may be considered but is not critical or appropriate now) rating. Ratings were based upon (1) alignment with the intended scope of AOPOC, (2) number of affected users, (3) frequency of request, and (4) whether a user could circumvent the issue. The project leader made an initial rating assignment. This was provided to the project team who reviewed and revised ratings individually and then met for a consensus meeting to finalize ratings. The available development effort was used to implement change requests in order of priority until it was expended.

Beta-Phase Usability Data

All beta-phase patient-level data were exported by a software developer and deidentified by a data manager following a standardized protocol. All available data were included in analysis, including sites which did not participate in usability interviews. Descriptive statistics including the number of Patient Groups set up within each beta test site, number of measures in addition to the AOPOC battery of measures that were administered per Patient Group, and number of unique patients providing data were calculated. Frequency distributions were constructed for the use of other PROMIS CATs and number of items needed to complete the default and supplemental PROMIS CATs.

Should change requests that were identified but not implemented during alpha testing were merged with issues identified in beta testing. All were reviewed, and redundant entries were combined. Potential system modifications to address user issues were identified. All change requests were prioritized using new Must, Should, Could, or Would ratings. The project leader provided the initial prioritization, distributed it to the project team, and a meeting was held to reach consensus on ratings. The available development effort was used to implement change requests in order of priority until it was expended.

Results

Alpha-Phase Testing

Patients

Across the three sites, 1793 unique patients were registered in AOPOC and eligible to complete 2640 assessments across all office visits. About half (935/1793, 52.14%) completed an initial assessment. Of the 614 eligible, 160 (26.1%) completed a second assessment at a follow-up clinic visit. Across all office visits, almost all of the registered patients who did not complete an assessment (1505/1511, 99.60%) were from one site that registered patients the day before his or her clinic visit.

Patient-Reported Outcome Scores

In alpha testing, separate Mobility and Upper Extremity Function CATs were used instead of a single Physical Function CAT. Half of the subjects completed the entire assessment battery (3 CATs) in under 3.7 min (mean 4.7 [SD 5.2], 95% CI 4.5-5.0). Long completion times were partly because of interruptions from the clinic staff (eg, moving the patient to the visit room). About 85% of patients answered only the minimum of 4 questions for the Mobility (781/923, 84.6%) and Pain Interference (766/897, 85.4%) CATs compared with only 22.1% (200/907) of patients for the Upper Extremity CAT. For the Upper Extremity CAT, 42.3% (384/907) of patients answered the maximum number of questions which was 12 (Table 1). Mean T-scores were in the moderate impairment range for Mobility (mean 38.7 [SD 8.7], 95% CI 38.1-39.2) and at the border among mild symptoms and within normal limits for Pain Interference (mean 59.2 [SD 9.4], 95% CI 58.6-59.9) with fairly well-distributed scores (Figures 6 and 7). Upper Extremity Function was also in the moderate impairment range (mean 39.8 [SD 10.7], 95% CI 39.1-40.5). The best possible score (T=56.4) was received by 15.7% (142/907) of patients, indicating that the measure may be unable to distinguish among patients with excellent function (*ceiling effect*).

Table 1. Performance of instruments in the AO Patient Outcomes Center battery.

Measure	Completion time (seconds)		Number of items administered		Assessments with minimum number of items, n (%)	Assessments with maximum number of items, n (%)	T-score	
	Mean (SD)	Median (min-max)	Mean (SD)	Median (min-max)			Mean (SD)	Median (min-max)
PROMIS[a] Mobility CAT[b] (n=923)	131.5 (133.7)	85.0 (5.0-1108.0)	4.7 (2.1)	4.0 (4-12)	781 (84.6)	69 (7.5)	38.7 (8.7)	37.2 (18.3-60.2)
PROMIS Upper Extremity CAT (n=907)	96.6 (109.3)	70.0 (4.0-1010.0)	8.2 (3.5)	7.0 (4-12)	200 (22.1)	384 (42.3)	39.8 (10.7)	38.7 (14.7-56.4)
PROMIS Pain Interference CAT (n=897)	60.0 (69.7)	42.0 (4.0-790.2)	4.8 (2.3)	4.0 (4-12)	766 (85.4)	76 (8.5)	59.2 (9.4)	60.1 (38.5-80.1)

[a]PROMIS: Patient-Reported Outcomes Measurement Information System.

[b]CAT: computer adaptive test.

Figure 6. Frequency distribution of Patient-Reported Outcomes Measurement Information System (PROMIS) mobility and upper extremity function computer adaptive test (CAT) T-scores.

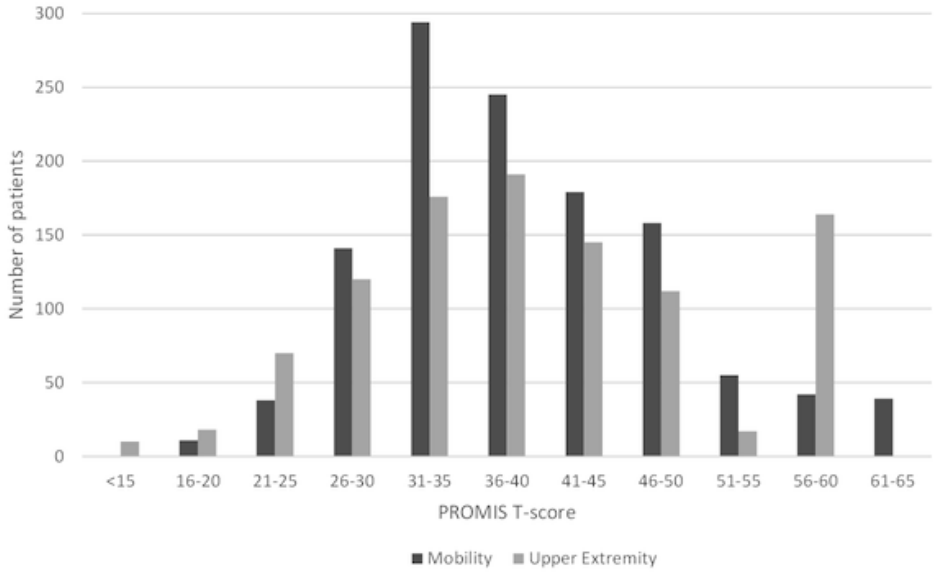
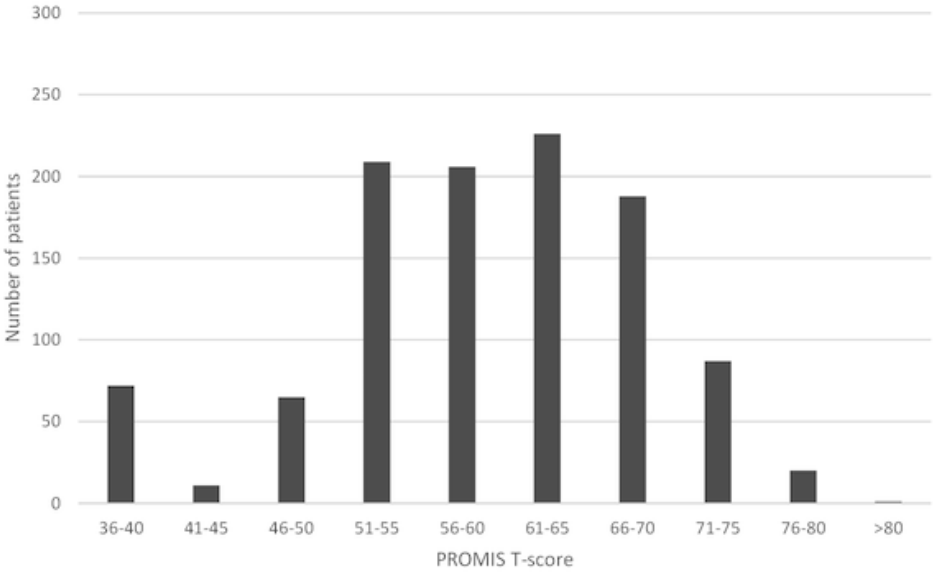


Figure 7. Frequency distribution of Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference computer adaptive test (CAT) T-scores.



Usability

Overall, most patients were familiar with using computers; 85.9% (736/857) used a computer within the past year. A similar number (724/856, 84.6%) used a touchscreen such as automated teller machine or airline check-in kiosk. A majority (721/839, 85.9%) owned a device with internet connectivity and reported use 5 to 7 days a week (551/741, 74.4%). AOPOC was not difficult for patients to use (Table 2). Most participants (686/842, 81.5%) reported they had no difficulty using the data collection device (tablet or desktop computer). Only 7% (58/840, 6.9%) were “somewhat” or “quite a bit” uncomfortable, anxious, or nervous using the data collection device. Most (721/841, 85.7%) had no difficulty answering the PRO questions. A strong majority (760/839, 90.6%) would be willing to complete a similar assessment at a future clinic visit. Furthermore, ratings of the AOPOC interface design were favorable, including data collection screens (741/843, 87.9% good, very good, or excellent) and the response button design (743/825, 90.1% good, very good, or excellent; Table 3).

Table 2. Usability of AO Patient Outcomes Center for patients.

Questions	Not at all, n (%)	A little bit, n (%)	Somewhat, n (%)	Quite a bit, n (%)
Did you have any difficulty using this computer? (N=842)	686 (81.5)	89 (10.6)	35 (4.2)	32 (3.8)
Did you ever feel uncomfortable, anxious, or nervous while using the computer? (N=840)	685 (81.5)	97 (11.5)	33 (3.9)	25 (3.0)
How difficult was it to answer the questions shown on this computer? (N=841)	721 (85.7)	77 (9.2)	27 (3.2)	16 (1.9)

Table 3. Patients' satisfaction with design of AO Patient Outcomes Center.

Questions	Excellent, n (%)	Very good, n (%)	Good, n (%)	Fair, n (%)	Poor, n (%)
What is your overall rating of the design of the screens including the colors and layout? (N=843)	182 (21.6)	256 (30.4)	303 (35.9)	87 (10.3)	15 (1.8)
What is your overall rating of the buttons on the screens, including their size and shape? (N=825)	197 (23.9)	275 (33.3)	271 (32.8)	65 (8.0)	17 (2.1)

Clinicians

Of the 13 clinic staff who were invited, 11 participated in a usability interview. Interviewees were from all 3 sites and were providers (surgeon, physician assistant; n=5), research staff (n=3), or in other positions (nurse manager, program director, medical secretary; n=3). One provider did not personally interact with AOPOC and therefore questions concerning application usability were skipped. All 3 sites utilized a single Patient Group with only the default assessment content. Each site followed a slightly different workflow (eg, staff register patient in AOPOC when he or she checks in, staff registers all patients for the following day). Data collection occurred during an existing wait time, such as in the clinic waiting room, on an iPad or in the visit room on an iPad or desktop computer.

Clinicians described feeling comfortable using AOPOC at the time of the interview (mean 4.7 [SD 0.5], n=10). AOPOC was easy to learn (mean 4.7 [SD 0.7], n=10) and easy to use (mean 4.5 [SD 0.8], n=10). The process for completing the application for access to AOPOC was described as "A little bit" difficult by the 2 respondents who did this task. Registering as a clinical user was "Not at all" or "A little bit" difficult for the 2 clinicians who answered this question. Clinicians who set up a Patient Group reported it as not difficult (mean 1.3 [SD 0.5], n=4). Clinicians also had little difficulty registering patients (mean 1.4 [SD 0.7], n=8), starting a patient's assessment (mean 1.3 [SD 0.8], n=6), and accessing a single patient's data (mean 1.8 [SD 0.8], n=5). Only 2 attempted to export data from a Patient Group and both reported no difficulty. Areas where clinicians experienced more difficulty included entering clinical data (eg, fracture classification code, mean 3.5 [SD 2.1], n=2) and understanding the patient's data including PROMIS CAT scores (mean 3.0 [SD 1.3], n=6). There was a wider range in responses concerning how disruptive AOPOC was to the clinic workflow (mean 2.3 [SD 1.2], n=9).

The qualitative feedback from the usability interviews and queries to the help desk identified 17 bugs and 104 change requests. Of the 17, 10 bugs were resolved during the pilot phase. The remaining bugs could not be recreated (n=4), they were recategorized to change requests (n=2) or required additional investigation time after the alpha-test period (n=1). Change requests were clustered in several areas. First, the process to register as a new site, register as a clinical user, and to provide access to other site members was reported to be challenging. Second, there was technical difficulty in utilizing an iPad as a data collection device. For example, users were not aware of the setup requirements to enable AOPOC on an iPad (eg, turn off pop-up blocker). Multiple clinicians commented that the staff had more difficulty interacting with an iPad than patients. Although support material including instructions for iPad setup was available, some users did not know it existed. Finally, the AOPOC Administrator identified multiple areas of difficulty in registering new users, including being unable to view those who were sent a registration email but had not completed the registration process, restrictions in the ability to make edits to user email addresses, health care organization names, and demographic fields (eg, State). In the consensus meeting, 17 *Must*, 31 *Should*, 44 *Could*, and 12 *Would* change requests were identified. The Must requests were implemented before the beginning of beta testing. In addition, on the basis of the range restriction of the PROMIS Mobility and Upper Extremity Function CATs, these measures were replaced with the PROMIS v1.2 Physical Function CAT.

Beta-Phase Testing

Load Testing

Throughout beta testing, no users reported problems with system speed. However, load testing identified 2 Web server settings that contributed to reduced speed: *keep alive* and the maximum number of connections. Tests using simultaneous requests and an initiation rate of 2 to 4 sec between requests were conducted. Changing default Microsoft Internet Information Services 7 settings and increasing the number of central processing units (CPUs) did not increase the number of requests. After suspecting that requests were being blocked from finishing, the extra CPU used on the staging database was applied to the staging Web

server that was reaching capacity. This resulted in doubling the performance of requests finishing in multiple rounds of testing. Several recommendations were identified to prepare for wider distribution of AOPOC, including (1) updating hardware and increasing CPUs to 4, (2) continuous monitoring of performance by server host, and (3) engaging in ongoing evaluation with updated information about volume of simultaneous users.

Usability

Of the 16 enrolled sites, 8 had completed business associate agreements (BAAs) between their institution and AOPOC at the time of usability interviews. The remaining 8 sites completed BAAs after usability interviews were concluded, but they were able to provide data on the initial setup of AOPOC at their clinics. Reasons for not enrolling as a test site included no support from other clinic personnel, utilization of other data collection systems (eg, state-mandated system), and difficulties in executing a BAA. BAA challenges included (1) difficulty in identifying who had the authority to sign this agreement, (2) institutional staff requiring modifications to the existing BAA, which required negotiation (eg, removing AO Foundation's right to use a deidentified dataset from AOPOC for research purposes), and (3) requiring that the local institution's own standard BAA be utilized, requiring review and discussion with the project team.

Across 16 sites, 71 unique Patient Groups were created. Sites utilized 1 of 3 approaches to organizing Patient Groups: (1) a single Patient Group for all patients being treated by the same surgeon, (2) 2 large groups based upon location of injury (ie, upper extremity and lower extremity), or (3) multiple Patient Groups based upon location of injury (eg, acetabulum, elbow, foot or ankle, forearm or wrist, hip or femur, knee or tibia, pelvis, polytrauma, and shoulder or humerus). There was a wide range (2 to 24) of patient- and clinician-completed instruments per Patient Group. Approximately 34% (24/71) only collected the default battery. Between 3 and 5 additional instruments were included in 38% (27/71) of Patient Groups. Added measures were other PROs (47%, 153/326) and injury or treatment information (eg, mechanism of injury; 48%, 155/326). There were 9725 assessments completed by 5088 patients. Most patients completed 1 or 2 assessments, and the maximum completed by the same person was 14. The default assessment (2 CATs) required 9.5 items on average. For Pain Interference, 80% (6355/7895) of the assessments required only the minimum number of items per CAT (see Table 4). Similarly, 78% (6178/7965) of Physical Function assessments used the minimum number of items. An additional 8 PROMIS CATs were administered by at least one clinician. Most (n=6) were completed with 4 to 5 items. Depression (mean 7.2 [SD 3.8]) and Upper Extremity Function (mean 8.0 [SD 3.5]) required the most items, but in both cases, the number of items was bimodally distributed, with a substantial number completing the CAT in 4 or 5 items (for Depression and Upper Extremity Function, respectively) and a minority requiring the maximum of 12 items.

Table 4. Utilization and average length of Patient-Reported Outcomes Measurement Information System (PROMIS) computer adaptive tests (CATs) in beta phase.

PROMIS CAT	Assessments[a]	CAT length (items), mean (SD)	Assessments with minimum items, n (%)	Assessments with maximum items, n (%)
Pain interference (default assessment)	7895	5.0 (2.5)	6355 (80.49)	857 (10.85)
Physical function (default assessment)	7965	4.5 (1.4)	6178 (77.56)	167 (2.10)
Upper extremity function	488	8.0 (3.5)	118 (24.2)	191 (39.1)
Mobility	636	5.8 (3.2)	452 (71.1)	132 (20.8)
Pain behavior	78	4.7 (2.2)	70 (89.7)	6 (8)
Depression	39	7.2 (3.8)	20 (51)	14 (36)
Anxiety	19	4.9 (2.5)	17 (89)	2 (11)
Fatigue	75	4.3 (1.2)	67 (89)	1 (1)
Sleep disturbance	37	5.1 (2.4)	19 (51)	2 (5)
Ability to participate in social roles and activities	18	4.7 (1.9)	14 (78)	1 (6)

[a]Some patients completed more than 1 assessment.

A total of 16 clinicians were invited to participate in a usability interview. Of these, 10 were not yet using AOPOC in clinic. A total of 5 clinicians across 4 sites completed the interview. All interview participants reiterated the ease of learning and using AOPOC. The most significant concern was the impact of PRO collection on clinic workflow. For example, patients completing an assessment in the exam room did not always finish the assessment before the surgeon arrived, making PRO information unavailable in the clinic visit. Aligning the assessment with existing wait time (eg, waiting for x-ray, waiting for exam room) required trial and error and was not always consistent across patients. Some clinicians carried a tablet computer to view scores, which was additional equipment with a new log-in. Adding a 1-min task for the staff was significant when a clinic included more than 40 appointments. Change requests were related to usability (eg, alphabetize patient list, use consistent messaging with *save* buttons, ensure graphical report fits on a standard paper size, and orient all graphs so that higher points are consistently good), security (eg, institution-specific tablet computer settings), and default assessment content (eg, appears to be a ceiling of possible high scores, weight-bearing activity limitations should be in default assessment, and minimal

questions on Upper Extremity Function). Following prioritization, 9 change requests related to usability were evaluated as *Musts* and implemented (eg, improve consistency in use of checkboxes, increase visibility of location within the application, and clarify reminders to clinicians about missing clinical information). Of these, 2 were also reported and rated as *Shoulds* during the alpha-phase testing. A total of 6 bugs were identified with only 1 being critical—1 test site blocked incoming registration emails from AOPOC. All bugs were resolved during the beta-phase testing. In addition, 9 security improvements (eg, server-side validation, improved encryption of URLs, construction of log of all user log-ins and failed log-ins) were implemented.

Discussion

Summary

AOPOC was demonstrated to be an easy-to-learn and easy-to-use software application for patients and clinicians that can be integrated into routine orthopedic care. In alpha-phase testing, a battery of PROMIS CATs was completed in under 5 min with usually only the minimum number of questions required. The measures performed well, although Upper Extremity Function demonstrated a limitation in assessing patients with better functioning. Patients were comfortable using the data collection device and answering questions with 90.6% (760/839) willing to complete an assessment again. Clinicians also reported AOPOC was easy to learn and its multiple features were easy to use. The most frequently cited areas for improvement were in onboarding as a new site and clinical user and in mitigating the impact of PRO collection on the clinic workflow. A small number of bugs were reported, none of which were critical (ie, prevented data collection). In beta-phase testing, areas for improving system speed were identified and addressed. PROMIS CATs performed well; they were completed quickly and there were no ceiling effects in the revised default assessment. Only 1 critical bug was identified, which was resolved. Clinicians demonstrated the ability to establish more complex assessment plans through multiple assessment types and tailored content. Of the small number of clinicians who completed interviews, concerns included executing a BAA and achievable future modifications to improve usability.

Patient-Reported Outcomes in Orthopedic Clinical Practice

AOPOC addresses some of the barriers to the collection and use of PROs in routine orthopedic clinical practice. First, similar to other studies in orthopedic patient populations [13,14], the PROMIS Physical Function, Mobility, and Pain Interference CATs demonstrated acceptable assessment at the very high and very low ends of the range. However, the PROMIS v1.2 Upper Extremity Function CAT did demonstrate poor ability to distinguish among levels of excellent function and therefore may not be able to capture the full degree of improvement following intervention. CATs also remove a second assessment barrier—time burden [15]. By tailoring the items that are administered, measures were most frequently completed in 4 to 5 items. Finally, AOPOC provided measure scores immediately in table and graphical presentations, thus removing the need to calculate and display results [16].

This project highlights 2 issues related to integrating PRO collection in clinical practice that are not specific to AOPOC: (1) managing the impact of adding a PRO assessment to the clinic workflow is critical and (2) the site-specific requirements for utilizing a software application in parallel with an EHR are substantial. In this project, clinic workflow disruption was frequently identified as a concern, which is consistent with previous research [5]. Low participation from clinicians at beta-test sites and by registered patients at 1 alpha-test site may also reflect workflow problems. Collection of PROs requires patients' time to complete measures and care providers' time to access and review results [17]. Enabling patients to complete assessments outside of the clinic setting can reduce the time demand on patients at the care setting, though participation has been low [18,19]. Another strategy has been to improve the usefulness of PRO results to increase patients' and clinicians' engagement in PRO collection. Aligning the assessment content with the clinical purpose (eg, screening vs monitoring a primary outcome of care) [18,20] and making PRO results more interpretable and actionable [21-24] have been recommended. Clinician training programs have also been successful in improving interpretation and the use of PRO results [25].

Software apps that work in parallel with an EHR require BAAs. Most of the beta-testing sites required more than 4 months for a BAA to be finalized and some sites were not successful in reaching an agreement even after 8 months. As reimbursement is increasingly tied to PRO collection [7,26], the prioritization by health care systems to enable PROs in clinical care is expected to increase. Non-EHR data collection software apps like AOPOC are able to quickly integrate advances in PRO measurement science such as improved measures (eg, a PROMIS Upper Extremity CAT with a higher measurement ceiling) and graphical displays of results (eg, integrate newly published normative scores for a particular patient population). Without increasing the efficiency of adopting software apps into clinical care, the breadth of advances in patient-centered care will remain difficult to implement.

Limitations

Several limitations are noted. Most of the patient participants had previous experience interacting with a computer and a touch screen. Consequently, the positive usability feedback may not represent the experience of those patients without past experience. Information on the number of patients who were approached to complete an assessment but declined was not captured. Therefore, it is not known to what extent patient factors (eg, computer fluency, concerns about privacy, and English literacy) and/or clinic factors (eg, barriers to adding an assessment to clinic workflow, insufficient data collection devices) contributed to patients not completing an assessment. Similarly, there may have been selection bias inherent in getting clinician feedback from those who used the system; clinicians who were more comfortable or open to computerized testing might have been more likely to use AOPOC. In addition, both alpha and beta testing occurred in the clinics of orthopedic

surgeons who were members of the AO Foundation, which may not be representative of all orthopedic surgeons.

Conclusions

AOPOC is a feasible, robust software application that enables collection of CATs within orthopedic clinical care. Barriers to routinely integrating PROs, including modification of clinic workflow and execution of BAAs remain. However, addressing those barriers enables the integration of the patient's perspective in his or her health care. This is particularly important in orthopedics as physical function and pain are regularly the targets of interventions and the reasons why patients seek care.

Acknowledgments

Financial support for this project was provided by AO North America and AO Trauma. AO Clinical Investigation and Documentation staff contributed to software design (BH) and manuscript preparation (AB, AJ). NER, MB, RCG, AK, SP, and MVD also receive grant funding for PROMIS from the National Institutes of Health (U2C CA186878).

Conflicts of Interest

RCG and MSV served on the AOPOC Inc Board of Directors.

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Abbreviations

AOPOC: AO Patient Outcomes Center
BAA: business associate agreement
CAT: computer adaptive test
CPU: central processing unit
EHR: electronic health record
PRO: patient-reported outcome
PROMIS: Patient-Reported Outcomes Measurement Information System
QA: quality assurance
UAT: user acceptance testing

Edited by G Eysenbach; submitted 25.04.18; peer-reviewed by M Hung, H Zheng; comments to author 28.08.18; revised version received 03.10.18; accepted 31.12.18; published 12.04.19.

Please cite as:
Rothrock NE, Bass M, Blumenthal A, Gershon RC, Hanson B, Joeris A, Kaat A, Morrison S, O'Toole RV, Patel S, Stover M, Weaver MJ, White R, Varela Diaz M, Vrahas MS
AO Patient Outcomes Center: Design, Implementation, and Evaluation of a Software Application for the Collection of Patient-Reported Outcome Measures in Orthopedic Outpatient Clinics
JMIR Form Res 2019;3(2):e10880
URL: https://formative.jmir.org/2019/2/e10880/
doi:10.2196/10880
PMID:30977735

Original Paper

iCanCope PostOp: User-Centered Design of a Smartphone-Based App for Self-Management of Postoperative Pain in Children and Adolescents

Kathryn A Birnie[1,2], BA, PhD; Fiona Campbell[3], BSc, MD, FRCA; Cynthia Nguyen[1], MPH; Chitra Lalloo[1], BHSc, PhD; Argerie Tsimicalis[4,5], PhD, RN; Clyde Matava[3], MB, ChB, MMed; Joseph Cafazzo[6,7,8], PhD, PEng; Jennifer Stinson[1,2], PhD, RN, CPNP

[1]Child Health Evaluative Sciences, The Hospital for Sick Children, Toronto, ON, Canada

[2]Lawrence S Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON, Canada

[3]Department of Anesthesia and Pain Medicine, The Hospital for Sick Children, University of Toronto, Toronto, ON, Canada

[4]Ingram School of Nursing, Faculty of Medicine, McGill University, Montreal, QC, Canada

[5]Shriners Hospitals for Children - Canada, Montreal, QC, Canada

[6]Centre for Global eHealth Innovations, Techna Institute, University Health Network, Toronto, ON, Canada

[7]Institute of Health Policy, Management, and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

[8]Institute of Biomaterials and Biomedical Engineering, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Kathryn A Birnie, BA, PhD
Child Health Evaluative Sciences
The Hospital for Sick Children
Peter Gilgan Centre for Research and Learning
686 Bay Street
Toronto, ON, M5G 0A4
Canada
Phone: 1 416 813 7654
Email: kathryn.birnie@sickkids.ca

Abstract

Background: Moderate to severe postoperative pain in children is common. Increased pediatric day surgeries have shifted postoperative pain management predominantly to the home setting. Mobile health technology has the potential to overcome barriers to pain care by improving access to self-management resources. However, pain apps generally lack scientific evidence and are highly underutilized due to lack of involvement of end users in their development. Thus, an evidence-based pain self-management smartphone app that incorporates the needs and perspective of children and adolescents (end users) has potential to improve postoperative pain management.

Objective: This paper aimed to describe how the principles of user-centered design were applied to the development of *iCanCope PostOp*, a smartphone-based pain self-management app for children and adolescents after surgery. Specifically, it presents 2 completed phases of the user-centered design process (concept generation and ideation) for the *iCanCope PostOp* app.

Methods: Phase 1 was a multisite needs assessment from the perspective of 19 children and adolescents who had undergone various day surgeries, 19 parents, and 32 multidisciplinary health care providers. Children, adolescents, and parents completed individual semistructured interviews, and health care providers participated in focus groups. Data were summarized using qualitative content analysis. Phase 2 developed a pain care algorithm for the app using Delphi surveys and a 2-day in-person design workshop with 11 multidisciplinary pediatric postoperative pain experts and 2 people with lived experience with postoperative pain.

Results: Phase 1 identified self-management challenges to postoperative pain management and recovery; limited available resources and reliance on medications as a predominant postoperative pain management strategy; and shared responsibility of postoperative pain care by children and adolescents, parents, and health care providers. Key app functions of tracking pain, pain self-management strategies, and goal setting were identified as priorities. Phase 2 led to the successful and efficient generation of a complete preliminary pain care algorithm for the *iCanCope PostOp* app, including clinically relevant inputs for feasible

assessment and reassessment of pain and function (rest or sleep, movement or play, and mood or worry), as well as a catalog of pain management advice to be pushed to end users (psychological, physical, pharmacological, and education).

Conclusions: The concept ideation and generation phases of the user-centered design approach were successfully completed for the *iCanCope PostOp* app. Next steps will include design finalization, app development (iOS or Android), evaluation through a randomized controlled trial, and subsequent implementation of the *iCanCope PostOp* app in clinical care.

(JMIR Form Res 2019;3(2):e12028) doi:10.2196/12028

KEYWORDS

postoperative pain; smartphone; mobile applications; mHealth; pain management; self-management; adolescent

Introduction

Background

More than 3 million children and adolescents in Canada and the United States undergo surgery each year [1-3]. Despite the availability of evidence-based clinical practice guidelines for postoperative pain [4], children and adolescents continue to experience moderate to severe pain once home in the days following outpatient surgery [5]. Unrelieved or undertreated postoperative pain can delay remobilization, lead to increased opioid use, and negatively impact health-related quality of life, including sleep, anxiety, social, and school functioning [6-10]. Furthermore, approximately 20% of children undergoing surgery develop chronic pain [11], an expensive and debilitating health problem [12].

Due to health system changes, an increasing number of pediatric surgical procedures are performed as day surgeries [1], resulting in greater postoperative pain management within the home setting. Problematic, however, are reports that parents infrequently give postoperative pain medications to their children after hospital discharge [13]. Moreover, children and adolescents feel challenged by the need to rely on others, such as nurses, for assistance with postoperative pain relief [14]. Greater confidence in one's ability to manage pain ("pain coping self-efficacy") contributes to decreased postoperative pain and lowered risk for chronic pain in children [6,11], and is a mechanism by which effective disease self-management is achieved [15].

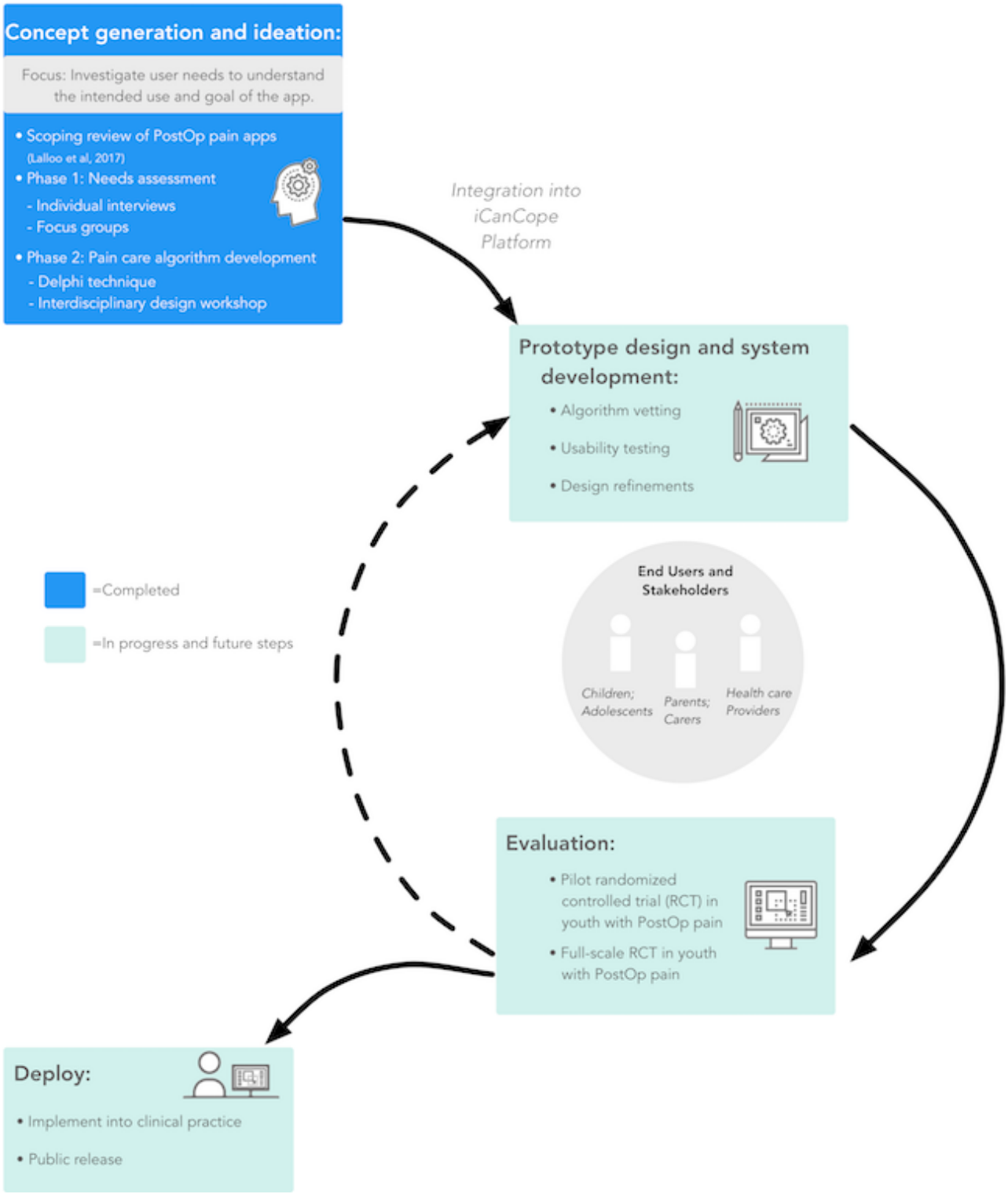
Growing evidence supports the use of mobile health (mHealth) technology to improve disease self-management [16]. Smartphones are widely used by children and adolescents, with 88% having access to a mobile device [17]. Despite this availability, relatively few apps have been designed for children and adolescents to support disease self-management [18]. mHealth apps have shown potential for improving postoperative symptom monitoring and self-management in adults [19]; however, none currently exist for children and adolescents [20]. Estimates from a 2017 report of digital health indicated that over 318,000 mHealth apps are available worldwide with more than 200 new health apps added daily [21]; however, more than 85% of apps have less than 5000 downloads, suggesting that users do not find them relevant or effective [22]. Also notable is the lack of scientific evidence underlying mHealth apps, particularly among apps for pain [21,23]. A recent scoping review of all apps for postoperative pain revealed that none had comprehensive pain or self-management content, had undergone scientific evaluation, or had involved end users in their development [20].

User-Centered Design Process for Mobile Health App Development

User-centered design is a collaborative evidence-based approach that incorporates the needs and context of a specific end-user group to inform the development and design of mHealth apps [24,25]. General steps in user-centered design include understanding the environment in which the app will be used and end-user needs; evaluating and applying relevant theory, design science, and content area evidence; as well as iteratively producing and evaluating app prototypes and the final product [24,25]. Typically, an iterative process with multiple diverse user-centered design qualitative research methods is used for the design and development of the app, including focus groups, interviews, participatory design sessions, and usability testing, with randomized controlled trials to evaluate app efficacy [24,25]. Consideration of the end-user experience and their involvement at every stage of the design process closes the research-practice gap by producing apps that are patient-centered, effective, novel, feasible, and acceptable in daily life [22,24,25]. The focus on end-user concerns ensures individual relevance and tailoring for effective disease self-management [15]. Thus, application of user-centered design to the development of a self-management app has the potential to critically improve postoperative pain care for children and adolescents at home.

This paper presents an overview of the user-centered design process in developing "iCanCope with Postoperative Pain" (*iCanCope PostOp*), a smartphone-based app for children and adolescents' self-management of acute postoperative pain (see Figure 1). This paper focuses on results from 2 completed early design phases that fall within the user-centered design: the first stage of concept generation and ideation (phase 1) involves a needs assessment from the perspective of children and adolescents who have undergone any type of day surgery (app end users), parents, and health care providers; and the second phase involves (phase 2) development of a preliminary evidence-based expert-generated pain care algorithm for the app. User-centered design and disease self-management provided evidence-based frameworks for all study methods [15,24,26]. A previously completed scoping review of postoperative pain self-management apps [20] also supports the development of *iCanCope PostOp*. Similar applications of user-centered design for pediatric pain self-management apps include those for chronic and cancer-related pain [27-29].

Figure 1. Steps in the user-centered design process. PostOp: postoperative; RCT: randomized controlled trial.



Methods

Phase 1: Needs Assessment

Participants

Participants included a convenience sample of 15 to 20 dyads of children and adolescents aged 8 to 18 years who had undergone surgery in the past 7 days with self-reported acute postoperative pain and a parent as well as a purposive sample of 20 to 30 health care providers recruited for variability in terms of discipline and level of experience treating acute postoperative pain. Potential patient-parent dyads were identified through a review of the operating room list and consultation with preanesthesia clinic coordinators. Eligible patients and parents were initially introduced to the study by a member of their health care team before their scheduled procedure. Patients and parents were excluded if they had severe cognitive impairments or a major medical or psychiatric illness that precluded their ability to participate in a verbal interview. Children and adolescents with an existing recurrent or chronic

pain condition were also excluded, given the potential differences in managing acute postoperative pain alone versus in addition to chronic pain. Eligible health care providers had worked in the pediatric perioperative setting for at least 1 year and were not trainees. They were recruited through study invitation emails and at departmental rounds. Participants were recruited from 2 pediatric tertiary care centers, including The Hospital for Sick Children (primarily English-speaking) and Shriners Hospitals for Children, Canada (primarily French-speaking). Children, adolescents, and parents were recruited from the outpatient surgery preanesthesia clinic area. Research ethics approval was obtained from both the institutions. As parent-child dyads were recruited together, all parents provided informed consent, and children and adolescents provided informed consent or assent, as appropriate. Interviews with children, adolescents, and parents were conducted by phone. Focus groups took place at the hospitals.

Individual Semistructured Interviews and Focus Groups

All participants reported demographics. Individual interviews were conducted with children, adolescents, and parents, whereas focus groups were conducted with health care providers. Semistructured interview guides were informed by evidence and team expertise in mHealth [29,30], disease self-management, and pediatric postoperative pain (see Textbox 1). Interviews and focus groups were conducted in iterative cycles until data saturation was reached and explored participants' (1) experience managing acute postoperative pain (eg, pain, challenges, resources available, and responsibility for pain management) and (2) perceptions about proposed optimal design of a smartphone-based app to support postoperative pain management, including design functions of tracking pain, pain self-management strategies, and goal setting.

Textbox 1. Needs assessment questions from semistructured interviews and focus groups.

- Can you tell me about [the child's] pain after surgery?
  - What were the biggest challenges?
- Who do you think is responsible for managing [the child's] postoperative pain?
  - Child's role, parents' role, and health care providers' role?
- Did you feel like there are adequate tools or resources needed to manage pain at home after surgery?
  - What services would you like to have available to help [the child] manage pain? For example, health care providers, education, and strategies to track or manage pain.
- Can you tell me about other troublesome symptoms that [the child] had after surgery?
  - Mood, sleep, physical activities, social activities, physical symptoms, missed school, or other symptoms?
- Did you feel like [the child] had the tools or resources that [the child] needed to manage these other symptoms at home after surgery?
- What do you think about having a smartphone app that could help better manage pain at home after surgery?
  - Would you be interested in tracking [the child's] pain and other symptoms after surgery? Why or why not?
  - Would you want a function on the app to help [the child] set goals related to pain and function? Why or why not?
  - Would you find it useful for [the child] to have an app toolbox of ways to manage pain in the moment? Why or why not?

Data Analysis

Audio-recordings were transcribed verbatim. Interviews and focus groups were independently coded in NVivo (QSR International) 10 [31] by 2 research assistants fully bilingual in English and French using simple content analysis [32]. A subset of the English-language transcripts was initially reviewed by 2 research team members to establish overarching themes and develop a coding scheme informed by frameworks of effective pain and disease self-management to be iteratively revised as needed during the coding process. Interrater reliability of all coded text was calculated using percent agreement [31] as well as comparative analysis, whereby coders reviewed each other's coded interviews followed by discussion [32]. Percent agreement from 13 (of 19) interviews and 2 (of 4) focus groups was 97%. Disagreements were resolved through consensus and consultation with a third person (study investigator), if needed.

Phase 2: Development of the App Pain Care Algorithm

Delphi Survey

A 2-stage Delphi survey technique [33] was used to determine pain inputs by app end users corresponding to app features endorsed by children, adolescents, parents, and health care providers in phase 1. Clinically important pain inputs were defined as self-reported clinical characteristics by children and adolescents about their postoperative pain experience that should result in pain management advice being generated by the app. Email invitations for study participation were sent to 16 multidisciplinary researchers and health care providers identified by the research team for their recognized expertise in the assessment and management of pediatric postoperative pain. Overall, 2 survey iterations asked participants to rank the importance, or indicate the necessity of, suggested pain input items (Survey 1: 11-point scale from 0="not at all important" to 10="extremely important;" Survey 2: select "necessary,"

"desirable," or "not needed") as well as possible item rewording or additional comments. Surveys were Web-based using the Vanderbuilt University REDCap survey software [34]. Invited experts were given a 2-week period to complete the surveys, with 1 email reminder. Moreover, 9 participants completed survey 1 and 14 completed survey 2. Participant demographics are reported in Table 1. Research ethics approval was obtained from The Hospital for Sick Children.

Table 1. Delphi survey and expert design workshop participant demographic characteristics.

Characteristics	Pain care algorithm interprofessional experts[a] (n=13)
Sex, n (%)	
Female	10 (77)
Male	3 (33)
Age (years), mean (SD)	46.31 (13.32)
Type of expert, n (%)	
Anesthesiologist	3 (23)
Advanced practice nurse	2 (15)
Child life specialist	1 (8)
Surgeon	1 (8)
Psychologist or psychology intern	2 (15)
Physical therapist	1 (8)
Other physician (eg, pediatrician)	1 (8)
Person living with chronic postoperative pain[b]	2 (15)
Years of experience as a health care provider, mean (SD)	22.33 (12.23)
Years of experience in pediatrics, mean (SD)	18.00 (11.45)

[a]An additional 3 experts completed the Delphi survey, but did not attend the design workshop (psychologist, surgeon, and nurse).

[b]Not included in the Delphi survey.

Interprofessional Expert Design Workshop

A 2-day face-to-face interprofessional expert design workshop was held in Toronto, Canada, to develop a preliminary pain care algorithm for the *iCanCopePostOp* app including features endorsed by children, adolescents, parents, and health care providers in phase 1 as well as important pain inputs by end users, evidence-informed pain self-management advice, and end-user app flow. A total of 13 participants attended this. All participants from the Delphi survey were invited and 11 of 14 attended in addition to 2 people with lived experience with postoperative pain (1 adult and 1 adolescent). Participant demographics are reported in Table 1. Research ethics approval was obtained from The Hospital for Sick Children.

The workshop was facilitated by a member of the research team and structured based on previous successful design and consensus workshops for developing self-management apps in pediatric pain [27]. Participants were provided an overview of workshop goals, the user-centered design process (presented by 2 experts in user-centered design and development of the mHealth apps), results from previously completed app development phases (scoping review [20]; phase 1 needs assessment and phase 2 Delphi survey), and available evidence for the management of pediatric postoperative pain (eg, [35]). Small and large group discussions were used to refine clinically important pain inputs from app end users (eg, what pain inputs would trigger a pain alert to the child/adolescent?) and evidence-informed pain self-management advice (eg, what are the patient-driven pain management techniques children and adolescents should use to manage their acute postoperative pain?). mHealth experts provided input on technical practicality and feasibility of system suggestions made by workshop participants. To improve rigor and transparency of findings informing the pain care algorithm, ideas generated from the first day were summarized and presented to workshop participants for feedback on the second day. In generating the final algorithm, audio-recordings of the workshop and research team field notes were referenced.

Results

Phase 1: Needs Assessment

Participants

Demographic characteristics for children and adolescents (n=19), parents (n=19), and health care providers (n=32) are reported in Table 2. A total of 4 focus groups were conducted; 1 with 7 health care providers, 2 with 8 health care provides, and 1 with 9 health care providers. Overall, 4 patient and parent interviews and 2 of 4 focus groups were conducted in French. Children and adolescents were aged between 8 and 18 years. Health care providers were multidisciplinary and practiced across perioperative inpatient and outpatient hospital care settings, including the operating room, preanesthesia clinics, and postanesthesia care units.

Table 2. Needs assessment participant demographic characteristics.

Characteristics	Children and adolescents (n=19)	Parents (n=19)	Health care providers (n=32)
Sex, n (%)			
Female	13 (68)	3 (16)	25 (78)
Male	6 (32)	16 (84)	7 (22)
Age (years)[a], mean (SD)	15.26 (2.51)	—[b]	—
20 to 29, n (%)	—	3 (16)	2 (6)
30 to 39, n (%)	—	13 (68)	5 (17)
40 to 49, n (%)	—	3 (16)	11 (35)
50 to 59, n (%)	—	—	8 (26)
60 to 69, n (%)	—	—	5 (16)
Type of day surgery, n (%)			
Orthopaedic	12 (63)	—	—
Plastic	2 (10)	—	—
Urology	5 (27)	—	—
Ethnicity[c], n (%)			
White	6 (39)	6 (39)	—
Arabic or West Asian	2 (13)	2 (13)	—
South Asian	2 (13)	2 (13)	—
Black	1 (7)	1 (7)	—
Filipino	1 (7)	1 (7)	—
South East Asian	1 (7)	1 (7)	—
Other	1 (7)	1 (7)	—
Prefer not to answer	1 (7)	1 (7)	—
Type of expert, n (%)			
Anesthesiologist	—	—	4 (12)
Staff nurse	—	—	13 (41)
Advanced practice nurse	—	—	4 (12)
Child life specialist	—	—	3 (11)
Surgeon	—	—	4 (12)
Psychologist or psychology intern	—	—	0 (0)
Physical therapist	—	—	2 (6)
Other physician (eg, pediatrician)	—	—	0 (0)
Occupational therapist	—	—	2 (6)
Years of experience as a health care provider, mean (SD)	—	—	20.18 (11.56)
Years of experience in pediatrics, mean (SD)	—	—	17.05 (11.75)

[a]Missing data from 1 health care provider.

[b]Not applicable.

[c]Missing data from 4 children or adolescents and 4 parents.

Interview and Focus Group Themes

Responses from the semistructured interviews and focus groups were categorized into 4 overarching themes: (1) challenges to managing pediatric postoperative pain, (2) available resources and postoperative pain management strategies, (3) responsibility for postoperative pain management, and (4) reactions to proposed smartphone-based app and app features to facilitate child and adolescent self-management of postoperative pain.

Challenges Managing Postoperative Pain

All interviewed children and adolescents reported postoperative pain, described with varying intensity from "just a little bit" to "a lot." Children, adolescents, and parents identified more intense pain in the initial days following surgery and difficulty managing pain at home. As one parent stated:

> *The 24 hours after the surgery, she had severe pain...I ended up taking her to Emerg.* [P-6]

In addition to pain intensity, children, adolescents, and parents identified negative impacts of pain and surgical recovery on movement and mobilizing, sleep, drowsiness or fatigue, nausea, mood (feeling frustrated or bored), and worry. Parents identified additional challenges related to managing postoperative pain medications as well as uncertainty as to when to allow children to return to normal activity. Challenges identified by health care providers in managing postoperative pain included individual variability and subjectivity in pain experience (eg, intensity and response to medications). Other stated challenges were understanding each patient's postoperative experience and context as well as effectively assessing and communicating with families about pain management once families had returned home.

Available Resources and Postoperative Pain Management Strategies

Children and adolescents generally identified that they had the needed resources to manage pain after surgery, although their responses reflected a reliance on medications as a sole pain management strategy. As 1 adolescent stated:

> *We really didn't use anything to help me, all we used was the medications.* [A-2]

Parents identified a desire to have greater access and contact with health care providers, if needed. Health care providers identified a need for greater ongoing resources and education to support postoperative pain management. As 1 health care provider summarized:

> *We are kind of pushing them out the door sometimes, without proper instructions and it's [an] overload of information...plus they're confused with how much pain is normal.* [HCP-1]

Responsibility for Postoperative Pain Management

Children and adolescents, parents, and health care providers all held responsibility in postoperative pain care. Some children identified themselves as primarily responsible:

> *...it would be myself because...I was helping my foot get better.* [A-5]

Other children and adolescents emphasized the primary role of health care providers and parents:

> *I was in the hospital and then it was the doctors and nurses...but now that I am home, [it's] my mom.* [A-7]

Parents generally identified themselves in collaboration with symptom reporting from the child or adolescent:

> *It's both the parents as well as the child. The child needs to tell the parent how much [pain]...so based on [what pain rating] she would tell me I would give medication.* [P-2]

Health care providers identified a team approach as necessary for optimal postoperative pain care. As 1 health care provider summarized:

> *It's a team approach...I mean yes, everyone from the healthcare team, but the family is part of the team, and the patient is part of the team...that's the only way that we're going to be totally successful.* [HCP-2]

Response to Proposed Smartphone-Based App and App Features

Children, adolescents, parents, and health care providers all thought a proposed smartphone app would improve accessibility and self-management of children and adolescents in postoperative pain care.

Tracking Pain

All children, adolescents, and parents identified the value of tracking pain as a means of increasing communication with each other and with the health care team as well as to inform pain management strategies. As 1 adolescent stated:

> *It's a great idea so you don't have to remember what your pain was like 3 weeks ago after the surgery...you can have your phone and show your doctor.* [A-14]

Health care providers also identified symptom tracking as valuable:

> *Day to day activities, that's how we measure it because depending on what [the child] can and can't do indicates the level of the pain they're experiencing.* [HCP-9]

Pain Self-Management Advice

All children, adolescents, parents, and health care providers saw the value of including proposed pain self-management advice within the app. Parents identified a key benefit of the app for increasing children's and adolescents' independence in pain management:

> *I think it would be great for her as a teenager to have the control and the input into how to make decisions around managing her pain.* [A-13]

Children and adolescents also identified the relevance of including information about surgery. For example, 1 adolescent stated:

> *I think it would be a good idea to explain all of the operations.* [A-1]

Another adolescent reported:

> *I could type in [the type of surgery] and search and I can just bring up all the facts about it and explain it more.* [A-3]

Goal Setting

All children, adolescents, parents, and health care providers felt inclusion of the proposed goal setting within the app would be helpful for postoperative pain and recovery, emphasizing the

need for goals to be individually tailored and realistic. One adolescent shared:

> *It could be helpful because it would sort of be a challenge for me. I could write [the doctors' recommendations] in and then it could be like a reminder when they pop up on the.* [A-14]

Goals were identified as potentially helping to address the uncertainty about return to normal function. As a health care provider summarized:

> *[Adolescents] usually want to know if they can return to physical activities, sports...school. Parents want to know the goal of recovery and when they can we expect less pain...[and] return to normal functioning.* [HCP-10]

Other Suggestions

Additional app features for consideration were also suggested by children, adolescents, parents, and health care providers. Specifically, the possibility of direct communication between children, adolescents, parents, and health care providers was proposed. As 1 adolescent described:

> *Maybe a chat system if [patients] have questions and they can easily ask the [hospital] staff if they need to.* [A-12]

As 1 parent stated:

> *What would have been really helpful for the first night and second day would probably have been if you could call a 1-800 number and get an online service...specific about post-op.* [P-1]

Parents also suggested including a function to track postoperative pain medications:

> *I think the biggest thing was some way to track the medications...when's the next dose...because there's so much information when your child gets surgery.* [P-6]

Phase 2: Development of the App Pain Care Algorithm

Delphi Survey

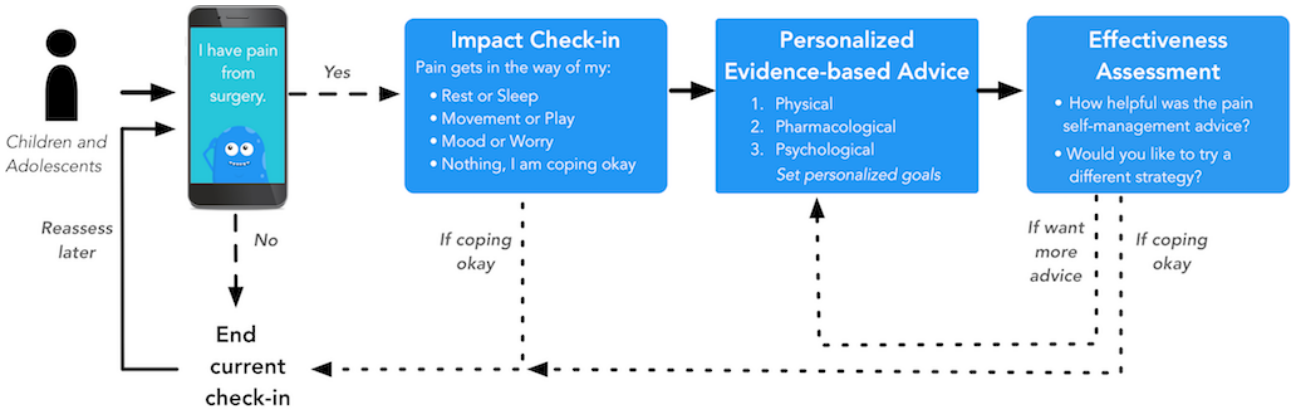
The first survey included 21 possible pain input items with a mean item importance rating of 7.73 (SD 1.38; range mean importance of 4.88 to 9.89 per item). Rewording was suggested for all items. On the basis of participant responses and comments from the first survey iteration, 4 items were removed: least and average pain intensity, duration of pain, and impact of pain on relationships with friends and family since last entry on the app. In addition, 1 item was added to assess the impact of pain on eating and drinking. As such, a total of 18 items were included in the second survey iteration. Items and results from survey 2 are reported in Table 3 and informed the interprofessional expert design workshop.

Table 3. Results from Delphi survey regarding clinically important pain inputs for the app.

Pain assessment or pain tracking item	Is this item:		
	Necessary, n (%)	Desirable, n (%)	Not needed, n (%)
Have you had pain since your last entry?[a]	11 (79)	3 (21)	0 (0)
How much pain do you have right now?	14 (100)	0 (0)	0 (0)
Show your worst pain since your last entry	11 (79)	3 (21)	0 (0)
When you had your worst pain, how long did it last?	10 (72)	3 (21)	1 (11)
Show on body map where you hurt	12 (86)	2 (14)	0 (0)
Does your pain bug, annoy, or bother you right now?	9 (64)	3 (21)	2 (14)
Select the words that best describe your pain	10 (71)	4 (29)	0 (0)
Does your pain:			
Make you feel mad or angry?	6 (42)	4 (29)	4 (29)
Make you feel sad?	5 (36)	6 (43)	3 (21)
Make you feel worried?	4 (29)	8 (57)	2 (14)
Affect your sleep?	13 (93)	1 (7)	0 (0)
Get in the way of you doing things?	13 (93)	1 (7)	0 (0)
Affect being able to move around (eg, walking)?	14 (100)	0 (0)	0 (0)
Affect your eating or drinking?[a]	11 (79)	3 (21)	0 (0)
Do you have any other symptoms related to your pain?[a]	11 (85)	2 (15)	0 (0)
Have you taken any pain medicine?	14 (100)	0 (0)	0 (0)
Did your pain medicine cause any side effects?	9 (64)	4 (29)	1 (7)
What other strategies did you use to try and reduce your pain?	10 (71)	4 (29)	0 (0)
Show how well you felt you were able to manage your pain[a]	10 (77)	2 (15)	1 (8)
Is there anything else you want to tell us about your pain?	10 (72)	2 (14)	2 (14)

[a]n=13 participants.

Figure 2. iCanCope PostOp pain care algorithm.



Interprofessional Expert Design Workshop

Data generated at the workshop were synthesized into a preliminary app pain care algorithm (Figure 2) that provides a framework for app system requirements for (1) clinically important postoperative pain inputs by children and adolescents and (2) evidence-based pain self-management strategies.

Clinically Important Pain Inputs by Children and Adolescents

Discussion about clinically important pain inputs focused on the 9 pain-assessment or pain-tracking items identified as "necessary" by more than or equal to 75% of participants in the Delphi survey (Table 3). These items focused on the presence of pain, current and worst pain intensity, pain location, and pain impact on function. A tenth item regarding use of pain

medications was discussed as part of app pain management advice.

The use of validated self-report pain intensity scales was considered, such as an 11-point numeric rating scale or faces scales; however, participants identified that the primary goal of pain assessment within the app was to identify the need for automated generation of pain advice. It would be difficult to rely on scores from numeric or faces pain rating scales, given their idiosyncratic meaning to determine when pain advice should be pushed within the app. As 1 health care provider stated:

> *When we ask about pain with a number, it doesn't mean anything...when we ask about pain it should be none, bearable, unbearable...[or] I have pain but it's tolerable. This would then tie it to impact.* [PP-3]

Another health care provider also said:

> *[I] strongly suggest not using a number because that [pain] threshold is going to be different for every kid. So, it's the impact and whether they are doing things to get better.* [PP-11]

Participants considered pain location and pain quality descriptors as pain inputs to inform whether pain was from the surgical site or to identify the type of pain (eg, musculoskeletal versus neuropathic). However, with input from mHealth design experts, participants deemed it would be difficult to easily and meaningfully synthesize this information in an automated way. The app needs to generate appropriate advice based on inputs by the end user. Although pain locations and descriptors may vary significantly, participants identified that pain management advice would be more effectively tailored to the functional impact of pain. As such, pain location and pain descriptors were omitted as pain inputs from the pain care algorithm.

Participants recommended self-reported assessment and tracking of the impact of pain on function and recovery after surgery, particularly in areas where useful self-management information could be generated by the app. Identified areas included impact of postoperative pain on rest or sleep, movement (including play), and emotions (such as mood and anxiety). As a person living with chronic postoperative pain stated:

> *I think it's really important to find out how the patient is feeling. Whatare their emotions? I know I had surgery...when I woke up, I wasn't expecting the pain levels that I had and I was really worried, I was really concerned.* [PP-10]

A health care provider added:

> *[It] would be important to include questions that can trigger a response.* [PP-4]

Finally, participants recommended reassessment of pain and impact. Participants discussed frequency of assessments and tracking within the app (range every 4 to 12 hours) with potential tapering with greater time (days) since surgery. Participants recommended a pain and impact reassessment to judge effectiveness of generated pain advice. This approach would inform pain management strategies to be pushed to the user in future or the need to suggest a different strategy if not effective. Participants also recommended that the app should generate advice to seek additional support from a health care provider or hospital should the user report repeated high levels of pain or functional difficulty over the course of several days when postoperative pain reduction and improved function would typically be expected (eg, 5 days after day surgery).

Evidence-Based Pain Management Advice

As endorsed by children, adolescents, parents, and health care providers in phase 1, participants at the workshop generated pain management advice for the app that could be self-directed by the child or adolescent with minimal training, previous experience, or involvement or direction of an adult, such as a parent or health care provider. A biopsychosocial approach to the management of postoperative pain was recommended and used as a framework to group pain management advice into pharmacological, psychological, and physical strategies, in addition to education [36]. A list of specific strategies was generated from available research evidence in pediatric postoperative, acute, and chronic pain [4,35] and clinical expertise. Participants recommended key strategies to be pushed based on assessed areas of pain impact (Table 4). Given the focus of the app on self-management, participants deemed it would be too difficult and inappropriate to provide individualized advice regarding frequency or dosing of pain medications in the app. Furthermore, integration of medication management into the app would have implications regarding classification of the app as a medical device, thus potentially limiting its accessibility via health care provider only instead of directly to the public via the consumer app store [37]. As such, a generic recommendation regarding medications was proposed with a greater emphasis on psychological, physical, and education strategies. Participants recommended introducing the app before surgery, such as during preoperative appointments, to prepare for postoperative pain management (eg, to identify or practice preferred strategies).

Table 4. Summary of expert-generated pain self-management strategies for the app.

Category, pain management advice[a]	Area of pain impact self-reported in the app		
	Rest or sleep	Movement or play	Mood or worry
Psychological			
Deep breathing	✓[b]	✓	✓
Active distraction *(eg, reading, talking to a friend, and videogames)*	—[c]	✓	✓
Passive distraction *(eg, listen to music or watch television or a movie)*	✓	✓	—
Imagery	✓	✓	✓
Mindfulness	—	—	✓
Cognitive restructuring	—	—	✓
Coping talk	—	✓	✓
Humor	—	—	✓
Meditation	✓	—	✓
Relaxation	✓	—	—
Physical			
Movement	✓	✓	✓
Comfort positioning	✓	—	✓
Heat	✓	✓	—
Cold	✓	—	—
Pacing	—	✓	✓
Walking or upright activities	—	✓	✓
Massage	✓	✓	—
Pharmacological			
Pain medication *(eg, "Take medications as prescribed. If you have any concerns, speak to your healthcare team.")*	✓	✓	—
Education			
Pain	✓	✓	✓
Surgery	✓	✓	✓
Other (*eg, sleep*)	✓	✓	✓

[a]Examples provided in italics.

[b]Applicable.

[c]Not applicable.

Discussion

Summary of Findings

This paper presents 2 early phases applying a user-centered design approach to developing an evidence-based mHealth app for self-management of pediatric acute postoperative pain. The needs assessment with children and adolescents, their parents, and health care providers identified challenges to acute postoperative pain care in the home setting that they felt could be addressed through a smartphone-based self-management app. All participants reported the 3 proposed features of the app as important (pain tracking, pain advice, and goal setting). Pain tracking can improve information and communication regarding pain and related symptoms to inform personalized intervention planning and tailoring. Not surprisingly, the needs assessment revealed a heavy reliance on medication for postoperative pain management. Pain advice within the app can increase children's and adolescents' independence and ability to self-manage their own symptoms after surgery as well as increases accessibility to a greater variety of evidence-based pain management interventions beyond the primary reliance on medications to include physical, psychological, and education strategies [4,36]. Finally, goal setting offered potential individual tailoring in identifying and moving toward realistic postoperative recovery. Comprehensively, these features address core disease self-management tasks of medical, behavioral, emotional, and role management [15]. Additional features of direct communication with health care providers and medication tracking were proposed. These features were considered during the subsequent interprofessional expert design workshop and attempts made to address these needs within feasible and

sustainable limitations such as project budget. However, due to concerns about reduced feasibility and goal of widespread sustainable implementation of the app across clinical care settings, the potential integration of these features will require continued consideration within future iterations of the *iCanCope PostOp* app.

The Delphi survey and interprofessional expert design workshop were built on the needs assessment by tangibly formulating the app functions of pain tracking and pain advice endorsed by children, adolescents, parents, and health care providers. Specifically, the Delphi survey and design workshop led to the successful and efficient generation of a complete preliminary pain care algorithm for the *iCanCope PostOp* app, including clinically relevant inputs for feasible assessment and reassessment (tracking) of pain and function, as well as a catalog of pain management advice to be pushed to end users. This collaboratively developed algorithm integrated end users' (children and adolescents) identified needs and perspectives with research evidence and interprofessional clinical expertise. The final list of clinically important pain inputs includes some, but not all, of the suggested elements of postoperative pain assessment, for example, omitting pain location and quality, and aggravating factors [4]. It potentially facilitates more accurate tracking of pain onset and patterns, functional impact, and identification of effective treatments. Despite the commonplace nature of acute postoperative pain in children, relatively limited research has addressed how to best manage it [4,35]. As such, in generating the list of pain advice, experts also drew on their knowledge of evidence-based strategies for managing acute and chronic nonsurgical pain. Furthermore, the need to provide individualized medication information via a self-management app presented with substantive challenges, leading to the development of generic pharmacological advice despite evidence of an identified need [13].

Our previously conducted scoping review of available postoperative pain apps identified that none of the apps were comprehensive in terms of core disease self-management features nor addressed key features of recommended postoperative pain care [20]. Furthermore, they had poor scientific foundation, lacked involvement of end users in their development, and none were designed for pediatric populations. This evidence suggests that currently available apps for postoperative pain are likely to perpetuate poor uptake and unclear effectiveness of apps for pain despite increasing interest [21-23]. Participants identified areas of need for pediatric patients that are currently poorly addressed in clinical practice guidelines for postoperative pain management, given a dearth of empirical evidence in pediatric populations [4]. Specifically, guidelines focus on education regarding medication tapering in discharging postoperative patients from hospital; however, children, adolescents, and health care providers identified challenges with pain and symptom assessment and interventions that were readily integrated into the *iCanCope PostOp* app design. The application of user-centered design ensures that *iCanCope PostOp* will address the context-specific patient-perceived problems in managing acute postoperative pain at home.

Strengths and Limitations

The needs assessment was conducted with a convenience sample of children and adolescents who had recently undergone surgery and their parents. Although this group includes diverse types of surgeries, it is potentially limited by a lack of comprehensiveness of all types of surgeries for potential end users of the *iCanCopePostOp* app. Subsequent iterative stages to be completed in the user-centered design process (Figure 1) will allow confirmation and/or modification as needed with a more diverse group of end users. Given that a smartphone app and potential app features were proposed to participants in the needs assessment, it is also possible that their responses supporting the use of an app could reflect social desirability bias or observer-expectancy bias. However, assessment of multiple key stakeholders' perspectives (parents and health care providers) increases the credibility and likelihood of app recommendation and use. Despite some empirical literature on pediatric postoperative pain, recent guidelines for the management of postoperative pain suggest a significant dearth in available scientific evidence in pediatric populations [4], providing rationale for beginning with user-centered design phases of concept ideation and generation. Strengths of this work are the inclusion of pediatric patients, parents, and health care providers from 2 pediatric tertiary care centers in the needs assessment as well as international interprofessional representation of experts and people living with chronic postoperative pain in developing the pain care algorithm.

iCanCope PostOp is being developed as part of a larger self-management platform for youth with persistent pain, called *iCanCope*. *iCanCope* has been iteratively developed as per a user-centered design approach initially for youth with chronic pain [29], with subsequently developed iterations for arthritis and sickle cell disease currently undergoing evaluation. Sustainability is a key benefit of developing *iCanCope PostOp* as part of the larger *iCanCope* platform. *iCanCope* is designed to leverage economies of scale such that any new feature expansions benefit the whole platform. This integration enables *iCanCope PostOp* to benefit from updates and revisions completed as part of the development of other iterations of the *iCanCope* platform as relevant and applicable. Thus, updates and revisions to *iCanCope* require fewer resources (time and cost) to complete and are applied across the platform to all iterations as appropriate. Similarly, *iCanCope PostOp* benefits from the existing back-end infrastructure, design, and functionalities developed for previous iterations of the *iCanCope* platform and can build on top of it.

Conclusions

This work completes the crucial first stage of concept generation and ideation in the user-centered design process fundamental to the subsequent design, development (iOS or Android), evaluation, and implementation of the *iCanCopePostOp* app. Future phases include vetting of the expert-generated pain care algorithm from the perspective of app end users (children and adolescents), parents, and health care providers; usability testing and design sessions with end users to develop and refine the app prototype and final product; evaluation of app effectiveness for postoperative pain care; and app implementation and public

deployment [24,25]. A similar user-centered design approach can be effectively applied in the development and design of mHealth apps to address self-management needs for other pediatric conditions.

Acknowledgments

The authors would like to thank the children and adolescents, parents, and health care providers who participated in this research as well as all attendees at the interdisciplinary expert design workshop. The needs assessment (phase 1) was funded by a Perioperative Services Innovation Grant from The Hospital for Sick Children awarded to FC (PI) for data collected at The Hospital for Sick Children. Data collected at Shriners Hospitals for Children, Canada, was made possible by funding from the Newton Foundation, Tunis Shriners, and Scotiabank awarded to AT. The interdisciplinary expert design workshop (phase 2) was funded by a Planning and Dissemination Grant-Institute Community Support from the Canadian Institutes of Health Research (CIHR) awarded to JS (PI). KAB was funded by a CIHR Fellowship. The authors would also like to acknowledge Aimee Castro, Marc Napoleone, Maurry Ganeshamoorthy, Tracy Nghiem, and Claudette Bilodeau for their research assistance as well as Dr Jean Ouellet and Androniki Tsoybariotis for their assistance facilitating focus groups at Shriners Hospitals for Children, Canada.

Conflicts of Interest

None declared.

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Abbreviations

CIHR: Canadian Institutes of Health Research
mHealth: mobile health

Edited by G Eysenbach; submitted 24.08.18; peer-reviewed by L McCann, E Sezgin, S Stones; comments to author 22.11.18; revised version received 15.01.19; accepted 24.02.19; published 22.04.19.

Please cite as:
Birnie KA, Campbell F, Nguyen C, Lalloo C, Tsimicalis A, Matava C, Cafazzo J, Stinson J
iCanCope PostOp: User-Centered Design of a Smartphone-Based App for Self-Management of Postoperative Pain in Children and Adolescents
JMIR Form Res 2019;3(2):e12028
URL: http://formative.jmir.org/2019/2/e12028/
doi:10.2196/12028
PMID:31008704

Original Paper

Measuring Free-Living Physical Activity With Three Commercially Available Activity Monitors for Telemonitoring Purposes: Validation Study

Martine JM Breteler[1,2], MSc; Joris H Janssen[2], PhD; Wilko Spiering[3], MD, PhD; Cor J Kalkman[1], MD, PhD; Wouter W van Solinge[4], PhD; Daan AJ Dohmen[2], PhD

[1]Department of Anesthesiology, University Medical Center Utrecht, Utrecht University, Utrecht, Netherlands

[2]FocusCura, Driebergen-Rijsenburg, Netherlands

[3]Department of Vascular Medicine, University Medical Center Utrecht, Utrecht University, Utrecht, Netherlands

[4]Department of Clinical Chemistry and Haematology, University Medical Center Utrecht, Utrecht University, Utrecht, Netherlands

Corresponding Author:
Martine JM Breteler, MSc
Department of Anesthesiology
University Medical Center Utrecht
Utrecht University
Heidelberglaan 100
Utrecht,
Netherlands
Phone: 31 647396841
Email: m.j.m.breteler@umcutrecht.nl

Abstract

Background: Remote monitoring of physical activity in patients with chronic conditions could be useful to offer care professionals real-time assessment of their patient's daily activity pattern to adjust appropriate treatment. However, the validity of commercially available activity trackers that can be used for telemonitoring purposes is limited.

Objective: The purpose of this study was to test usability and determine the validity of 3 consumer-level activity trackers as a measure of free-living activity.

Methods: A usability evaluation (study 1) and validation study (study 2) were conducted. In study 1, 10 individuals wore one activity tracker for a period of 30 days and filled in a questionnaire on ease of use and wearability. In study 2, we validated three selected activity trackers (Apple Watch, Misfit Shine, and iHealth Edge) and a fourth pedometer (Yamax Digiwalker) against the reference standard (Actigraph GT3X) in 30 healthy participants for 72 hours. Outcome measures were 95% limits of agreement (LoA) and bias (Bland-Altman analysis). Furthermore, median absolute differences (MAD) were calculated. Correction for bias was estimated and validated using leave-one-out cross validation.

Results: Usability evaluation of study 1 showed that iHealth Edge and Apple Watch were more comfortable to wear as compared with the Misfit Flash. Therefore, the Misfit Flash was replaced by Misfit Shine in study 2. During study 2, the total number of steps of the reference standard was 21,527 (interquartile range, IQR 17,475-24,809). Bias and LoA for number of steps from the Apple Watch and iHealth Edge were 968 (IQR −5478 to 7414) and 2021 (IQR −4994 to 9036) steps. For Misfit Shine and Yamax Digiwalker, bias was −1874 and 2004, both with wide LoA of (13,869 to 10,121) and (−10,932 to 14,940) steps, respectively. The Apple Watch noted the smallest MAD of 7.7% with the Actigraph, whereas the Yamax Digiwalker noted the highest MAD (20.3%). After leave-one-out cross validation, accuracy estimates of MAD of the iHealth Edge and Misfit Shine were within acceptable limits with 10.7% and 11.3%, respectively.

Conclusions: Overall, the Apple Watch and iHealth Edge were positively evaluated after wearing. Validity varied widely between devices, with the Apple Watch being the most accurate and Yamax Digiwalker the least accurate for step count in free-living conditions. The iHealth Edge underestimates number of steps but can be considered reliable for activity monitoring after correction for bias. Misfit Shine overestimated number of steps and cannot be considered suitable for step count because of the low agreement. Future studies should focus on the added value of remotely monitoring activity patterns over time in chronic patients.

(JMIR Form Res 2019;3(2):e11489) doi:10.2196/11489

KEYWORDS

activity trackers; telemedicine; exercise

Introduction

Background

The use of wearable activity trackers has moved into the mainstream, helping people chart their activity behavior over time or see how they perform compared with others. These activity trackers have rapidly evolved from relatively simple mechanical pedometers to sophisticated "connected" activity monitors with built-in accelerometers. Due to this, consumers are increasingly uploading their physical activity record through apps on their mobile phone [1]. Studies have demonstrated that physical activity interventions delivered via internet may result in small increases in activity [2-4].

Activity monitors should not only be used to increase the consumers' awareness about their physical activity behavior. It is widely known that increased physical activity levels significantly improve health in patients with cardiovascular risk factors such as hypertension or obesity [5-9]. In addition, a substantial body of evidence shows that regular physical activity reduces hospital admissions and mortality in patients with chronic obstructive pulmonary disease (COPD) [10-12]. Measuring activity levels is not only useful to provide patients with personalized feedback, a progressive decrease in activity level could also be an early warning sign for deterioration. For example, patients experiencing a COPD exacerbation may become inactive because of sudden worsening of their lung function [10]. Therefore, daily monitoring of physical activity levels in patients with chronic conditions might be important and could be used as additional measurement in electronic health programs to guide patients via telemonitoring to prevent hospital readmissions or unnecessary outpatient visits.

Simple pedometers have been used in health care for decades. For example, to monitor physical activity or to deliver a step count prescription strategy for patients with type 2 diabetes or hypertension [13,14]. However, these pedometers are difficult to use for remote monitoring, as they require the patient to manually record the daily number of steps and to send these data to the caregiver. On the other hand, consumer activity monitors that can be coupled with mobile apps have the potential to result in positive behavior change [15,16]. At the same time, they offer health professionals real-time assessments of their patients' daily activity pattern, which allows adjustment of treatment.

Although these new consumer activity trackers offer considerable promise to health care professionals and patients, their adoption into clinical practice is currently limited. Data of activity trackers are rarely integrated into clinical applications for chronic disease management [17]. In part, this is because of the limited evidence regarding validity and reliability of consumer activity trackers, although some studies have examined the reliability of activity trackers in healthy participants as a measure of free-living activity [18-20]. Although a number of studies show the utility of activity monitors to promote behavior change [21], little research is available that shows the potential of using activity trackers in patients with chronic diseases [22,23], which hampers uptake in clinical practice. At the same time, most application studies that involved the use of smart activity monitors lacked any form of usability testing before implementation in health care [24]. In addition, the added value of remote monitoring of physical activity on clinical outcome is unknown. A recent meta-analysis [4] suggested that remote activity programs resulted in small increases in activity in overweight or obese patients. Furthermore, in the ever-growing activity trackers market, it is unclear which consumer activity trackers are sufficiently reliable to be used for remote monitoring rather than for wellness or sports purposes. Most studies evaluated activity trackers under laboratory conditions or controlled environments, such as treadmill walking [25-28]. These results showed moderate-to-good agreement in measuring steps, except for walking at a slower speed. Activity trackers that are validated during free-living conditions were typically worn for a working-day of 8 hours or less, which makes it difficult to draw conclusions about the ability to remotely detect changes in physical activity over time [29].

Given the large number of activity trackers now commercially available, it is important to validate the accuracy and reliability of consumer activity trackers that can be integrated in third-party apps to be able to remotely monitor the patient's physical activity level. In addition, it is important to evaluate such activity trackers on usability aspects to prevent unnecessary expenses on reliable activity trackers while performance on usability aspects were known inadequate beforehand.

Objective

The objective of this study was to evaluate the usability and test the validity of 3 commercially available activity monitors as a measure of free-living activity within healthy participants. To investigate which consumer activity trackers are suitable for remote monitoring of physical activity, we used a dual approach in which we first evaluated the usability of activity trackers before testing the validity of the activity trackers in healthy volunteers.

Methods

Study Design

The dual approach of this study required the combination of a qualitative and quantitative method. The qualitative part comprised a usability evaluation to explore individuals' perceptions on different consumer-level activity trackers. The results of this usability evaluation were used to select the activity trackers for validation. The quantitative part comprised a validation study with a comparative design to assess the concurrent validity of 3 consumer activity trackers as measure of physical activity compared with the Actigraph GT9X Link

(Actigraph Inc) activity monitor. The Actigraph GT9X Link is considered the gold standard for research grade activity monitoring and has been extensively validated [30,31].

Study 1: Usability Evaluation

A total of 3 consumer-level activity monitors were chosen on the basis of having a software development kit available that allows their data to be integrated with a third-party app to be used for telemonitoring purposes. The following activity trackers were selected: iHealth Edge (iHealth Labs Inc), Misfit Flash (Misfit Wearables), and Apple Watch (Apple Inc) smartwatch.

A total of 10 adult volunteers were asked to wear one of the selected activity trackers for a period of 30 days. The duration of 30 days was chosen to ensure valuable feedback and prevent integrating activity trackers in third-party apps, which are not perceived as user friendly. At the end of the 30-day period, participants were asked to fill in a questionnaire with open and closed questions about wearability, ease of use, and experiences. These results on usability and experience were discussed afterwards with all participants during a round table discussion. Results of this usability evaluation were used to select the activity trackers for validation. Minimum criteria were a neutral or good score on ease of use and at least a neutral or comfortable score on wearability to proceed to the validation phase. In addition, agreement on the selected activity trackers for validation among the participants of the round table discussion was needed.

Study 2: Validation Study

The quantitative part comprised a validation study with a comparative design to assess the concurrent validity of 3 consumer activity trackers as measure of number of steps compared with the Actigraph GT9X Link activity monitor. The results from the usability evaluation were used to select the appropriate activity trackers to proceed with the validation study.

In addition to the 3 selected consumer activity trackers, the Yamax Digiwalker SW-200 pedometer was added as the fourth activity tracker to be examined. Although this pedometer cannot be integrated with third-party apps for telemonitoring purposes, we decided to add this pedometer as this is currently being used as standard of care at the outpatient clinic to check whether patients with hypertension exercise 30 min a day. Consequently, a comparison can be made between the accuracy of this pedometer and the 3 activity monitors. All the activity devices used for validation measure various physical activity parameters, except the Yamax Digiwalker (Table 1).

Recruitment

Participants were eligible to take part if they were aged 18 years or older and reported no known disease or injury that would prevent them from ordinary physical activity for a 72-hour period. Participants were recruited to participate via targeted emails within the Universtity Medical Center Utrecht and by using the individual networks of the researchers. A sample of 30 participants was recruited on the basis of a power calculation with findings of observed step counts (correlation of 0.5), alpha=.05, and a power of 0.80 that indicated a sample size of 28 participants. With an expected dropout rate of 2 participants, it was planned to recruit 30 participants. This is comparable with the sample size used in previous validation studies [32-34]. The study was conducted in accordance with the moral, ethical, and scientific principles as outlined in the Declaration of Helsinki. Formal approval for this study was obtained from the local ethical committee of the University Medical Center Utrecht, the Netherlands (number 16/376).

Table 1. Details of activity measurement devices.

Activity measurement devices	Actigraph GT9X Link (reference monitor)	iHealth Edge (activity tracker)	Misfit Shine (activity tracker)	Yamax Digiwalker SW-200 (pedometer)	Apple Watch (smartwatch)
Parameters measured					
Steps	✓	✓	✓	✓	✓
Distance	x	✓	✓	x	✓
Intensity levels	✓	x	✓	x	x
Heart rate	x	x	x	x	✓
Calories burned	✓	✓	✓	x	✓
Elevation	x	x	x	x	x
Sleep time	✓	✓	✓	x	x
Sleep quality	✓	✓	✓	x	x
Wear site	Right hip (and wrist)	Right hip (and wrist)	Right hip (and wrist)	Right hip (and wrist)	Wrist
Software	Actilife v6.6.3	iHealth MyVitals v	Misfit App v	None	WatchOS

[a]✓: parameter being measured.

[b]x: parameter not being measured.

Data Collection

All participants were asked to attend an appointment just before the start of the study at which demographic data (gender, date of birth, height, and weight) were obtained and an explanation was given about the study. Participants were asked to wear the Apple Watch on the wrist and all other devices on their waist on the right-hand side. Participants were instructed to leave all devices on simultaneously for a 72-hour period (excluding sleep, swimming, and showering) to capture 3 full days of activity. Compliance was checked using the reference device, which automatically detected nonwear time. The wear period was not restricted to a particular period of the week, and no restrictions on activity were provided to ensure representative data of free-living physical activity. Participants were only advised to be cautious not to lose the devices during extreme activities. Furthermore, they were given an iPhone, which was connected to the activity monitors. As the Yamax Digiwalker cannot distinguish among days, participants were asked to write down the number of steps (read from the display) on a step-log sheet that was provided and reset the pedometer by the end of the day. Data collection took place from June to October 2016.

Data Handling

Data were cleaned by removing nonwear time for the activity trackers and the Actigraph reference. Before the start of the 72-hour period of each participant, the Actigraph devices were initialized using the manufacturer's software, ActiLife Version 6.13.2. This software was also used to download all activity data. Data from the Apple Watch were retrieved by importing the xml file, including all data from the Apple Health app. Data from the Misfit Shine were exported using the raw JavaScript Object Notation format. Data from the iHealth Edge were retrieved with comma-separated values' exports. The update rate differed among activity trackers. The Actigraph and iHealth Edge have a fixed update time of once every minute or once every 5 min, respectively. Both the Apple Watch and Misfit have a variable update rate. The steps per day from the Yamax pedometer were retrieved from the written diary of each participant.

Statistical Analysis

Statistical analysis was performed using Matlab (The MathWorks, Inc, Version 2016b). The agreement between the consumer level activity monitors and the Actigraph was assessed by calculating the bias (mean difference), the SD, and the 95% limits of agreement (LoA) as described by Bland and Altman [35]. Furthermore, median absolute difference (MAD) compared with the Actigraph was calculated with the following formula: median of |steps activity tracker–steps Actigraph|/steps Actigraph [33]. The MAD was used as data were highly skewed. We considered a MAD ≤15% to be acceptable for clinical purposes [36]. In addition, a correction for potential bias was estimated and validated using the leave-one-out cross validation. Subsequently, the original data were randomly partitioned into *k* (with *k*=30) subsamples. Of the 30 subsamples, k-1 subsamples were used as training data, and the remaining subsample was used as test data. The cross-validation was repeated k times, each time leaving out a different pair to use as the single test data. Of the predicted estimate, the MAD was calculated and evaluated.

Results

Usability Evaluation

A total of 10 volunteers participated in the usability evaluation for a period of 30 days each. A total of 2 volunteers wore the iHealth Edge, whereas Misfit Flash and Apple Watch each were tested by 4 volunteers. iHealth Edge and Apple Watch were described as comfortable or very comfortable to wear (see Tables 2 and 3). The wearability of the Misfit Flash was perceived as uncomfortable or neutral by 2 out of 4 participants. Moreover, this activity tracker broke down or was lost in 2 cases. Participants reported the following:

> *The fixation was so unstable that I unfortunately lost it.*
>
> *The lifetime of the waist clip is very short.*

No complaints were mentioned regarding the other activity trackers; however, 2 volunteers reported that they needed a little more time to understand the basic working principles of the Apple Watch. One volunteer reported that tapping on the iHealth screen did not always show the number of steps immediately.

On the basis of these results, the Misfit Flash was replaced by the more sustainable Misfit Shine during the subsequent validation study.

Study Population

A total of 30 volunteers participated in the quantitative study. Gender distribution was approximately equal with 14 females and 16 males, with age ranging from 23 to 58 years (mean age 40.4, SD 10.6 years) and body mass index (BMI) ranging from 18.8 to 36.6 kg/m^2—median BMI 23.8 (21.8-25.7).

All 30 participants wore the full set of 3 activity trackers, the pedometer, and reference for a 72-hour period. However, some data were lost because of device malfunctioning (7 days for the Yamax Digiwalker and 3 days for the iHealth Edge), participant error (2 days for Misfit Shine because of losing the activity tracker), empty battery in 3 participants for the Apple Watch, or data extraction error (9 sets of Misfit Shine data). A total of 11 hours were missing for the reference standard in 2 participants. Nonwear time of the reference monitor was analyzed and corrected in all data pairs. Empty or invalid data ("not-a-number") were removed and excluded for analysis. Number of data points received varied considerably among activity trackers. On average, over a period of 72 hours per participant, 4300 data points were received from Actigraph, 722 data points from iHealth Edge, 467 data points from Apple Watch, 33 data points from Misfit Shine, and 2.8 data points from the Yamax Digiwalker. No data points were received during nighttime and showering.

Table 2. Usability evaluation activity trackers in general. For these "general questions" we used the information of all participants asked during the usability part (N=10).

Question	General (N=10)
What is your preferred location to wear an activity tracker?	
Wrist	7
Waist	2
On the shoe	1
Have you worn an activity tracker before?	
Yes	6
No	4
In general, how have you perceived wearing an activity tracker?	
Very bad	0
Bad	2
Not good, not bad	3
Good	4
Very good	1
How important is the look and feel of an activity tracker?	
Not important	0
Slightly important	2
Moderately important	1
Important	7
Very important	0
On which device would you like to see your activity records?	
Phone	10
Tablet	2
Computer	1

Table 3. Usability evaluation of the activity trackers.

Question	Total (N=10)	iHealth Edge (N=2)	Apple Watch (N=4)	Misfit Flash (N=4)
What is the ease of use?				
Very difficult	0	0	0	0
Difficult	0	0	0	0
Neutral	2	1	0	1
Easy	7	1	3	3
Very easy	1	0	1	0
How did you perceive the wearability?				
Very uncomfortable	0	0	0	0
Uncomfortable	1	0	0	1
Neutral	1	0	0	1
Comfortable	6	2	2	2
Very comfortable	2	0	2	0
To what extent stimulated the activity tracker to move more?				
Not at all	2	0	0	2
To some extent	2	1	0	1
To a moderate extent	3	1	2	0
To a great extent	2	0	1	1
To a very great extent	1	0	1	0

Level of Agreement

Activity as measured with the reference device varied between 10,757 and 35,818 steps (median: 21,527 steps, IQR 17,475-24,809). Bias and precision (95% LoA) from comparisons between the activity trackers and the reference standard are shown in Table 4. The mean difference (bias) in steps was 968 between the Actigraph and Apple Watch, with a 95% LoA of −5478 to 7414 steps over a 72-hour period. The iHealth Edge showed a mean difference of 2021 and a 95% LoA of −4994 to 9036 steps. The Misfit Shine showed a mean difference of −1874 steps with wide limits levels of agreement (95% LoA: −13,869 to 10,121 steps). The mean difference of the Yamax Digiwalker compared with the Actigraph was on average 2004, also with wide levels of agreement (95% LoA of −10,932 to 14,940 steps).

Figures 1 to 4 illustrate the Bland-Altman plots of all 4 activity trackers. The Apple Watch (Figure 1) and iHealth Edge (Figure 2) showed the narrowest LoA, whereas the Misfit Shine and Yamax Digiwalker both showed wide LoA (Figures 3 and 4).

Table 4. Bland-Altman analysis for the activity measurement devices versus the reference monitor.

Activity measurement devices	MAD[a] (%)	SD	Bias[b]	Lower 95% LoA[c]	Upper 95% LoA	MAD (% after correction)[d]
Apple Watch	7,7	3289	968	−5478	7414	10.3
iHealth Edge	19,0	3579	2021	−4994	9036	10,7
Yamax Digiwalker	20,3	6600	2004	−10,932	14,940	21.6
Misfit Shine	16,7	6120	−1874	−13,869	10,121	11.3

[a]MAD: median absolute differences.

[b]A positive bias indicates an underestimation of number of steps, whereas a negative bias means an overestimation.

[c]LoA: limits of agreement.

[d]Accuracy estimate using leave-one-out cross validation.

Figure 1. Bland-Altman plot for Apple Watch versus Actigraph step counts over a 72 hour period (n=30).

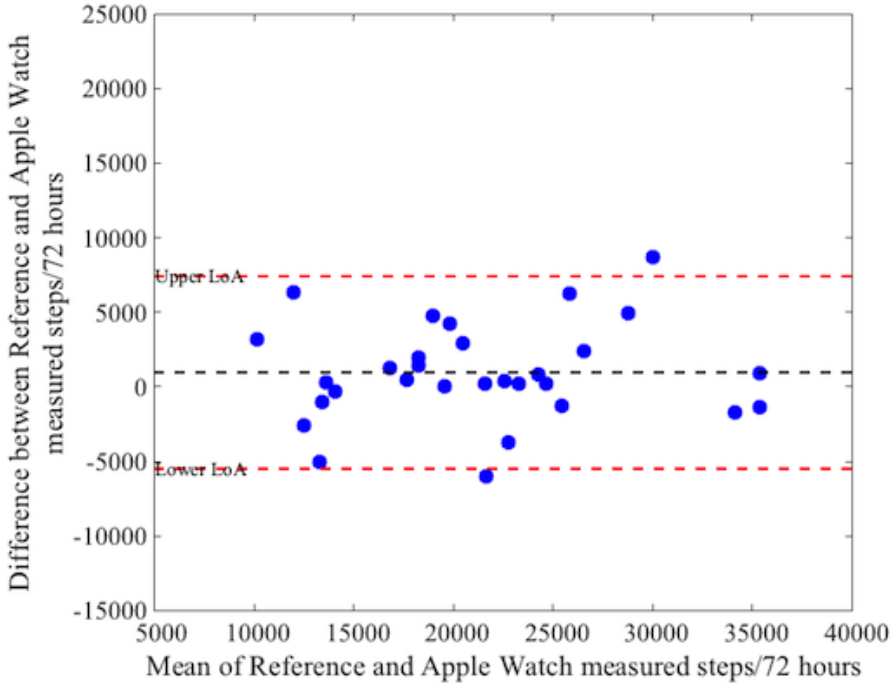


Figure 2. Bland-Altman plot for iHealth Edge versus Actigraph steps over a 72 hour period (n=30).

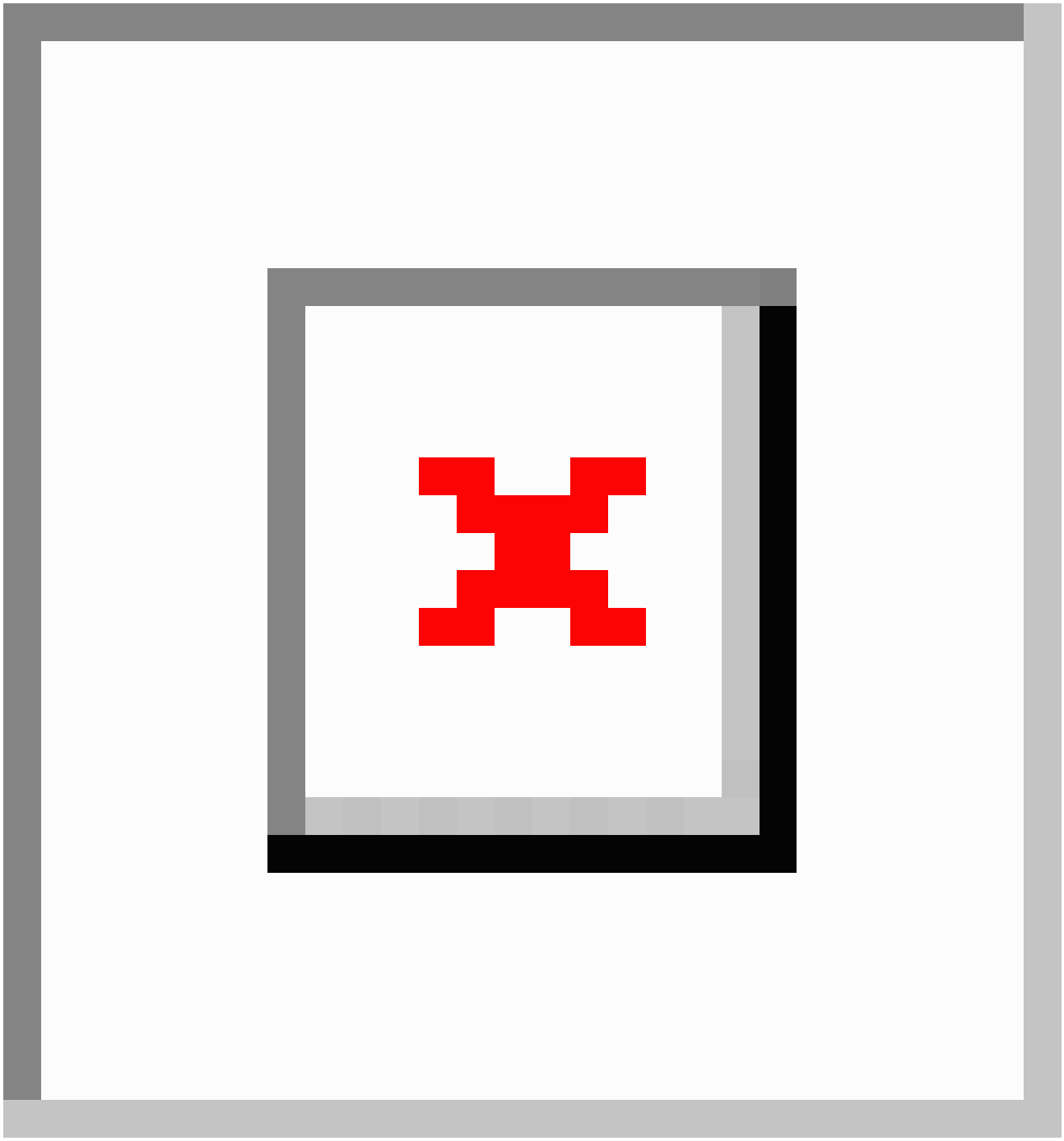


Figure 3. Bland-Altman plot for Misfit Shine versus Actigraph steps over a 72 hour period (n=21).

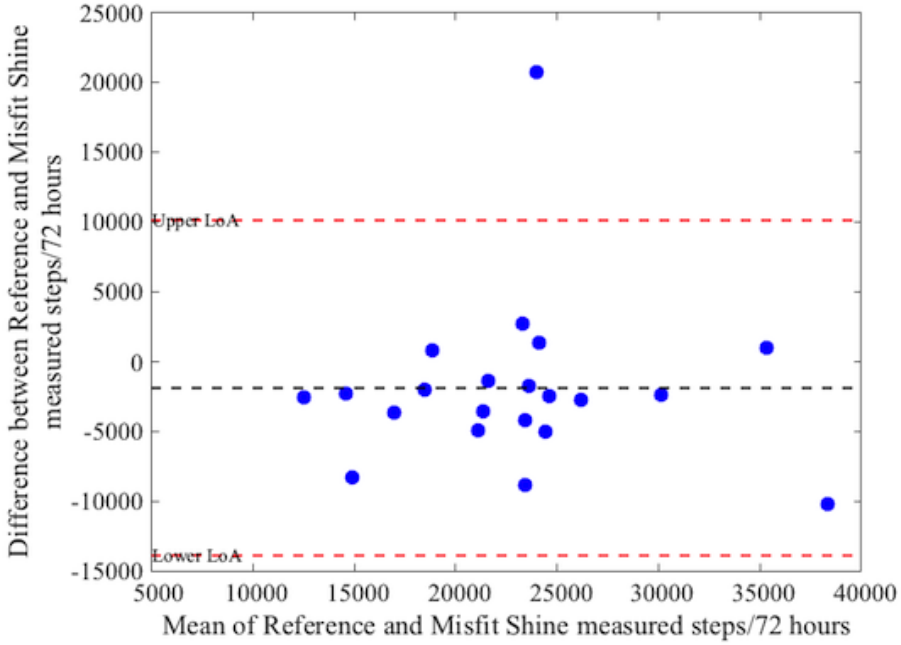
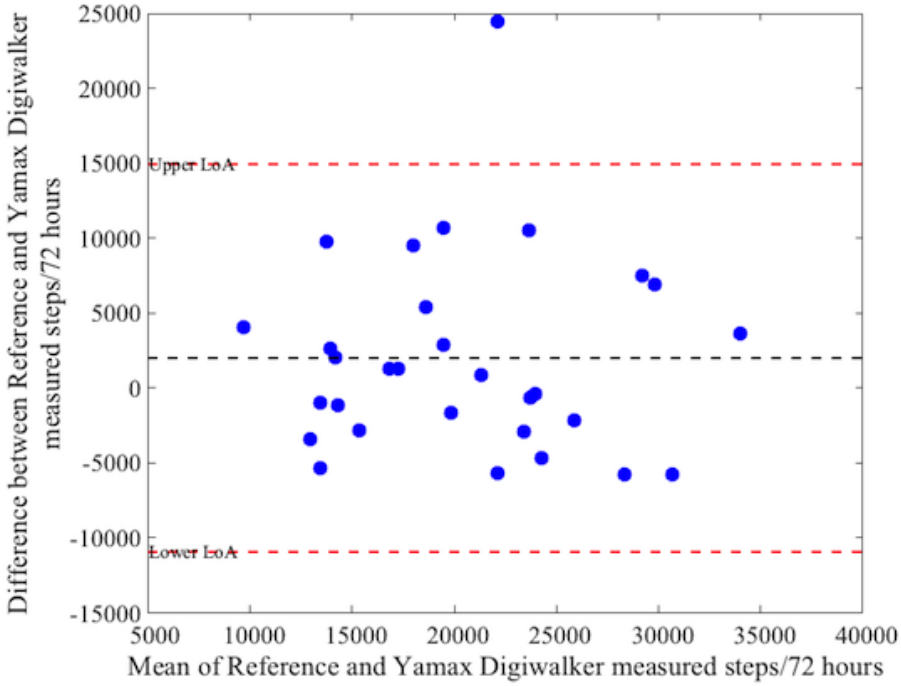


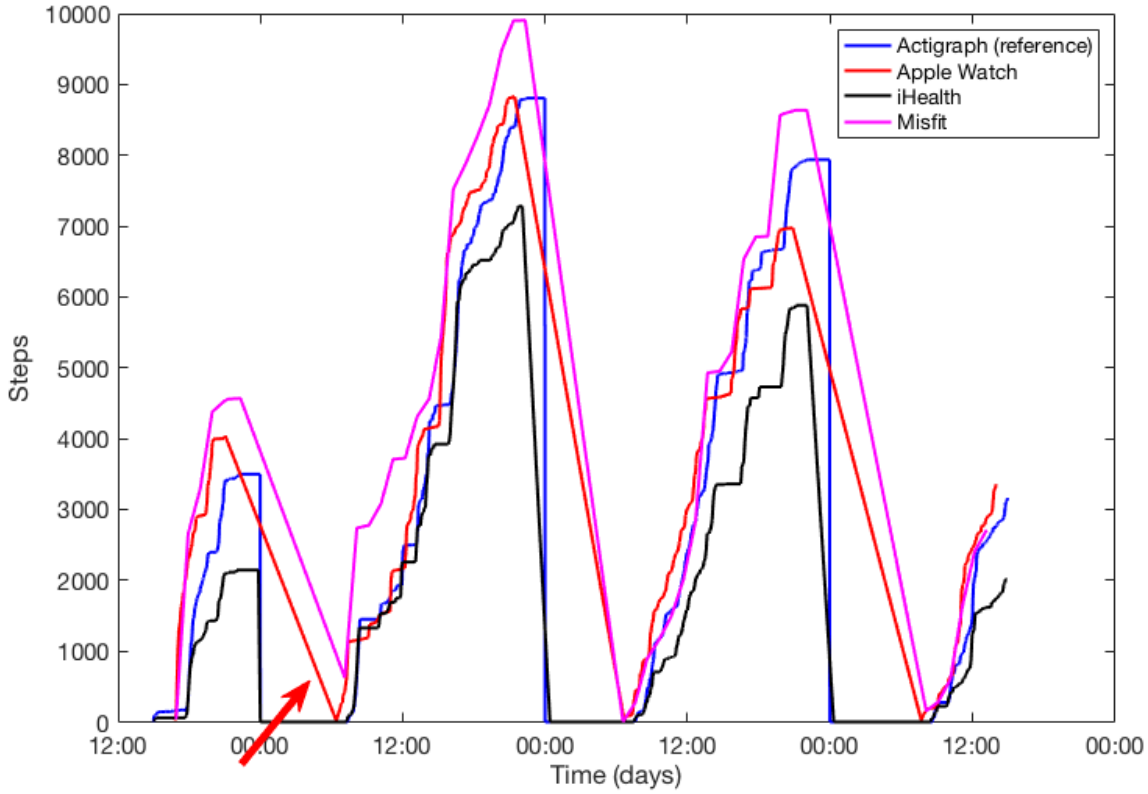
Figure 4. Bland-Altman plot for Yamax Digiwalker versus Actigraph steps over a 72 hour period (n=30).



Median Absolute Difference

The MAD percentages are shown in Table 3. The Apple Watch noted the smallest MAD of 7.7% with the Actigraph. The MAD of the iHealth Edge, Yamax Digiwalker, and Misfit Shine were higher than the accepted clinical difference of 15% (19.0%, 20.3%, and 16.7%, respectively). Note that the number of steps of the Misfit Shine (SD 6120) and Yamax Digiwalker (SD 6600) was highly variable when compared with the iHealth Edge (SD 3579) and Apple Watch (SD 3289). After correction for potential bias using leave-one-out cross validation, the accuracy estimates for MAD improved for the iHealth Edge (10.7%) and Misfit Shine (11.3%). Figure 5 shows an example of the number of steps of all activity trackers of 1 participant. Although the MAD of the Misfit Shine compared with the Actigraph after leave-one-out cross validation may be clinically acceptable, it seems to add number of steps (ie, not reset to 0 completely) during the first night. After inspection, this pattern was seen in 13 participants.

Figure 5. Example of the number of steps over time of the different activity trackers within one participant. The red arrow is pointed towards the number of steps of Misfit Shine that seems to add number of steps overnight or at the beginning of a day.



Discussion

Principal Findings

In this study, we investigated the performance of different activity trackers intended for potential use in clinical monitoring applications. In 2 studies, we evaluated the usability of different consumer-level activity monitors and subsequently validated selected activity monitors in adult healthy volunteers during free-living conditions. Usability evaluation showed inferior usability of the Misfit Flash activity tracker and better usability of the iHealth Edge and Apple Watch. The validation study showed that the performance of activity monitors varied considerably. The Apple Watch can accurately measure number of steps with a deviation within 15% of the reference standard. In contrast, the accuracy of both Misfit Shine and Yamax Digiwalker was outside the limits we considered acceptable. The mean difference of the iHealth Edge with the Actigraph was high and showed substantial underestimation of steps. After correction for bias using leave-one-out cross validation, accuracy of the iHealth Edge was within acceptable limits. The accuracy of Yamax Digiwalker did not improve after correction for bias, and it was therefore least accurate as compared with the activity trackers with accelerometer. Furthermore, the wide level of agreement and the inability to measure the number of steps more frequent during the day makes this conventional pedometer unsuitable for step count monitoring.

Although the mean difference of the Misfit Shine with the Actigraph was acceptable after leave-one-out cross validation, it cannot be considered suitable for step count monitoring because of the low agreement. In addition, Misfit Shine seems to add number of steps overnight or at the beginning of a day (ie, not completely reset to 0) or at the beginning of a day. We do now know what caused this phenomenon but speculate that it may be related to the low frequency of data transmission from the activity tracker to the mobile phone (approximately once every 2 hours).

Physical activity monitors that allow patients to upload their data within a clinical telemonitoring app may offer significant advantages over traditional pedometers, as it helps doctors remotely to assess their patients' activity pattern over time and inform treatment [37]. To rely on such activity monitors, it is important to be able to recognize trend patterns in activity over time. Given the results on accuracy and usability in this study, the use of the Apple Watch seems a suitable device to measure physical activity for telemonitoring. Although the MAD of the Misfit Shine improved after leave-one-out cross validation, the number of steps is highly variable. Therefore, a low MAD may not necessarily indicate a high reliability as can be seen in Figure 5. Furthermore, it should be noted that using the iHealth Edge for telemonitoring purposes may disappoint or discourage patients who try to reach their daily activity goals because of the underestimation in steps. However, one might decide to correct for the systematic underestimation.

The results of this study show that not all consumer activity trackers are reliable enough for use in telemonitoring purposes. Both the Apple Watch and iHealth Edge could be used to

integrate in third-party apps for personalized care of chronic patients. However, health benefits are only achieved when patients engage in using activity trackers for a prolonged time. A recent yearlong study showed that the use of the Fitbit Zip barely motivated people to move more over time [38]. After the incentive period with cash stopped at 6 months, compliance to wear the activity tracker dropped further from 90% to 40% at 12 months. This suggests that it may be difficult to persuade patients to use the activity tracker for a long time. However, this is difficult to conclude, as cash incentives may work different on intrinsic behavior [39]. At this point, a smartwatch such as the Apple Watch may favor prolonged use, as it returns individualized feedback on the basis of monitoring.

Limitations

This study has some limitations. First, it should be noted that this study was conducted in healthy participants and not in chronic patients who may have different activity patterns, although it is also known that reliability of activity trackers is reduced at slower walking speed [28,40,41]. In addition, participants were not asked to annotate their variety of different activities from low to more intensive exercise. Consequently, activity trackers may perform differently during different exercise levels. The advantage of this method was that we could identify the reliability of the trackers during free-living conditions, which is more realistic than within a controlled environment. The latter is important when remote monitoring of physical activity levels is being used for telemonitoring purposes.

In this study design, both a usability evaluation and a validation study were performed. Although the combination of a qualitative and quantitative approach is a strength of this study, the number of volunteers who evaluated each of the activity trackers on usability was limited. However, it was assumed that user experience needed to be sufficient before proceeding to the validation phase. Without this usability evaluation, other activity monitors would have been validated, which potentially will not be used for remote monitoring. Conducting both studies separately would therefore not direct to the conclusions as provided in this study.

A third limitation was the use of only step counts as outcome measure of physical activity. The number of steps may not give an adequate picture regarding the amount of physical activity; therefore, intensity of movements and the amount of time spent in different intensities would be more effective to use. Nevertheless, remote monitoring of the number of steps over time may still recognize a changing trend in activity. For example, inactivity in patients with COPD may be recognized as a manifestation of disease severity or the onset of an exacerbation [10]. Another limitation was that the results of the activity trackers were compared with fewer number of Misfit Shine measurements because of errors in extraction of the data. However, the weak correlation of Misfit with the reference monitor and the highly variable mean differences in steps over time make more accurate results for a larger dataset of Misfit measurements unlikely.

Comparison With Previous Work

The design of this study is unique; therefore, other studies that confirm our findings are limited. Most of the research studies have used Fitbit devices and found preliminary evidence for validity in measuring steps, although some of the results have recorded significant higher number of steps during free-living conditions [18,19,33]. These differences could arise from differences in instrument sensitivity thresholds of devices or because of differences in attachment while wearing the activity tracker [42]. The high variety in number of steps measured over 72 hours among subjects and among devices may be explained by the longer measurement period or could be a result of more nonwalking activities. The few studies that investigated the Misfit Shine all reported good agreement with the reference device in contrast to the findings of this study [29,33,43,44]. This may be explained by the different measurement setups, which was either a controlled environment where participants were instructed to walk repeated sets of 200, 500, or 1000 steps [43], or the analysis included only a maximum of 1 full calendar day or 1 working day, and as such, this may not fully represent free-living conditions [33,36]. As found in this study, the study by Farina et al [44] also found an overestimation of the number of steps with the waist-worn Misfit Shine; however, they found good agreement as compared with the reference. The main difference with this study is that healthy community dwelling older adults with a mean age of 72.5 years were asked to participate, which is much higher as compared with the mean age of this study (40.4 years).

Although it is known that Apple Inc collected more data on activity with the Apple Watch in their exercise lab, results within literature are scarce. One study showed high accuracy (>99.1%) for step count, but these results were obtained under controlled walking conditions [43]. Although the Actigraph is the most commonly used reference standard during research studies, another study showed weak-to-moderate accuracy of the Actigraph during slower speeds (3.2 and 4.0 km/h^{-1}) when compared with manually counted steps [34]. It is likely that participants in this study may have been active with lower speeds as well, as most of them also wore the activity trackers during working hours where a slower speed is common. A recent study showed that the mean relative error of the iHealth Edge increases when speed decreased in healthy adults during laboratory conditions [45]. However, the iHealth Edge has not been studied within free-living conditions to confirm the findings of this study. The Yamax Digiwalker used to be one of the best pedometers with regard to accuracy for counting steps years ago [26,46], but the accuracy of a pedometer highly depends on the placement on the waist. The other activity monitors investigated in this study contain microelectromechanical system accelerometers, which can track acceleration in 3 dimensions, and therefore provide increased sensitivity. In this study, no steps were counted in 7 days, possibly because of wrong placement. Furthermore, the accuracy on measuring the number of steps was least accurate as compared with the activity monitors with accelerometers. Beside this, the number of steps can only be manually collected once a day. Therefore, the Yamax Digiwalker is not suitable for objectively measuring the number of steps.

The findings of this study extend the previous research by indicating that the Apple Watch and iHealth Edge can accurately measure steps in-free living conditions over longer durations. As opposed to previous studies, none of the research performed show results on the consistency and variability of steps measured over time as compared with the results as shown in Figure 5 of this study. Furthermore, none of the studies showed results of coupled activity trackers within third-party apps for remote monitoring. Future research should use a more comprehensive framework to study a variety of usability aspects of patients who interact with activity trackers. We also suggest that future studies should integrate validated activity trackers within clinical apps to become part of the treatment "prescription" of health care professionals for remote monitoring of patients.

Conclusions

The Apple Watch is usable and reliable for activity monitoring within healthy participants. The iHealth Edge underestimates number of steps, but it can be considered reliable for activity monitoring after correction for bias. Misfit Shine overestimated number of steps and cannot be considered reliable because of high variability. The Yamax Digiwalker pedometer performed least accurately for step count and is not reliable to indicate number of steps per day. Both Apple Watch and the iHealth Edge show the potential to be integrated within clinical apps for tracking activity patterns over time. Future studies should focus on the added value of monitoring activity trend patterns within chronic patients, whether or not in combination with other vital signs measured remotely.

Acknowledgments

The authors would like to thank Petra Boddé, Ruben van Eijk, and Marieke Vissers from the University Medical Center Utrecht for their great support and assistance in study execution.

Conflicts of Interest

At the time of the study, MB and JJ were employees of FocusCura (Health IT company, Driebergen-Zeist, The Netherlands), and DD is founder and CEO of FocusCura.

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Abbreviations

BMI: body mass index
COPD: chronic obstructive pulmonary disease
IQR: interquartile range
LoA: limits of agreement
MAD: median absolute differences

Edited by G Eysenbach; submitted 06.07.18; peer-reviewed by S O'Keefe, J Lei, E Chiauzzi; comments to author 06.10.18; revised version received 28.11.18; accepted 27.01.19; published 24.04.19.

Please cite as:
Breteler MJM, Janssen JH, Spiering W, Kalkman CJ, van Solinge WW, Dohmen DAJ
Measuring Free-Living Physical Activity With Three Commercially Available Activity Monitors for Telemonitoring Purposes: Validation Study
JMIR Form Res 2019;3(2):e11489
URL: http://formative.jmir.org/2019/2/e11489/
doi:10.2196/11489
PMID:31017587

Original Paper

An Adaptive Mobile Health System to Support Self-Management for Persons With Chronic Conditions and Disabilities: Usability and Feasibility Studies

I Made Agus Setiawan[1,2], MSc; Leming Zhou[1], ScD, PhD; Zakiy Alfikri[1], MS; Andi Saptono[1], PhD; Andrea D Fairman[3], OTR, PhD; Brad Edward Dicianno[4,5], MD; Bambang Parmanto[1], PhD

[1]Department of Health Information Management, School of Health and Rehabilitation Sciences, University of Pittsburgh, Pittsburgh, PA, United States

[2]Department of Computer Science, Udayana University, Badung, Bali, Indonesia

[3]Department of Occupational Therapy, School of Health and Rehabilitation Sciences, MGH Institute of Health Professions, Boston, MA, United States

[4]Department of Rehabilitation Science and Technology, School of Health and Rehabilitation Sciences, University of Pittsburgh, Pittsburgh, PA, United States

[5]Department of Physical Medicine and Rehabilitation, School of Medicine, University of Pittsburgh, Pittsburgh, PA, United States

Corresponding Author:
Bambang Parmanto, PhD
Department of Health Information Management
School of Health and Rehabilitation Sciences
University of Pittsburgh
6025 Forbes Tower
Pittsburgh, PA, 15260
United States
Phone: 1 412 383 6649
Email: parmanto@pitt.edu

Abstract

Background: Persons with chronic conditions and disabilities (PwCCDs) are vulnerable to secondary complications. Many of these secondary complications are preventable with proactive self-management and proper support. To enhance PwCCDs' self-management skills and conveniently receive desired support, we have developed a mobile health (mHealth) system called iMHere. In 2 previous clinical trials, iMHere was successfully used to improve health outcomes of adult participants with spina bifida and spinal cord injury. To further expand use of iMHere among people with various types of disabilities and chronic diseases, the system needs to be more adaptive to address 3 unique challenges: 1) PwCCDs have very diverse needs with regards to self-management support, 2) PwCCDs' self-management needs may change over time, and 3) it is a challenge to keep PwCCDs engaged and interested in long-term self-management.

Objective: The aim of this study was to develop an *adaptive* mHealth system capable of supporting long-term self-management and adapting to the various needs and conditions of PwCCDs.

Methods: A scalable and adaptive architecture was designed and implemented for the new version, iMHere 2.0. In this *scalable* architecture, a set of mobile app modules was created to provide various types of self-management support to PwCCDs with the ability to add more as needed. The *adaptive* architecture empowers PwCCDs with personally relevant app modules and allows clinicians to adapt these modules in response to PwCCDs' evolving needs and conditions over time. Persuasive technologies, social support, and personalization features were integrated into iMHere 2.0 to engage and motivate PwCCDs and support long-term usage. Two initial studies were performed to evaluate the usability and feasibility of the iMHere 2.0 system.

Results: The iMHere 2.0 system consists of cross-platform client and caregiver apps, a Web-based clinician portal, and a secure 2-way communication protocol for providing interactions among these 3 front-end components, all supported by a back-end server. The client and caregiver apps have 12 adaptive app modules to support various types of self-management tasks. The adaptive architecture makes it possible for PwCCDs to receive personalized app modules relevant to their conditions with or without support from various types of caregivers. The personalization and persuasive technologies in the architecture can be used to engage PwCCDs for long-term usage of the iMHere 2.0 system. Participants of the usability study were satisfied with the iMHere 2.0 client app. The feasibility evaluation revealed several practical issues to consider when implementing the system on a large scale.

Conclusions: We developed an adaptive mHealth system as a novel method to support diverse needs in self-management for PwCCDs that can dynamically change over time. The usability of the client app is high, and it was feasible for PwCCDs to use in supporting personalized and evolving self-care needs.

(JMIR Form Res 2019;3(2):e12982) doi:10.2196/12982

KEYWORDS

mHealth; adaptive mHealth; mobile apps; telemedicine; personalized medicine; self-management; self-care; caregivers; chronic disease; persons with disabilities

Introduction

Background

Chronic conditions have become one of the greatest challenges for the US health care system [1]. According to a report published in 2017, 60% of US adults had at least 1 chronic condition, 42% had more than 1 chronic condition, and 12% had 5 or more chronic conditions [1]. People with chronic conditions account for 90% of health care spending [1,2], and the spending on health care services increases with the number of chronic conditions [1]. More specifically, the 12% of Americans with 5 or more chronic conditions account for 41% of total health care spending. In addition, about a quarter of persons with chronic conditions have some type of disability (hereafter, *persons with chronic conditions and disabilities*—PwCCDs, in this paper). These disabilities limit daily activities and social participation, can significantly impact quality of life, and can increase susceptibility to developing secondary complications [1,2].

One population of PwCCDs is individuals with pediatric onset or congenital malformations of the brain and spinal cord, including individuals with spina bifida (SB) and cerebral palsy (CP). SB is the most common permanently disabling birth defect in the United States [3]. SB refers to the incomplete development of the neural tube closure, which results in loss of sensation and major muscle weakness in the lower portion of the body [4]. Individuals with SB are at substantial risk for paralysis, bladder dysfunction and gastrointestinal issues, and orthopedic abnormalities [4]. CP involves impairment of motor function as a result of brain damage, which often occurs to the cerebral motor cortex owing to nonprogressive disturbances during brain development in fetuses or infants. Individuals with CP experience varying levels of activity limitation [5,6]. Other issues include gastrointestinal and urinary problems, abnormal neurologic control, abnormal sensation and perception, mental health issues, epilepsy, and intellectual disability [5-8]. Some of these conditions can lead to other secondary conditions, such as urinary tract infections and pressure ulcers [9-11]. These secondary complications can have a major impact on all aspects of an individual's life.

Self-management support has been found to be useful for PwCCDs to prevent secondary complications [12-14]. However, it is challenging to provide desired self-management support to PwCCDs for several reasons.

First, many different chronic conditions exist and these vary in severity and differ broadly in terms of characteristics. Consequently, PwCCDs have *very diverse needs with regard to self-management support*.

Second, the phases of chronic conditions and life circumstances change over time [15]. Many chronic conditions become worse over time without treatment or become better with proper treatment. PwCCDs also commonly experience change in their emotional states, such as frustration and depression [16]. When these changes happen, adjustments in the self-management strategy need to take place. For instance, an individual may need certain self-management support to prevent pressure ulcers, but once an ulcer develops, a different self-management routine may be needed to treat it. Moreover, different individuals may need to follow different treatments for pressure ulcers depending on their own particular circumstances, for example, the location or depth of the wound may necessitate different treatment strategies. In other words, *PwCCDs' self-management needs may change over time*. Therefore, the strategies to support self-management vary by individual and within the individual over the course of a lifetime.

Third, the majority of chronic conditions and disabilities are inherently long-lasting, generally lifelong [17]. Therefore, the self-management will be long-term as well [16]. As a result, it is a challenge *to keep PwCCDs engaged and interested in long-term self-management*.

A mobile health (mHealth) intervention is one approach to encourage proactive self-management skills and improve well-being to reduce the development of secondary complications and health care costs [18-20]. Several studies have evaluated the benefit of mHealth in managing chronic conditions [21-24], and the results indicated that mHealth could provide better adherence to intervention regimens, such as compliance with taking medications, and better self-tracking capability to support self-management. Therefore, mHealth showed promise in promoting health-related activities.

Previous studies have also indicated that social influence from caregivers would be helpful for long-term adherence to self-management [25,26]. The integration of persuasive technologies to induce action or foster belief through encouragement or inspiration may help to maintain the level of engagement in a long-term care plan [27-29]. Moreover, a recent study revealed the importance of personalization and adaptability of digital support in different contexts for supporting self-management of PwCCDs [30].

However, currently there is no integrated mHealth system available for adaptive and long-term self-management support, especially for PwCCDs.

Objectives

The aim of this study was to develop an adaptive mHealth system, Interactive Mobile Health and Rehabilitation (iMHere) 2.0, which can support self-management for long-term usage and allow PwCCDs to receive personalized and adaptive treatment strategies according to their needs and conditions. It is expected that this system will provide the ability to personalize the treatment strategies at any time according to the PwCCDs' specific situation, which may eventually prevent many secondary conditions and improve quality of life.

Methods

Overview

This project utilized the information and experience obtained from previous studies to create an adaptive mHealth system [31-39]. The system incorporates persuasive technologies and social support to maintain the level of engagement of PwCCDs [25-29]. As we desired to expand use of the system to different diagnoses and demographics, a user-centered approach was used to gather knowledge of additional requirements [40]. The iMHere 2.0 system was iteratively designed and incrementally developed and evaluated with users involved in all stages. Figure 1 shows the general workflow of the iMHere 2.0 system development. PwCCDs with different diagnoses and demographics were involved in all of these steps, providing requirements, feedback, and comments.

The findings from the previous studies and the themes elicited from the focus groups are highly consistent [31-40]. These findings and themes revealed that a significant architecture change was necessary to improve the iMHere system. Following are several major changes incorporated in the iMHere 2.0 system in response:

- Redesign of the overall architecture of the system to make it *scalable* and convenient to add more components and new mobile app modules into the system.
- Implementation of *adaptive intervention* approaches to allow the system to address different characteristics and needs in different individuals and within individuals over time [41].
- Incorporation of social support from caregivers via a mobile app to maintain PwCCDs' long-term engagement in the mHealth system [40].
- Ability of the mHealth apps to run on different platforms, including Android, iOS, and Windows Phone systems, which makes the iMHere 2.0 system available to almost any PwCCDs [42].
- Enhancement of the existing mobile app modules (iMHere 1.0 with 5 modules) and addition of 7 new modules to meet the need for diverse types of self-management support.
- Addition of accessibility features to increase the ease of use of the mobile app, especially for individuals with fine motor and visual impairments [36].

A Scalable System Architecture

The iMHere 2.0 system consists of 5 components: a client app, a caregiver app, a Web-based clinician portal, a back-end server, and a 2-way secure communication protocol (see Figure 2). The first 3 are user-facing front-end components.

The client app is used by the PwCCDs (client) for self-management via a set of modules tailored to the PwCCDs' needs. The client app can synchronize PwCCDs' care data among multiple personal mobile devices, the caregiver's app, and the Web-based portal.

The caregiver app is for caregivers (family members, friends, and professional caregivers) to provide monitoring and social support to the PwCCDs. Both the client and caregiver apps can run on multiple mobile platforms including Android, iOS, and Windows Phone systems.

The Web-based portal is for clinicians to monitor the PwCCDs' progress and prepare the intervention regimens. All data from the client app are presented in the Web-based portal to help clinicians evaluate the PwCCDs' progress and then perform adjustment on the intervention regimens if needed. In other words, according to the PwCCDs' current situation, the clinician can easily update their intervention strategies for an individual PwCCD via the Web-based portal and synchronize it to the client and caregiver apps in real time. The 2-way secure communication protocol enables all 3 front-end components to communicate in real time.

Figure 1. Timeline and workflow of the iMHere 2.0 system development.

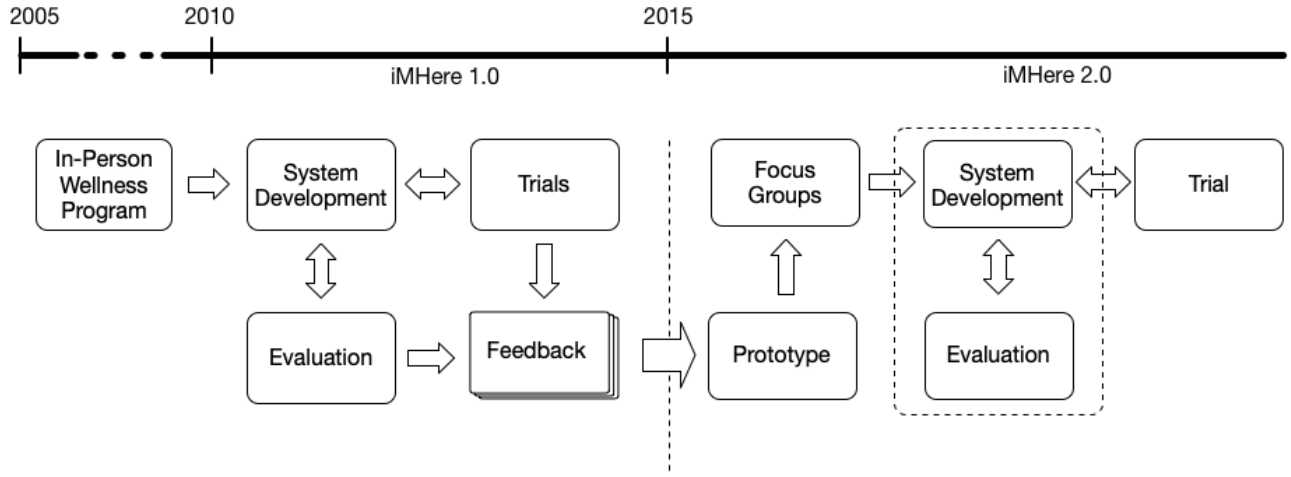
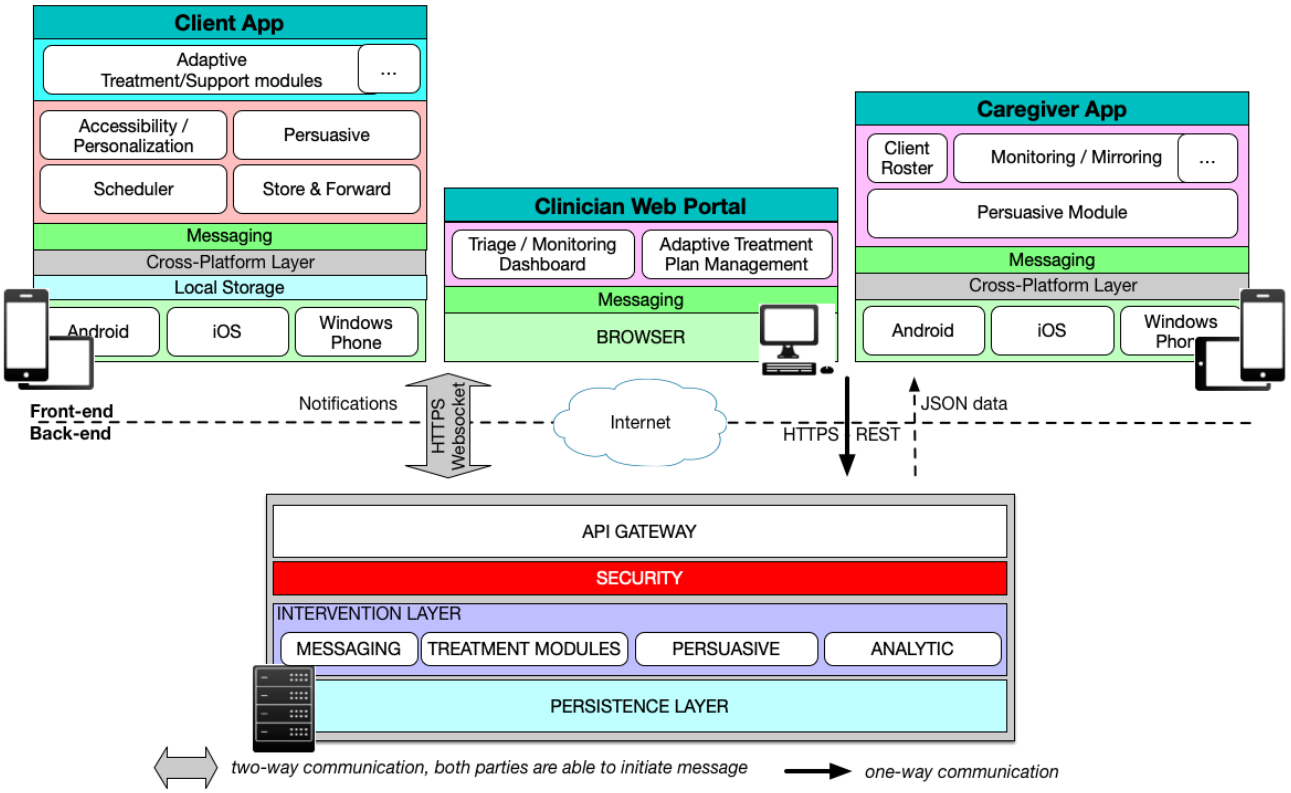


Figure 2. The architecture of the iMHere 2.0 system.



All 3 components are connected and supported by the back-end server, which has been designed to be highly scalable using microservices. In microservices, applications are composed of multiple small independent services that can be implemented and deployed independently [43]. This approach offered us the possibility of extending the iMHere 2.0 system without disturbing the other existing components. For example, one can add a new app module into the iMHere 2.0 system for PwCCDs with needs that are unavailable in the current version; one can also link the iMHere 2.0 system with an external electronic health record system to exchange patient information.

This scalable system architecture provides the foundation for creating various types of self-management app modules to meet the highly diverse needs of PwCCDs. In the next section, we have described the 12 app modules created on this scalable architecture to demonstrate this feature.

A Web-Based Clinician Portal for Personalized and Adaptive Interventions

The primary purpose of the Web-based portal is to allow clinicians to prescribe personalized treatment plans, monitor the PwCCDs' conditions and their adherence to the intervention regimens, perform adjustments on the regimens according to the progress of the PwCCDs (Figure 3), and communicate with the PwCCDs via instant messaging. All information regarding PwCCDs' adherence to intervention regimens and data from the client app are presented in the portal to help clinicians evaluate PwCCDs' progress. Communication with PwCCDs can be engaged in through the messaging feature, if there is any issue that clinicians want to discuss with PwCCDs. Once a clinician adjusts a PwCCD's treatment plan on the Web-based portal, the changes are immediately pushed to the client and caregiver apps.

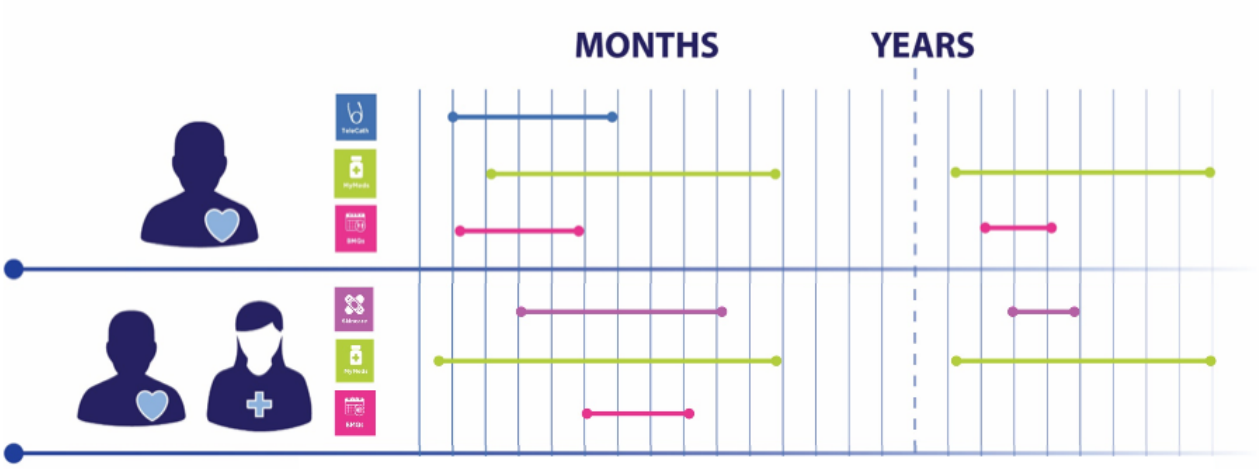
Client App Modules for Diverse Self-Management Needs

The current version of the iMHere 2.0 client app has 12 app modules. They were created according to feedback from clinicians, caregivers, and PwCCDs themselves [31-40]. In total, 5 of these app modules (MyMeds, BMQ, TeleCath, Mood, and Skincare) are an updated version of the 5 existing modules in the iMHere 1.0 system.

The major update on these 5 app modules included providing more flexible ways for the user to arrange schedules and improving the accessibility. The updated app modules provide the capability to create a fine-grain schedule for reminders, including the ability to make different schedules for weekdays and the weekend as well as hour-based schedules. A customized camera feature was added in the Skincare module to guide the user in taking more consistent wound pictures, and a binding physical button was added to trigger the camera in addition to the soft-button on the screen [34].

These 5 updated app modules are able to provide support for medication management, bowel management, bladder self-catheterization, mood assessment, and skin problem reporting and tracking. For instance, the new version of the MyMeds module provides a mechanism for tracking medication that is taken on an as needed basis, such as medication for pain.

Figure 3. Different support between clients and for one client across time. The icon and color of the line correspond to a specific app module and the length of the line shows the duration of using each app module.



As the client app will be used for long-term care, the screening test for depression and anxiety using the complete version of the Patient Health Questionnaire (PHQ-9) and Generalized Anxiety Disorder (GAD-7) may add too much burden if performed on a weekly basis. Therefore, in the updated Mood module, shorter versions of the 2 instruments (PHQ-2 and GAD-2) are used [44,45]. A follow-up evaluation will be performed using the complete version of PHQ and GAD if the screening shows positive results [44,45].

In all 5 modules, a feedback mechanism was added to inform the user of their adherence status.

The other 7 app modules are new. They were added into the iMHere 2.0 system to provide more diverse self-management services to PwCCDs. These include the following:

1. *Exercise*: This module allows PwCCDs to keep track of the exercise and physical activity they perform each day as well as the duration (in minutes) of each. A library of 49 activities (eg, stretching, hand-cycling, gardening, shopping, strolling, and horseback riding) was provided so that the PwCCDs can easily make selections and record the duration of each activity. PwCCDs are also able to add new activities if they are not available in the activity library.
2. *Nutrition*: This module allows PwCCDs to keep track of their food and drink consumption daily by simply checking the serving amount for each. A slightly modified MyPlate program was used to guide PwCCDs' daily food and drink consumption [46], including water, fruit, vegetables, grains, protein, dairy, cheese, fast food, snacks, and caffeine.
3. *Education*: This module consists of 12 major sections covering topics relevant to supporting self-management routines, such as information about SB, CP, spinal cord injury (SCI), skin integrity, bowel and bladder, exercise, nutrition, time management, relationship, stress management, and anxiety. This module can deliver health-related information to PwCCDs that is tailored to their conditions. Various types of information delivery approaches are included in the Education module, such as text, picture, audio, and video. Self-assessment in the form of quizzes is provided to allow PwCCDs to evaluate their own knowledge.
4. *Goals*: This module allows PwCCDs to keep track of their progress toward their goals and to rate their progress periodically using a 10-point scale.
5. *Personal health record (PHR)*: This module allows PwCCDs to securely manage their own health information, such as medical history, surgical history, past and current medications, allergies, immunization history, family history, and social history. This module was created to encourage PwCCDs to play a more active role in their own health data management and to make frequently used health records readily available when needed.
6. *Supplies*: This module allows PwCCDs to keep track of needed supplies and set up reminders to reorder each supply at an indicated time.
7. *Wheelchair*: This module is a guidebook for wheelchair users. This guidebook contains information about the manual and power wheelchairs, such as information on wheelchair components, guidance on how to set up a wheelchair, and video tutorials about how to master wheelchair use skills.

These app modules are presented here as examples of the diverse self-management services offered by the iMHere 2.0 system. The scalable architecture will allow us to add more app modules easily into this system in the future to meet the needs of other PwCCD populations when needed.

Caregiver App for Monitoring and Social Support

The iMHere 2.0 caregiver app is a companion app for PwCCD caregivers. The caregiver app mirrors the app modules in the client app so that the caregiver can monitor the status of a PwCCD in each module and then deliver positive reinforcement to the PwCCD in the form of thumbs up symbols and motivational messages. Motivational messages can be selected from prebuilt templates in the caregiver app or custom messages can be entered by the caregiver. In this app, the caregiver can also set up an amount of points to be awarded for meeting each goal to encourage PwCCDs to reach those goals.

There are several different situations that may exist related to the number of caregivers and the type of caregiver. PwCCDs may have no caregiver, 1 caregiver, or multiple caregivers.

Caregiving can be provided by family members, friends, or professional (paid) caregivers. In some instances, the paid caregivers are the PwCCDs' family members or friends. The iMHere 2.0 system was designed to support all of these caregiver situations. Each type of caregiver is implemented as a different role in a role-based access control approach. Once a caregiver becomes a member of the PwCCDs' care team and chooses 1 specific caregiver role, the corresponding settings are applied to the caregiver app and the caregiver is able to monitor the situation of the PwCCD and provide appropriate positive reinforcement through the caregiver app.

Customizable User Interface

Significant efforts have been made in the iMHere 2.0 system to make this mHealth system highly flexible, user-friendly, and easy to use by introducing a number of personalization features in the user interface of the client app. For example, PwCCDs can select a desired color theme, avatar, and profile background picture according to their personal preferences. PwCCDs can also choose font size, font style, button size, line and button space, and hand preference according to their needs. All these user interface changes are applied to all the pages in the client app and they are also synchronized to all the devices that the PwCCDs use.

Evaluation

In total, 2 studies were performed to evaluate the iMHere 2.0 system, one was a usability study and the other was a feasibility study. The protocols of both studies were approved by the Institutional Review Board office at the University of Pittsburgh.

The usability evaluation was performed to identify usability problems. Study participants were recruited in the Greater Pittsburgh area via study flyers posted at various places and an advertisement posted on the Pitt+Me website. The inclusion criteria were age between 18 and 65 years and capable of communicating with investigators in both oral and written English. The usability study was conducted in a controlled laboratory environment. The study participants were asked to perform several tasks on the iMHere 2.0 client app modules. The 3 modules (MyMeds, Skincare, and PHR) used in this study were chosen because they are relevant to most people and include most of the user interface components utilized in the other modules of this app. Therefore, it is reasonable to assume that if study participants were satisfied with the design and implementation in these 3 app modules, they would also be satisfied with the ones having similar design and implementation but different content in the other modules. In this usability study, the iMHere 2.0 client app was first introduced and the 3 modules were briefly demonstrated. Then, the study participants were asked to perform several tasks on the app using the investigator-provided 9.7 inch Apple iPad Air 2 tablet. Their performance was observed, and the comments of study participants were collected. At the end of the session, each of the participants was asked to fill out the Post-Study System Usability Questionnaire (PSSUQ) [47] to report their overall impression of the app. They were subsequently briefly interviewed to allow us to collect further comments and suggestions.

The feasibility evaluation was performed after the usability study to evaluate the extent to which self-management support can be successfully delivered to the intended participants (PwCCDs) via the iMHere app and identify issues that could occur and affect the implementation process [48]. The study participants were recruited from one of the author's clinics and through referral from our collaborators. The inclusion criteria were PwCCDs with a diagnosis of SB, SCI, CP, or Traumatic Brain Injury and aged 12 years or older. The feasibility study was conducted in the natural environment of the participants using the participants' personal mobile devices. The participants were first guided on how to install the app on their own devices and how to use the app for self-management. All 12 modules were made available to them. They were encouraged to use the app for about 3 months regularly. Their app usage data were collected and summarized.

Results

Dynamic Interactions in the iMHere 2.0 System

The iMHere 2.0 system consists of 5 components: a cross-platform client app, a cross-platform caregiver app, a Web-based clinician portal, a 2-way secure communication protocol, and a back-end server. The dynamic interactions among the 3 front-end components can be seen in Figure 4. The communication protocol and back-end server transparently support all the activities in these front-end components.

The main components of the Web-based portal are a triage dashboard, patient-context panel, and settings page (Figure 5). The triage dashboard shows a list of PwCCDs with the indicators related to each of the modules selected by clinicians according to PwCCDs' needs and conditions. These indicators show the severity level and urgency of the PwCCDs' condition, which can be used by the clinician to determine the priority of the treatment. When an urgent or severe condition occurs while the clinician is not on the Web portal, the iMHere 2.0 system sends notifications to the clinician via short message service text messaging or email so that the clinician can respond to them quickly.

Each PwCCD's name in the triage dashboard can be used to navigate the clinician to the patient-context panel. The patient-context panel shows all of the components related to the treatment of the PwCCDs, including module management, care team management, and instant messaging.

Figure 4. The interactions among the 3 front-end components in the iMHere 2.0 system.

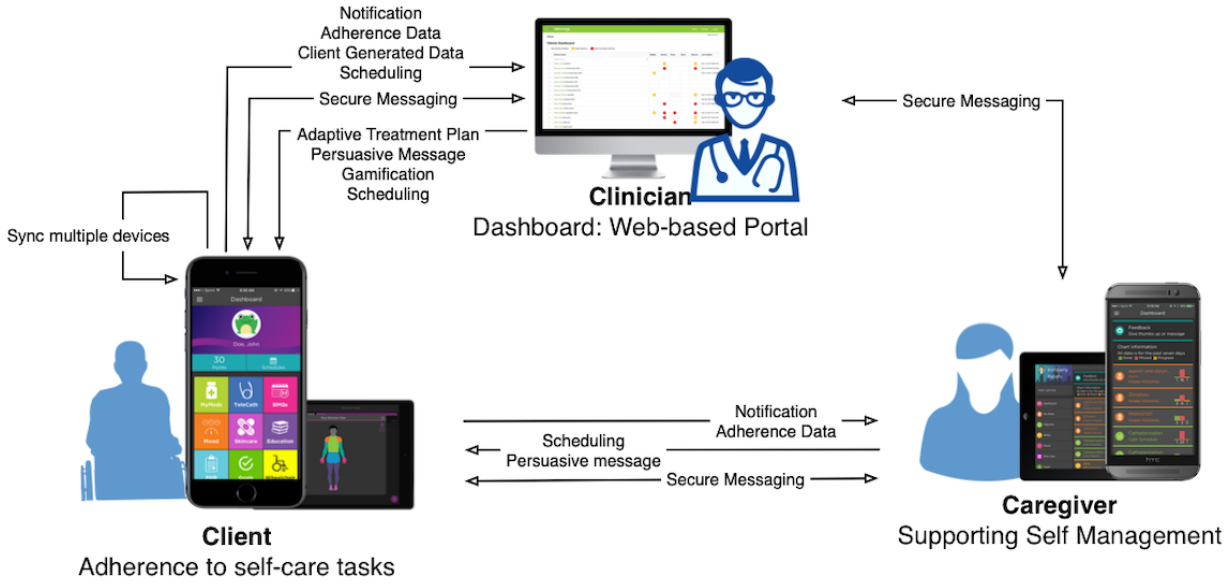
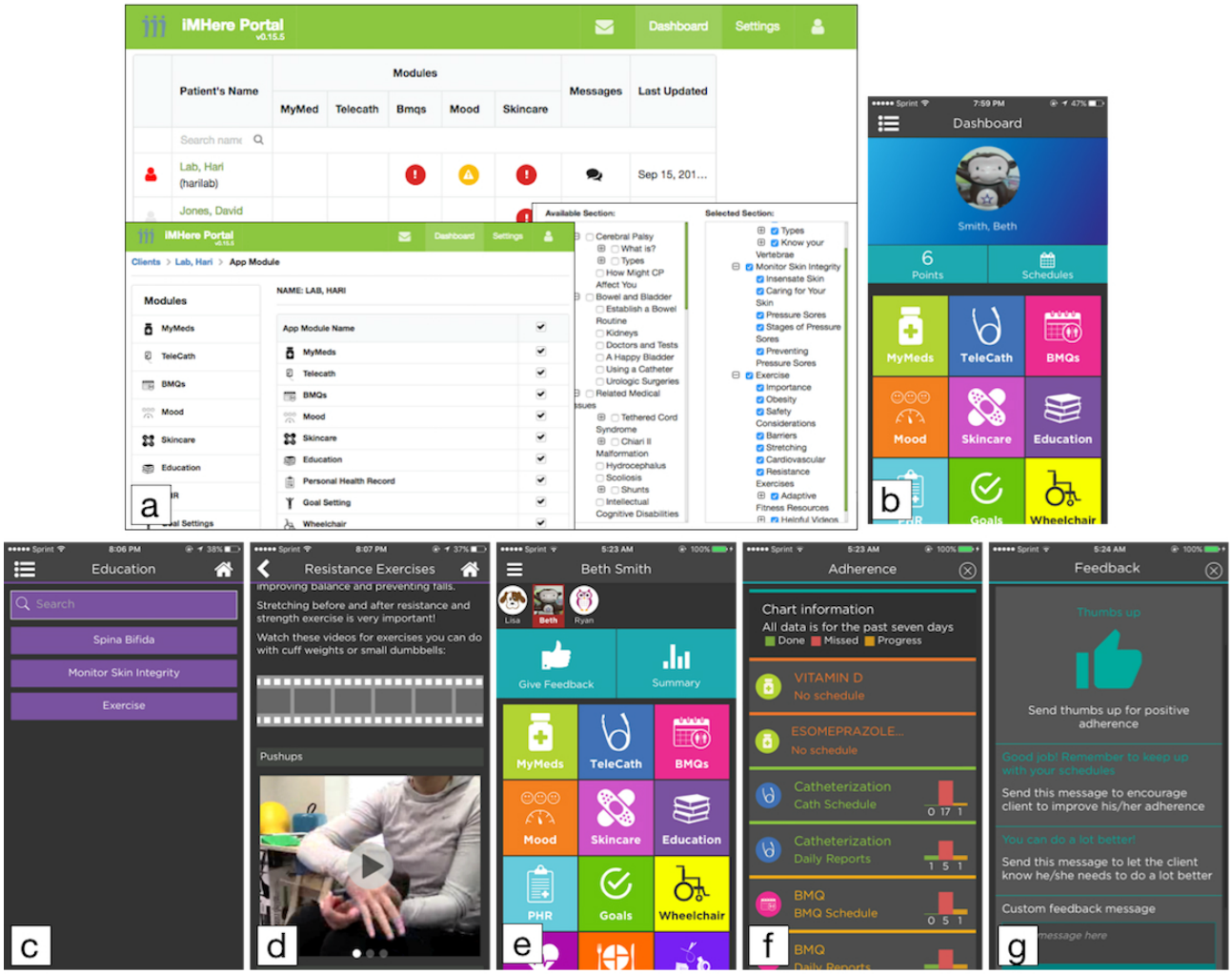


Figure 5. Screenshots of the Web-based clinician portal, the client app, and the caregiver app. (a) The Web-based portal, (b) the dashboard of the client app with chosen app modules, (c) chosen education topics shown in the Education module, (d) an example of a multimedia education page, (e) the dashboard of the caregiver app, (f) the persons with chronic conditions and disabilities' progress monitoring page in the caregiver app, and (g) the social support page in the caregiver app.



As a part of the adaptive treatment, in the settings page, clinicians can select the app modules to be used by PwCCDs at any time. In the selected modules, clinicians can provide customized interventions to PwCCDs according to their specific situation. For instance,

- The clinicians are able to select relevant modules based on the baseline evaluation of the client or based on the client's preferences. Clients are able to request certain modules orally during face-to-face sessions or via the instant messaging service offered in the app.
- When the client reports a problem related to a condition such as a wound (through instant messaging or the Skincare module), the clinicians are able to adapt the existing intervention based on the information provided by the client, such as adjusting the frequency of the skin check reminder.
- If the MyMeds module is selected, clinicians can adjust prescriptions (medication, dosage, and schedule) on the Web-based portal for PwCCDs.
- If the Skincare module is selected, the clinicians can view the pictures of wound sites taken by PwCCDs and provide treatment.
- If the Education module is selected, as patient education materials are arranged into several major sections and subsections, clinicians can choose the relevant education sections and subsections for each of the PwCCDs on the Web-based portal and deploy them as *care bundles* (Figure 5).

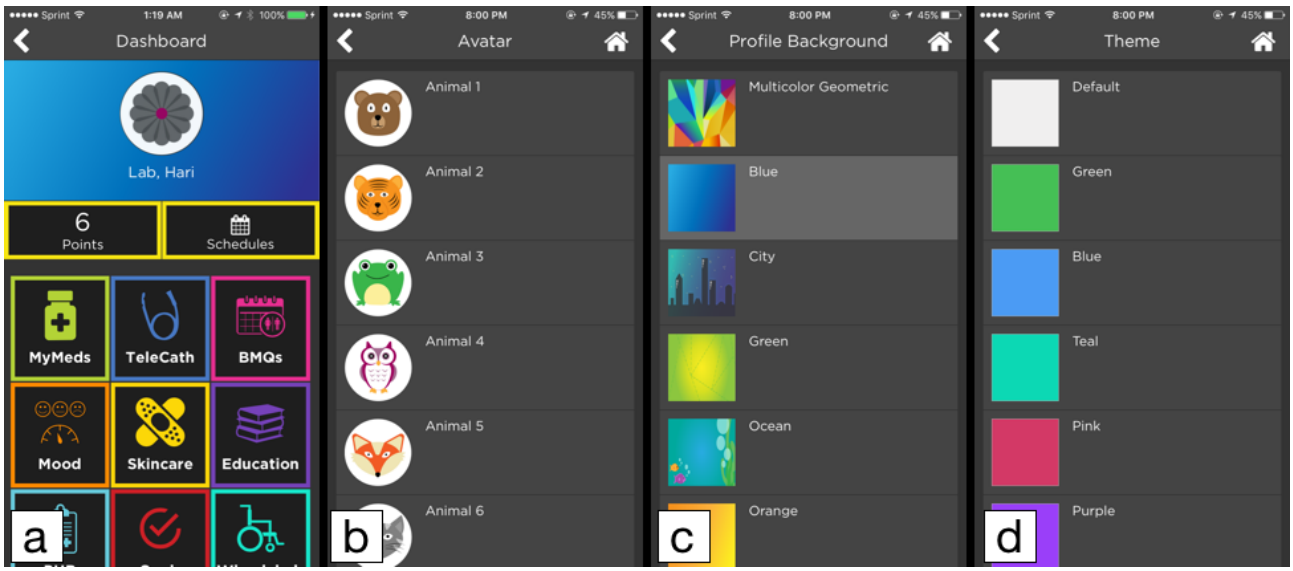
All setting changes on the Web-based portal are synchronized with both the client and caregiver apps immediately after they are saved and applied on the portal.

Figure 5 shows how the dashboard of the client app looks corresponding to the app modules selected by the clinician on the Web-based portal. Besides the list of selected modules, this dashboard of the client app also shows patient name, earned reward points, the current day's schedule, and a chosen avatar on the profile background. Figure 5 shows how the education contents were selected by the clinician in the Web-based portal. Once updated, the education contents were synchronized to the client app. Figure 5 also shows one sample education page, which demonstrates multimedia education content (text, audio, and video).

The layout of the caregiver app is similar to the client app. As a caregiver may have more than one client, the dashboard shows the client roster (Figure 5) and the caregiver can easily switch clients. The dashboard shows a list of modules corresponding to the selected client's modules. Two buttons are provided to bring up a page with the summary of the client's progress toward the regimens and a page for positive reinforcement, such as encouragement and thumbs up (Figure 5). The caregiver app allows the caregiver to help the client set up a schedule for self-management tasks, for example, creating or updating schedules for medication taking, mood assessment, and regular skin checking. In addition, the caregiver can set reward points for each of the client's completed goals to motivate the client toward goal accomplishment.

In the client app, each app module is color-coded to help the client identify the correct module while using the app [36]. These sets of colors were arranged into a list of themes for the PwCCDs to choose from. PwCCDs can select 1 theme according to their own preferences. Similarly, there are a list of avatars and a list of profile background pictures. PwCCDs can choose their desired avatar and profile background picture. After these options are selected, the theme, profile background, and avatar are applied to the dashboard of the client app (Figure 6).

Figure 6. Screenshot of various customization features. (a) The dashboard of the client app with a theme different from the default, (b) a list of avatars, (c) a list of profile background pictures, and (d) a list of themes.



Evaluations

Usability Study Results

In total, 81 study participants were recruited in the usability study. Their demographic information is summarized in Table 1.

All 81 participants responded to the 19 statements in the PSSUQ on a 7-point Likert scale, where 1 indicates *Strongly Agree* and 7 indicates *Strongly Disagree*. In other words, a lower number in the answer indicates a stronger agreement with the statement, which corresponds to high usability of the mHealth app in iMHere 2.0. The overall average of responses for PSSUQ was 1.64 out of 7. This means the usability of this mHealth app was high; in other words, these 81 participants believed that the mHealth app was easy to learn and comfortable to use, and they were satisfied with the features provided by this mHealth app.

The feedback from the usability study participants during the informal interview at the end of the usability study was also positive. All 81 participants said they " . . . liked the app," "it was easy to learn and use the app," and "the app was very useful for self-management." Participants specifically liked how easy it was to set up the schedule and reminders and were glad to have the capability to customize the pages and app modules. They also thought that ". . . this app would be useful for all people, not just people with disabilities."

Some study participants provided suggestions for the further development of the mHealth app in iMHere 2.0, and we made changes in the app accordingly. The following are a few examples:

- In the version used in the study, after a medication schedule was chosen and submitted, there was no message to indicate whether or not the selection was saved. In an updated version, a message was generated to indicate that the medication or schedule had been saved.
- Some icons were used as major app component indicators, but some study participants thought that those icons were clickable and became frustrated after they believed that there was no response from the icons. We chose to remove those icons and added simple texts to label those components so that they would not confuse the client.
- Some participants indicated that it was not intuitive to click the button at the bottom-right corner in MyMeds and Skincare to add medication schedules or report skincare cases because of the large screen of the iPad. A brief instruction was added in the main pages of MyMeds and Skincare to guide the client to use the button at the bottom-right corner.
- Some study participants mentioned other desired features, for instance, tracking of appointments, managing other body symptoms other than skin problems, osteoporosis, and pain, and loading contact information from the contact list to the contacts in the app. We are currently implementing some of these desired features, such as appointment tracking and pain management.

Feasibility Study Results

For this feasibility study, 6 participants were recruited. They had all been diagnosed with SB, and their ages were between 23 and 50 years. In total, 2 participants were iPhone users and 4 participants were Android phone users. A total of 90 days' app usage data for each participant were extracted from the system and analyzed.

The most accessed module during the study was Education (315 times), followed by messaging (116 times). The rest of the modules were accessed 1 to 50 times. The most frequently visited Education sections were *bowel and bladder* (55 times), *monitor skin integrity* (40 times), and *spina bifida* (35 times).

Among these 6 participants, P06 was the most active participant, with 81% (73/90) of the study period actively interacting with the app (Figure 7). P06 was also the participant who was the most compliant to reminders generated by the app, with level of adherence around 88.7% (764/861) based on scheduled reminders during the study period. The frequently visited modules by P01 were Education, messaging, TeleCath, and MyMeds. P04 and P05 lived together and were the least active participants, barely using the app. Unfortunately, it was extremely difficult to reach them using any communication approach (phone, email, text message, or letter) to investigate the reasons behind their underutilization of the app.

P01 and P03 had problems with the reminders. Both participants had part-time jobs and their work schedule was not predictable. This made it difficult for them to set up a regular schedule or respond to the reminders generated according to the schedule. P01 was active in this study for about 23% (21/90) of the time with level of adherence around 38% (5/13) based on scheduled reminders. P03 was active in this study for about 63% (57/90) of the time with level of adherence around 79.1% (349/441) based on scheduled reminders. Both participants frequently visited Education, messaging, and Skincare modules. The different level of interaction in spite of being in the same situation can be explained by the level of support needed by the 2 participants. P01 explicitly mentioned that "...I would not need reminders for certain tasks since I am able to complete the task independently by my own."

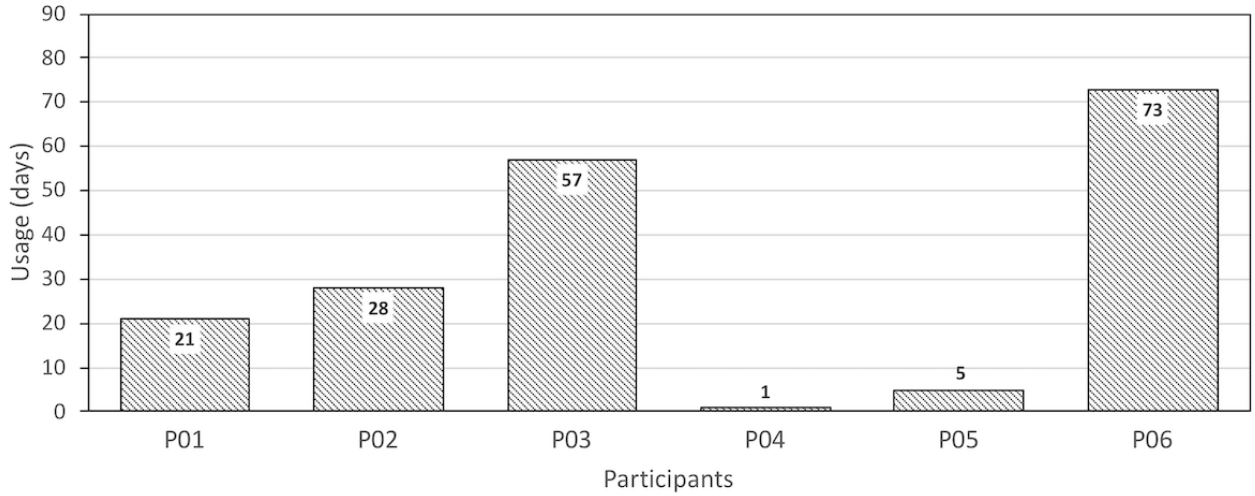
P02 had to stop using the app owing to technical problems. P02 had an old Android device (Samsung S3), which could run an older version of the app but not the newer version, whereas the latter was the one used in the major part of the study. P02 was active for about 31% (28/90) of the study period with level of adherence around 63.3% (112/177) based on scheduled reminders. The most frequently visited modules for P02 were Education, messaging, MyMeds, and TeleCath.

During the study period, participants with Android devices had a number of technical issues, such as incompatible Android versions, interaction problems (screen protector issues, stylus issues, and small keyboard), and the app freezing while in use.

Table 1. Demographic characteristics of the study participants (N=81).

Demographic characteristics	Statistics
Gender, n (%)	
Male	34 (42)
Female	47 (58)
Age (years), mean (SD)	30.4 (12.82)
Race, n (%)	
Black	12 (15)
White	48 (59)
Asian	21 (26)
Education, n (%)	
High school	2 (2)
Some college credits	21 (26)
Technical training	1 (1)
Associate degree	4 (5)
Bachelor's degree	24 (30)
Master's degree	23 (28)
Professional degree	3 (4)
Doctoral degree	3 (4)
Marital status, n (%)	
Single	62 (77)
Married	17 (21)
Divorced or separated	2 (2)
Employment, n (%)	
Employed	55 (68)
Not employed	20 (25)
Retired or disabled	6 (7)
Household income, n (%)	
≤ US $10,000	16 (20)
US $10,001- US $50,000	33 (41)
US $50,001- US $100,000	14 (17)
> US $100,000	11 (14)
Decline to answer	7 (8)
Occupation, n (%)	
Student	32 (40)
Researcher	16 (20)
Administrator	9 (11)
Customer service	6 (7)
Other (advisor, attorney, designer, health care provider, teacher, professor, programmer, set up person, unemployed, disabled, or no answer)	18 (22)

Figure 7. Days the participants actively used the app during the study.



With regard to the app, P01 believed that there were too many confirmation steps required when sending a report. More flexible scheduling was preferred by P01, P02, and P03, such as an hourly basis or *every other day* options in MyMeds or an *every two weeks* option in Mood. The app has been modified accordingly by reducing confirmation steps in reporting and adding more flexible scheduling options.

Discussion

Principal Findings

To meet the long-term, highly diverse, and changing self-management support needs of PwCCDs, we developed the adaptive mHealth system (iMHere 2.0), which consists of cross-platform client and caregiver apps, a Web-based clinician portal, and a back-end server with a 2-way secure communication protocol. In this system, the adaptive treatment regimens are delivered according to the individual's specific needs and ongoing performance during treatment [41]. Treatment strategies can be adjusted over time in response to the individual's performance and needs.

The architecture of the system is highly scalable, which means one can add new self-management services into this system independently if they are needed. In total, 12 highly diverse and commonly used app modules were created in the client and caregiver apps to demonstrate the scalability and flexibility of this system architecture.

The Web-based clinician portal can be used to prescribe personalized treatment strategies for PwCCDs according to their specific conditions and the PwCCDs can follow these personalized instructions in the client app to perform self-management. During the course of the treatment, clinicians are able to adapt the treatment strategies in response to PwCCDs' performance. Once the treatment strategies are updated by the clinician on the Web-based portal, those strategies are synchronized with the client and caregiver apps. The Web-based portal also enables the clinician to monitor PwCCDs' adherence to the prescribed treatment strategies and to communicate with the PwCCDs via instant secure messaging.

Social support is also critically important for long-term engagement in self-management [12,49]. In the iMHere 2.0 system, caregivers can conveniently monitor PwCCDs' performance and provide social support to PwCCDs via the caregiver app. Previous studies have demonstrated that leveraging social influence is an effective strategy to motivate PwCCDs to adhere to treatment regimens [25]. For instance, there is evidence about the significant influence of family members (partners, parents, children, and siblings) on long-term engagement in health care [25]. Therefore, the motivational messages from caregivers may help PwCCDs to endure lengthy treatment procedures. The instant secure messages exchanged between PwCCDs and the clinicians may also provide the desired social support for long-term engagement with the mHealth system.

The availability of multiple caregiver modes makes it feasible for caregivers to provide appropriate support to PwCCDs. For instance, family members may not have formal medical training, but they may have a very close relationship with the PwCCD and extensive knowledge about the PwCCD's situation. Therefore, the motivational messages from family members mainly show intimacy, love, and encouragement. Paid caregivers typically have some patient care training and, therefore, the motivational messages are mainly professional suggestions and reminders of the potential benefits of consistent self-management. In terms of a caregiver's access to client's personal health information, it is desired to have different access levels for different types of caregivers, such as family members and professional caregivers. This feature is currently in our development plan, and it will be implemented in the near future.

Both the client and caregiver apps are cross-platform, which means that these 2 apps can run on the Android, iOS, and Windows Phone systems. In the vast majority of cases, PwCCDs can use the iMHere 2.0 system on their current mobile devices because these 3 mobile operating systems (mainly Android and iOS together) have close to 100% of the global mobile operating system market share [50]. This cross-platform feature also makes it possible for PwCCDs and caregivers to use this system on multiple mobile devices that may have different mobile operating systems or switch mobile operating systems without

worrying about losing the opportunity to continue to use the iMHere 2.0 system for self-management.

The data entered by PwCCDs, caregivers, and clinicians are synchronized in real time as long as a network connection is available. If the network connection is not available at some specific moment, PwCCDs can still use most of those app modules as the data are stored locally on the mobile device temporarily and are securely transmitted to a remote secure server using the Secure Sockets Layer protocol once the connection is restored. The only exception is the PHR module, which always requires a network connection as personal medical records are not stored on the local device, even temporarily, to protect the security of patient data. As all the data are stored on a secure remote server, if PwCCDs or caregivers change to new mobile devices, they still can access their complete data.

As the iMHere 2.0 system is for PwCCDs, the accessibility of the app is very important. In iMHere 1.0, some accessibility features were introduced and their use by people with fine motor impairment was studied; the results indicated that participants desired to have the ability to change text size, button size, and color [34]. Therefore, in iMHere 2.0, we introduced these accessibility features so that PwCCDs have the ability to change the font size, font style, button size, space between lines and buttons, and hand preference. These accessibility features are very useful for long-term usage of the iMHere 2.0 system. For instance, when PwCCDs become older, their vision may become worse. If the accessibility features were not available, they might have to switch to a different mHealth app simply because they cannot read the materials in this system anymore. With the accessibility features, they can make adjustments in the settings according to their needs (eg, selecting a larger font size) and so can continue to use the iMHere 2.0 system.

Comparison With Previous Studies

To our knowledge, this is the first adaptive mHealth platform to provide long-term self-management support for individuals with various types of chronic conditions and disabilities. Intellicare is a suite of 13 mobile apps for depression and anxiety care [51]. These are separate apps and one can choose to install the apps he or she needs. In iMHere 2.0, the client app is one single app and the specific modules can be customized. The biggest advantage of iMHere 2.0 is the instant and adaptive support from caregivers and clinicians, which is not available in Intellicare.

Limitations

In this paper, we have described the design, development, and evaluation of the iMHere 2.0 system. A usability study was performed with 81 study participants from the general population and the results indicated that the usability of the iMHere 2.0 client app was high. A feasibility study was performed with a small number of PwCCDs and the study participants demonstrated different app module preferences. Some practical issues during implementation were also identified in the feasibility study. A usability study with a group of PwCCDs is currently ongoing. The personalization, especially the accessibility features, has been evaluated in one other study with participants with fine motor impairments. The details about that study will be reported in a separate paper.

Although all of the approaches we implemented in this iMHere 2.0 system have a solid theoretical background and have proved to be effective in certain areas, the effectiveness of this novel approach eventually needs to be determined on a large scale and in long-term randomized clinical trials with participants with various types of chronic conditions and disabilities. One such randomized clinical trial is currently under development, and the results from that trial will be reported in a few years.

In certain circumstances or for some PwCCDs, there is no clinician available to provide care to PwCCDs or to customize app modules. Sometimes, there is no caregiver available, either. Therefore, we created a version of the client app in which the PwCCDs themselves can make selections from available app modules to meet their self-management needs. The evaluation of this version of the client app is currently ongoing.

Conclusions

The iMHere 2.0 system provides a novel solution in delivering personalized and adaptive preventive interventions to PwCCDs, empowering these individuals to be more independent in managing their conditions with support from clinicians and caregivers. The participants of the usability study were satisfied with the iMHere 2.0 client app and recommended it for a wider target population. The feasibility evaluation revealed different usage and preferences of participants and several practical issues that we need to consider when implementing the system on a larger scale among PwCCDs. This new mHealth system may eventually help PwCCDs prevent many secondary conditions and improve their quality of life.

Acknowledgments

This research was funded in part by grants from the National Institutes of Health (NIH) 1 R43 DC04246-01 and 1 R43 DC04472-01 and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) 90RE5018, 90DP0064, and 90DPGE0002. The contents of this paper do not represent the views of the NIH, NIDILRR, or the United States Government.

Conflicts of Interest

BP, BED, and ADF are the inventors of the iMHere system.

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Abbreviations

CP: cerebral palsy
GAD: Generalized Anxiety Disorder
iMHere: Interactive Mobile Health and Rehabilitation
mHealth: mobile health
NIDILRR: National Institute on Disability, Independent Living, and Rehabilitation Research
NIH: National Institutes of Health
PHQ: Patient Health Questionnaire
PHR: personal health record
PSSUQ: Post-Study System Usability Questionnaire
PwCCD: persons with chronic conditions and disabilities
SB: spina bifida
SCI: spinal cord injury

Edited by G Eysenbach; submitted 28.11.18; peer-reviewed by J Pollak, D Freed; comments to author 05.01.19; revised version received 05.04.19; accepted 06.04.19; published 25.04.19.

Please cite as:
Setiawan IMA, Zhou L, Alfikri Z, Saptono A, Fairman AD, Dicianno BE, Parmanto B
An Adaptive Mobile Health System to Support Self-Management for Persons With Chronic Conditions and Disabilities: Usability and Feasibility Studies
JMIR Form Res 2019;3(2):e12982
URL: http://formative.jmir.org/2019/2/e12982/
doi:10.2196/12982
PMID:31021324

Original Paper

Smartphone-Based Meditation for Myeloproliferative Neoplasm Patients: Feasibility Study to Inform Future Trials

Jennifer Huberty[1], PhD; Ryan Eckert[2], MS; Linda Larkey[3], PhD; Jonathan Kurka[1], PhD; Sue A Rodríguez De Jesús[1], PhD; Wonsuk Yoo[1], PhD; Ruben Mesa[2], MD

[1]College of Health Solutions, Arizona State University, Phoenix, AZ, United States

[2]Mays Cancer Center, University of Texas Health MD Anderson, San Antonio, TX, United States

[3]College of Nursing and Health Innovation, Arizona State University, Phoenix, AZ, United States

Corresponding Author:
Jennifer Huberty, PhD
College of Health Solutions
Arizona State University
500 North 3rd St
Phoenix, AZ, 85004
United States
Phone: 1 402 301 1304
Email: jhuberty@asu.edu

Abstract

Background: Myeloproliferative neoplasm (MPN) patients often report high symptom burden that persists despite the best available pharmacologic therapy. Meditation has gained popularity in recent decades as a way to manage cancer patient symptoms.

Objective: The aim of this study was to examine the feasibility of 2 different consumer-based meditation smartphone apps in MPN patients and to examine the limited efficacy of smartphone-based meditation on symptoms compared with an educational control group.

Methods: Patients (n=128) were recruited nationally through organizational partners and social media. Eligible and consented patients were enrolled into 1 of 4 groups, 2 of which received varying orders of 2 consumer-based apps *(10% Happier* and *Calm*) and 2 that received one of the apps alone for the second 4 weeks of the 8-week intervention after an educational control condition. Participants were asked to perform 10 min of meditation per day irrespective of the app and the order in which they received the apps. Feasibility outcomes were measured at weeks 5 and 9 with a Web-based survey. Feasibility outcomes were acceptability, demand, and limited efficacy for depression, anxiety, pain intensity, sleep disturbance, sexual function, quality of life, global health, and total symptom burden.

Results: A total of 128 patients were enrolled across all 4 groups, with 73.4% (94/128) patients completing the intervention. Of the participants who completed the *10% Happier* app, 61% (46/76) enjoyed it, 66% (50/76) were satisfied with the content, and 77% (59/76) would recommend to others. Of those who completed the *Calm* app, 83% (56/68) enjoyed it, 84% (57/68) were satisfied with the content, and 97% (66/68) would recommend to others. Of those who completed the educational control, 91% (56/61) read it, 87% (53/61) enjoyed it, and 71% (43/61) learned something. Participants who completed the *10% Happier* app averaged 31 (SD 33) min/week; patients completing the *Calm* app averaged 71 (SD 74) min/week. *10% Happier* app participants saw small effects on anxiety (P<.001 d=−0.43), depression (P=.02; d=−0.38), sleep disturbance (P=.01; d=−0.40), total symptom burden (P=.13; d=−0.27), and fatigue (P=.06; d=−0.30), and moderate effects on physical health (P<.001; d=0.52). *Calm* app participants saw small effects on anxiety (P=.29; d=−0.22), depression (P=.09; d=−0.29), sleep disturbance (P=.002; d=−0.47), physical health (P=.005; d=0.44), total symptom burden (P=.13; d=−0.27), and fatigue (P=.13; d=−0.27). Educational control participants (n=61) did not have effects on any patient-reported outcome except for a moderate effect on physical health (P<.001; d=0.77).

Conclusions: Delivering meditation via the *Calm* app is feasible and scored higher in terms of feasibility when compared with the *10% Happier* app. The *Calm* app will be used to implement a randomized controlled trial, testing the effects of meditation on symptom burden in MPNs.

Trial Registration: ClinicalTrials.gov NCT03726944; https://clinicaltrials.gov/ct2/show/NCT03726944 (Archived by WebCite at http://www.webcitation.org/77MVdFJwM)

(JMIR Form Res 2019;3(2):e12662) doi:10.2196/12662

KEYWORDS

mindfulness; meditation; smartphone; mHealth; cancer; quality of life

Introduction

Myeloproliferative neoplasms (MPNs) are a rare blood cancer with the most common subtypes including polycythemia vera, essential thrombocythemia, and myelofibrosis. Those afflicted with MPN report a high prevalence of fatigue, anxiety, depression, pain, and sleep disturbance [1,2]. The vast majority of MPN patients (81% to 95%) report fatigue as the most prevalent and severe symptom reducing physical, social, and cognitive functioning as well as quality of life [2-4]. MPN patients often have a favorable life expectancy, with as many as 60% of patients living up to 15 years after diagnosis. Many patients even have the same life expectancy as the general population [5,6]. This means that MPN patients live much of their lives with fatigue, other symptoms, and the associated detrimental effects on overall functioning and quality of life [3,7].

There has been significant advancement in the pharmacological treatment of MPNs; however, for most patients, residual symptoms (ie, fatigue, anxiety, depression, pain, and sleep disturbance) persist, even with active pharmacologic therapy [8,9]. Additionally, standard-of-care treatments for MPN, including medication/drug therapy (ie, hydroxyurea), phlebotomy, and bone marrow transplant (the only curative therapy, reserved for those with severely reduced life expectancy), are associated with worsened symptoms and a reduced quality of life [10]. There is a need for research examining adjuvant, nonpharmacologic approaches (eg, mindfulness-based therapies) for MPN patients that may improve symptoms and that are not accompanied by negative side effects.

Extensive research in recent decades demonstrates the benefits of mindfulness-based therapies for alleviating fatigue, anxiety, depression, and sleep disturbance in both cancer and noncancer populations [11-16]. Mindfulness meditation has gained increasing attention as a complementary therapy for cancer patients, particularly for alleviating psychological comorbidities associated with cancer and its treatment [17]. Mindfulness meditation is the practice of moment-to-moment awareness in which the person purposefully focuses on the present moment without judgment [18]. Mindfulness meditation (hereinafter referred to as meditation) may be a potentially beneficial complementary therapy that improves MPN symptoms through increased nonjudgmental awareness of thoughts, feelings, and body sensations. These increases in awareness may help reduce feelings of anxiety and depression and may also help alleviate sleep disturbances resulting from sleep-interfering cognitive processes (ie, ruminating thoughts while trying to sleep) [12,16]. However, there has been minimal research investigating the effects of mindfulness meditation as a complementary therapy in hematological cancer patients and, specifically, no research conducted on MPN patients [19].

There has been a growing trend in recent decades toward digital (ie, Web-based and smartphone-based) interventions for health care access and to improve well-being. MPN patients may be a population that can greatly benefit from a digital intervention owing to (1) the rarity of MPNs, (2) the lack of specialized treatment centers in the United States, (3) the increasing prevalence of smartphone ownership in the United States, and (4) reported limitations to participation in in-person interventions among cancer patients. In a recent study, it was demonstrated that only 64% (18/28) and 29% (8/28) of MPN patients received their specialty care in the same state or city, respectively, in which they resided [20]. Additionally, the vast majority of Americans (more than 77%) own a smartphone, with 62% using their smartphones to get health information and 30% accessing a Web-based/mobile app to get educational content [21-23]. Finally, cancer patients report barriers to participating in in-person interventions, including fatigue, pain, and transportation/scheduling difficulties [24]. This asserts MPN patients as a population with the potential to benefit from digital meditation because they are more readily accessible and implemented with fewer resources than in-person meditation interventions.

As of January 2018, there were almost 6 million consumer-based smartphone apps available across both the Google Play Store and Apple's App Store, the 2 leading app stores in the world [25]. Of these, there are over 500 mindfulness/meditation-based smartphone apps available [26]. Despite the large number of consumer-based smartphone mindfulness/meditation apps available, very little research has investigated the feasibility and efficacy of these apps. Components and features across meditation apps may be more feasible (ie, acceptable, demanded, and practical) than others, potentially impacting user outcomes such as frequency of use and long-term compliance [27]. Although research is limited investigating the desired features of a consumer-based smartphone meditation app, there are reports about desired features in physical activity smartphone apps (eg, automatic tracking of activity, tracking of progress toward goals, and integrated features) [28] and across health behavior change apps more broadly (eg, accuracy of information, security of personal information, effort required to track progress, and immediate effects on mood) that help to inform interventions [29]. However, no research has specifically investigated the feasibility and desirability of one meditation app compared with another, especially to inform future interventions in specific populations.

Owing to the potential beneficial effects that meditation may have on residual MPN symptoms, the potential ease of delivery to a rare cancer such as MPNs, and the potential for dissemination of a consumer-based smartphone meditation app across other cancer populations, there is a need to examine meditation delivered via consumer-based smartphone apps in MPN patients. Therefore, the aim of this study was to examine the feasibility of 2 different consumer-based meditation

smartphone apps in MPN patients and to examine the limited efficacy of smartphone-based meditation on symptoms compared with an educational control group. According to Bowen et al [30], limited efficacy refers to testing the intervention with limited statistical power and is appropriate for feasibility studies.

Methods

This study was approved by the Institutional Review Board at Arizona State University, and all participants signed an informed consent before participating in the study. All personal information was collected electronically and was stored in a password-protected computer at Arizona State University. The study was retrospectively registered with ClinicalTrials.gov.

Study Design

This was a 4-group randomized controlled trial (RCT) with a cross-over design. A convenience sample of eligible and consented MPN patients was recruited and enrolled into 1 of 4 groups with varying order of receiving 2 consumer-based meditation smartphone apps (ie, *10% Happier* app or *Calm* app) in 4-week increments over 8 weeks. Group 1 received the *10% Happier* app followed by the *Calm* app; Group 2 received the *Calm* app followed by the *10% Happier* app; Group 3 received educational control followed by the *10% Happier* app; and Group 4 received educational control followed by the *Calm* app. We chose the 4-group design to maximize the number of participants who use both apps. We did not have a washout period because the primary goal was to assess feasibility, not efficacy.

We used the *Calm* app for this study because *Calm* is one of the most popular consumer-based mobile apps (ie, Apple's app of the year in 2017), the lead author developed a relationship with *Calm* to conduct research using the app, and *Calm* agreed to provide the memberships to the app and share the tracking data with the research team without cost. The *10% Happier* app was chosen because they were one of the competing meditation mobile apps of *Calm* and they agreed to provide the memberships to the app and share the tracking data with the research team without cost. Additionally, both smartphone apps are available across all major smartphone platforms (ie, Android and iOS).

Recruitment and Enrollment

MPN patients (n=128) were recruited online through MPN organizational partners with a flier outlining the study and its requirements. The study was advertised as a smartphone app meditation study. MPN patients interested in the study were asked to complete a Web-based eligibility questionnaire administered via Qualtrics. Textbox 1 describes the eligibility criteria. Researchers checked the eligibility questionnaires as they were completed and emailed patients their eligibility status. Eligible patients were invited to participate in a 20-min phone appointment in which the study details and informed consent were described in detail. MPN patients who completed the intake appointment were then sent an informed consent electronically via Qualtrics that included a place for their electronic signature. Ineligible patients received an email stating their ineligibility status as well as links to both consumer-based apps used in the study, in case the ineligible participant was interested in trying meditation.

Upon receipt of the completed informed consent, participants were randomly assigned to one of 4 groups. A group assignment list was computationally generated through randomizer.org by a research assistant to randomly allocate participants to one of 4 equally sized groups before study commencement This pre-generated list was then used by the same research assistant to place eligible, consented MPN patients into their group assignment in the order in which they consented to participate. Randomized participants were provided with a *welcome email* that contained (1) a welcome letter introducing them to the study, (2) a calendar detailing important study dates, and (3) instructions specific to the first assigned condition (ie, *CB* app, *Calm* app, or educational control) to be introduced for the first 4 weeks. After participants completed the first of their 2 4-week conditions (ie,*10% Happier* app, *Calm* app, or control), they were provided with another email that included instructions specific to their final condition (ie, *10% Happier* app, *Calm* app, or educational control).

Textbox 1. Eligibility criteria.

Inclusion criteria:

- Had a diagnosis of essential thrombocythemia, polycythemia vera, or myelofibrosis identified by the treating physician
- Owned a mobile smartphone and were willing to download and use a meditation app (ie, *10% Happier* or *Calm*)
- Could read and understand English
- Were aged 18 years or older
- Were willing to be randomized to one of 4 groups: (1) *10% Happier* 4 weeks/*Calm* 4 weeks, (2) *Calm* 4 weeks/*10% Happier* app 4 weeks, (3) educational material 4 weeks/*10% Happier* app 4 weeks, and (4) educational material 4 weeks/*Calm* 4 weeks

Exclusion criteria:

- Engaged in ≥10 min/day of meditation on ≥5 days/week for the past 6 months
- Engaged in ≥60 min/week of tai chi, qigong, or yoga each week
- Utilized either the *10% Happier* app or the *Calm* app
- Resided outside of the United States

Procedures

All participants were instructed to listen to the app's introduction to meditation and, following this, were instructed to participate in a 10-min meditation each day, which they selected from the app's library of meditations. The dose for the intervention was chosen because (1) the *Calm* and *10% Happier* app currently offer 10-min meditations (daily and series meditations), thus representing the length of time users are most likely to meditate using the app; and (2) to date, the ideal dose for mindfulness meditation interventions has not been established and effective mindfulness meditation interventions have ranged from 10-min sessions to 2-hour sessions and from one day per week to a daily practice [31-33]. Practical guidelines recommend that beginners start with short meditations lasting between 10 min and 30 min per session [34].

All study participants were asked to complete Web-based surveys at baseline, Week 5, and Week 9 via Qualtrics to assess feasibility outcomes (described in detail below), including study satisfaction and patient-reported outcomes. The survey consisted of 40 to 50 questions (depending on the condition the participant just completed and whether it was at baseline or post-condition) and was developed and tested internally among the research team for usability and functionality before use in the study. At the end of each 4-week condition, participants were emailed a unique survey link specific to their study identification number and were asked to complete the survey within 24 to 48 hours, if possible. Responses were collected electronically in Qualtrics and were then entered manually into a de-identified Excel spreadsheet for later data analysis. All participants received the same surveys in the same question order each time. The only difference between surveys was the wording of the satisfaction questions based on which condition they completed. Participants were able to scroll back through their survey responses by navigating back and forth through pages with a *back* button, giving them the flexibility to revise questions if they needed. Participants were only allowed to complete the survey once, and after it was submitted, they were not allowed access back into the survey.

Additionally, all study participants were instructed to wear a Fitbit (Fitbit Inc) device on their nondominant wrist throughout the 8-week intervention to measure physical activity and sleep; however, these data are not reported here. The intervention was 8 weeks because this is an appropriate length of time for a feasibility study in which the primary purpose was *not* to determine efficacy. Similar lengths have been used in other feasibility studies [30,35].

Description of the Apps and the Control

10% Happier App

The *10% Happier* app's introduction to meditation incorporated basic information for those new to meditation. Daily meditations were selected from a library of meditations included within the app. Each of the meditations had a different focus (eg, grief, gratitude, choice, and letting go) and were approximately 10 to 12 min in length.

Calm App

The *Calm* app's introduction to meditation incorporated basic educational information for those new to meditation while introducing brief experiential practices. Daily meditations were called the *Daily Calm* and were new and unique, provided by the app each day. The daily meditations had a different focus (eg, practicing patience, loving kindness, and gratitude) and were approximately 10 to 12 min in length. Meditations were also selected from a library of meditations with the app.

Educational Control

The control condition was provided with a 7-page educational handout that was developed by the research team before the study. The handout addressed MPN patient fatigue (eg, what causes fatigue?) as well as examples of and information related to evidence-based fatigue management strategies.

Feasibility Outcomes

Feasibility (ie, acceptability, demand, and limited-efficacy testing) was defined according to Bowen et al [30]. Acceptability was measured with an investigator-developed set of satisfaction survey questions at Week 5 and Week 9 after participants completed each of their 4-week group assignments. Satisfaction questions were the same for all 3 conditions, with the exception of the wording that was altered slightly so that the question fit each condition. For example, a question asked in the satisfaction survey included: "How likely are you to continue using the (*insert condition here*) on a 1 to 5 scale (1 being very poor; 5 being excellent)". Benchmarks for acceptability included ≥70% satisfaction with the apps' content, ≥70% intending to continue using the app, ≥70% enjoying using the app, and ≥70% recommending it for other MPN patients. Demand was measured using adherence to the meditation intervention. Meditation participation was tracked by the smartphone app developers and reported weekly to the research team. Reports included (1) the date and time of each meditation participated in, (2) the title of the meditation, and (3) the duration of participation (ie, the time spent viewing the meditation) for each participant. Adherence benchmarks were defined as an average of ≥49 min/week of meditation across all participants (ie, ≥70% of prescribed meditation). There is little research suggesting appropriate benchmarks for acceptability and demand [30]. We based our benchmarks on a recently published methods paper for a National Institute of Health–funded study for the feasibility of a Web-based yoga intervention [36]. Patient-reported outcomes were assessed in all study participants via a Qualtrics questionnaire at baseline, Week 5, and Week 9. Demographics and MPN-related health history were included within the baseline questionnaire only. The National Institutes of Health Patient Reported Outcomes Measurement Information System (NIH PROMIS) and the MPN Symptom Assessment Form (MPN-SAF) were used to measure patient-reported outcomes. MPN-SAF measures included total symptom score and fatigue (Question 1 on MPN-SAF). NIH PROMIS measures included anxiety, depression, pain intensity, sleep disturbance, sexual function, global health, and quality of life (Question 2 on the global health scale). Table 1 describes each of these outcome measures.

Table 1. Summary of self-report outcome measures.

Measure, outcome	Scoring
MPN SAF[a]	
Total symptom score	10 items (0-10 scale); total score range of 0-100 with higher score indicating worse symptom burden
Fatigue	Item #1 from MPN SAF; 0-10. Scale with higher score indicating more fatigue
NIH PROMIS[b]	
Anxiety	8-item measure with each question asked on a 1-5 scale; total cumulative raw score converted to standardized t-score; higher t-score represents more of the construct being measured
Depression	8-item measure with each question asked on a 1-5 scale; total cumulative raw score converted to standardized t-score; higher t-score represents more of the construct being measured
Pain intensity	3-item measure with each question asked on a 1-5 scale; total cumulative raw score converted to standardized t-score; higher t-score represents more of the construct being measured
Sleep disturbance	8-item measure with each question asked on a 1-5 scale; total cumulative raw score converted to standardized t-score; higher t-score represents more of the construct being measured
Sexual function	11-item measure with each question asked on a 1-5 scale; total cumulative raw score converted to standardized t-score; higher t-score represents more of the construct being measured
Global health	10-item measure with each question asked on a 1-5 scale; total cumulative raw score converted to standardized t-score; higher t-score represents more of the construct being measured
Quality of life	Item #2 on the Global Health scale; scored on a 1-5 scale with a higher raw score indicating a lower quality of life

[a]MPN-SAF: MPN Symptom Assessment Form.

[b]NIH PROMIS: National Institutes of Health Patient Reported Outcomes Measurement Information System.

Data Analysis

Descriptive analyses were performed for baseline demographic characteristics using means and SDs of continuous data and using frequencies and proportions of discrete data for the 2 apps and 2 control groups, and dropouts. To test the limited efficacy of the intervention, a series of analysis of covariance analyses were performed for each of the NIH PROMIS outcomes using raw scores on measures of pain intensity, anxiety, depression, sleep disturbance, sexual function and discomfort indicators, global health, and quality of life. The analysis was adjusted for baseline PROMIS levels and covariates of the group membership (sequence effects), gender, education, and marital status. Race was not considered as a covariate as less than 5% of the sample was non-white Dunnett's post hoc tested differences between treatment outcomes compared with baseline. A 2-tailed alpha error of .05 was the threshold for statistical significance. In addition, effect sizes (Cohen *d*) were calculated and classified as small (*d*=0.2), medium (*d*=0.5), and large (*d*=0.8) to examine differences at postcondition time. A negative effect size indicates the outcome measure decreased between the baseline and postcondition measure [37]. All analytical and visual evidence including appropriate statistics, *P* values, and graphs was reported using Statistical Analysis Software (SAS Institute, version 9.4) and Microsoft Excel (2016). A *P* value of <.05 was considered statistically significant.

Results

Recruitment and Enrollment

A total of 289 MPN patients were recruited and completed the eligibility survey between July 31 and October 18, 2017 (ie, two-and-a-half months). Of the 289 MPN patients who completed the eligibility survey, 33.2% (96/289) were ineligible and 44.2% (128/289) signed the informed consent and were enrolled into the study (see Multimedia Appendix 1). Eligible participants were enrolled into the study in the order they completed the eligibility questionnaire. A total of 73.4% (94/128) patients across all 4 groups completed the intervention. See Table 2 for protocol adherence and completion rates across groups. The results below are reported for participants who completed the intervention (ie, completed both postcondition surveys at Week 4 and Week 8).

Table 2. Protocol adherence.

Group	N (signed informed consent)	Completed post-Week 4 survey[a], n (%)	Completed post-Week 8 survey[a], n (%)
10% Happier followed by *Calm*	33	28 (85)	26 (79)
Calm followed by *10% Happier*	32	26 (81)	26 (81)
Control followed by *10% Happier*	35	24 (69)	24 (69)
Control followed by *Calm*	28	18 (64)	18 (64)
Total	128	96 (75)	94 (73)

[a]These surveys include satisfaction questions related to the completed 4-week group assignment.

There were no significant differences between groups on any demographic variable. Across all participants (n=128), average age was 58 (SD 12) years ($F_{1,126}$=2.45; *P*=.12) and average body mass index was 27 (SD 6) kg/m^2 ($F_{1,123}$=.28; *P*=.60). The majority were female (104/128; χ^2_3=4.0; *P*=.26), white (123/128; χ^2_9=9.8; *P*=.36), well-educated with a bachelor's education or higher (79/128; χ^2_{15}=15.7; *P*=.40), and married (95/128; χ^2_{15}=14.4; *P*=.49). In addition, the most common diagnosis among all participants was Essential Thrombocythemia (54/128) followed by Polycythemia Vera (48/128) and Myelofibrosis (26/128). Most participants had been diagnosed with their MPN for more than 3 years (81/128).

Feasibility Outcomes

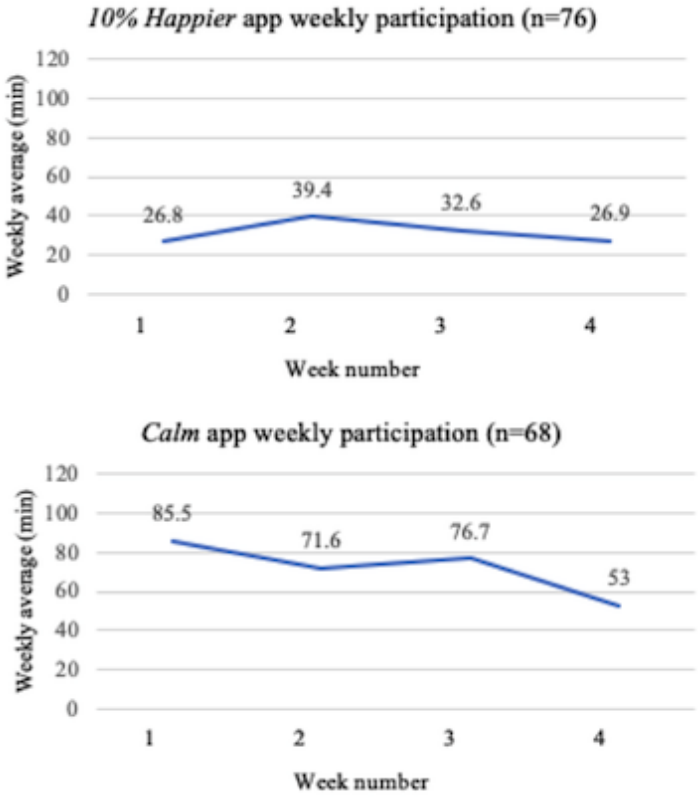
Acceptability

See Multimedia Appendix 2 for satisfaction survey responses. Of the participants who used the *10% Happier* app, 61% (46/76) enjoyed it, 66% (50/76) were satisfied with the content, and 77% (59/76) would recommend it to others. Of those who completed the *Calm* app, 83% (56/68) enjoyed it, 84% (57/68) were satisfied with the content, and 97% (66/68) would recommend it to others. Of those who completed the educational control, 91% (56/61) read it, 87% (53/61) enjoyed it, and 71% (43/61) learned something.

Demand

Participants who completed the *10% Happier* app averaged 31 (SD 33) min/week and 30% (23/76) averaged ≥49 min/week of meditation, whereas participants who completed the *Calm* app averaged 71 (SD 74) min/week and 56% (38/68) averaged ≥49 min/week of meditation. See Figure 1 depicting average weekly meditation minutes completed by participants.

Figure 1. Weekly meditation participation.



Limited Efficacy Testing

Mean differences in patient-reported outcomes from baseline to postcondition are reported in Multimedia Appendix 3. After completing 4 weeks of meditation using the *10% Happier* app (n=76), significant differences were found between baseline and postcondition for anxiety (P<.001; d=−0.43), depression (P=.02; d=−0.38), sleep disturbance (P=.01; d=−0.40), and physical health (P<.001; d=0.52). Mental health (P=.07; d=−0.30) and fatigue (P=.06; d=−0.30) were approaching significance. Although not statistically significant, a small-to-medium effect size and the 95% CI indicate differences in total symptom burden (d=−0.27; 95% CI −11.75 to −0.09).

After completing 4 weeks of meditation using the *Calm* app (n=68), significant differences were found between baseline and postcondition for sleep disturbance (P=.002; d=−0.47), vaginal discomfort (P=.03; d=−0.36), and physical health (P=.005; d=0.44). Small-to-medium effects and 95% CI indicated differences for measures of depression (P=.09; d=−0.29; 95% CI −3.49 to −0.14), total symptom burden (P=.13; d=−0.27; 95% CI −11.81 to −0.11), and fatigue (P=.13; d=−0.27; 95% CI −1.68 to −0.02), but were not significant.

After completing 4 weeks of the educational control (n=61), the only effect seen between baseline and postcondition was for physical health (P<.001; d=0.77).

Discussion

Principal Findings

The purpose of this study was to examine the feasibility of 2 different smartphone-based meditation apps in MPN patients and to examine the limited efficacy of smartphone-based meditation on symptoms compared with an educational control group. The findings of this study will inform the app to be used for a larger RCT to test for efficacy. We have identified the *Calm* app as being feasible for our future RCT as it met nearly all of our a priori feasibility criteria (ie, demand, acceptability, and limited-efficacy testing).

Our findings suggest that the *Calm* app had higher demand than the *10% Happier* app. Overall, the average weekly meditation across participants that completed *Calm* was greater than the prescribed 70 min/week and over half averaged ≥49 min/week of meditation (ie, demand cutoff criterion). Comparatively, those who participated in the *10% Happier* app only averaged 31 min/week of meditation and less than a third averaged ≥49 min/week of meditation. The adherence rates of the *Calm* app group are promising findings related to the potential for delivering meditation using a consumer-based smartphone app in MPN patients.

The adherence rates demonstrated by those completing *Calm* in this study are better than adherence rates of other smartphone-based meditation app studies [38,39]. A recent study conducted by Economides et al [38] investigated the effects of meditation delivered using the Headspace app on stress, affect, and irritability in novice meditators and found that participants (n=41) averaged approximately 44 min/week of meditation when asked to complete a total of 10 introductory 10-min meditations as they desired. Participants used the app for a short duration (approximately 16 days). Another recent study conducted by Bostock et al [39] that examined the effects of a 45-day Headspace meditation app intervention on work stress and well-being in healthy workers found that participants averaged approximately 42 min/week of meditation. Our study was 28 days in length (ie, the length participants were asked to use each app) and the *Calm* app group averaged approximately 71 min/week. It is not clear why our study had better participation in meditation as compared with the aforementioned studies. However, *Calm* may have characteristics (eg, app layout, presentation of content, and variety of content) within the app that make it more likely to be accepted and used by participants [28,29] when compared with Headspace or other meditation apps (ie, *10% Happier* app).

Those who completed *Calm* indicated that they enjoyed it (83%), were satisfied with the content (84%), and would recommend it to others (97%), each of which meets our benchmarks for acceptability. Of those that used the *10% Happier* app, 61% enjoyed it, 66% were satisfied with the content, and 77% would recommend to others. With the exception of those that would recommend it to others, the *10% Happier* app fell short of meeting benchmarks for acceptability. Self-report responses from those in *Calm* indicate the acceptability of the app compared with the *10% Happier* app. We conducted qualitative interviews related to the content and preferences for each of the apps; these data are being reported elsewhere [40]. However, briefly, the reasons *Calm* may have been more accepted than the *10% Happier* app were related to audio features (ie, the narrator voice was soothing and calming background sounds available) and other features such as pictures, stories, and a wide range of meditation topics.

Research with physical activity and other health behavior apps suggests automatic tracking of the specific activity, tracking of progress toward goals, and integrated features (eg, syncing with social media and connecting with music apps) are features most liked by users [28]. Both the *Calm* app and the *10% Happier* app share similarities in terms of their tracking features consistent with those reported in the literature as desired features of smartphone apps [28,29,41]. However, the *Calm* app automatically displays the tracking information following participation in meditation (*pops* up onto the screen) and includes minutes meditated, days in a row of mediating (ie, streak), and a calendar that highlights the days in which the app was used. To see the tracking of meditation in the *10% Happier* app, the user must navigate to their profile to look up the statistics that are displayed as days and minutes meditated. The differences in the way that the tracking is offered to the user may contribute to the differences in the acceptability of the apps. More exploration about the type of tracking and how participants prefer to interact with a tracking mechanism within a mobile app, specifically, a mediation app, is warranted.

Unlike the *10% Happier* app, *Calm* allows users to immediately share their meditation statistics (eg, number of meditations and time spent in meditation) through social media platforms (eg, Facebook) or text messages and emails (called *share status*). Even though we did not measure the use of the *share status*, the offering of this on the app may also contribute to its enhanced acceptability. Recent research has shown that

participants like to share progress and that sharing progress updates and interacting within an online social platform may help increase feelings of accountability and may improve adherence rates in interventions [42,43]. In a recent qualitative study, participants with diverse health-related goals that shared updates on their progress via social media reported sharing their updates helped contribute to their accountability [42].

Both the *Calm* and *10% Happier* apps include a variety of content for users outside of just listening to meditation tracks. *Calm* includes sleep stories or sleep meditations to help users fall asleep. They also offer *Calm* Breathe, *Calm* Music, *Calm* Body, and relaxing scenes and nature sounds. *Calm* has masterclasses to educate participants about topics such as mindful eating, gratitude, and the importance of rest. The *10% Happier* app offers some similar content but is organized and delivered differently. For example, the content is organized on the bottom tool bar and users scroll to find the content they want to use (Calm organizes with a toolbar but also includes other screens for organization of content). The sleep content is only in the form of meditations (not sleep stories). Education for participants is in the form of courses with a meditation to follow-up the content (eg, a short 3 to 5 min lecture-based video followed by a meditation). On the basis of our findings, the way in which the *Calm* app organizes and delivers their content may be more appealing as compared with the *10% Happier* app. Future studies are warranted to determine what users specifically find most acceptable related to how content is organized and offered.

We observed limited efficacy on symptoms across both apps. Of note are the small effects observed in both apps on anxiety, depression, sleep disturbance, and total symptom burden. Although this is the first meditation study to be conducted in MPN patients, Huberty et al [20] identified that 12 weeks of Web-based yoga (60 min/week) had limited efficacy on anxiety, depression, sleep disturbance, and total symptom burden in MPN patients. Meditation and yoga differ in the sense that yoga includes a component of physical postures (asanas), but yoga does contain a meditation component and it is known that some of yoga's benefits come from the meditation [44-48]. Meditation has been shown to improve anxiety, depression, and sleep disturbance symptoms in both cancer and noncancer populations through increased nonjudgmental awareness of thoughts, feelings, and body sensations [12,16]. Therefore, it is not surprising that this study showed limited efficacy in only 4 weeks on anxiety, depression, and sleep disturbances across both meditation apps. Studies of a longer duration may show larger effects. Our findings are preliminary in nature and RCTs powered for effectiveness are needed to determine the effects of consumer-based smartphone meditation on MPN patients.

Limitations

There are limitations to this study that should be noted. First, our sample was disproportionately female (ie, 81% in this study vs approximately 53% female being typical of the MPN population [49]) and white (ie, 123/128, 96%). Second, we did not have a washout period in between each condition within the group assignments (ie, lack of washout time period between apps or between control and app conditions). As this was a feasibility study and we were not determining efficacy, a washout period was not necessary [50]. Finally, it is likely that the study findings represent those already motivated to use smartphones for health-related purposes. However, the literature suggests smartphone use is popular among cancer patients overall and that there is a large interest in accessing supportive care via smartphones in cancer patients [51,52]. Importantly, future studies could determine the effects of a mobile app to improve health-related outcomes in cancer patients, especially when cancer patients are already using mobile apps.

Conclusions

Delivering smartphone meditation via the *Calm* app is feasible as it met most of our feasibility criteria (ie, demand, acceptability, and limited-efficacy testing) and scored higher in terms of feasibility when compared with another consumer-based app (ie, *10% Happier* app). Future RCTs are needed to examine meditation with the *Calm* app and its effects on MPN patient symptoms. The findings of this study will be used to inform the development of a National Institutes of Health R01 grant app for an RCT examining the efficacy of *Calm* on MPN patient symptoms.

Acknowledgments

This study was funded with philanthropic funds. The authors would like to acknowledge both *10% Happier* and *Calm* for donating memberships for participants in this study.

Conflicts of Interest

RM reports research support by Incyte, Celgene, CTI BioPharma, Abbvie, and Genetech. In addition, RM acts as a consultant for Novartis, La Jolla, and Sierra Oncology. The authors do not report any additional conflicts of interest.

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

Multimedia Appendix 1

Enrollment.

[PDF File (Adobe PDF File), 140KB - formative_v3i2e12662_app1.pdf]

Multimedia Appendix 2

Satisfaction Survey Responses.

[PDF File (Adobe PDF File), 70KB - formative_v3i2e12662_app2.pdf]

Multimedia Appendix 3

Patient-Reported Outcomes.

[PDF File (Adobe PDF File), 76KB - formative_v3i2e12662_app3.pdf]

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Abbreviations

MPN: myeloproliferative neoplasm
MPN-SAF: Myeloproliferative Neoplasm Symptom Assessment Form
NIH PROMIS: National Institutes of Health Patient Reported Outcomes Measurement Information System
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 31.10.18; peer-reviewed by Y Zhang, L Morrison, W van Harten, U Subnis, C Jacob; comments to author 27.12.18; revised version received 11.02.19; accepted 24.03.19; published 29.04.19.

Please cite as:
Huberty J, Eckert R, Larkey L, Kurka J, Rodríguez De Jesús SA, Yoo W, Mesa R
Smartphone-Based Meditation for Myeloproliferative Neoplasm Patients: Feasibility Study to Inform Future Trials
JMIR Form Res 2019;3(2):e12662
URL: http://formative.jmir.org/2019/2/e12662/
doi:10.2196/12662
PMID:31033443

Original Paper

Feasibility Randomized Controlled Trial of ImpulsePal: Smartphone App–Based Weight Management Intervention to Reduce Impulsive Eating in Overweight Adults

Samantha B van Beurden[1], PhD; Jane R Smith[1], PhD; Natalia S Lawrence[2], PhD; Charles Abraham[3], PhD; Colin J Greaves[4], PhD

[1]College of Medicine and Health, University of Exeter, Exeter, United Kingdom

[2]Psychology, University of Exeter, Exeter, United Kingdom

[3]School of Psychological Sciences, University of Melbourne, Melbourne, Australia

[4]School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, United Kingdom

Corresponding Author:
Samantha B van Beurden, PhD
College of Medicine and Health
University of Exeter
Smeall Building, Heavitree Road
Exeter, EX1 2LU
United Kingdom
Phone: 44 139272 ext 6440
Email: s.b.vanbeurden@exeter.ac.uk

Abstract

Background: ImpulsePal is a theory-driven (dual-process), evidence-informed, and person-centered smartphone app intervention designed to help people manage impulsive processes that prompt unhealthy eating to facilitate dietary change and weight loss.

Objective: The aims of this study were to (1) assess the feasibility of trial procedures for evaluation of the ImpulsePal intervention, (2) estimate standard deviations of outcomes, and (3) assess usability of, and satisfaction with, ImpulsePal.

Methods: We conducted an individually randomized parallel two-arm nonblinded feasibility trial. The eligibility criteria included being aged ≥16 years, having a body mass index of ≥25 kg/m^2, and having access to an Android-based device. Weight was measured (as the proposed primary outcome for a full-scale trial) at baseline, 1 month, and 3 months of follow-up. Participants were randomized in a 2:1 allocation ratio to the ImpulsePal intervention or a waiting list control group. A nested action-research study allowed for data-driven refinement of the intervention across 2 cycles of feedback.

Results: We screened 179 participants for eligibility, and 58 were randomized to the intervention group and 30 to the control group. Data were available for 74 (84%, 74/88) participants at 1 month and 67 (76%, 67/88) participants at 3 months. The intervention group (n=43) lost 1.03 kg (95% CI 0.33 to 1.74) more than controls (n=26) at 1 month and 1.01 kg (95% CI −0.45 to 2.47) more than controls (n=43 and n=24, respectively) at 3 months. Feedback suggested changes to intervention design were required to (1) improve receipt and understanding of instructions and (2) facilitate further engagement with the app and its strategies.

Conclusions: The evaluation methods and delivery of the ImpulsePal app intervention are feasible, and the trial procedures, measures, and intervention are acceptable and satisfactory to the participants.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 14886370; http://www.isrctn.com/ISRCTN14886370 (Archived by WebCite at http://www.webcitation.org/76WcEpZ51)

(JMIR Form Res 2019;3(2):e11586) doi:10.2196/11586

KEYWORDS

weight loss; mHealth; digital behavior change; obesity; dual-process

Introduction

Obesity continues to be a major public health challenge. In the United Kingdom alone, in line with current trends in obesity prevalence, the economic burden of obesity and related health conditions on the National Health Service (NHS) and United Kingdom society is predicted to reach £49.9 billion/year by 2050 [1]. Given this, the development and implementation of cost-effective, scalable weight management interventions is imperative.

Systematic reviews and meta-analyses suggest that behavioral weight management interventions can result in significantly greater weight loss compared with controls (2 kg or more) [2-4]. However, people often struggle to lose or maintain weight, despite their strong intentions to do so [5,6]. This is thought to be due to, at least in part, people's tendency to make food choices impulsively with little conscious awareness [7,8]. Traditional weight loss interventions focus on conscious, reflective processes, such as planning, monitoring progress, and problem-solving. However, impulsive processes (eg, automatic, habitual, or mindless snacking) are able to undermine conscious reflective processes and are considered to be a major barrier to successful behavior regulation [9-12]. Researchers in the field increasingly recognize the need for interventions that target impulsive, as well as reflective, processes to facilitate health behavior change [12]. This has resulted in the development and evaluation of a range of impulse management techniques with some showing promise in terms of changing eating-related outcomes such as snack intake, craving strength, and body weight [13].

Impulsive processes are triggered by situational cues (eg, [10,11,14]) and individuals may therefore benefit from in-the-moment (or just-in-time) support to modify or otherwise manage such processes for successful behavior change. In 2016, the UK user base for smartphones reached 18% of the population (91% among those aged 18 to 44 years) [15]. Smartphone use continues to permeate daily life with people carrying their phones with them most of the time and looking at them frequently throughout the day [16-18]. Therefore, smartphone apps provide a useful platform for such intervention. Meta-analyses suggest modest effectiveness of mobile health (mHealth) apps targeting weight loss [19,20]. However, reviews of weight loss mHealth apps show that such apps incorporate few theory- and evidence-based features, primarily relying on reflective behavior change techniques such as goal setting and self-monitoring [21,22], rather than techniques specifically supporting impulse management [13].

This study has presented data from a feasibility randomized controlled trial (RCT) of a smartphone app–based weight management intervention, ImpulsePal, that was developed to support dietary behavior change by helping people learn how to modify impulsively regulated eating of unhealthy foods, using evidence-based strategies that explicitly target impulsive processes identified in a recent systematic review [13]. This study encompassed the second stage of the Medical Research Council framework for complex interventions [23] and was designed to (1) inform the planning of a fully powered trial to determine the clinical effectiveness of the intervention in overweight adults and (2) inform the refinement of the intervention in close collaboration with its intended users. Data pertaining to the nested mixed-methods process evaluation are reported elsewhere [24].

The objectives for this feasibility trial were to

1. Assess feasibility of the trial procedures, including rates of recruitment, data collection methods, and retention.
2. Obtain estimates of the SDs of continuous outcome measures to inform sample size calculations for a full-scale trial.
3. Assess the usability of, and satisfaction with, the ImpulsePal intervention and trial methods and procedures.

Methods

This study has been reported in accordance with the Consolidated Standards for Reporting Trials (CONSORT) [25] recommendations specifically for reporting of pilot RCTs and Template for Intervention Description and Replication (TIDieR) recommendations on reporting of behavior change interventions [26].

Study Design and Setting

This was a parallel randomized controlled feasibility study with nested quantitative and qualitative process evaluation. Participants were randomized in a 2:1 ratio to the intervention or a waiting list control arm to maximize data on engagement with the intervention. This study incorporated a nested Action Research (AR) study [27,28], with 2 cycles of intervention delivery and user feedback. Refinements were made to intervention content at the end of each cycle, informed by qualitative feedback from participants. Data collection primarily took place at the University of Exeter Medical School. However, home visits were offered to those who were not able to attend study visits at the university. The intervention development and process evaluation are reported in detail elsewhere [24,29], and combined data from both cycles are reported here. This study was approved by the UK NHS National Research Ethics Services Committee South West—Exeter (Ref: 15/SW/0181).

Participants

Participants were recruited between September 2015 and March 2016 for Cycle 1 and October 2016 and April 2017 for Cycle 2 in the county of Devon in the United Kingdom.

Eligibility Criteria

People were eligible to take part if they (1) were aged at least 16 years, (2) had a body mass index (BMI) of 25 kg/m^2 or more, (3) owned an Android-based smartphone, and (4) lived within a 45-min travelling distance of Exeter, United Kingdom (Devon's capital city). Exclusion criteria included (1) pregnancy within the last 6 months or planned pregnancy during the study period, (2) not speaking or understanding written English, (3) participation in concurrent weight-related interventional research (though participants could be accessing weight loss services outside of the research), and (4) currently receiving treatment for an eating disorder. Our original protocol required a minimum

BMI of 30 kg/m^2 (and 27.5 for specific ethnicities) but we reduced this to 25 kg/m^2 to facilitate recruitment and capture a broader range of experiences with the intervention.

Identification and Recruitment Routes

At the time the study commenced, weight management services operating in Devon were receiving referrals from General Practitioners or other NHS health professionals. Such referrals were directed to Health Promotion Devon (HPD), a lifestyle hub that helped individuals to select a weight management program from a range of group and one-to-one options. Once a week, a staff member of the HPD referral hub ran a database search to generate a list of people who met the study inclusion criteria and checked for any recorded exclusion criteria (ie, pregnancy and referral to concurrent interventional research). Where appropriate, a study invitation on the HPD letterhead was sent out with the Participant Information Sheet, a reply slip, and a freepost envelope addressed to the researcher (SvB). To allow estimation of the representativeness of the sample recruited in relation to the eligible population, anonymized data including age, gender, (preservice) BMI, and postcode for all individuals who were invited to take part by HPD were requested.

In our original protocol, we stated that we would recruit solely through the local Tier 2 (referral to face-to-face lifestyle intervention) weight management service. However, to increase our recruitment rate and because the HPD service was withdrawn after commencement of the study, additional recruitment routes were added. These included (1) displaying study posters in 3 local GP surgeries, 3 local gym facilities, and 2 local Web-based community noticeboards; (2) offering study flyers to individuals referred to local Tier 3 (hospital-based) weight management services in Devon; (3) inserting a study advert in the university's newsletter; and (4) placing 2 separate adverts in the Exeter 10,000 project's (ExTend) yearly newsletter. All adverts, posters, and flyers informed potential participants that (1) the study involved a smartphone app for weight management and (2) a draw-based incentive of a £50 shopping voucher was offered for participation and included the primary investigator's (SvB) contact details for seeking further information about the study.

Procedures

Telephone Screening and Consent

The people who expressed interest in the study by directly contacting the researcher (SvB) or returning a reply slip were contacted by telephone. The researcher provided further information, addressed any questions about the study, and screened verbally for eligibility. Those who were eligible but declined to participate were invited to give reasons but were not obliged to do so.

Consent and Assessments

Potential participants who were eligible and provided oral consent to take part were invited to attend a baseline assessment visit. A baseline invitation pack was sent with information about the visit, and a baseline questionnaire was sent for completion in advance. At the baseline visit, after obtaining written consent, the researcher (1) asked for the questionnaire and checked for completeness and understanding, (2) took other baseline measurements, and (3) randomized the participant to either the intervention or control group. Participants randomized to the intervention group (see below) were provided with instructions for downloading and installing the ImpulsePal app and an anonymized username and password. Follow-up assessments were carried out in the same way at 1 month and 3 months post baseline, although semistructured interviews were conducted at the 1-month follow-up assessment with a subsample of the intervention group only, as part of the process evaluation.

Randomization

Participants were allocated in a 2 (intervention) to 1 (control) ratio using a centralized Web-based randomization service [30]. The allocation sequence was stratified in an attempt to achieve balance across the groups in terms of gender, age group (16 to 24, 25 to 35, 36 to 54, and 55+ years), and BMI categories (<35, 35 to 40, >40 kg/m^2). Block randomization was used, with a block size of 6, to ensure minimal variation from the desired 2:1 ratio. Following entry of a unique participant number and the participant's gender, age, and BMI, the participant's allocation code was generated. Neither the participant nor the researcher was aware of group allocation until this point. The same researcher (SvB) enrolled participants and assigned participants to the study arms.

Intervention

The ImpulsePal intervention was developed using Intervention Mapping methods [31] to (1) support the reduction of unplanned and unhealthy snacking, drinking, and overeating for weight management in people who are overweight, (2) include components for which there was promising evidence that they could modify or otherwise assist in managing impulsive processes related to unhealthy eating, and (3) have the potential for delivery on a large scale. Drawing on dual-process approaches (eg, Reflective Impulsive Model [10]), the intervention contains techniques that help manage the impulsive processes by either preventing their initiation or modifying the direction or strength of the triggered impulse (impulse-focused techniques) or using cognitive resources in identifying and suppressing the impulsively activated behavioral schemas (reflective techniques) [13]. As well as building on our systematic review of techniques to modify impulsive processes [13], the development process involved extensive consultation with service users and behavior change experts.

The intervention is described in the Multimedia Appendix 1, and fuller details of the intervention and its development are described elsewhere [24,29]. Briefly, ImpulsePal is a self-delivered smartphone app that aims to help people modify or manage impulsive processes to facilitate dietary changes (such as reductions in snack consumption). Table 1 presents the key components of ImpulsePal comprising techniques informed by the review [13], their respective mechanisms of action, recommended timing of use, and the operationalization of the technique into a workable app component.

Table 1. Key components, mechanisms, timing of use, and operationalization in the ImpulsePal app.

Technique	Theoretical or conceptual background	Mechanism of action	Timing	Operationalization
Visuospatial Loading (eg, [32])	Elaborated Intrusion Theory of Desire [33,34]	Inhibit elaboration of craving imagery by loading the visuospatial cortex with a competing task.	This is used *in-the-moment*, when a craving occurs.	Present dynamic visual noise a visual interference pattern (such as television snow). This is triggered by pressing the emergency button and is presented in the background to the emergency button text (see in accompanying text).
Implementation Intentions (eg, [35])	Implementation Intentions [36]	Establishing goal, preempting problem situations, and making specific plans to overcome problems—specific plans (such as if-then plans) brings to mind automatically the alternative action to overcome the problem situation when it is encountered.	This technique requires users to preemptively plan for risk situations. However, the alternative response is proposed to be brought to mind *in-the-moment* when the preempted situation is encountered.	Provide option to create *if-then* plans. Prompt identification of *high-risk situations* and preemptive problem-solving, using prespecified *if* situations and *then* responses to select and save to *my plan* or to create own if-then plans.
Inhibition Training (eg, [37,38])	Associative Learning, Pavlovian conditioning, and executive response inhibition (see [39])	Improve inhibitory control, devaluing of stimuli.	The user is to engage with this training regardless of currently experiencing an eating impulse.	Present as a *Brain Training game* consisting of a stimulus-response task (go/no-go) containing images of unhealthy food/snack and drink items and neutral images (nonfood). Images of food are consistently paired with a no-go signal (appearing 100 milliseconds after the image). Neutral images are paired with go or no-go signals (50/50; appearing 100 milliseconds after the image). Feedback: For each response, a score is shown on the screen, which takes into account accuracy and speed.
Mindfulness strategies (eg, [40])	Mindfulness (see [41])	Raise awareness of the present moment by purposefully paying attention, without judgment, to the current experience that is unfolding, and observing its path without acting.	The user is to engage with this strategy *in-the-moment* when a craving is experienced. Although preemptive practice is encouraged.	Text-based steps guide the user through principles of *Urge-Surfing*. Cravings are conceptualized as being like a wave, which may build in intensity, but will eventually subside. Practice in absence of a craving is encouraged to develop this skill.
Location-specific goal primes	Goal priming (see [42])	Bringing long-term goals and goal structures.	Context-specific primes trigger goals and behavior *in-the-moment*. However, identification of risk situations/locations where a prime needs to occur requires planning and scheduling in advance.	Use of geo-caching and location services to highlight high-risk locations on a map along with specific goals for the location. Notifications are sent in the app when the user enters the location. The user is able to specify time boundaries for the notifications.

Additional components, which were identified from service user and expert consultations and additional engagement literature, were also incorporated. These included an emergency button to provide easy access to specific impulse management techniques to be used *in-the-moment*, as well as providing quick access to other techniques (see Table 1). Once the user presses the emergency button, they are presented with text congratulating them on putting their impulse on hold and prompting further action (pressing the *next* button) by saying "Now let's see if you can take control of the situation...." This emergency button text is displayed against a background of dynamic visual noise to induce visuospatial loading, which aims to reduce craving strength by preventing the elaboration of craving imagery. Further strategies were included to enhance engagement with the intervention and effects of the behavior change techniques such as gamification (whereby users are provided with scores, which take into account both the speed and accuracy of responding to the *Brain Training* game) and personalization (in version 2 whereby the individual was able to select the food categories in the inhibition training). Participants were verbally encouraged during the baseline assessment to use the app for the first 4 weeks. However, they were allowed to use the app as much or as little as they wanted throughout the study period. After the 4 weeks, there was no further verbal encouragement given to the participants.

Control Group (Waiting List)

Participants in the control group did not receive the ImpulsePal app during their study participation; instead, they were provided with access to the ImpulsePal app intervention after their 3-month follow-up.

Sample Size

In line with the feasibility aims of the study, our sample size was calculated to obtain realistic estimates (and CIs) for the

uptake and retention rates, as well as SDs of the primary outcome. From recent UK-based trials of interventions to support dietary change, it was estimated that 25% to 30% of those contacted would take part and of those 70% to 75% would be retained at 3 months [43,44]. A sample size of 90 would allow estimation of a retention rate of 70% to 75% with a margin of error of +/−9%. On the basis of recruiting 90 participants and assuming an uptake rate of 25%, we would need to invite 360 people, and this would yield CIs around the uptake estimate of +/−4.5%. This sample size (with a 2:1 allocation ratio) also provides an ample pool of intervention participants from whom to collect qualitative feedback. A retention rate of 70% to 75% would be large enough to allow estimation of the SD for weight loss to allow sample size calculation for a future full-scale trial [45,46].

Blinding

Post randomization, blinding of the participant was not possible as participants were by necessity aware of whether they were receiving an app or not. In addition, the researcher was not blinded to group allocation at follow-up as interviews with the intervention group participants were conducted during the assessment visit. Blinding to group allocation during analyses was not possible either because of the uneven group sizes (2:1 allocation to intervention or control group).

Outcomes and Measures

For this feasibility study, the main outcomes of interest were (1) uptake rate, (2) study completion rate (the proportion providing data at 3 months), and (3) the SD of weight loss at 3 months of follow-up. Other feasibility outcomes of interest were measures completion rates (the proportion of participants who completed each measure at each time point) and acceptability of the intervention and study procedures (percent satisfied with the ImpulsePal app and study procedures).

Questionnaires and study records were used to record demographic data at baseline in terms of age, gender, level of education, ethnicity, and area deprivation using the Index of Multiple Deprivation derived from postcode and national census data, which is the official measure of relative deprivation for localities in England [47]. In addition, participants reported their smoking status, any medications or diagnoses that might affect weight (such as thyroid problems), or diet (such as food allergies) and concurrent participation in other lifestyle-related weight management program at baseline, and any changes in these at 1-month and 3-month follow-up.

A full measurement schedule can be found in the Multimedia Appendix 1 (see Table S1). All measures intended for use in the full-scale trial were also taken (at baseline and follow-up, unless otherwise stated) as follows.

Body Measurements

Body weight in kilograms (primary outcome) was measured using calibrated scales (Seca 899 Weighing Scale). Height was measured using the Seca 213 portable stadiometer at baseline only to calculate BMI.

Secondary Outcomes

We measured unhealthy snack food/drink consumption using a 7-day recall 11-item food frequency questionnaire (FFQ) adapted from a questionnaire used by Churchill and Jessop [48]. This FFQ asked participants to rate how often they had eaten food from specific categories over the course of the last week. The items in the FFQ included crisps, chocolate, ice cream, chips, sweets, cakes, biscuits, pastries/sweet pies, soft drinks, low sugar/diet soft drinks, and alcoholic drinks. A 7-point response scale was presented for each item (ranging from *1=never, to 7=3 or more times per day*). A total FFQ index was calculated as the average of the scores. In this index, a higher score indicates more unhealthy eating as previously used by Lawrence et al [37]. In total, 2 subscales were created in the same way for the 8 snack items (FFQ Snack) and for the 3 drink items (FFQ Drink). To gather frequency data on episodes of overeating, we used 3 items from the Eating Disorder Examination Questionnaire referring to the frequency of overeating episodes and loss of control during overeating (over a period of 28 days) and the number of days in which uncontrolled overeating occurred [49].

App Usage

Intervention usage was measured via the app, which recorded time and date stamps for each screen visited alongside the time spent on the respective screen. For the purposes of this feasibility study, overall intervention usage is measured as the total time spent using the ImpulsePal app and the number of days the app had been accessed. However, engagement (rather than usage) with the intervention and its key components is explored in more depth in the process evaluation.

Feasibility of Use and Satisfaction of Users

At the 1-month assessment visit, intervention group participants were asked to complete an anonymous satisfaction questionnaire and were offered the choice of completing and returning the questionnaire at the end of the study visit (while the researcher was present) or take it home and return it by freepost envelope. The questionnaire asked about the usability of, and satisfaction with, the ImpulsePal app. For example:

> *How easy is ImpulsePal to understand and use?*
>
> *Please indicate how satisfied you are/were with ImpulsePal.*

The questionnaires used 5-point Likert response scales (1=disagree to 5=agree and 1=very dissatisfied to 5=very satisfied). In addition, an open-ended question (ie, “Is there anything we could do to improve ImpulsePal?”) was used to prompt ideas for intervention improvement.

Similar questions, with the same rating scales and return procedures described above, were asked of all participants at the 3-month visit pertaining to satisfaction with the study procedures:

> *The study procedures were easy to understand.*
>
> *The questionnaires were easy to complete.*
>
> *Is there anything we could do to improve the study?*

Please indicate how satisfied you are with your research study experience.

In addition to these satisfaction questionnaires, at the 3-month follow-up (during the visit or over the phone), participants were also asked for quantitative and qualitative feedback on their trial participation experience. Questions included:

In deciding to take part in the study you were given a Participant Information Sheet. Was this helpful?

with a yes/no response,

How would you rate the amount of information that the researchers collected from you?

rating from 1-Far too much, to 5-Far too little, and

Did you have problems with your information being sent via the ImpulsePal app (intervention group only) or your weight being measured?

with a yes or no response and further comments were noted where offered.

Process Evaluation Measures

A mixed-methods process evaluation (which is reported elsewhere [24]) was conducted to further assess the feasibility and acceptability of the intervention in more depth, the usefulness of different intervention components, to explore mechanisms of action, and to identify ways to refine the intervention and the process measures for a full-scale trial. In brief, this incorporated (1) semistructured interviews, (2) questionnaires at baseline and follow-up to assess changes in process variables targeted by the intervention (ie, Barratt Impulsiveness Scale (BIS)-15 [50], Food Cravings Questionnaire-Trait [51]; Cognitive Restraint subscale of the Three Factor Eating Questionnaire—R18 [52]; Power of Food Scale (PFS) [53]; and a self-efficacy questionnaire constructed for this study), and (3) fidelity checks in terms of the delivery/receipt and enactment of intervention components.

Analysis

To assess recruitment and retention, participant flow through the study was summarized using a CONSORT diagram. Recruitment and attrition rates were also summarized using descriptive statistics with 95% CIs. Completion rates are reported using frequency (N) and group percentages (%). Sample characteristics were analyzed using descriptive statistics reporting mean and SDs for continuous data and N (%) for categorical data.

Although the study was not statistically powered for between-group comparisons, we conducted exploratory analyses based on the intention-to-treat (ITT) principle where participant data were analyzed in the groups they were allocated to following randomization. Moreover, we followed a complete case principle to deal with missing outcome data (including only participants who provide data at both time points; in this study ITT and missing outcome data are considered separate issues, for a detailed discussion on the use of ITT analyses and guidance for reporting see Alshurafa et al [54]). We used analysis of covariance (ANCOVA) to compare differences in weight loss (reported as mean difference with 95% CIs) between intervention and control groups at 1 month and 3 months controlling for baseline BMI. Where baseline characteristics suggested potential differences between groups, analyses were conducted including and excluding the potential covariates to explore the sensitivity of the findings to baseline differences. We also calculated the mean changes in secondary outcomes between baseline and follow up time points for each group. Where questionnaire data were incomplete, scores were imputed using the participant's average for the respective scale if at least 80% of the items were completed.

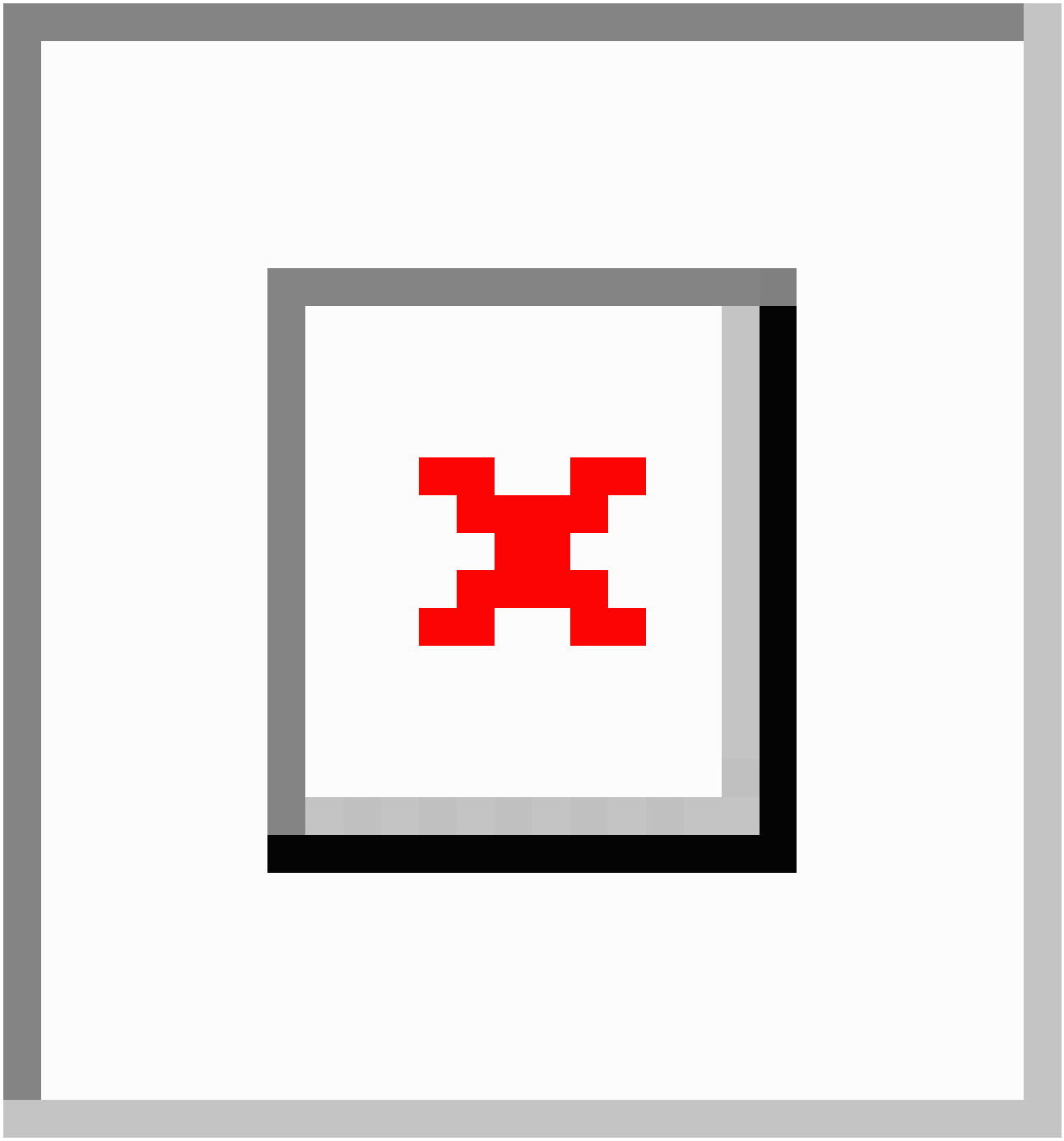
App usage data were analyzed using descriptive statistics reporting median and interquartile ranges, and usability and satisfaction questionnaires were analyzed using descriptive statistics, reporting means, and SDs.

Results

Recruitment and Retention

A total of 194 people responded to the HPD invites, local advertising, or snowballing/word-of-mouth invitations of which 93% (179/194; 95% CI 88.5% to 96.0%) were assessed for eligibility and 45% (88/194; 95% CI 38.4% to 52.4%) were eligible for inclusion and randomized into the trial between September 2015 and April 2017 (see Figure 1). Recruitment efforts stopped in April 2017 after the target number of 90 participants had been scheduled for enrolment into the study. The primary reason for exclusion was not being able to run the Android-based app (37% (66/179) of individuals assessed for eligibility). The average recruitment rate was 7.3 participants per month and was achieved with 1 researcher working on an average of 1.5 days per week during recruitment periods. Of those randomized, 84% (74/88) provided weight data at 1 month (95% CI 76.4% to 91.7%) and 76% (67/88) at 3 months (95% CI 67.2% to 85.0%; see Figure 1).

Figure 1. CONSORT flow diagram for the ImpulsePal feasibility study participants. One participant in the intervention group was unable to attend an assessment visit to provide weight data. AR: action research; HPD: Health Promotion Devon; WoM: word of mouth.



Measures Completion, Internal Consistency, and Missing Data

The proportion of participants completing specific measures ranged from 94% (83/88) for overeating episodes to 100% (88/88) for weight at baseline, from 78% (68/88) for loss of control during overeating to 84% (74/88) for weight (and BMI) at 1 month, and from 73% (65/88) for loss of control during overeating to 76% (67/88) for weight at 3 months. Cronbach alphas for multi-item scales ranged from .64 to .96 at baseline, .62 to .96 at 1 month, and .48 to .96 at 3 months (see Multimedia Appendix 1, Table S2). Among the completed questionnaires, the most frequently missing were an item on the BIS "I plan for job security" (8% (7/88) missing) and an item assessing the participant's confidence to successfully stick to their healthy eating goals *in the work place* (13% (11/88) missing).

Sample Characteristics

The sample was 65% (57/88) female and 95% (81/88) white with a mean age of 46.8 years. The mean BMI was 33.3 kg/m^2; 67% (59/88) had a BMI of 30 or higher (obese), and 26% (22/88) started the study alongside another existing weight management program. Most participants had completed professional training, undergraduate training, or a postgraduate course (71%; 60/88); were nonsmoking (91%; 80/88); and 17%

(14/88) disclosed a comorbidity that might affect their weight or diet such as thyroid problems and diabetes.

There were no substantial differences between the recruited sample and the wider HPD population in terms of age and gender (Table 2), except that the recruited sample had a substantially lower BMI (mean difference −5.71 kg/m^2; 95% CI −6.94 to −4.48). Although the BMI of the HPD participants did not differ from that of the wider HPD population, the participants who came into the study through the other recruitment routes had a substantially lower BMI than the HPD participants (mean difference −6.7 kg/m^2), which has likely driven the difference between the recruited sample and the wider HPD population. There were no substantial differences between the participants who completed the study and those who dropped out in terms of age, gender, or BMI. Within the recruited sample, there were no substantial differences between the intervention and control groups in terms of age, gender, or other demographic variables. However, the control group was on average 5.2 kg heavier than the intervention group and had BMI scores that were 1.6 kg/m^2 higher than the intervention group. Snacking scores from the FFQ were also slightly higher in the control group (Table 3).

Table 2. Characteristics of participants and the wider HPD[a] population. The HPD invitees include those who participated in the feasibility trial as we were unable to identify them from the anonymized data provided.

Characteristics	Participants						HPD invitees	
	Non-HPD	N	HPD	N	All	N	All	N
Age (years), mean (SD)	45.6 (14.2)	71	51.8 (12.0)	16	46.8 (13.9)	87	48.0 (14.2)	585
Female, n (%)	46 (64)	72	12 (75)	16	57 (65)	88	420 (71.8)	585
Body mass index, mean (SD)	32.1 (5.4)	72	38.8 (6.1)	16	33.3 (6.1)	88	39.0 (5.4)	585
IMD[b] score, mean (SD)	18.5 (10.7)	65	16.8 (9.3)	13	18.2 (10.4)	78	19.9 (10.0)	564
IMD quintile, n (%)								
1 (least deprived)	8 (12)	65	0 (0)	13	8 (10)	78	58 (10.3)	564
2	18 (28)	65	7 (54)	13	25 (32)	78	181 (32.1)	564
3	17 (26)	65	2 (15)	13	19 (24)	78	172 (30.5)	564
4	17 (26)	65	3 (23)	13	20 (26)	78	91 (16.1)	564
5 (most deprived)	5 (8)	65	1 (8)	13	6 (8)	78	62 (11.3)	564

[a]HPD: Health Promotion Devon.

[b]IMD: Index of Multiple Deprivation.

Table 3. Sample characteristics at baseline.

Variable	Intervention	N	Control	N	Whole sample	N
Weight (kg), mean (SD)	93.1 (17.8)	58	98.3 (20.9)	30	94.9 (19.0)	88
Body mass index (kg/m^2), mean (SD)	32.8 (5.6)	58	34.4 (6.9)	30	33.3 (6.1)	88
Female, n (%)	37 (64)	58	20 (67)	30	57 (65)	88
Age (years), mean (SD)	46.7 (13.6)	58	46.9 (14.8)	30	46.8 (13.9)	87
Ethnicity, n (%)						
White	52 (93)	56	29 (100)	29	81 (95)	85
Other	4 (7.1)	56	0 (0)	29	4 (4.7)	85
Area deprivation						
Index of Multiple Deprivation (IMD) score, mean (SD)	17.7 (10.9)	51	19.2 (9.5)	27	18.2 (10.4)	78
IMD quintile, n (%)						
1 (least deprived)	6 (12)	51	2 (7)	27	8 (10)	78
2	20 (39)	51	5 (19)	27	25 (32)	78
3	10 (20)	51	9 (33)	27	19 (24)	78
4	11 (22)	51	9 (33)	27	20 (26)	78
5 (most deprived)	4 (8)	51	2 (7)	27	6 (8)	78
HPD referral, n (%)	10 (17)	58	6 (20)	30	16 (18)	88
Cointervention (including Orlistat), n (%)	16 (29)	56	6 (21)	28	22 (26)	84
Comorbidity, n (%)	8 (14)	56	6 (21)	28	14 (17)	84
Medication (not for weight loss but that can affect weight), n (%)	17 (30)	56	5 (18)	28	22 (26)	84
Education, n (%)						
Secondary up to 16 years	7 (13)	56	3 (10)	29	10 (12)	85
Secondary up to 18 years	5 (9)	56	3 (10)	29	8 (9)	85
Professional training or university	39 (70)	56	21 (72)	29	60 (71)	85
Other	5 (9)	56	2 (9)	29	7 (8)	85
Smoking status, n (%)						
Never smoked	29 (52)	56	15 (54)	28	44 (52)	84
Currently smoking	5 (9)	56	3 (10.7)	28	8 (10)	84
Given up smoking[a]	22 (39)	56	10 (36)	28	32 (38)	84
Cognitive restraint[b], mean (SD)	37.8 (20)	56	35.6 (18.1)	29	37.2 (19)	85
FFQ[c] , mean (SD)						
FFQ Total	2.1 (0.4)	56	2.4 (0.8)	29	2.2 (0.6)	85
FFQ Snack	2.1 (0.5)	56	2.3 (0.8)	29	2.2 (0.6)	85
FFQ Drink	2.1 (0.8)	56	2.6 (1.3)	29	2.2 (1.0)	85
Overeating, mean (SD)						
Overeating Frequency (number of times during 28 days)	7.6 (8.0)	55	6.6 (6.9)	28	7.2 (7.6)	83
Loss of control (number of times during 28 days)	5.4 (7.6)	55	3.0 (4.6)	28	4.6 (6.8)	83
Uncontrolled overeating (number of days)	5.4 (7.2)	55	4.7 (6.7)	29	5.19 (7.0)	84

Variable	Intervention	N	Control	N	Whole sample	N
Process Questionnaires						
BIS[d], mean (SD)						
BIS—NP[e] score	11.5 (3.6)	56	11.4 (3.2)	29	11.5 (3.4)	85
BIS—M[f] score	11.0 (2.8)	56	11.6 (3.8)	29	11.2 (3.2)	85
BIS—A[g] score	10.1 (3.1)	56	10.2 (2.5)	29	10.2 (2.9)	85
BIS total	32.6 (7.0)	56	33.2 (7.3)	29	32.8 (7.1)	85
PFS[h]—aggregate domains, mean (SD)	3.0 (0.8)	56	3.1 (1.0)	29	3.0 (0.8)	85
Food Cravings Questionnaire-Trait reduced[i], mean (SD)	59.4 (14.3)	56	60.3 (18.9)	29	59.7 (15.9)	85
Self-efficacy[j], mean (SD)	50.1 (14.0)	55	51.0 (21.7)	29	50.4 (16.9)	84

[a]Average 9.6 years since quit date.

[b]Cognitive Restraint scores, from 0 to 100 with higher scores indicating greater restraint.

[c]FFQ: Food Frequency Questionnaire scores, out of a maximum 7 with higher scores representing more frequent unhealthy food/snack/drink consumption.

[d]BIS: Barratt Impulsivity Scale—Short form, scores of 15 to 60 with higher scores representing higher impulsivity.

[e]NP: non-planning impulsiveness.

[f]M: motor impulsiveness.

[g]A: attentional impulsiveness.

[h]PFS: Power of Food Scale score, ranging from 1 to 5 with higher scores indicating greater susceptibility to the food environment.

[i]Food Cravings Questionnaire-Trait reduced scores ranging from 15 to 90 with higher scores indicating more thinking about food, intentions to eat, loss of control, and emotional impact on eating behavior.

[j]Self-efficacy scores ranging from 0 to 100 with higher scores representing greater confidence in ability to regulate eating habits.

Exploratory Analyses of Weight Loss

An ITT complete case analysis (see Tables 4 and 5) showed that the intervention group lost 0.88 kg at 1 month and continued to lose weight, with an average weight loss of 1.63 kg at 3 months. The control group initially gained 0.12 kg at 1 month but then lost 0.95 kg by 3 months. Adjusting for baseline BMI, this resulted in mean differences in weight loss between groups (favoring the intervention group) of 1.03 kg at 1 month (95% CI 0.33 to 1.74), P=.005, and d=0.2 and 1.01 kg at 3 months (95% CI −0.45 to 2.47), P=.17 and d=0.2. Our sample showed a pooled SD of weight loss of 1.48 kg at 1 month and of 3.11 kg at 3 months.

Sensitivity Analyses

Sensitivity to missing data was explored using an ITT analysis, this time dealing with missing outcome data through imputation, using the method of last observation carried forward. Adjusting for differences in baseline BMI, the pattern of weight loss remained the same, with the intervention group losing 0.91 kg more weight than the control group at 1 month, 95% CI (0.30 to 1.52), and 0.84 kg more at 3 months, 95% CI (−0.35 to 2.02). In addition, sensitivity to baseline differences in snacking behavior, cointerventions, weight-affecting medications, and ethnicity distribution was examined, and none of these factors substantially altered the pattern of the findings.

To explore the potential utility of ImpulsePal as a standalone intervention, a subgroup analysis (using an ITT with complete case analysis, see above) was conducted exploring variations in weight change alongside cointerventions. Among the control participants, those who took part in other weight management programs (23% (6/26)) lost 2.12 kg more than those who did not (85% (22/26); 95% CI 0.55 to 3.70) and 3.42 kg more at 3 months (21% (5/24) vs 79% (19/24); 95% CI −0.96 to 7.81). In the intervention group, those who engaged in cointerventions (31% (15/48)) only lost 0.49 kg more than those who used ImpulsePal as a standalone intervention (69% (33/48); 95% CI −0.35 to 1.33) and 0.96 kg at 3 months (30% (13/43) vs 69% (30/43); 95% CI −0.45 to 2.38).

Eating Behavior

There were positive changes in nearly all measures reflecting reductions in consumption behavior and overeating, reductions in loss of control and uncontrolled eating episodes from baseline to 1 month and 3 months in both the intervention and control group, with greater reductions in the intervention group (except for drink consumption) and significantly greater reductions in frequency of loss of control during overeating and number of days of uncontrolled overeating when adjusting for baseline differences in BMI (Tables 4 and 5).

Table 4. Changes in the primary and secondary outcomes proposed for a full-scale trial at 1 month.

Outcome	0 to 1 month, mean (SD)	Adjusted between group mean difference[a] (95% CI)
Weight (kg)		**−1.03 (−1.74 to −0.33)**
Intervention (N=48)	−0.88 (1.34)	
Control (N=26)	0.12 (1.73)	
Body mass index		**−0.36 (−0.62 to 0.11)**
Intervention (N=48)	−0.32 (0.49)	
Control (N=26)	0.02 (0.63)	
FFQ[b] total		**−0.16 (−0.41 to 0.80)**
Intervention (N=47)	−0.36 (0.50)	
Control (N=24)	−0.20 (0.45)	
FFQ snack		**−0.19 (−0.46 to 0.08)**
Intervention (N=47)	−0.42 (0.51)	
Control (N=24)	−0.23 (0.60)	
FFQ drink		**−0.09 (−0.47 to 0.29)**
Intervention (N=47)	−0.20 (0.79)	
Control (N=24)	−0.11 (0.68)	
Overeating frequency		**−3.33 (−6.69 to 0.02)**
Intervention (N=45)	−4.99 (7.75)	
Control (N=24)	−1.67 (4.27)	
Loss of control		**−4.81 (−7.81 to −1.82)**
Intervention (N=44)	−4.60 (7.19)	
Control (N=24)	0.21 (2.89)	
Uncontrolled overeating (no days)		**−3.82 (−6.73 to −0.90)**
Intervention (N=45)	−4.14 (6.85)	
Control (N=24)	−0.33 (2.76)	

[a]Analysis of covariance analyses of change scores with baseline body mass index value entered into the model to adjust for baseline differences.
[b]FFQ: Food Frequency Questionnaire.

Table 5. Changes in the primary and secondary outcomes proposed for a full-scale trial at 3 months.

Outcome	0 to 3 months, mean (SD)	Adjusted between group mean difference[a] (95% CI)
Weight (kg)		**−1.01 (−2.47 to 0.45)**
Intervention (N=43)	−1.63 (2.1)	
Control (N=24)	−0.95 (4.4)	
Body mass index		**−0.36 (−0.88 to 0.16)**
Intervention (N=43)	−0.58 (0.76)	
Control (N=24)	−0.35 (1.55)	
FFQ[b] total		**0.07 (−0.20 to 0.33)**
Intervention (N=43)	−0.34 (0.46)	
Control (N=23)	−0.40 (0.58)	
FFQ snack		**−0.86 (−0.34 to 0.17)**
Intervention (N=43)	−0.43 (0.46)	
Control (N=23)	−0.34 (0.53)	
FFQ drink		**0.47 (0.02 to 0.91)**
Intervention (N=43)	−0.09 (0.75)	
Control (N=23)	−0.55 (1.01)	
Overeating frequency		**−2.33 (−5.79 to 1.12)**
Intervention (N=43)	−4.87 (7.47)	
Control (N=22)	−2.89 (4.52)	
Loss of control		**−3.31 (−6.65 to 0.03)**
Intervention (N=43)	−3.76 (7.41)	
Control (N=22)	−0.66 (3.27)	
Uncontrolled overeating (no days)		**−3.02 (−6.40 to 0.35)**
Intervention (N=43)	−3.85 (7.31)	
Control (N=22)	−1.07 (4.56)	

[a]Analysis of covariance analyses of change scores with baseline body mass index value entered into the model to adjust for baseline differences.

[b]FFQ: Food Frequency Questionnaire.

App Use

Usable app usage statistics were available for 56 (out of 58) participants in the intervention group. The majority had seen the instructions for the app and its components (ie, brain training, urge surfing, if-then planning, emergency button, and the danger zones; Table 6), with improvements in receipt of the instructions seen after refinements to the intervention had been made (Cycle 2). The total minutes spent on the app during the first month (from first log in) ranged from 3.5 min to 446.8 min with a median usage of 38.1 min (Table 7). Of these 56 participants, 39 (70%) continued use after the first month (based on app usage statistics). Of those who did not access the app after the first month (n=17), 35% (6/17) had dropped out of the study. Usage time (total minutes or number of days) was not significantly correlated with weight loss within the intervention group either at 1 month (r=–0.16 and r=–0.01, respectively), or at 3 months (r=0.04 and r=–0.02, respectively).

Table 6. Delivery/receipt of intervention instructions and impulse management strategy instructions.

App component	Cycle 1 (N=26)	Cycle 2 (N=30)	Total (N=56)
First time log in, n (%)	26 (100)	28 (93)	54 (96)
App instructions, n (%)	26 (100)	29 (97)	55 (98)
Brain training, n (%)	24 (92)	30 (100)	54 (96)
Urge surfing, n (%)	22 (84)	29 (97)	51 (91)
If-then planning, n (%)	24 (92)	30 (100)	54 (96)
Emergency button, n (%)	25 (96)	30 (100)	55 (98)
Danger zones, n (%)	24 (92)	27 (90)	56 (91)

Table 7. App usage statistics.

Usage time period	Total minutes spent using the ImpulsePal app	Number of separate days ImpulsePal accessed
During first month of use (N=56)		
Range	3.5 to 446.8	1 to 23
Median (IQR[a])	38.1 (53.7)	7.0 (5.0)
Excluding lost to follow-up (N=47)		
Range	3.48 to 446.8	1 to 23
Median (IQR)	39.2 (54.9)	7.0 (5.0)
During first 3 months (N=56)		
Range	3.5 to 1444.6	1 to 51
Median (IQR)	46.4 (70.3)	10.0 (11.0)
Excluding lost to follow-up (N=41)		
Range	3.48 to 1444.6	1 to 51
Median (IQR)	52.6 (96.5)	11.0 (10.5)
Following the first month for continuing users (N=39)[b]		
Range	0.02 to 1376.10	1 to 29
Median (IQR)	17.7 (38.7)	10 (10.3)
Excluding lost to follow-up (N=31)		
Range	0.98 to 1376.10	1 to 29
Median (IQR)	19.1 (3.5)	5.0 (7.0)

[a]IQR: interquartile range.

[b]Use measured up until the end of the 3-month study participation.

Feasibility of Use and Satisfaction With the ImpulsePal App

In total, 43 (74%) usable app satisfaction questionnaires were returned by the intervention group participants at 1 month. Data from these questionnaires suggested a high level of satisfaction with the intervention. In total, 98% agreed or strongly agreed that ImpulsePal was easy to understand mean 4.6 (out of 5; SD 0.6), 98% agreed or strongly agreed that ImpulsePal was easy to use mean 4.7 (SD 0.5), and 93% was satisfied or very satisfied with ImpulsePal mean 4.3 (SD 0.7). In the available app satisfaction questionnaires of Cycle 1 (n=19), the open-ended question elicited qualitative data, which suggested that (1) the Brain Training (go/no-go task) component was too lengthy (5 min) and became boring over time. Suggestions for improvement included shortening the time to complete the task and including a greater variety of images; (2) the app and strategy instructions are not always read; and (3) the Danger Zones (Global Positioning System-enabled reminders) were not accurate enough and required a better reminder system. After Cycle 2 (n=24 questionnaires), answers to the open-ended question still suggested that further improvements to the Brain Training component were required and elements of gamification were mentioned (eg, adding difficulty levels and rewards).

Feasibility of Use and Satisfaction With the Trial Procedures

The study satisfaction questionnaires (returned by 75% (66/88) of the participants in both groups at the 3-month visit) also indicated high usability of, and satisfaction with, the trial materials and procedures. In total, 97% agreed or strongly agreed that the trial procedures were easy to understand mean 4.8 (SD 0.7) and 99% agreed or strongly agreed that the questionnaires were easy to complete mean 4.7 (SD 0.5). Finally, 96% were satisfied or very satisfied with their research study experience mean 4.7 (SD 0.5). The qualitative feedback in the open-ended questions suggested that improvements could be made to (1) the questionnaires (eg, shorter or fewer questions and the use of a Web-based form instead of pen and paper) and (2) the study visit reminder. Although this question asked participants about the study procedures, some intervention group participants were referring to the ImpulsePal app in their answer, suggesting to make ImpulsePal available on iOS or include variety in the *Brain Training* component. In addition, the brief structured interviews indicated that (1) the amount of data collected was *about right* (100%), (2) the Participant Information Sheet was helpful in their decision making about the study (85%) and some could not remember reading it (15%), (3) they did not have any issues with data being sent via the app (100%; intervention group only), and (4) they did not mind being weighed by the researcher (100%). In terms of suggested improvements, some mentioned Web-based or shorter questionnaires, better parking arrangements at the research site, and a text reminder on the day of the study visit in addition to the phone call reminder before the day.

Discussion

Principal Findings

This study examined the feasibility of conducting a full-scale trial of the ImpulsePal intervention. We successfully recruited a sample of overweight adults seeking weight management support in the South West of England, suggesting that people are willing to use smartphone apps to support their weight management. This study showed acceptable uptake and retention rates and high participant satisfaction with, and use of, an intervention targeting impulsive processes to support changes in eating behavior for weight management. Moreover, this feasibility study showed high participant satisfaction with, and completion of, the trial procedures. The exploratory analysis of differences in weight loss between groups suggests that approximately 1 kg of weight loss may be achievable at the 1- and 3-month follow-up with medium and small effect sizes, respectively. It is interesting to note that app usage (total times or number of days) was not significantly associated with weight loss. This is further explored in the process evaluation [24]. On the basis of our findings, a fully powered RCT would need to recruit a total of 457 participants, assuming a pooled SD of 3.1 kg and the lower bound CI of retention (67%) to have 80% power to detect a 1.0 kg difference between groups at 3 months of follow-up at the 5% significance level. Longer term follow-up may require larger sample sizes as our data suggest that the SD for weight loss increases over time.

With regard to trial procedures, first, our uptake improved following the addition of a variety of recruitment routes (eg, local advertising and the Exeter 10,000 project newsletter). Another way in which recruitment for a full-scale trial could be further improved would be to offer ImpulsePal on devices using other operating systems in addition to Android. A third of the potentially eligible participants were eligible to take part based on age, gender, and BMI but were excluded as their devices were using iOS. Thus, there is scope for substantially extending the reach and uptake of the study. Second, retaining participants in trials of mHealth or other digital behavior change interventions is challenging [55,56] but our retention rates compare well with other digital weight management studies, which typically range from 70% to 85% at up to 3 months of follow-up [57-59]; therefore, our follow-up procedures are acceptable for use in a full-scale trial.

The pattern of weight change in this study is similar to that found in other app–based weight management interventions. One meta-analysis found that adding mHealth apps for weight management interventions significantly reduced body weight by 1.04 kg and reduced BMI by 0.43 kg/m^2 compared with various control groups (ranging from waiting list control groups to intensive counseling [19]). However, these apps primarily focused on weight change through dietary self-monitoring, physical activity trackers, and nutritional information. To our knowledge, this is the first study to examine the potential impact of a theory- and evidence-based weight management app that explicitly targets both impulsive and reflective processes that underpin eating behavior, promoting small sustainable behavior changes without focusing on a prescribed restrictive diet.

Even if mHealth apps (including ImpulsePal) only produce 1 kg of weight loss, this is likely to be at a cost far lower than conventional interventions that deliver higher weight loss. This may result in a cost per kilogram weight loss well below that found in popular effective weight loss programs ranging from commercial programs to medications [60]. Furthermore, mHealth apps are likely to have a greater reach than face-to-face programs because of their accessibility. Nonetheless, considering 26% of our sample took part in concurrent weight management programs, it may also be interesting to investigate whether the use of ImpulsePal alongside other weight management support would result in additive effects, which may improve cost-effectiveness of existing programs [3]. In light of ongoing major cuts to public health infrastructure and services in the United Kingdom [61], including face-to-face weight management services as occurred during this study, there is a need for low-cost solutions to provide efficiencies in public health spending and mHealth may provide such solutions.

Strengths and Limitations

The main strengths of this feasibility study were the use of rigorous methods to assess the feasibility of conducting a full-scale randomized trial of a smartphone app–based intervention using trial procedures that closely mirror those to be used in a full-scale trial, and the use of objective weight measurements to estimate SDs. However, some limitations need to be acknowledged. First, there are limitations that may have influenced the outcomes of this feasibility study. This study had

a low uptake rate from the initial intended recruitment route through an existing weight management referral system (3% of those invited), which may be due to the timing of the invitation. Referrals were invited to take part in this feasibility study once they had been referred to existing local weight management groups but before commencement of their program. Therefore, this population had already been offered another service and may not have felt the need for additional support (study involvement was offered in addition to their weight management program, not as a replacement). Thus, this study failed to recruit a representative sample of the individuals referred to existing weight management interventions via primary care. However, the study successfully recruited a volunteer-based sample through additional community-based routes, which targeted overweight individuals who wanted to lose weight. However, these self-selected individuals may have been more motivated to change and do well compared with participants who are referred to weight management.

Second, because of limited resources, blinding of the researcher was not feasible. Although we used objective methods for body measurements to reduce the risk of bias, blinding of researchers collecting follow-up data would be preferable in a full-scale trial [62]. Moreover, offering the control group an alternative app with no active components would allow for blinding of the participants as well. This would minimize the potential for social desirability bias affecting self-report assessments differently between groups but would also remove any difference between the groups in motivation to stay in the trial, which was present in the current study where control participants were told they would receive the ImpulsePal at the end of their study participation (incentive). Similarly, face-to-face interviews were only conducted with intervention group participants. This qualitative evaluation may have a therapeutic effect, which may have influenced these participants over and above the ImpulsePal intervention, resulting in better outcomes in this group. The greater likelihood of a motivation to change and do well in volunteer-based samples, the potential for social desirability bias in the nonblinded assessments, and the potential therapeutic effects from the qualitative interviews may have resulted in an overestimation of the potential effect size and more favorable reports of acceptability. Moreover, satisfaction with the app was quantitatively measured using a questionnaire constructed for this study. However, a standardized satisfaction or usability questionnaire would be preferable for future evaluation.

Third, this study used a relatively short follow-up period (3 months) compared with evaluations of face-to-face weight management interventions [2]. Fourth, the minimal diversity in this sample is a limitation commonly faced by evaluations of digital weight management interventions [56]. Although the prevalence of obesity is similar for men and women, weight management trials tend to recruit samples that are on average 27% male and 73% female [63]. Our study managed to recruit a slightly higher proportion of men (35%); however, women still comprised a substantial majority. Furthermore, the majority of smartphone interventions targeting obesity have been tested in samples that were predominantly white [64] as was the sample in this study, primarily owing to its geographical location. Given that obesity and overweight differentially impact ethnic minority populations, it is important to assess the effectiveness of digital weight management interventions in diverse populations [65]. Increasing efforts to advertise the study to the male population and in additional geographical locations may provide further opportunity to extend its reach and uptake. Finally, owing to the small sample size and the fact it was a feasibility study, the comparative analysis was only exploratory, and therefore, no definitive conclusions can be drawn from differences between groups for any of the outcomes measured in this study. Therefore, a fully powered RCT is required to assess the effectiveness, and ideally cost-effectiveness, of the ImpulsePal intervention.

Conclusions

This feasibility study demonstrated high levels of satisfaction with both the intervention and study methods. The findings suggest that an RCT is feasible, likely to recruit well, and to have good rates of follow-up. A full-scale evaluation is required to conclusively investigate the effectiveness and cost-effectiveness of ImpulsePal for people who are overweight, but initial exploratory findings are in a promising direction.

Acknowledgments

This study was funded through a University of Exeter Medical School PhD Scholarship. SBvB's input was supported by a University of Exeter Medical School PhD scholarship. CA and CJG's input was supported by the UK National Institute for Health Research (NIHR) through the Collaboration for Leadership in Applied Health Research and Care in the South West Peninsula (PenCLAHRC) and a Career Development Fellowship (CDF-2012-05-259), respectively. The authors would like to thank Richard Merrifield and Rose Sloman from HPD, and Katarina Kos and Jo Ratford of Royal Devon and Exeter Hospital and the Exeter 10,000 project team for help with advertising the study to their patients and volunteers. The views expressed in this publication are those of the authors and not necessarily those of the NIHR, NHS, or the Exeter 10,000 project members involved.

Authors' Contributions

SBvB made substantial contributions to the conception and design of the study; the collection, analysis, and interpretation of the data; and drafting of the manuscript as part of her doctoral training program. CJG and JRS contributed to the design of the study, provided advice on the analysis and interpretation of the data, and commented on the manuscript. NSL and CA advised on the interpretation of data and commented on the manuscript.

Conflicts of Interest

The authors are owners and developers of the intervention. CJG conducted paid consultancy work for Weight Watchers in 2018.

Multimedia Appendix 1

Supplementary file for randomised controlled feasibility trial of ImpulsePal: A smartphone app–based weight management intervention to reduce impulsive eating in overweight adults.

[PDF File (Adobe PDF File), 556KB - formative_v3i2e11586_app1.pdf]

Multimedia Appendix 2

CONSORT-eHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 3MB - formative_v3i2e11586_app2.pdf]

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Abbreviations

ANCOVA: analysis of covariance
AR: action research
BIS: Barratt Impulsiveness Scale
BMI: body mass index
CONSORT: Consolidated Standards for Reporting Trials
FFQ: food frequency questionnaire
HPD: Health Promotion Devon
ITT: intention-to-treat
mHealth: mobile health
NHS: National Health Service
NIHR: National Institute for Health Research
PFS: Power of Food Scale
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 13.07.18; peer-reviewed by H Oh, L Solbrig, A Rodríguez-Molinero; comments to author 27.09.18; revised version received 03.01.19; accepted 27.01.19; published 30.04.19.

Please cite as:
van Beurden SB, Smith JR, Lawrence NS, Abraham C, Greaves CJ
Feasibility Randomized Controlled Trial of ImpulsePal: Smartphone App–Based Weight Management Intervention to Reduce Impulsive Eating in Overweight Adults
JMIR Form Res 2019;3(2):e11586
URL: https://formative.jmir.org/2019/2/e11586/
doi:10.2196/11586
PMID:31038464

Original Paper

An Intervention to Increase Condom Use Among Users of Chlamydia Self-Sampling Websites (Wrapped): Intervention Mapping and Think-Aloud Study

Katie Newby[1], BSc, MSc, PhD; Rik Crutzen[2], PhD; Katherine Brown[1], PhD; Julia Bailey[3], PhD; John Saunders[4], PhD; Ala Szczepura[5], BA, DPhil; Jonny Hunt[6], MA; Tim Alston[7], BEng; S Tariq Sadiq[8], MD, FRCP; Satyajit Das[9], MD, FRCP

[1]Centre for Advances in Behavioural Science, Faculty of Health and Life Sciences, Coventry University, Coventry, United Kingdom
[2]Health Promotion, School for Public Health and Primary Care, Maastricht University, Maastricht, Netherlands
[3]Primary Care and Population Health, Institute of Epidemiology and Health, University College London, London, United Kingdom
[4]Health Protection Services, Public Health England, London, United Kingdom
[5]Enterprise and Innovation, Coventry University, Coventry, United Kingdom
[6]Going Off The Rails, Coventry, United Kingdom
[7]Preventx, Sheffield, United Kingdom
[8]Institute for Infection and Immunity, St George's, University of London, London, United Kingdom
[9]Coventry and Warwickshire Partnership Trust, Coventry, United Kingdom

Corresponding Author:
Katie Newby, BSc, MSc, PhD
Centre for Advances in Behavioural Science
Faculty of Health and Life Sciences
Coventry University
RC Building (4th Floor)
Priory St
Coventry, CV1 5FB
United Kingdom
Phone: 44 02477 657459
Email: k.newby@coventry.ac.uk

Abstract

Background: Young people aged 16-24 years are disproportionately affected by sexually transmitted infections (STIs). STIs can have serious health consequences for affected individuals and the estimated annual cost of treatment to the National Health Service is £620 million. Accordingly, the UK government has made reducing the rates of STIs among this group a priority. A missed opportunity to intervene to increase condom use is when young people obtain self-sampling kits for STIs via the internet.

Objective: Our aim was to develop a theory-based tailored intervention to increase condom use for 16-24-years-olds accessing chlamydia self-sampling websites.

Methods: The intervention, Wrapped, was developed using Intervention Mapping and was co-designed with young people. The following steps were performed: (1) identification of important determinants of condom use and evidence of their changeability using computer and digital interventions; (2) setting the intervention goal, performance objectives, and change objectives; (3) identification of Behavior Change Principles (BCPs) and practical strategies to target these determinants; and (4) development of intervention materials able to deliver the BCPs and practical strategies.

Results: Users of existing chlamydia self-sampling websites are signposted to Wrapped after placing an order for a sampling kit. Salient barriers to condom use are identified by each user and relevant intervention components are allocated to target these. The components include the following: (1) a sample box of condoms, (2) an online condom distribution service, (3) a product for carrying condoms, (4) a condom demonstration video, (5) a series of videos on communication about condom use, and (6) erotic films of real couples discussing and demonstrating condom use.

Conclusions: This intervention will be directed at young people who may be particularly receptive to messages and support for behavior change due to their testing status.

(JMIR Form Res 2019;3(2):e11242) doi:10.2196/11242

KEYWORDS

sexually transmitted infection; condoms; sexual behavior; young adult; intervention development; internet; eHealth; co-design

Introduction

The UK Department of Health has made reducing the rates of sexually transmitted infections (STIs) a priority, particularly among young people who are disproportionately affected [1]. STIs can lead to serious health consequences, such as pelvic inflammatory disease, ectopic pregnancy, and infertility, which have a significant impact on quality of life [2]. The estimated annual cost to the National Health Service of STI treatment is £620 million [3]. One of the most effective ways to avoid STIs is to use a condom during penetrative sex [1] but young people report inconsistent use [4,5]. A missed opportunity to intervene to increase condom use is when young people obtain self-sampling kits for STIs via the internet.

As part of the National Chlamydia Screening Programme (NCSP) [6], there are a number of websites offering free self-sampling kits to young people living in England for the STI *Chlamydia trachomatis*. These kits are used by young people to collect a specimen, which is sent to a laboratory for testing. Laboratories then send the test results back to individuals. A total of 132,000 15-24-year-olds were tested via this route in 2017, representing once again an increase in use from the previous year [7]. Those tested are at high risk of acquiring STIs and include groups that other services, such as general practice and community sexual and reproductive health services, have found difficult to engage [8]. These websites therefore provide a unique opportunity to intervene with a priority population; however, they typically provide little or no sexual health promotion [8] despite the personal relevance of testing, making this an ideal "teachable moment" [9].

Digital health behavior-change interventions targeting young people have good potential reach. Access to the internet by young people living in the United Kingdom is now almost universal, with 99% of 16-24-year-olds reporting that they use the internet at home or elsewhere [10]. Digital interventions also offer a number of advantages to users over face-to-face delivery, including enabling access to content anonymously, repeatedly, and at convenient times [11,12]. The relatively low running costs of digital interventions following development [13] and their potential to deliver tailored content to individual users [14] with high levels of fidelity [15] also make them attractive to developers. Systematic reviews seeking to establish the efficacy of digital interventions for increasing protective sexual behavior have so far, however, only identified small effects (Cohen d<0.3) [16,17]. In order to harness their potential, it is necessary to identify efficacious content and characteristics.

Digital interventions are more effective at changing sexual behavior when tailored than nontailored [17]. Tailoring content often requires users to respond to multiple survey-style questions prior to receiving the intervention. It is essential, however, that tailoring methods used in digital interventions are acceptable, particularly in terms of burden, otherwise users in the real world will disengage. One parsimonious approach asks users to simply self-select from a predefined list the most important determinants of their behavior and to present content to match these. This has been identified as a reliable technique for isolating important behavioral determinants [18-20] but, to date, this approach has not been applied within a digital sexual health intervention [21].

This article describes the development of a tailored behavior change intervention, *Wrapped*, for increasing condom use among 16-24-year-olds using chlamydia self-sampling websites. The aim of the intervention is to reduce the incidence of STIs in this at-risk population. To the authors' knowledge, this is the first digital sexual health intervention developed specifically for young people accessing STI self-sampling websites.

Methods

Overview

Wrapped was developed using Intervention Mapping [22]. Intervention Mapping provides a framework for the development of theory- and evidence-based interventions and is consistent with Medical Research Council guidance on the development of complex interventions [23]. It involves a number of sequential and iterative steps. Steps 1-4 relate to intervention development per se; the purpose and outcomes of these steps are described in Table 1 below. Steps 5 and 6 relate to planning for implementation, adoption, and evaluation. These plans are described at the end of the Results section.

Throughout steps 1-4, a combination of primary research, secondary research, and co-design methods were used to determine and refine intervention content.

Step 1: Needs Assessment

The research team was made up of three health psychologists (KN, KB, and RC) and a sexual health doctor (JB), all with considerable sexual health research experience. The team consulted a number of sources of evidence in order to select determinants to be targeted by the intervention. Firstly, a review of reviews [24] reporting on the strength of association between condom use and behavioral determinants was examined. Determinants of condom use with a correlation above .2, corresponding to a small-to-medium effect size, were considered to be important and were selected. Secondly, three recent meta-analyses examining the effect of digital interventions on the determinants of health behavior [21,25,26] were consulted to establish the changeability of the selected determinants.

Table 1. Intervention Mapping steps, their purpose, and their outcomes.

Intervention Mapping step	Purpose	Outcome
1. Needs assessment	To identify what the intervention should address	Documented behavioral determinants
2. Intervention outcomes and objectives	To clarify the intervention goal and performance objectives, and to identify the immediate change objectives that need to be achieved in order to realize the intervention goal	Intervention goal and performance objectives, and matrices of change objectives
3. Intervention design	To identify Behavior Change Principles linked to change objectives and translate them into practical applications that are most likely to bring about the desired behavioral change via the identified determinants	Documented Behavior Change Principles linked to change objectives and their translation into practical applications
4. Intervention production	To develop and finalize the intervention structure and content	The final intervention

Step 2: Intervention Outcomes and Objectives

Establishing Intervention Goal and Performance Objectives

The intervention goal was discussed and agreed upon by the study steering group. The steering group consisted of the above research team as well as three additional sexual health doctors (STS, JS, and SD), a professor of health technology assessment (AS), a sex education consultant (JH), and the technical director of an STI diagnostics business, which runs an STI self-sampling website (TA). Subsequently, the research team broke the intervention goal down into performance objectives, specifying what was required of intervention participants to achieve this goal. These were approved and finalized by the steering group.

Developing the Matrix of Change Objectives

A matrix was developed by the research team by combining the performance objectives and associated determinants to create change objectives (ie, positive statements about what needs to happen in order for the performance objectives to be achieved). To inform the selection of change objectives, the review of reviews that was previously consulted to identify important determinants to target with the intervention [24] was further examined. Beliefs identified as having a correlation above .2 were selected and used to inform specification of change objectives where relevant. Change objectives were discussed, refined, and agreed upon by the research team.

Step 3: Intervention Design

Selection of Behavior Change Principles

The term *Behavior Change Principle* (BCP) is used to refer to any principle that can be applied to change a determinant of behavior [27]. The term *BCP* is used interchangeably to refer to two overlapping but distinct terms, namely *Behavior Change Techniques* (BCTs) and *Behavior Change Methods* (BCMs). Taxonomies of BCTs [28] and BCMs [29] were consulted by the research team to identify BCPs suitable for changing the selected determinants of condom use. The BCM taxonomy provides methods linked to behavioral determinants. Only methods that have been "shown to be able to change one or more determinants of behavior" [29] are listed, as are the conditions or *parameters* under which they have been shown to be effective. The BCM taxonomy was used by the team to identify BCMs suitable for targeting the determinants of this intervention. The parameters of these methods were also noted.

The BCT taxonomy was initially developed to enable the coding of BCTs within existing behavioral interventions. As such, BCTs are not linked to behavioral determinants within the taxonomy. However, a recent consensus exercise has been undertaken, in which one hundred behavior change experts rated their agreement of the link between 61 BCTs, taken from the 93-item BCT taxonomy, and 26 mechanisms of action: 80% agreement was judged as consensus having been reached. This enables intervention developers to use the BCT taxonomy in a new way, that is, to select BCTs to target specific behavioral determinants. The first author (KN) participated in the consensus exercise and, accordingly, was provided with the confidential report of findings currently under preparation for publication. The findings identified BCTs to which 80% or more of the experts responded "definitely yes" when asked whether they were linked to the determinants to be targeted by the intervention. At the end of this process, a list of BCTs and BCMs identified as suitable for targeting the chosen determinants was produced.

Co-Design Workshop

A co-design workshop was convened to generate ideas or *practical applications* for targeting the change objectives. The intention was to create an environment in which thinking was creative, bold, and unrestricted. For this reason, the identified BCPs were set aside for this event, and attendees were encouraged to think openly about ideas that might work to target the performance objectives. Attendees included a group of 15 young people aged 16-24 years whose involvement was facilitated and supported by a sex education consultant (JH). This group was formed from the following: young people under the care of the Youth Offending Service (n=2), pupils from a city center training college (n=8), and student nurses from one university (n=5). Also in attendance were members of the steering group (KN, RC, JB, JS, and AS), a product designer, two cocreation researchers, an electronic artist, a visual artist and designer, and the head of digital for a sexual health charity.

Ahead of the workshop, a large wall display was created with images to reflect each of the five performance objectives that were described to the attendees (see Figure 1). Attendees were split into groups so that each group was working on generating ideas for one performance objective. Each table had a variety

of materials placed on it to inspire and support creativity (eg, colored pens and highlighters, paper, sticky notes, tablets, Blu Tack, and plasticine). Additionally, a description of the relevant performance objective was provided, along with questions that directed the groups to focus on the related change objectives. Everyone was encouraged to come up with novel ideas about how the intervention could address the issues presented (see Figure 2).

The workshop took place on Coventry University premises in Coventry, England, and was facilitated by KN. Throughout the day, attendees were instructed to rotate around the groups so that everyone contributed to each performance objective. This also ensured that each group had a mixture of experts in it at all times to include, as a minimum, one health psychologist, one individual with relevant clinical and public health experience, and one individual with expertise in creative techniques (eg, product designer, electronic artist, or visual artist and designer). At the start of each new rotation, groups were free to continue to work on the ideas of the previous group or to work up something new. One person who had participated in each group's discussion always remained at the table to provide continuity.

Figure 1. Wall display of images reflecting performance objectives.

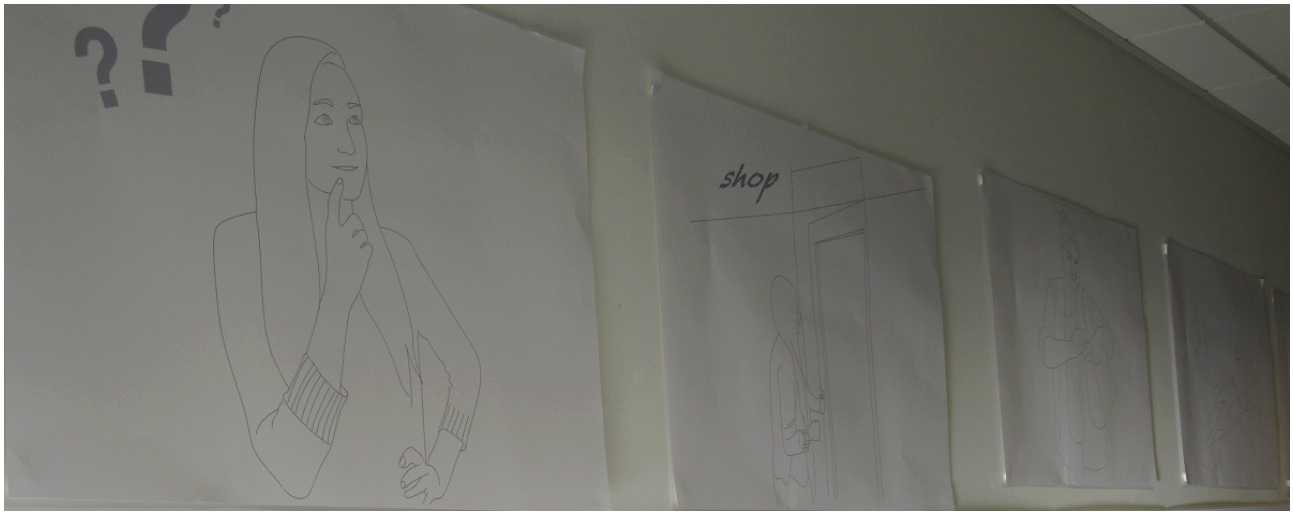

Figure 2. Workshop group discussion.

At the end of the day, the whole group came back together and the wall display representing the five issues was populated. The whole group then discussed the ideas that had arisen and a number were further developed. After the workshop, a subgroup of the research team continued to work on and refine the ideas. Inherent BCPs were identified for each of the ideas. All ideas were then judged according to their feasibility (ie, ability to be delivered digitally and their cost), their ability to engage the priority population, and their ability to effectively achieve the change objectives. The latter was judged on the basis of whether the idea delivered an identified BCP that could be as effective in changing the relevant behavioral determinant and whether the parameters for use could be met. A final selection of ideas (ie, practical applications) was made based on these criteria.

Step 4: Intervention Production

Development of Prototypes

The selected practical applications were worked up into six intervention components. The development of each component involved input from young people and experts as follows. Students from the training college (n=8) and members of the Respect Yourself Advisory Board, a group assembled to provide guidance on sexual health issues, services, and support in their area (n=6), met on multiple occasions to give feedback on prototypes for components 1 and 3. They also gave guidance on the nature of the service to be delivered through component 2. This feedback was given at face-to-face meetings; additionally, the Respect Yourself group also provided this via a private Facebook page. A youth theater group (n=25) advised on the content and design of component 6. Components 4 and 5 were informed by the same theater group who also went on to be filmed for the content.

Components 1-3 were developed with support from a product designer. A filmmaker was commissioned to film, edit, and produce the videos for components 4 and 5. Component 6 was developed in partnership with the Pleasure Project [30], an organization that campaigns for sex and relationships education that acknowledges the role that pleasure plays in sexual health decision making. Consultation with specific individuals and teams was also made with regard to the safeguarding of users of the intervention and concerning systems and processes to ensure compliance with current UK data protection legislation.

Website Development

The full suite of components was developed over a period of 9 months, during which time a design team worked on the branding of the intervention and on the digital architecture of a website required to host the components. The design team was appointed following an open tender process. The design team worked closely with the project lead (KN) to deliver the required functionality and look of the intervention. At a number of stages, the Respect Yourself Advisory Board provided direct input. This included, for example, commenting on intervention branding (ie, name, logo, and colors), early wireframes (ie, a set of images showing proposed functional elements of Wrapped), and copy to be used on the website. This level of user input was considered vital to ensure high levels of usability and appeal. The name for the website, Wrapped, was chosen by this group, as was the branding. Different colors and styles were uploaded onto a private Facebook page; the group discussed each of these and then nominated their favorite three. The branding with the highest number of votes was selected. See Multimedia Appendix 1 for the chosen logo.

Think-Aloud Study

Think-aloud interviews were conducted to test the usability of the full intervention prior to making final changes. Institutional ethical approval was received for this study and all participants were required to provide informed consent. A total of 12 young people aged 17-24 years—5 male (42%) and 7 female (58%)—were recruited through the chlamydia self-sampling website freetest.me [31]. Participants were given a £20 Amazon e-voucher in recognition of their time. Ahead of the interview, examples of intervention products (see components 1-3 in the Results section) were posted to all participants. They were instructed not to open these. Participants met virtually with a researcher via Skype for one-on-one interviews. At the start of the interview, participants were provided with the URL for Wrapped and asked to load the website. They were then asked to share their screen via Skype. This enabled synchronous viewing of the intervention by the researcher and the participant. Each participant was asked to work through the content, as they would if browsing in their own time, and to “think aloud” as they did so, verbalizing thoughts on the look, feel, content, and ease of use and navigation. Prompts were used to encourage participants to “think aloud” and to provide feedback on particular aspects. Due to the personal nature of component 6, participants were asked to view the video content in their own time and provide written feedback after the interview via email. At relevant points during the interview, participants were instructed to open the appropriate items that had been posted to them. First impressions and thoughts on whether these would be used and how they could be improved were then collected. Multimedia Appendix 2 provides the interview schedule for the think-aloud interviews. The researcher made notes throughout. Content analysis [32] was used to organize the data into themes.

Results

Step 1: Needs Assessment

Overview

The priority population for the intervention was determined to be young people aged 16-24 years. The intention from the outset was for the intervention to be embedded within the pathway of existing chlamydia self-sampling websites. These services are commissioned at a local level by public health departments under local government control and are part of the NCSP [6]. The age range that the NCSP provides chlamydia testing to is 15-24 years. The target age range for the Wrapped intervention was therefore largely determined by NCSP provision. However, the lower age limit was increased to 16 years for safeguarding reasons.

Evidence Review

Table 2 presents the determinants of condom use selected as the basis of the intervention as a result of the evidence review.

Table 2. Determinants of condom use selected for targeting based on importance, that is, the strength of association with condom use.

Determinant of condom use	Definition	Evidence regarding importance
Attitude and outcome expectancies	Extent to which people value the behavior	Overall attitude, r^a=.32 [33] Affective attitude components (ie, general affect regarding condoms, for example, good or bad): adult men, *r*=.34 [34]; prospective, *r*=.37, and cross-sectional studies, *r*=.42 [35] Beliefs about pleasure, *r*=.28 [34] Beliefs about spontaneity, *r*=.35 [34] Beliefs about partner reactions, *r*=.43 [34] Belief that condoms prevent STIs[b], including that they are reliable, will not break, etc: adult men, *r*=.24 [34]
Perceived norms	Beliefs about what is usual and acceptable	Descriptive norm, *r*=.37 [33]
Self-efficacy	Confidence in performing the behavior	Self-efficacy for condom use: cross-sectional, *r*=.24, and prospective studies, *r*=.33 [35]; correlations (cross-sectional or prospective designs included), *r*=.25 [33]
Behavioral capability[c]	Knowledge and skills required to perform the behavior	Necessary for achievement of self-efficacy
Resources	External objects and services that address barriers	Availability of condoms, *r*=.41 [33] Carrying condoms, *r*=.31 [33]

[a]The strength of the correlation, *r*, is qualified as weak (≤.1), weak to moderate (.1 to .3), moderate to strong (.3 to .5), or high (≥.5) [36].

[b]STI: sexually transmitted infection.

[c]This determinant was included on the basis that self-efficacy for condom use could not be effectively increased without first providing users with the behavioral capability to correctly apply them.

As part of the evidence review, meta-analyses examining the effect of digital interventions on the determinants of health behavior were also examined. The largest effects of digital interventions were observed for knowledge, followed by attitude and self-efficacy, albeit all were still in the small effect size range (standardized mean difference <0.5) [36]. It was clear that previous digital interventions had not been particularly effective in changing these determinants. It was not appropriate therefore for the research team to further refine the selection of behavioral determinants based on this evidence. It was acknowledged that the limited efficacy of digital interventions may in part be due to a failure as yet to establish what works to change behavioral determinants using this type of media. It was agreed that development of this intervention was therefore justified and that, in order to contribute to the knowledge base, future evaluations should seek to "unpick" the intervention in order to identify what worked or did not work to change the targeted determinants and why.

Step 2: Intervention Outcomes and Objectives

Establishing Intervention Goal and Performance Objectives

The intervention goal (ie, aim) was for "young people to use condoms correctly and consistently at every instance of sexual intercourse." The agreed upon performance objectives were as follows:

1. Decide to use condoms for vaginal or anal sex
2. Obtain condoms
   - Identify where and how to access condoms
   - Select preferred type of condom
   - Buy or request condoms
   - Maintain supply of condoms
3. Make condoms available at all times
4. Make partner aware of intention to use condoms
   - Identify when to make intention to use condoms known
   - Have plan for what one will say and do to make intention to use condoms known
   - Have plan for how to deal with, and pose solutions to, partner's disagreement or refusal to use condoms
5. Correctly use condoms

Developing the Matrix of Change Objectives

Multimedia Appendix 3 displays the final matrix of change objectives.

Step 3: Intervention Design

Selecting Behavior Change Principles

Multimedia Appendix 4 displays the pool of available BCPs linked to theoretical determinants of condom use.

Co-Design Workshop

At the end of the workshop, the wall display and a table positioned underneath were populated with numerous notes, drawings, and models to communicate the ideas discussed within the groups. Ideas ranged from simple and practical to complex and aspirational. Multimedia Appendix 5 provides a summary of the ideas generated on the day and the research team's initial assessment of the ideas. As described in the Methods section, all ideas were judged according to their feasibility, ability to engage the priority population, and ability to effectively achieve the change objectives. A final selection of ideas (ie, practical

applications) was made based on these criteria and worked up into prototypes as described in the next section.

Step 4: Intervention Production

Development of Prototypes

Overview

The ideas generated by the workshop led to the development of six specific intervention components. These evolved and were refined through an iterative process that involved considerable input from young people and experts as described within the Methods section. The finalized components are briefly described in the following sections. Please refer to Multimedia Appendix 6 for a detailed description.

Component 1: Sample Pack

The sample pack is a box containing 12 condoms and two sachets of lubricant. This component aims to help young people to identify their preferred type of condom and lubricant; to help them overcome any issues around the smell, fit, and feel of condoms; and to make positive associations between condoms and pleasure (see Multimedia Appendices 7 and 8).

Component 2: Order Condoms

Young people are able to order condoms via a free mail-order condom distribution service. This component aims to make condoms more accessible (ie, affordable and obtainable) to young people (see Multimedia Appendix 9).

Component 3: Condom Carrier

The carrier is a small headphone case that has a hidden compartment for storing condoms and lubricant. This aims to increase condom availability (see Multimedia Appendix 10).

Component 4: Using Condoms

This video provides step-by-step instructions on how to put on a condom using a demonstrator. As well as practical tips, advice is given on how to make this part of the flow of sex. This aims to increase young people's self-efficacy for condom use (see Multimedia Appendix 11).

Component 5: Discussing Condoms

This is a series of seven videos where young people talk about ways in which they have brought up condom use with partners in the past and introduced them into sex. The aim is to help users plan the best time to bring up condom use with their partner and what to do or say if they resist (see Multimedia Appendix 12).

Component 6: Real Life

This is a series of three videos featuring three real couples aged 18-24 years who talk about and demonstrate condom use: who does it, techniques, how to make their use part of sex. The aim is to build positive associations between condom use and pleasure (see Multimedia Appendix 13).

Website Development

The basis for the tailoring of intervention components were the behavioral determinants, particularly beliefs underlying these determinants that were identified as important. These were phrased as barriers to condom use; users of the intervention are asked to select which beliefs are relevant to them when they first access the website. Logic rules were written to enable allocation of relevant components to users based on their selections (see Table 3). After selecting barriers to condom use, users are presented with the website home page. This displays between one and six image and text blocks, each representing an intervention component. Users are informed that these components were selected for them based on the barriers they selected. From this point onward, users are free to browse the content, returning as frequently as they choose. While the condom sample pack and carrier were designed to be a one-off order, the condom delivery service was designed to be available to users on an ongoing basis. The video content was also made continuously available. The decision was made to make component 1 (ie, free sample box of condoms and lubricant) available to all users, that is, not to make it subject to tailoring. This was to ensure that regardless of response to tailoring statements, every user was guaranteed access to some content. It was also agreed that a sample box of condoms and lubricant was a product that all young people could benefit from and that it would provide a potentially useful incentive for encouraging first-time users to visit Wrapped.

Multimedia Appendix 14 describes the change objectives and overall behavioral determinants targeted by each component. BCTs used within each component have also been coded according to the 93-item BCT taxonomy [28].

Think-Aloud Study

Data were organized into five categories reflecting young people's perceptions of intervention usability and value, as described in the following sections.

Website Design

Participants liked the website design, commenting that it had a "professional," "clean," and "friendly" look. They also commented on the tone, which they perceived as "relaxed," "not too preachy," and struck the right balance between sounding "fun but not too childish."

Style and Tone of Language

The style of language was also appreciated: "the content is not gendered and so accessible to everyone" and "sex positive—doesn't skirt around anything." Views on the name Wrapped were also positive, with a number of participants commenting that is was "cryptic" and would not give away what it was about.

Functionality and Navigation

One feature of the original specification that was particularly unpopular was having components that "unlocked" over time. Instead, participants said that they would want all allocated components made available to them immediately. Accordingly, the developers were instructed to remove this feature.

Table 3. Logic rules for the allocation of intervention components to users based on their self-selected salient barriers to condom use.

Statement	Ages	Components
I can't always get the type of condoms I want	All ages	2
I find condoms expensive to buy	All ages	2
I find buying condoms embarrassing	All ages	2
I don't always have a condom on me when it's needed	All ages	3
I find it awkward or difficult letting someone know that I want to use condoms	All ages	5
I'm not always able to put a condom on with confidence and ease	All ages	4
I find using condoms a turn-off	Under 18 years	N/A[a]
	18 years and over	6
I find using condoms interrupts the flow of sex	Under 18 years	4 and 5
	18 years and over	4, 5, and 6
Condoms make sex less enjoyable or pleasurable for me	Under 18 years	4
	18 years and over	4 and 6
Condoms make sex less enjoyable or pleasurable for the person I'm with	Under 18 years	4
	18 years and over	4 and 6

[a]N/A: not applicable.

Copy

User testing demonstrated that copy on the website, while minimal, was rarely read. All copy was therefore shortened to one-to-two sentences and additional formatting used to draw attention. In addition, while users on the whole navigated the site with ease (eg, "easy to click through" and "process feels quite classy, like a shopping experience"), the design team were instructed to make a small number of changes to improve the user experience, for example, providing clearer visual feedback to users that they had selected specific products.

Perceived Value of Components

Participants commented that they liked being able to personalize the condom sample pack (component 1) and condom carrier (component 3) (eg, "I like the idea of designing your own box, it's fun") and described the products as "discrete" and "subtle." Participants also indicated that they appreciated and would use the products and services: "would use next to bed in drawer—perfect for bedroom," "makes me more excited about using condoms," "sets itself apart from other free methods of getting condoms, you know," and "you get what you are given."

The condom demonstration video (component 4) and the videos of young people talking about condom use (component 5) were also enjoyed: "uncensored, covers things that are often overlooked," "interesting, relaxed and funny at times but practical advice," "good ideas," and "you can relate to the people in the videos." A few people, however, found the component 5 videos too long and a bit repetitive; some also had problems with buffering. Subject to future funding, the seven videos within this section will be combined into one to address these issues.

Finally, the real-life videos (component 6) were also viewed positively: "good insight into how condoms can be a normal part of sex and not an awkward nuisance," "nice to see sex and condoms so openly discussed and it felt really real, so easier to apply to real-life situations," and "initially I thought they would be awkward but they were done in a classy and intimate way, which felt natural and not at all acted." Some participants commented that they might not be to everyone's taste but felt that their inclusion was nonetheless important: "the style was a lot more controversial than the other videos, which some people might not like, but I think it's nice to give people that option of watching something a little more intense and serious if they want to." Importantly, the real-life videos are only made available to users aged 18 years or older and access is preceded by a warning regarding explicit sexual content.

Adoption and Implementation Plan

The intention is that users of chlamydia self-sampling services will be signposted directly to the Wrapped intervention immediately after making a self-sample request. All users of Wrapped will be eligible to receive component 1 (ie, free sample box of condoms and lubricant) and this will be used as an incentive to visit and register. The technical director of an STI diagnostics business worked with the research team throughout this project. Having an industry partner involved in this way was considered crucial to the success of future implementation. The technical director was on the steering group and was regularly consulted to ensure that as Wrapped continued to develop, the content and messages would be supported and that the digital architecture was compatible with their systems. Wrapped will initially be made available to users of this self-sampling website. This service fulfils approximately 150,000 self-tests per year, making potential reach high. There is also the potential to make the intervention available to other sexual health services. These include providers of other STI self-sampling websites, but also other clinical and community-based services offering STI testing. Local sexual health commissioners were also kept abreast of developments throughout the project. It is likely that any future implementation

of Wrapped will require it to be commissioned at a local level. Understanding commissioning arrangements and securing the buy-in of those in a position to make funding decisions is therefore considered essential if future adoption is to be successful.

Evaluation Plan

The study authors plan to apply for further funding to test the feasibility of trialing the Wrapped intervention. This feasibility study will consist of two parts. Firstly, a qualitative study aimed at identifying methods to enhance the recruitment and retention of participants. This will be followed by a feasibility randomized controlled trial (RCT) to examine the success of these methods. Accordingly, the primary outcome measures will be the rate of recruitment and attrition. If such a feasibility study demonstrates that it is possible to recruit and retain sufficient participants, then a full RCT will be conducted to examine the effect of the intervention on the primary outcome, namely STI incidence.

Discussion

Principal Findings

This paper describes the development of Wrapped, a fully automated, tailored, digital behavior change intervention for young people aged 16-24 years accessing chlamydia self-sampling websites. Wrapped aims to reduce the incidence of STIs among this group by increasing correct and consistent condom use with sexual partners. Wrapped was developed using Intervention Mapping [22]. This provides a robust framework for the development of interventions grounded in theory and evidence. In accordance with calls for full disclosure of intervention development and content [37], this paper provides a transparent and detailed account of this process and, using supplementary files, a full manualization in line with the template for intervention description and replication (TIDieR) guidance [38].

Key determinants identified as important and targeted by the intervention are attitude toward condoms, perceived norms for condom use, self-efficacy for condom communication and use, behavioral capability for condom use, and resources to increase condom accessibility. The intervention addresses these determinants through the following six different components: a condom sample pack, condom postal distribution service, a condom carrier, a condom demonstration video, a series of videos on communication about condom use, and erotic films of real couples discussing and demonstrating condom use. Each component operates in isolation and users are allocated these components when they first access the intervention in accordance with their self-identified salient barriers to condom use.

The usability of Wrapped was examined using a think-aloud study. Participants reported that Wrapped had high levels of design and was intuitive to use. They liked the branding and graphics, which they reported had a stylish and friendly feel. The importance of developing engaging digital interventions should not be underestimated. Consumers of digital media, especially young people, have come to expect quality products that are enjoyable to use and easily navigable. A great deal of care and attention was put into these aspects by the research team. A substantial budget was set aside for development of the digital interface, and the design team was selected through open competition. Furthermore, the look, feel, and functionality of Wrapped was guided throughout by a working group of young people. The tone of copy used throughout the site and on materials accompanying products was also carefully considered. In line with advice received from the working group, all copy has a sex-positive tone and is gender neutral and no assumptions are made about sexual identity. The care taken to get the tone right was worthwhile as it was frequently commented on by participants in the think-aloud study. Participants also reported that they liked being able to select personalized products; the condom carrier comes in four colors and has color-matched headphones, and the condom sample pack had four variations of box to choose from along with four different insert designs, creating 16 possible combinations. It is hoped that this level of personalization will encourage users to order products and increase users' sense of ownership and use.

Comparison With Prior Work

As far as the authors are aware, this is the first digital sexual health intervention to tailor content to behavioral determinants. It is proposed that the tailoring of content will enhance users' active engagement with the intervention and potentially enhance consolidation of learning and behavior change due to relevance of the content to the user's own situation. Wrapped is also one of the few sexual health interventions to use the eroticization of condoms as a strategy for achieving behavior change [39], specifically through videos of real couples discussing and demonstrating condom use (component 6). This approach has been found to lead to more risk-preventive sexual attitudes and behaviors [40]. Interventions embedding such strategies are rare, perhaps due to real or perceived resistance from stakeholders such as parents, religious groups, or sexual health commissioners. However, participants in the user testing responded positively to these videos. Wrapped includes an online condom distribution scheme, which is made available to users who indicate that they experience difficulties obtaining condoms. This is in line with recent guidance issued by the National Institute for Health and Care Excellence, that condom distribution schemes providing a choice of free condoms and lubricant be made easily available to young people at risk of STIs [41].

Strengths and Limitations

Intervention Mapping proved to be a valuable tool to guide development of the intervention. It provides a robust and transparent process that results in an intervention that is not only grounded in theory and evidence, but also in the needs of the intended recipients. Furthermore, involvement of stakeholders, particularly in this case, including sexual health doctors, sexual health commissioners, and an online STI self-sampling service, increases the likelihood that the resulting intervention will be acceptable to the organizations required to adopt it.

One limitation of the approach taken in this study relates to the needs-assessment stage. Users of Intervention Mapping are advised to draw upon multiple sources of evidence, such as

literature reviews and qualitative and quantitative research, to identify determinants to be targeted by the intervention. Resource limitations meant that the needs assessment for Wrapped was restricted to examination of evidence from a review of reviews. While this is a robust approach to identify high-level determinants, because only those with at least a small-to-medium effect on condom use are taken forward, it should be acknowledged that this fails to identify more nuanced but potentially important beliefs held by the target population. These may relate, for example, to their age or risk status. This more-detailed insight would have been helpful at the point of identifying change objectives, for example, understanding any particular outcome expectancies influencing negative attitudes toward condoms among this group that should be targeted by the intervention.

The most challenging aspect of development was related to step 3, intervention design. As part of this stage, BCMs suitable for targeting the behavioral determinants were selected as per the guidance. Tables of BCMs capable of achieving change in behavioral determinants are provided to facilitate this process [29]. Another dominant framework that exists to guide intervention development is the Behavior Change Wheel [42]. The equivalent to BCMs in this context are BCTs. There are no such tables for the selection of BCTs, but recent work to establish expert consensus on the link between BCTs and behavioral determinants has enabled tentative conclusions to be made. In this project, the team drew on both taxonomies to select relevant BCPs: a term used to cover both BCMs and BCTs. Due to the prominence of the BCT taxonomy, in the United Kingdom at least, the research team wanted to use this to support selection of BCPs for Wrapped. On reflection, however, this did not enhance development and simply added an additional layer of unnecessary complexity. Given the explicit links between BCMs and behavioral determinants afforded by Intervention Mapping, the authors would advise others using the Intervention Mapping framework to select BCMs alone. However, there may be merit in coding finished interventions according to the BCT taxonomy, as was also done in this case, given that this enables direct comparison with other behavior change interventions coded in the same way. This can be useful, for example, when synthesizing existing evidence that aims to draw conclusions about which BCTs work best to target particular behaviors, determinants, or populations.

Conclusions

As demonstrated in this article, Wrapped was developed to ensure that not only was it theory-based and grounded in the needs of the target audience, but also had high levels of design and appeal. Whether it is an effective intervention for increasing condom use among users of STI self-sampling websites will be tested in a future trial. If the results are positive, Wrapped will have good potential reach as it can be easily embedded within STI self-sampling websites, which are becoming increasingly popular [7]. With the increased digitalization of health services in an effort to reduce costs, this could be an important means of providing sexual health promotion and support to young people who would otherwise receive these face-to-face.

Acknowledgments

We express our gratitude to all of the young people, support workers, and professionals who worked with us to create the Wrapped intervention. We would also like to thank the Medical Research Council for funding this work (MRC MR/N010922/1).

Conflicts of Interest

None declared.

Multimedia Appendix 1

Wrapped logo.

[PNG File, 243KB - formative_v3i2e11242_app1.png]

Multimedia Appendix 2

Think-aloud interview schedule.

[PDF File (Adobe PDF File), 172KB - formative_v3i2e11242_app2.pdf]

Multimedia Appendix 3

Finalized matrix of change objectives.

[PDF File (Adobe PDF File), 182KB - formative_v3i2e11242_app3.pdf]

Multimedia Appendix 4

Pool of available Behavior Change Principles (BCPs) linked to theoretical determinants.

[PDF File (Adobe PDF File), 136KB - formative_v3i2e11242_app4.pdf]

Multimedia Appendix 5

Summary of ideas for intervention components resulting from the co-design workshop.

[PDF File (Adobe PDF File), 78KB - formative_v3i2e11242_app5.pdf]

Multimedia Appendix 6

Detailed description of intervention components.

[PDF File (Adobe PDF File), 177KB - formative_v3i2e11242_app6.pdf]

Multimedia Appendix 7

Image of Wrapped webpage showing options for component 1 (Sample Pack).

[PDF File (Adobe PDF File), 297KB - formative_v3i2e11242_app7.pdf]

Multimedia Appendix 8

A page from the booklet contained within component 1 (Sample Pack).

[PDF File (Adobe PDF File), 297KB - formative_v3i2e11242_app8.pdf]

Multimedia Appendix 9

Selection of condoms available via component 2 (Order Condoms).

[PNG File, 1MB - formative_v3i2e11242_app9.png]

Multimedia Appendix 10

Image of component 3 (Condom Carrier, in choice of four colors).

[PNG File, 1MB - formative_v3i2e11242_app10.png]

Multimedia Appendix 11

A selection of stills taken from component 4 (Using Condoms).

[PDF File (Adobe PDF File), 700KB - formative_v3i2e11242_app11.pdf]

Multimedia Appendix 12

One of the seven videos making up component 5 (Discussing Condoms).

[MP4 File (MP4 Video), 17MB - formative_v3i2e11242_app12.mp4]

Multimedia Appendix 13

Excerpts from the videos making up component 6 (Real Life).

[MP4 File (MP4 Video), 157MB - formative_v3i2e11242_app13.mp4]

Multimedia Appendix 14

Specification of the Behavior Change Techniques (BCTs), targeted determinants, and change objectives.

[PDF File (Adobe PDF File), 172KB - formative_v3i2e11242_app14.pdf]

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Abbreviations

BCM: Behavior Change Method
BCP: Behavior Change Principle
BCT: Behavior Change Technique
NCSP: National Chlamydia Screening Programme
RCT: randomized controlled trial
STI: sexually transmitted infection
TIDieR: template for intervention description and replication

Edited by G Eysenbach, N Kuter; submitted 07.06.18; peer-reviewed by A Bedendo, Å Revenäs; comments to author 10.07.18; revised version received 04.12.18; accepted 06.01.19; published 01.05.19.

Please cite as:
Newby K, Crutzen R, Brown K, Bailey J, Saunders J, Szczepura A, Hunt J, Alston T, Sadiq ST, Das S
An Intervention to Increase Condom Use Among Users of Chlamydia Self-Sampling Websites (Wrapped): Intervention Mapping and Think-Aloud Study
JMIR Form Res 2019;3(2):e11242
URL: http://formative.jmir.org/2019/2/e11242/
doi:10.2196/11242
PMID:31042156

Original Paper

The Implementation of an mHealth Intervention (ReZone) for the Self-Management of Overwhelming Feelings Among Young People

Chloe Edridge[1,2], Bsc (Hons), MSc, MPhil; Jessica Deighton[1,2], PhD; Miranda Wolpert[1,2], DClinPsy; Julian Edbrooke-Childs[1,2], PhD

[1]Anna Freud National Centre for Children and Families, London, United Kingdom

[2]Clinical, Educational and Health Psychology, University College London, London, United Kingdom

Corresponding Author:
Chloe Edridge, Bsc (Hons), MSc, MPhil
Anna Freud National Centre for Children and Families
12 Maresfield Gardens
London, NW3 5SU
United Kingdom
Phone: 44 020 7433 6191
Email: chloe.edridge@annafreud.org

Abstract

Background: The association between mental health difficulties and academic attainment is well established. There is increasing research on mobile health (mHealth) interventions to provide support for the mental health and education of young people. However, nonadoption and inadequate implementation of mHealth interventions are prevalent barriers to such trials.

Objective: The aim of this study was to bridge this gap and examine the implementation of an mHealth intervention, ReZone, for young people in schools.

Methods: Preliminary data for 79 students collected as part of a larger trial were analyzed. We additionally conducted postimplementation consultations with teachers.

Results: ReZone was used 1043 times by 36 students in the intervention arm during the study period. Postimplementation teacher consultations provided data on implementation strategies, barriers, and facilitators.

Conclusions: Implementation strategies, barriers, and facilitators for digital interventions need to be considered to limit nonadoption and inadequate implementation in larger trials. Important considerations involve tailoring the characteristics of the intervention to the requirements of the intended user group, the technology itself, and the organization in which it is implemented.

Trial Registration: International Standard Randomised Controlled Trial Number: 13425994; http://www.isrctn.com/ISRCTN13425994

(JMIR Form Res 2019;3(2):e11958) doi:10.2196/11958

KEYWORDS

cluster trial; behavioural difficulties; schools; mHealth, digital; mental health; mobile phone

Introduction

Recent evidence suggests that the levels of mental health difficulties in young people are increasing; for example, 1 in 4 young women experience emotional problems, including anxiety and depression [1]. The previous protocol published [2] for this study highlighted the prevalence of behavioral problems in young people and its association with academic attainment and mental health difficulties [3-6].

Mobile health (mHealth) provides new opportunities to support young people's mental health. About 95% of adolescents aged 13-17 years own or have access to a smartphone [7]. Moreover, 69% of schools in the United Kingdom are currently using tablet computers [8].

The authors have co-designed an mHealth intervention, ReZone, with young people, parents/carers, and teachers. As described in detail previously [2], ReZone is based on cognitive behavioral therapy, mindfulness, and attention bias–modification training. These methods have been shown to be effective in addressing thought processes [9,10], self-regulation of attention [11], behavior and emotions [12,13], and negative cognitive biases [14,15].

However, a limitation of the existing technology-enabled interventions for young people is that the content of many of these interventions is not grounded in psychological theory or evidence-based practice [16]. There is a need for evidence from rigorous trials regarding the effectiveness of digital interventions for mental health among young people [17] in addition to research investigating the ways to best integrate these interventions into support provision [18].

Implementation and sustained adoption of interventions within schools can be impacted by a range of contextual issues. The general organizational structure, level and quality of support available, leadership, and administrative resources are factors of successful implementation of such interventions [19,20]. A wider system view must be adopted to consider the whole school in terms of alignment of the intervention with the school's philosophy, goals, and policies [19]. The role, views, knowledge, and skills of the staff member who is most often at the forefront of implementation within the school must also be considered [21]. Teachers play a crucial role in the successful implementation of digital technologies, and their beliefs regarding teaching practices impact the level of resistance or acceptability of new technologies within the school [22].

Challenges are further highlighted in a recent evidence framework proposed for theorizing and evaluating nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) of health and care technologies [23]. The NASSS framework outlines seven areas included for prediction and evaluation of the success of technology-supported health or social care programs. Areas for consideration are the condition or illness, the technology, the value proposition (ie, benefits of the intervention), the adopter system (comprising professional staff, patient, and lay caregivers), the organization(s), the wider context (institutional and societal), and the interaction and mutual adaptation between all these domains over time. Within these domains, there are potential challenges to consider, each classified as simple (few straightforward, predictable components), complicated (multiple interacting components or issues), or complex (dynamic, unpredictable, not easily disaggregated into constituent components).

The aim of this research was to bridge the gap in evidence of the implementation of mHealth interventions and examine the implementation of one such intervention, ReZone, for young people in schools. We report preliminary data from a cluster randomized trial of ReZone within schools. We additionally conducted postimplementation consultations with teachers to examine their views on and experiences of the facilitators and barriers to implementation.

Methods

Further details on the methodology of the full randomized controlled trial (RCT) can be found in the published protocol [2]; this trial was pre-registered in a clinical trial registry (ISRCTN 13425994).

Recruitment and Setting

Two types of schools were involved in the study: alternative provision primary/secondary schools and mainstream primary schools. Alternative provision schools are settings that provide education for young people who are unable to engage in mainstream education due to emotional or behavioral issues. All students within the participating classes were invited by their school to take part in this study. The preliminary data used in this paper relate to 10 clusters (classes), across six rural and urban schools (two primary and four alternative provision) within the United Kingdom.

Participants and Procedure

At the time of manuscript preparation, 10 classes were recruited (four mainstream and six alternate provision), resulting in a sample of 79 students with a mean (SD) age of 11.14 (1.31) years (58% male). We lost 20 students to follow-up, yielding an attrition rate of 25%. All students (aged 10-15 years) in the schools participating in the project were eligible to participate in the study. Participant demographics are shown in Table 1 for the RCT dataset discussed in this paper. Postimplementation consultations were carried out with eight teachers from participating schools.

Table 1. Demographic characteristics (N=79).

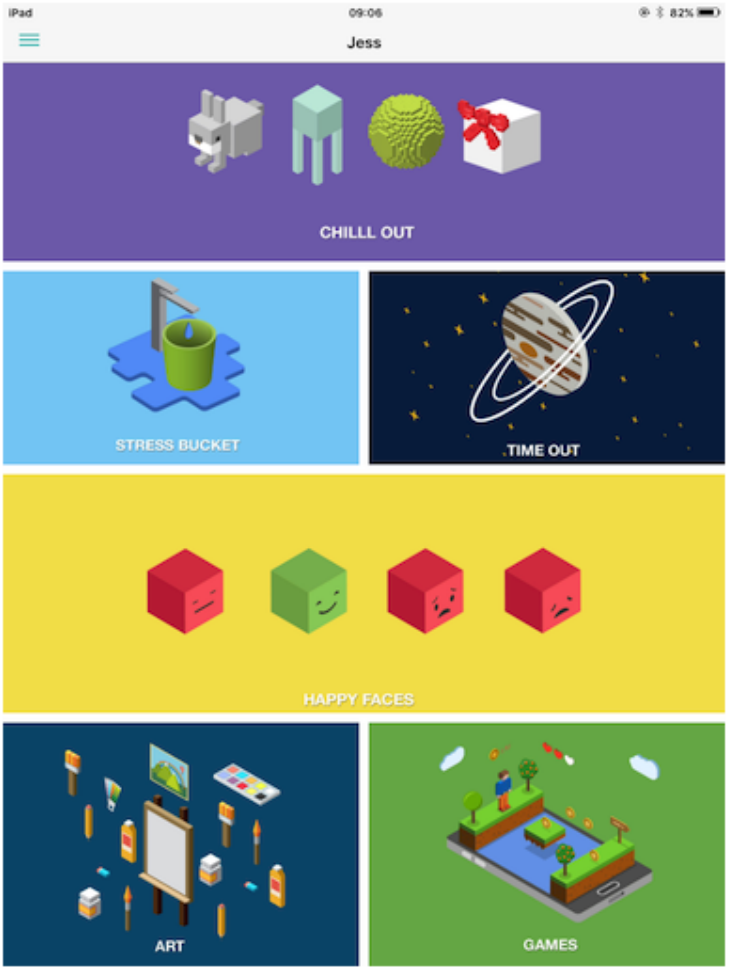
Characteristic	Statistic
Age (years), mean (SD)	11.14 (1.31)
Male, n (%)	46 (58)
Alternate provision schools, n (%)	33 (42)
English as first language, n (%)	68 (86)
Ethnicity, n (%)	
White	20 (25)
Mixed	14 (18)
Asian	36 (46)
Black	8 (10)
Other	1 (1)

The University College London Research Ethics committee provided ethics approval (number: 7969/001), and the study adhered to the relevant ethical guidelines (eg, the British Psychology Society [24]). This research is reported in line with Consolidated Standards of Reporting Trials (CONSORT) guidelines [25].

Intervention

Figure 1 presents the ReZone home screen. Textbox 1 presents the features of ReZone according to the guidelines for reporting mHealth interventions [26].

Figure 1. ReZone home screen.



Textbox 1. Main features of ReZone.

Stress bucket: The stress bucket lets the user add any stressors that he/she is experiencing to a bucket. The user is then able to introduce activities that help them cope with each stressor. The user can see the water in the bucket rise and fall as he/she adds and relieves stressors, respectively. If the bucket reaches 50 stress points, it will overflow (Figure 2).

Timeout: Timeout asks the user to think through a time when he/she felt stressed, angry, or upset. On the app, the user then works through all the events that led up to feeling this way and the following events that occurred. The user can also think through what he/she could have done differently to help the situation as a behavioral plan. The visualization is a rocket, and each thought process creates a cloud.

Chill out: Chill out uses breathing to help the user calm down and relax. Each chill out activity is based around an object or animal (ie, rabbit, jellyfish, ball, or square) and uses breathing in different ways (Figure 3).

Art therapy: The user can choose between a castle, dinosaur, fish, goat, heart, helicopter, unicorn, rocket, footballer, sea, or turtle to color in. There is a range of colors and utensils to complete the drawing.

Happy faces: The user is given 30 seconds to find as many happy faces as he/she can amongst other faces depicting negative emotions.

Game: There is a game of “balloon blast” on the app. The user taps the screen to move the balloon up, trying to avoid all the obstacles, as hitting one will end the game. This game was created to provide a break or reward for the user in between the other features.

Figure 2. The stress bucket feature.

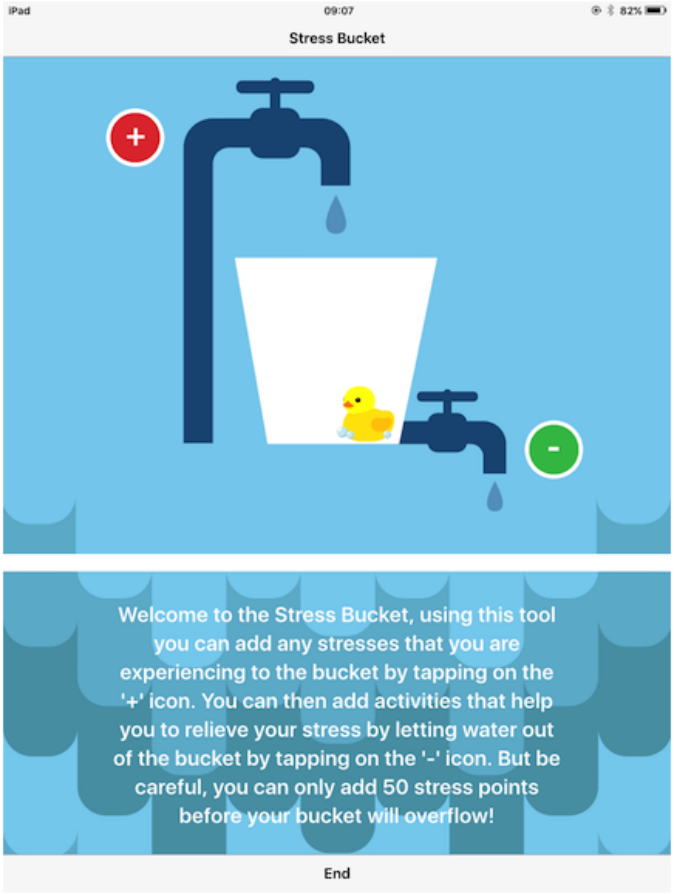
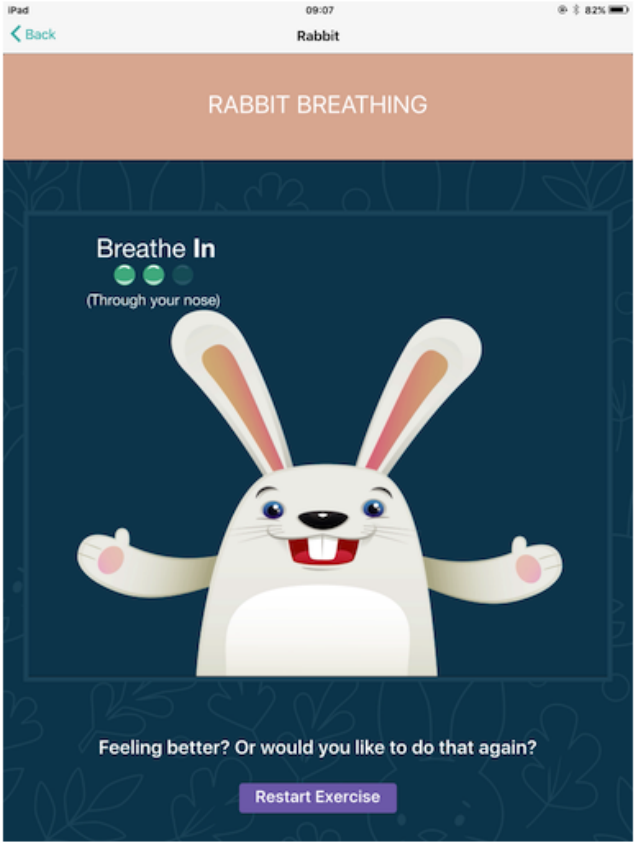


Figure 3. The breathing exercise.



Analytic Strategy

The usage data for this sample were collected and aggregated across all users, reporting the number of times each element of the tool was used. The postimplementation consultations were analyzed using framework analysis with determined topics and are discussed in line with the NASSS framework.

Results

Usage Statistics

Over the period of data collection, 1082 usage sessions were conducted for the 36 students in the intervention arm. In terms of usage statistics, the game (n=308), breathing exercises (n=276), and happy faces (n=241) were used the most; stress bucket (n=117), art (n=81), and time out (n=20) were used the least.

Postimplementation Consultations

Consultations with teachers identified implementation strategies and barriers and facilitators as listed below.

Implementation Strategies

Teachers described two main implementation strategies for ReZone. Responsive use was the most common strategy, where teachers embedded ReZone into current tools to be used when students are feeling overwhelmed or a specific incident has occurred (eg, exams). The second strategy was preventative use where ReZone was used at set time points during the day (eg, start of lessons, tutor session, and break times) or in the morning to address any issues from the previous night and to inoculate against stressors that may arise during the day. Some teachers in mainstream schools reported that ReZone was available to students at all times on request, as part of a specified rota or other mental health support services offered (such as one-to-one support). Individual use of ReZone was preferred over whole-class use by some teachers in order to better tailor its use to individual needs and avoid influence or distraction of peers.

Following these overarching strategies, teachers described a combination of teacher-directed and student-led strategies that were often used. If use was completely led by students without any direction from the teacher, ReZone was not likely to be used. Nevertheless, some teachers extensively directed use at the beginning, but over time, transitioned control to students who asked to use ReZone.

Barriers and Facilitators to Implementation

Teachers described the pivotal role of school culture on the implementation of ReZone. In particular, teachers felt that incorporating the app into daily routines was more challenging when technology-enabled interventions were not widely used in the school. Resources to support use, including time and reminders, were highlighted, as was the need for local support, because a minimum of two engaged teachers were needed. Ideally, this would be a combination of senior and junior teachers, as the school head teacher or the special educational needs coordinator would often want to roll out the intervention but was not required to actually implement it (the class teacher was needed to implement it). Some teachers reported that they were happy to support the use of ReZone, but not necessarily promote its use due to their lack of engagement with the intervention or their busy schedules with competing priorities such as exams and other targets.

Teachers felt the facilitators of ReZone were visually engaging and that the app was interactive in nature and complimented other tools with which students were familiar. However, the lack of availability of tablet computers was at times described as a barrier. In addition, the need for teachers to be present and monitor usage limited implementation predominantly due to concerns of risk of students damaging the computers. The teachers reported availability as an important factor for fostering engagement, because if a student asked to use ReZone but the tablet computer was not available, the student was unlikely to ask again.

Parental engagement in the research was described as a barrier to implementation, especially because it led to consent forms being returned and prevented bigger groups from taking part; in addition, some schools felt an alternative approach (eg, opt-out parental consent) would increase the ease of implementation. In the mainstream schools, some teachers reported that parents specifically did not want their child using an intervention related to mental health and well-being. Moreover, teachers reported that parents/carers of students who were identified to be most in need were, at times, the hardest to engage and least likely to provide consent for the study.

Teachers reported maintaining student engagement in the app as a barrier to implementation, especially after the initial novelty had worn off. Some teachers reported that students enjoyed revisiting activities in the app, whereas other teachers thought the students wanted different stimuli and activities that offered immediate rewards each time. Similarly, some teachers reported that some students did not want to revisit situations after they had occurred and, in turn, did not want to use ReZone to reflect on the situation.

Teachers reported that some students would spontaneously discuss what they were working on with other students while using ReZone. Unsurprisingly, teachers reported that the most engaged students were the ones actively seeking help with their emotions. Moreover, teachers reported that implementing ReZone at the start of a new school year with a cohort of students was much easier than trying to integrate it as part of school routines after the year had started.

Discussion

The aim of this study is to address the gap in evidence of the implementation of mHealth interventions. We used preliminary data and data from teacher consultations from a larger RCT conducted in schools to consider implementation barriers, facilitators, and strategies. The preliminary data include 36 students in the intervention arm across 6 schools who participated in 1082 sessions.

Implementation strategies should involve both teacher-directed and student-requested use of the tool. Feedback points to initial teacher direction for new resources, as needed, with steady integration, allowing students to independently request use over

time. ReZone can be embedded into the current tools offered to students when they are feeling overwhelmed or when an incident has occurred, or as a reward/incentive or a preventative measure.

Use of the tool for the whole class can work to address the general well-being or a specific stressful period, for example, exams. Any limitations can be overcome if the school has a sufficient number of digital devices and can find time within the timetable to set aside for use of ReZone. In a class-use scenario, sessions would be less individually tailored, and there is a possibility of lower concentration and openness while discussing feelings in a group setting and more influence of social concerns.

Based on teacher guidance, implementation barrier themes seem to be widely related to the domains within the NASSS framework [23], mainly the technology, the adopter system, and the organization. A common issue raised by the consultations was related to the point of contact: The advocate for the intervention was not necessarily the one who actually implements it on a daily basis (ie, the class teacher). Due to barriers such as competing priorities, busy schedules, and engagement with the intervention, teachers could support but not promote the use of the tool. Implementation can also be impacted by staff agenda, opinions, preferences, and resistance to change routine practice. The NASSS framework and other evidence [19,20] highlight that the school system, as a whole, needs to be considered with a shared vision and plan to encompass a new technology program. School-wide capacity, readiness, and willingness are all potential barriers. These barriers are related to the feedback regarding who has the main investment in the program, emphasizing the importance of the school head being on board and active. As briefly addressed in our consultations, reluctance or unmanageable change to routine, specifically, the potential change brought on by a new technology program, is a possible barrier. Work routines can be disrupted, with a sensitive transition period when merging old and new routines. Other issues include the novelty of the technology to the school's current system, the level of support, and the visibility of the impact of the program. Implementation of the intervention also depends on whether the school already incorporates tablets into its daily methods and routines and the level of change.

Teachers felt that technology can increase engagement through illustrations, design, interactive elements, and general appeal within the population of young people [27,28]. However, within alternative provision schools, the concern related to the risk of damage was evident and can increase reluctance to suggest tablet use in some circumstances. In mainstream schools, budgets often permit only one tablet per class or school-wide sharing of tablets. This system can be implemented using a booking system and extra planning. However, when a student asks for the tool, it may not always be available, which could be a possible deterrent for future requests of the tool. The NASSS framework highlights the importance of our methods of prototyping ReZone sufficiently, ensuring it is usable and attractive to the target user. The issue of budget allocation is also a potential barrier in the framework and was evident when some teachers discussed only having one tablet per class for use.

Parental engagement is another potential barrier: Teachers felt that some parents were difficult to engage in general communication and were therefore unlikely to sign and return letters sent home, including those for consent for their child to take part in a research study. Teachers often felt frustrated by this, as it was often these parents/carers whose children could potentially benefit from the intervention the most. Additionally, some parents were apprehensive about the level of technology their child was using and did not want them to take part in such a study. It is therefore worthwhile to attempt addressing parent/carer views, opinions, and communication preferences before the start of such a study. We worked with parents/carers on the layout and language for our information sheets and consent forms. Future work should also consider ways to increase acceptability of the research, particularly with a digital focus within this population. The NASSS framework questions what is required from those indirectly involved, such as carers. Although nothing may be required from them, if the child is using the tool at school, the question of acceptability persists.

The barriers related to students were more commonly highlighted in alternative provision schools than in mainstream schools. These barriers included opposition to repeating activities, revisiting an incident to talk through it, difficulty concentrating on a specific task, and the need for instant impact from activities. Acceptance and consideration of the work required by the adopter is a challenge considered in the NASSS framework. It can be difficult to implement long-term mental health interventions when their effect is not always immediately evident. Teacher consultations aligned with the framework in drawing attention to the level of support needed to use the technology. Most young people are familiar with the use of tablets [27] and can use them independently. However, teacher guidance and support are needed to address the initial hesitation for new things and to remember that the tool is available for use. Due to the high pupil turnover in these types of schools, attrition can be higher than that in mainstream schools.

Implementation strategies, barriers, and facilitators for digital interventions need to be considered in order to limit nonadoption and inadequate implementation in larger trials. Topics that need attention involve requirements and characteristics of the intended user group, the technology, and the organization where the tool will be implemented.

As this study was an analysis of preliminary data, the results of the full trial are needed to examine the effectiveness of ReZone. Other limitations of the present study are mentioned below. First, the consultations were conducted with a small number of teachers, and it is likely that most teachers who engaged with the study were more likely to give their views and experiences. Future research should examine implementation strategies with teachers least likely to adopt technology entirely or identify nonadopters early if implementation needs to be abandoned. Second, as with digital psychotherapy research, in general, a lack of allocation concealment and a reliance on self-report measures are also limitations.

Notwithstanding the abovementioned limitations, the findings of this research suggest that ReZone was successfully implemented and utilized, and this study identified implementation strategies, barriers, and facilitators, which are essential ingredients of larger effectiveness trials. Important considerations involve tailoring the characteristics of the intervention to the requirements of the intended user group, the technology itself, and the organization in which it is implemented.

Acknowledgments

The research was supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health.

Conflicts of Interest

None declared.

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
mHealth: mobile health
NASSS: nonadoption, abandonment, scale-up, spread, and sustainability
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 16.08.18; peer-reviewed by A Aventin, P Sylim; comments to author 11.10.18; revised version received 06.12.18; accepted 31.01.19; published 02.05.19.

Please cite as:
Edridge C, Deighton J, Wolpert M, Edbrooke-Childs J
The Implementation of an mHealth Intervention (ReZone) for the Self-Management of Overwhelming Feelings Among Young People
JMIR Form Res 2019;3(2):e11958
URL: http://formative.jmir.org/2019/2/e11958/
doi:10.2196/11958
PMID:31045499

Original Paper

Considerations of Privacy and Confidentiality in Developing a Clinical Support Tool for Adolescent Tobacco Prevention: Qualitative Study

Ryan P Theis[1], MPH, PhD; Ali M Malik[2], BSc; Lindsay A Thompson[1,3], MD; Elizabeth A Shenkman[1], PhD; Lori Pbert[4], PhD; Ramzi G Salloum[1], PhD

[1]Institute for Child Health Policy, Department of Health Outcomes and Biomedical Informatics, University of Florida, Gainesville, FL, United States
[2]College of Medicine, University of Florida, Gainesville, FL, United States
[3]Department of Pediatrics, University of Florida, Gainesville, FL, United States
[4]Department of Population and Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA, United States

Corresponding Author:
Ryan P Theis, MPH, PhD
Institute for Child Health Policy
Department of Health Outcomes and Biomedical Informatics
University of Florida
2004 Mowry Road, Suite 2252
Gainesville, FL, 32610
United States
Phone: 1 352 294 5973
Email: rtheis@ufl.edu

Abstract

Background: Electronic clinical support tools show promise for facilitating tobacco screening and counseling in adolescent well-care. However, the application of support tools in pediatric settings has not been thoroughly studied. Successfully implementing support tools in local settings requires an understanding of barriers and facilitators from the perspective of both patients and providers.

Objective: This paper aimed to present the findings of a qualitative study conducted to inform the development and implementation of a support tool for adolescent tobacco screening and counseling in 3 pediatric clinics in North Florida. The primary objective of the study was to test and collect information needed to refine a tablet-based support tool with input from patients and providers in the study clinics.

Methods: A tablet prototype was designed to collect information from adolescents on tobacco susceptibility and use before their well-care visit and to present tobacco prevention videos based on their responses. Information collected from adolescents by the support tool would be available to providers during the visit to facilitate and streamline tobacco use assessment and counseling components of well-care. Focus groups with providers and staff from 3 pediatric clinics (n=24) identified barriers and facilitators to implementation of the support tool. In-depth interviews with racially and ethnically diverse adolescent patients who screened as susceptible to tobacco use (n=16) focused on acceptability and usability of the tool. All focus groups and interviews were audio-recorded and transcribed for team-based coding using thematic analysis.

Results: Privacy and confidentiality of information was a salient theme. Both groups expressed concerns that the tool's audio and visual components would impede privacy and that parents may read their child's responses or exert control over the process. Nearly all adolescents stated they would be comfortable with the option to complete the tool at home via a Web portal. Most adolescents stated they would feel comfortable discussing tobacco with their doctor. Adolescent interviews elicited 3 emergent themes that added context to perspectives on confidentiality and had practical implications for implementation: (1) *purity*: an expressed lack of concern for confidentiality among adolescents with no reported history of tobacco use; (2) *steadfast honesty*: a commitment to being honest with parents and providers about tobacco use, regardless of the situation; and (3) *indifference*: a perceived lack of relevance of confidentiality, based on the premise that others will "find out anyway" if adolescents are using tobacco.

Conclusions: This study informed several modifications to the intervention to address confidentiality and introduce efficiency to well-care visits. The support tool was integrated into the electronic health record system used by the study clinics and modified

to offer videos to all adolescents regardless of their tobacco use or susceptibility. Future studies will further test the acceptability of the intervention in practice.

(JMIR Form Res 2019;3(2):e12406) doi:10.2196/12406

KEYWORDS

clinical decision support; adolescent; primary care; tobacco use; confidentiality; implementation science; qualitative research

Introduction

Background

Primary care providers (PCPs) play an important role in screening, counseling, and early intervention for adolescent tobacco use [1]. Brief interventions by PCPs, as recommended by the United States Preventive Services Task Force (USPSTF), can reduce the risk of tobacco initiation in adolescents [2,3]. However, PCP practices for tobacco screening and counseling are inconsistent, with studies reporting low rates of physician adherence to evidence-based practices for smoking cessation and for routine screening of adolescent electronic cigarette (e-cigarette) use [4,5]. Barriers to effective counseling by PCPs can include limited time and lack of privacy during the visit, whereas possible facilitators include checklists for adolescents to complete before the visit and assurances of confidentiality by the PCP [6,7].

Electronic clinical support tools show promise for promoting adolescent tobacco screening and counseling, in part because they help clinics overcome barriers and leverage facilitators to well-care. Such tools have become increasingly common in behavioral health interventions as a means of facilitating patient-provider communication and ensuring thorough and consistent application of evidence-based practices [8]. Although there is evidence for the effectiveness of support tools for adolescent substance abuse screening in primary care [9], the more general application of support tools to the adolescent population remains to be thoroughly explored and documented. Furthermore, the successful implementation of support tools can depend on their capacity to integrate into clinical workflow, appropriateness to patient populations, competing clinical priorities, and other local contextual factors [10].

Objectives

To address the challenges that PCPs face with regard to limited time in well-care visits and concerns about privacy and confidentiality, we developed an electronic tool to support PCPs in adolescent tobacco screening and counseling. The tool includes a survey about tobacco use, susceptibility, and concerns that adolescents can complete before their well-care visit, educational videos tailored to the responses they provide, and electronic transmission of their responses to their PCP to facilitate counseling. These design elements can help overcome gaps in the consistent application of evidence-based practices for adolescent tobacco screening and counseling, which can in turn lead to reductions in tobacco use initiation and promote tobacco cessation.

This paper has presented the findings from a qualitative pilot study conducted to refine the design and content of the support tool and understand the context needed to effectively implement it in local clinical settings. In particular, we sought to elicit the perspectives of PCPs and adolescent patients on the confidentiality of information that adolescents provide about their tobacco use in well-care visits. Triangulating the responses of both types of end users, this study informed important modifications to the support tool to address concerns about privacy and improve the support tool's acceptability and feasibility for implementation.

Methods

Setting

This study was conducted in collaboration with pediatric primary care clinics in the University of Florida (UF) Health System, which serve urban and rural communities in North Florida and represent a diverse patient population with regard to income, education, and race/ethnicity [11]. The UF Health System is a member of the OneFlorida Clinical Research Consortium—a research collaborative that includes a centralized cooperative institutional review board, shared governance, and implementation support from a network of community practice facilitators and local providers [12].

Intervention

Following a stakeholder engagement approach that included methodologists, clinicians, and community representatives, we developed an initial prototype of an electronic tobacco screening tool, which includes a questionnaire for adolescents to complete before their scheduled well-care visit (see prototype slides in Multimedia Appendix 1). The questionnaire begins with an initial screening to assess the adolescent's history of tobacco use, collecting separate information on 5 types of nicotine and tobacco product classes (cigarettes, cigars/cigarillos, hookah, smokeless tobacco, and e-cigarettes), as shown in Figure 1. For nonusers, the tool assesses susceptibility to any tobacco products, indicated by a lack of firm commitment to avoid tobacco use [13]. Specifically, the susceptibility screener asks whether the adolescent would use a cigarette, e-cigarette, or other tobacco product (1) if offered by a friend, (2) at any time in the next 12 months, and (3) 5 years from the time of screening.

Figure 1. Screenshot of the electronic clinical support tool: tobacco use screener.

Although the questions in the screening tool are similar to what may be asked in a standard preclinical visit survey, their collection in electronic format allows for additional functions to facilitate tobacco screening and counseling—including options to complete the tool using a Web-based portal (outside the clinical setting), the presentation of educational content, and transmission of responses to PCPs. For both users and susceptible nonusers, the tool presents a list of consequences of using tobacco products and asks them to rate which consequences they are most likely to ask their doctor about (see example in Figure 2).

Then, based on their pattern of responses, the tool presents 1 brief educational video from the US Food and Drug Administration tobacco prevention campaign, which can supplement and optimize face-to-face counseling provided by the PCP [14]. For adolescents with a history of tobacco use, the video applies to the tobacco product that the adolescent selected; in the case of multiple selected products, the selection algorithm prioritizes videos based on relative harm (eg, combustible products taking precedence over e-cigarettes). For nonusers who screen as susceptible to tobacco, the video is based on their selection of tobacco use consequences. The decision to limit the tool to a single video was based on the need to keep the screening brief and minimize user burden. Finally, questionnaire responses are made available to providers to prime them to further counsel adolescents on tobacco use.

Figure 2. Screenshot of the electronic clinical support tool: tobacco consequences rating.

Data Collection

The support tool was further tested through collaboration with pediatric clinics in the UF Health system. Our qualitative approach included (1) focus groups with providers and staff to identify barriers and facilitators to implementation and (2) in-person qualitative interviews with adolescent patients to test the usability of the tool. The focus groups and interviews were conducted sequentially between July 2016 and June 2017 to obtain provider and patient perspectives on a working prototype of the tool in iterative stages.

The provider focus groups were conducted in 3 different clinics, with topics selected based on Proctor's Framework for Implementation Outcomes—focusing specifically on acceptability, appropriateness, adoption, and feasibility of the tool within the context of clinical workflow [15]. All focus groups included a presentation of the tool to participants and were facilitated by the study's qualitative investigator. Focus groups lasted 45 min on average and were audio-recorded for later transcription and analysis.

In-depth interviews were conducted with adolescents (aged 12 to 17 years) recruited from the UF Adolescent Clinic, which serves racially and ethnically diverse patients with a high rate of Medicaid coverage (80%) [11]. Adolescents meeting the age criteria who had a visit to the clinic during the study period were eligible for inclusion and invited to participate by the study's clinician investigator. All assenting patients were later contacted by telephone and administered a brief tobacco use history and susceptibility screener (the same screeners used in the support tool, as shown in Multimedia Appendix 1). Those who indicated a history of tobacco use or nonusers who screened as susceptible to tobacco use were scheduled for in-person interviews. Adolescents with no history of tobacco use and who did not screen as susceptible were not eligible for the study; this exclusion was made because many important features of the tool we sought to test—including the tobacco use consequence rating and the educational video—are completed only by adolescents who report using or being susceptible to tobacco.

Interview topics included (1) adolescents' perceptions and attitudes about tobacco products, (2) their personal experiences using or being offered tobacco products, and (3) their opinions of the prototype support tool. Discussions about the tool focused on the ease of use, comprehension of content, and assessment of acceptability and appropriateness to the target population. Adolescents were asked to discuss how comfortable they would be talking with their doctor about using tobacco, completing the screening in the presence of their parent (eg, in the clinic's waiting room), and completing the screening in a more private setting (eg, using a Web-based patient portal). Interviews were led by 2 interviewers trained in qualitative data collection methods and were audio-recorded for later transcription and analysis. Parents provided informed consent for their child's participation but were not physically present during the interviews. The research protocol was approved by the UF Institutional Review Board.

Data Analysis

For both focus group and interview transcripts, analyses involved an initial phase of deductive coding (using categories derived from the moderator guides), a secondary phase of inductive coding (to identify emerging themes), and an

interpretive phase in which findings from both data types were synthesized [16]. This approach allowed for the iterative development of separate codebooks for the provider focus groups and adolescent interviews, whereby transcripts were back-coded with any new themes identified during the inductive phase. To ensure high interrater reliability, each transcript was coded independently by 2 trained coders and then reviewed in team meetings to discuss and obtain consensus on coding discrepancies [17]. Team meetings included, at minimum, both coders and a third study investigator who was familiar with the content but had not participated in coding. Independently coded transcripts were reviewed side by side, and all coding discrepancies were discussed and resolved by consensus. In the event that the coders could not come to a consensus on a particular coding discrepancy, the third team member made the final determination. The analysis was conducted using NVivo 11 (QSR International, 2015).

In addition, a framework analysis method was used to organize the findings from the adolescent interviews [18]. A summary template was developed for initial review of transcripts, in which content could be abstracted for domains specific to the study aims (eg, support tool acceptability, message relevance, and comfort discussing with doctor). Completed summaries were reviewed in regular team meetings and compiled into a descriptive participant-by-domain matrix [19]. As a complementary analytic strategy, the team reviewed the final matrix to assess patterns in domain responses across interview participants.

To facilitate the final, interpretive phase of the analysis, queries for codes related to support tool acceptability and appropriateness (which applied to both study populations) were produced for the provider and adolescent transcripts separately. These queries were reviewed for emergent themes relevant to the 2 types of implementation outcomes, and commonalities and contrasts in themes were documented between providers and adolescents.

Results

Provider Perspectives

The focus groups were each attended by 7 to 9 participants (24 participants overall), including physicians, midlevel providers (physician assistants and nurse practitioners), and office staff (Table 1).

Confidentiality of patient information was a salient theme in all focus groups. In early phases of the study, the waiting room was the setting proposed for adolescents to complete the support tool (in tablet format) to minimize disruption of clinical workflow. Providers in the first 2 focus groups voiced concerns with this approach, calling upon their past experiences with patient intake forms. As 1 provider remarked:

> *Most of the time we give out our handout, it's supposed to be filled out by the patient. But the parent takes it and they fill it out for them. So how do we prevent that from happening?*

In cases where adolescents might complete the screening on their own, providers still had concerns about confidentiality, noting that parents would be able to see the tablet screen (including their child's responses to the questionnaire) and hear the videos. They expected that adolescents would not respond honestly to the tobacco susceptibility and history questions. This issue raised questions about the feasibility of the intervention:

> *We do a physical survey that 99% of the time, the parents are watching them do. So, I am not sure how effective it is, and I am not sure how honest they are… Then, you have a video that now confirms that they probably said that they smoked and that the parent can now hear, even if the teenager can somehow hide it from them. I would worry about that as a barrier.*

As a possible solution, providers proposed separating the adolescent from the parent before administering the screener. However, this came with its own concerns, as some clinics may not have a separate room or area where adolescents could complete the tool privately, posing an important barrier to broader implementation. More relevant to the question of confidentiality, some providers also noted that parents would question why their child was being brought aside and what the staff were asking them:

> *We have parents who respect that, and we have parents who absolutely get very angry if we start talking to their teenager about keeping things from them.*

Another proposed solution was to integrate the tool into a Web-based patient portal that was at the time being expanded to adolescent populations in the UF Health System pediatric clinics. The portal would allow adolescents to complete the screening on their own computer or mobile device at home before their visit. For adolescent patients aged 12 years and older who have enrolled in the portal, only they would have access to their information on the portal, allowing for the privacy necessary to ensure confidentiality.

Table 1. Provider focus group participants.

Focus group participants	Clinic number 1 July 2016	Clinic number 2 April 2017	Clinic number 3 June 2017
Physician (n)	3	3	3
Registered nurse/Licensed practical nurse (n)	4	2	3
Advanced practice registered nurse/Physician assistant (n)	0	1	2
Office staff (n)	0	2	1

On the basis of this feedback, the support tool was modified to be used through the portal —allowing adolescents the option to complete the tool at home or in the office using the original tablet intervention. In both cases, the tool was integrated with the electronic health record (EHR) system used by the clinics, allowing providers real-time access to the information provided by the adolescents. These modifications were tested in the third provider focus group, who generally perceived them as positive. One provider remarked on several potential advantages of the intervention, including the promotion of clinical efficiencies:

> *I think that adolescents are going to feel… like their privacy is better protected if they can [do it] on their iPhone, their iPad, or at home prior to the clinic visit… It's an ultimate timesaver. It's not adding something if it's more efficient. It has to be done only once. It auto-populates our charts and can be done beforehand when a child's at home and potentially in a more private situation. We might get more accurate information as well.*

Nevertheless, providers in the third focus group maintained concerns related to parents' access to information. Although the portal is confidential for adolescents, parents may still "bully" their children to gain access and they would be more likely to see the responses on a larger screen. With regard to the waiting room intervention, providers stated that some parents would offer to complete the screening themselves, on behalf of their children—echoing concerns expressed in the earlier focus groups.

Finally, providers in all focus groups noted that certain behavioral characteristics of adolescents could impede the feasibility of the intervention, regardless of the setting or mode of administration. One provider commented on adolescents' reluctance to self-report weaknesses or to talk about risky behaviors—raising the question of whether the more private Web portal mode would actually encourage more honest responses. Other providers suggested that some adolescents would become bored with the tool, as evident in the following exchange:

> *After four or five screens, they're probably going to check out at that point. They're just going to be clicking.* [Provider 1]
>
> *Then they're just going to start Christmas Treeing, trying to get through it.* [Provider 2]

Adolescent Perspectives

Among 128 adolescent patients who initially agreed to participate, 65 could not be reached after 3 attempts (51%), 46 were ineligible to participate because they were nonsmokers who did not screen as susceptible to tobacco (36%), 1 refused to participate (1%), and 16 participated in an interview (13%).

Participants represented a fairly even mix of female and male patients (56% and 44%, respectively) and included patients of black (38%), Hispanic (25%), white (19%), and other (19%) racial and ethnic groups (Table 2). All participants initially screened as being susceptible to tobacco or nicotine products; however, only 2 (13%) reported any active tobacco use during the interview.

Table 2. Adolescent interview participant characteristics.

Characteristics	Statistics, n (%)
Age (years)	
12	1 (6)
13	4 (25)
14	2 (13)
15	3 (19)
16	4 (25)
17	2 (13)
Gender	
Female	9 (56)
Male	7 (44)
Race and ethnicity	
Black, non-Hispanic	6 (38)
Hispanic	4 (25)
Other, non-Hispanic	3 (19)
White, non-Hispanic	3 (19)
Ever used tobacco or nicotine product	
No	14 (88)
Yes	2 (13)
Ever been offered tobacco or nicotine product	
No	10 (63)
Yes	6 (38)
Comfortable discussing tobacco with doctor	
No	0 (0)
Yes	9 (56)
Maybe	1 (6)
Unknown[a]	6 (38)
Comfortable using support tool near parents	
No	4 (25)
Yes	12 (75)
Would complete support tool honestly in a home setting	
No	1 (6)
Yes	15 (94)

[a]Six adolescents were not asked whether they would feel comfortable talking with their doctor about tobacco after using the support tool.

Using the Tool in Clinical Settings

Nearly all adolescents stated they would be less comfortable using the tool in the clinic's waiting room than in a more private setting. Moreover, 2 participants specifically expressed concerns with the tool's media components if they were to use it in the waiting room. Both remarked that the sounds and images of the video would be noticed by others, which might discourage them from responding honestly. However, 1 adolescent acknowledged that once in the examination room, the tool could help adolescents who are uncomfortable with face-to-face interactions. She noted that, by asking many of the questions about tobacco use that a doctor might otherwise ask, the tool could help ease and streamline the visit:

> *That'll get them away from talking face-to-face with the problem they might be having, and then the doctor or your counselor going straight to the questions they need to be asking.* [Participant 5, aged 14 years, female, black]

Most adolescents stated that they would feel comfortable discussing tobacco with their doctor. Several mentioned they

were already comfortable with their doctors, suggesting that a level of rapport necessary for honest discussions had been built during the course of previous visits with the same provider. Others stated they would disclose tobacco use with their doctor because they expected confidentiality or because they considered disclosure to be in their best interest. When asked why he would be comfortable talking about tobacco with his doctor, 1 adolescent replied:

> *Because I will probably most likely learn something new. And it would give me a better chance to understand why people like to do it.* [Participant 1, aged 17 years, male, Hispanic]

Using the Tool at Home

Nearly all adolescents stated a preference for using the tool via the Web portal at home. Some indicated that completing the screening at home would afford them more privacy and encourage them to respond more honestly. When asked her opinion of using the tool at home, 1 adolescent responded positively, stating:

> *Because I feel like at a doctor's office or somewhere else you're always like, "Oh, who's watching me?" And at home you have the privacy of your own.* [Participant 6, aged 17 years, female, Hispanic]

However, 1 adolescent stood out from the others in acknowledging that the in-home portal option could lead to a less honest response. A private setting is also an unsupervised setting, with little to encourage adolescents to actually engage with the tool, read its content, and provide thoughtful responses.

> *I wouldn't think that I would answer them more honestly at home, but rather click and skim through it… They don't have people asking, really, for the truth, and they can just be scrolling through it and clicking whatever they think is right.* [Participant 1, aged 17 years, male, Hispanic]

Nuances of Disclosure—Purity, Steadfast Honesty, and Indifference

In many cases, adolescents did not agree that the Web-based option would encourage them to respond more honestly—primarily because they would already have responded honestly in any format or setting. Overall, 3 distinct themes emerged that helped to explain this finding. First, a theme of purity was observed among the majority of adolescent participants who were never smokers, many of whom stated they had "nothing to hide." Anticipating no potentially sensitive responses to the tool, these adolescents reported they would be equally comfortable completing it in the waiting room or at home. The presence of parents was not a barrier because parents "already know" how their children would respond to the questions about personal use. Several adolescents acknowledged that although they would have no hesitations in using the tool, other peers who used tobacco might have hesitations. As 1 adolescent stated:

> *I know I wouldn't answer any differently, but friends of mine probably would, and other people my age just 'cos they have more to hide about it. I don't really care much 'cos I'm not smoking... Their parents – if they see anything that they've answered, they could get in trouble and just the presence of their parents being there would be intimidating for them.* [Participant 3, aged 16 years, female, white]

Second, many participants commented on the value of steadfast honesty—a commitment to provide honest responses regardless of the situation. Steadfast honesty was connected to positive relationships with parents and with perceptions of well-being. As 1 adolescent stated:

> *I feel like nobody should be afraid to talk about things… It's better to talk about things to people instead of holding it in.* [Participant 14, aged 16 years, female, other]

Third, several adolescents expressed a sentiment of indifference toward privacy and confidentiality of sensitive information. Some stated that they would respond honestly because they were not concerned with who might read their responses. Others remarked that their parents were "nosy" and would find out their responses anyway. As 1 adolescent remarked:

> *If I smoke tobacco, I would tell them because, I mean, they're my parents. Eventually, they're gonna find out. Well, it doesn't matter if I did it or didn't, either way, they will know.* [Participant 2, aged 16 years, male, Hispanic]

Discussion

Principal Findings and Comparison With Previous Work

Both providers and adolescents in this study stressed the importance of privacy and confidentiality for successful implementation of the clinical tool. Confidentiality was considered essential for encouraging adolescents to use the screener and to ensure honest responses among those who completed it. Themes relevant to the parental influence also emerged, including the control exerted by parents over the screening process. These findings are consistent with a similar qualitative study that found confidentiality and parental influence to be important in adolescent perspectives of comprehensive risk assessments [20].

When used in a waiting room in tablet format, the tool has features that can easily be noticed by others, and the presence of parents may lead adolescents to underreport their tobacco use and risk. Consequently, the majority of adolescents expressed a preference for the Web-based version and reported that they would respond to the screener more honestly at home. This contrasts with findings of a study by Jasik et al [21], in which adolescents preferred completing behavior screening using a tablet in the waiting room, rather than at home. It is likely that adolescents' preference for the Web-based tool in our study is related to the more intrusive audio and video components of the intervention. A recent study on the same confidential adolescent portal used in our study (MyChart) also found that adolescents consistently used the portal after enrollment [22]. Although based on the response of a single adolescent, there remains the possibility that unsupervised use

of the Web-based tool at home may not result in complete or honest responses, which is a concern that warrants further study.

Some providers also expressed concerns that parents might complete the screener for their child or question the child's need for privacy. Although the prospect of a Web-based version alleviated some of these concerns, some providers maintained that parents might "bully" their children to gain access to the portal. However, the extent to which these actions by parents may constitute the norm is unclear. A study by Miller et al [23] of parental perspectives on factors influencing adolescent communication with physicians found that most parents valued their adolescent having time alone with their physician.

As the majority of adolescent participants were never-smokers, it is unsurprising that they would express few concerns about confidentiality of information about their smoking history. However, these participants screened as tobacco-susceptible for the study, likely making them a higher-risk group. This suggests that adolescents may perceive less risk in disclosing their intent to use tobacco, supporting the inclusion of susceptibility questions in screening tools. Assessment of susceptibility is important and should be utilized in future screening tools, given that greater than one-quarter of never-smoking adolescents are susceptible for future tobacco use as adults and rates of susceptibility to tobacco products increase with age [24].

The theme of steadfast honesty clarifies adolescent perceptions of disclosure in clinical settings, as many expressed a commitment to provide honest responses regardless of the setting or situation. Most stated they would feel comfortable discussing tobacco with their doctor—a finding that is consistent with the USPSTF recommendation for PCP-led tobacco interventions [2]. This study revealed pathways that may encourage adolescents to discuss tobacco with their doctors, including having a positive patient-provider relationship, an understanding of the value of disclosure for health promotion, and a curiosity about the physiological effects of tobacco and the psychosocial factors behind its use. Regardless of their tobacco use status, wellness visits may represent a learning opportunity for adolescents that can help them make healthier choices. Furthermore, it is possible that the tool may itself increase adolescents' trust in their doctors and foster more positive relationships—an association that has been found in similar interventions with adult populations and that requires further study among adolescents [25].

Several modifications to the intervention were made from our iterative approach. First, the tool is now integrated into the EHR system used by the study clinics, introducing efficiency to the well-care visit and adding value to the learning health system. The tool is bundled with the American Academy of Pediatrics Bright Futures health risk assessment—an important adaptation that streamlines the intervention with existing clinical practice. Second, the tool offers videos to all adolescents regardless of their tobacco use or susceptibility. Patients and their parents learn that the videos are offered to all clinic patients as part of its preventive services, thereby mitigating concerns about confidentiality.

Strengths and Limitations

This study has several strengths and limitations. The perspectives of multiple stakeholders were considered throughout the intervention's design, enhancing its utility. Furthermore, triangulation of sources with both patients and providers increased credibility of the qualitative findings, permitting a comprehensive understanding of acceptability and perceived feasibility of the intervention by key users [26]. These data were collected before implementation, which allowed stakeholder feedback to increase the intervention's chances of success. However, this also introduced a limitation in that concerns by participants had not yet been tested or validated in practice. Future phases will study the acceptability of the intervention after implementation, permitting a more focused evaluation of the degree to which confidentiality may be a concern.

The study included purposeful samples of participants, allowing for in-depth understanding of the perspectives of stakeholders in clinical settings where the intervention is targeted. Although the generalizability of findings to other populations is not an aim of qualitative work, it is important to acknowledge how findings may or may not be transferable to similar, specific contexts [26,27]. The decision to integrate the tool with the adolescent's EHR was appropriate for this study's clinics, which are part of a large academic health center. In clinical settings that are not part of a similar collaborative, providers may be less willing to support such integration out of concerns for protecting confidentiality of sensitive information *within* the EHR [28].

The study's focus on adolescents who screened as susceptible was a strength. However, our findings were limited by the small number of adolescents who reported any history of tobacco use—an important subgroup whose perspectives may not have been sufficiently explored. Furthermore, because this information was based on self-reporting, the extent to which smoking history may have been underreported is unknown. Thematic saturation was reached within the 16 adolescents overall, with no new themes emerging after review of the fifth transcript. However, it is unlikely that saturation was reached specifically for adolescents who reported a history of tobacco use. This subgroup will be more fully included in future phases of this study.

Conclusions

In summary, we found commonalities and differences between provider and patient perspectives on the confidentiality of information collected in an electronic clinical support tool for adolescent tobacco screening and counseling. The resulting intervention allows PCPs to have expedient access to reliable information on susceptibility and tobacco use history during adolescent well-care visits. The intervention can both enhance counseling for active tobacco users and provide content to potentially prevent tobacco uptake among adolescents who screen as susceptible. Future studies are planned to further test the acceptability of the intervention in practice and will include adolescents across the full spectrum of tobacco use and susceptibility.

Acknowledgments

Research reported in this publication was supported in part by the OneFlorida Clinical Research Consortium, funded by the Patient-Centered Outcomes Research Institute (award number CDRN-1501-26692), in part by the OneFlorida Cancer Control Alliance, funded by the Florida Department of Health James and Esther King Biomedical Research Program (award number 4KB16), and in part by the UF Clinical and Translational Science Institute, which is supported in part by the NIH National Center for Advancing Translational Sciences (award number UL1TR001427). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Patient-Centered Outcomes Research Institute , its Board of Governors or Methodology, the OneFlorida Clinical Research Consortium, the UF's Clinical and Translational Science Institute, the Florida Department of Health, or the National Institutes of Health. Publication of this paper was funded in part by the UF Open Access Publishing Fund.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Tobacco counseling support tool prototype used in focus groups and interviews.

[PPTX File, 2MB - formative_v3i2e12406_app1.pptx]

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Abbreviations

e-cigarette: electronic cigarette
EHR: electronic health record
PCP: primary care provider
UF: University of Florida
USPSTF: United States Preventive Services Task Force

Edited by G Eysenbach; submitted 03.10.18; peer-reviewed by A Majmundar, M Baghernia; comments to author 06.03.19; accepted 24.03.19; published 28.04.19.

Please cite as:
Theis RP, Malik AM, Thompson LA, Shenkman EA, Pbert L, Salloum RG
Considerations of Privacy and Confidentiality in Developing a Clinical Support Tool for Adolescent Tobacco Prevention: Qualitative Study
JMIR Form Res 2019;3(2):e12406
URL: http://formative.jmir.org/2019/2/e12406/
doi:10.2196/12406
PMID:31066687

Original Paper

Feasibility of a Mobile Phone App to Promote Adherence to a Heart-Healthy Lifestyle: Single-Arm Study

Pernille Lunde[1], MSc; Birgitta Blakstad Nilsson[1,2], PhD; Astrid Bergland[1], PhD; Asta Bye[3,4], PhD

[1]Department of Physiotherapy, Faculty of Health Sciences, Oslo Metropolitan University, Oslo, Norway

[2]Section for Physiotherapy, Division of Medicine, Oslo University Hospital, Oslo, Norway

[3]Department of Nursing and Health Promotion, Faculty of Health Sciences, Oslo Metropolitan University, Oslo, Norway

[4]European Palliative Care Research Centre, Department of Oncology, Oslo University Hospital and Institute of Clinical Medicine, University of Oslo, Oslo, Norway

Corresponding Author:
Pernille Lunde, MSc
Department of Physiotherapy
Faculty of Health Sciences
Oslo Metropolitan University
P50
PB 4, St Olavs Plass
Oslo,
Norway
Phone: 47 48 06 35 37
Email: plunde@oslomet.no

Abstract

Background: Long-term maintenance of preventive activities is fundamental for achieving improved outcomes in cardiac rehabilitation (CR). Despite this, it has been shown to be a major challenge for many patients to follow recommendations and thereby adhere to a heart-healthy lifestyle. Mobile phone apps have been emphasized as potential tools to promote preventive activities after attendance in a CR program. Before commencing a trial to assess the potential effect of using an app to promote long-term adherence to preventive activities after attendance in CR, a study to assess if it is feasible to use an app is warranted.

Objective: The goal of the research is to assess if it is feasible to use a mobile phone app for promoting and monitoring patients' adherence to a heart-healthy lifestyle after CR.

Methods: The study included an experimental, pre-post single-arm trial lasting for 12 weeks. All patients received access to an app aimed to guide individuals to change or maintain a heart-healthy lifestyle. During the study period, patients received weekly, individualized monitoring through the app, based on their own goals. Feasibility outcomes assessed were recruitment rate, adherence to the app, resource requirements, and efficacy regarding capability to detect a change in quality of life, health status, and perceived goal achievement as well as evaluating ceiling and floor effect in these outcomes. Criteria for success were preset to be able to evaluate whether the app was feasible to use in a potential future RCT.

Results: In total, 71% (17/24) of the patients who completed CR were eligible for a potential RCT as well as for this study. All 14 patients included in the study used the app to promote preventive activities throughout the study. Satisfaction with the technology was high, and the patients found the technology-based follow-up intervention both useful and motivational. Ceiling effect was present in more than 20% of the patients in several domains of the questionnaires evaluating quality of life (36-Item Short Form Health Survey and COOP/WONCA functional health assessments) and health status (EQ-5D). Overall self-rated health status (EuroQol Visual Analog Scale) and perceived goal achievement were found to be outcomes able to detect a change.

Conclusions: Individual follow-up through an app after attendance in CR is feasible. All patients used the app for preventive activities and found the app both useful and motivating. Several points of guidance from the patients in the study have been adopted and incorporated into the final design of the RCT now in the field.

(JMIR Form Res 2019;3(2):e12679) doi:10.2196/12679

KEYWORDS

mHealth; eHealth; mobile phone app; cardiac rehabilitation

Introduction

Heart disease is the leading cause of death and disability worldwide [1]. Participation in cardiac rehabilitation (CR) is the recommended first step for secondary prevention and is associated with improved prognosis [2,3]. Exercise is the cornerstone in CR, but current guidelines recommend programs that include dietary counseling, optimizing of medical treatment, education, psychological support, and support for smoking cessation [2]. However, it has been shown to be a major challenge for many patients to follow recommendations and thereby adhere to a heart-healthy lifestyle [2,4]. A heart-healthy lifestyle includes regular physical activity, heart-healthy diet, and cessation of tobacco consumption [2]. Only 15% to 50% of individuals attending CR still exercise 6 months after participation, and even less after 12 months [5,6]. Approximately 50% of patients who are smokers prior to a coronary event still smoke 6 months after the cardiac event, and less than 50% of obese patients follow dietary recommendations [7].

Common barriers to adherence to health recommendations after a CR program are lack of social support, patient health beliefs (eg, cause of disease, controllability of a condition), past medical history, and anxiety and depression [8]. To increase adherence, there is a need for long-term individualized follow-up that takes patients' barriers into account [2,8]. The best way to promote adherence and monitor preventive activities is not known and represents an important knowledge gap in CR [2]. What is known is that the follow-up should use a patient-centered approach that focuses on the patients' priorities and goals and incorporates lifestyle changes within the context of the patients' life [2].

Digital health interventions may act as follow-up tools and deliver necessary support for patients either in CR or after attendance in CR [9-11]. Mobile health, or mHealth, defined as the use of mobile computing and communication technologies for health services and information [12], includes many of today's digital health interventions. Mobile phone apps are considered a particularly promising mHealth tool for secondary prevention for heart patients due to their ability to monitor patients' health from anywhere at any time [13,14]. As the population becomes more and more technology savvy, apps may appeal to more people. Apps offer advantages to health care providers through access to deliver direct support, interact with patients, and monitor engagement and progress [15]. As such, apps are potential tools for long-term follow-up of patients after attendance in a CR program [9,16]. However, there is limited research on the effect of using an app to promote and monitor adherence to heart-healthy lifestyle after CR. A recent systematic review [17] on the effectiveness of interventions with apps to promote lifestyle changes in patients with noncommunicable diseases found only one study conducted in heart patients [18]. The main outcome was drug adherence, which was significantly better in the intervention group compared with the control group [18].

Randomized clinical trials (RCTs) are needed to assess potential effects of an app that enables individualized monitoring of heart patients after attendance in CR with regard to exercise capacity and other cardiovascular risk factors. Before commencing such a trial, it is necessary to evaluate if it is feasible to use an app for this purpose. The main aim of this study was to assess if a mobile phone app was feasible to use for promoting and monitoring patient adherence to a heart-healthy lifestyle after CR. The following research questions were addressed: To what extent are patients willing to take part in such a study? Will the patients use the app as intended? What resources are needed to deliver follow-up messages and interact with patients? Are the outcomes (questionnaires and self-perceived goal achievements) able to detect a change? The results from this study will guide the design and software in a subsequent RCT.

Methods

Study Design

This study was an experimental, pre-post single-arm trial. The evaluation lasted for 12 weeks.

Setting

The study took place in the eastern part of Norway during spring and early summer 2017. Patients were recruited from two rehabilitation centers. One rehabilitation center offered a 12-week CR program and the other offered 1-week and 4-week programs. Approximately one-third of the participants were recruited from each of the three CR programs for this feasibility trial, the same proportions planned for the upcoming RCT.

Participants

Eligible patients were women and men over the age of 40 years who completed CR in one of the three programs during a period of two weeks. They had to own and use an Android or iOS mobile phone and be able to read and understand Norwegian or English. Exclusion criteria were restrictions regarding exercise intensity for any reason due to the primary end point in the planned RCT, which is intended to be maximal oxygen consumption (VO_{2peak}). Descriptive data collected at baseline included sex, age, diagnosis, treatment, history of smoking, educational level, exercise habits last year, and VO_{2peak}.

Using the App

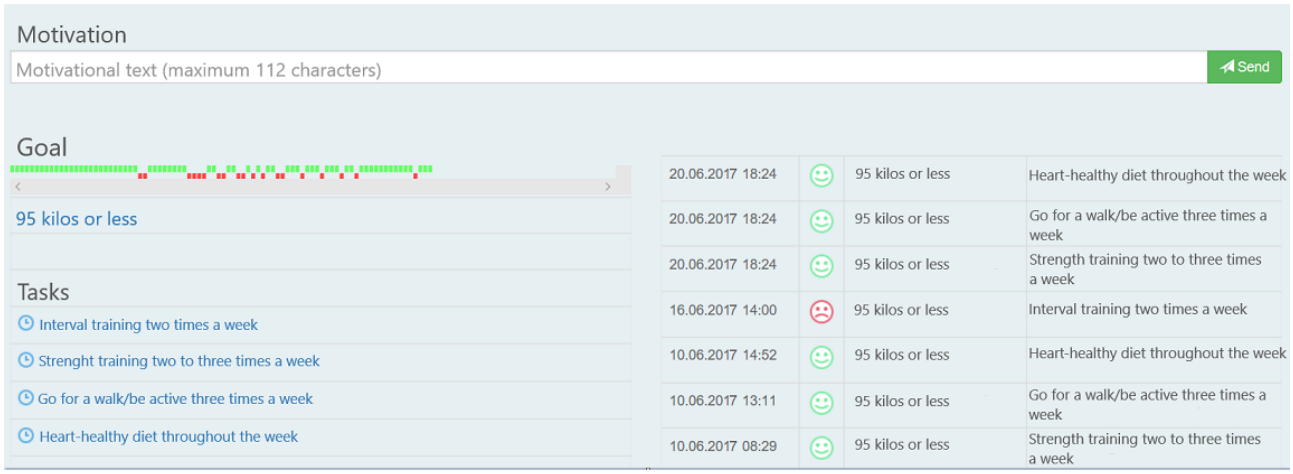
Patients received the app after attendance in CR. The app was developed to guide and help individuals change behavior and maintain habits. The follow-up was based on the transtheoretical model of behavior change [19]. According to this model, health behavior change involves progress through six stages of change: precontemplation, contemplation, preparation, action, maintenance, and termination [19]. In this connection, motivational interviews are used to help people access motivation to change a particular behavior through collaboration, evocation, autonomy, and exploration [20]. The patients are supposed to set goals that are small, important to them, specific, and realistic to achieve [21]. The app used in this study permits the user to create and set such goals (Figure 1) with tasks and accompanying reminders. A supervisor has access to an administrator interface (Figure 2) and can monitor the goals and tasks of each patient. In addition, the patient can write reflections in the app that the supervisor can read in the administrator interface. The app itself provides reminders and

evaluations of tasks and weekly goal achievement that automatically pop-up. In these evaluations, the patients must reply with a red or green face depending on whether they have completed the planned tasks or not and rate the weekly goal achievement on a scale from 0 to 100.

At baseline, a supervisor guided the patients in setting individual goals by using elements from motivational interviewing. The supervisor in the study was a physiotherapist specializing in cardiovascular and pulmonary physiotherapy with five years of experience in CR. Each patient was encouraged to set a minimum of two goals with related tasks to be able to reach each goal. The patient decided when and how often reminders of the tasks should appear on their mobile phone. During the follow-up period, the patients received short, tailored, individualized motivational feedback directly through the app 1 to 3 times a week and comprehensive individual feedback through email once a week. Patients could submit questions to the supervisor at any time, receiving an answer within 2 working days. If the question was medically related (eg, changing medication or chest pain), patients were advised to contact their general practitioner. Patients were followed for 12 weeks by the same supervisor who included the patients at baseline.

Figure 1. User interface of the app showing individual goals.

Figure 2. Administrator interface of the app showing one goal with related tasks.



Outcome and Measures

Recruitment Rate

The proportion of patients willing and able to take part in the study after finishing CR was established. During a 2-week period, all patients at two different centers were invited to participate. Information about restrictions on exercising (exclusion criteria) was collected from health providers at the centers.

Adherence to the App

Use of the app was registered in terms of actual use and if patients answered tasks within a week, all based on data shown in the administrator interface (Figure 2). Patient satisfaction with the technology was assessed with the System Usability Scale (SUS), a paper questionnaire completed at the end of the study. The SUS is a technology independent, 10-item questionnaire with a score between 0 and 100 where 0 represents low usability and 100 represents high usability [22]. Patient experiences with the app and follow-up were evaluated through a questionnaire designed for this study consisting of 20 questions; 13 questions with answers on a Likert scale (0 to 100), 5 multiple-choice questions, and 2 open-ended questions (Multimedia Appendix 1). The Likert scale questions allowed patients to evaluate the app with regard to usefulness and motivational effect. The multiple-choice questions provided information about patient satisfaction with follow-up time and frequency of individual feedback. The open-ended questions gave the patients an opportunity to give additional guidance for the upcoming RCT. Any problems with the technology were continuously observed through the administrator interface. Additionally, the supervisor used the app throughout the study to enable early discovery and mitigation of technical issues.

Resource Requirements

Throughout the study period, the supervisor logged all time spent monitoring patients.

Change and Ceiling and Floor Effect in Outcomes

These outcomes were determined by evaluating whether changes in quality of life, health state, and perceived goal achievement over the 12-week period could be observed and whether these outcomes disclosed ceiling or floor effects. Quality of life was assessed with two questionnaires: the 36-Item Short Form Health Survey (SF-36) and the Dartmouth COOP/World Organization of Family Doctors functional health assessment (COOP/WONCA) [23,24]. The SF-36 consists of 36 questions across eight domains [23]. Item scores were transformed to 0 to 100 point scales (0=worst, 100=best) using the SF-36 syntax [23]. COOP/WONCA consists of six questions across six domains with a score of 1 in each domain representing the best possible score while a score of 5 is the worst possible score [24]. Health status was assessed with EQ-5D [25]. The EQ-5D consists of five questions with five answer options to each question, where a score of 1 is the best possible score and 5 is the worst possible score [25]. In addition, the EQ-5D consists of an overall health question (EQ-VAS) where the patient answers on a Likert scale (0 to 100, where 0 represents the worst possible health and 100 is the best possible health) [25]. All questionnaires were answered by patients on paper at baseline and after 12 weeks. Floor and ceiling effects were considered present in the scales if more than 20% of respondents achieved the lowest or highest possible score, respectively [26]. Therefore, if more than 20% of patients reached floor or ceiling effect, extra emphasis was placed on the evaluation of whether the questionnaire was suitable for the upcoming RCT. Perceived goal achievement was evaluated through the database platform. Every week patients got an automated question in the app—"How close do you think you are to reaching this goal?"—where they would answer on a Likert scale (0 to 100, where 0 represents far away from reaching the goal and 100 that the goal has been reached) for each goal.

Criteria for Success

In order to determine whether follow-up of patients after CR through an app was feasible in an RCT, we chose the following criteria for success:

- At least 80% of the patients used the app during the study period
- Patients answered at least 50% of the tasks within a week
- Mean SUS score ≥65

Statistical Analysis and Ethical Consent

Based on Treweeks' [27] recommendations for pilot and feasibility trials, we needed 10-15 patients to be able to have confidence in the conclusions drawn from the data. Data were analyzed using SPSS Statistics for Windows version 24.0 (IBM Corp). Descriptive statistics are reported for each case and in means and standard deviations for the whole group. Differences in outcome variables (baseline to 12-week) were analyzed using nonparametric tests due to the small number of patients. Significance was set to $P<.05$. In case of missing data, we used the last observation carried forward method.

The Regional Committee for Medical Research Ethics, Region Eastern Norway, reviewed the study and found that approval was not required. All participants provided written informed consent.

Results

Recruitment Rate

In total, 24 patients were available for inclusion in the study (Figure 3), and 17 (71%) were eligible for the potential RCT. Ultimately, 14 patients were enrolled in this study.

Half (50%) of the patients were iOS users, and half were Android users. Approximately one-third had attended each of the three CR programs—12 weeks, 4 weeks, and 1 week. Table 1 provides the baseline characteristics: 71% (10/14) were men, mean age for all participants was 60.1 (SD 8.5) years, and mean VO_{2peak} was 27.6 (SD 6.2) mL/kg/min.

Figure 3. Flow diagram.

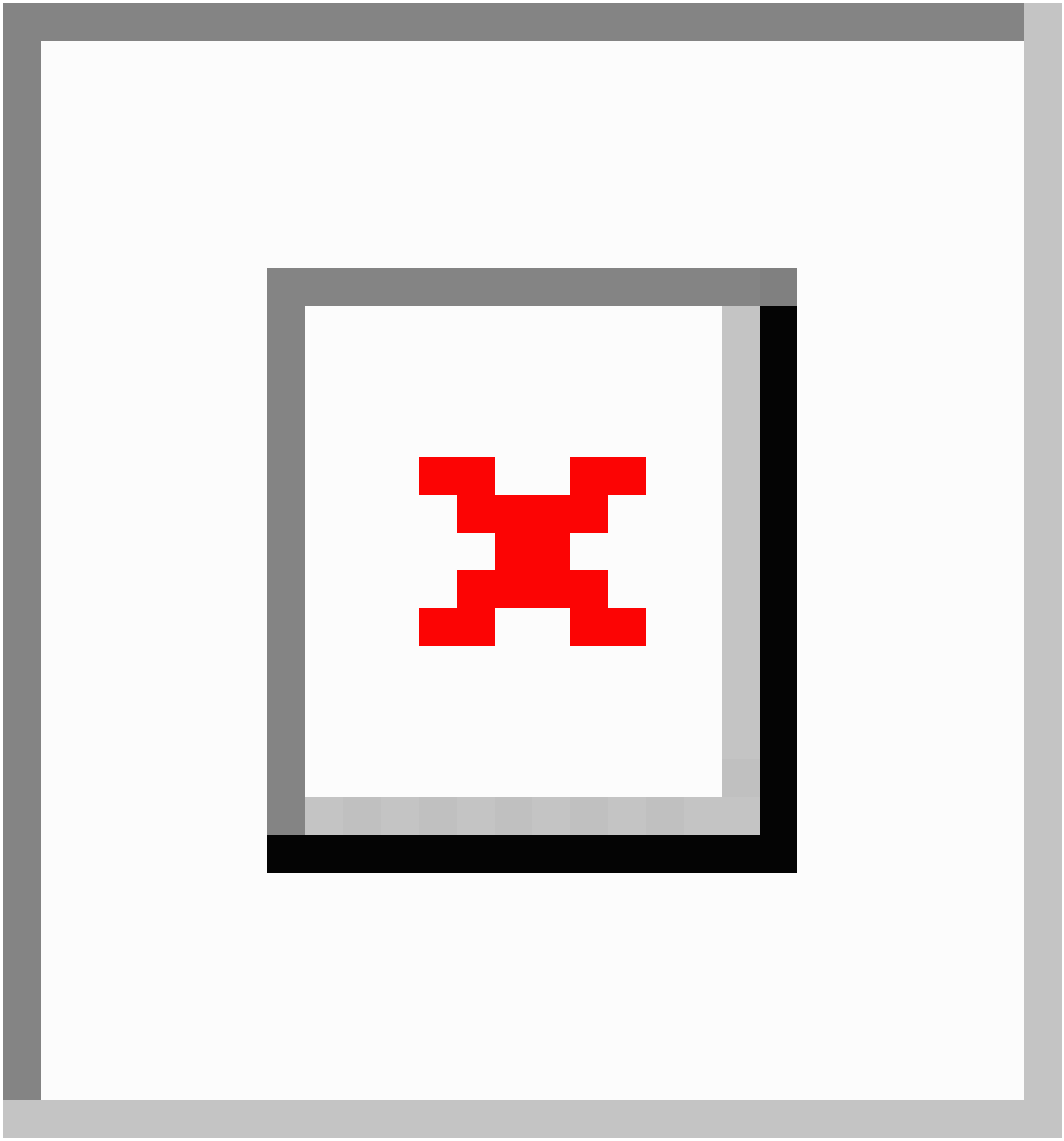


Table 1. Baseline characteristics.

Sex	Age	Diagnosis	Treatment	Smoker	Education[a]	Weekly exercise last year[b]	Exercise capacity (VO_{2peak}[c], mL/kg/min)
F[d]	42	ACS[e]	PCI[f]	Earlier	0	3	37.4
M[g]	66	ACS	PCI	Never	5	0	35.6
M	64	ACS	PCI	Earlier	1	1.5	29.4
M	55	CAD[h]	PCI	Earlier	4	0.5	28.1
M	45	ACS	PCI	Never	2	1.5	36.5
F	68	ACS with cardiac arrest	ICD[i] and medication	Earlier	0	0	16.2
F	62	CAD	PCI	Earlier	5	1	26.6
F	66	Spasm angina	Conservatively	Earlier	0	0	27.6
M	66	CAD	CABG[j]	Earlier	0	0	19.7
M	68	CAD	PCI	Never	7	7	25.6
M	52	CAD	PCI	Never	4	2	28.3
M	66	CAD	Conservatively	Current	3	0	19.7
M	62	CAD and AS[k]	CABG and AVR[l]	Earlier	3	0	28.2
M	60	Atrial flutter	Pacemaker	Never	1	4	27.5

[a]Years of education after high school.

[b]Number of exercise sessions per week lasting at least 30 minutes where participants became sweaty and breathless.

[c]VO_{2peak}: maximal oxygen consumption.

[d]F: female.

[e]ACS: acute coronary syndrome.

[f]PCI: percutaneous coronary graft.

[g]M: male.

[h]CAD: coronary artery disease.

[i]ICD: implantable cardioverter defibrillator.

[j]CABG: coronary artery bypass graft.

[k]AS: aortic stenosis.

[l]AVR: aortic valve replacement.

Adherence to the App

All patients used the app regularly throughout the 12 weeks. Additionally, all patients answered all tasks within a week. Table 2 provides the app use for all patients. All patients had goals or tasks related to exercise or fitness training, and 9 of 14 had goals or tasks related to maintaining or improving their dietary habits. The mean numbers of individual goals, tasks, and weekly reminders were 1.9 (SD 0.5), 3.5 (SD 1.1), and 10.3 (SD 4.5), respectively. The mean SUS score for all patients was 84.8 (SD 12.8). iOS users scored higher in SUS than Android users (90.4 [SD 7.7] vs 79.3 [SD 15.0]) (Mann-Whitney test, P=.12), but the difference was not significant. Patients scored 96.8 (SD 7.2) on the questions on usefulness of the app and 91.3 (SD 14.2) on questions regarding their own motivation. Most of the patients (9/14, 64%) reported it to be useful to use the app for 6 to 12 months after attendance in CR. All patients felt it was very important that they were closely monitored by the supervisor during the first months. After that, monitoring could be less frequent.

Table 2. App use for all patients.

Sex	Age	Mobile phone model	Number and type of goal	Number of tasks	Number of weekly reminders	SUS[a] score
F[b]	42	iPhone 5S	Fitness training; Healthy nutrition; Strength training	4	11	90
M[c]	66	iPhone 6S	Fitness training; Physical activity	2	4	80
M	64	Samsung Galaxy S5	Fitness training; Healthy nutrition	3	9	77.5
M	55	Sony Xperia	Fitness training; Healthy nutrition	4	12	62.5
M	45	iPhone 6S	Weight loss; Healthy nutrition	5	17	92.5
F	68	Huawei	Fitness training; Relaxation	4	18	67.5
F	62	iPhone 6S	Fitness training; Mindfulness	5	17	95
F	66	iPhone SE	Fitness training; Overcome anxiety	4	5	95
M	66	Samsung Galaxy S4	Weight loss	4	10	90
M	68	iPhone 6S	Weight loss	2	8	80
M	52	Samsung Galaxy S5	Fitness training; Weight loss	4	7	65
M	66	HTC Sense 6	Smoking cessation; Fitness training	2	8	92.5
M	62	Samsung Galaxy A5	Fitness training; Weight loss	3	8	100
M	60	iPhone 7S	Activity and exercise; Healthy nutrition	4	11	100

[a]SUS: System Usability Scale.

[b]F: female.

[c]M: male.

Only minor problems with the technology appeared during the study. Patients could not report that they had completed tasks for a 9-hour period, and for 4 weeks, patients could not save the score on the weekly perceived goal achievement question that appeared in the app.

Resource Requirements

The supervisor spent approximately one hour to include each patient to the study. During this hour, the supervisor obtained written consent; collected sociodemographic data; created a user for the app in the administrator interface; helped the patient download the app and set realistic, specific, important, and individual goals and tasks; and trained the patient to use the app. Thereafter, time spent monitoring patients was, on average, 6 minutes per patient per week for the 12 weeks. In addition, on average 7 minutes each week was spent answering patient emails and 9 minutes was spent talking to the service provider about bug fixes and update needs of the app.

Change and Ceiling and Floor Effect in Outcomes

The domain physical fitness in COOP/WONCA improved from 2.2 (SD 1.0) to 1.9 (SD 0.9), P=.046. There were no statistically significant changes in any of the other domains. The domain pain and discomfort in EQ-5D improved significantly, from 2.1 (SD 1.1) to 1.8 (SD 1.1) (Wilcoxon signed-rank test, P=.046). There were no statistically significant changes in any of the other domains. On the SF-36, no statistically significant changes were found in any of the domains.

Mean scores with standard deviations for both baseline and 12 weeks with P values of the changes are presented in Table 3 in addition to minimum and maximum observed scores and percent of ceiling and floor effects for each questionnaire at baseline, with associated domains.

Table 3. Quality of life and health status at baseline and 12 weeks, with *P* values of changes, minimum and maximum scores, and percentages of n reaching floor or ceiling effect at baseline.

Outcome and measure	Baseline mean (SD)	12 weeks mean (SD)	*P* value	Observed (baseline)			
				Min	Max	Floor	Ceiling
COOP/WONCA[a] (score 1-5)							
Physical fitness	2.2 (1.1)	1.9 (0.9)	.046	1	4	0	36
Feelings	2.0 (1.0)	1.8 (1.0)	.08	1	4	0	36
Daily activities	1.7 (0.8)	1.8 (1.0)	>.99	1	4	0	43
Social activities	1.8 (1.0)	1.6 (0.6)	.32	1	4	0	50
Change in health	2.4 (1.1)	2.5 (0.9)	.48	1	5	7	21
Overall health	2.4 (0.9)	2.1 (0.9)	.10	1	4	0	7
SF-36[b] (score 1-100)							
Vitality	54 (21)	56 (18)	.69	20	85	0	0
Physical functioning	87 (14)	89 (12)	.64	55	100	0	21
Bodily pain	67 (25)	67 (29)	.80	22	100	0	14
General health perception	67 (19)	67 (18)	.61	25	100	0	7
Physical role functioning	54 (43)	54 (45)	.73	0	100	29	36
Emotional role functioning	83 (36)	91 (51)	.74	0	100	14	79
Social role functioning	84 (20)	88 (15)	.30	37.5	100	0	50
Mental health	76 (17)	74 (14)	.91	48	100	0	7
EQ-5D[c] (score 1-5)							
Mobility	1.4 (0.9)	1.1 (0.5)	.29	1	3	0	79
Self-care	1.0 (0)	1.0 (0)	>.99	1	1	0	100
Usual activities	1.4 (0.6)	1.1 (0.3)	.06	1	2	0	64
Pain or discomfort	2.1 (1.1)	1.8 (1.1)	.046	1	4	0	36
Anxiety or depression	1.6 (0.9)	1.6 (0.8)	.79	1	4	0	57
EQ-VAS[c]	68.9 (11.6)	72 (13.6)	.35	40	93	0	0

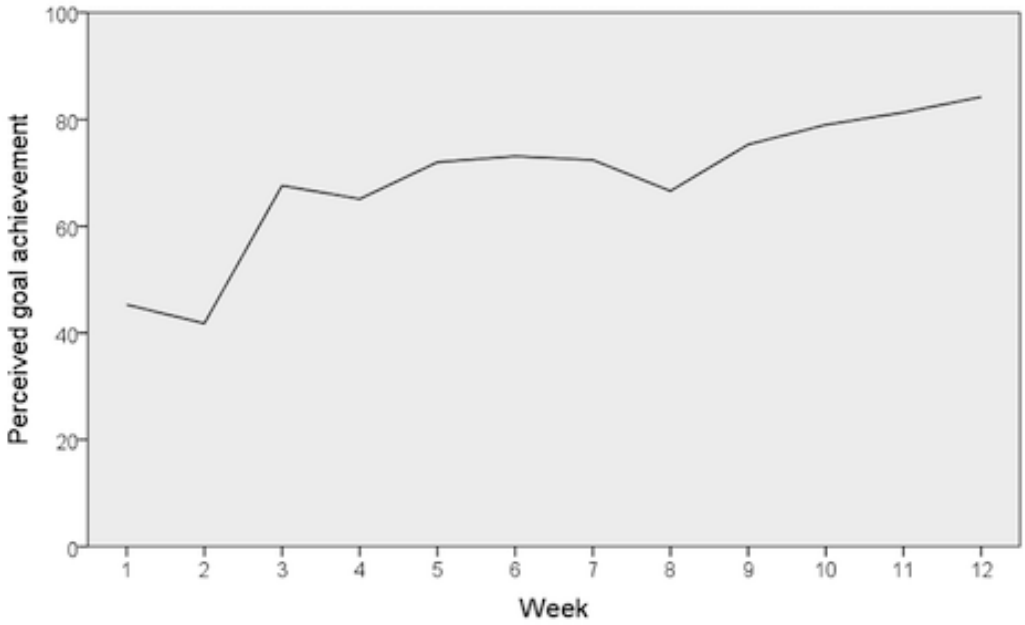
[a]COOP/WONCA: Dartmouth COOP/World Organization of Family Doctors functional health assessment chart.

[b]SF-36: 36-Item Short Form Health Survey.

[c]EQ-VAS: EQ-5D Visual Analog Scale.

Mean scores of perceived goal achievement, week by week, are presented in Figure 4. There was a statistically significant improvement in goal achievement from baseline to week 12 with a mean change of 41.2 (SD 39.0) (*P*=.002). None reached ceiling or floor effect. Distribution of scores in COOP/WONCA and EQ-5D at baseline and after 12 weeks are presented in Multimedia Appendix 2 and 3, respectively.

Figure 4. Mean score of perceived goal achievement, week by week.



Discussion

Principal Findings

To our knowledge, this is the first study to evaluate the feasibility of using an app as a tool to promote and monitor adherence to a heart-healthy lifestyle after attendance in CR with predefined criteria for success. Results demonstrated a high recruitment rate and high adherence to use of the app. In total, 71% of available patients were eligible and wanted to participate in the study, and all patients used the app during the entire intervention period and answered all tasks. The supervisor spent in average of 6 minutes each week to give individualized feedback to each patient. Quality of life, health state, and self-perceived goal achievement improved; however, we observed a ceiling effect in questionnaires measuring quality of life and health status. The strengths of feasibility studies are to report the possible pitfalls of a large RCT, weigh strengths against weaknesses of the intervention, investigate the feasibility of patient recruitment and outcome measures, and come up with solutions on how to conduct the RCT [28]. A strength of our study was its clear eligibility criteria and rigorous protocol, which ensured that the sample included the targeted patient population and accurate data collection at predefined study time points.

Our findings are in line with results from studies evaluating mHealth interventions for chronic disease management. In a systematic review [10], 62 of 107 included studies evaluated usability, feasibility, and acceptability of mHealth interventions. The most used mHealth intervention was text messaging. The number of studies including mobile phone apps is not specified, but it is stated that 25 used specialized software or a mobile phone app. Generally, the review concluded that the usability, feasibility, and acceptability of mHealth tools were high in connection with chronic disease management. Both patients and providers appreciated the mHealth tools [10]. Specific results from studies with mobile phone apps are not presented. In addition, none of the 25 studies that used specialized software or a mobile phone app were conducted in heart patients [10]. A review by our group determined that mobile phone apps seem to be most common in studies conducted in patients with diabetes mellitus [17].

According to the technology acceptance model, usefulness and ease of use are key factors that influence whether people accept or reject technology and thereby influence adherence to a technology-based intervention [29]. In this study, the overall satisfaction with technology measured with the SUS was 84.8. This score is considered as very high with a high degree of usability [30]. There was a difference in SUS score between Android and iOS users in favor of the iOS users. This is not surprising as the iOS operating system has a unified user interface for all mobile phones, whereas the Android operating system comprises several user interfaces due to the wide range of mobile phone producers using the platform. Because of the difference in SUS score between Android and iOS users, it is necessary to make the Android version of the app more stable for the upcoming RCT.

Patients reported clear and realistic goals for a heart-healthy lifestyle that they were able to evaluate weekly in the app. It was surprisingly easy to guide the patients in setting goals. This can be explained because goal-setting is often used as an approach in CR programs [31]. Both CR centers from where the patients were recruited emphasize goal-setting in their CR program. In addition, the supervisor's background and experience in CR may have contributed to the effective goal-setting. Continuation of focus on their own goals for a heart-healthy lifestyle in the follow-up after attendance in CR may have contributed to patients' perceived usefulness of the intervention and perceiving it would be useful to be followed up for a longer period of time. Most patients reported that it would be beneficial to use the app for a year. Whether the patients actually preserved or improved their exercise capacity

or nutritional-related goals is still uncertain, but the results from this feasibility study support moving on to the RCT.

From Single-Arm Feasibility to Randomized Controlled Trial

Several points of guidance from the patients in the study have been adopted and incorporated into the final design. First, although satisfaction with the technology was high, some potential improvements were discovered. One to three times a week, individualized motivational messages were sent to each patient. These messages appeared on the patients' mobile phones as a push notification. It turned out that several of the patients were not familiar with push notifications, and therefore these messages were lost without some of the patients having read the content. Based on the feedback, the app has been adjusted, and individualized motivational messages are saved in the app. Each patient can then decide when they want to read and delete them. A technical problem with weekly goal achievement was fixed during the fifth week of the study, and it is now fully functional. In addition, there were some options in the app with regard to when a task should start. In example, patients could create a task with any start time they wanted. This function did not work properly, and patients reported that they didn't need it. Therefore, the functionality has been deleted in order to keep the app as simple and easy to use as possible.

Quality of life was evaluated with the questionnaires SF-36 and COOP/WONCA. It turned out that more than 20% of the patients achieved ceiling effect on 50% or more of the domains in these questionnaires, which makes it difficult to detect any improvement in these domains. Floor effect was achieved only in the domain physical role functioning on the SF-36. The high number of patients reaching the upper limits may have been a result of the non–disease-specific questionnaires that were used. Additionally, the included patients were relatively young, not in any acute phase of disease or illness, and had just completed an extensive rehabilitation program [32]. To be able to evaluate possible changes in quality of life in the upcoming RCT, we have decided to use the HeartQoL health-related quality of life questionnaire. HeartQoL has been found to be both valid and reliable in patients with the primary diagnoses the CR patients normally have (eg, angina, myocardial infarction and heart failure [33], stable coronary artery disease [34], atrial fibrillation [35] as well as in patients with implantable cardioverter defibrillators [36] and patients following heart valve surgery [37]). On the EQ-5D, ceiling effect was reached for more than 30% of the patients in all domains. Again, this can be explained by the patients' relatively young age and the inclusion of nonhospitalized patients [32] and is in line with other research on this population [38,39]. Despite this, we have chosen to keep the EQ-5D in the planned RCT due to its ability to conduct health economic statistics and because HeartQoL doesn't include an overall health status like EQ-VAS.

In line with the general Norwegian population according to Statistics Norway [40], 92% of the patients at CR were owners and users of mobile phones. Although 71% of the patients were eligible for inclusion in the study and therefore for the upcoming RCT, it is not likely that these patients would sustain participation if they perceived that randomization to the control group resulted in an inferior intervention.

Although the results from this feasibility study are promising for the upcoming RCT, we have to be aware that the patients in the study were only followed for three months, and it is reasonable to believe that there will be dropouts when the study runs over a year. This must be taken into account in the calculation of how many participants will be needed to detect an effect in the RCT, and we have added 20% for possible dropouts.

Conclusions

Based on preset criteria for success, our study shows that an intervention with an app that allows individualized monitoring after attendance in CR is feasible. All patients used the app to get help for preventive activities such as exercise and dietary change. Implementation of mobile phone apps as a tool to promote adherence to preventive activities after CR is a novel approach. Since research in this area is warranted, this paper may serve as a foundation for other upcoming RCTs as well and inform the development of RCT management.

Acknowledgments

The authors would like to express their gratitude to both the Norwegian Institute of Sports Medicine and the National Association for Pulmonary and Cardiac Diseases for letting us recruit patients from their CR centers. Additionally, the authors would like to thank M4Influence for providing access to their software solutions.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire.

[PDF File (Adobe PDF File), 52KB - formative_v3i2e12679_app1.pdf]

Multimedia Appendix 2

Distribution of scores in COOP-WONCA at baseline (pre) and after 12 weeks (post).

[PDF File (Adobe PDF File), 66KB - formative_v3i2e12679_app2.pdf]

Multimedia Appendix 3

Distribution of scores in EQ-5D at baseline (pre) and after 12 weeks (post).

[PDF File (Adobe PDF File), 56KB - formative_v3i2e12679_app3.pdf]

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Abbreviations

COOP/WONCA: functional health assessment charts developed by the Dartmouth COOP Functional Health Assessment Project and promoted by the World Organization of Family Doctors
CR: cardiac rehabilitation
EQ-5D: standardized measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal
RCT: randomized controlled trial
SF-36: 36-Item Short Form Health Survey
SUS: system usability scale
VO2peak: maximal oxygen consumption

Edited by G Eysenbach; submitted 03.11.18; peer-reviewed by S Gandhi, E Gong; comments to author 17.01.19; revised version received 05.03.19; accepted 24.03.19; published 19.04.19.

Please cite as:
Lunde P, Nilsson BB, Bergland A, Bye A
Feasibility of a Mobile Phone App to Promote Adherence to a Heart-Healthy Lifestyle: Single-Arm Study
JMIR Form Res 2019;3(2):e12679
URL: http://formative.jmir.org/2019/2/e12679/
doi:10.2196/12679
PMID:31066684

Original Paper

The Use of Smart Technology in an Online Community of Patients With Degenerative Cervical Myelopathy

Oliver Daniel Mowforth[1*], BA; Benjamin Marshall Davies[1*], BSc, MRCS; Mark Reinhard Kotter[1], MD, MPhil, PhD

Division of Neurosurgery, Department of Clinical Neurosciences, Addenbrooke's Hospital, University of Cambridge, Cambridge, United Kingdom

[*]these authors contributed equally

Corresponding Author:
Mark Reinhard Kotter, MD, MPhil, PhD
Division of Neurosurgery
Department of Clinical Neurosciences
Addenbrooke's Hospital, University of Cambridge
Hills Road
Cambridge,
United Kingdom
Phone: 44 1223 763366
Email: mrk25@cam.ac.uk

Abstract

Background: Degenerative cervical myelopathy (DCM) is a prevalent and progressively disabling neurological condition. Treatment is currently limited to surgery, the timing of which is not without controversy. New international guidelines recommend that all patients should undergo lifelong surveillance and those with moderate-to-severe or progressive disease should be offered surgery. Long-term surveillance will place substantial burden on health services and short clinic assessments may risk misrepresenting disease severity. The use of smart technology to monitor disease progression could provide an invaluable opportunity to lessen this burden and improve patient care. However, given the older demographic of DCM, the feasibility of smart technology use is unclear.

Objective: The aim of this study was to investigate current usage of smart technology in patients with self-reported DCM to inform design of smart technology apps targeted at monitoring DCM disease progression.

Methods: Google Analytics from the patient section of Myelopathy.org, an international DCM charity with a large online patient community, was analyzed over a 1-year period. A total of 15,761 sessions were analyzed.

Results: In total, 39.6% (295/744) of visitors accessed the website using a desktop computer, 35.1% (261/744) using mobile, and 25.3% (188/744) using a tablet. Of the mobile and tablet visitors, 98.2% (441/449) utilized a touchscreen device. A total of 51.3% (141/275) of mobile and tablet visitors used iPhone Operating System (iOS) and 45.8% (126/275) used an Android operating system. Apple and Samsung were the most popular smart devices, utilized by 53.6% (241/449) and 25.8% (116/449) of visitors, respectively. The overall visitor age was representative of DCM trials. Smart technology was widely used by older visitors: 58.8% (113/192) of mobile visitors and 84.2% (96/114) of tablet visitors were aged 45 years or older.

Conclusions: Smart technology is commonly used by DCM patients. DCM apps need to be iOS and Android compatible to be accessible to all patients.

(JMIR Form Res 2019;3(2):e11364) doi:10.2196/11364

KEYWORDS

spinal cord diseases; cervical vertebrae; spinal osteophytosis; spondylosis; biomedical technology; chronic disease; follow-up studies

Introduction

Background

Degenerative cervical myelopathy (DCM) is a chronic and progressive neurological condition of symptomatic spinal cord compression secondary to degenerative changes in the cervical spine [1,2].

In classical descriptions, DCM patients present complaining of a broad-based gait and clumsy hands [3-5]. In reality, symptoms are varied and often subtle, which contributes to significant

underdiagnosis, misdiagnosis, and delayed diagnosis [6]. This has hindered accurate characterization of its epidemiology, but based on imaging studies, the prevalence of DCM could be as high as 5% in those over 40 years old [6]. Ultimately, the condition is progressive and in extreme circumstances can lead to paralysis [5]. This significant disability severely impacts quality of life; a recent study found that quality of life in DCM patients is lower than in almost any other chronic disease, including cancer, diabetes, and chronic lung disease [7].

At present, surgical decompression is the only effective treatment for DCM. It is able to halt disease progression and provide some degree of improvement. However, despite surgery, most patients will continue to suffer from neurological deficits [8,9], and therefore, the timing of surgery is crucial [10]. If offered too late, this will expose patients to irreversible damage; if offered prematurely, surgery may expose patients to an invasive procedure with a risk of potential unintended effects, such as adjacent segment degeneration leading to future DCM development at nonoperated spinal levels.

Consequently, there is an increasing need for close monitoring of patients with DCM. New international guidelines recommend that for moderate-to-severe disease, surgery should be offered and patients should be monitored after surgery [10]. For mild disease, long-term follow up is recommended [10]. Surveillance of this large and increasing cohort of patients poses many problems, including a huge burden on health services. Moreover, snapshot outpatient clinic assessments once or twice per year risk misrepresenting disease severity. In addition, current disease severity measures are poorly sensitive to change and poorly adapted to research studies, limiting outcomes for both present and future patients [11].

Technological advances, especially smart technologies such as mobile phones, offer a novel and innovative solution to this problem. Smart technology is increasingly prevalent in the general population: in 2017, it was estimated that there were almost 4 billion internet users worldwide [12]. Moreover, a recent survey found that 85% of the adult population of the United States own a mobile phone and 45% own a smartphone [13]. A study of 300 participants seeking health care in a US emergency department found that 71% owned smartphones, of which 95% had apps and 44% had health apps [14].

Smart devices have highly sophisticated inbuilt technologies, including global positioning systems, accelerometers, microphones, speakers, and cameras capable of fulfilling medical assessments [15]. Smart technology has average to excellent accuracy in measuring a range of physical activities including differentiation of static activity, stair climbing, cycling, walking, and running [16], allowing widespread use of smartphone apps in measuring biological parameters, such as in diabetes, in cardiac rehabilitation, and falls in the elderly [15].

Smart technologies allow users to input data at high frequency, making it much easier to detect change with time, which is important in DCM. Current DCM disease severity measures are relatively simple, focusing largely on gait and motor functioning, making them highly accessible for patients to understand and accurately score [17,18] and highly compatible with a mobile smart device. Moreover, users appear motivated to engage with smart technology: 52% of smartphone users reported using their smartphone to search for health information [13].

Such assessment tools may have additional benefits, transferring assessments to nonspecialists to facilitate earlier diagnosis and may offer a useful research tool. There are also clear financial benefits; a report for the European Union estimated that mobile health (mHealth) could save 99 billion euros in health care costs in the European Union and add 93 billion euros to the European Union's gross domestic product in 2017 if its adoption is encouraged [19].

Owing to its degenerative nature, the average age of patients undergoing surgery for DCM is in the mid-50s [2]. Currently available clinical trial data suggest that the DCM patient demographic is approximately 60% male and 80% Caucasian with the mean age of presentation reported as 56 to 64 years [20,8]. Clearly, for smart technology to offer an immediate benefit, it would need to be accessible to a high proportion of patients. Whether this is feasible for the current DCM population is unknown.

Objectives

This study aimed to assess the current usage of smart technology in patients with DCM to ascertain the feasibility of introducing a smart technology–based assessment tool. Specifically, we aimed to establish the relative use of smart technologies (mobile phones and tablets) and traditional desktop devices by patients with DCM to engage with Myelopathy.org, a health charity specifically designed for DCM patients. We hypothesized that smart technology is utilized by DCM patients of all age groups.

Methods

Study Design

A cross-sectional observational study was conducted. All reporting adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines from the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network [21].

Setting

Data on visitor demographics to the patient section of Myelopathy.org (Figure 1), an international myelopathy charity, were collected over a 1-year period from April 2016 to April 2017 using Google Analytics (Google). Myelopathy.org is designed for patients, professionals, and carers and has a growing online community.

Figure 1. Homepage screenshot from Myelopathy.org, an international myelopathy charity.

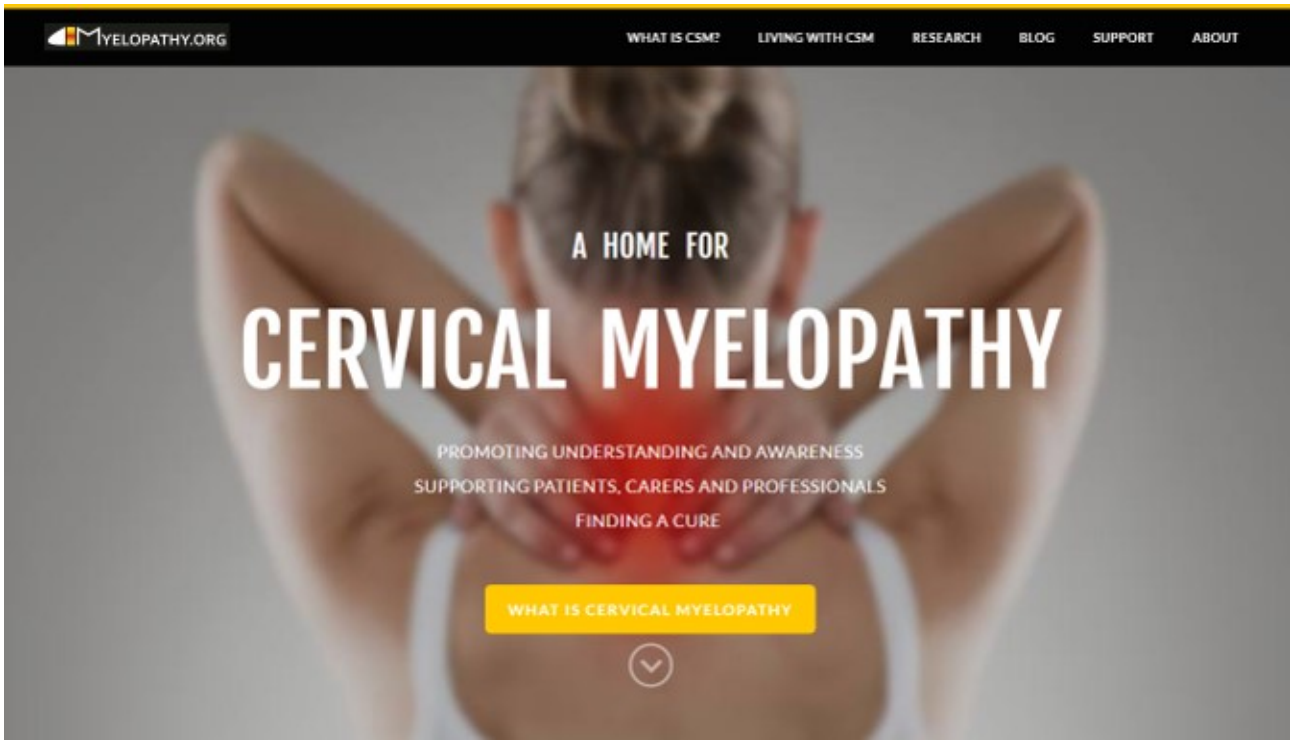
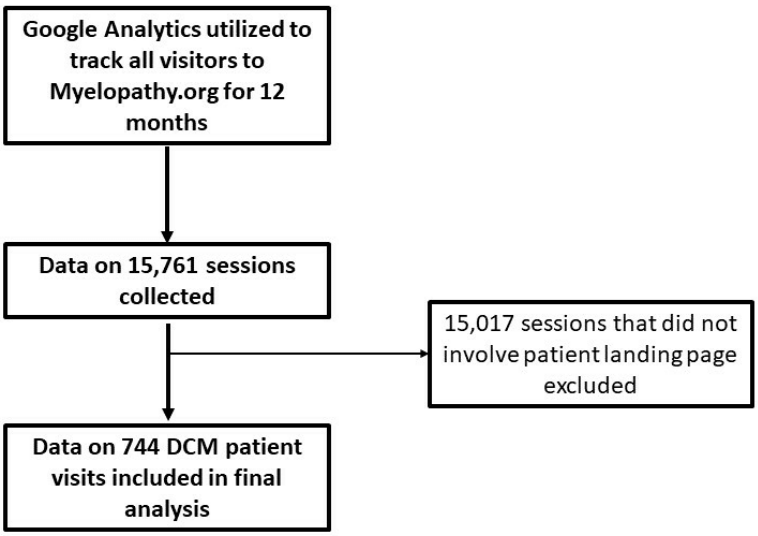


Figure 2. A total of 15,761 sessions were analysed, 4.7% (744) of which involved the degenerative cervical myelopathy patient survey page. DCM: degenerative cervical myelopathy.



Participants

Patients with DCM were identified by selecting visitors who accessed an e-survey landing page, intended for patients, hosted by Myelopathy.org [22]. This unique landing page required visitors to click through a description of the disease to confirm they had a diagnosis of DCM. A total of 15,761 website visiting sessions were analyzed. Sessions were undertaken by 10,294 visitors, of which 10,261 were new visitors. Although many of the discarded visits were likely from patients, only the 744 visits that involved clicking through to the patient landing page from the main website were included in the analysis to ensure greater certainty that included visits were from patients (Figure 2).

Data Sources

All data were extracted directly from Google Analytics. Data were analyzed using Microsoft Excel (Office 365, Microsoft).

Variables

Variables of interest extracted from Google Analytics were sessions (visits); users; demographics including age, gender, and location; device use and device characteristics including mobile and tablet operating systems; mobile and tablet manufacturer; and mobile and tablet input selector.

Bias

No visitors were excluded. As a self-selected population, it is possible that nonpatient visitors were included in the total website visits. We suspected that most website visitors were patients: for example, approximately 800 complete survey responses were received from patients and 50 from carers to similar surveys over the same time period. Nonetheless, using only visits to the patient landing page increases the certainty of including only patients in our analysis. Given this study design, we believed any nonpatient influence was likely to be very small and, in the context of our large sample size, was unlikely to influence the overall results. To mitigate against ascertainment selection bias, we included a subsection with total website visitor data in the Results section; the similarity of these data to the patient landing page data provides some reassurance against selection bias and suggests that most website visitors are likely to be patients.

Study Size

Overall 43,004 page views from 15,761 visits were analyzed. A total of 10,261 new visitors were analyzed, of which 744 visited the patient landing page via the Myelopathy.org homepage. All DCM patient visitors over the 12-month study period were included.

Statistical Methods

Formal statistical analysis was deemed inappropriate.

Ethics Approval and Consent

The study was ethically approved by the Cambridge Human Biology Research Ethics Committee, University of Cambridge.

Results

Participant Demographics

Key demographic characteristics of DCM patient visitors are summarized in Table 1. In total, 29.8% (145/487) of visitors were male. The age range was broad from 18 years to over 65 years. The overall visitor location was diverse. Patient visitors came from over 31 different countries, predominantly the United States (34.1% (254/744)) and the United Kingdom (53.8% (400/744)), representing 87.9% (654/744) of overall visitors.

Smart Technology Use

Device

The Myelopathy.org patient survey was accessed by desktop, mobile, and tablet devices. A total of 35.1% (261/744) of visitors accessed the survey using a mobile phone, 39.6% (295/744) using a desktop device, and 25.3% (188/744) using a tablet device.

Smart Technology Users

Of the smart technology (mobile and tablet) visitors, 98.2% (441/449) utilized a touchscreen device. Although iPhone Operating System iOS (51.3% (141/275) and Android (45.8% (126/275) operating systems were dominant in their share of visitors, with a combined 97.1% (267/275) of patient visitors utilizing 1 of the 2 operating systems, use by device manufacturer was more diverse. Although Apple (53.6% (241/449)) and Samsung (25.8% (116/449)) were the most popular device manufacturers, 20.6% (92/449) of devices were produced by 22 other manufacturers. No manufacturer other than Apple or Samsung was utilized by more than 2.5% (11/449) of visitors, and 86.4% (388/449) of visitors utilized devices from one of the top 5 most popular manufacturers, including LG (2.5% (11/449)), Amazon (2.5% (11/449)), and Motorola (2.0% (9/449)), in addition to Apple and Samsung.

Smart Technology Engagement Across Age Groups

Overall, the visitor age range was broad (Table 1), with 68.0% (328/482) of visitors aged 45 years or older. The overall modal visitor age group was 45 to 54 years.

The patient visitor profile for each technology according to age is shown in Figure 3. The modal age group was 45 to 54 years for mobile visitors, 65+ years for tablet visitors, and 55 to 64 for desktop visitors. All 3 device types were widely used among older patients, with 58.8% (113/192) of mobile, 84.2% of tablet (96/114), and 67.6% (119/176) of desktop visitors aged 45 years or older. Of all tablet visitors, the number of visitors per age group increased with age, up to a peak in the modal 65+ age group. The number of desktop visitors per age group also tended to increase with age, whereas for mobile devices, the number of visitors per age group increased with age up to the modal age group of 45 to 54 years, before declining in older age groups.

Gender composition was 29.8% (145/487) male (Table 1). The modal age of both male and female patient visitors was 45 to 54 years. The number of visitors increased as age increased for both sexes, with males plateauing from the 35 to 44 years age group whereas female visitors showing a clear peak at the 45 to 54 years group.

Almost identical age distributions were seen between visitor populations from the United States and the United Kingdom. The modal age group was 55 to 64 years for US patient visitors and 45 to 54 years for UK patient visitors. A total of 75.0% (132/176) of US patient visitors were aged 45 years or older, whereas 64.0% (162/253) of UK visitors were aged 45 years or older.

Comparison of Visitors to the Patient Landing Page and All Website Visitors

Visitors to the patient landing page were similar to overall website visitors for variables of interest (Table 2). In particular, age and gender demographics were similar, as were data on device and mobile operating system and manufacturer. Although percentages of visitors from each of the 5 most common locations showed some variation, for both groups the United Kingdom and the United States were the most prevalent locations, followed by Canada, Australia, and India.

Table 1. Demographic characteristics of visitors to the patient survey page of Myelopathy.org.

Demographic characteristic	Total, n (%)	Mobile, n (%)	Tablet, n (%)	Desktop, n (%)
Age (years)				
18-24	26 (5.4)	7 (3.7)	4 (3.5)	15 (8.5)
25-34	49 (10.2)	22 (11.5)	2 (1.8)	25 (14.2)
35-44	79 (16.4)	50 (26.0)	12 (10.5)	17 (9.7)
45-54	134 (27.8)	67 (34.9)	27 (23.7)	40 (22.7)
55-65	109 (22.6)	31 (16.1)	34 (29.8)	44 (25.0)
65+	85 (17.6)	15 (7.8)	35 (30.7)	35 (19.9)
Gender				
Male	145 (29.8)	53 (27.6)	22 (19.1)	70 (38.9)
Visitor location				
United States	254 (34.1)	107 (41.0)	58 (30.9)	89 (30.2)
United Kingdom	400 (53.8)	117 (44.8)	120 (63.8)	163 (55.2)
Canada	29 (3.9)	10 (3.8)	4 (2.1)	15 (5.1)
Australia	12 (1.6)	5 (1.9)	3 (1.6)	4 (1.4)
India	6 (0.8)	4 (1.5)	0 (0)	2 (0.7)
Ireland	6 (0.8)	2 (0.8)	3 (1.6)	1 (0.3)
Malaysia	4 (0.5)	3 (1.2)	0 (0)	1 (0.3)
Other	33 (4.5)	13 (5.0)	0 (0)	20 (6.8)

Figure 3. Percentage age distributions of total visits using each device. The percentage of visitors in each age group differed depending on device used.

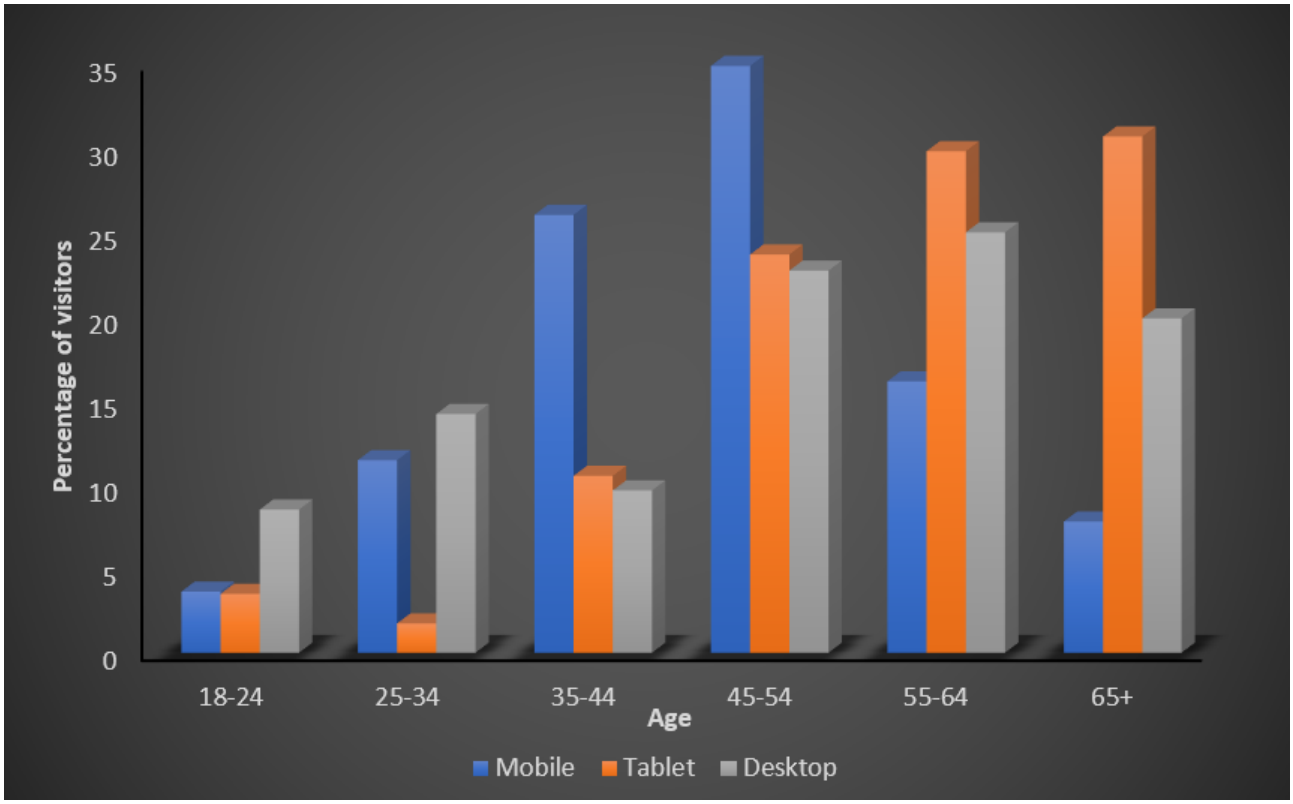


Table 2. Comparison of visits to patient landing page and all website visits.

Variables	Patient landing page, n (%)	Website, n (%)
Visitors		
Sessions (visits)	744	15,761
New visitors	478 (64.3)	10,261 (65.1)
Returning visitors	266 (35.7)	5500 (34.9)
Age (years)		
18-24	26 (5.4)	621 (6.4)
25-34	49 (10.2)	1504 (15.5)
35-44	79 (16.4)	1811 (18.7)
45-54	134 (27.8)	2527 (26.1)
55-64	109 (22.6)	2088 (21.5)
65+	85 (17.6)	1145 (11.8)
Gender		
Female	342 (70.2)	6483 (66.1)
Male	145 (29.8)	3331 (33.9)
Visitor location		
United States	254 (34.1)	6491 (41.2)
United Kingdom	400 (53.8)	5768 (36.6)
Canada	29 (3.9)	813 (5.2)
Australia	12 (1.6)	382 (2.4)
India	6 (0.8)	280 (1.8)
Other	43 (5.8)	2027 (12.8)
Device		
Desktop	295 (39.6)	6795 (43.1)
Mobile	261 (35.1)	6311 (40.0)
Tablet	188 (25.3)	2655 (16.9)
Mobile operating system		
iPhone Operating System	141 (51.3)	3593 (57.3)
Android	126 (45.8)	2531 (40.4)
Other	8 (2.9)	147 (2.3)
Mobile device manufacturer		
Apple	241 (53.6)	5161 (57.5)
Samsung	116 (25.8)	1915 (21.4)
LG	11 (2.5)	221 (2.5)
Motorola	9 (2.0)	197 (2.2)
Amazon	11 (2.5)	144 (1.6)
Other	61 (13.6)	1328 (14.8)
Mobile input selector		
Touchscreen	441 (98.2)	8640 (96.4)
Desktop age stratification (years)		
18-24	15 (8.5)	399 (11.1)
25-34	25 (14.2)	758 (21.0)
35-44	17 (9.7)	514 (14.3)

Variables	Patient landing page, n (%)	Website, n (%)
45-54	40 (22.7)	705 (19.6)
55-64	44 (25.0)	684 (19.0)
65+	35 (19.9)	540 (15.0)
Mobile age stratification (years)		
18-24	7 (3.7)	185 (4.2)
25-34	22 (11.5)	662 (15.0)
35-44	50 (26.0)	1110 (25.1)
45-54	67 (34.9)	1431 (32.4)
55-64	31 (16.1)	794 (18.0)
65+	15 (7.8)	235 (5.3)
Tablet age stratification (years)		
18-24	4 (3.5)	37 (2.2)
25-34	2 (1.8)	84 (5.0)
35-44	12 (10.5)	187 (11.1)
45-54	27 (23.7)	391 (23.3)
55-64	34 (29.8)	610 (36.3)
65+	35 (30.7)	370 (22.1)

Discussion

Principal Findings

The use of smart technology is prevalent in patients of all ages with DCM, with patients favoring portable devices such as mobiles and tablets. The distribution of technology usage across age groups differed, with mobiles favored in middle age and tablet and desktop usage more common in later years. Android and iOS are the predominant mobile operating systems utilized by patients with DCM.

Generalization of Findings

From the outset, it is important to consider the limitations of this study and, in particular, whether this population represents DCM as a whole; an internet platform is a self-selected population, both in terms of confirming the diagnosis of DCM and for which access requires technology usage.

Although this is a potential limitation, it is important to recognize that internet usage among older age groups is well described [23] and the focus was instead the use of smart technology, for which desktop visitors could act as a surrogate control group.

In addition, visitor age was representative of DCM trials, which frequently report a mean patient age of 56 years [8,9]. In this study, 40.2% (194/482) of overall visitors were aged 55 years or older and the modal visitor age was 45 to 54 years. Unfortunately, owing to the limitations of Google Analytics, age is presented in age ranges and the age group 65+ years is particularly broad and would benefit from subanalysis.

Although the gender constitution differed (29.8% (145/487) male compared with trial populations of between 60% and 65% male [8,9]), gender did not influence technology usage in this study and thus is unlikely to have substantially influenced results. In addition, it has been shown that women utilize the internet for health information and support more widely than men [24,25]. We have previously shown that this relates to the weighting of Facebook patient support groups, which are predominantly female and which were the most successful recruitment strategy [22]. Therefore, increasing male participation in DCM electronic health (eHealth) initiatives likely requires an approach much broader than anything targeted specifically at DCM. Nonetheless, targeted advertising, information leaflets, and signposting in hospital outpatient clinics may form first steps. Moreover, current development of a DCM repository to directly capture data from health records will help validate internet survey data. Finally, a designated patient-run section of Myelopathy.org, Myelopathy Support, has a large Web-based patient following and appears to be encouraging males to engage.

There is a small risk that some visitors included did not in fact have DCM. However, the focus on those visitors accessing a patient survey, in which they had to click through a description of symptoms to confirm they had a diagnosis of DCM before accessing the patient survey page alongside the rational demographics, makes this unlikely. In addition, we have previously shown that, at present, the platform is infrequently used by nonpatients [26]. Therefore, any contribution from non-DCM patients is likely to be small and have a negligible influence on results. The similarity of data on visitors to the patient landing page and data on all website visitors provides reassurance that any selection biases likely had a negligible influence on results and suggests that the total website visitors were mostly patients.

In addition, although visitors were mostly from the United States or the United Kingdom, visitors were also from across the globe, showing potential for smart technology elsewhere.

The Emerging Role of Smart Technology for Health, Including Degenerative Cervical Myelopathy

The potential of smart technology for health is rapidly becoming established. There has been an explosion of health-related smart technology apps, aimed at a multitude of areas including education, medical assessment, and medical intervention [15].

To date, much focus has been on educational apps for both patients and professionals. In addition, apps have incorporated simple assessments, the inputting of survey data, simple sensor metrics, such as physical activity, and partnership with third-party technologies, such as blood sugar monitors [27]. However simple, their usage is being shown to have a significant clinical benefit with easy uptake by patients. For example, a recent systematic review of mobile and smart technology use in diabetes care found that the majority of interventions improved primary endpoints such as HbA1c and that technologies that interacted with both patients and providers were most likely to be successful [28]. A public opinion survey applied to a Greek population found strong significant effects of perceived usefulness, relative advantage of use, and perceived ease of use of a smart mHealth app [29]. Moreover, Anderson et al utilized a semistructured interview format to explore how health consumers use apps for health monitoring in Australia. They found that apps were used to monitor conditions including diabetes, asthma, depression, coeliac disease, blood pressure, migraine, and menstrual cycle irregularity on an approximately weekly basis [30]. This clear potential and appetite is contributing to significant investment and rapid growth in mHealth [19], including more sophisticated systems.

This includes patients with DCM, where new guidelines [10] advise close surveillance; however, current clinical assessments have shown poor responsiveness to change [11]. Laboratory gait analysis is a quantitative assessment, which is showing promise to overcome these limitations as it can provide a sensitive and reproducible measure of walking [31], is able to detect subtle progression [32], can distinguish patients from healthy controls [33], can predict outcome after surgery [34], and can predict disease progression [35,36]. Researchers in the field of Parkinson's disease have demonstrated that a similar analysis can occur using smartphones [37-39], which would offer the additional benefit of continuous monitoring in a patient's own environment.

Clearly, a significant barrier to the uptake of any potential smart technology app would be its accessibility to the target audience. Therefore, the prevalence of smart technology among patients with DCM in this study is a reassuring finding. However, it is worth noting that not all smart technology has the same eHealth potential; for example, although desktops have input capabilities, they may lack monitoring sensors; tablets may have similar monitoring capabilities as smartphones, but their larger size may preclude certain measurements such as pocket-mediated gait analysis. In addition, owing to the requirement for Web browsing, this study has not captured the use of smart watches, which also have significant mHealth potential [40].

Conclusions

Smart technology use is prevalent in patients with DCM. An app to monitor DCM disease severity must be compatible with both iOS and Android and multiple device manufacturers. For greatest immediate uptake, both phone and tablet compatibility are desirable, although this must be considered in the context of an app's objectives. Although such an app is yet to be developed, this study has shown that the user group is at least in possession of the necessary technology and has the willingness to use it.

Acknowledgments

Research in the senior author's laboratory is supported by a core support grant from the Wellcome Trust and the Medical Research Council to the Wellcome Trust-Medical Research Council Cambridge Stem Cell Institute. MRK is supported by a National Institute for Health Research Clinician Scientist Award.

This report is independent research arising from a Clinician Scientist Award, CS-2015-15-023, supported by the National Institute for Health Research. The views expressed in this publication are those of the authors and not necessarily those of the National Health Service, the National Institute for Health Research, or the Department of Health and Social Care.

Conflicts of Interest

All authors have voluntary, unpaid roles with Myelopathy.org, an international charity for patients with cervical myelopathy.

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Abbreviations

DCM: degenerative cervical myelopathy
eHealth: electronic health
iOS: iPhone Operating System
mHealth: mobile health

Edited by G Eysenbach; submitted 21.06.18; peer-reviewed by A Nouri, R Foraker; comments to author 06.10.18; revised version received 13.01.19; accepted 27.01.19; published 09.05.19.

Please cite as:
Mowforth OD, Davies BM, Kotter MR
The Use of Smart Technology in an Online Community of Patients With Degenerative Cervical Myelopathy
JMIR Form Res 2019;3(2):e11364
URL: http://formative.jmir.org/2019/2/e11364/
doi:10.2196/11364
PMID:31094330

Original Paper

Barriers and Facilitators for Implementing a Decision Support System to Prevent and Treat Disease-Related Malnutrition in a Hospital Setting: Qualitative Study

Mari Mohn Paulsen[1,2], MS; Cecilie Varsi[3], PhD; Ingvild Paur[1], PhD; Randi Julie Tangvik[4], PhD; Lene Frost Andersen[2], PhD

[1]National Advisory Unit on Disease-related Malnutrition, Department of Cancer Medicine, Oslo University Hospital, Oslo, Norway

[2]Institute of Basic Medical Sciences, Department of Nutrition, University of Oslo, Oslo, Norway

[3]Center for Shared Decision Making and Collaborative Care Research, Division of Medicine, Oslo University Hospital, Oslo, Norway

[4]Department of Clinical Medicine, Faculty of Medicine, University of Bergen, Bergen, Norway

Corresponding Author:
Mari Mohn Paulsen, MS
National Advisory Unit on Disease-related Malnutrition
Department of Cancer Medicine
Oslo University Hospital
Sognsvannsveien 20
Oslo, 0372
Norway
Phone: 47 22851103
Email: m.m.paulsen@medisin.uio.no

Abstract

Background: Disease-related malnutrition is a challenge among hospitalized patients. Despite guidelines and recommendations for prevention and treatment, the condition continues to be prevalent. The MyFood system is a recently developed decision support system to prevent and treat disease-related malnutrition.

Objective: To investigate the possible implementation of the MyFood system in clinical practice, the aims of the study were (1) to identify current practice, routines, barriers, and facilitators of nutritional care; (2) to identify potential barriers and facilitators for the use of MyFood; and (3) to identify the key aspects of an implementation plan.

Methods: A qualitative study was performed among nurses, physicians, registered dietitians, and middle managers in 2 departments in a university hospital in Norway. Focus group discussions and semistructured interviews were used to collect data. The Consolidated Framework for Implementation Research (CFIR) was used to create the interview guide and analyze the results. The transcripts were analyzed using a thematic analysis.

Results: A total of 27 health care professionals participated in the interviews and focus groups, including nurses (n=20), physicians (n=2), registered dietitians (n=2), and middle managers (n=3). The data were analyzed within 22 of the 39 CFIR constructs. Using the 5 CFIR domains as themes, we obtained the following results: (1) Intervention characteristics: MyFood was perceived to have a relative advantage of being more trustworthy, systematic, and motivational and providing increased awareness of nutritional treatment compared with the current practice. Its lack of communication with the existing digital systems was perceived as a potential barrier; (2) Outer settings: patients from different cultural backgrounds with language barriers and of older age were potential barriers for the use of the MyFood system; (3) Inner settings: no culture for specific routines or systems related to nutritional care existed in the departments. However, tension for change regarding screening for malnutrition risk, monitoring and nutritional treatment was highlighted in all categories of interviewees; (4) Characteristics of the individuals: positive attitudes toward MyFood were present among the majority of the interviewees, and they expressed self-efficacy toward the perceived use of MyFood; (5) Process: providing sufficient information to everyone in the department was highlighted as key to the success of the implementation. The involvement of opinion leaders, implementation leaders, and champions was also suggested for the implementation plan.

Conclusions: This study identified several challenges in the nutritional care of hospitalized patients at risk of malnutrition and deviations from recommendations and guidelines. The MyFood system was perceived as being more precise, trustworthy, and motivational than the current practice. However, several potential barriers were identified. The assessment of the current situation

and the identification of perceived barriers and facilitators will be used in planning an implementation and effect study, including the creation of an implementation plan.

(JMIR Form Res 2019;3(2):e11890) doi:10.2196/11890

KEYWORDS

malnutrition; implementation science; eHealth; qualitative research; decision support systems, clinical

Introduction

Disease-related malnutrition is a challenge in hospitals, with 30% to 50% of patients being malnourished or at risk for malnutrition [1-5]. The condition leads to higher morbidity and mortality rates among patients [5-8] and longer length of stay [6,9,10]. This generates increased economic costs for the health care sector [7,10,11]. According to Norwegian [12] and European [13] guidelines, all patients at malnutrition risk should have an individualized nutrition care plan, including documentation of nutritional status, needs, dietary intake, and recommended treatment. The reported barriers to adequate nutritional care for hospitalized malnourished patients include the absence of routines [14,15], lack of knowledge, assignment of responsibility [16], and lack of skills and tools to estimate individual dietary needs and the energy and protein content in hospital food [14,17].

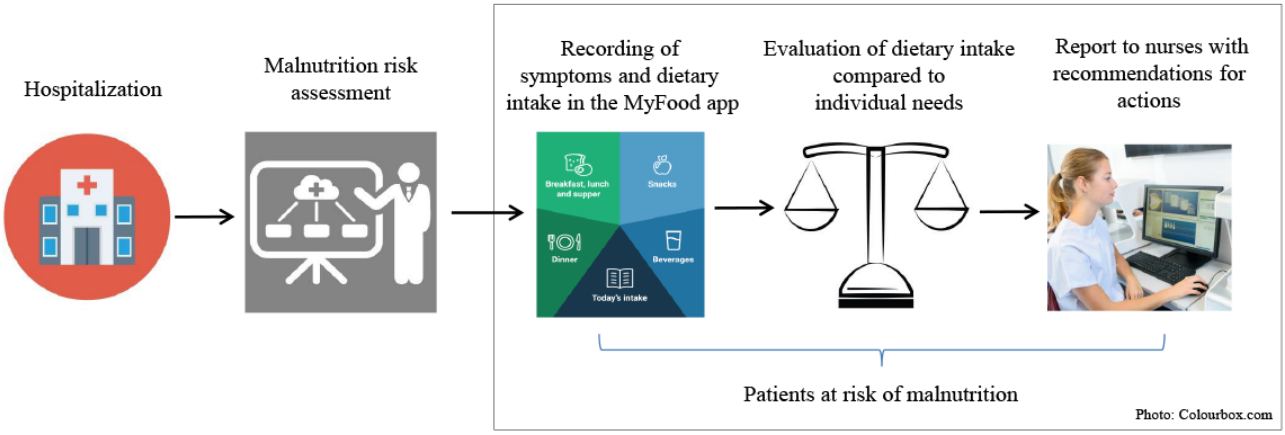
Studies have shown that hospitals can benefit from implementing technology to identify, handle, and follow up with patients at risk of malnutrition. Digital tools and apps may reduce the workload of health care professionals and the time spent for nutritional assessment [18].

We developed the *MyFood* tool, a decision support system for use among hospitalized patients at risk of malnutrition. The MyFood system includes an app for tablets and a website. Figure 1 shows the intended use of the MyFood system.

A consistent finding in clinical and health services research is the failure to translate evidence into practice [19]. The implementation of electronic health (eHealth) interventions is often challenging, with many failing to demonstrate predicted benefits [20]. For implementation to succeed, it is recommended that the readiness for implementation be assessed and the barriers and facilitators be identified in advance [21]. Theoretical frameworks may guide this assessment. The Consolidated Framework for Implementation Research (CFIR) [22] is widely used to identify barriers and facilitators [23-26].

To obtain a better understanding of how to implement the MyFood system in clinical hospital practice and to be able to create an implementation plan, we performed a qualitative study among health care professionals. The specific aims were (1) to identify current practice, routines, barriers, and facilitators for nutritional care; (2) to identify potential barriers and facilitators for the use of a decision support system (MyFood); and (3) to identify the key factors for an implementation plan.

Figure 1. Patient flow from hospitalization, identification of malnutrition risk, and use of the MyFood system.



Methods

This study is part of a research project involving the development and evaluation of a decision support system to prevent and treat disease-related malnutrition as a proof of concept. The MyFood intervention will be implemented in the hospital departments in a randomized controlled trial after this study is completed.

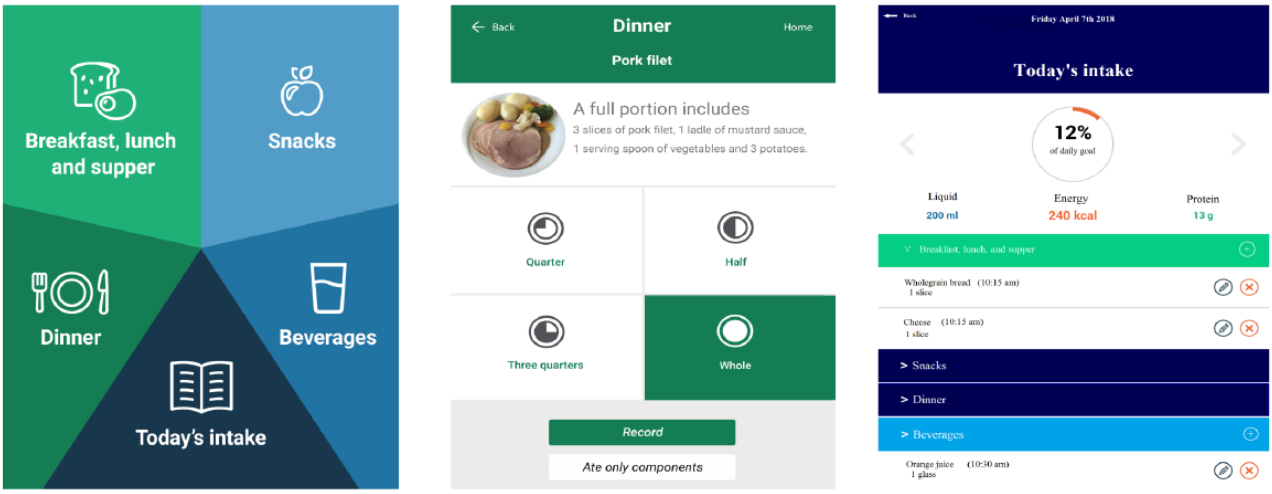
The MyFood System

The MyFood system is developed in response to an identified need for better tools to follow up with patients who suffer from disease-related malnutrition. The functions and content of the tool are based on the Norwegian guidelines for prevention and treatment of disease-related malnutrition [12], the Norwegian Directorate of Health recommendations on nutrition in health and care services [27], and the recommended tasks included in the focus area of disease-related malnutrition in the Norwegian Patient Safety Program [28]. According to the patient safety program, 4 tasks are necessary to prevent and treat disease-related malnutrition in hospitals: (1) screening for risk of malnutrition; (2) dietary assessment; (3) nutritional treatment; and (4) documentation [28]. Hence, MyFood does not provide new tasks for health care professionals but intends to provide a system to perform and follow the guidelines and recommendations available.

The MyFood system consists of 4 modules: module 1, collection of information about the patient (body weight, height, nutrition-related symptoms, nutritional situation, and allergies); module 2, dietary assessment function; module 3, evaluation of recorded dietary intake compared with individual needs for energy, protein, and liquids; and module 4, report function, including recommendations for nutrition-related actions tailored to the individual patient and a template for a nutrition care plan. Figure 2 illustrates the dietary assessment and evaluation functions (modules 2 and 3) of the app. The patients record their daily dietary intake in the app. If the patient is unable to record, the nurses perform the recording on behalf of the patient. Both patients and health care professionals may keep track of the evaluation in module 3. The development of the MyFood app (modules 1 to 3) and evaluation of the dietary assessment function are described in a previous study [29]. The report function (module 4) is intended for use by nurses or other health care professionals to monitor and follow up on a patient's nutritional status and treatment. Module 4 is a website where the nurses gain access and retrieve information about patients by logging into the system.

The MyFood system was externally developed in cooperation with selected hospital departments. The managers of the hospital departments were involved in the structural issues and facilitated the research project. Nurses, registered dietitians, and patients participated in the development of the design, content, usability, and functionality [29].

Figure 2. Dietary assessment in the MyFood app and evaluation of dietary intake compared with individual needs.



Study Design and Participants

We conducted a qualitative study among health care professionals from 2 departments at a university hospital in Norway. The data collection period was January to February 2018. The study was based on 4 focus group discussions and 7 individual interviews. The health care professionals were purposively selected for the focus group discussions and interviews.

The study was performed in accordance with the Helsinki declaration and was acknowledged by the Norwegian Regional Ethical Committee (2016/1464). Written informed consent was obtained from all participants.

The Consolidated Framework for Implementation Research Framework as a Basis for the Interview Guide

The CFIR is a compilation of 39 constructs related to implementation and divided into 5 domains: characteristics of the intervention, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. These constructs can be considered when identifying local barriers to implementation [22]. According to Damschroder et al [22], researchers may select the constructs from the CFIR that are most relevant for their study setting. In this study, the 39 constructs of the CFIR [22] were explored and used to develop a semistructured interview guide. A total of 13

constructs were considered relevant for the context, and open-ended questions based on these were included. The interview guide was adapted for different groups of health care professionals to adjust for relevant differences in roles or tasks. For example, the construct regarding structural characteristics in the outer setting domain was only addressed to middle managers. Not all the CFIR constructs were considered relevant. For example, several of the constructs related to the process and the outer setting domains were not included. This study was a preimplementation study, and at this stage, we were most interested in the local factors in the 2 hospital departments to be able to set the performance goals of an implementation and effect study and to develop an implementation plan. The interview guide included questions about the organization and the routines related to the food and nutritional care of the patients, including responsibility, management commitment, and challenges. Perceived barriers and facilitators for the use of the MyFood tool and for performing an intervention study in the departments were also included in the guide. During the focus group discussions and interviews, the MyFood app was demonstrated for the health care professionals.

Focus Group and Interview Procedure

The focus group discussions and individual interviews were conducted by the first author in a meeting room in the hospital department or at the interviewee's office. A secretary assisted the first author during the focus groups. The focus group discussions were 45 to 55 min long, and the individual interviews were 30 to 50 min long. Focus groups facilitate communication between participants [30] and were chosen as the method for nurses because they are engaged in the daily care of patients. Each focus group included 4 to 7 nurses. The first focus group discussion served as a pilot to test the interview guide. After the focus group discussion, the interviewees were asked for feedback on the structure and phrasing of questions as well as the focus group situation. The pilot focus group did not result in any fundamental changes to the interview guide and was therefore included in the main analysis. Individual interviews were performed among the middle managers, physicians, and registered dietitians for feasibility reasons.

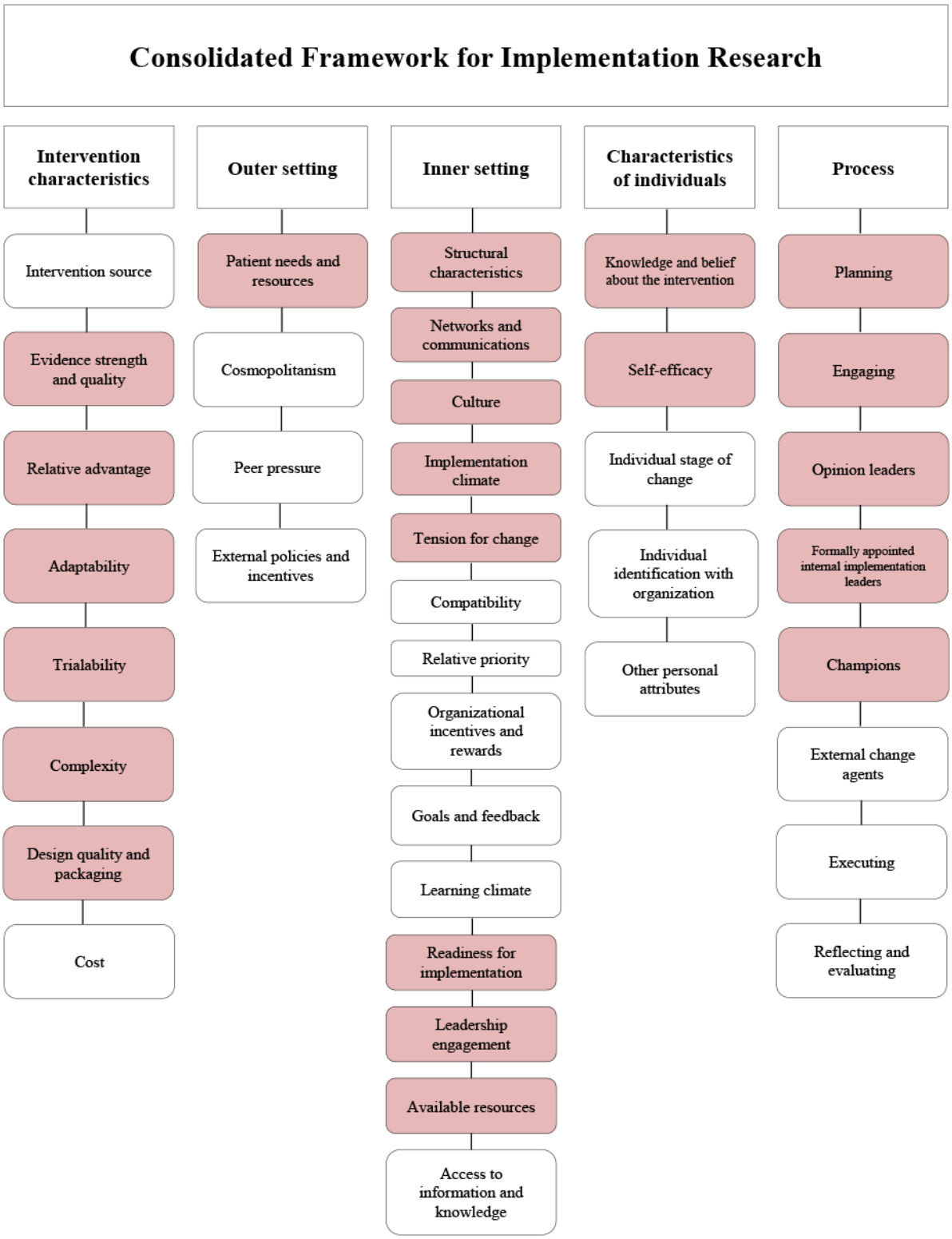
The focus group discussions and the individual interviews were recorded with a digital voice recorder (Olympus WS-853). A dictaphone app developed by the University Center for Information Technology at the University of Oslo (UiO) [31] was used as a backup. In addition, notes were taken immediately after each focus group and interview. The audio recordings were transcribed verbatim using the software f4transkript (Marburg).

Analysis

The transcripts and notes were analyzed using a thematic analysis in a stepwise manner as described by Braun and Clarke [32], using a deductive approach. The transcripts were analyzed using NVivo version 11 (QSR International). The first step in the analysis was to read through all the transcripts and take notes to obtain an overall understanding of the material. Second, initial codes were created as nodes based on the 5 domains in the CFIR framework and subnodes for the 39 CFIR constructs [22]. Some parts of the transcripts did not directly fit into any of the CFIR constructs, and in these cases, new codes were created. Phase 3 involved searching for themes. As we followed a deductive approach, based on the domains and constructs in the CFIR framework, the primary task here involved resorting and reevaluating the codes. The final step was the review process. The codes that did not fit into the CFIR framework were particularly evaluated and reconsidered. If they were found relevant, they were included in the current constructs. A total of 22 CFIR constructs were included in the analysis (Figure 3). The results described for the 22 CFIR constructs were reviewed and have been elaborated with regard to the specific study aims in the Discussion section.

To enhance trustworthiness [33], including credibility, confirmability, dependability, and transferability [34], the results were analyzed systematically in a stepwise manner. This included the following: involving all authors in the development of the interview guide and involving the first (MMP) and second (CV) authors in the development of the coding categories and the interpretation of the results; including different health care professionals in the interviews; and audio taping and transcribing the material verbatim.

Figure 3. Overview of the Consolidated Framework for Implementation Research. The analyzed data were sorted into 22 constructs (red boxes) for the assessment of current practices and the identification of barriers and facilitators. Data for the remaining constructs (white boxes) could not be obtained.



Results

Demographics

The focus group discussions included 20 nurses, with a mean age of 30 years and a range of 24 to 39 years. Table 1 shows the characteristics of the nurses in the 4 focus group discussions.

The individual interviews included 2 physicians, 2 registered dietitians, and 3 middle managers. They were all female with a mean age of 39 years, ranging from 27 to 45 years.

Table 1. Characteristics of the nurses in the 4 focus group discussions.

Characteristic	FGD[a] 1 (n=4)	FGD 2 (n=4)	FGD 3 (n=7)	FGD 4 (n=5)
Gender (n)				
Male	1	1	0	0
Female	3	3	7	5
Age (years)				
Mean	32	27	29	31
Range	26-39	26-30	25-38	25-36
Experience (n)				
<4 years	0	3	2	1
≥4 years	4	1	5	4

[a]FGD: focus group discussion.

Table 2. Potential barriers and facilitators for use of the MyFood system, identified in stakeholder focus group discussions and semistructured interviews.

CFIR[a] domain	Barriers	Facilitators
Intervention characteristics	Lack of automatic transfer to the electronic patient record; Hygienic aspects of using tablet computers among the patients; Potentially demotivational for patients who strive to meet their dietary needs	More trustworthy, systematic, fun, and easy to use than the current practice; May increase awareness on nutritional care and treatment; Positive attitudes among health care providers to test the MyFood tool in an intervention study; Intuitive, neat, and user-friendly design
Outer setting	Lack of current routines for screening for malnutrition risk; Nurses' perceptions of nagging patients regarding food intake; Different cultural backgrounds among patients; Language barriers among non-native patients; Patients fasting before surgery or medical examinations; Elderly patients not familiar with tablet computers	Potentially earlier implementation of nutritional treatment among the patients; Empowerment of patients in the recording of dietary intake
Inner setting	Ambiguity among health care providers who have the primary responsibility for nutritional care and treatment; Prejudices among some physicians regarding the role of nutrition in the treatment process; Diverging focus between different health care providers, which may confuse the patients; Lack of culture and specific routines for nutritional care; Weak foundation on nutritional care among management; Limited availability of computers to use the MyFood report function; Limited available time	High stability in the departments' staff of health care professionals; Good cooperation between health care professionals; Assumptions among nurses regarding the importance of nutrition; Desire among nurses for better tools for dietary assessment and follow-up; Potentially time saving if nurses do not have to do manual calculations of dietary intake themselves
Individual characteristics	—[b]	Perceived self-efficacy among nurses in the ability to use the MyFood tool.

[a]CFIR: Consolidated Framework for Implementation Research.

[b]Not applicable.

Identification of Barriers and Facilitators Using the Consolidated Framework for Implementation Research

The current practice with nutritional care, perceived barriers and facilitators for the use of the MyFood system, and the identified key aspects to include in an implementation plan are presented according to the 5 domains of the CFIR framework and subdivided into the relevant constructs (Figure 3).

The perceived barriers and facilitators for use of the MyFood system are summarized in Table 2.

Intervention Characteristics

Evidence strength and quality relates to stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes [22].

The interviewees acknowledged that the evidence-based recommendations forming the basis of the MyFood system were known and accepted. They claimed that several of the functions in the MyFood tool were already performed at the hospital departments, although in a more unstructured manner:

> *I think this is kind of the same, but gathered more in one place. And this [MyFood] provides a better overview.* [Registered dietitian]

Relative advantage is the stakeholders' perceptions of the advantage of implementing the intervention versus an alternative solution [22]. Most of the interviewees perceived the dietary assessment function in MyFood as easier, more trustworthy, systematic, and precise compared with the paper-based dietary assessment forms currently in use. They also reported that

MyFood could increase awareness of nutritional deficiencies and lead to the implementation of nutritional treatment at an earlier stage:

> *I think it's easier when you can trust it. [...] Then the physician will trust it more I think, that this is actually correct recorded, this is exactly what was eaten [...] Compared to using a form that you don't know is complete. Then it's easier to take action if you trust the recording. I think.* [Nurse]

The health care professionals' perceptions of the dietary recording in the app were that it would be more fun and motivational than traditional paper recordings and that the tool was better suited for the future:

> *You know, we are not spoiled with new, fun technical solutions in the healthcare system. So most of us think it's fun when something new arrives. Because it's fun to have a gadget, you know. I think people would suddenly regard it as fun to record food, compared to that form [the paper-based dietary recording form] for which you need to scratch your head to guess the calorie intake.* [Nurse]

Adaptability relates to the degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs [22]. The respondents gave feedback on how they perceived MyFood could fit into their existing work practice. A potential barrier was that MyFood does not communicate with the electronic patient record (EPR), which means that the health care professionals need to copy the information from the MyFood website and paste it into the EPR. However, suggestions for how to overcome this issue were proposed:

> *It's quite okay because we try to become paperless. And if we can just copy from that [MyFood] to the electronic journal. The dietary paper forms [paper-based dietary assessment forms used today] easily gets lost. This is like... It seems more secure.* [Nurse]

The hygienic aspects of using tablet computers among the patients were discussed, including patients with special considerations regarding infections. Several solutions for getting around this issue were suggested, for example, using a cover or plastic bag around the tablet computer.

Trialability is defined as the ability to test the intervention on a small scale in the organization and to be able to reverse course if warranted [22]. Attitudes to being part of an intervention study to test the MyFood system were positive. All groups of respondents reported being used to participate in clinical trials owing to having an ongoing study in the department at almost any time.

The complexity construct describes the perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, intricacy, and the number of steps required for implementation [22]. MyFood was perceived as easy to use and navigate. None of the interviewees reported that the tool seemed complex:

> *I'm technically retarded and even I think this seems okay.* [Nurse]

Design quality and packaging are defined as the perceived excellence in how the intervention is bundled, presented, and assembled [22]. The layout of the MyFood system was described by health care professionals as having a user-friendly, intuitive, and neat design. The possibility to record only the components of a dish, in addition to the proportion of portion size (Figure 2), was highlighted as an advantage. However, a few nurses mentioned that the illustration of the percent of achievement of energy, protein, and liquid intake compared with individual needs (Figure 2) could potentially be demotivational for some patients:

> *When you have only eaten 10% of your need, and feel that you have eaten a lot and that you'll never be able to achieve your goal.* [Nurse]

Outer Setting

The patient needs and resources construct concerns the extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization [22]. The health care professionals elaborated on current practices and whether screening for malnutrition risk was performed. Some routines with screening existed in one of the departments. In the other department, there were preconceptions that few of the patients eat and, therefore, they did not conduct routine malnutrition risk screening:

> *We haven't done that [screening for malnutrition] until now. We really expect that no one eats. We expect that they either become nauseous or the food tastes strange, after quite a short time. And we expect that everyone at some time point will start with TPN [total parenteral nutrition]. So I think we aren't good enough to..., you know, we know that we'll get there [TPN] in 4 days anyway, so there's no point to keep it going with ordinary food.* [Nurse]

The experience of nagging patients about food intake was highlighted by several nurses, middle managers, and registered dietitians:

> *[...] They [the patients] think we are whining too much about the food because they don't regard it as very important. You know, sick, reduced appetite, and all that...* [Nurse]

However, some patients were described as being very motivated and perceived the achievement of eating enough and being independent of total parenteral nutrition (TPN) or tube feeding as their ticket home from the hospital. Those patients were often classified as being the most resourceful and understanding of the importance of nutrition for their overall health status.

Barriers to good nutritional care include fasting before surgery and being transferred to other hospitals with loss of the opportunity to follow-up. Different cultural backgrounds or language barriers of patients were mentioned as other potential barriers. Older patients were identified as a group that could potentially have some challenges with dietary recording in the app, especially the elderly who are not used to smartphones or

tablets. However, most of the interviewees thought the elderly would be able to use the app after a short introduction:

> *I even think that elderly persons who are not so fond of technical gadgets would have understood this, you know.* [Nurse]

Inner Setting

The social architecture, age, maturity, and size of an organization constitute the structural characteristics construct [22]. Stability in the staff was described as being high. The 2 departments included in the study were organized differently. One was subdivided into groups, where each nurse belonged to one group taking care of patients in that specific group, whereas the physicians were rotating between the groups. This department also had group leaders organizing each of the groups, which was highlighted as being successful for the organization. The other department did not have any subdivision, and all nurses were potentially involved with all patients. The registered dietitians served the whole hospital, except for the children's department.

The networks and communication construct involves the nature and quality of social networks and the formal and informal communication within an organization [22]. The middle managers of the department that was subdivided into groups reported that the communication and social networks were stronger within specific groups; however, they all recognized each other as colleagues.

There was uncertainty among the interviewees about the primary responsibility for nutritional care of patients. The majority described nurses as having the primary responsibility:

> *It's mostly something the nurses try to talk about and assess. Ehm... but personally, I usually ask how things are going related to nutrition, and the nurses notify us how they [the patients] are doing with regard to food intake and digestion in general. [...] And we may contact the dietitian if we really need help, you know.* [Physician]

However, some respondents claimed that the physicians had formal responsibility for nutritional treatment, whereas the nurses took care of the day-to-day follow-up. Several nurses reported that they had to repeatedly remind the physicians about the prospect of tube feeding if the patient had no intake or very low intake.

The cooperation among nurses, physicians, and registered dietitians on the nutritional care of patients was, however, described as good in most cases. A diverging focus among the different groups of health care professionals was described among some of the nurses. This difference could potentially be confusing for patients:

> *It's like, the physiotherapists are concerned about one thing [eg, do not drink juice because of coughing and possibility to get it in the lungs], and the dietitians are concerned about another thing [eg, eating enough protein]. We [the nurses] try to keep the threads together, and then the others are never satisfied.* [Nurse]

Culture includes norms, values, and basic assumptions of a given organization [22]. The majority of the health care professionals expressed that nutrition has an important role in the overall course of the disease for the patient, but the middle managers reported that they had no culture for specific routines related to screening for malnutrition or nutritional care:

> *Maybe it's kind of based on what you feel, I don't think it's like it's done the same way for all... [...] I guess we aren't good enough to add something extra to the food or think about whole fat milk instead of fat-reduced milk, butter instead of... I guess it's like... there's no system I think. We could get very much better.* [Middle manager]

However, a positive shift with increased focus on nutrition had occurred recently. This included increased monitoring of food intake among malnourished or at-risk patients, use of medical nutrition drinks, and availability of food service hosts in the department's buffet kitchen. Whereas an increased focus on the importance of nutrition was mentioned by several respondents, others reported on the challenges still present, especially among the physicians:

> *The physicians, the surgeons, are often pretty far away from recognizing nutrition as part of the whole. So I guess that's a group who are a little more narrow-minded than the other physicians. But, it's understandable. When you are so highly specialized you focus on your thing.* [Registered dietitian]

Tension for change is the degree to which stakeholders perceive the current situation as intolerable or needing change [22]. A general tension for change with regard to screening for malnutrition risk, monitoring, and treatment was highlighted by all groups of health care professionals. A perception among nurses was that they should probably have taken action with regard to nutrition earlier:

> *I wonder how many times I have heard like "oh, but I have several kilos to take away, so it's no problem, it doesn't matter if I don't eat." Because they are used to the disease passing away after a week when they are sick, and then there is no big deal because I eat when I get better. So I think we... Maybe you let it go too far before we start pushing that food, you know.* [Nurse]

The respondents were positive about the MyFood intervention because they wanted better tools for dietary assessment and follow-up. The nurses find the paper-based dietary recording forms used today to be time-consuming and unprecise. Uncertainty regarding the purpose of using the dietary recording forms existed. For some patients, dietary recording forms were used to identify the amount the patients could eat by themselves to supplement the remaining nutritional requirement through TPN or tube feeding. In some cases, the registered dietitians used the form to create a nutrition care plan. Several respondents described that the number of calories calculated from the forms was noted in the patient's EPR, whereas others reported that this was only done in rare cases. They reported that the nurses working night shifts were supposed to perform the calorie calculations of the forms, but the compliance varied:

> *[...] I experience many patients having a dietary recording form lying on their nightstand that no one really... that has been lying there for several days, you know. And when the night shift replaces the form it's like "Oh, this is from last week."* [Nurse]

The readiness for implementation construct describes tangible and immediate indicators of organizational commitment to its decision to implement an intervention, including leadership engagement and available resources [22]. Leadership engagement is the commitment, involvement, and accountability of leaders and managers regarding the implementation [22]. Nutrition was described as having low priority in hospital management. None of the nurses or physicians was told by the management that nutrition should be prioritized:

> *Ehm... very seldom [signals from the management of nutrition focus]. This [nutrition] is seldom an issue from the management; at least as I have noticed.* [Physician]

A similar opinion was expressed by the middle managers. Nutrition was not a particular focus of the departments. The middle managers did not experience challenges regarding nutrition in their position between the nurses and top management:

> *No, I really think it works fine. Nutrition has so far been kind of a thing like anything else. It's something we're aware of, but maybe not enough. It constitutes a small part of all the challenges our patients have. But now that more focus has been set on nutrition, I feel that it's established in all parts. That the nurses are positive about it and also those above me.* [Middle manager]

Available resources are the level of resources dedicated for implementation and ongoing operations, including finance, training, education, physical space, and time [22]. A concern regarding the availability of computers to check the reports in the MyFood system and read through recommended measures was raised. Some nurses mentioned a lack of time as a potential barrier:

> *The only thing I can think of is of course time, you know. Because that's often a challenge in everything we do and all focus areas we're supposed to have.* [Nurse]

Others expressed that the MyFood system would be a time saver:

> *This would have saved us a lot of time–not having to do that calculation [manual calculation of nutritional content] yourself.* [Nurse]

Characteristics of Individuals

Knowledge and beliefs about the intervention involve individuals' attitudes and the value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention [22]. The health care professionals expressed, in general, a positive attitude toward the MyFood intervention and saw several potential advantages related to the system compared with the current practice. Self-efficacy is the individuals' belief in their own capabilities to execute courses of action to achieve implementation goals. The health care professionals expressed that they believed they would be able to use and follow up with MyFood.

Process

Planning is defined as the degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, with the consideration of the quality of those schemes or methods [22]. The interviewees were asked to elaborate on their thoughts on how to perform an intervention study in the departments, including how to engage the nurses to follow up on the intervention within their busy schedules. The importance of providing everyone with information and assigning responsibility was highlighted among the nurses. The lack of information and assignment of responsibility will potentially decrease motivation. As the nurses are shift workers, it might be challenging to reach all nurses:

> *I think it's important to inform absolutely everyone. Because we work in triple turrets many don't get information, especially those working night shifts, and then they don't see the importance of it maybe, because they haven't received the information we have gotten now. And that has a lot to do with motivation, because if you haven't received information and don't know why we are doing it, then no one cares. So I think it's very important to inform absolutely everyone who is going to take part, you know.* [Nurse]

Concrete examples of suggestions received were communicating information during morning meetings, increasing the night shift by an extra 30 min at the end of the shift, or requiring the nurses to arrive half an hour before the shift to reach all nurses working on all 3 shifts. Email communication was not recommended, as many nurses do not read their emails daily. Availability and daily visits to the department, including assistance and follow-up, were suggested. The possibility for nurses to call if they have questions was also recommended.

Engaging involves attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training, and other similar activities [22]. Opinion leaders are individuals in an organization who have a formal or informal influence on the attitudes and beliefs of their colleagues with regard to implementing the intervention [22]. The physicians were described by some of the nurses as filling such an opinion leader role. However, not all nurses had this impression. Some claimed that some authorities among the nurses were more important as opinion leaders than the physicians. Group leaders and nurses with developmental responsibility were suggested as important to fill the position of implementation leaders. Nurses on the night shift were also suggested as key personnel, as they have the task of summarizing daily nutritional intake. Others expressed that a criterion for success was to assign the same responsibility to all nurses in the department. Group leaders and nurses with developmental responsibility were seen as potential champions to support and drive the implementation. Creating superusers

with more experience who may inspire and help other nurses was also suggested.

Discussion

Principal Findings

This study used the CFIR framework [22] to identify current practices related to nutritional care in 2 departments in a university hospital in Norway. Perceived barriers and facilitators for the use of the MyFood system were assessed, and key aspects for an implementation plan were discussed. Screening for malnutrition risk was not prevalent or established as a routine in these departments. Dietary assessment and monitoring varied, as the nurses considered current procedures as being time- and resource-demanding. The use of the MyFood system was perceived as easier, more trustworthy, precise, fun, timesaving, and potentially facilitating increased awareness and implementation of nutritional treatment compared with the current practice. Cultural and language barriers, age of the patient, hygiene, availability of computers, time, and lack of interaction with EPRs were identified as potential barriers for use.

Current Nutritional Care Practices

To explore how the MyFood system may be utilized in a hospital setting, it was important to obtain information on the current practices related to nutritional care. Despite national and European guidelines for screening for malnutrition risk [12,13], this was not routinely performed in the 2 departments (CFIR: Culture). This corresponds with results from Eide et al [14]. A recent scoping review on the use of technology to identify hospital malnutrition revealed malnutrition in the acute hospital setting to largely be an unrecognized problem, owing to insufficient monitoring, identification, and assessment of malnourished patients [18]. We emphasized a general tension for changing nutritional care practice among all the health care professional groups investigated. For the purpose of planning the upcoming implementation and effect study in the MyFood project, it is important to be aware that screening for malnutrition risk is not routinely performed. In this study, some of the interviewees mentioned that a screening procedure was now being implemented as part of the Norwegian Patient Safety Program [28].

Dietary recording among patients at risk of malnutrition was performed to some extent, and all interviewees seemed to be aware of this practice. However, dietary recordings were seldom followed up and the forms were frequently forgotten on the patient's nightstand. A recent study at Oslo University Hospital based on the nutritionDay survey identified that only 41% of patients at malnutrition risk received nutritional treatment [1]. Several challenges with the current practice of using paper-based forms were described. The nurses in this study found it difficult to calculate the patients' intake of energy, and they described the hospital food lists as containing too few details. This is in line with previous findings in which Eide et al [14] identified nurses to be uncertain about how to evaluate nutritional status, estimate nutritional needs, and measure energy and nutrient intake among hospitalized patients. An Australian study showed that poor knowledge of the nutrition care processes among nondietetic staff was a barrier to nutritional care of elderly hospitalized patients [17]. A lack of knowledge on nutritional treatment and follow-up has been reported as an important barrier to nutritional care among physicians and nurses in Scandinavian hospitals [16,35].

We did not reveal significant differences in the responses between the different groups of health care professionals. As described in the results for the networks and communication construct, the physicians stated that the nutritional care of patients was the nurses' responsibility, whereas several nurses described the physicians as having the primary, formal responsibility. Eide et al [14] found that nurses were frustrated about the physicians' low involvement and engagement in nutritional care of the patients. They also identified that the support from physicians in nutritional care made it easier to prioritize nutrition. This corresponds to our finding of the physicians' important role in implementing new tools. Some nurses described communication between disciplines as challenging when different types of health care professionals have conflicting views. A literature review on communication between physicians and nurses revealed that communication tends to be unclear and unprecise, delaying patient care and increasing medical errors [36].

Facilitators for the Use of the MyFood System

The health care professionals were generally positive about the MyFood system and acknowledged that the evidence-based recommendations forming the basis of the tool [12,28] were acceptable, as described for the CFIR construct of evidence strength and quality. They perceived the tool as easy to use (CFIR: Complexity), having a user-friendly and intuitive design (CFIR: Design, quality, and packaging), and believed they would be able to use the tool (CFIR: Self-efficacy). They saw the tool as potentially time saving, more precise, and trustworthy compared with current practices, as it related to the CFIR constructs of relative advantage and knowledge and beliefs about the intervention. The perceptions of the preciseness and trustworthiness of the dietary recording function in the MyFood system seemed to be based on assumptions that everything recorded in the app would be correct. Self-reported dietary assessment methods are, however, often associated with errors. The memory of intake, lack of motivation to record over several days, ability to estimate portion sizes, and perceptions of socially desirable responses are well-known challenges in self-reported intake [37]. An evaluation of the dietary recording function in the MyFood app found that MyFood was relatively accurate in estimating the patients' intake of energy, protein, liquids, food, and beverages [29].

The MyFood system was perceived as potentially more fun and motivational to use compared with the current practice. Studies among adolescents have shown that dietary assessment using technology is preferred over paper-based food recording because electronic methods are perceived as more fun and motivational [38,39]. A systematic review of electronic methods to record food intake described that seeing progress toward fulfilment of goals can be highly motivational [40].

Barriers for the Use of the MyFood System

Although the health care professionals were positive about MyFood, several potential barriers were identified. MyFood was recognized as potentially time saving, but some also described time used to follow up as a barrier for use. A lack of automatic transfer to the EPR was described as another potential barrier, related to the adaptability construct. Lack of time and integration with the EPR were also found to be barriers in the implementation of the eHealth intervention *Choice* for symptom reporting into clinical practice in a Norwegian university hospital [41]. Another potential barrier linked to adaptability was hygiene aspects related to the use of tablet computers among patients.

Perceived barriers associated with the CFIR construct patient needs and resources concerned different languages and cultural backgrounds among the patients. The MyFood tool includes both icons and pictures that may overcome some language challenges. If the use of the MyFood system turns out to be effective, the inclusion of several languages may be considered in the future. With regard to cultural barriers and patients eating foods not included in the hospital's assortment, the MyFood app includes the possibility to record intake manually using a description of food or beverages consumed. In the long run, a wider range of food items may be included in the system. Challenges related to hygiene aspects may be solved by using plastic covers around the tablets. Older age was reported as a potential barrier to the use of MyFood owing to an increased risk of cognitive deficits or low self-efficacy among the elderly. However, qualitative studies among older persons have demonstrated that elderly people are often positive about using tablets and eager to learn [42,43]. A recent study describing an app to inspire home-dwelling elderly at nutritional risk to eat healthy foods showed that the elderly found the app easy to use [44].

Key Aspects for an Implementation Plan

The health care professionals were positive about performing an intervention study to test the MyFood system in their department (CFIR: Trialability). The results related to the CFIR construct planning, where the interviewees elaborated on their thoughts on how to perform the intervention study, follow up, and engage the nurses, will be particularly relevant for the creation of an implementation plan. Of interest for the implementation plan are also results from the CFIR constructs: structural characteristics, networks and communication, and available resources. Important elements may include ongoing training, local technical assistance, clinical supervision, educational materials, support, availability, establishing an implementation team, and organizing clinician implementation meetings. To engage potential users of MyFood and identify opinion leaders, the involvement of potential champions and early adopters may also be of importance. These findings are previously described as relevant implementation strategies in the Expert Recommendations for Implementing Change project [21,45]. An important finding in this study is that nutritional care has low priority in management (CFIR: Leadership engagement). Leadership support and engagement are crucial [46] for successful implementation [47] and strategies toward the leaders should be included in the implementation plan.

Strengths and Limitations

The strengths of the study are the inclusion of different health care professions and middle managers to reveal several views. The majority of the respondents were nurses, as they were considered to be the most important group with regard to the day-to-day nutritional care of the patients. Saturation is often described as the basis for sample size in qualitative studies [48]. However, this might not be the most appropriate [49]. Malterud et al [50] describe information power as related to the specificity of experiences, knowledge, or properties among the participants included in the sample. In this study, the health care professionals were holding characteristics specific to the study aim, in light of their professions. The aims of this study were relatively narrow and precise. Information power indicates that the more information the sample holds, relevant to the actual study, the lower the number of participants needed [50]. On the basis of these criteria, we considered our sample size to be sufficient.

The focus groups were originally composed of nurses with the same level of work experience to ensure that everyone's voice was heard and to enable the more inexperienced nurses to talk freely in a separate group that was not dominated by more experienced nurses. Owing to illness among some nurses on the days of the interviews, some adjustments had to be made to be able to perform the focus group discussion with a sufficient number of nurses. Interviewing patients may have strengthened this study. Therefore, the patients will be included in the planned study of the implementation and effect of using the MyFood system.

Using an existing framework within the field of implementation science is considered an important strength to better understand, describe, and identify factors that predict the likelihood of implementation success. The CFIR framework identified the importance of knowledge for designing an implementation plan [51].

This study was performed in the same departments where the planned implementation and effect study will take place, thereby providing a local identification of potential barriers and facilitators that may be crucial. However, conducting the study at only 2 departments in 1 hospital may imply that our results are not necessarily representative of other departments or hospitals. A limitation is that this study was performed before the implementation of the MyFood system. The impression of MyFood was therefore based on a demonstration and perceived barriers and facilitators for use. This perception does not necessarily correspond to the real barriers and facilitators experienced in practice.

Whether or not the MyFood or a similar system, at some point in time, will be included and implemented in the Norwegian health care system is yet to be determined. There is a shift in the health care system toward increased use of digital systems. A need for the development of information and communication technology tools to screen, assess needs, monitor food intake, create a nutrition care plan, and follow up on disease-related

malnutrition is described in a report from the Norwegian National Council for Nutrition [52].

Conclusions

This study identified several challenges in the nutritional care of hospitalized patients at malnutrition risk in 2 departments in a university hospital in Norway. The use of the decision support system MyFood was anticipated to have several advantages compared with the current practice with nutritional follow-up. The MyFood system was perceived as more precise, trustworthy, fun, and motivational than the current practice. However, cultural, language, age, and hygiene aspects were perceived as potential barriers. The identification of perceived barriers and facilitators will be used in the creation of a plan to implement the MyFood system in clinical practice in an implementation and effect study.

Acknowledgments

The development of the *MyFood* app was performed on the *services for sensitive data* (tjenester for sensitive data [TSD]) facilities, owned by the UiO, operated and developed by the TSD service group at the UiO IT Department.

Conflicts of Interest

None declared.

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
eHealth: electronic health
EPR: electronic patient record
TPN: total parenteral nutrition
TSD: tjenester for sensitive data (services for sensitive data)
UiO: University of Oslo

Edited by G Eysenbach; submitted 09.08.18; peer-reviewed by J Constantin, AK Lindroos, M Mileski, G Fico; comments to author 07.01.19; revised version received 18.02.19; accepted 29.03.19; published 09.05.19.

Please cite as:
Paulsen MM, Varsi C, Paur I, Tangvik RJ, Andersen LF
Barriers and Facilitators for Implementing a Decision Support System to Prevent and Treat Disease-Related Malnutrition in a Hospital Setting: Qualitative Study
JMIR Form Res 2019;3(2):e11890
URL: http://formative.jmir.org/2019/2/e11890/
doi:10.2196/11890
PMID:31094333

Original Paper

An E-Learning Adaptation of an Evidence-Based Media Literacy Curriculum to Prevent Youth Substance Use in Community Groups: Development and Feasibility of REAL Media

Anne E Ray[1], PhD; Kathryn Greene[2], PhD; Michael L Hecht[3], PhD; Sarah C Barriage[4], PhD; Michelle Miller-Day[3,5], PhD; Shannon D Glenn[3], BA; Smita C Banerjee[6], PhD

[1]Department of Health Behavior, Society, and Policy, School of Public Health, Rutgers, The State University of New Jersey, Piscataway, NJ, United States

[2]School of Communication and Information, Rutgers, The State University of New Jersey, New Brunswick, NJ, United States

[3]REAL Prevention LLC, Clifton, NJ, United States

[4]College of Nursing, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, MB, Canada

[5]Department of Communication Studies, School of Communication, Chapman University, Orange, CA, United States

[6]Department of Psychiatry and Behavioral Sciences, Memorial Sloan Kettering Cancer Center, New York, NY, United States

Corresponding Author:
Anne E Ray, PhD
Department of Health Behavior, Society, and Policy
School of Public Health
Rutgers, The State University of New Jersey
683 Hoes Lane West
Piscataway, NJ, 08854
United States
Phone: 1 732 235 5716
Email: aer108@sph.rutgers.edu

Abstract

Background: There is a need for evidence-based substance use prevention efforts that target high school-aged youth that are easy to implement and suitable for dissemination in school and community groups. The Youth Message Development (YMD) program is a brief, four-lesson, in-person curriculum that aims to prevent youth substance use through the development of youth media literacy. Specifically, YMD aims to increase understanding of advertising reach and costs, along with the techniques used to sell products; develop counterarguing and critical thinking skills in response to advertisements; and facilitate application of these skills to the development of youth-generated antisubstance messages. Although YMD has demonstrated evidence of success, it is limited by its delivery method and focus on alcohol and smoking.

Objective: Study objectives were two-fold: (1) to adapt the YMD curriculum to a self-paced, interactive, electronic-learning (e-learning) format and expand its content to cover alcohol, combustible cigarettes, e-cigarettes, smokeless tobacco, marijuana, and prescription drugs, and (2) to test the feasibility of the adapted curriculum in partnership with a national youth organization.

Methods: An iterative process was employed in partnership with the 4-H youth development organization and a technology developer and consisted of six phases: (1) focus groups to guide adaptation, (2) adaptation to an e-learning format renamed REAL media, (3) pilot-testing of the REAL media prototype to determine feasibility and acceptability, (4) program revisions, (5) usability testing of the revised prototype, and (6) final revisions. Focus groups and pilot and usability testing were conducted with 4-H youth club members and adult club leaders.

Results: Focus group feedback guided the build of an e-learning prototype of REAL media, which consisted of five online levels and interactive content guided by a mix of narration and on-screen text. Results of a pilot test of the prototype were neutral to positive, and the program was refined based on end-user feedback. An independent usability test indicated that youth 4-H members felt favorably about navigating REAL media, and they reported high self-efficacy in applying skills learned in the program. Additional refinements to the program were made based on their feedback.

Conclusions: The iterative build process involving the end user from the outset yielded an overall successful technology-driven adaptation of an evidence-based curriculum. This should increase the likelihood of effectively impacting behavioral outcomes as well as uptake within community organizations.

(JMIR Form Res 2019;3(2):e12132) doi:10.2196/12132

KEYWORDS

substance use; prevention; media literacy; e-learning; adaptation

Introduction

National survey results show a significant increase in prevalence rates of youth substance use during high school, which typically spans ages 14 to 18 in the United States [1,2]. For example, recent Monitoring the Future data [2] indicate that by 12th grade, 61% of youth have consumed alcohol, 45% have used marijuana, 36% tried vaping (including nicotine, marijuana, and/or just flavoring), 27% smoked cigarettes, and 11% have used smokeless tobacco. These figures represent a two- to three-fold increase from lifetime prevalence rates reported in eighth grade. This is of particular concern given the growing body of research that suggests there are detrimental effects on brain development among youth in this age range [3-5]. Research also shows that there is an inverse relationship between age of onset of substance use and risk for problematic use later in life [6].

Given that youth experimentation with substance use begins in early adolescence (or middle school), the majority of evidence-based substance use prevention efforts target youth of this age to prevent further escalation of use [7-9]. Yet, the transition to high school and the corresponding rise in prevalence rates nationwide suggest this may provide another meaningful opportunity for intervention. Given that fewer evidence-based options exist for high school-aged youth, there is a need for prevention efforts among this population to complement programming delivered earlier in adolescence [10,11]. Brief, theory-driven approaches that can be easily implemented with fidelity, require minimal resources, and are suitable for dissemination among community groups are important given the limitations of school- and community-based implementation [12].

Youth Message Development (YMD) is one example of an evidence-based program targeting youth in middle adolescence [13,14]. YMD is a brief, developmentally appropriate intervention for early high school-aged youth (ages 13-15 years) that aims to prevent adolescent substance use via increasing media literacy skills. A large body of evidence suggests that youth exposure to substance-related advertisements is associated with actual use [15]. YMD content (1) increases youth awareness of advertising reach and costs, (2) increases their knowledge of techniques advertisers use to sell products, (3) develops youth counterarguing and critical thinking skills in response to advertisements, and (4) includes an active learning component in which youth apply these skills and techniques to create and disseminate their own antisubstance messages [14]. This approach is developmentally appropriate because it responds to youth increases in executive function, independence, and rebelliousness that occur during middle adolescence. It also capitalizes on adolescents' increasing media focus and social media connectedness [16]. Guided by the Theory of Active Involvement, YMD is thought to impact youth behavior via engaging youth in the curriculum leading to an increase in knowledge and skills, followed by a period of reflection on one's own behavior and subsequent change in expectancies and normative beliefs related to substance use [17].

Initial research on YMD focused on smoking-specific ads, and results indicated a positive impact on beliefs about smoking as well as intentions to smoke among youth who received YMD relative to controls [18,19]. A follow-up study focused on alcohol ads and demonstrated positive effects on youth self-efficacy to apply curriculum skills [13]. Whereas many existing prevention curricula are time-intensive and are school- and family-based, YMD is unique in that it is designed to be brief (90 minutes or less) and delivered by community groups. For wide-scale implementation and dissemination, the timing is a benefit, whereas the need for an in-person facilitator necessitates resources such as time and availability, as well as training to increase fidelity. Additionally, as youth begin to experiment with other substances (eg, marijuana and other types of tobacco products) [1,2], it would be useful to expand the focus of programming to include content beyond alcohol and smoking.

To overcome these challenges of YMD, this paper focuses on adapting YMD from an in-person to an electronic-learning (e-learning) program, as well as broadening its focus to include other commonly used substances in adolescence. Much of human interaction and information seeking is migrating to electronic format, particularly among this age group, and substance use prevention efforts are no exception [20,21]. This raises issues about developing practices for electronic delivery, and also for those migrating from print or face-to-face delivery. These issues are particularly challenging when addressing the needs of populations like youth who are "digital natives" [16] and for whom interactivity has been identified as a key component of any effective substance use prevention intervention [22]. The objectives of this research were to (1) adapt an evidence-based, in-person media literacy-based substance use prevention curriculum for youth ages 13 to 15 years (YMD program) to a self-paced, interactive, e-learning format for implementation and dissemination in a youth organization, and (2) test the feasibility of this e-learning approach via both pilot and usability testing among the target audience.

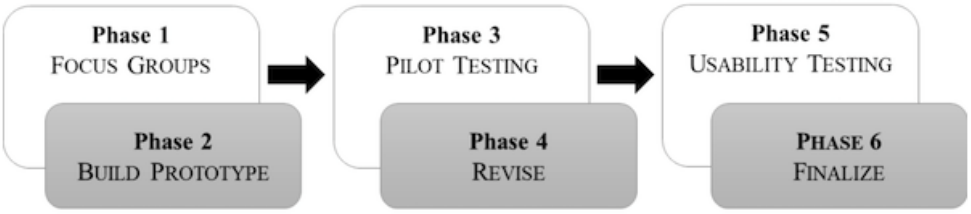
Methods

Overview of the Adaptation Process

A six-phase process was employed to adapt the YMD curriculum from an in-person, paper-based curriculum to an e-learning program, and subsequently test the feasibility (see Figure 1): (1) focus groups were conducted to elicit feedback on existing content and suggestions for adaptation to e-learning, (2) an e-learning prototype was built in partnership with a technology firm, (3) the prototype was pilot-tested to establish feasibility, (4) modifications were made based on results from the pilot testing, (5) a usability test was conducted with a new set of

users, and (6) the program was finalized based on usability findings. Phases 1, 3, and 5, which focused on gathering user feedback, were implemented with our target audience of 4-H youth members and adult club leaders, whereas phases 2, 4, and 6 were led by our technology partner. Thus, our adaptation process included a unique partnership model that went beyond adapting the evidence-based curricula with the help of a technology partner, and included the end user (in this case, 4-H members and leaders) from the outset. 4-H offers youth development programming via university-based cooperative extensions in communities throughout the United States and reaches nearly six million youth per year [23]. Their programming spans several areas including healthy living and incorporates a hands-on learning approach [24]. Accordingly, they were an optimal partner from both a content and dissemination standpoint. Recruitment and study procedures were approved by the Institutional Review Board of Rutgers University (New Brunswick, NJ).

Figure 1. The six-phase adaptation process to convert Youth Message Development program to an e-learning format.



Participants and Recruitment

Participants for our user feedback phases (ie, focus groups, pilot testing, and usability testing) consisted of 4-H members (n=76) and leaders (n=16) recruited from clubs in New Jersey and Maryland (see Table 1 for demographics by phase). For each phase, club leaders were recruited via an email announcement from the state 4-H office. Interested leaders were then provided with a recruitment flyer to share with their teen members that described the purpose of the research activity, timing, and compensation. Flyers targeted high school-aged youth in grades 9 and 10. Parental consent and teen assent were obtained for all 4-H members, and informed consent was obtained from all 4-H leaders. Participants were provided with food during each user feedback phase, and members and leaders received US $30 and US $50 gift cards, respectively, as compensation for their participation.

Table 1. Participant demographics by phase.

Variable	Focus groups[a] (n=27), n (%)	Pilot testing[a] (n=43), n (%)	Usability testing[b] (n=22), n (%)
Participant type			
Members	19 (70)	38 (88)	19 (86)
Leaders	8 (30)	5 (12)	3 (14)
Gender			
Female	14 (52)	27 (63)	15 (68)
Male	13 (48)	16 (37)	7 (32)
Ethnicity			
Hispanic or Latino	6 (22)	3 (7)	0 (0)
Not Hispanic or Latino	21 (78)	36 (84)	22 (100)
Unknown	0 (0)	4 (9)	0 (0)
Race			
American Indian/Alaska Native	0 (0)	1 (2)	0 (0)
Asian	2 (7)	2 (5)	0 (0)
Black or African American	1 (4)	7 (16)	3 (14)
White	18 (67)	24 (56)	19 (86)
More than one race	0 (0)	2 (5)	0 (0)
Unknown	6 (22)	7 (16)	0 (0)

[a]Location: New Jersey.

[b]Location: Maryland.

Procedures and Measures by Phase

Phase 1: Focus Groups

Four 2-hour focus groups were conducted with 4-H members and leaders to generate key ideas to guide the development of the e-learning version.

Procedures

Focus groups were led by the study principal investigators and cofacilitated by either the study project manager or a graduate research assistant. Focus group participants read copies of the in-person YMD curriculum, and subsequent discussions centered on improvements to curriculum content, including the use of acronyms and illustrative advertisements, framing of content, and providing ideas for transferring the content to an online platform (ie, use of voiceovers, program pacing, and various interactive features). Input was also solicited regarding the new program name. All focus group sessions were audio recorded and later transcribed. Detailed notes were taken for each session by the cofacilitator and circulated to the lead facilitator after each focus group to confirm accuracy.

Phase 2: REAL Media Development

The YMD curriculum was adapted to an e-learning prototype in a collaborative effort between the research team and technology developer.

Youth Message Development

The YMD curriculum consists of four lessons, is approximately 90 minutes in length, and is delivered in-person by a trained facilitator either all at once or in multiple sessions. Lessons focus on (1) media reach and strategies advertisers use to sell products, (2) claims in advertisements and counterarguments to those claims, (3) production techniques advertisers use to get attention (eg, setting, colors, font size), and (4) the application of content learned in lessons 1 to 3 to the development of a drug prevention message in the form of a poster [13,14].

Procedures

The development of the e-learning version of YMD, named REAL media based on focus group input and project team discussions, was an iterative process. Guided by the YMD curriculum, as well as feedback from the focus groups, the research team developed scripts for each lesson to guide the translation of content to e-learning format including on-screen text, narration, and interactive components. The Web development team offered its own expert feedback, and the entire team worked together to clarify the vision for REAL media. After each lesson was developed, the research team would provide feedback and the Web development team would make additional modifications. This process continued until the content was accurate and any observed technical glitches were resolved.

Phase 3: Pilot Testing

Five 2-hour pilot-testing sessions were conducted with 4-H leaders and members to assess the feasibility and acceptability of the REAL media prototype.

Procedures

Each participant was provided with a laptop computer with a wireless internet connection, mouse, and headset. Participants were asked to complete, at their own pace, as much of the REAL media program as possible during the 2-hour session. Participants were not asked to create an antisubstance use message—the final component of the REAL media program—due to time constraints, but they were provided with sample files to upload to test the program's functionality. Participants also completed a brief survey to evaluate the performance of and their engagement in each level, what they liked and did not like, as well as demographic items. This was followed by a participant debrief led by the research team.

Measures

The 4-H members' engagement at the end of each level was assessed with 12 items adapted from the Audience Engagement Scale [25] and Narrative Engagement Scale [26]. Participants were asked to indicate their agreement with each item on a 5-point scale from strongly disagree to strongly agree. Six items were from three subscales of the Audience Engagement Scale, including personal reflection (eg, "This level made me think a lot about my substance use [drugs, alcohol, tobacco]"), perceived novelty (eg, "This level was just like what we normally do in school"), and critical thinking (eg, "This level made me think about the truthfulness of ad claims"). The remaining six items were from three scales of the Narrative Engagement Scale, including interest (eg, "This level held my attention"), realism (eg, "The information in this level was very realistic"), and identification (eg, "The information in this level was relevant for me"). 4-H leaders responded to parallel items, which were adjusted to reflect their perception of how 4-H members would respond (eg, "They would think the information in this level is very realistic"). Open-ended feedback also was solicited. After each level was completed, participants were asked to respond to two prompts that captured (1) what they liked best about the level and (2) suggestions for improvement.

Phase 4: Revision to REAL Media

Changes were made to the prototype based on feedback from the pilot-testing sessions.

Procedures

The research team communicated the suggested changes to the programmer, who in turn made the edits before the usability test. The team verified the changes and performed internal testing before moving onto the next phase.

Phase 5: Usability Testing

After revisions to the prototype were made, an independent usability test was conducted with a sample of 4-H members and leaders with no prior knowledge of the REAL media adaptation process.

Procedures

Procedures for the usability test were similar to the pilot-testing procedures. Each participant was provided with a laptop computer with a wireless internet connection, mouse, and headset, and asked to complete levels 1 to 4 of the REAL media program during the 2-hour session. Participants were not asked

to complete level 5 due to time constraints. Participants completed a brief survey to evaluate the usability after each level and the overall program.

Measures

Program usability of each level was assessed with 10 items adapted from the System Usability Scale (SUS) [27]. Sample SUS items were "I thought this level was easy to use" and "I found the various functions in this level were well integrated." Coefficient alphas for SUS scores by level ranged from .83 to .92. Usability of the overall program was assessed with 19 items adapted from the Computer System Usability Questionnaire (CSUQ) [28]. Items fit into one of three subscales including system use (eg, "Overall, I am satisfied with how easy it is to use this program"), information quality, (eg, "The information provided for the program is easy to understand"), and interface quality (eg, "I like using the interface of this program"). Participants were asked to indicate their agreement with each item on a 5-point scale from strongly disagree to strongly agree. Mean scores were created for each subscale, and a total score was computed as the mean of all items. Coefficient alphas ranged from .89 to .98. Participants were also asked to list three positive and negative aspects of the overall program. Finally, self-efficacy to apply curriculum concepts was assessed among 4-H members only. This measure consisted of four items created for this study (eg, "I am confident that I can use these lessons to create my own counterarguments").

Phase 6: Finalizing REAL Media

A list of changes to be made to REAL media before conducting a large-scale evaluation were identified.

Procedures

After the usability test, the research team analyzed the findings and documented a list of recommended changes to be made upon securing funding to finalize the program and evaluate its efficacy. This list also included any lingering issues identified in the pilot test that could not be accommodated before usability testing.

Results

Phase 1: Focus Groups

Focus group feedback was solicited on curriculum content and format with considerable time spent brainstorming suggestions for adapting the face-to-face content to a Web-based platform. Feedback was consistent across both youth and leaders, and it was organized by type (eg, content vs technology).

Content Feedback

Much of the content-specific discussion focused on the advertisements depicted in the curriculum, including their appropriateness and relevance to the audience. Youth participants were able to identify sample ads they liked as well as ads that did not resonate with their age group. One of the concepts in the curriculum focuses on ads that use sex appeal as a strategy to sell products. Youth participants acknowledged the importance of including this imagery because it was an accurate representation of what they were exposed to, but also noted the need to avoid showing "overly" sexual images for the more conservative members and leaders and/or younger club members. For example, showing a male celebrity in an underwear advertisement was deemed acceptable only if the image was cropped above the waist.

Another focus of the content-specific conversations related to the need for acronyms that resonated with the audience, and to adjust existing labels for key concepts accordingly. For example, the original acronym for the four strategies advertisers use to sell products was FUGE, which stood for fun with the group, unexpected/humor, glamor/sex appeal, and endorsement techniques, respectively. Youth participants suggested swapping the "G" to an "S" to produce FUSE, which would be easier to remember and could even be represented with an animated fuse. They also suggested relabeling the "S" from sex appeal to style, to avoid terminology that might be deemed inappropriate.

Technology-Based Feedback

Participants had many suggestions for how to adapt the curriculum content to a Web-based platform, including the use of narration to minimize on-screen text, interactive activities or games to maximize user engagement, positive feedback to encourage users when completing activities, the need for user flexibility in navigating the content, and age-appropriate communication. For example, they suggested avoiding a narrator with an adult voice, but also cautioned against someone who sounded too youthful or kid-like. Similarly, they wanted the narrator to offer positive feedback for correct answers that was simple (eg, "good job" or "way to go") without being overly enthusiastic. Examples of suggested interactions were to allow the user to be able to manipulate images or ads to better highlight relevant lesson concepts and/or maximize contrasts and to offer a variety of interaction types. Participants also suggested that some users might want additional information on topics of interest and asked that additional content be made available to those seeking it. Labels were offered for program features that would avoid a school-like feel. For example, "lessons" could be "levels" and a "quiz" at the end of each lesson could be called a "challenge." Finally, participants suggested potential names for the curriculum.

Phase 2: REAL Media Development

Guided by the focus group results as well as the iterative feedback process described in the Methods, a five-level (ie, lesson) e-learning course was produced. From submission of the first script to completion, the build process took approximately 12 weeks. The main concepts from the face-to-face curriculum were retained and presented via a mix of on-screen text and narration, the latter of which was recorded by a younger, college-aged female. Although the face-to-face YMD curriculum consisted of four lessons, the first lesson was split into two separate lessons for REAL media to achieve a better balance of content and timing throughout. Each lesson was projected to take approximately 20 minutes to complete. In addition to the on-screen text, there were several interactions per level, including drag and drop, multiple choice, fill in the blank, sliders, and hover/reveal. Each level concluded with a brief "challenge" in which users were asked to apply the core concepts illustrated in the level. Finally, to offer interested users the option to see additional content, levels included "optional

depth" segments in which users could learn more about the topics covered in that level. Additional resources were also included with each level. The inclusion of optional depth and resources allowed the user to "customize" or "personalize" their experience, a technique found to increase engagement and effectiveness [29].

Once built, the five levels were hosted on the technology company's Learning Management System that was programmed so that users would be able to log in to their own personal account page and access the program. Each level was locked, meaning that participants had to proceed through the program sequentially by level; they did not gain access to the next level until the prior one was completed. To accommodate the less tech-savvy users, written instructions and a video were placed on the Learning Management System home screen to guide users through the log-in process.

Phase 3: Pilot Testing

Level Engagement Self-Report

Ratings on indicators of realism, interest, and identification for the audience were neutral to positive overall as reported by both members and leaders (see Table 2). Average member ratings for realism across levels mostly ranged between agree (=4) and strongly agree (=5). Average member ratings for identification were between the neutral point (=3) and agree (=4), but closer to agree. Average member ratings for interest were around the neutral point (=3).

Table 2. Means and SDs for engagement scales by level for 4-H members and leaders. The n varies for each level because participants did not rate any levels they did not begin.

Scale	Level 1, mean (SD)		Level 2, mean (SD)		Level 3, mean (SD)		Level 4, mean (SD)		Level 5, mean (SD)	
	Member (n=38)	Leader (n=5)	Member (n=38)	Leader (n=5)	Member (n=36)	Leader (n=5)	Member (n=34)	Leader (n=5)	Member (n=15)	Leader (n=1)
Audience Engagement Scale										
Personal reflection	3.33 (0.87)	3.70 (0.67)	2.99 (0.84)	3.50 (0.61)	3.35 (0.94)	4.10 (0.74)	3.18 (0.80)	3.80 (0.67)	3.33 (0.72)	3.50 (—)
Novelty	3.89 (0.87)	3.70 (0.67)	4.07 (0.82)	4.20 (0.84)	3.43 (1.04)	4.10 (1.02)	3.91 (0.88)	3.90 (0.89)	3.60 (0.89)	2.00 (—)
Critical thinking	4.18 (0.70)	4.40 (0.42)	3.86 (0.96)	4.40 (0.55)	4.31 (0.83)	4.50 (0.50)	3.96 (0.78)	4.00 (0.94)	3.77 (0.94)	4.00 (—)
Total	3.80 (0.58)	3.93 (0.35)	3.64 (0.68)	4.03 (0.52)	3.69 (0.71)	4.23 (0.69)	3.68 (0.57)	3.90 (0.79)	3.57 (0.60)	3.17 (—)
Narrative Engagement Scale										
Interest	3.01 (0.27)	2.80 (0.45)	2.92 (0.43)	3.10 (0.22)	2.99 (0.57)	3.20 (0.27)	2.88 (0.30)	3.00 (0.00)	3.13 (0.23)	3.50 (—)
Realism	4.53 (0.65)	3.90 (0.89)	4.36 (0.56)	4.00 (0.94)	4.19 (0.68)	4.10 (0.65)	4.22 (0.68)	4.00 (0.71)	3.80 (0.32)	5.00 (—)
Identification	3.76 (0.95)	4.00 (1.17)	3.76 (0.98)	4.20 (0.84)	3.50 (1.25)	4.10 (0.89)	3.94 (0.92)	3.90 (0.74)	3.63 (0.61)	2.00 (—)
Total	3.77 (0.42)	3.59 (0.65)	3.68 (0.49)	3.77 (0.40)	3.56 (0.59)	3.80 (0.48)	3.68 (0.48)	3.61 (0.40)	3.51 (0.25)	3.50 (—)

Ratings on indicators of personal reflection on the impact of advertising and substance use, perceived novelty, and critical thinking about advertisements also were positive, with most averages for members close to agree (=4) for novelty and critical thinking. Member ratings for personal reflection were closer to the neutral point (=3), suggesting that not all members thought a lot about their own substance use after using the program.

Given the small sample of leaders, formal comparisons of their responses with those of members were not conducted. Nonetheless, means for leaders' perceptions of personal reflection and critical thinking were higher than mean scores of members. Conversely, realism scores were higher for members than leaders.

Level Open-Ended Responses Feedback

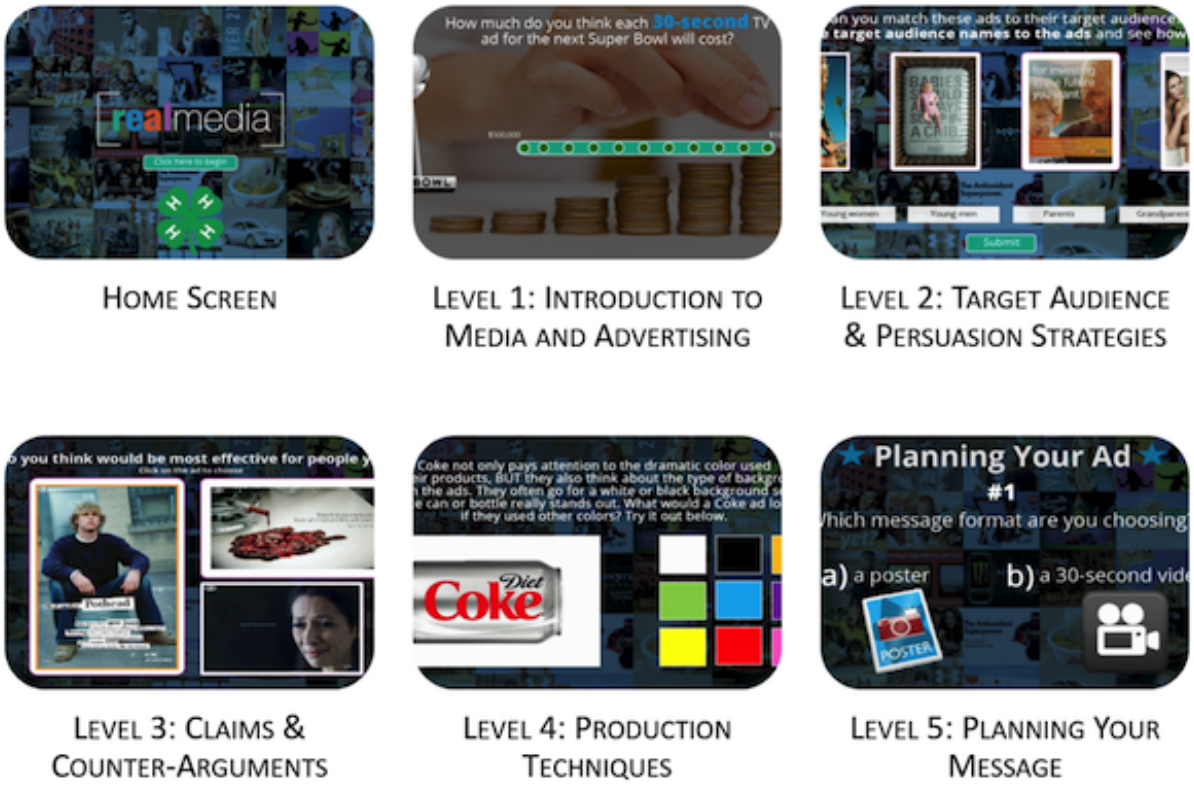
Positive comments focused on content and technical aspects of the program. For example, specific to content, one user noted the examples were realistic and that made the program more relatable for teens. Comments related to technical aspects were focused on visuals, audio, interactive features, and overall program pace. Users reported the interactive features helped them to feel more engaged, the imagery helped keep their attention, the sound effects were positive, and the program was conducted at a nice pace.

Negative comments also focused on both content and technical aspects. Specific to content, participants noted words and concepts that were hard to understand. On the technical side, participants noted frustration with load time and other technical glitches. Other comments related to overall user experience focused on increasing flexibility, such as making it easier to go back to concepts they wanted to review. Although some participants noted they liked pacing, others noted it felt rushed. Other suggestions were to increase font size in certain places and to use more narration and less text.

Phase 4: Revisions to REAL Media

Based on feedback from the pilot test, edits were made following a procedure similar to the original development such that the research team reviewed the changes and offered feedback until minimal glitches were observed and the revised content was satisfactorily incorporated. Specific edits made included adding additional content to the log-in page to aid users in navigating the program (eg, explanations of program features), adding a feature so users could enlarge images, uploading higher quality versions of embedded video content, updating screens with new images, fixing minor content issues such as errors in grammar, fixing minor technical glitches (eg, voiceovers cutting off at the end of a screen), and adjusting contrast of text and/or background colors to enhance the visual experience. Figure 2 shows select screens from the revised prototype.

Figure 2. Images from the Revised REAL media prototype.



Phase 5: Usability Testing

Means for all constructs assessed during the usability test are presented in Tables 3 and 4.

Usability

Mean SUS scores were favorable, with scores falling between agree (=4) and strongly agree (=5) for all levels (see Table 3). Scores for the CSUQ, which captured participants' perceptions of the program, overall were also positive (see Table 4). Notably, both the SUS and CSUQ scores were higher among 4-H members than leaders, suggesting youth members had an easier time navigating the program overall.

Self-Efficacy

Ratings for confidence in using the information learned in REAL media to create counterarguments, use those arguments to convince others about media messages, use lessons to create advertisements, and change other people's behavior via self-created advertisements were all high, with average scores falling between agree (=4) and strongly agree (=5) (see Table 4).

Table 3. Means and SDs for usability for 4-H members and leaders by level. The n varies for each level because participants did not rate any levels they did not begin.

Scale	Level 1		Level 2		Level 3		Level 4	
	Members (n=19)	Leaders (n=3)	Members (n=19)	Leaders (n=3)	Members (n=19)	Leaders (n=3)	Members (n=17)	Leaders (n=3)
SUS[a], mean (SD)	4.24 (0.62)	3.93 (0.75)	4.28 (0.54)	3.93 (0.75)	4.10 (0.58)	3.07 (1.42)	4.28 (0.59)	3.73 (0.81)

[a]SUS: System Usability Scale.

Table 4. Overall program means and SDs for usability and self-efficacy for 4-H members and leaders.

Scale	Overall, mean (SD)	
	Members (n=19)	Leaders (n=3)
CSUQ[a]		
System use	4.39 (0.82)	3.89 (0.96)
Information quality	4.32 (0.84)	3.71 (0.62)
Interface quality	4.40 (0.82)	3.83 (1.04)
Total score	4.37 (0.80)	3.81 (0.85)
Self-efficacy		
To create counterarguments	4.05 (1.13)	—
To use counterarguments to convince others	4.26 (0.93)	—
To create advertisements	4.21 (1.03)	—
To change other people's behavior	4.00 (1.20)	—

[a]CSUQ: Computer System Usability Questionnaire.

[b]Leaders did not complete this measure.

Open-Ended Responses Feedback

Similar to the pilot-testing feedback, comments from users on what they liked and did not like related to both technological aspects of the program and content. From a positive standpoint, participants liked the narration overall (eg, "it talks to you, keeps you involved"), visuals (eg, "pretty design," "bright colors," "cool pictures"), and the overall ease of use or navigation of the program (eg, "simple," "easy to use"). Related to content, participants reported the program was informative, fun, and engaging, and liked the interactions.

Technological areas to improve included a more appealing sign-in page, as well as ongoing timing issues (eg, words went too fast on screen) and loading errors (eg, video would stop playing, some screens were slow). Some features were confusing and needed additional explanation (eg, the zoom button on images). Participants also noted the overall program could be shortened, particularly for a 2-hour session. From a content perspective, participants noted some sections were challenging (eg, the claims, evidence, and counterarguments), and they suggested refining the content presented to make concepts covered in this level easier to understand. Participants also requested more feedback from the program when they provided an answer (eg, they want to be told if they are right or wrong for open-ended responses).

Phase 6: Finalizing REAL Media

Based on the feedback from both the usability and pilot, the research team identified further modifications for potential implementation in phase 2, the goal of which is to evaluate the impact of REAL media on user behavior prospectively and test the conceptual model guided by the Theory of Active Involvement as described previously.

From a technical perspective, a user-friendly log-in system is needed. Minor issues include edits to slide timing, transitions in content, and load time for each level.

From a content perspective, the youth requested more voiceovers, so there would be less on-screen text for users to read. In addition, we plan to streamline some of the repetitive content (particularly in level 3), which will be helpful for individuals who complete the program in one sitting. We will also offer more examples of challenging concepts, including claims, missing claims, and counterarguments (level 3). Finally, we plan to add a social media contest as an outlet for youth to share their antisubstance messages with their family and peers once they complete the e-learning curriculum.

Discussion

Adolescent substance abuse remains a significant public health concern [1,2], and media literacy-based interventions appear to be a promising and novel approach to addressing this problem [13,17-19]. This study adapted a brief face-to-face media literacy alcohol and tobacco intervention for high school students (an underserved cohort in substance use prevention) for an online delivery system targeting multiple substances. Focus groups, a pilot study, and a separate usability study were conducted in the process of iteratively developing the curriculum. The resulting brief curriculum can be implemented in approximately 90 minutes (plus lesson 5 that occurs separately) or split into two to four separate lessons of approximately 20 to 25 minutes each, the latter of which is encouraged based on user feedback from pilot and usability tests. The findings highlight the potential for brief, focused active involvement interventions that can be applied to other substances as well as other public health concerns. In the discussion that follows, we highlight implications of this study and share lessons learned through employing a multiphase adaptation design that includes a partnership with a technology developer as well as the end user.

One of the main implications of these findings is the need for high levels of engagement with prevention materials. The potential for an online curriculum to meet these needs, and the challenges in doing so, are amply illustrated. This work identified both content and technical techniques for engaging

the user. At the same time, the need for customization and personalization was also illustrated. For example, users want flexibility to navigate the program on their own terms, explore additional content if they choose, and receive personalized feedback on interactive elements including open-ended responses and some responses with feedback (eg, challenges).

One of the benefits of this innovative, brief, intervention component is that while potentially affecting substance use alone or in combination with a comprehensive intervention, it encourages the development of higher-order critical thinking skills valued in high school curricula under current teaching standards in most states. Favorable ratings on self-efficacy to use the skills REAL media aimed to build were notable and should only improve once additional edits are made particularly around the challenging concepts in level 3. This complementarity with curriculum standards should foster dissemination.

It is worth noting that the iterative process employed to adapt content to REAL media (ie, three data collections, three separate technology development phases) allowed the research team and technology developers to gain greater understandings of each other's desires and limitations. Although extensive discussions occurred prior to initiation, it is our experience that differences in language, culture, and expectation require continued adjustments (and patience). Even though the technology company had considerable experience in training and implementation development, the media literacy approach was new to them and required considerable adjustments. Further, much discussion was required for both parties involved to understand respective goals. For example, our technology partner did not initially grasp our need for extensive program data capture to support self-report measures.

Overall, the curriculum demonstrated sound functionality and engagement through the iterative adaptation process. Although initial engagement ratings reported during the pilot test were not as high as we would have liked, improvements were made before usability testing. and the self-reported usability scores were very positive. We hope that additional changes scheduled to be made in response to usability feedback, as well as pilot feedback that was not able to be incorporated due to a short timeline, will further improve engagement. There may also be a ceiling effect for engagement in any intervention that has educational and prevention goals. It is an empirical question whether further improvements in engagement would yield increases in program outcomes.

We would also be remiss if we did not note the partnership model adopted throughout this research. Although the obvious partnership is between program developers (research team) and the technology developers, one cannot underestimate the importance of including the end user, in this case the 4-H organization, from the start. As opposed to the "build it, and they will come" model of intervention development, the research team adopted a partnership model that incorporates the end user from inception and has been applied successfully to other curricula adaptations [30]. As a result, REAL media is uniquely suited for dissemination through 4-H, which should facilitate the process of being taken to scale. Currently, 4-H clubs in nine states are using the curriculum in an efficacy trial to evaluate its impact on participants' substance use.

Finally, there were a few limitations of note. Given the pilot nature of the study, we did not assess teen participants' expectancies related to and actual use of substances. It is possible youth substance use tendencies and beliefs could influence their perceptions of the intervention. Accordingly, future feasibility studies on this topic should consider including these measures. In addition, participants were not selected at random. Thus, it is possible the individuals who self-selected into the study are not representative of 4-H participants as a whole. The sample was also small in size and predominately white. All these factors together potentially limit the generalizability of the results. The small sample size also limited our ability to look at differences in results between participating clubs.

In conclusion, this paper describes an iterative development process for adapting evidence-based, face-to-face, manualized prevention programming to an online format whereby the end user is involved from the outset. Both challenges and triumphs were experienced throughout the process, and efforts were generally successful overall. We believe that entering the field with a more fully developed curriculum increases the chances of effectively impacting behavioral outcomes as well as the likelihood of uptake.

Acknowledgments

This research was supported by National Institute on Drug Abuse (NIDA)/National Institutes of Health (NIH) (R21DA027146, R41DA039595, R42DA039595) and National Cancer Institute (NCI)/NIH (P30CA008748) grant funding. The sponsors did not influence the design or conduct of the study; the collection, management, analysis, or interpretation of the data; or the preparation, review, or approval of the manuscript. We gratefully acknowledge the contributions of participating 4-H clubs and their members, particularly Rachel Lyons of 4-H and Rutgers University.

Conflicts of Interest

KG, SCBan, MLH, and MM-D disclose intellectual property interests in the REAL media curriculum.

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Abbreviations

CSUQ: Computer System Usability Questionnaire
e-learning: electronic learning
NCI: National Cancer Institute
NIDA: National Institute on Drug Abuse
NIH: National Institutes of Health
SUS: System Usability Scale
YMD: Youth Message Development

Edited by G Eysenbach; submitted 06.09.18; peer-reviewed by J Zhang, K Champion; comments to author 06.02.19; revised version received 01.03.19; accepted 04.03.19; published 09.05.19.

Please cite as:
Ray AE, Greene K, Hecht ML, Barriage SC, Miller-Day M, Glenn SD, Banerjee SC
An E-Learning Adaptation of an Evidence-Based Media Literacy Curriculum to Prevent Youth Substance Use in Community Groups: Development and Feasibility of REAL Media
JMIR Form Res 2019;3(2):e12132
URL: http://formative.jmir.org/2019/2/e12132/
doi:10.2196/12132
PMID:31094328

Original Paper

Young Adults' Engagement With a Self-Monitoring App for Vegetable Intake and the Impact of Social Media and Gamification: Feasibility Study

Monica Nour[1], PhD, APD; Juliana Chen[1], PhD, APD; Margaret Allman-Farinelli[1], PhD, FDAA

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

Corresponding Author:
Monica Nour, PhD, APD
School of Life and Environmental Sciences
Charles Perkins Centre
The University of Sydney
Level 4 EAST, Charles Perkins Centre D17 The University of Sydney
Camperdown, 2006
Australia
Phone: 61 403094095
Email: mnou2973@uni.sydney.edu.au

Abstract

Background: Social media and gamification have been used in digital interventions for improving nutrition behaviors of young adults, but few studies measure engagement.

Objective: This feasibility study aimed to explore user engagement with a 4-week smartphone program for improving vegetable intake.

Methods: A goal setting and self-monitoring app was developed for feasibility testing. We assessed if additional components of gaming and/or social media support increased engagement. A 2 × 2 factorial study design was used with participants randomly allocated to each group. Engagement with the app (usage) was captured via inbuilt software, which recorded total days of app usage (duration) and the frequency of logging vegetable intake. Uptake of the social media (Facebook) content was measured by tracking views, likes, and comments on posts.

Results: Out of the 110 potential participants who completed the prescreening questionnaire online, 97 were eligible (mean age 24.8 [SD 3.4]). In total, 49% (47/97) of participants were retained at 4 weeks. Attrition within the first week was the highest among users of the gamified app without social support (Facebook; $P<.001$). Over the intervention period, 64% (62/97) of participants logged into their app, with vegetable intake recorded on average for 11 out of 28 days. The frequency of recording decreased each week (mean 4 [SD 2] days in week 1 versus mean 2 [SD 2] days in week 4). No effects of gaming or social support on the frequency of recording vegetables or the duration of app engagement were found. However, regardless of the app type, the duration of app engagement was significantly associated with vegetable intake post intervention ($P<.001$). In total, 60% of Facebook posts were viewed by participants but engagement was limited to likes, with no comments or peer-to-peer interaction observed.

Conclusions: As duration of usage was associated with vegetable intake, a deeper understanding of factors influencing engagement is needed. Dimensions such as personal attributes and the setting and context require further exploration in addition to content and delivery.

(JMIR Form Res 2019;3(2):e13324) doi:10.2196/13324

KEYWORDS

vegetables; young adults; mHealth; social media; experimental game

Introduction

An association between increased vegetable consumption, reduced all-cause mortality, and death from cardiovascular disease and some cancers has been reported [1]. Poor vegetable consumption is a global concern, with the World Health Organization launching a joint initiative with the Food and Agriculture Organization to improve intake [2]. Population-wide

consumption of vegetables is inadequate [3,4], but young adults are the lowest consumers among adults in Australia [3] and the United States [4]. The Australian Dietary Guidelines recommend 5 and 6 serves of vegetables daily for females and males, respectively, [5] but only 4.2% and 1.7% of young adult females and males, respectively, meet this requirement [6]. In addition to consuming inadequate amounts, the variety of vegetables eaten is also poor [7]. This pattern of suboptimal intake is also observed in the United States, with 6.7% of 18 to 30-year-olds meeting the recommendation of 2.5 cups of vegetables per day [8-10]. Clearly, interventions are needed to improve intake.

This age group is typically less risk aversive and unconcerned with longer term benefits of healthful behaviors [11-13]. Thus, novel age-relevant strategies are indicated to motivate behavior change [14,15]. Information and communication technology (electronic health) interventions may be a suitable approach to engage young adults in behavior change [16]. In 2016, it was estimated that 95% and 92% of young adults owned a smartphone in Australia and the United States, respectively [17]. Furthermore, 2018 statistics show that young adults in Australia and the United States are the most frequent users of multiple social media platforms [18,19], with 91% of Americans aged 18 to 29 years using their devices for social networking [20].

In the last decade, social media has been rapidly adopted for health promotion, education, and behavior change, as it aligns with the social cognitive theory [21,22]. The social support, interactive sharing of content, peer influence, and empowerment (reinforcement and gratification) that social media offers may motivate users and enhance engagement with interventions [23-25]. However, social networking alone may be insufficient to change behavior, as recent reviews indicate that these platforms are usually a part of multicomponent interventions and independent effects cannot be discerned readily [24-30].

Gamification, whereby game strategies are used to motivate behavior change, is another strategy that can be delivered using technology and is becoming popular in public health interventions [31]. Gaming has been shown to have positive impacts on physical activity levels and nutrition knowledge [29]. However, research demonstrating its effectiveness in improving nutrition behavior of young adults is limited [29].

The effectiveness of programs using modern information and communication technology to deliver theory-based behavior change interventions is dependent on user engagement [32]. Engagement refers to the manner in which users interact with an intervention and the amount or dose received (measured as time of interaction with intervention components) [33]. Digital interventions that do not have human support may be particularly susceptible to high dropout and nonusage attrition, in which participants do not remain engaged with intervention technologies [34,35]. However, few studies have reported on user engagement with electronic interventions. The available evidence indicates that dropout rates are high in social media–based studies [27], but it is suggested that the use of interactive strategies, gaming, or competitions may increase retention [30,36,37].

Public health programs need to be evidence-based and piloted to ensure that the selected features are effective and adaptable to the population at large. Generally, feasibility studies are used to test program components and determine whether they should be trialed in a larger intervention to measure impact on behavior [38]. Currently, the evidence base concerning the feasibility of gaming and social networking strategies in nutrition interventions is lacking [27,29,30].

This study has described the feasibility testing of a 4-week program using apps and social media to deliver an intervention to improve vegetable intake designed using the COM-B (Capability, Opportunity, Motivation and Behavior) system. We assessed if gaming and/or social media support increases engagement and has any additive effect on improvements in vegetable intake in young adults.

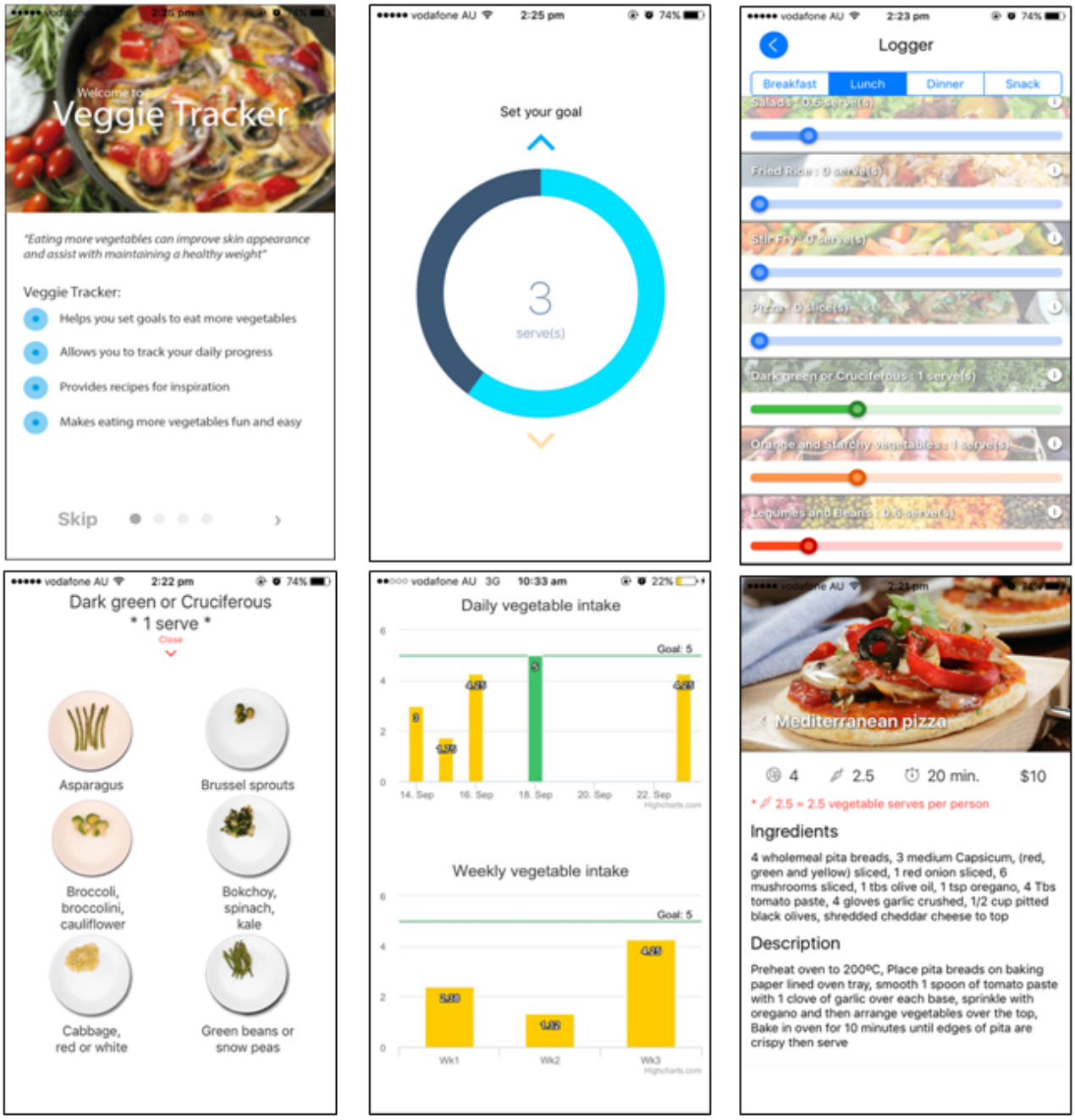
Methods

Intervention Components

A goal setting and self-monitoring app with feedback on vegetable intake was developed by dietitians and experts in computer-human interaction. The app aimed to provide users the opportunity for self-evaluation of vegetable intake. The behavior change techniques (BCTs) of goal setting, self-monitoring, and the provision of feedback are successful strategies to maintain motivation and improve self-efficacy for practicing healthful lifestyle behaviors [14,39-42]. A second gamified version of the app was developed and incorporated rewards as incentivization. Figure 1 shows the standard self-monitoring app prototype, which featured the goal setting and recording components and a recipe database that was searchable by meal or ingredient. Figure 2 shows the gamified app prototype that had additional features, including challenges and badges as rewards for goal attainment. Providing rewards is recognized as an effective BCT for enhancing self-regulation by reinforcing the desired behavior [43,44]. The challenges were designed to be tailored to the user's intake and were provided on a weekly basis. For example, if a user reports only consuming vegetables at dinner, they will be prompted with a *meal time challenge*, encouraging vegetables to be included in other meals such as breakfast, lunch, or snacks.

Additional program materials such as infographics, meal plans, and cooking videos were developed by a dietitian to address the key barriers to vegetable intake among young adults, including their poor knowledge of daily recommendations and serving sizes [45,46] and low confidence in planning meals that include vegetables and inadequate cooking skills [46,47]. These materials were designed for delivery within a private social support (Facebook) group. Facebook serves as both a platform for sharing additional resources and for providing participants with additional social support from the dietitian and other peers within the group. The provision of social support has been recognized as an effective technique for behavior change as it provides empowerment and positive peer pressure [48].

Figure 1. Screenshots of the standard self-monitoring app (left to right: welcome screen with instructions, goal setting screen, logging screen, information on serving sizes to assist with logging, progress screen, and recipe database).



Tables 1-3 provide a summary of the selected intervention functions to support change in vegetable intake and suggested BCTs [49]. All program materials and the smartphone app prototypes were tested for acceptability and relevance in focus groups with a sample of the target audience. A structured focus group setting was used to present participants with mock Facebook posts to be evaluated. The young adults were also asked for feedback on app *wire frames*, that is, still images of the app pages, to determine the appropriate features to be included. A detailed explanation of the views and preferences of the young adults have been reported elsewhere [46]. The final app (usable product) was tested for functionality internally within the research team.

Figure 2. Screenshots of the gamified self-monitoring app (left to right: home screen, knowledge quiz, example challenge, badges to reward progress in knowledge, and other behaviors related to vegetable intake).

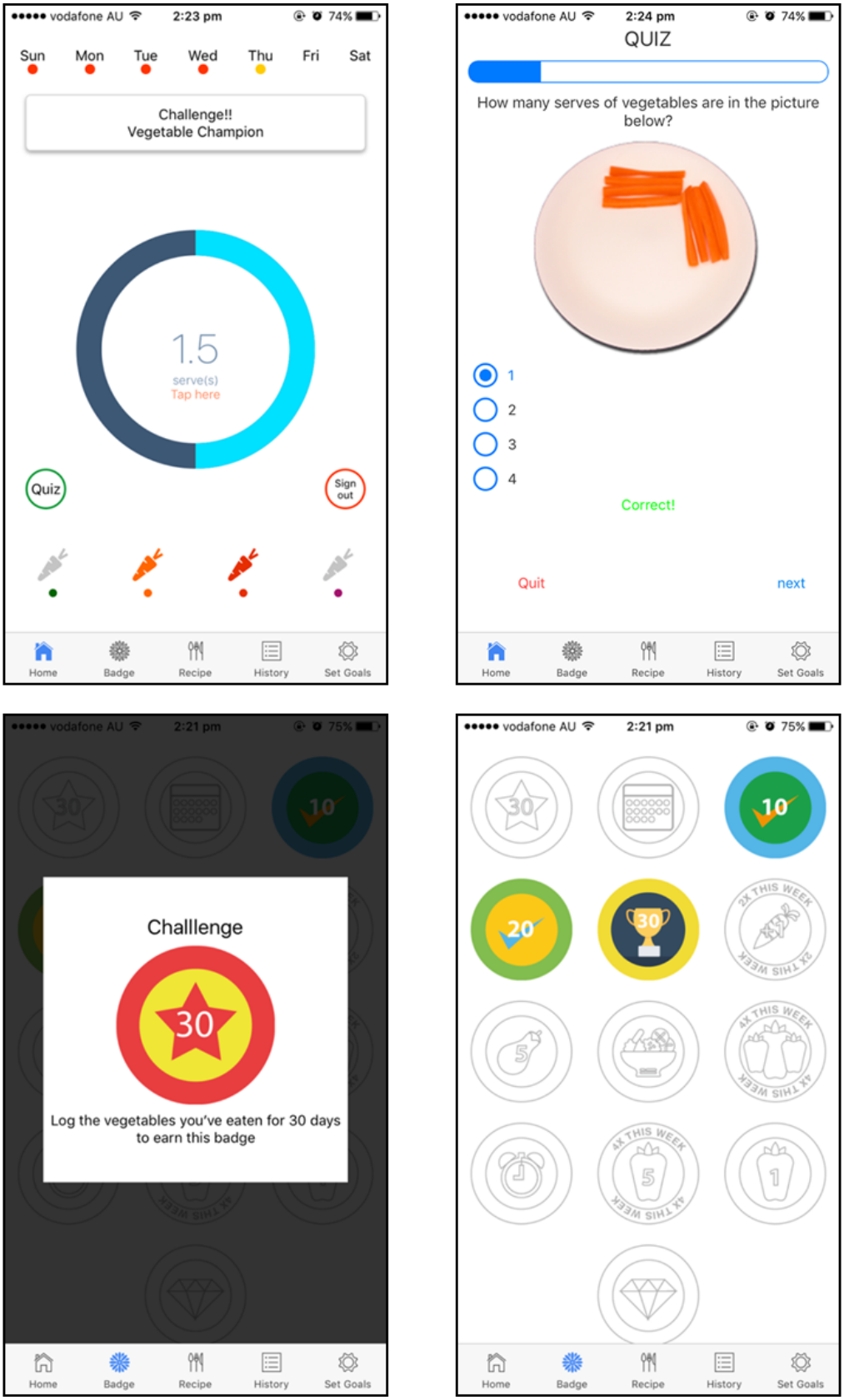


Table 1. A summary of the behavior change techniques selected, their context within the Capability, Opportunity, Motivation and Behavior framework, and their application within the platform.

Capability, Opportunity, Motivation and Behavior Framework	Description of behavioral determinant	Behavior change technique[a]	Application within the program		
			Standard app	Gamified app	Social support (Facebook) group
Capability					
Psychological					
Knowledge; Intervention function: Education	Knowledge of recommended vegetable intake and serve sizes; Understanding health benefits	Information about health consequences	Infographic on recommended daily intake and what constitutes a vegetable serve	Infographic (see Multimedia Appendix 1) on recommended daily intake and what constitutes a vegetable serve and quiz-based game on recommended vegetable intake and serve sizes according to Dietary Guidelines	Infographic (see Multimedia Appendix 1) on recommended daily intake and what constitutes a vegetable serve and Facebook posts on the health benefits of vegetables
Self-monitoring and Feedback on behavior; Intervention function: Enablement and Education	Recording vegetable consumption and review discrepancy between current intake and goal to encourage continued improvement	Self-monitoring of behavior; Feedback on behavior	App enables user to enter serves of vegetables consumed at each meal and review progress against personalized goal	App enables user to enter serves of vegetables consumed at each meal and review progress against personalized goal	—[b]
Physical					
Skill building; Intervention function: Training	Cooking skills: practicing the process of cooking with vegetables	Demonstration of the behavior; Instruction on how to perform a behavior	Recipe database searchable by ingredient or meal type	Recipe database searchable by ingredient or meal type	Short cooking videos to model cooking with vegetables, with challenges to encourage young adults to practice cooking skills and upload pictures of their dish
Opportunity					
Physical					
Reducing barriers; Intervention function: Environmental restructuring	Addressing flavor, time, and cost as a barrier to vegetable intake by developing meal planning and budgeting skills	Prompts/cues	—	—	Facebook posts providing cues on how to enhance flavor of vegetables and plan meals on a budget
Habit formation; Intervention function: Training	Prompt rehearsal and repetition of vegetable consumption	Habit formation	The app requires participants to monitor vegetable intake against their goal daily	The app requires participants to monitor vegetable intake against their goal daily	—

[a]Based on Susan Michie's Behavior Change Taxonomy behavior change techniques [40].

[b]Not applicable.

Table 2. A summary of the behavior change techniques selected, their context within the Capability, Opportunity, Motivation and Behavior framework, and their application within the platform (continued).

Capability, Opportunity, Motivation and Behavior Framework	Description of behavioral determinant	Behavior change technique[a]	Application within the program		
			Standard app	Gamified app	Social support (Facebook) group
Opportunity					
Physical					
Cues to action; Intervention function: Environmental restructuring	Providing reminders to consume vegetables to increase the likelihood of practicing the behavior; Creating healthy triggers within the environment to support increased vegetable consumption	Prompts/cues	—[b]	—	Providing tips on the Facebook page on how to maximize exposure to vegetables as a means of increasing consumption such as "Take your forgotten veg out of that bottom fridge draw and place on the top shelf so you're reminded to cook with them"
Cues to action; Intervention function: Enablement	Providing weekly challenges to increase vegetable intake	Graded tasks	—	Challenge based on personal opportunities, for example, add veg to breakfast	—
Social					
Social support; Intervention function: Enablement	Instigating positive peer rivalry to encourage vegetable intake	Social support (practical)	—	—	Competitions such as *best cooked vegetable dish*, *quirkiest vegetable of the week* between peers on the Facebook page
Motivation					
Reflective					
Cognitive strategies; Intervention function: Persuasion	Restructuring beliefs and perceived barriers by *debunking* myths about vegetables, for example, bad taste	Framing/reframing	—	—	*Myth busting* articles encouraging participants to reevaluate beliefs, for example, Top 5 ways to enjoy the taste of vegetables
Automatic					
Goal setting and self-monitoring; Intervention function: Enablement	Setting SMART[c] goals for increasing vegetable intake	Goal setting (behavior); Review behavior goal(s)	App prompts user to set goal for vegetables serves/day, personalized based on current intake so it is achievable. Can assess progress against goal and recommended intake in review page	App prompts user to set goal for vegetables serves/day, personalized based on current intake so it is achievable. Can assess progress against goal and recommended intake in review page	—

[a]Based on Susan Michie's Behavior Change Taxonomy behavior change techniques [40].

[c]SMART: Specific, Measurable, Achievable, Relevant, Time-bound.

[b]Not applicable.

Table 3. A summary of the behavior change techniques selected, their context within the Capability, Opportunity, Motivation and Behavior framework, and their application within the platform (continued).

Capability, Opportunity, Motivation and Behavior Framework	Description of behavioral determinant	Behavior change technique[a]	Application within the program		
			Standard app	Gamified app	Social support (Facebook) group
Motivation					
Rewards/Incentives; Intervention function: Incentivization	Increasing the value of consuming vegetables through rewards	Incentive	—[b]	Rewards (badges) provided for recording intake, consuming a variety of vegetables, achieving challenges and playing knowledge quiz	Competitions such as uploading a picture of a dish containing vegetables rewarded with a voucher
Self-efficacy; Intervention function: Enablement and Modeling	Providing the opportunity to gain confidence in eating more vegetables by breaking the behavior up into small achievable tasks	Goal setting (behavior); Demonstration of the behavior	Weekly goals for increasing vegetable intake slowly	Weekly goals for increasing vegetable intake slowly. Weekly challenges providing easy ways to increase vegetables in the diet, for example, add some vegetables to breakfast	Cooking videos, meal planning resources and recipes, tips on simple ways to eat more vegetables, for example, "What's for dinner tonight? Add in veggies, make a side salad or stir fried veg"
Social support; Intervention function: Persuasion	Validating and reinforcing improvements in vegetable intake to encourage repetition of the desired behavior	Information about others' approval	—	—	Participants can post pictures of vegetable dishes to receive positive reinforcement from the researchers

[a]Based on Susan Michie's Behavior Change Taxonomy behavior change techniques [40].

[b]Not applicable.

Study Design

Feasibility testing of the proposed program components was conducted using a 2 × 2 factorial study design (standard goal setting and self-monitoring app vs gamified self-monitoring app × social support vs no social support) with random allocation to each group. This design allowed for the comparison of 4 different conditions to determine which generated the best engagement. Participants were randomized into 1 of 4 groups. Each group was given access to a smartphone app for goal setting, self-monitoring, and the provision of feedback. In total, 2 groups received the additional gaming features within their app for incentivization and 2 groups (one using the gaming app and one using the standard app) received daily support and additional materials through a social support (Facebook) group. Multimedia Appendix 2 shows the 4 groups, their study conditions, and program components.

The reporting of outcomes was guided by the CONSORT E-HEALTH checklist of information to include when reporting on social media, serious games, or mobile health trials [50]. All study materials were delivered electronically. The study materials and methods were approved by the University Human Ethics Committee, approval number 2017/306.

Participants and Recruitment

Young adults aged 18 to 30 years who owned a smartphone were eligible to participate. Pregnant women and those with a history of disordered eating or medical contraindications were excluded from this study. This study was advertised in the community at large throughout New South Wales (NSW) over 5 months between October 2017 and February 2018. Recruitment strategies included Facebook posts, flyers posted in tertiary education campuses and distributed through local club newsletters, and information stands. The recruitment flyers used the university logo to meet ethical requirements; however, affiliation with the institution did not appear on other program material. Recruitment advertisements were centered on eating more vegetables to improve health and well-being. For example, one Facebook advertisement stated "Feeling tired? Essential nutrients in vegetables can enhance your wellbeing. Learn how to eat a little more veg every day through the 4-week smartphone program designed by researchers at The University of Sydney."

Participants expressing interest in this study were directed to a Web-based survey providing information about the study and eligibility screener. If eligible, participants were directed to the baseline questionnaire assessing usual vegetable intake and motivation for consuming vegetables. Informed consent was collected via this survey. Participants agreed that all data collected as part of the study could be shared within publications in a deidentified form. The survey was delivered using the Redcap software (Vanderbilt), a secure Web-based application for building and managing Web-based surveys [51]. As part of the consent, participants were informed that upon completing the 4-week intervention, they would be entered into a draw to win one of 4 Aus $25 grocery vouchers. Separate informed consent was obtained from 10 participants agreeing to participate

in a postprogram interview. Respondents received a gift voucher valued at Aus $10 for participation in the interview.

Randomization and Participant Instructions

Participants who met study eligibility and provided consent were enrolled into a study group by an independent researcher (JC). A Web-based number generator allowed randomization and stratification by gender [52]. The researcher collecting and analyzing the data was blinded to allocations throughout the duration of the study, data collection, and analysis (MN).

All participants were emailed an infographic educating on the recommended daily vegetable intake and what constitutes a vegetable serve (Multimedia Appendix 1) as well as a link to download the app for their allocated intervention group. The app was available at no cost from the Google Play or Apple store. They were instructed to set intake goals at baseline and use the app daily to record and monitor vegetable intake throughout the 4-week study period. Short pop-up instructions explained the functions of the app to users on first log in. The app was designed to reset the logging status at midnight each day. Throughout the 4-week intervention period, reminder text messages were sent to prompt recording of vegetable intake if a participant had not logged into the app for 3 consecutive days. Those randomized into a social media support group in addition to their designated app were invited via email to join the study social support (Facebook) group specific to their allocated intervention condition (gaming or nongaming). Participants were informed in the participant information sheet that the study comprised different *technologies* (ie, app and Facebook) and so could not be blinded completely. However, separate social support groups were created to avoid contamination between participants using the different apps (gaming vs nongaming). The dietitian used a predetermined schedule to share identical material within the social support (Facebook) groups each day for 4 weeks, with a total of 28 posts shared. Participants were asked to check the content posted daily. There was no human involvement other than the email correspondence for trial registration and regulation of Facebook posts. No counseling was given to participants.

After 4 weeks of using the designated app with or without the social media page, the participants received an email invitation to complete the follow-up questionnaire similar to baseline, but with additional questions asking for their experience/feedback on the program.

Outcomes

The primary outcome of interest was the change in vegetable consumption (serves per day) at 4 weeks, including canned and frozen varieties but excluding fried potatoes. Engagement was measured as a secondary outcome.

Data Collection

Demographic details, including age, gender, postcode (for categorizing socioeconomic status), education level, occupation, cultural background, and income were collected at baseline through a Web-based questionnaire. Vegetable intake (serves/day) was assessed at baseline and at the conclusion of the trial (4 weeks) using validated short questions [53], which quantified intake by the following vegetable groups: (1) potatoes (not fried), (2) salad vegetables, for example, lettuce/leafy vegetables, tomatoes, capsicum, and cucumber, (3) cooked vegetables, for example, zucchini, eggplant, sweet corn, green beans, and Asian greens, (4) legumes, for example, baked beans, lentils, and chickpeas, and (5) 100% vegetable juice. The questions asked participants to reflect on the last month and quantify the average servings they ate per day of each of the vegetable groups. Vegetable intake was reported using 9 response options (None, Less than 1 serving per day, 1 serving per day, 2 servings per day, 3 servings per day, 4 servings per day, 5 servings per day, 6 servings per day, and 7 or more servings per day). Autonomous and controlled motivation for consumption of vegetables was quantified using 4-point scale questions adapted from the self-regulation questionnaire [54,55], with a maximum possible score of 16. A higher score indicated greater motivation.

Engagement with the program was measured through usage (the uptake of intervention material) [56] and qualitative methods. Data related to the participant's app usage were captured via an inbuilt software, which gives the time and date of app activity. The recorded log-ins were used as the measure of total days of app engagement (duration) and the data on recording of vegetable intake was used as an indicator of frequency of self-monitoring. Engagement with material posted within the social support groups was measured through user reactions such as *likes* and *comments* according to the Facebook definition of engagement [57]. This outcome measure reflects the ability of content to capture user attention rather than an estimation of total uptake. Uptake was measured using the *seen* data from Facebook analytics, which provides a list of people who have viewed the post.

Acceptability of program components was captured using a short postintervention questionnaire (all participants). The questionnaire included 4 5-point Likert scale questions as follows: "Rate how easy it was to use this program"; "Rate how much you liked this program"; "On a scale of 1-5, how likely would you recommend this program to others?"; and "How useful was the program to you?"

Qualitative assessment included semistructured interviews conducted via telephone. At conclusion of the 4-week trial, a random selection of participants received an email invitation to participate in a 15-min semistructured telephone interview for gathering subjective opinions of user experiences and feedback on the program components. The telephone interview was audio-recorded and transcribed for later thematic analysis.

Data Analysis

Data analysis was conducted using IBM SPSS software for Windows version 22 [58]. Descriptive statistics were used to summarize the baseline characteristics of participants. Chi-squared tests were used to examine differences between groups in the education level, gender, and socioeconomic status. Analysis of variance was used to determine differences in baseline age and vegetable intake. Although the feasibility study numbers are not powered for detecting change, analysis of covariance was applied to measure the impact of the intervention on vegetable intake after 4 weeks (primary outcome) between

groups, controlling for baseline vegetable intake. The analysis was by *intention to treat* with multiple imputation used for missing values so that all participants randomized at the commencement of the trial were retained for analysis regardless of compliance. In total, 5 imputed datasets were created based on age, gender, baseline vegetable intake, and Socioeconomic Index For Areas (SEIFA), which is a measure of the impact of the area of residence, rather than an individual's income, occupation, or level of education, on intake. The imputed values were pooled using Rubin's rule [59].

The differences in rates of attrition by group were assessed using chi-squared analysis for changes in proportions. Engagement with the app was explored quantitatively by summarizing log data by frequency of recording intake and period of app use by group. To investigate the relationship between the amount of app usage and changes in vegetable consumption, we used the Spearman correlation coefficient with significance assessed at P=.05. Facebook engagement was examined by totaling the *likes* and *comments*. Uptake of social media content was explored by calculating the percentage of participants who viewed each post. The most and least popular posts were determined using the following criteria—most popular: viewed by 80% or more of the study sample and least popular: viewed by 30% or less of the study sample. This criterion was based on previous literature, which shows that engagement can range from as low as 30% to as high as 73% [60,61]. Feedback collected through the follow-up semistructured interviews with participants was audio-recorded and later transcribed by one researcher who also coded into the NVivo Software program (QSR International Pty Ltd. Version 10, 2012). A thematic analysis using an open coding method and inductive approach was applied to group together common themes. Quotes were selected to represent the key themes.

Results

Participants

A total of 115 young adults expressed interest in participating in the study. Out of the 110 potential participants who completed the prescreening questionnaire online, 97 were eligible and randomized into one of the 4 groups. The breakdown of group allocation is displayed in Multimedia Appendix 2.

The characteristics and demographics of participants at baseline are presented in Table 4. The mean age was 24.8 (SD 3.4) years. The sample comprised 40% males. A total of 52 participants (54%) reported their highest level of education as a university degree or higher. The majority of participants (51/97, 53%) were of Australian or New Zealand descent, 1 of Aboriginal or Torres Strait Islander descent, 18 were of Asian descent, 5 of African descent, 18 of European descent, 1 of Middle Eastern descent, 1 of South American descent, and 2 of North American descent. The sample captured young adults across all socioeconomic areas, with 28% (n=27) categorized in the lower 2 SEIFA quartiles. There were no statistically significant differences found between the groups for: vegetable intake (P=.27), education (.79), gender (.95), and SEIFA (.3). The group using the standard app with social support (Facebook) was younger than the other 3 groups (P=.04). At baseline, the mean (SD) motivation score among all participants was 12.3 (1.8) out of a possible 16. A significant time effect was observed (P=.04) with an increase in motivation 4 weeks post intervention for all groups, but no group by time effect was found (P=.2).

Attrition

In total, 10 participants withdrew from the intervention (10/97, 10%): 3 because of injury or illness; 4 because of lack of time; and 3 withdrew without giving a reason. At the end of the 4-week study period, participants were emailed the follow-up survey. Approximately half (47/97, 49%) completed this assessment (Multimedia Appendix 2). Females were more likely to complete the 4-week program than males (P<.001). The attrition rates by group and intervention week are presented in Table 5. The number of participants who dropped out after downloading the app in the first week of the intervention was significantly greater among the group who received the gamified app alone without social support (Facebook; P<.001). In the second week, drop out was highest for the group using the standard app with social support (Facebook; P<.001). Out of the 62 participants who downloaded the app, 29 (47%) remained engaged (logged vegetable intake) after 4 weeks. The overall proportion of completers was not significantly different between groups (P=.81).

Table 4. Baseline characteristics of participants by group condition.

Baseline characteristics	Standard app[a]	Gamified app[b]	Standard app with social support (Facebook)	Gamified app with social support (Facebook)	*P* value
Age (years), mean (SD)	25.7 (3.2)[c]	24.6 (3.8)[d]	23.3 (3.0)[c,d]	25.5 (3.1)[c]	.04
Gender, n (%)					
Male	12 (44)	9 (41)	9 (38)	9 (38)	.95
Female	15 (56)	13 (59)	15 (62)	15 (62)	—[e]
Highest level of education, n (%)					
High school	7 (26)	5 (23)	7 (29)	4 (17)	.79
Diploma or certificate	7 (26)	5 (23)	6 (25)	4 (17)	—
University degree or higher	13 (48)	12 (54)	11 (46)	16 (66)	—
Socioeconomic Index For Areas, n (%)					
Quartile 1 (Lowest)	2 (7)	5 (23)	2 (8)	2 (8)	.3
Quartile 2	3 (11)	2 (9)	5 (21)	6 (25)	—
Quartile 3	10 (37)	3 (13)	3 (12)	4 (17)	—
Quartile 4	5 (19)	5 (2)	4 (17)	2 (8)	—
Quartile 5 (Highest)	7 (26)	7 (32)	10 (42)	10 (42)	—
Vegetable intake (serves/day), mean (SD)	1.6 (1.4)	2.0 (1.5)	2.4 (1.3)	1.8 (1.6)	.27

[a]Standard app for goal setting and self-monitoring with feedback.

[b]Gamified app for goal setting and self-monitoring with feedback with the addition of gamification. *P* values are for differences between groups using Tukeys post hoc analysis; shared subscripts represent statistically significant differences.

[c]*P*<.001.

[d]*P*=.003.

[e]Not applicable.

Table 5. The number of participants who dropped out of the program by group and by intervention week. Percentages are presented as proportions of those randomized.

Attrition by stage of intervention	Total, n (%)	Standard app, n (%)	Gamified app, n (%)	Standard app with social support (Facebook), n (%)	Gamified app with social support (Facebook), n (%)	*P* value for difference between groups [a]
Randomized	97(100)	27 (28)	22 (22)	24 (25)	24 (25)	—[b]
Drop out week 1 (did not download app)	35 (36)	10 (37)	7 (32)	6 (25)	11 (46)	—
Drop out week 1 (after downloading app)	7 (7)	1 (4)	5 (23)	0 (0)	0 (0)	<.001
Drop out week 2	6 (6)	2 (7)	0 (0)	3 (13)	1 (4)	<.001
Drop out week 3	2 (2)	0 (0)	1 (4)	1 (4)	1 (4)	.005
Drop out week 4	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)	.07
Completed 4 weeks	47 (49)	14 (52)	9 (41)	13 (54)	11 (46)	.81

[a]*P* value for differences in proportions between groups using chi-square tests.

[b]Not applicable.

Change in Vegetable Intake

Significant differences in vegetable intake over time (*P*=.001) were found. However, no change was observed in the group by time differences (*P*=.43; Table 6).

Engagement

Self-Monitoring Apps

Analysis of the app log data showed that 64% (62/97) of participants logged into the app. On average, each participant logged their vegetable intake on 11 out of 28 days during the intervention. The frequency of recording decreased each week for the overall sample (Figure 3). There were no significant

differences between groups for frequency of recording intake and days of engagement with the app (Table 7). However, regardless of app type, the duration of app engagement (total days of use) was significantly positively associated with vegetable intake post intervention ($P<.001$; Figure 4). The frequency of recording was significantly associated with vegetable intake among those using the standard self-monitoring app only (Figure 5).

Table 6. Changes in vegetable intake from baseline to follow-up by group (N=97, using imputed dataset).

Group	Standard app[a]	Gamified app[b]	Standard app with social support (Facebook)	Gamified app with social support (Facebook)
Baseline, mean (SD)	1.6 (1.4)	2.0 (1.5)	2.4 (1.3)	1.8 (1.6)
Follow-up, mean (SD)	1.7 (1.2)	1.6 (1.2)	2.2 (1.6)	1.5 (1.2)
Change	0.1	−0.4	−0.1	−0.3
P value (time)	.001	—[c]	—	—
P value (group × time)	.43	—	—	—

[a]Standard app for goal setting and self-monitoring with feedback.

[b]Gamified app for goal setting and self-monitoring with feedback with the addition of gamification.

[c]Not applicable.

Figure 3. The mean frequency at which vegetable intake was recorded each week for the total sample (N=97), regardless of app type.

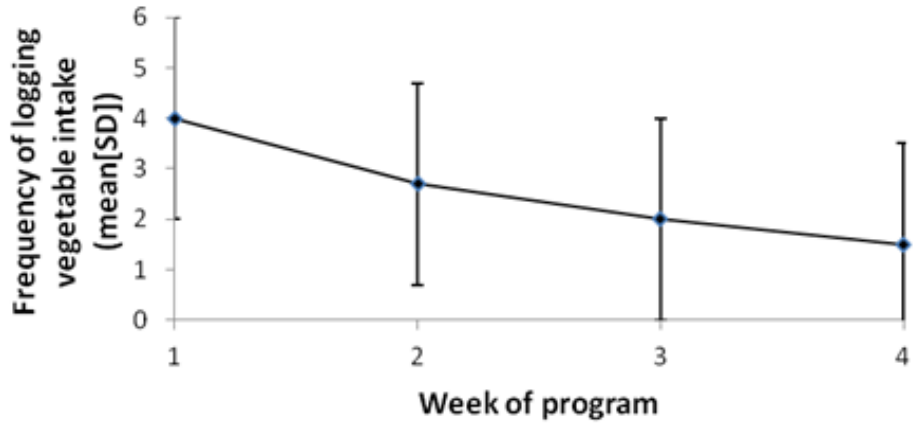


Table 7. Data on engagement with the app and Facebook material by group according to frequency of logging intake, days engaged with the app, uptake of Facebook material, and number of likes.

Group	Standard app	Gamified app	Standard app with social support (Facebook)	Gamified app with social support (Facebook)	*P* value for difference between groups[a]
Frequency of logging intake in app, mean (SD)	11 (7)	8 (5)	11 (7)	14 (8)	.30
Number of days engaged with app (log-ins), mean (SD)	23 (9)	20 (8)	22 (9)	23 (6)	.80
Uptake of Facebook material (posts seen), %	—[b]	—	58.4	61.2	.80
Engagement with Facebook material, number of likes	—	—	32	46	.30

[a]*P* value for differences between groups using analysis of variance.

[b]Not applicable.

Figure 4. Correlation between total days of use of apps (with or without social support (Facebook)) and vegetable intake postintervention measured by validated short questionnaire. Gamified app: r=0.64; n=24; P=.001; Standard app: r=1; n=23; P<.00001.

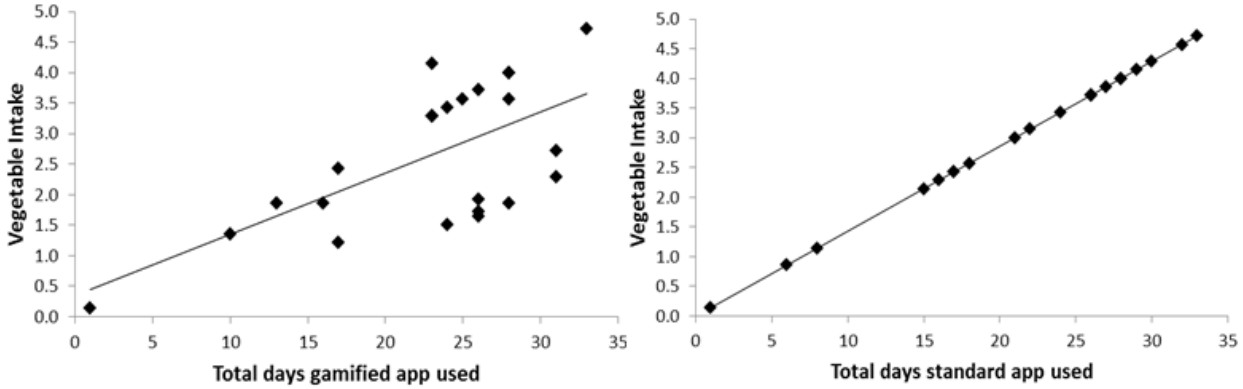
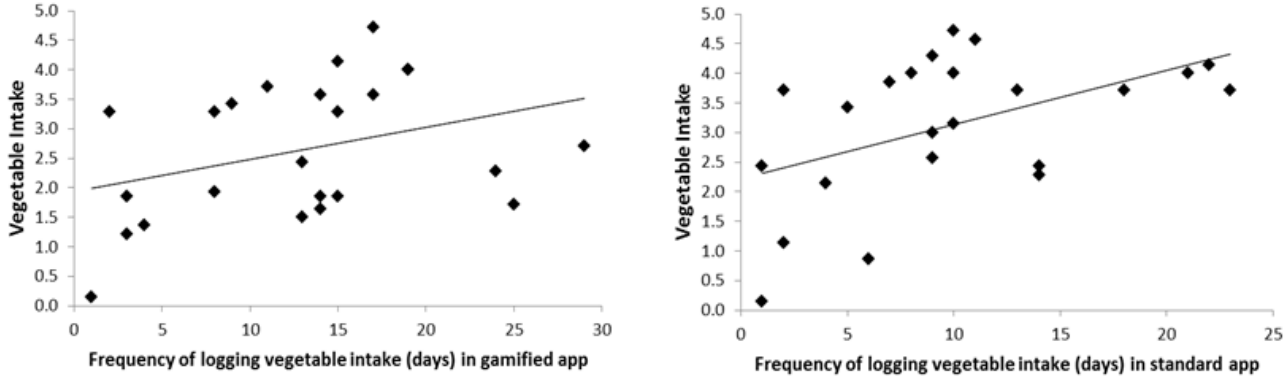


Figure 5. Correlation between frequency of logging (days) in the apps (with or without social support (Facebook)) and vegetable intake postintervention measured by a validated short questionnaire. Gamified app: r=0.35; n=24; P=.09; Standard app: r=0.49; n=23; P=.02.



Facebook Posts

Uptake (Views)

Uptake of Facebook posts (percentage of posts viewed by participants) did not differ between the group that used the gaming app and the group that used the standard app (mean [SD] percentage of posts seen by participants; 61.2 [22.1] and 58.4 [23.9], respectively; Table 7). The percentage of posts viewed was well maintained over the intervention period. The mean percentage of views was 63.5 in week 1 (SD 17.8) and 62.5 in week 4 (SD 10.2). The most popular Facebook posts (ie, viewed by ≥80% of participants) were recipes with time-saving elements (eg, using frozen vegetables) and those that offered vegetable preparation hacks such as how to quickly chop a capsicum. Meal inspiration posts that suggested new ways to try vegetables such as by adding spinach to smoothies, making vegetable-based dips, or adding beans to salads were well received. Meal planning information was also very popular (particularly posts that featured a weekly meal plan and shopping list). Additionally, uptake was high on posts that suggested money saving tips and used infographics to pictorially illustrate 5 serves a day (Figure 6).

The least popular Facebook posts (ie, seen by ≤30% of participants) were cooking videos with unfamiliar ingredients (eg, squash), meal inspiration posts based on *cliché* ingredients such as avocado, and suggestions to shop at farmer's markets for cheap vegetables (Figure 6). The uptake of cooking videos and posts made regarding the health benefits of vegetables was moderate (approximately 60%). Overall retention within the social support (Facebook) groups was good. This was measured from when a participant joined the Facebook group until the end of the intervention period regardless of whether the final questionnaire was completed. All but 2 participants were retained.

Engagement (Likes)

Interaction with posts was limited to likes, with no comments made by participants. Only 1 participant shared their own material within the group as shown in Figure 7. These posts (made by a participant) were very well received with 100% uptake from group participants.

Overall Engagement

The data on engagement are displayed in Table 7. No significant differences are detected.

Figure 6. Examples of most (top row) and least popular (bottom row) posts.

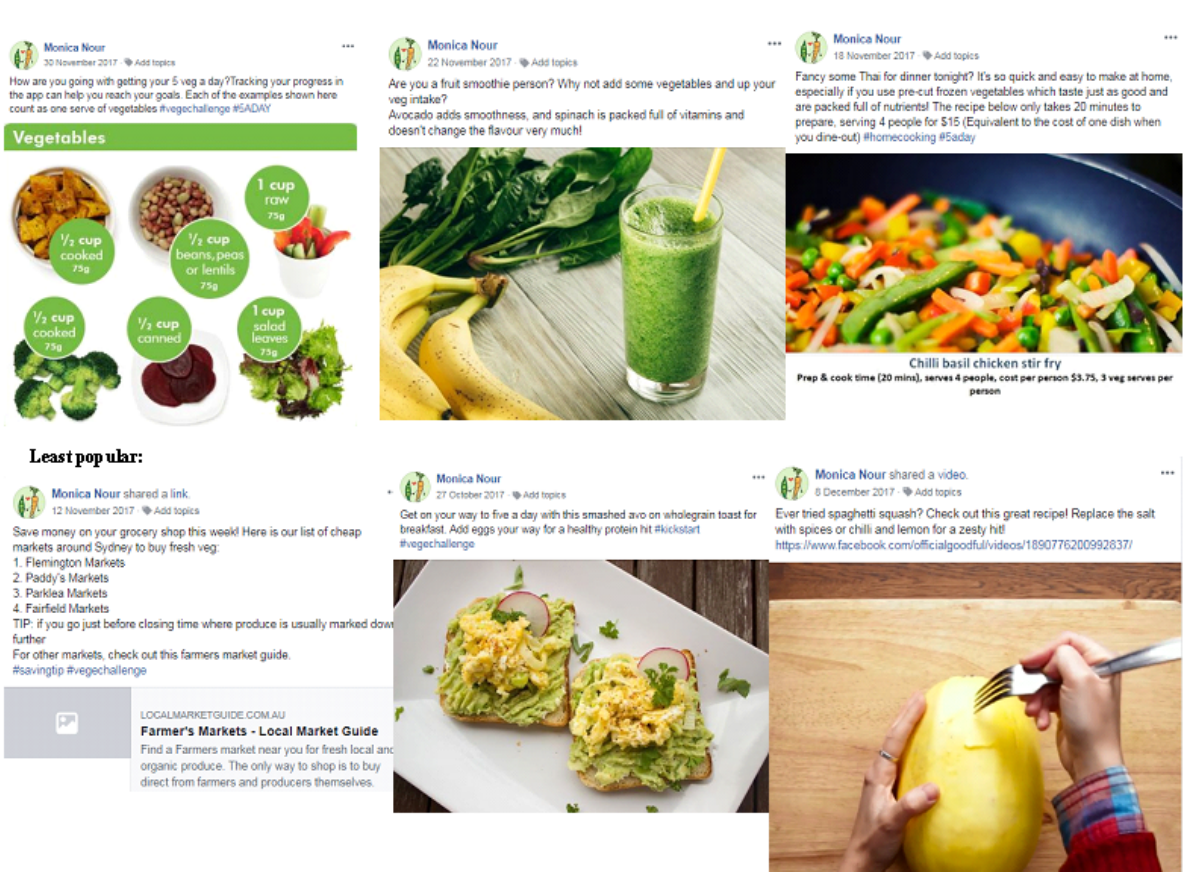
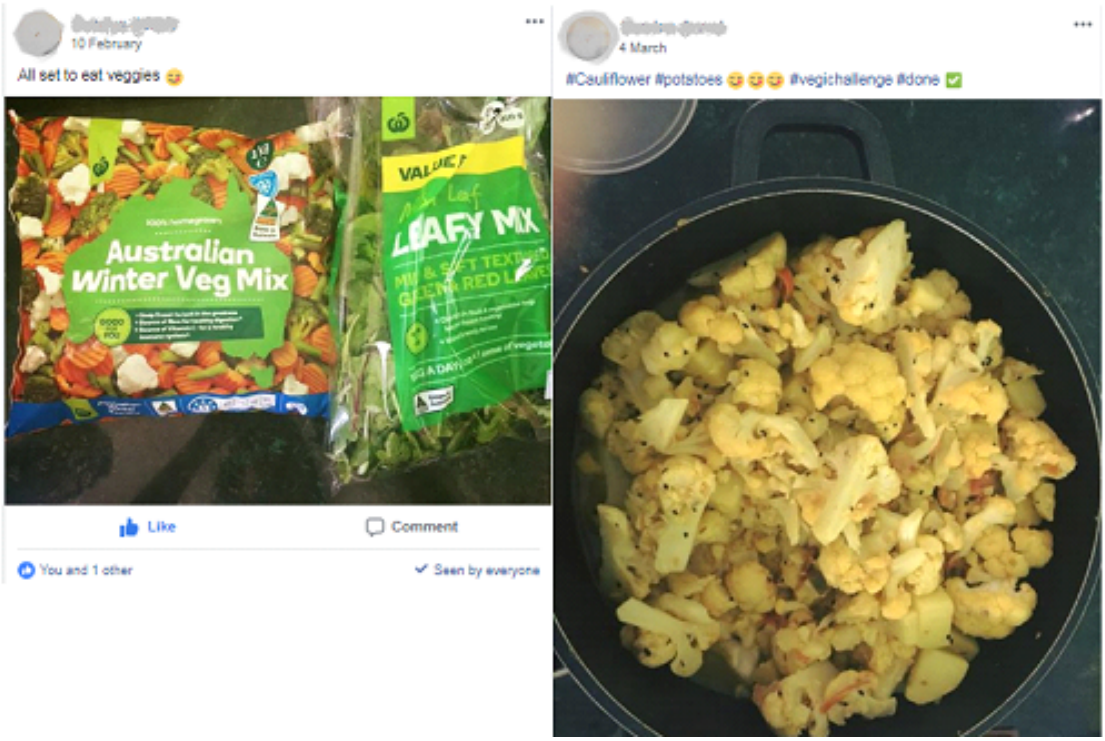


Figure 7. Posts made by members of the Facebook group.



Program Acceptability

Among participants who completed the follow-up questionnaire, the mean rating given to reflect how much the program was *liked* was 3.3 out of 5 (SD 1.2). On average, the program was rated 3.5 out of 5 (SD 1.2) for how useful it was. The differences between groups were not statistically significant in ratings of *liking* or *usefulness*. However, ratings regarding *ease of use*

were more positive for the 2 groups who were allocated the standard self-monitoring app (than people allocated the gaming app for self-monitoring; mean 4.1 [SD 0.85]; *P*=.06).

Qualitative Analysis

App Usability

Back-Logging

One of the most commonly cited disadvantages of the app design was the inability to log vegetables eaten from previous days. In total, 8 out of 10 participants interviewed indicated that on several occasions they remembered to log their vegetable intake too late at night (after midnight) or only remembered the following morning, making it difficult to accurately monitor progress. As stated by a female:

> *I couldn't go back log in the app and put in what I had forgotten so that made it hard to keep track of when I achieved my goals.*

Understanding Vegetable Categories

It was frequently reported by participants that they were unfamiliar with the *vegetable categories* at the start of the program and this made it more challenging to quickly navigate through the app to add in vegetables eaten. For some, they stopped logging; however, for others, they found this as a good opportunity to learn the categories that vegetables belonged to. A male stated:

> *To keep track of the different categories at first was challenging, like which vegetable goes in which category.*

Offline Functionality

In total, 3 participants noted that the apps' inability to allow use when offline made it hard to log at the moment of the meal occasion. These participants would revert to logging their meal consumed on the go when they returned to internet connectivity, which often resulted in missed logging opportunities because of forgetfulness. One male summarized this experience with the statement:

> *The app only loaded when I had internet connection, so when I was out for lunch for example I couldn't add in what I had eaten and would later forget about it.*

Self-Monitoring Saturation

Most participants reported that the goal setting and self-monitoring features of the app were the most useful for increasing vegetable intake. As summarized by 1 male:

> *I found it useful to set a goal of how many veggies to have a day and revise the target over time.*

Despite the positive implications of self-monitoring, a majority of those interviewed also indicated that recording with the app discontinued toward the end of the 4-week period and this resulted in a slight drop in their consumption. As stated by 1 female:

> *It definitely helped to increase vegetable intake at the time when I was using the app, but since I stopped tracking I haven't been accountable for my intake so I feel I am not as conscious." It became apparent in the interviews that use of the app for self-monitoring is likely short-lived. Some stated that they would keep the app on their devices for access to recipes and meal ideas after the interventions end.*

Key Skills Obtained

Self-Assessing Adequacy of Intake

Several participants expressed that they learnt to self-assess daily vegetable intake as well as the variety consumed within a couple of weeks of logging. They liked that the app gave them a *benchmark* goal to work against. A few mentioned that they now give consideration to what they eat throughout the day, and if their consumption of vegetables is low, they would compensate through the dinner meal. This is well summarized by 1 male who stated:

> *I didn't realize how many serves you are meant to eat and the variety, and now I think about the whole day, like I've had some this morning but none all day so I should have some at dinner.*

Meal Planning and Recipe Modification

Many participants reported that they learnt simple ways to increase their vegetable intake such as adjusting commonly prepared meals so that vegetables featured as an ingredient or including vegetables in meals where they would not usually consume them, such as breakfast. For example, 1 male stated:

> *I learnt that it was quite easy to increase your vegetable intake without trying too hard or taking too much time, effort or cost. Like just adding some mushrooms or tomatoes to breakfast.*

The young adults who were responsible for meal preparation indicated that the simple in-app recipes provided good ideas on how to cook with vegetables on a budget. As summarized by one female:

> *The recipes were so simple whereas recipes I look up online are not using my usual pantry items. I liked that I could use leftovers in the fridge especially since I am watching my budget a bit more. The pricing was good.*

Young adults who did not prepare meals at home indicated that they did not use the recipe function within the app, as stated by one male:

> *I live with my parents so they do most of the cooking and that's why I didn't find the recipes relevant.*

Motivation Instilled by Facebook Posts

Participants reported that Facebook notifications served as a reminder to log vegetables when they had forgotten to do so. One male stated:

> *Logging helped me keep track of what I was eating and I did find sometimes the Facebook post would be a reminder to log (especially at the end of the day when I'm busy)." It was indicated that although the tips provided on the Facebook page were motivating,*

the app was critical for keeping track of progress and maintaining motivation to achieve personal intake goals. As one female stated:

Recipes and tips posted on the Facebook group helped but the app was the most motivating to help me achieve my goals and seeing my progress.

Personal Motivations for Participation in the Program

The top 3 reasons for joining the program were: first, being eager to assess whether their current intake was sufficient; second, having the objective of learning ways to add more vegetables to their diet; and finally, a desire to be healthier. As summarized by 1 male participant:

I thought it would be interesting as I have wondered whether I eat enough vegetables. I try to eat healthy as I do a lot of sport and stuff.

Discussion

Principal Findings

This feasibility study established that it is technically possible to deliver an app and social media intervention to improve vegetables intake in young adults, although the impact over 4 weeks was negligible and the prevalence of engagement in the target population with a drop off in engagement over time may limit the overall usage and intervention effectiveness. App use halved over the 4-week period. Similar patterns of attrition are observed in other studies delivered using mobile apps [62]. Although game-based incentives (eg, badges) previously have been shown to enhance engagement with digital interventions [63], we did not find any benefit from the addition of incentives. Paradoxically, the group allocated the gamified app had the highest dropout in week 1. Some research in this field has suggested that gamification is not motivating for all users. Points, levels, and leaderboards are usually encouraging for extraverted people, but not necessarily for the population at large [64]. Thus, future work should consider tailoring the use of incentives in a way that is unique to individual personality traits and user preferences. Furthermore, researchers who integrate gaming features into research-based apps should prioritize usability in the design stage, with detailed end-user testing applied. We found that the more complex user experience associated with our gamified app resulted in a lower score from participants for *ease of use*. This may have contributed to the higher drop out among those allocated the gaming app at enrollment, with evidence suggesting that if ease of use of an app is rated low and complexity high, it is possible that participants will disengage [56].

Although reviews of social media–based studies suggest that engagement is likely to decrease over time [29,65], we found that the percentage of Facebook posts viewed was well maintained over the intervention period with a decrease of only 1% between week 1 and week 4. This may be a result of the efforts expended to pretest the Facebook material before use in the intervention, ensuring what was presented was relevant, acceptable, and sustained the interest of the participants. User engagement in the process of development of intervention materials has been recognized by other researchers as a way to improve retention in social media–based studies [65].

Although we attempted to facilitate opportunities for participants to socialize and support each other within the Facebook group, we observed no peer-to-peer interaction and only 1 participant posted their own material within the group. Thus, the social support (Facebook) groups functioned mainly as an information resource and platform to receive support from a dietitian coach. Given that networking platforms such as Facebook are primarily used to maintain existing social relationships rather than foster new connections [66], future research should consider whether using existing connections of participants such as friends and family results in higher peer-based social support and whether this encourages further improvements in behavioral outcomes or engagement with the program.

Unexpectedly, 3 of 4 groups showed a small decline and only the group using the standard goal setting and self-monitoring app had a small increase in vegetable intake. Although these results were not statistically significant, one possible explanation for the absence of notable improvements in intake may be that the dose (period of exposure to the intervention materials) was not long enough to produce behavior change. The positive correlation observed in our study between app engagement (duration) and vegetable intake post intervention supports the upward trajectory that may be observed in vegetable intake if young adults remain engaged over a longer period of time. There is no existing evidence that suggests the optimal amount of time that is required for engagement with a self-monitoring app to yield behavior change. It has been suggested that participants may rely on such apps sporadically, resuming use when they experience difficulty in maintaining the behavior, and thus change could be incremental [67]. A longer term trial, which follows participants for at least 12 months, will be necessary to capture such patterns of engagement and the downstream behavioral outcomes.The observed decrease in vegetable intake in 3 out of 4 groups may be a true effect, a reflection of the fluctuations that are likely occurring in the diets of young adults or may be a result of the reliance on a self-report measure of intake. Evidence exists to confirm selective over-reporting of vegetables in self-report dietary studies [68]. Furthermore, the poor knowledge of standard serving sizes for vegetables at baseline may have caused overestimation of intake, followed by a more accurate report of intake at follow-up after receiving education on vegetable servings through the program. Finally, although the self-report questionnaire was validated, the tool estimated portions using household measures; whereas in the intervention, participants were trained to record intake using the plate method. The impact of this on the reported intake is uncertain. Future research should consider the use of objective measures such as biomarkers on subsamples of the study population to correct for measurement/reporter bias in results.

Strengths and Limitations

To the best of our knowledge, this was the first study to explore the impact of social support using social media in combination with gaming elements in a nutrition intervention for young adults. A significant strength of this feasibility trial was the development of program components using BCTs, guided by

the COM-B framework. A review on the mediators of successful interventions indicated the importance of a systematic approach to selecting BCTs [69]. In addition, all program materials were pretested for acceptability in focus groups with the target audience [46]. This qualitative user-centered approach of addressing the needs of a population is important for the development of tailored interventions for health behavior change [70,71]. Furthermore, measures were taken to streamline the intervention by delivering all material over the Web and over the phone, allowing implementation of the program at scale. The trial also attracted a higher proportion of males than most other nutrition studies [72-74] and participants from a range of socioeconomic status and education levels. Although a wide range of ethnicities were represented among the included participants, the results are not generalizable to all populations, with people of Aboriginal or Torres Strait Islander and South American descent being underrepresented.

One of the main limitations of this research was that it was a feasibility study and not adequately powered for statistical analysis. To measure a change in vegetable intake by one serve, which is considered a clinically significant outcome [75,76], a sample size of 1000 participants would be required in a 4 group factorial study. Given that the intervention period was only 4 weeks, it is also possible that the program was too short to result in behavior change.

Conclusions

The purpose of this trial was to provide insight into the process of disseminating a social media– and smartphone-based intervention to young adults and assess the acceptability and feasibility of the program. There was no reliance on in-person interaction for dissemination of the program, and the selected platforms (social media, email, and a smartphone app) indicated the feasibility of modern communication technology for the delivery of behavior change interventions to young adults. We found that the uptake of Facebook study materials was better than previously reported in the literature; however, participants engaged passively with no peer-to-peer interaction. Furthermore, engagement with self-monitoring apps decreased over time. We observed that the duration of usage was associated with vegetable intake. Thus, moving forward, this program will require some adaptation and refinement before testing in a larger sample. Further qualitative research with the target audience is needed to develop a deeper understanding of factors influencing engagement, such as personal attributes, and to explore factors that would encourage more effective social support such as using existing social connections or optimizing group size. In addition, consideration should be given to tailoring the use of incentives based on personality traits. Finally, it may be necessary to use a more accurate tool for measuring vegetable intake that does not rely on short self-report questions and instead uses a dietitian-led series of 24-hour dietary recalls or objective measures of change in vegetable intake such as biomarkers.

Acknowledgments

Mr Jisu Jung wrote the necessary codes for the development of the mobile apps used in this 4-week intervention. He received guidance on Human Computer Interaction and design and programming from Professor Judy Kay. Statistician Dr Kevin McGeechan provided advice on the appropriate statistical analysis.

Conflicts of Interest

MAF has received funding from National Health and Medical Research Council, Australian Research Council and Cancer Council NSW and NSW Health.

Multimedia Appendix 1

Educational infographic provided to all participants at baseline via email.

[PNG File, 272KB - formative_v3i2e13324_app1.png]

Multimedia Appendix 2

Diagrammatic description of the intervention with protocol flow for each treatment group including randomization, intervention materials, timeline and frequency of measures. a. Standard app has goal setting and self-monitoring feature with recipe database b. Gamified application has goal setting and self-monitoring feature for improving vegetable intake with weekly challenges around eating more vegetables rewarded with badges. Also includes a knowledge quiz on vegetable types and serving sizes as well as a recipe database c. Facebook page provides social support and access to cooking videos, budgeting & meal planning materials, additional educational resources addressing the link between eating more vegetables and health outcomes.

[DOCX File, 36KB - formative_v3i2e13324_app2.docx]

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Abbreviations

BCT: behavior change technique
COM-B: Capability, Opportunity, Motivation and Behavior
SEIFA: Socioeconomic Index For Areas

Edited by G Eysenbach; submitted 07.01.19; peer-reviewed by M Leung, T Fazzino; comments to author 21.02.19; revised version received 01.03.19; accepted 30.03.19; published 10.05.19.

Please cite as:
Nour M, Chen J, Allman-Farinelli M
Young Adults' Engagement With a Self-Monitoring App for Vegetable Intake and the Impact of Social Media and Gamification: Feasibility Study
JMIR Form Res 2019;3(2):e13324
URL: http://formative.jmir.org/2019/2/e13324/
doi:10.2196/13324
PMID:31094322

Original Paper

Feasibility and Acceptability of Using a Mobile Phone App for Characterizing Auditory Verbal Hallucinations in Adolescents With Early-Onset Psychosis: Exploratory Study

Runar Elle Smelror[1,2], MSc; Josef Johann Bless[3,4], PhD; Kenneth Hugdahl[3,4,5], PhD; Ingrid Agartz[1,2,6], MD, PhD

[1]Department of Psychiatric Research, Diakonhjemmet Hospital, Oslo, Norway

[2]NORMENT Center of Excellence, Institute of Clinical Medicine, University of Oslo, Oslo, Norway

[3]Department of Biological and Medical Psychology, University of Bergen, Bergen, Norway

[4]NORMENT Center of Excellence, Haukeland University Hospital, Bergen, Norway

[5]Division of Psychiatry, Haukeland University Hospital, Bergen, Norway

[6]Centre for Psychiatric Research, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

Corresponding Author:
Runar Elle Smelror, MSc
Department of Psychiatric Research
Diakonhjemmet Hospital
PO Box 85 Vinderen
Oslo, 0319
Norway
Phone: 47 95744029
Fax: 47 22495862
Email: runar.smelror@medisin.uio.no

Abstract

Background: Auditory verbal hallucinations (AVH) are the most frequent symptom in early-onset psychosis (EOP) and a risk factor for increased suicide attempts in adolescents. Increased knowledge of AVH characteristics can lead to better prediction of risk and precision of diagnosis and help identify individuals with AVH who need care. As 98% of Norwegian adolescents aged 12 to 16 years own a mobile phone, the use of mobile phone apps in symptom assessment and patient communication is a promising new tool. However, when introducing new technology to patients, their subjective experiences are crucial in identifying risks, further development, and potential integration into clinical care.

Objective: The objective was to explore the feasibility and acceptability of a newly developed mobile phone app in adolescents with EOP by examining compliance with the app and user experiences. Indication of validity was explored by examining associations between AVH dimensions, which were correlated and analyzed.

Methods: Three adolescents with EOP and active AVH were enrolled. Real-time AVH were logged on an iPod touch using the experience sampling method (ESM), for seven or more consecutive days. The app included five dimensions of AVH characteristics and was programmed with five daily notifications. Feasibility and acceptability were examined using the mean response rate of data sampling and by interviewing the participants. Validity was assessed by examining associations between the AVH dimensions using nonparametric correlation analysis and by visual inspection of temporal fluctuations of the AVH dimensions.

Results: One participant was excluded from the statistical analyses but completed the interview and was included in the examination of acceptability. The sampling period of the two participants was mean 12 (SD 6) days with overall completed sampling rate of 74% (SD 30%), indicating adequate to high compliance with the procedure. The user experiences from the interviews clustered into four categories: (1) increased awareness, (2) personal privacy, (3) design and procedure, and (4) usefulness and clinical care. One participant experienced more commenting voices during the sampling period, and all three participants had concerns regarding personal privacy when using electronic devices in symptom assessment. The AVH dimensions of content, control, and influence showed moderate to strong significant correlations with all dimensions (P<.001). Days of data sampling showed weak to moderate correlations with localization (P<.001) and influence (P=.03). Visual inspection indicated that the app was able to capture fluctuations within and across days for all AVH dimensions.

Conclusions: This study demonstrates the value of including patients' experiences in the development and pilot-testing of new technology. Based on the small sample size, the use of mobile phones with ESM seems feasible for patients with EOP, but the

acceptability of using apps should be considered. Further investigation with larger samples is warranted before definitive conclusions are made.

(JMIR Form Res 2019;3(2):e13882) doi:10.2196/13882

KEYWORDS

experience sampling method; ecological momentary assessment; schizophrenia; mHealth; health care technology

Introduction

Early-onset psychosis (EOP) is psychotic disorders with age of onset before 18 years of age. EOP is often characterized by a chronic illness course with impaired social and daily functioning [1,2]. The most frequent symptom in EOP is auditory verbal hallucinations (AVH), which is found in 82% of patients [3]. Although AVH are relatively common among adolescents in the general population (prevalence ranging from 7.3% to 12.4%) [4-6], 34% of adolescents with AVH and psychopathology have had at least one suicide attempt compared to 13% of adolescents without AVH [7]. This emphasizes the need to further investigate AVH in youth to better identify individuals with need for care and learn more about the underlying mechanisms causing this phenomenon [8].

Assessing AVH using traditional retrospective measures, such as the Positive and Negative Syndrome Scale (PANSS) [9] or the Scale for the Assessment of Positive Symptoms (SAPS) [10], may lead to loss of symptom information due to recall errors and state-dependent biases [11-13]. Real-time monitoring of symptoms increases the ecological validity and enables researchers to gather new and different information from patients [12,14,15]. The experience sampling method (ESM) [16] was originally based on self-reports (such as diary entries) to monitor real-time experiences and symptom frequency daily. Therefore, ESM would seem well-suited for use with mobile phone apps to assess and monitor psychopathology and symptom characteristics in patients with schizophrenia [15,17-20], including AVH [21]. In an ESM study of adults with schizophrenia spectrum and affective disorders, Delespaul and colleagues [22] found that AVH had higher intensity than visual hallucinations, and that anxiety was the strongest predictor of hallucination intensity compared to other mental states. They also found that anticipatory anxiety was present before the start of AVH, but not for visual hallucinations.

In Norway, 98% of adolescents aged 12 to 16 years own a mobile phone [23], and the Norwegian Health Authority suggests using mobile phones in communication with youth with EOP to support school attendance [24]. The use of mobile phone apps for symptom assessment in adolescents and young adults with psychotic disorders is feasible over longer time periods [25,26]. There are at least 11 mobile phone apps that have been developed for schizophrenia [20,27-33]. However, most of the apps focus on self-management, in which symptoms are a small part [21]. Increased knowledge of AVH characteristics, such as localization (external/internal), cognitive control (uncontrollable/controllable), distress (negative/positive), and fine-grained temporal patterns of frequency and fluctuations, can lead to better quantification of symptom dynamics over time and contribute to new treatment opportunities. This could come about through improving the prediction of risk and precision of diagnosis, identifying needs for services, enabling measurement-based care, and increasing autonomy and independence in patients [34-36]. When introducing new technology to vulnerable groups, such as EOP patients, the risks need to be considered against potential benefits [35]. Thus, patients' subjective experiences are crucial in further development and potential integration of new technology into clinical care [37,38], which was a focus of this study.

We piloted a newly developed mobile phone app designed to monitor AVH characteristics at the moment they occur in adolescents with EOP. It is of particular interest to investigate these phenomena in adolescents because this life period is a challenging maturation process for neurological and psychological development [39,40], and because they are less influenced by confounding factors (eg, long-term medication use, lifestyle-related illnesses, substance use). The objective was to explore the feasibility and acceptability of the app by examining compliance with the sampling procedure and the patients' subjective experiences. In addition, validity was explored by analyzing associations between the five AVH dimensions included in the app. Data collected with the app have also been analyzed in a larger sample of patients, focusing on the statistical aspects of the AVH dimensions (JB and KH, unpublished data, 2019). Those results are not presented in this study.

Methods

Participants

The study was approved by the South East Regional Committee for Medical and Health Research Ethics, Oslo, Norway, and conducted in accordance with the Helsinki Declaration. Four adolescents with EOP and active AVH, already included in the larger ongoing Thematically Organized Psychosis Study for Youth (Youth-TOP) from 2016 to 2018, were invited to participate in this pilot study. One patient refused to participate for unknown reasons, resulting in a total of three enrolled participants. Of the three, one used the app in a psychiatric unit and two used it in their home environment.

The participants were recruited from adolescent psychiatric inpatient units and outpatient clinics in the Oslo region. The inclusion criteria were (1) nonaffective EOP (schizophrenia, schizoaffective disorder, schizophreniform disorder, psychotic disorder not otherwise specified, brief psychotic disorder) according to the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition); (2) having experienced AVH during the past week at the time of inclusion, defined as scoring 4 or higher on item P3 of the PANSS [9]; (3) written informed consent obtained from participants, parents, or guardians (if the

participant was younger than 16 years); and (4) language abilities to complete the interviews and self-rating questionnaires. Exclusion criteria were (1) general intelligence quotient (IQ) less than 70, (2) previous moderate/severe head injury, (3) diagnosis of substance-induced psychosis, (4) organic brain disease, and (5) noncompliance to the sampling procedure (ie, insufficient amount of self-assessments in the app, not using the app for a minimum of seven consecutive days). The participants received monetary compensation of 500 Norwegian kroner (approximately €50) after completing the sampling period. They were informed that participation was voluntary, it would not influence their clinical care, and they could stop using the app at any time and still get the monetary compensation.

Measures

Diagnoses were confirmed using the Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime version [41]. Global functioning was assessed using the Children's Global Assessment Scale (CGAS) [42]. IQ was assessed using the Wechsler Abbreviated Scale of Intelligence [43]. Current psychopathology, including degree of hallucinatory experiences, and individual beliefs about AVH were assessed before and after the app sampling period using the PANSS and the Beliefs About Voices Questionnaire-Revised version (BAVQ-R) [44,45]. The BAVQ-R includes three subscales regarding beliefs about voices: malevolence ("bad voices"), benevolence ("good voices"), and omnipotence ("powerful voices") and two subscales regarding emotional and behavioral reactions to voices: resistance and engagement. The participants' subjective experiences were collected using a semistructured user-experience interview developed in-house by us.

Overview of the Mobile Phone App

The mobile phone app was originally developed by coauthors KH and JB at the University of Bergen, Norway (see [46]). It was programmed in Xcode 4.2 (Apple Inc, Cupertino, CA, US), which makes it compatible with iOS devices such as the iPod touch. The selected AVH dimensions in the app were based on relevant research (see Johns and colleagues [47]). We received input from one service user during the development. The app includes five visual analog scales (VAS), each representing a separate AVH dimension: cognitive control (no control/full control of voices), emotionality of content (negative/positive voices), perceptual localization (voices perceived outside/inside head), intensity (voices are yelling/whispering), and influence (not at all/very disturbing voices). The outline of the app is illustrated in Figure 1. The prototype of the app was reviewed and approved by an adult user representative before pilot-testing with adolescents was initiated.

Figure 1. How the app is used by the participants. In the first screen the participant chooses yes or no to whether they hear voices right now. If they answer "yes," the five following screens with the visual analogue scales for the five auditory verbal hallucinations (AVH) dimensions appear. Each screen represents the following AVH characteristic: content (emotional), localization (perceptual), control (cognitive), intensity (intensity), and influence (influence). Previously presented on a poster at the International Congress on Schizophrenia Research, March 24-28, 2017; San Diego, CA, with the abstract by Bless et al [46]. iPhone frames adopted from a design by Todd Zaki Warfel.

Procedure

The participants sampled real-time AVH experiences on an iPod touch (Apple Inc, Cupertino, CA, US) provided by us, with a preinstalled version of the app. We chose to use iPods instead of mobile phones in the pilot study to guarantee the personal privacy of the participants. The iPods were not connected to the internet. The app was programmed with five daily notifications at pseudorandom time points from 10:00 to 22:00 (within five time intervals of 1.5 hours), in accordance with recommendations from Palmier-Claus and colleagues [48]. The participants were asked to respond to the five daily notifications as soon as possible after the beep, for a minimum of seven consecutive days. They were also informed that they could sample data in addition to the five times if they experienced AVH. Before and after completing the data sampling period the participants were asked to complete the BAVQ-R and a short version of the PANSS, covering the positive subscale. The sampling period began immediately after instructions of the app were given and the informed consent was collected. To facilitate compliance with the procedure, the first author (RES) contacted the participants once per week to ask about any difficulties using the app and offer support. The app file contained the date and time of the reports, and the VAS scores (ranging from 0 to 1) in chronological order. No personal user information was stored on the iPod. After completing the sampling period,

user-experience interviews were conducted with each participant by author RES. To increase the face validity of the participant responses, alliance and trust were established before the interviews. Moreover, one of the participants' parents was present during the interviews, and the participants were encouraged to report their subjective experiences of the app, either positive or negative.

Data Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows version 25. Feasibility was examined using the mean response rate of the data sampling, calculated by dividing the total number of responses by days using the app multiplied by five (as five daily registrations indicated 100% compliance). Acceptability was examined by interviewing the participants about their subjective experiences of using the app. The participant experiences were written down. No voice or video recordings were used. Thus, the transcriptions of the participants' subjective experiences are not verbatim quotes, but reproductions based on the written material. Indication of validity was assessed by examining associations between the AVH dimensions using two-tailed Spearman rho (ρ) nonparametric correlation analysis and visual investigation of the fluctuations of the AVH dimensions. This was done by making a graph with the mean symptom scores and days of sampling, defined as the number of data entries. Different time intervals between each data entry were not taken into consideration (ie, the time period between the first and second data entry might have differed from the second and third entry).

Results

Participants

The demographics of the three participants were mean age 17.7 (SD 1.6) years, mean age of onset for psychosis 14.9 (SD 0.7) years, mean duration of untreated psychosis 32 (SD 22) weeks, mean illness length 2.8 (SD 1.8) years, mean IQ score 93.7 (SD 8.0), and mean CGAS score 36 (SD 4). Two of the three participants were taking atypical antipsychotic medications. One of the three was excluded from the statistical analyses due to noncompliance with the procedure. This participant did not sample real-time data for seven consecutive days and had some aggregated registrations (ie, five samplings at the same time during the afternoon/evening). According to the participant, the reason for noncompliance was partly due to having to bring two devices to daily activities. The participant did not differ from the remaining two regarding age, sex, global functioning, or symptom severity. Thus, the participant's subjective experiences were included in the examination of acceptability. The average sampling period of the two remaining participants was mean 12 (SD 6) days with a mean response rate of 74% (SD 30%) indicating adequate to high compliance with the sampling procedure.

Clinical Assessment

The participants had stable PANSS scores before and after the sampling period with an average positive sum score of 14 and a P3 score of 4. The malevolence scale on the BAVQ-R was reduced by 3 points, from 11.0 to 8.0. The omnipotence scale was similarly reduced by 1.6 points, from 13.3 to 11.7. The resistance scale was also reduced by 0.7 points, from 16.0 to 15.3, and the engagement scale was reduced by 2 points, from 6.0 to 4.0. The BAVQ scores thus showed a general improvement in AVH characteristics regarding malevolence and omnipotence during the sampling period.

Acceptability

Mixed experiences of the app were reported when exploring the acceptability, clustered into four main categories: (1) increased awareness, (2) personal privacy, (3) design and procedure, and (4) usefulness and clinical care. Examples of the participant subjective reports are presented in Table 1.

Table 1. Illustrations of participant experiences after the sampling period (N=3).

Experience	Sample statements[a]
Increased awareness	I became aware at every registration. It was okay to become more aware. Nothing was negative.
	I was reminded of the voices. I usually try to avoid that. I got more commenting voices, saying 'now he/she's doing it again, why is he/she registering us?' That's why I haven't used it so much.
Personal privacy	I was a bit worried of being watched when I used the app. I saw the camera in front of the iPod. I don't like cameras.
	I have felt monitored when using the app, particularly in the beginning, because of the notifications. I liked that it was offline. I'm afraid of leaving traces on the internet.
	It's not secure, you may get hacked.
Design and procedure	The app was short and easy to understand. It was a bit much of the same questions. I was watching the iPod all the time, not knowing when the next notification would come. I thought a lot about when the next notification would come.
	It was okay with five notifications per day. If the notifications came at set time points it could help reduce thoughts about being monitored. I liked that I could write notes at the end.
	The layout was nice; the visual scales and the order of the statements were nice. Maybe three registrations in one day instead.
Usefulness and clinical care	It wasn't very useful. Might be helpful to others, I don't know.
	Nice to register symptoms. It would be very nice to have in clinical care. When I'm feeling down it's hard to answer questions. It's okay to use the app if the voices are not in control, that they don't have opinions about what you should answer. If the voices are in control you might give the wrong answer.
	It was useful to learn about the voices. It was difficult to remember to sample data toward the end. I forgot the iPod at home or in my backpack. I don't want it as part of my treatment, I prefer to talk.

[a]The statements are illustrations of the participants' subjective experiences, not quotes.

Increased Awareness

Two participants reported becoming more aware of their AVH when using the app. One participant reported that the increased awareness was positive, whereas the other reported it as negative, resulting in more commenting voices. This was reported as the main reason for stopping using the app by the latter participant.

Personal Privacy

The participants had concerns regarding personal privacy when using apps and technology as part of their symptom assessment. Although they knew that the iPod was offline during the sampling period, they reported having fears of being monitored through the camera or the notifications from the app. In general, they reported worries about leaving electronic traces on the internet and being hacked. All participants considered it positive that the iPod was not connected to the internet during the pilot testing. This may be an argument to use iPod-like devices rather than real mobile phones to reduce these kinds of worries. However, it should be noted that such worries and concerns may also be part of the illness, as increased suspiciousness of being "monitored" from the outside is a not uncommon symptom.

Design and Procedure

The participants liked the design of the app, that it was short (completed the self-assessments in about 1 minute), easy to understand, and it had the option of writing notes at the end. One participant would have preferred having numbers on the VAS scales to make scoring easier. Two participants reported that five daily notifications were adequate, whereas one thought this was too much and suggested three as an alternative. Two participants reported discomfort from the random notifications, reporting thoughts of being monitored and concerns and preoccupations regarding the next notification. They suggested having notifications at set times. Furthermore, one participant reported that the repetitiveness of the self-assessments was a bit much when sampling data five times per day for one week, and suggested adding more varied self-assessments to the app. The reports were mixed, which points to the importance of considering more technical issues such as design when developing apps.

Usefulness and Clinical Care

Two participants reported that it was nice to register symptoms and learn more about the voices. However, the same participants reported decreased motivation toward the end of the sampling period and when their mood was low. One participant reported that using technology in treatment could be a useful alternative to answer verbal questions, but that self-reports could be biased if the voices were in control and had opinions about what to report. This is not an argument against the use of apps because the same could apply using traditional self-reports. However, the statement indicates that personal contact is an important part of clinical care and that apps and technology potentially can be used to monitor remission and relapse as part of measurement-based care, as suggested by Insel [35]. Two participants did not want to include the app as part of their clinical care. All participants reported concerns about personal privacy regarding the use of technology in clinical care.

Validity

Indications of validity were assessed by examining associations between the AVH dimensions and by examining the fluctuations of the AVH dimensions during 1 week of sampling. Table 2 shows correlations between the five AVH dimensions and days of sampling (ie, number of data entries). Content, control, and influence showed moderate (defined as ρ=±.5-.7 [49]) to strong (defined as ρ=±.7-.9) significant correlations with all dimensions: content and influence (ρ=–.80, *P*<.001), control (ρ=.73, *P*<.001), intensity (ρ=.43, *P*<.001), and localization (ρ=.50, *P*<.001); control and influence (ρ=–.77, *P*<.001), intensity (ρ=.48, *P*<.001), and localization (ρ=.41, *P*<.001); and influence and intensity (ρ=–.44, *P*<.001) and localization (ρ=–.56, *P*<.001). No significant correlation was found between intensity and localization. Days of data sampling showed weak (defined as ρ=±.3-.5) to moderate correlations with localization (ρ=.51, *P*<.001) and influence (ρ=–.25, *P*=.03), and nonsignificant correlations with content (ρ=.22, *P*=.06) and control (ρ=.21, *P*=.07). As shown in Figure 2, the app was able to capture the fluctuations of the five AVH dimensions within and across 7 days of sampling.

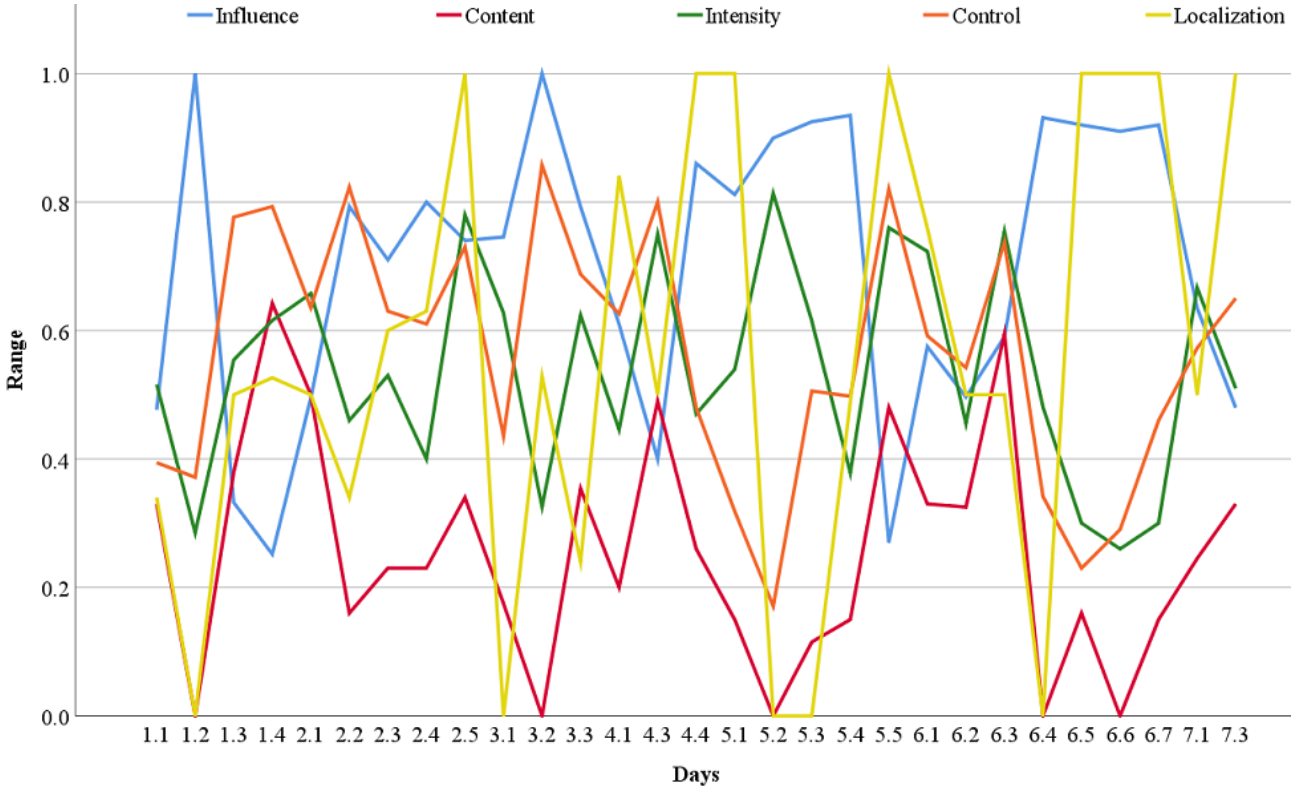
Table 2. Spearman rho (ρ) correlations for the participants completing the sampling period (N=2). Influence: not at all (0) to very disturbing (1); content: negative (0) to positive (1); intensity: yelling (0) to whispering (1); control: no control (0) to full control (1); localization: outside head (0) to inside head (1). All correlations were two-tailed.

AVH[a] dimension	Content		Control		Influence		Intensity		Localization		Day	
	ρ	*P* value	ρ	*P* value	ρ	*P* value	ρ	*P* value	ρ	*P* value	ρ	*P* value
Content	1	—[b]	.73	<.001	–.80	<.001	.43	<.001	.50	<.001	.22	.06
Control	.73	<.001	1	—	–.77	<.001	.48	<.001	.41	<.001	.21	.07
Influence	–.80	<.001	–.77	<.001	1	—	–.44	<.001	–.56	<.001	–.25	.03
Intensity	.43	<.001	.48	<.001	–.44	<.001	1	—	.12	.30	.05	.64
Localization	.50	<.001	.41	<.001	–.56	<.001	.12	.30	1	—	.51	<.001
Day	.22	.06	.21	.07	–.25	.03	.05	.64	.51	<.001	1	—

[a]AVH: auditory verbal hallucinations.

[b]Not applicable.

Figure 2. Mean scores of two participants for the five auditory verbal hallucination dimensions within and across 7 days of sampling.



Discussion

The objective of this exploratory study was to examine the feasibility, acceptability, and indication of validity of a newly developed mobile phone app for auditory verbal hallucination characteristics in adolescents with EOP.

Auditory Verbal Hallucination Fluctuations Captured by the Experience Sampling Method

Although the statistical analyses of this study only included two participants, the correlation analyses and the graph containing within and across day fluctuations indicate that the app is valid for use in adolescents with EOP. The content, control, and influence dimensions were significantly correlated with all the AVH dimensions, indicating that these characteristics are important among these patients. This finding is in accordance with a study in adults with AVH, showing that experiences of mostly negative, uncontrollable, and distressing voices were important characteristics in separating nonpsychotic individuals from individuals with psychotic disorders [34]. Furthermore, the presence of this pattern of AVH characteristics (ie, negative content associated with less control and more disturbing voices) required that the participants consistently scored the influence dimension in the opposite direction to the content and control dimensions on the VAS scales, which confirms intentional responses from the participants. This indicates that the AVH dimensions in the app demonstrate internal consistency and construct validity, although further investigations in larger samples must be conducted before conclusions can be made. We also found significant correlations between the negative content, lack of control and disturbing voices, and external localization, suggesting that the AVH were perceived as more outside their heads when they were negative, uncontrollable, or distressing. However, perceived localization of voices was not significantly different between nonpsychotic and psychotic patients, in which individuals with psychotic disorders to a similar extent perceived the voices coming from inside their heads [34].

Increased Awareness

The user-experience interviews revealed that two participants experienced increased awareness of the AVH when using the app, highlighting the need for researchers to consider that the assessment process itself may exert an influence on the individual through reactivity effects [50]. Increased self-awareness is associated with increased negative affect, particularly in individuals with existing high negative affectivity [51,52]. In a mobile phone study of happiness, Conner and Reid [53] found a negative association between happiness and number of daily reports in participants with high negative affectivity, whereas a positive association was found in participants with low negative affectivity. The authors suggested that frequent data sampling increased the participants' self-awareness, which in turn intensified the underlying emotional state (negative or positive) [53]. The increased awareness is in accordance with a previous study of adults with schizophrenia, showing increased preoccupation with thoughts when repeatedly assessing symptoms using a mobile phone [36]. In terms of metacognitive theory [54], this finding suggests that repetitive sampling of AVH increased the participants' metacognitive level of cognitive self-consciousness (ie, preoccupation of thoughts; see also [55,56]). The findings can be interpreted that both participants in our study showed increased levels of cognitive self-consciousness, yet the participant with the negative experience was more preoccupied with the AVH and had stronger beliefs regarding the need to control thoughts and the uncontrollability of thoughts. However, the BAVQ-R showed reduction of experienced malevolence and omnipotence. Moreover, nonsignificant correlations were found in the direction of more positive content and control of voices across the days of app use, as shown in Table 2.

Privacy Concerns

The participants reported concerns about personal privacy when using electronic devices for symptom assessment and considered it positive that the iPod was offline during the pilot study. This is in accordance with a study showing that one-third of a sample of young adults with psychotic disorders experienced discomfort in online settings [37]. This finding suggests that personal privacy concerns should be carefully discussed before data sampling is initiated. It also suggests that offline sampling devices, such as iPods, are perhaps preferred if the participants are uncomfortable using online apps.

Adherence to the Protocol

Previous mobile phone studies including adolescents and adults with psychotic disorders showed enrollment and dropout rates of approximately 50% and 5%, respectively [25,26]. However, comparisons of enrollment and dropout rates in this study are difficult due to the small number of participants included. The two participants compliant with the sampling procedure had a mean response rate of 74% over an average of 12 days, which is considerably more than the recommended minimum of 33% [48]. This finding indicates that adolescents with EOP are willing to participate in research using electronic devices to self-assess symptoms several times per day. The mean response rate also illustrates that the participants confirmed having AVH several times per day for a minimum 1 week, which is consistent with the moderate hallucination score they received on the PANSS and suggests that the app measured the target construct of hallucinations. According to the noncompliant participant, the insufficient amount of sampling was primarily caused by having to bring two devices to daily activities. This suggests that the noncompliance was a result of the pilot test (having to bring two devices), not the app itself.

The number and randomness of notifications and the repetitiveness of the statements were reported as too much and associated with discomfort. Studies have found that too many notifications and repetitive self-assessments may result in higher dropout rates in ESM studies and a biased representation of participants completing the sampling period [38,48]. Furthermore, although random notifications are preferred in ESM studies [48], this was associated with discomfort among the participants in this pilot study, suggesting that compliance among adolescents with EOP may increase by having fewer daily notifications than in studies involving adult patients, and having notifications at fixed time points instead of at random times. Alternatively, the use of machine learning approaches

has been suggested as a means to individualize the number of notifications and variation in questions, and thus increase compliance and engagement with ESM studies [36,57].

Integration into Clinical Care

One participant considered integrating technology into clinical care as a potentially useful alternative to verbal communication if the voices were not in control. However, the interpersonal aspect of existing care was emphasized as an important factor. This finding is in accordance with a previous study in adults with psychotic disorders, showing that technology may be perceived as a threat to existing care and that self-reports may be biased [36]. Furthermore, although support was offered during the sampling period, we were not able to capture the mixed experiences of the participants over the phone. In a mobile phone study of adults with psychotic disorders, Kumar and colleagues [26] found lower completion rates among participants with more severe symptoms, suggesting that additional support is warranted in such cases. In sum, these findings suggest that the use of mobile phones as part of clinical care is viable for adolescents with EOP as an addition to existing care. The results also suggest that the assessment of psychotic symptoms may be more suitable for use over shorter time periods, (eg, after discharge from the hospital, starting a new medication), as suggested by Palmier-Claus and colleagues [36], and that adolescents may require more support during the sampling period compared to adults.

Conclusions

This study shows that including patients' subjective experiences in the development and pilot-testing of health care technology may provide useful information in addition to statistical analyses. Based on the mean response rate of the two participants included in the statistical analyses, the use of mobile phones with ESM in adolescents with EOP seems feasible, although this warrants further investigation with larger samples. Regarding acceptability, there are limitations with the use of apps, and care should be taken such that the app is perceived as meaningful, comfortable, and safe. As mentioned previously, limitations may be that apps produce unexpected distressing thoughts and unwanted focus on negative feelings such as anxiety. Therefore, it may help to have a plan if distress is experienced. As an alternative to online apps, offline versions could be considered to avoid the risk of inducing or reinforcing unwanted persecutory delusions. Our conclusion is that the use of app technology for real-time monitoring of psychotic symptoms can provide new knowledge of daily and even hourly fluctuations and severity of hallucinatory episodes, which can increase diagnostic resolution. Moreover, such information can have therapeutic effects if it corresponds with similar fluctuations in cognitive control and experienced distress, for example, which can be suitable targets for psychosocial interventions, such as cognitive therapy.

Acknowledgments

The authors would like to thank the research participants and their families who provided the data. This work was supported by the South-Eastern Norway Regional Health Authority (2016-118), and the Research Council of Norway (213700, 250358) to Ingrid Agartz, and the European Research Council (ERC) (249516), and the Western Norway Regional Health Authority (912045) to Kenneth Hugdahl.

Authors' Contributions

RES recruited and interviewed the participants, drafted the manuscript, and performed the statistical analyses. KH and JB designed and developed the mobile phone app. IA and KH obtained research funding and contributed to the design of the study protocol. JB, KH, and IA gave feedback on the manuscript draft. All authors have read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AVH: auditory verbal hallucinations
BAVQ-R: Beliefs About Voices Questionnaire-revised version
CGAS: Children's Global Assessment Scale
EOP: early-onset psychosis
ESM: experience sampling method
IQ: intelligence quotient
PANSS: Positive and Negative Syndrome Scale
VAS: visual analog scale

Edited by G Strudwick; submitted 02.03.19; peer-reviewed by P Urwyler, J Duffecy; comments to author 18.03.19; revised version received 21.03.19; accepted 30.03.19; published 14.05.19.

Please cite as:
Smelror RE, Bless JJ, Hugdahl K, Agartz I
Feasibility and Acceptability of Using a Mobile Phone App for Characterizing Auditory Verbal Hallucinations in Adolescents With Early-Onset Psychosis: Exploratory Study
JMIR Form Res 2019;3(2):e13882
URL: http://formative.jmir.org/2019/2/e13882/
doi:10.2196/13882
PMID:31094321

Original Paper

Internet-Based Cognitive Therapy for Social Anxiety Disorder in Hong Kong: Therapist Training and Dissemination Case Series

Graham R Thew[1,2,3], DClinPsy, DPhil; Candice LYM Powell[4], PsyD; Amy PL Kwok[5], PhD; Mandy H Lissillour Chan[6], PsyD; Jennifer Wild[1], DClinPsy; Emma Warnock-Parkes[1,7], DClinPsy; Patrick WL Leung[8], PhD; David M Clark[1], DPhil

[1]Department of Experimental Psychology, University of Oxford, Oxford, United Kingdom
[2]Oxford University Hospitals National Health Service Foundation Trust, Oxford, United Kingdom
[3]Oxford Health National Health Service Foundation Trust, Oxford, United Kingdom
[4]New Life Psychiatric Rehabilitation Association, Hong Kong, China (Hong Kong)
[5]New Territories East Cluster, Hospital Authority, Hong Kong, China (Hong Kong)
[6]Kowloon Central Cluster, Hospital Authority, Hong Kong, China (Hong Kong)
[7]Kings College London, London, United Kingdom
[8]The Chinese University of Hong Kong, Hong Kong, China (Hong Kong)

Corresponding Author:
Graham R Thew, DClinPsy, DPhil
Department of Experimental Psychology
University of Oxford
The Old Rectory
Paradise Square
Oxford, OX1 1TW
United Kingdom
Phone: 44 01865 618600
Email: graham.thew@psy.ox.ac.uk

Abstract

Background: Guided internet-based psychological interventions show substantial promise for expanding access to evidence-based mental health care. However, this can only be achieved if results of tightly controlled studies from the treatment developers can also be achieved in other independent settings. This dissemination depends critically on developing efficient and effective ways to train professionals to deliver these interventions. Unfortunately, descriptions of therapist training and its evaluation are often limited or absent within dissemination studies.

Objective: This study aimed to describe and evaluate a program of therapist training to deliver internet-based Cognitive Therapy for social anxiety disorder (iCT-SAD). As this treatment was developed in the United Kingdom and this study was conducted in Hong Kong with local therapists, an additional objective was to examine the feasibility, acceptability, and initial efficacy of iCT-SAD in this cultural context, based on data from a pilot case series.

Methods: Training in iCT-SAD was provided to 3 therapists and included practice of the face-to-face format of therapy under clinical supervision, training workshops, and treating 6 patients with the iCT-SAD program. Training progress was evaluated using standardized and self-report measures and by reviewing patient outcomes. In addition, feedback from patients and therapists was sought regarding the feasibility and acceptability of the program.

Results: The training program was effective at increasing therapists' iCT-SAD knowledge and skills, resulting in levels of competence expected of a specialist Cognitive Behavioral Therapy practitioner. The 6 patients treated by the trainees all completed their treatment and achieved a mean pre- to posttreatment change of 53.8 points (SD 39.5) on the primary patient outcome measure, the Liebowitz Social Anxiety Scale. The within-group effect size (Cohen *d*) was 2.06 (95% CI 0.66-3.46). There was evidence to suggest that the patients' clinical outcomes were sustained at 3-month follow-up. These clinical results are comparable to those achieved by UK patients treated by the developers of the internet program. Patient and therapist feedback did not identify any major cultural barriers to implementing iCT-SAD in Hong Kong; some modest language suggestions were made to assist understanding.

Conclusions: The therapist training implemented here facilitated the successful dissemination of an effective UK-developed internet intervention to Hong Kong. The treatment appeared feasible and acceptable in this setting and showed highly promising initial efficacy. A randomized controlled trial is now required to examine this more robustly. As therapist training is critical to the successful dissemination of internet interventions, further research to develop, describe, and evaluate therapist training procedures is recommended.

(JMIR Form Res 2019;3(2):e13446) doi:10.2196/13446

KEYWORDS

anxiety; social phobia; internet; cognitive therapy; clinical competence; cross-cultural comparison; Hong Kong; benchmarking; psychology, clinical; mental health

Introduction

Background

The delivery of psychological therapies via the internet has received a good deal of research attention in recent years. Multiple randomized controlled trials (RCTs) have shown that CBT-based internet interventions can be effective in treating depression and anxiety disorders when compared with no treatment [1-3], with the effects being larger when patients' online work is guided and supported by a clinician or coach [4-6]. Some guided internet treatments have also shown results comparable to face-to-face treatment in RCTs, despite requiring much less clinician time [1,7-9]. These findings suggest that internet therapies have substantial potential for expanding access to effective psychological treatments, which is critical given the undertreatment of common mental health problems such as social anxiety in almost all countries [10]. However, this potential will only be realized if the results that are obtained by the developers of these internet interventions in tightly controlled RCTs can be maintained when those interventions are made available in other settings, providing treatment routinely and with guidance from clinicians who were not involved in developing the program. Whether this is possible will depend critically on the extent to which the field can develop efficient and effective ways of training clinicians to support and guide patients going through these interventions. Large-scale dissemination of therapist-guided interventions will only be achievable if effective therapist training methods are in place.

Promisingly, several studies have attempted to disseminate internet therapies beyond the teams that have developed the interventions and have reported promising results. These include the translation and trialing of Swedish internet-based Cognitive Behavioral Therapy interventions in Romania [11] and Norway [12], a Swiss intervention implemented in China [13], and a Spanish intervention trialed in the Netherlands [14]. However, none of these studies have provided sufficient detail about how the therapists or coaches in the dissemination sites were trained and how the effectiveness of the training was evaluated. There is a clear need for such descriptions if the field is to reliably succeed with dissemination. This study aimed to address this by describing in detail an example of how clinicians in Hong Kong were trained to deliver an effective internet therapy for social anxiety disorder (SAD) that was developed in the United Kingdom and how this training was evaluated.

The internet-based Cognitive Therapy for social anxiety disorder (iCT-SAD) program is based on Clark and Wells' face-to-face Cognitive Therapy for SAD (CT-SAD). CT-SAD has strong empirical support for the treatment of SAD, showing efficacy superior to that of various alternative treatments in RCTs [15-18] and a network meta-analysis [19]. As a result, the UK National Institute for Health and Care Excellence recommends CT-SAD as a first-line treatment for adults with SAD [20]. The iCT-SAD program implements all the procedures of face-to-face CT-SAD online, including special features such as video feedback of social performance and behavioral experiments that allow patients to test out their feared concerns. It includes multiple brief video clips illustrating key assignments that patients are encouraged to do to challenge their fearful beliefs, as modeling has been shown to be one of the most effective ways of reducing anxiety [21]. The treatment is delivered through a series of online modules, which include core modules given to all patients, and a range of optional modules targeting different specific concerns (eg, blushing, feeling boring, worrying in advance). These allow the therapist to tailor the treatment to patients' individual needs. As most of the therapy content is delivered by the program, iCT-SAD greatly reduces the amount of therapist time required per patient compared with face-to-face CT-SAD [22]. The aim of iCT-SAD is that most of the key learning that occurs in the treatment can be achieved by the patient's self-study on the internet, facilitated by therapists who are themselves skilled in delivering the face-to-face treatment. This online facilitation draws strongly on the clinical knowledge expected of an experienced clinician but asks them to apply this in a very different way. The program introduces the key concepts that would normally be introduced by the therapist and guides much of the patient's learning. Therefore, the therapist must carefully monitor patients' progress within the program, looking closely at what the patient has and has not already learnt, and then make clinically informed suggestions to help them deepen and extend their learning. For example, they may support the patient to plan new behavioral experiments or direct them to other sections of the program that are most appropriate for their particular concerns. Therefore, it may be particularly critical to pay close attention to how therapists are trained to deliver an internet intervention of this sort, given that the therapist's role, and the application of their clinical knowledge, is different compared with face-to-face interventions.

As this study involved dissemination to a different culture as well as to a different team, it also had to consider issues about the extent of cultural adaptation of the treatment that would be required. One approach to this problem would be to assume that

if the treatment is delivered in a different culture it has to be adapted in ways beyond linguistic translation alone and that this must be done before any evaluation of the treatment in the new context. An alternative approach is to first pilot the intervention in its unadapted form to benchmark it against results from studies in its country of origin and, at the same time, to obtain feedback from clients and therapists about what adaptations they think might be needed. This latter approach, which aims to identify the minimum number of adaptations required, was taken for this study.

Objectives

This study therefore aimed to describe and evaluate a program of therapist training for iCT-SAD. As this treatment was developed in the United Kingdom and this study was conducted in Hong Kong with local therapists, an additional objective was to examine the feasibility, acceptability, and initial efficacy of iCT-SAD in this cultural context, based on data from a pilot case series. We aimed to identify whether significant cultural adaptations would be required for further dissemination in this setting.

Methods

Therapist Training Procedure

The training consisted of 3 phases, outlined below:

Phase 1: Initial Face-To-Face Cases Under Supervision

As iCT-SAD is a direct adaptation of the face-to-face Cognitive Therapy (CT) protocol, it is important that therapists are familiar with CT before learning internet-based Cognitive Therapy (iCT). This permits a greater understanding of the key points the online modules are aiming to convey.

Training for this study therefore started with 3 therapists from Hong Kong undertaking a phase of face-to-face CT-SAD. The therapists had been qualified as clinical psychologists for an average of 10.3 years (7, 9, and 15 years). All spoke English as an additional language. Although they were experienced in delivering cognitive-behavioral interventions for anxiety, including SAD, and 2 of them had previously attended a CT-SAD workshop, none of them had used the full CT protocol previously. The therapists were sent the most recent version of the treatment manual [23], which explains the CT-SAD protocol as applied to adults as well as how treatment is adapted for adolescents. The 3 therapists then implemented the treatment in Cantonese with a total of 5 cases between January and May 2017, with weekly group supervision from the first author via Skype, which focused on learning and implementing the treatment protocol.

Phase 2: Internet-Based Cognitive Therapy for Social Anxiety Disorder Training

The second phase consisted of training in the iCT-SAD program and treatment protocol. The iCT-SAD training was developed and delivered by the authors (GT, DMC, and JW) and was informed by the results of interviews with 3 iCT-SAD therapists from the United Kingdom who were involved in the development of the treatment as well as the first author's own experience of learning and delivering iCT-SAD. Training was delivered in an intensive format, totaling 7.5 days over a 2-week period. Each therapist was registered with an account on the iCT-SAD site, together with a *test patient* account to allow them to view the site content from the patient's perspective and to practice using the site within the training sessions. The training was divided into the following sections:

Site Navigation and Functionality

Learning to navigate the site and use the site functions, such as releasing treatment modules, sending messages, and using the resource library.

Structure and Timings

Learning how the iCT-SAD treatment protocol is implemented over the treatment period, for example, when each core module is released and when to schedule phone calls.

Module Content

The majority of the training focused on reviewing the content and general aims of each module to help the therapists know how to review and discuss modules with patients.

Therapist Communication

Effective use of the iCT-SAD communication methods (messaging, short message service (SMS), and phone calls) was demonstrated and practiced by the therapists using role play.

Implementing Key Techniques

As some of the key therapy techniques from CT, such as developing an individualized model, and the *self-focused attention and safety behaviors experiment* are implemented slightly differently online, time was allocated to review and practice these specifically.

Behavioral Experiments

The training included experiential practice of planning and completing behavioral experiments in real social situations. The aim was to support the therapists to generate ideas for appropriate experiments and to provide them with first-hand experience to draw on when discussing experiments in iCT-SAD.

The Role of the Therapist in Internet-Based Cognitive Therapy for Social Anxiety Disorder

Training focused on understanding the role of the therapist in iCT-SAD as a guide and facilitator, how they apply their clinical expertise, and how this differs from face-to-face work.

Troubleshooting

Common problems, such as patients not logging into the site, low motivation, or avoidance of behavioral experiments, were discussed and possible solutions reviewed.

Phase 3: Internet-Based Cognitive Therapy for Social Anxiety Disorder Pilot Cases Under Supervision

Phase 3 consisted of piloting the iCT-SAD treatment with a small number of cases under weekly group clinical supervision from the first author via Skype. Each therapist treated 2 clients from a local clinical service in Hong Kong using the program. Supervision focused on reinforcing learning from Phase 2, adherence to the treatment protocol, and further development

of skills. The therapist training and a subsequent clinical trial were approved by the Joint Chinese University of Hong Kong—New Territories East Cluster Clinical Research Ethics Committee (Ref: 2016.611-T) and by the University of Oxford Tropical Research Ethics Committee (Ref: 531-17).

Training Evaluation

The training was evaluated using the following 4 methods:

Face-to-Face Cognitive Therapy for Social Anxiety Disorder: Cognitive Therapy Competence Scale for Social Phobia

The Cognitive Therapy Competence Scale for Social Phobia (CTCS-SP) [24] (also available in an unpublished manuscript by Clark et al) is a disorder-specific adaptation of the general Cognitive Therapy Scale—Revised (CTS-R) [25], allowing the assessor to rate skills and techniques specific to the face-to-face CT-SAD treatment protocol. This competence measure has been shown to be a strong predictor of patient outcomes [26]. The CTCS-SP contains 15 skill areas, each rated on a 0 to 6 scale, with higher scores indicating greater competence. A mean score of 3 (ie, 50%) is considered the threshold to demonstrate competence in delivering the treatment. During Phase 1 (face-to-face CT training), 1 complete session from each therapist was rated by the first author using a video of the session (in Cantonese) together with an English transcript of the conversation. Sessions were chosen by each therapist, but could not include the first or last sessions, and were required to include at least one behavioral experiment. Feedback from these assessments was provided in a subsequent supervision session.

Internet-Based Cognitive Therapy for Social Anxiety Disorder Self-Evaluation Assessment

This self-report assessment was developed specifically for this study. It asks respondents to rate their own knowledge and skills in relation to 34 internet therapy components and activities, including those applicable to most online interventions (eg, “Developing and maintaining client engagement with the online programme”) and those more specific to iCT-SAD (eg, “Suggesting strategies to overcome problems clients may experience with video feedback”). An initial item pool was generated through interviews with 3 experienced UK iCT-SAD trial therapists and their supervisor, which was then reviewed and refined in consultation with these experts to ensure face validity. For each item, respondents provide 1 rating for knowledge (ie, how much they know about the item) and 1 for skills (ie, how well they think they can currently implement it). Ratings are given on 0 to 8 Likert scales, where 0, 2, 4, 6, and 8 represent *no*, *limited*, *some*, *good*, and *extensive* knowledge or skills, respectively. Mean scores for each subscale are calculated. The full assessment is provided in Multimedia Appendix 1. The therapists completed the assessment following each phase of training.

Internet-Based Cognitive Therapy for Social Anxiety Disorder Skills Test

To obtain a more objective assessment of what the therapists had learned following Phase 2, a standardized skills test was developed and completed by the therapists at this timepoint. The test consisted of brief information about a series of fictional patients undertaking iCT-SAD. For each, an extract of some completed work on the site is shown and the respondent is asked questions about what the patient has written and how they would proceed with the treatment. For example, questions might ask how they would help a patient to improve their individualized cognitive model or to write a response to a message where the patient reports a drop in mood (The test is provided in Multimedia Appendix 2). Items were generated following the same iterative process of consultation with iCT-SAD experts as used for the self-evaluation assessment. Respondents’ answers are scored in relation to set of exemplar responses generated by iCT-SAD experts. Exemplar responses were divided into distinct components, with a point awarded for each one mentioned by the respondent. The maximum score was 55.

Internet-Based Cognitive Therapy for Social Anxiety Disorder Patient Outcomes

The final method to evaluate the training effectiveness was to examine the outcomes of the pilot patient cohort being treated by the therapists using the program. This study also provided an initial test of the iCT-SAD program in Hong Kong, examining its feasibility, acceptability, and technical functioning, while also offering a tentative indication of efficacy and cultural applicability.

Internet-Based Cognitive Therapy for Social Anxiety Disorder Pilot Case Series

Participants

A cohort of 6 patients (3 female; mean age 31.3 years, age range 18 to 49 years) was recruited from the New Life Psychiatric Rehabilitation Association, Hong Kong. The cohort represented a consecutive series of referrals for probable social anxiety. All the patients met the Diagnostic and Statistical Manual 4th Edition (DSM-IV) criteria for SAD, which was confirmed at assessment using the Anxiety Disorders Interview Schedule for DSM-IV [27]. Within the cohort, 4 patients showed generalized social anxiety, whereas 2 experienced anxiety in a more restricted range of situations. The mean duration of social anxiety was 7.5 years (SD 8.8). Comorbidities were assessed using the Structured Clinical Interview for DSM-5 [28]. SAD was the primary diagnosis for all 6 patients, but 1 met the criteria for comorbid Generalized Anxiety Disorder (GAD), 1 for comorbid major depressive disorder, and 1 for comorbid GAD, other specified depressive disorder, panic disorder, agoraphobia, specific phobia, and separation anxiety. The remaining 3 only met the criteria for SAD. Assessments were conducted by a trainee clinical psychologist under supervision. All patients were Chinese residents of Hong Kong, with non-native but sufficient proficiency in English to undertake the treatment in its original language. All participants were in full-time employment or study. Regarding marital status, 2 participants were married or cohabiting and 4 were single.

Procedure

The iCT-SAD program, which was written in English, was implemented as described by Stott et al [22]. Therapists communicated with their patients using brief secure messages,

telephone calls, and occasional webcam chats. Therapists' messages were written in English, and the telephone calls were conducted in both English and Cantonese as required. The treatment lasted 14 weeks, followed by a 3-month booster period, during which participants retained access to the program. At the end of treatment, participants were invited to complete a brief online survey about their experience of treatment and their suggestions for how it could be improved. Questions examined the ease of understanding the treatment in English, helpfulness of therapists' behaviors, overall likes and dislikes, and general ease of use. The respondents were not asked to give their name and completed the survey outside of the treatment website, meaning the therapists could not see their responses. The therapists were also invited to share their feedback and suggestions during a focus group discussion within clinical supervision. This centered on the cultural applicability of the treatment and the need for any adaptation in future.

Measures

The primary patient outcome measure was the self-report version of the Liebowitz Social Anxiety Scale (LSAS) [29]. Secondary patient outcome measures included other measures of SAD to facilitate comparison with other studies, process measures, and assessments of general mood and functioning:

Social Anxiety:

- Social Phobia Weekly Summary Scale [30]
- Social Phobia Inventory (SPIN) [30,31]
- Fear of Negative Evaluation Scale [30,32].
- Social Phobia Scale (SPS) and Social Interaction Anxiety Scale [30,33].

Social anxiety process measures:

- Social Cognitions Questionnaire [30]
- Social Behavior Questionnaire (SBQ) [30]
- Social Attitudes Questionnaire (SAQ) [30]
- Social Participation and Social Satisfaction scales [34]

General Mood and Functioning Measures:

- Patient Health Questionnaire (PHQ)—9-item version [35]
- Generalized Anxiety Disorder Questionnaire (GAD)—7-item version [36]
- Work and Social Adjustment Scale [37]

Analysis of Clinical Data

Mean scores on each measure at pretreatment, posttreatment, and 3-month follow-up were examined. Given the small sample size, these were evaluated using effect size estimates and 95% CIs rather than significance tests. In addition, the reliability of each patient's change in scores was examined using the response and remission criteria outlined below. Effect sizes (Cohen *d*) were calculated using the pooled SD as the denominator, calculated as $SQRT((SD^2_{initial}+SD^2_{post})/2)$ [38]. Interpretation followed the rules of thumb outlined by Cohen [39], with effect sizes of 0.2, 0.5, and 0.8 indicating small, medium, and large effects, respectively. CIs for Cohen *d* were calculated using the Hedges and Olkin formula [40].

Response and Remission Criteria

For classifying patients as treatment responders and/or remitted social anxiety, we used the criteria described by Stott et al's [22] original iCT-SAD case series, which use both the reliable change formulae described by Jacobson and Truax [41] and normative data from Fresco et al [42]. Response to treatment was defined as an improvement greater than 31% on the LSAS between pretreatment and posttreatment [43]. Remission was defined as a drop of at least 12 points on the LSAS between pretreatment and posttreatment combined with a posttreatment score at or below the clinical threshold of 38 points.

We also examined reliable improvement and reliable recovery from social anxiety using the English *Improving Access to Psychological Therapies* (IAPT) [44] outcome criteria, which consider change on both anxiety disorder–specific (SPIN) and depressed mood (PHQ) measures [45]. Reliable improvement was defined as a decrease of 10 or more points on the SPIN and/or 6 or more points on the PHQ and no reliable deterioration (increases of 10 or more, or 6 or more, respectively) on either measure. Reliable recovery was defined as reliable improvement combined with scores on both measures below the clinical threshold, that is, a SPIN score of 18 or below and a PHQ score of 9 or below.

Results

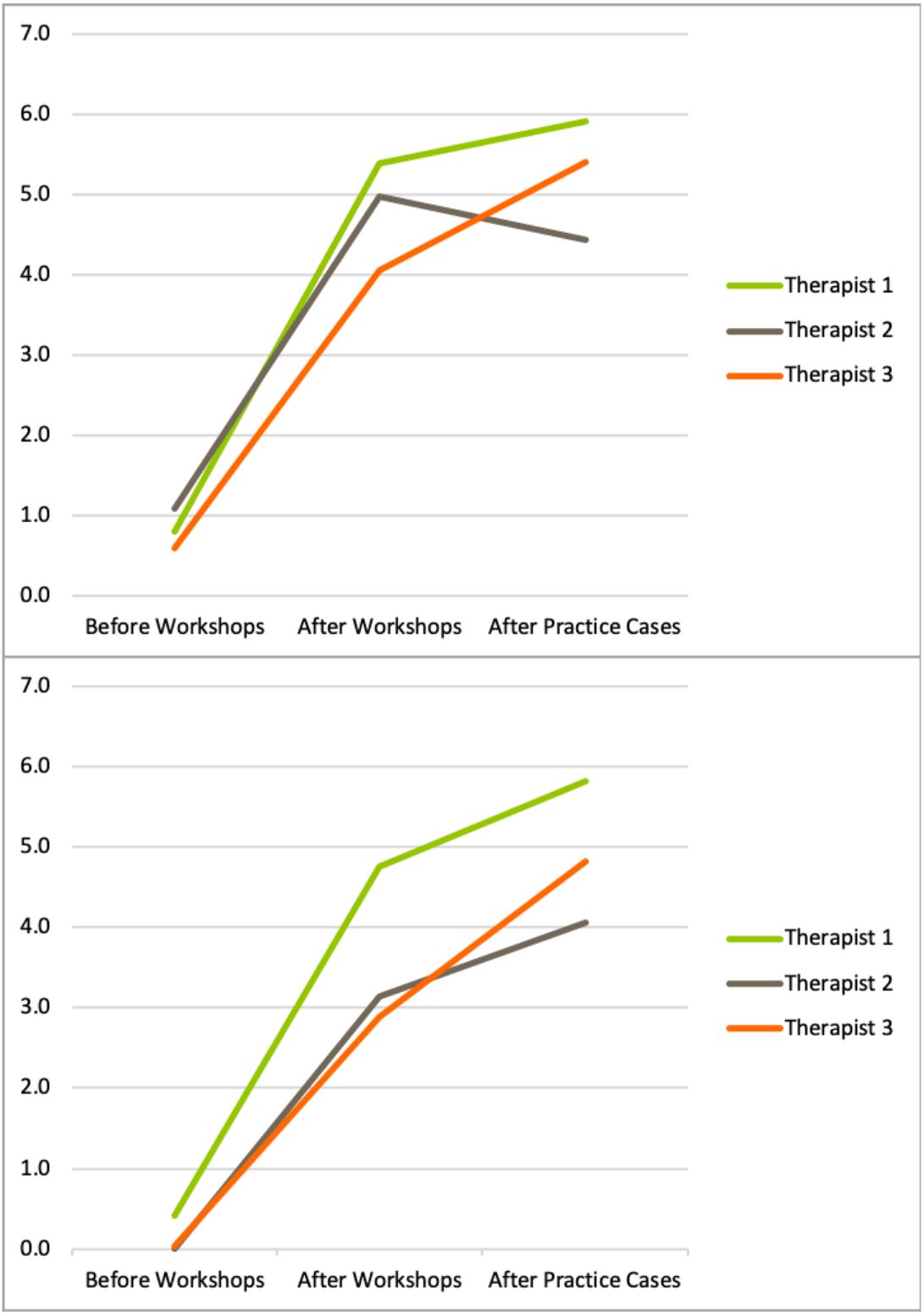
Face-to-Face Cognitive Therapy for Social Anxiety Disorder: Cognitive Therapy Competence Scale for Social Phobia

Mean CTCS-SP scores across the 15 face-to-face CT skill areas were 3.9, 3.9, and 4.0 across the 3 therapists. These scores indicated that all 3 therapists achieved a level of competence in the delivery of the face-to-face treatment that would be expected of a high-intensity IAPT therapist (mean score >3).

Internet-Based Cognitive Therapy for Social Anxiety Disorder Self-Evaluation Assessment

Therapists' self-reported knowledge and skills ratings across the 3 timepoints are shown in Figure 1. This figure shows that at baseline, where therapists had been trained in the face-to-face CT protocol but not iCT, self-reported iCT knowledge and skills ratings were low. These mean scores increased following the iCT training workshops in Phase 2 and further increased following completion of iCT practice cases under supervision in Phase 3.

Figure 1. Therapists' self-reported knowledge (top panel) and skills (bottom panel) ratings for internet-based Cognitive Therapy for social anxiety disorder following each phase of training.



Internet-Based Cognitive Therapy for Social Anxiety Disorder Skills Test

The 3 therapists' scores on the different components of the skills test are shown in Table 1. As this is a newly developed instrument, there are no established competency cutoffs. However, as the test was designed in a similar manner to the CTCS-SP, with each item examining competence in a distinct skill, the CTCS-SP competency threshold of 50% is thought to be broadly applicable to the skills test and is used here to aid interpretation.

Table 1. Therapists' scores on each component of the skills test.

Skill assessed	Maximum score	Therapist 1	Therapist 2	Therapist 3
Interpreting client questionnaire responses and treatment planning	16	12	13	11
Reviewing patients' individualized cognitive models	9	6	4	4
Conducting the *self-focused attention and safety behaviors experiment*	3	3	2	3
Planning phone calls	5	3	4	4
Reviewing patients' behavioral experiments	6	5	5	6
Reviewing patients' writing in modules	5	3	1	2
Responding to a patient message	7	4	2	3
Reviewing patients' therapy blueprints	4	3	2	2
Total	55	39 (71%)	33 (60%)	35 (64%)

In this skills test, the 3 therapists achieved overall scores of 71%, 60%, and 64%, indicating good proficiency in the skills assessed. Benchmarking against the CTCS-SP, these scores therefore indicate a level of competency well above a 50% minimum standard. It should be noted that this assessment was completed following Phase 2 of the training, before the therapists' pilot cases; this means they had further opportunities to practice and consolidate their skills in Phase 3.

Patient Adherence

All patients showed excellent adherence. Each patient completed all of the core treatment modules. Overall, patients were issued with a mean of 13.7 modules (SD 1.4) and completed a mean of 12.8 modules (SD 1.7). They spent an average of 40.2 hours (SD 26.4) using the website in the 14-week treatment period. As the program includes an automatic logout feature following periods of inactivity, the activity recorded on the site is thought to be a fair reflection of the time spent actively using the program.

Internet-Based Cognitive Therapy for Social Anxiety Disorder Patient Outcomes

Mean scores on all outcome measures are shown in Table 2 and effect sizes in Table 3. On the primary patient outcome measure, the LSAS, the mean decrease across the weekly treatment period was 53.8 points (SD 39.5). The within-group effect size (Cohen *d*) was 2.06 (95% CI 0.66-3.46), indicating an effect of medium to very large magnitude in the direction of reduced social anxiety. These figures are at least as good as data from the developers of the treatment [22], where the mean pre-post LSAS decrease was 40.2 points and the effect size was 1.64. Effect size point estimates for the present secondary outcome measures were also large, ranging from 0.92 to 1.89, with the lower limit of the CIs falling in the small-to-medium range for most, though not all, measures. Although highly tentative because of the sample size, these findings suggest the treatment was effective in reducing social anxiety, negative social cognitions, safety behaviors, worry, and functional impairment, and increasing social participation, but did not show a reliable effect on depressed mood or social satisfaction.

Table 2. Means and SDs at pretreatment, posttreatment, and 3-month follow-up (N=6).

Measure	Pretreatment, mean (SD)	Posttreatment, mean (SD)	3-Month follow-up, mean (SD)
LSAS[a]	75.8 (30.4)	22.0 (21.0)	17.8 (17.2)
SPWSS[b]	31.7 (11.0)	14.0 (8.1)	14.0 (8.9)
SPIN[c]	43.3 (16.5)	20.0 (12.2)	18.7 (16.9)
FNE[d]	25.2 (3.0)	19.3 (8.5)	18.7 (9.8)
SPS[e]	32.7 (20.4)	12.7 (7.4)	9.7 (9.4)
SIAS[f]	53.3 (16.2)	28.7 (10.1)	27.3 (12.2)
SCQ-f[g]	3.1 (1.1)	1.5 (0.6)	1.5 (0.8)
SCQ-b[h]	47.7 (20.5)	15.6 (13.5)	14.5 (20.3)
SBQ[i]	43.0 (13.2)	22.7 (9.5)	27.7 (17.0)
SAQ[j]	214.5 (44.1)	146.3 (39.2)	159.7 (73.8)
Social participation	37.2 (5.8)	53.5 (14.9)	60.3 (18.5)
Social satisfaction	17.5 (5.8)	22.8 (3.2)	22.5 (8.4)
PHQ[k]	11.3 (7.1)	5.2 (2.6)	6.2 (5.7)
GAD[l]	13.2 (4.5)	6.3 (3.3)	6.8 (5.9)
WSAS[m]	19.5 (7.8)	8.5 (4.2)	9.2 (9.2)

[a]LSAS: Liebowitz Social Anxiety Scale.
[b]SPWSS: Social Phobia Weekly Summary Scale.
[c]SPIN: Social Phobia Inventory.
[d]FNE: Fear of Negative Evaluation Scale.
[e]SPS: Social Phobia Scale.
[f]SIAS: Social Interaction Anxiety Scale.
[g]SCQ-f: Social Cognitions Questionnaire (frequency; mean score).
[h]SCQ-b: Social Cognitions Questionnaire (belief; mean score).
[i]SBQ: Social Behavior Questionnaire.
[j]SAQ: Social Attitudes Questionnaire.
[k]PHQ: Patient Health Questionnaire.
[l]GAD: Generalized Anxiety Disorder Questionnaire.
[m]WSAS: Work and Social Adjustment Scale.

Table 3. Within-group effect sizes between pretreatment, posttreatment, and 3-month follow-up (N=6).

Measure	Cohen *d* (95% CI)		
	Pre-to-Post	Pre-to-Follow-up	Post-to-Follow-up
LSAS[a]	2.06 (0.66 to 3.46)	2.34 (0.88 to 3.81)	0.22 (−0.92 to 1.35)
SPWSS[b]	1.83 (0.48 to 3.18)	1.76 (0.43 to 3.10)	0.00 (−1.13 to 1.13)
SPIN[c]	1.61 (0.31 to 2.91)	1.48 (0.20 to 2.75)	0.09 (−1.04 to 1.22)
FNE[d]	0.92 (−0.27 to 2.10)	0.90 (−0.29 to 2.09)	0.07 (−1.06 to 1.20)
SPS[e]	1.30 (0.06 to 2.55)	1.45 (0.18 to 2.72)	0.35 (−0.79 to 1.49)
SIAS[f]	1.82 (0.48 to 3.17)	1.81 (0.46 to 3.15)	0.12 (−1.01 to 1.25)
SCQ-f[g]	1.89 (0.53 to 3.25)	1.71 (0.39 to 3.03)	−0.02 (−1.15 to 1.11)
SCQ-b[h]	1.85 (0.50 to 3.20)	1.63 (0.32 to 2.93)	0.06 (−1.07 to 1.19)
SBQ[i]	1.76 (0.43 to 3.10)	1.01 (−0.19 to 2.21)	−0.36 (−1.50 to 0.78)
SAQ[j]	1.63 (0.33 to 2.94)	0.90 (−0.29 to 2.09)	−0.23 (−1.36 to 0.91)
Social participation	1.45 (0.17 to 2.72)	1.69 (0.37 to 3.01)	0.41 (−0.74 to 1.55)
Social satisfaction	1.14 (−0.08 to 2.36)	0.69 (−0.47 to 1.86)	−0.05 (−1.18 to 1.08)
PHQ[k]	1.15 (−0.07 to 2.37)	0.80 (−0.38 to 1.98)	−0.22 (−1.36 to 0.91)
GAD[l]	1.72 (0.39 to 3.04)	1.20 (−0.03 to 2.43)	−0.10 (−1.24 to 1.03)
WSAS[m]	1.75 (0.42 to 3.08)	1.21 (−0.02 to 2.44)	−0.09 (−1.23 to 1.04)

[a]LSAS: Liebowitz Social Anxiety Scale.

[b]SPWSS: Social Phobia Weekly Summary Scale.

[c]SPIN: Social Phobia Inventory.

[d]FNE: Fear of Negative Evaluation Scale.

[e]SPS: Social Phobia Scale.

[f]SIAS: Social Interaction Anxiety Scale.

[g]SCQ-f: Social Cognitions Questionnaire (frequency; mean score).

[h]SCQ-b: Social Cognitions Questionnaire (belief; mean score).

[i]SBQ: Social Behavior Questionnaire.

[j]SAQ: Social Attitudes Questionnaire.

[k]PHQ: Patient Health Questionnaire.

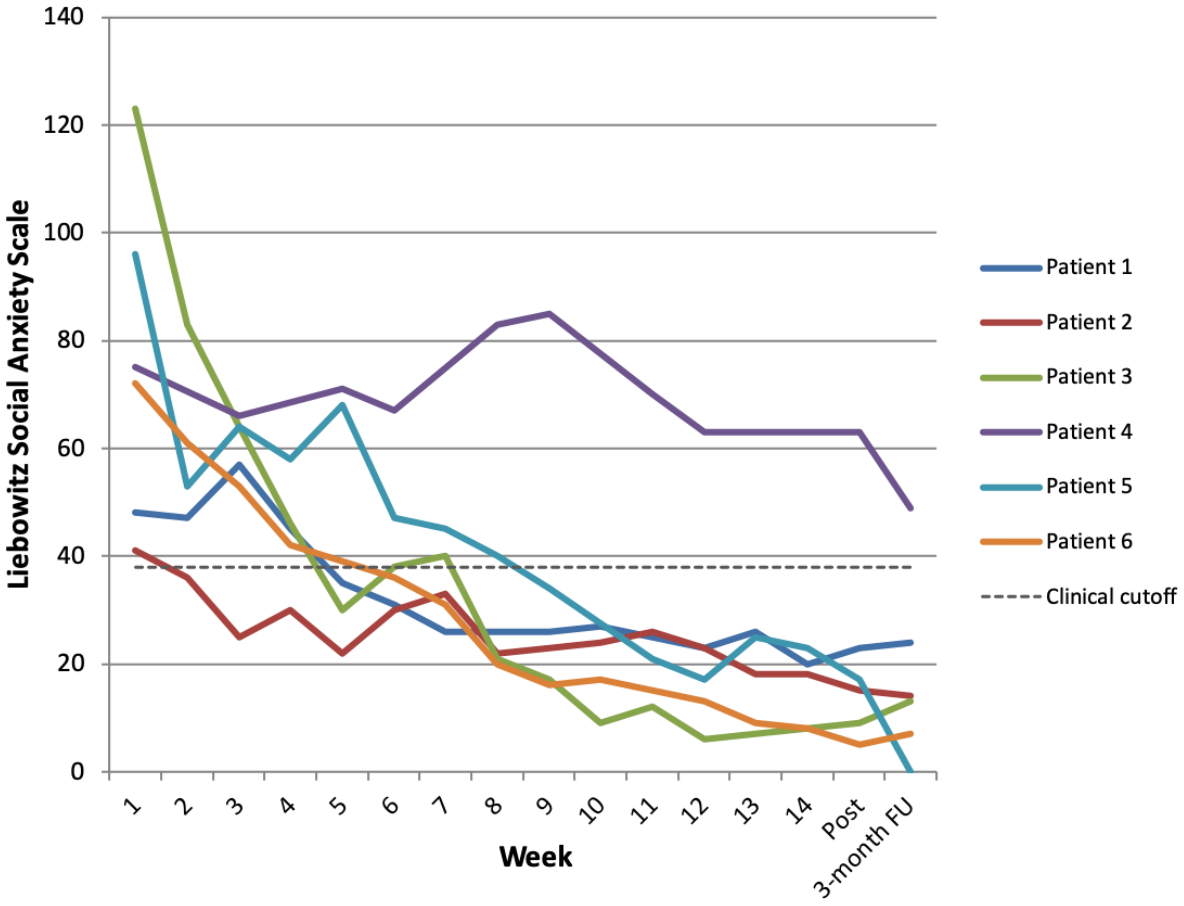
[l]GAD: Generalized Anxiety Disorder Questionnaire.

[m]WSAS: Work and Social Adjustment Scale.

Changes in scores from posttreatment to 3-month follow-up were analyzed to review the maintenance of treatment gains over this period. Patients retained access to the program during this 3-month phase, though therapist contact was reduced to just one brief phone call at monthly intervals. As shown in Table 3, the effect size point estimates for most measures ranged between −0.20 and 0.20, meaning the threshold for a small effect in either direction was not reached. This suggested that the improvements from treatment had been maintained over this period. There was some evidence of a small effect in the direction of further improvement on the LSAS, SPS, and social participation measures during this period. On the SBQ, SAQ, and PHQ, there was some evidence of a small effect indicating a deterioration. Although this may indicate a lessening of some secondary treatment effects during the booster phase, these results may have been heavily influenced by the scores of 1 patient who did not respond to treatment and showed a decline on secondary outcome measures over the booster phase. Again, the CIs for these effect sizes were extremely wide because of sample size, so they can only provide a preliminary indication of the maintenance of treatment gains.

Overall, 5 of the 6 patients showed an improvement on the LSAS greater than 31% at the posttreatment assessment and were thus classified as treatment responders. All 5 patients were also classified as remitted from their social anxiety, showing a drop of at least 12 points and falling below the clinical cutoff at posttreatment. Individual LSAS scores over time are shown in Figure 2. Using the IAPT criteria based on social anxiety (SPIN) and depression (PHQ) scores, 4 patients showed reliable improvement and 3 were classified as reliably recovered from SAD.

Figure 2. Weekly scores on the Liebowitz Social Anxiety Scale (self-report) across treatment for the 6 pilot patients. Week 15 represents the posttreatment assessment. The dotted line represents the clinical cutoff score of 38 points.



The 1 patient who was not classified as a responder to treatment within the weekly treatment phase experienced difficulties with depressed mood, which may have impacted their motivation to log in and work on the treatment website and to complete behavioral experiments. When compared with some other patients, they spent relatively little time on the website (12.5 hours total) and completed fewer behavioral experiments. Across the patient cohort, the amount of time spent on the website was positively correlated with percentage change on the LSAS (r=.584). It is also noted that the 2 patients with relatively lower baseline LSAS scores, because of more situation-specific forms of social anxiety, finished treatment with scores higher than some other patients whose baseline scores were more severe. The correlation between baseline LSAS score and percentage change on the LSAS was r=.443.

Patient and Therapist Feedback

All 6 patients completed the anonymous feedback survey at the end of the booster period. Given the small sample size, the frequencies of responses are reported. Overall, 5 of the patients felt that the program was relatively easy to understand in English, though 1 experienced some difficulties expressing their ideas and feelings and felt this could be a barrier for the therapy (respondent 4). Patients reported various therapist behaviors that they found helpful, including sending a written summary following phone calls, helping to generate new perspectives, identifying details of modules they may have missed, advising on behavioral experiments to try, and helping them to review their week. In terms of the treatment as a whole, respondents reported liking the phone calls (described as “intensive but helpful” by respondent 1); the practical nature of the contents; the effort, help, and professionalism of the therapist; the inclusion of both general and specific content; and the way the questionnaires allowed them to review their emotional state. In addition, 4 patients did not report any dislikes about the treatment. For security reasons, iCT-SAD uses 2-factor authentication at log-in, and 1 participant disliked having to enter an authentication code each time (respondent 1). One participant felt it was sometimes hard to motivate themselves to finish the tasks and expressed a concern that they may not have understood their own anxiety very well (respondent 4). All patients rated the program as easy to use on a desktop or laptop computer, but 2 reported difficulty when using a tablet or mobile phone. In sum, responses indicated a good level of treatment satisfaction and acceptability, with some but relatively few technical or practical difficulties.

Therapists’ feedback indicated that they did not think any major cultural adaptation was required to the program content or implementation procedures for the Hong Kong context. However, the therapists did identify certain aspects of the iCT-SAD program that may prove difficult to understand when patients are working in a nonnative language. This included some video and audio material where groups of people are chatting informally, perhaps talking at the same time or in

incomplete sentences. In addition, one of the exercises used in the program to practice externally focused attention asks patients to watch a video of someone reading a story to them while they alternate their attention between focusing on themselves and on the story content.

Discussion

Principal Findings

This study has provided an example of a procedure for training therapists to deliver a guided internet intervention, including details of the content covered, and how progress was evaluated. The results indicated that the training was effective in improving therapists' knowledge and skills in relation to iCT-SAD. The 3 therapists achieved a good level of competence when objectively measured using the skills test following Phase 2 of training. They were then able to consolidate these skills in their work with pilot cases, as demonstrated by the positive outcomes achieved by this cohort. These results suggested that the clinical outcomes for patients in Hong Kong undertaking iCT-SAD with local therapists were comparable to those seen in a UK study from the developers of the treatment [22].

The 6 patients showed good adherence to the iCT-SAD program, completing treatment modules, phone calls with the therapist, behavioral experiments, and weekly questionnaire measures. All patients completed the full weekly and booster phases of treatment, indicating a good level of treatment acceptability and feasibility in this setting and sufficiently reliable functioning of the website. The therapists successfully implemented the treatment in line with the protocol and no significant deviations from this were required. These findings are of course preliminary given the present sample size and an RCT would be required to establish the feasibility and efficacy of the program in Hong Kong more robustly.

This study took the approach of piloting the intervention in its unadapted form, meaning that the results could be benchmarked against the UK data and feedback could be elicited from both patients and therapists. Promisingly, the mean pre-post change on the LSAS and associated effect size point estimate (Cohen *d*=2.06) were large, suggesting that the high level of efficacy observed in the United Kingdom appears to have been maintained within a different cultural setting. Patient and therapist feedback did not identify any major cultural or linguistic barriers; the suggestions made to assist understanding were modest. We have since created some additional Chinese resources for the components of the program mentioned along with English-subtitled versions of the site videos. Overall, the findings in this study suggest that the approach of starting with the unadapted intervention was justified given the clinical outcomes obtained and that the adaptations suggested were quite modest and smaller than might have been expected at the outset of the project.

Limitations

Limitations of this study include the small number of therapists trained and the fact that the self-report assessment and skills test were developed specifically for this study and are therefore not yet externally validated. As mentioned above, the small number of patients in this pilot study can only tentatively indicate treatment efficacy and linguistic or cultural considerations, and larger controlled studies are therefore required. The training program implemented here was intensive and was not designed to be scalable at this stage. Future work should consider the best methods to provide such training in less time and to larger groups of therapists. In developing training programs for internet interventions that are based closely on a face-to-face treatment, our view is that familiarity with the face-to-face protocol is an important preliminary step and that treating a small number of training cases online under clinical supervision is essential for applying and consolidating skills. Online therapist training methods are likely to be the most scalable approach for the future, but preliminary work such as the approach taken here can help to develop a clearer understanding of what training should cover and how. The aim should be to determine what therapists need from training, making it easier to design online materials for that purpose. Our research team has recently started to develop online therapist training materials for iCT-SAD, which are available on our resources website [30]. Further research could also usefully explore whether less-experienced therapists can be trained to achieve similar outcomes.

Conclusions

This study has described and evaluated a program of therapist training in iCT-SAD, which appeared effective at increasing therapists' knowledge and skills and resulted in positive clinical outcomes among a pilot case series of 6 patients in Hong Kong, with initial evidence that these were sustained at 3-month follow-up. The treatment appeared feasible and acceptable in this setting. An RCT of the iCT-SAD treatment in Hong Kong is now in progress. Given that therapist training is critical to the successful dissemination of internet interventions, further research to develop, describe, and evaluate therapist training procedures is recommended.

Acknowledgments

The authors wish to thank the case series participants. GRT is supported by the Wellcome Trust (102176), the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre, and the NIHR Oxford Health Biomedical Research Centre. JW, EWP, and DC are supported by the Wellcome Trust (069777). The views expressed are those of the authors and not necessarily those of the National Health Service (NHS), the National Institute for Health Research (NIHR), or the Department of Health.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Internet-based Cognitive Therapy for social anxiety disorder self-evaluation assessment.

[DOCX File, 24KB - formative_v3i2e13446_app1.docx]

Multimedia Appendix 2

Internet-based Cognitive Therapy for social anxiety disorder skills test.

[DOCX File, 1MB - formative_v3i2e13446_app2.docx]

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Abbreviations

CT: Cognitive Therapy
CTCS-SP: Cognitive Therapy Competence Scale for Social Phobia
CT-SAD: Cognitive Therapy for social anxiety disorder
GAD: Generalized Anxiety Disorder
IAPT: Improving Access to Psychological Therapies
iCT: internet-based Cognitive Therapy
iCT-SAD: internet-based Cognitive Therapy for social anxiety disorder
LSAS: Liebowitz Social Anxiety Scale
PHQ: Patient Health Questionnaire
RCT: randomized controlled trial
SAD: social anxiety disorder
SAQ: Social Attitudes Questionnaire
SBQ: Social Behavior Questionnaire
SPIN: Social Phobia Inventory
SPS: Social Phobia Scale

Edited by G Eysenbach; submitted 20.01.19; peer-reviewed by A Bergin, J Högström; comments to author 06.03.19; revised version received 20.03.19; accepted 23.03.19; published 15.05.19.

Please cite as:
Thew GR, Powell CLYM, Kwok APL, Lissillour Chan MH, Wild J, Warnock-Parkes E, Leung PWL, Clark DM
Internet-Based Cognitive Therapy for Social Anxiety Disorder in Hong Kong: Therapist Training and Dissemination Case Series
JMIR Form Res 2019;3(2):e13446
URL: http://formative.jmir.org/2019/2/e13446/
doi:10.2196/13446
PMID:31094320

Original Paper

Treatment Preferences for Internet-Based Cognitive Behavioral Therapy for Insomnia in Japan: Online Survey

Daisuke Sato[1,2], PhD; Chihiro Sutoh[1], MD, PhD; Yoichi Seki[3], PhD; Eiichi Nagai[4], PharmD; Eiji Shimizu[1,3,5], MD, PhD

[1]Department of Cognitive Behavioral Physiology, Graduate School of Medicine, Chiba University, Chiba, Japan

[2]Department of Rehabilitation Sciences, Chiba Prefectural University of Health Sciences, Chiba, Japan

[3]Cognitive Behavioral Therapy Center, Chiba University Hospital, Chiba, Japan

[4]Clinical Research Center, Chiba University Hospital, Chiba, Japan

[5]Research Center for Child Mental Development, Chiba University, Chiba, Japan

Corresponding Author:
Daisuke Sato, PhD
Department of Cognitive Behavioral Physiology
Graduate School of Medicine
Chiba University
1-8-1, Inohana, Chuo-ku, Chiba-shi
Chiba, 260-8670
Japan
Phone: 81 43 226 2027
Email: daisuke-sato@umin.ac.jp

Abstract

Background: The internet has the potential to increase individuals' access to cognitive behavioral therapy (CBT) for insomnia at low cost. However, treatment preferences regarding internet-based computerized CBT for insomnia have not been fully examined.

Objective: The aim was to conduct an anonymous online survey to evaluate treatment preferences for insomnia among patients with insomnia and individuals without insomnia.

Methods: We developed an online survey to recruit a total of 600 participants living in the Kanto district in Japan. There were three subgroups: 200 medicated individuals with insomnia, 200 unmedicated individuals with insomnia, and 200 individuals without insomnia. The survey asked questions about the severity of the respondent's insomnia (using the Athens Insomnia Scale), the frequency of sleep medication use and the level of satisfaction with sleep medication use, the respondent's knowledge of CBT, his or her preference for CBT for insomnia before drug therapy, preference for CBT versus drug therapy, and preference for internet-based CBT versus face-to-face CBT.

Results: Of the 600 respondents, 47.7% (286/600) indicated that they received CBT before drug therapy, and 57.2% (343/600) preferred CBT for insomnia to drug therapy. In addition, 47.0% (282/600) preferred internet-based CBT for insomnia to face-to-face CBT. Although the respondents with insomnia who were taking an insomnia medication had a relatively lower preference for internet-based CBT (40.5%, 81/200), the respondents with insomnia who were not taking an insomnia medication had a relatively higher preference for internet-based CBT (55.5%, 111/200).

Conclusions: The results of our online survey suggest that approximately half of the people queried preferred CBT for insomnia to drug therapy, and half of the respondents preferred internet-based CBT for insomnia to face-to-face CBT.

(JMIR Form Res 2019;3(2):e12635) doi:10.2196/12635

KEYWORDS

patient preference; insomnia; internet-based cognitive behavioral therapy

Introduction

According to the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition), insomnia is a sleep disorder characterized by recurrent poor sleep quality or quantity that causes distress or impairment in important areas of functioning. Epidemiological studies suggest that the prevalence of clinical insomnia disorder ranges from 10% to 12% [1, 2], and the problems are often long-lasting [1]. There are two treatment options for individuals who have insomnia: cognitive behavioral therapy (CBT) [2-4] and pharmacotherapy, including nonbenzodiazepines, benzodiazepines, melatonin agonists, and an orexin receptor antagonist. In their systematic review, Mitchell et al [5] stated that over the long term the effectiveness of CBT for insomnia is superior to the effectiveness of benzodiazepine and non-benzodiazepine drugs. It is worthwhile to note that benzodiazepines are more frequently prescribed in Japan than in any other country [6].

Although there is evidence that pharmacological treatments improve insomnia (especially in the short term), these treatments have some significant potential adverse effects, including residual sedation and memory impairment. Patients with insomnia often report a preference for CBT. For example, Vincent and Lionberg [7] reported that at pretreatment in an outpatient hospital setting in Canada, CBT was significantly preferred over pharmacological therapy by 43 participants based on overall acceptability ratings. In a study from Australia, Walters et al [8] showed that a series of individuals with schizophrenia or schizoaffective disorders preferred CBT when given the choice of pharmacotherapy, melatonin, and CBT.

A problem related to CBT is that access to face-to-face CBT is extremely limited in some regions, including Japan, due to human resource and expertise constraints [9-12]. Accumulating evidence in recent years suggests that internet-based, computerized CBT for insomnia can be an effective treatment [13-15], and attention has turned to internet-based CBT for insomnia as an alternative to face-to-face CBT [16]. Web programs are accessible independent of the user's location and can be conducted on one's own time and at a low cost. Although the potential preference for CBT for insomnia over pharmacotherapy has been investigated in Western countries, there have been no studies of treatment preferences among individuals with and without insomnia in Japan [17,18]. In this study, we conducted an anonymous online survey to evaluate treatment preferences for insomnia among medicated individuals with insomnia, nonmedicated individuals with insomnia, and individuals without insomnia.

Methods

Survey Respondents

We had an online research agency (Cross Marketing Inc, Tokyo) oversee our Web-based survey. After being provided a thorough understanding of our research and agreeing to voluntarily participate in the study, 600 participants were recruited from the Kanto district in Japan through the online research provider. They consisted of 200 individuals with insomnia who were using a medication for insomnia, 200 individuals with insomnia who were not taking any insomnia medication, and 200 individuals without insomnia by their self-reports. Each group of 200 participants consisted of 100 men, including 20 men each in their twenties, thirties, forties, fifties, and sixties, and 100 women, including 20 women each in their twenties, thirties, forties, fifties, and sixties, to match the groups by age and gender.

Procedure

The candidate respondent received brief text-based information about the survey, including its objectives and conditions for participation (informed consent). The survey consisted of two parts. The first part asked demographic questions including gender, age, living area, employment status, and presence and severity of insomnia using the Athens Insomnia Scale (AIS), a self-reported psychometric questionnaire consisting of eight items developed by Soldatos et al [19].

The survey's second part consisted of the following questions about treatment for insomnia.

Frequency of sleep medication use and the level of satisfaction with sleep medication use:

1. How often do you take medication for insomnia?
2. Are you satisfied with your current insomnia medication?

Knowledge of CBT:

1. Have you heard of cognitive behavioral therapy (CBT)? Did you know that CBT is also a treatment for mental disorders such as depressive disorders and anxiety disorders?
2. As a treatment for insomnia, it has been shown that cognitive behavioral therapy (CBT) is medically effective. Did you know that CBT is effective for insomnia?

Preference for CBT before drug therapy, preference for CBT versus drug therapy, and preference for internet-based CBT versus face-to-face CBT:

1. Let's assume that you received your diagnosis of insomnia from your doctor. Imagine that you were advised to take cognitive behavioral therapy (CBT) before drug therapy. In such a case, have you received CBT?
2. If you had to choose either CBT for insomnia or drug therapy for insomnia, which would you choose?
3. Aside from the method of CBT for insomnia in face-to-face sessions with a therapist, if there is a way to receive CBT for insomnia via a computer program on the internet and support from a therapist by email, which would you choose?

Statistical Analysis

We used descriptive analyses (numbers, frequencies, percentages, means and standard deviations). We compared differences in each survey item among the three respondent groups, using the chi-square test, ANOVA, and a residual analysis [20]. An alpha level of .05 was used. All data were analyzed using SPSS for Windows version 21 (SPSS, Chicago, IL, USA).

Ethical Approval

The study was approved by the Regional Ethical Review Board, Faculty of Medicine, Chiba University (2017-5-19; No. 2711).

Results

Demographic Characteristics of the Survey Respondents

As designed, a total of 600 respondents (300 men and 300 women; mean age 45, SD 14 years, range 20-69 years) completed the online survey (Table 1). As shown by the respondents' use of the AIS, the respondents with insomnia who were taking an insomnia medication and respondents with insomnia who were not taking an insomnia medication had significantly more severe insomnia compared to the respondents without insomnia. When we defined an AIS total score of 6 or higher as insomnia, 90.0% (180/200) of the respondents with insomnia were using an insomnia medication and 94.5% (189/200) of the respondents with insomnia were not taking an insomnia medication compared to 52.0% (104/200) of the respondents without insomnia (see Table 1). There were also significant differences among the three respondent groups in employment status and AIS score (see Table 1).

Table 1. The demographic characteristics of the 600 survey respondents.

Variable	With insomnia, using medication (n=200)	With insomnia, not using medication (n=200)	Without insomnia (n=200)	χ^2 (df)	*F* value (df1,df2)	*P* value
Sex, n (%)				**0.0 (2)**		**>.99**
Women	100 (50.0)	100 (50.0)	100 (50.0)			
Men	100 (50.0)	100 (50.0)	100 (50.0)			
Age (years), mean (SD)	45 (14)	45 (14)	45 (14)		0.01 (2,398)	>.99
Employment status				**0.0 (10)**		**<.001**
Full-time	66 (25.9)	98 (38.4)	91 (35.7)			
Part-time	34 (41.0)	19 (22.9)	30 (36.1)			
Self-employed	11 (55.0)	2 (10.0)	7 (35.0)			
Housewife	25 (28.7)	36 (41.4)	26 (29.9)			
Unemployed	43 (45.3)	30 (31.6)	22 (23.2)			
Other	21 (35.0)	15 (25.0)	24 (40.0)			
AIS[a] score, mean (SD)	10.31 (4.46)	10.28 (3.60)	5.96 (3.14)		87.97 (2,597)	<.001
Insomnia (AIS ≥6)	180 (38.1)	189 (40.0)	104 (22.0)	130.7 (2)		<.001

[a]AIS: Athens Insomnia Scale.

Level of Satisfaction With Sleep Medication Use

The respondents with insomnia who were taking an insomnia medication (n=200) were asked about the frequency of their insomnia medication use; 68.0% (136/200) reported that they used an insomnia medication every night, and 95.5% (191/200) reported using such a medication at least once per week (Table 2). The respondents who indicated that they used an insomnia medication were also asked about their level of satisfaction with the sleep medication use: 54.0% (108/200) were satisfied, 27.5% (55/200) were neutral, and 18.5% (37/200) were dissatisfied.

Table 2. Frequency of sleep medication use and level of satisfaction with sleep medication use among the 200 respondents with insomnia who were using an insomnia medication.

Questions and answers	Respondents, n (%)
How often do you take medicine?	
Every night (time per day)	136 (68.0)
3-4 times per week	40 (20.0)
1 time per week	15 (7.5)
1 time per 2 weeks	4 (2.0)
1 time per month	1 (0.5)
<1 time per 2 months	4 (2.0)
Are you satisfied with your current medicine?	
Very satisfied	35 (17.5)
Satisfied	73 (36.5)
Neutral	55 (27.5)
Dissatisfied	28 (14.0)
Very dissatisfied	9 (4.5)

Knowledge of Cognitive Behavioral Therapy

All respondents were asked about their knowledge of CBT. There were significant differences among the three respondent groups in their knowledge of CBT and the effects of CBT (Table 3): 55.0% (330/600) of the respondents had no knowledge of CBT. Among the three groups, the percentage of those who had no knowledge of CBT were as follows: 39.0% (78/200) of the respondents with insomnia who were taking an insomnia medication, 54.0% (108/200) of the respondents with insomnia who were not taking an insomnia medication, and 72.0% (144/200) of the respondents without insomnia. In the group of respondents with insomnia who were using medication, the response "I have heard of CBT, and I know that it is an insomnia treatment" was significantly more frequent comparing the three respondent groups' answers. Conversely, the response "I have never heard of CBT, and I did not know that it is an insomnia treatment" was significantly less comparing the three respondent groups' answers. Among the group of respondents with insomnia who were not taking insomnia medication, the response "I have heard of CBT, and I know that it is an insomnia treatment" was significantly less frequent comparing the three respondent groups' answers, and "I have heard of CBT, and I did not know that it is an insomnia treatment" was significantly more frequent comparing the three respondent groups' answers. In the group without insomnia, the response "I have heard of CBT, and I know that it is an insomnia treatment" was significantly more frequent, and the response "I have never heard of CBT, and I did not know that it is an insomnia treatment" was significantly less frequent comparing the three respondent groups' answers (Table 4).

Even among the respondents who had heard of CBT (n=270), 68.5% did not know that CBT is effective for insomnia. Among the respondents with insomnia who were using an insomnia medication, the response "Do you know that CBT is effective for insomnia? Yes, I know" was significantly more frequent comparing the three respondent groups' answers, and "No, I do not know" was significantly less frequent comparing the three respondent groups' answers. Among the survey respondents with insomnia who were not using an insomnia medication, the response "Do you know that CBT is effective for insomnia? Yes, I know" was significantly less frequent comparing the three respondent groups' answers, and "No, I do not know" was significantly more frequent comparing the three respondent groups' answers (Table 3).

Table 3. Knowledge of cognitive behavioral therapy (CBT) in general.

Question and answers	With insomnia, using medication (n=200)		With insomnia, not using medication (n=200)		Without insomnia (n=200)		Total (N=600)	
	n (%)	Adjusted residual	n (%)	Adjusted residual	n (%)	Adjusted residual	n (%)	*P* value[a]
Have you heard of cognitive behavioral therapy (CBT)? Did you know that it is a treatment for mental disorders such as depression disorders and anxiety disorders?								
I have heard of CBT, and I know that it is an insomnia treatment	82 (41.0)	7.9[b,c]	32 (16.0)	−2.5[b,d]	18 (9.0)	−5.4[b,c]	132 (22.0)	<.001
I have heard of CBT, but I did not know that it is an insomnia treatment	40 (20.0)	−1.2	60 (30.0)	2.9[b,c]	38 (19.0)	−1.6	138 (23.0)	
I have never heard of CBT, and I did not know that it is an insomnia treatment	78 (39.0)	−5.6[b,c]	108 (54.0)	−0.3	144 (72.0)	5.9[b,c]	330 (55.0)	

[a]From Pearson chi-square values.

[b]Cells with significant adjusted standardized residuals.

[c]The adjusted standardized residual is 2.58 or greater (or, alternatively, less than −2.58), its associated probability is less than 0.01.

[d]The adjusted standardized residual is 1.96 or greater (or, alternatively, less than −1.96), its associated probability is less than 0.05.

Table 4. Knowledge of cognitive behavioral therapy (CBT) for insomnia.

Question and answers	With insomnia, using medication (n=122)		With insomnia, not using medication (n=92)		Without insomnia (n=56)		Total (N=270)	
	n (%)	Adjusted residual	n (%)	Adjusted residual	n (%)	Adjusted residual	n (%)	*P* value[a]
As a treatment for insomnia, it has been shown that CBT is medically effective. Did you know that CBT is effective for insomnia?								
Total	122 (100.0)		92 (100.0)		56 (100.0)		270 (100.0)	<.001
Yes, I know	54 (44.3)	4.1[b,c]	18 (19.6)	−3.0[b,c]	13 (31.5)	−1.5	85 (31.5)	
No, I did not know	68 (55.7)	−4.1[b,c]	74 (80.4)	3.0[b,c]	43 (68.5)	1.5	185 (68.5)	

[a]From Pearson chi-square values.

[b]Cells with significant adjusted standardized residuals.

[c]The adjusted standardized residual is 2.58 or greater (or, alternatively, less than −2.58), its associated probability is less than 0.01.

Preference for Internet-Based Cognitive Behavioral Therapy for Insomnia

All respondents were asked whether they had undergone CBT before drug therapy, and 47.7% (286/600) responded they had undergone CBT. There were no significant differences in the rate among the three groups: with insomnia using medication (51.5%,103/200), with insomnia not using medication (47.5%, 95/200), and without insomnia (44.0%, 88/200) (Table 5).

Notably, 57.2% (343/600) of the total respondents preferred CBT over drug therapy for insomnia. Among those with insomnia who were using an insomnia medication, the statement "I choose CBT" was significantly less frequent comparing the three respondent groups' answers, and "I choose drug therapy" was significantly more frequent comparing the three respondent groups' answers. In both groups of respondents with insomnia who were not taking an insomnia medication and the respondents without insomnia, the statement "I choose CBT" was significantly more frequent comparing the three respondent groups' answers, and "I choose drug therapy" was significantly less frequent comparing the three respondent groups' answers (Table 5). Although respondents with insomnia who were using insomnia medications had a relatively lower preference for CBT (40.5%, 81/200), both those with insomnia who were not taking an insomnia medication and the respondents without insomnia had a relatively higher preference for CBT (64.0%, 128/200 and 67.0%, 134/200, respectively).

Table 5. Preference for cognitive behavioral therapy (CBT) before drug therapy versus drug therapy, and preference for internet-based CBT versus face-to-face CBT.

Questions and answers	With insomnia, using medication (n=200)		With insomnia, not using medication (n=200)		Without insomnia, (n=200)		Total (N=600)	
	n (%)	Adjusted residual	n (%)	Adjusted residual	n (%)	Adjusted residual	n (%)	*P* value[a]
Let's assume that you received your diagnosis of insomnia from your doctor. Imagine that you were advised to participate in cognitive behavioral therapy (CBT) before drug therapy. In such a case, do you participate in CBT?								
Yes, I receive CBT	103 (51.5)	1.3	95 (47.5)	−0.1	88 (44.0)	−1.3	286 (47.7)	.32
No. I do not receive CBT	97 (48.5)	−1.3	105 (52.5)	0.1	112 (56.0)	1.3	314 (52.3)	
If you had to choose only one of the two as a treatment for insomnia, would you choose CBT or drug therapy?								
I choose CBT	81 (40.5)	−5.8[b,c]	128 (64.0)	2.4[b,d]	134 (67.0)	3.4[b,c]	343 (57.2)	<.001
I choose drug therapy	119 (59.5)	5.8[b,c]	72 (36.0)	−2.4[b, d]	66 (33.0)	−3.4[b,c]	257 (42.8)	
Other than CBT for insomnia in face-to-face sessions with a therapist, if there is a way to receive CBT via the internet and support from a therapist by email, which do you choose?								
I choose face-to-face CBT	119 (59.5)	2.3[b,d]	89 (44.5)	−2.9[b,c]	110 (53.0)	0.7	318 (53.0)	.009
I choose CBT on the internet	81 (40.5)	−2.3[b,d]	111 (55.5)	2.9[b,c]	90 (47.0)	−0.7	282 (47.0)	

[a]From chi-square values.

[b]Cells with significant adjusted standardized residuals.

[c]The adjusted standardized residual is 2.58 or greater (or, alternatively, less than −2.58), its associated probability is less than 0.01.

[d]The adjusted standardized residual is 1.96 or greater (or, alternatively, less than −1.96), its associated probability is less than 0.05.

Of the total number of respondents, 47.0% (282/600) preferred internet-based CBT for insomnia to face-to-face CBT. In the group with insomnia taking an insomnia medication, the statement "I choose face-to-face CBT" was chosen significantly more frequently comparing the three respondent groups' answers, and "I choose computerized CBT on the internet" was chosen less frequently when comparing the three respondent groups' answers. Among the respondents with insomnia not using insomnia medication, "I choose face-to-face CBT" was chosen significantly less frequently when comparing the three respondent groups' answers, and "I choose computerized CBT on the internet" was more chosen more frequently when comparing the three respondent groups' answers (Table 5).

Although the group with insomnia using an insomnia medication had a relatively lower preference for internet-based CBT (40.5%, 81/200), the group with insomnia not using medication for it had a relatively higher preference for internet-based CBT (55.5%, 111/200).

Discussion

Principal Findings

Our Web-based survey of 600 individuals in Japan revealed that approximately half (57.2%, 343/600) of the respondents preferred CBT for insomnia to drug therapy, and half (47.0%, 282/600) preferred internet CBT for insomnia over face-to-face CBT.

Culver et al [21] reported that 57.7% of female veterans (N=1538) in the United States rated nonmedication treatment of insomnia as very acceptable, whereas only 33.5% rated medication treatment as very acceptable. Sedov et al [22] reported that 50.9% of a series of pregnant women in Canada (N=187) described CBT as their first choice for the treatment of insomnia, 11.8% selected pharmacotherapy, and 37.3% selected acupuncture if they experienced insomnia. Together, these results suggest a preference for CBT for insomnia over pharmacotherapy [22].

Regarding internet-based CBT, Cheung et al [23] conducted semistructured interviews in Australia, and they reported that 56.86% of their patients with insomnia (N=51) had a preference for face-to-face CBT, and 43.13% had a preference for internet-based CBT. Their results are similar to ours.

The treatment plan for an individual with insomnia should be tailored according to his or her values and preferences. Further research is needed to increase the availability of more effective internet CBT in addition to face-to-face CBT and pharmacotherapy.

Limitations

Although our online survey obtained valuable information, our study has some limitations including the sampling methods. First, instead of random sampling, we used a stratified sample based on gender and age ranging from people in their twenties to their sixties from an internet inquiry to conduct our online survey. Individuals younger than 20 or older than 70 were excluded. However, all age groups are affected by insomnia, and the incidence tends to increase with age. In a study conducted in the United States, Ancoli-Israel et al [24] reported that 9% of 1000 subjects aged 18 years and older and 20% of

1000 subjects aged 65 years and older had chronic insomnia. Future studies should include people older than 70 years old. Older people have less access to online surveys than the general population. In that case, the use of a face-to-face survey and/or a telephone survey may be necessary to obtain data from people in their seventies. Second, we were unable to elucidate the insomnia severity or age. Third, the number of people using CBT was unclear. The questionnaires should include a number of insomnia patients using CBT with and without medication. Finally, the reason for preference was unclear. The questionnaires should include a reason for choice of medication, face-to-face CBT, and internet-based CBT.

Conclusions

The responses to our online survey indicate that approximately half of the respondents preferred CBT over drug therapy for insomnia, and half preferred internet-based CBT for insomnia over face-to-face CBT.

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy

Edited by G Eysenbach; submitted 04.11.18; peer-reviewed by A Sano, L Ranandeh; comments to author 05.01.19; revised version received 12.03.19; accepted 30.03.19; published 15.05.19.

Please cite as:
Sato D, Sutoh C, Seki Y, Nagai E, Shimizu E
Treatment Preferences for Internet-Based Cognitive Behavioral Therapy for Insomnia in Japan: Online Survey
JMIR Form Res 2019;3(2):e12635
URL: http://formative.jmir.org/2019/2/e12635/
doi:10.2196/12635
PMID:31094319

Original Paper

Digitizing a Face-to-Face Group Fatigue Management Program: Exploring the Views of People With Multiple Sclerosis and Health Care Professionals Via Consultation Groups and Interviews

Sarah Thomas[1], BSc (Hons), PhD; Andy Pulman[1], MA, PhD; Peter Thomas[1], BSc, PhD, CStat; Sarah Collard[1], BA, MSc, PhD; Nan Jiang[2], BEng, MSc, PhD; Huseyin Dogan[2], BSc, MSc, PG Cert, EngD; Angela Davies Smith[3], MCSP, PGCE, MSc; Susan Hourihan[4], MSc (Multiple Sclerosis), BAppSc(OT); Fiona Roberts[5], Dip COT; Paula Kersten[6], BSc, MSc, PG Cert, PhD; Keith Pretty[2], BSc (Hons), MBA, PGCE, FHEA; Jessica K Miller[7], BA (Hons), MPhil Cantab, PhD; Kirsty Stanley[8], BSc (Hons) OT; Marie-Claire Gay[9], BSc, PhD

[1]Bournemouth University Clinical Research Unit, Faculty of Health & Social Sciences, Bournemouth University, Bournemouth, United Kingdom
[2]Faculty of Science & Technology, Department of Computing and Informatics, Bournemouth University, Bournemouth, United Kingdom
[3]Bristol and Avon Multiple Sclerosis Service, North Bristol National Health Service Trust, Bristol, United Kingdom
[4]Therapy and Rehabilitation Service, National Hospital for Neurology and Neurosurgery, University College London Hospitals, London, United Kingdom
[5]Long Term Conditions Team, The Walton Centre National Health Service Trust, Liverpool, United Kingdom
[6]School of Health Sciences, University of Brighton, Brighton, United Kingdom
[7]Department of Sociology, University of Cambridge, Cambridge, United Kingdom
[8]Dorset Multiple Sclerosis Service, Poole Hospital National Health Service Foundation Trust, Poole, United Kingdom
[9]Paris Nanterre University, Paris, France

Corresponding Author:
Sarah Thomas, BSc (Hons), PhD
Bournemouth University Clinical Research Unit
Faculty of Health & Social Sciences
Bournemouth University
R506, Royal London House
Bournemouth,
United Kingdom
Phone: 44 1202961953
Email: saraht@bournemouth.ac.uk

Abstract

Background: Fatigue is one of the most common and debilitating symptoms of multiple sclerosis (MS) and is the main reason why people with MS stop working early. The MS Society in the United Kingdom funded a randomized controlled trial of *FACETS*—a face-to-face group-based fatigue management program for people with multiple sclerosis (pwMS)—developed by members of the research team. Given the favorable trial results and to help with implementation, the MS Society supported the design and printing of the FACETS manual and materials and the national delivery of FACETS training courses (designed by the research team) for health care professionals (HCPs). By 2015 more than 1500 pwMS had received the FACETS program, but it is not available in all areas and a face-to-face format may not be suitable for, or appeal to, everyone. For these reasons, the MS Society funded a consultation to explore an alternative Web-based model of service delivery.

Objective: The aim of this study was to gather views about a Web-based model of service delivery from HCPs who had delivered FACETS and from pwMS who had attended FACETS.

Methods: Telephone consultations were undertaken with FACETS-trained HCPs who had experience of delivering FACETS (*n=8*). Three face-to-face consultation groups were held with pwMS who had attended the FACETS program: London (n=4), Liverpool (n=4), and Bristol (n=7). The interviews and consultation groups were digitally recorded and transcribed. A thematic analysis was undertaken to identify key themes. Toward the end of the study, a *roundtable* meeting was held to discuss outcomes from the consultation with representatives from the MS Society, HCPs, and pwMS.

Results: Key challenges and opportunities of designing and delivering an integrated Web-based version of FACETS and maintaining user engagement were identified across 7 themes (delivery, online delivery, design, group, engagement, interactivity,

and HCP relationships). Particularly of interest were themes related to replicating the group dynamics and the lack of high-quality solutions that would support the FACETS' weekly homework tasks and symptom monitoring and management.

Conclusions: A minimum viable Web-based version of FACETS was suggested as the best starting point for a phased implementation, enabling a solution that could then be added to over time. It was also proposed that a separate study should look to create a free stand-alone digital toolkit focusing on the homework elements of FACETS. This study has commenced with a first version of the toolkit in development involving pwMS throughout the design and build stages to ensure a user-centered solution.

(JMIR Form Res 2019;3(2):e10951) doi:10.2196/10951

KEYWORDS

multiple sclerosis; fatigue; telemedicine; mobile health; FACETS; fatigue management

Introduction

Background

Multiple sclerosis (MS) is a neurological condition affecting the central nervous system. Over 2.5 million people have MS worldwide [1]. Fatigue is one of the most common and debilitating symptoms of MS and is the main reason why people with MS (pwMS) stop working early. Its invisible nature can make it difficult to understand and recognize. There are around 10,000 unique visits to the UK MS Society's fatigue Web page [2] each year. Fatigue management is one of the most common helpline enquiry topics and the most frequently accessed, printed, and downloaded resource material. Fatigue is the third priority in the James Lind Alliance research priorities for MS [3].

MS is typically diagnosed when people are at their most productive age (average onset at 29 years of age) [1] and the burden on the global economy is increasing as costs have shifted toward outpatient care since the mid-1990s [4]. Against a backdrop of a restrained health care environment and increased emphasis on self-management, digital solutions offer huge potential to provide personalized and cost-effective ways of improving aspects of health and social care [5-6].

FACETS (Fatigue: Applying Cognitive behavioural and Energy effectiveness Techniques to lifeStyle) is a group-based fatigue management program for pwMS, developed by a team based at Bournemouth University and Poole Hospital. The FACETS program blends energy effectiveness principles with cognitive behavioral (CB) approaches [7,8] and consists of 6, weekly, face-to-face (F2F) sessions (Table 1). It is designed to be delivered by 2 health care professionals (HCPs) in small groups (6 to 10 people). Each session incorporates brief presentations, group discussions, and activities. Attendees are asked to complete weekly homework tasks to try out strategies covered in sessions.

The MS Society funded a national multi-center pragmatic randomized controlled trial (RCT) of FACETS versus usual care. Findings from the RCT (n=164) indicated that FACETS was effective [9] with significant improvements in fatigue self-efficacy (Standardized Effect Size [SES]=.36) and fatigue severity (SES=−.35) at 4 months follow-up in the FACETS arm relative to the usual care arm, with most participants reporting they had successfully implemented fatigue management strategies [10]. These improvements largely persisted a year on from the FACETS program (SES fatigue self-efficacy=−.29 and SES fatigue severity=.34), and there was also a significant improvement in MS-specific quality of life (SES=−.24) that had not been present at 4 months [11]. Given these favorable results, and to help with FACETS implementation, the MS Society supported the design and printing of the facilitator manual and participant materials and the national delivery of 1-day training courses (designed by members of the research team) for HCPs. By 2015, around 200 HCPs had been trained to deliver FACETS and an estimated 1500 pwMS in the United Kingdom had received the FACETS program [12].

Rationale and Aims

The FACETS program is not available in all areas of the United Kingdom. Work commitments, mobility or cognitive impairments, rurality and transport issues, or personal preferences might mean digital delivery would be more convenient or appealing for some pwMS. The MS Society was therefore keen to consider alternative delivery models. The project aims were to undertake a consultation to:

1. Gather views from HCPs and pwMS about a Web-based model of service delivery, considering aspects of delivery format and mode.
2. Obtain feedback about how best to adapt FACETS for Web-based delivery (known as *cFACETS*).

Table 1. Overview of the FACETS program.

Session number	Session title	Homework element(s)
1	What is MS[a]-related fatigue?	Activity/fatigue diary; Energy measure
2	Opening an *energy account*	Rest/activity/sleep planner
3	Budgeting energy and *smartening up* goals	Goal-setting exercise
4	The stress response; the cognitive behavioral model	Fatigue thought diary
5	Putting unhelpful thoughts on trial	Thought challenge sheet
6	Recapping and taking the program forward	*Keeping on Track* planner

[a]MS: multiple sclerosis.

Methods

Ethical approval was obtained from Bournemouth University (ref. 14371).

Study Design

We used a combination of telephone interviews with health care professionals and consultation groups with people with MS. Toward the end of the project, we held a roundtable meeting in London to discuss the findings from the consultation with representatives from the MS Society, HCPs, and pwMS.

Participants, Recruitment, and Consent

We aimed to conduct 8 telephone interviews with HCPs. HCPs were identified via the project lead's networks and via an MS Society database. They were sent an information sheet and a copy of the consent form via email. Before the interview, the consultation coordinator answered any questions they had, checked whether they were willing to be audio-recorded, and explained the consent process. If they wished to take part, their verbal consent was recorded at the start of the telephone consultation. If they preferred not to be audio-recorded, they were given the option of providing written consent, with notes taken instead.

We planned to conduct consultation groups with pwMS in 3 UK locations (London, Bristol, and Liverpool). PwMS were identified via a gatekeeper (these were HCPs) at each location. The gatekeeper identified pwMS who had previously attended the FACETS program (Bristol and London), those attending MS clinics (London and Liverpool), or those currently attending a FACETS program (all 3 locations). They gave or sent them information about the service improvement consultation and a copy of the consent form. Those interested in participating were asked to email or telephone the consultation coordinator. Before the consultation group, the consultation coordinator answered any questions they had, checked if they were willing to be audio-recorded, and explained the consent process. If they preferred not to be audio-recorded, they were offered a one-to-one telephone interview with notes taken instead.

Procedures and Measures

The consultation groups and interviews were undertaken by an experienced qualitative researcher. Topic guides were used to ensure areas of interest (such as aspects related to delivery mode and format) were covered, while still allowing flexibility. The telephone interviews with HCPs were audio-recorded using a digital audio-recorder connected directly to the telephone.

The consultation groups with pwMS were held in local accessible venues. As fatigue is a major issue for many people with MS, we ensured that the groups lasted no longer than 90 min and included regular breaks, refreshments, and lunch. It was emphasized that participants could take a break or withdraw from the group at any time. To minimize burden, written consent was obtained on the day of the consultation groups. Following informed written consent, participants answered a brief self-report questionnaire (demographic information, MS-related characteristics, and familiarity with technology).

Interviews and consultation groups were audio-recorded and transcribed verbatim. Outcomes of the consultation were discussed at a roundtable meeting that included representatives from the consultation team, the MS Society, HCPs, and pwMS.

Analysis

Quantitative questionnaire data were analyzed and summarized using descriptive statistics.

A generic qualitative approach to thematic analysis was used [13] with inter-researcher interpretation. Following familiarization with the transcripts, a member of the team charted themes in a matrix. Subsequently, 2 other team members familiarized themselves with the transcripts and the matrix of initial themes. They developed an agreed coding scheme using an analytical framework that combined a priori issues from the original topic guide and emerging themes [14].

Results

Overview

In total, telephone interviews with 8 HCPs (6 occupational therapists and 2 physiotherapists) took place, 4 of whom were identified via the project lead's networks and 4 from an MS Society database. All HCPs were willing to be audio-recorded. All had been working as HCPs for 10 years or more and had delivered FACETS 72 times in total (mean 9 [SD 3.6] times, range 4 to 15). Four were based in the community, 3 worked in hospitals, and 1 worked in an inpatient setting. All had attended the FACETS facilitator training provided by the MS Society with the exception of one HCP who had been trained by a FACETS-trained colleague. Interview durations ranged from 36 to 81 min (mean 61 [SD 16.6] min).

All pwMS were willing to be audio-recorded. A total of 3 consultation groups were held with pwMS between May and September 2017 (London, n=4; Bristol, n=7; and Liverpool, n=4) with similar numbers of males and females participating. Most participants had attended FACETS within the past year; 3 had attended 2 to 3 years ago (based on their self-report). The mean age (SD) of the sample was 53 (12) years and time since diagnosis ranged from 1-5 years to >20 years. All types of MS were represented (Table 2).

A total of 15 people attended the roundtable meeting that was held on June 19, 2017 in an accessible building in central London. Attendees included representatives from Bournemouth University (psychology, qualitative research, and human computer interaction; n=4); the MS Society (information and support, digital, innovation, and self-management; n=6); clinical practice (occupational therapy and physiotherapy; n=3); and pwMS (n=2).

Qualitative Themes

A total of 7 themes were identified (Table 3 and Multimedia Appendices 1-7).

FACETS: Delivery

Key Aspects

A total of 7 key aspects of FACETS were identified (Table 4). The group aspect was considered central to the success of the program. It was seen to provide an environment for peer learning and sharing in which empathy, mutual support, and sometimes plain speaking could be highly beneficial. Some pwMS described how they continued to be in contact with others from their FACETS group.

FACETS integrates elements from cognitive behavioral, social cognitive, and energy effectiveness theories and principles. It aims to help pwMS to (1) understand more about and normalize MS fatigue; (2) learn how to use available energy more effectively; and (3) learn helpful ways of thinking about fatigue [7]. In the program, although there is a gradual transition from a practical to a more psychological orientation, the cognitive behavioral (CB) elements (thoughts, behaviors, emotions, and physical aspects) are introduced early. This means participants can explore these inter-related elements before the CB model is formally introduced during the fourth session. The CB aspects were considered crucial by HCPs in supporting changes in ways of thinking and lifestyle that often go beyond fatigue management. Other key aspects highlighted included provision of information, the relaxation training and practice, group activities, and the homework tasks (which translate into everyday life).

Positive Aspects and Changing Perspectives

HCPs highlighted that the program structure allows for personal reflections, discussion with trusted others in similar positions, and the opportunity to make behavioral and attitudinal changes with long-term impact. PwMS liked the fact that FACETS offers a positive approach to making lifestyle changes (in comparison with other groups some had attended) and opportunities to consider different ways of thinking that might pave the way for such changes.

Table 2. Self-reported descriptives for consultation group participants (n=15).

Variable	Descriptive statistics
Sex, n (%)	
Male	8 (53)
Female	7 (47)
Age (years), mean (SD) range	53 (12.0) 27-76[a]
Type of MS[b], n (%)	
Relapsing remitting	3 (20)
Secondary progressive	3 (20)
Primary progressive	5 (33)
Don't know	4 (27)
Adapted Patient Determined Disease Steps Scale (APDDS), mean (SD) range	4.13 (1.67) 1-6.5[c]
Time since diagnosis (years), n (%)	
1-5	5 (33)
6-10	3 (20)
11-15	3 (20)
16-20	1 (7)
>20	3 (20)
Employment status, n (%)	
Self-employed	2 (13)
Unable to work	4 (27)
Looking after house and family	4 (27)
Retired	2 (13)
Working full-time	1 (7)
Working part-time	2 (13)
Using phone for, n (%)	
Calling	14 (93)
Internet browsing	7 (47)
Watching videos	2 (13)
Playing games	3 (20)
Texting	12 (80)
Calendar	6 (40)
Reading news	2 (13)
Social networking	6 (40)
Emailing	9 (60)
Listening to music	4 (27)
Diary	6 (40)
Use of apps, n (%)	
Never	2 (13)
Use a few	10 (67)
Use a lot	3 (20)

[a]1 case missing

[b]MS: multiple sclerosis.

[c]Possible scores on the APDDS scale range from 0-10 corresponding to 11 ordinal levels of functioning. However, one participant gave a rating of 6.5 indicating they perceived their functioning to fall between 6 and 7 on the scale. Similarly, another participant gave a rating of 4.5.

Table 3. Key themes identified.

Theme	Description	Multimedia Appendix
FACETS: Delivery	Comments relevant to the delivery of the FACETS program	1
FACETS: Web-based delivery	Comments relevant to the Web-based delivery of the FACETS program	2
cFACETS: Design	Comments relevant to the design of cFACETS	3
cFACETS: Group	Comments relevant to the group dynamics of cFACETS	4
cFACETS: Engagement	Comments relevant to the engagement of users with cFACETS	5
cFACETS: Interactivity	Comments relevant to the interactivity of cFACETS	6
cFACETS: HCP[a] Relationships	Comments relevant to the relationships HCPs might have with cFACETS	7

[a]HCP: health care professional.

Table 4. Key aspects of FACETS identified by people with multiple sclerosis (pwMS) and health care professionals (HCPs).

Key aspects described	Example response
Group delivery format	“And somehow, somebody or something, some way to be able to troubleshoot problems. ‘Cause often that’s what the group does to each other. They help each other out. They find solutions. Sometimes you can just sit back and leave them to it and they, they do actually help each other. Which sometimes you can see, the penny drops for one person because somebody else has said it.” [HCP 1]
Group tasks and homework - how they translate into everyday life	“And the third thing is the tasks translating into real life. The tasks you’re asking people to do at home. So I think that’s one of the key parts.” [HCP 1]
Cognitive behavioral model	“I think the cognitive behavioural therapy aspect of FACETS is really important. ‘Cause that seems to be quite a big barrier I think, in terms of how people take the practical advice going forward, is in terms of how they then view fatigue management and fatigue itself. And often, again, it’s the interaction with people that helps them realise that. And then obviously, like the practical tips and hints from other people as well, so, kinda hearing what other people have tried.” [HCP 2]
Relaxation	“Another really core bit is the relaxation. Whether you can do that with a voice online, because the relaxation techniques become very important to a lot of them because they learn how they can take a quick 5 or 10 minutes while still seeming to be active at their desks. Things like that, you know when people start off by saying, “well I work. I’ve got no way I could possibly leave my desk” or “there’s nowhere to have a rest”, or “we don’t take lunch breaks”, and all those things. Getting them to re-evaluate that and start to take some breaks is one thing. But also, a quick deep breathing session when they practise, they can do it and pretty much look as if they’re still working.” [HCP 1]
Addressing thought barriers as well as providing practical management strategies	“Yeah, I think sometimes patients will challenge each other if they’re having some very unhelpful thoughts. For example, we’ve had somebody in the group who was once talking very much about doing a lot for her son and other patients were, ‘Well, he’s an adult. Why are you doing all of this for him?’ So I think sometimes they can take it better from people who are also patients, rather than from a professional as well. So obviously we can facilitate that conversation as well." [HCP 6]
Contact with a skilled and knowledgeable therapist	“I did think the group was good because you got 6 hours, no 12 hours, with an HCP who is an expert in the area who wants to help you as well and so you felt that. Just the advice, the perspective. I was kind of surprised. I suppose with my particular diagnosis there’s nothing else for me other than advice and guidance about how to just improve your health or deal with the condition. Do you know what I mean? It is so important and it was good that the recognition is there and courses have been developed.” [Participant 2–Consultation Group (CG) 3]
Length of program and the way each week builds on previous content (giving people time to reflect)	“I think a lot of it is common sense and we all know it. But it actually makes you realise that it can be addressed or dealt with maybe in a slightly different way, which you don’t get to stop and think of before. I think that’s another thing, you get time to just stop and discuss other things that you just deal with on a daily basis, but don’t necessarily do it in the best way really. Most effective.” [Participant 3—CG2]

FACETS: Web-based Delivery

Pros and Cons of a Web-based Delivery Model of FACETS

HCPs and pwMS described a variety of pros and cons. These suggest that although a Web-based version would provide a desirable solution offering many benefits, it would complement rather than replace a F2F version (Textboxes 1 and 2).

Textbox 1. Pros of a Web-based delivery model of FACETS.

Pros

- Potentially more cost-effective—would require less professional time than running face-to-face version. (health care professional [HCPs])
- Reduction of the logistical issues around delivering a physical course in a specific location each week. (HCPs)
- Immediately available to everybody—globally extending the reach to people who otherwise might not be able to access it. (HCPs, people with multiple sclerosis [pwMS])
- Addresses the waiting list issue for current course attendance in some areas. (HCPs, pwMS)
- More convenient method of delivery where pace and preferred time of learning—which might be affected by MS symptoms—could be personalized to individual needs and returned to many times if things were unclear. (HCPs, pwMS)
- Could act as a refresher or resource for those who had attended the F2F program. (HCPs, pwMS)
- Those used to interacting in online environments might prefer the online format as might pwMS who do not like the group aspect of delivery. (HCPs, pwMS)
- A Web-based delivery format could help to make some of the content more engaging by employing a wider range of audio and visual stimuli. (HCPs, pwMS)

Textbox 2. Cons of a Web-based delivery model of FACETS.

Cons

- Loss of F2F group aspect of FACETS. (health care professional [HCPs], people with multiple sclerosis [pwMS])
- Hosting a group in an online forum is different from one in which you are meeting others in person—where the group atmosphere with the facilitator is not easily replicated and is less personal. (HCPs, pwMS)
- A Web-based solution is not as responsive as a facilitator who is able to give tailored support when needed and can also proactively head off any misconceptions held by participants or medically concerning comments. (HCPs, pwMS)
- An online participant might need to be quite confident with IT to use a Web-based solution which has some implications for the target group. (HCPs, pwMS)
- There is a reliance on an individual to be motivated to engage and take on board information—which is easier to monitor and manage in a F2F environment. (HCPs)
- Getting buy-in for a Web-based solution to be used and the associated training and support costs for facilitating in a Web-based environment (whether via audio, video, short message service, or email) could be challenging. Providing telephone support has cost and time implications. (HCPs, pwMS)
- Would lack the responsiveness of an experienced facilitator to deal with individual comments and situations as they arise. (HCPs, pwMS)

cFACETS: Design

Audience Demographic

It was noted by HCPs that the age range of pwMS is broad and there will be differing attitudes to, levels of experience with, and acceptance of technology (such as what individuals choose to share online) as well as differing levels of patient activation [15]. Personal circumstances, attitudes to groups, stage of personal journey with MS, and ability to attend F2F sessions will all impact on preferences for a digital option:

> *Everyone's different.* [Participant 4]
>
> *Everyone's different so you give them the option.* [Participant 3—CG3]

The fluctuating nature of MS and MS symptoms make it particularly important to ensure that Web-based materials are easy to access and interact with. HCPs suggested that information about a person's MS and other aspects could be requested at the beginning of cFACETS and content could be individually tailored. This concept aligns with the MS Society's digital strategy in terms of patient activation and personalized self-management [15-17]. However, it was also noted by HCPs that mixed F2F groups seem to work well.

Timing and Pacing Considerations

Pacing considerations were highlighted by both HCPs and pwMS. Delivering content over a minimum of 6 weeks allows for adequate breaks between sessions, provides opportunities for reflection on the topics and homework elements, and increases the likelihood of behavior change. Suggestions also included the prompting of taking breaks within cFACETS.

Look or Structural Considerations

There was a general consensus that the linear structure of FACETS should be kept to ensure materials are not completed out-of-step or rushed through:

> *I think the order that it was delivered, because one thing, you started off as you said, looking at fatigue and types of fatigue and that led on to SMART targets which led on to the cognitive behaviour therapy, so I think it flowed quite nicely from one thing to the next so I think the order is right really. I don't think*

you could do it in any other order to get out of it what we got out of it. [Participant 3—CG3]

Formatting Considerations

When porting printed materials to a digital environment, both HCPs and pwMS emphasized the importance of ensuring they are structured into small, easily digestible chunks [18]. HCPs suggested including a mix of formats to suit different learning styles and providing summaries at the end of sections to enhance retention and consolidation. PwMS felt that an option to print homework materials should be provided in any digital solution. HCPs noted the importance of considering the intended end user of cFACETS in terms of design aspects, for example, using drop-down menus rather than requiring long segments of text to be inputted; avoiding the need for precise movements that may not be possible for those with tremor; and providing audio or video materials to complement text to reduce fatigue and concentration requirements.

Relevance for Important Others

Providing access to program content to others (eg, relatives, friends, carers, work colleagues, and employers) could provide greater awareness about MS fatigue and its impact. Several pwMS noted that with FACETS, this had been beneficial and they were keen to see this aspect preserved or extended:

You know because it is not like a normal fatigue. I just literally crash out but they used to get on my back and say you should just go to bed if you are tired. Trying to explain to them it is not tiredness as such. Luckily having all the info to hand I have been able to sort of say, "look this is what happens - it's the MS, it's not me being tired, it's the MS" which they now understand but I think having the online, maybe you know, there could be some opportunity for your partner if they want to access some of it as well, you know, so that they understand you; know what is happening to you. [Participant 3—CG3]

Phased Implementation Approach

At the roundtable meeting, the MS Society proposed a minimum viable Web-based version as the best starting point for a digital solution to enable core elements of content to be introduced in a timely manner. However, it was recognized by pwMS and HCPs that support elements would need to be considered to bring about and sustain long-term behavior change:

People, you know, behaviour change takes time for a reason and people need time to reflect and you can't just whip through it, like you could do for some other online courses. [HCP 3]

Yes I mean. I don't feel that just putting slides or a presentation on a website for someone to go through will be sufficient. [Participant 6—Roundtable]

Because there is a difference isn't there between finding out about fatigue and whether one of the aims of the [online] course is behaviour change and those are two very different things aren't they? [P1–Roundtable]

FACETS: Group

Online Group Ideas and Size

Capturing the group dynamics of FACETS raised challenges. One option would be to replicate the small closed groups of FACETS but in an online format. If groups were regionally organized, members could break out as a physical group to support each other following the program (which often occurs with connections formed by pwMS during FACETS).

Yeah, I think that would be really beneficial. 'Cause then you effectively have a group of people like you had here, like 8 in a room that say at the end of it, "you know what, let's all meet up, go for a drink!" [Participant 2—CG1]

Telephone Support/Ask the Expert

Providing telephone support during cFACETS or holding *Ask the Expert* sessions were deemed good ideas (albeit with logistical and cost implications) by both pwMS and HCPs. Making use of telephone support by a person unknown to users was not seen to be an issue by pwMS and examples were provided of obtaining support from the MS Society helpline. Web-based support was preferred to telephone support by HCPs (influenced perhaps by the perceived extra cost of providing this option). An advantage of *Ask the Expert* was that those unable to log-in for the live session could access a recording or transcript at a later date. Concerns raised included whether these support mechanisms would primarily tend to engage those who would already be calling helplines; whether they would be sufficient to achieve behavior and lifestyle changes; whether the group aspect would be lost; whether there would be adequate capacity to answer all the questions; and that *Ask the Expert* places the onus back on the HCP to have all the answers as the *expert*.

Given that regular weekly support sessions would likely be unfeasible, an introductory session was suggested as a means of building trust and promoting enthusiasm for asking questions in subsequent sessions and consolidating the key program concepts. Similarly, a closing session could be used to consider the way forward at the end. A computerized expert was proposed as a possible innovation. However, some pwMS viewed this approach as depersonalizing and potentially lacking credibility.

Forums

Forums were discussed as ways to enable peer discussion and sharing of experiences. HCPs had some concerns about a static forum (questions posted and responded to later by others) as it would mean that, unlike in FACETS, misinformation and problematic suggestions could not be dealt with immediately. Static forums would require continuous scanning and moderation of content (which is challenging and time consuming).

I think the only worry is, occasionally when that happens, you get, kind of, un-evidence based ideas. Like, a couple of times in our groups we've had people talk about or really pushing really extreme diets. Or, somebody that was really pushing oxygen therapy. And, we were able to say within that, what

> *the evidence base says about that. So I don't know how you quite monitor that in those forums.* [HCP 4]

However, most pwMS reported feeling comfortable with using forums, and there were no strong preferences in terms of a closed (restricted to cFACETS users) versus an open (available to others with MS) format.

Group Aspect/Webinar

Capturing the F2F facilitated group environment online was a key challenge that was identified. The use of webinars was proposed by HCPs and pwMS as an interactive way of complementing other online materials (and could either be viewed live or later). Getting a number of participants to *meet up* regularly at the same time each week was acknowledged to be more difficult to achieve online than F2F. From a logistical point of view, it could be challenging to ring-fence each separate cohort progressing through cFACETS to maintain the closed group dynamic:

> *There's something different that happens when you're physically in the room with someone. Even seeing their face online is not the same.* [Participant 5—CG1]

Other challenges concerned the format of the technology being used and whether sound and vision would be possible for everyone in the group or just for the facilitator. Discussions also included whether live or prerecorded sessions made available later could be used as a *catch-up* resource for those unable to attend specific sessions.

Trust and Safeguarding

One of the most positive aspects of FACETS described by pwMS was how meeting up regularly with the same group helped to build an element of trust that allowed close relationships to be formed. This enabled discussions about topics that might not otherwise have been discussed:

> *It's a safe place. When you're all together and expressing yourself, it's a safe place.* [Participant 7—CG1]

Booster Sessions

Booster sessions could be a helpful complement to FACETS to enable a facilitated review of progress and barriers encountered following the program [10]. These obtained favorable feedback as a means of providing opportunities for pwMS to revisit problematic issues, discuss new challenges, and refresh key principles.

cFACETS: Engagement

Keeping People Engaged or Adhering to It

It was suggested that some challenges to maintaining engagement could be addressed by ensuring that content is relevant for and useful to the user:

> *It's what you get out of it, isn't it? If you think, "I'm benefitting from this" then you'll want to do it. If you think "it's a waste of time" then you're not going to bother.* [Participant 1—CG2]

Interruption levels and distractions may be higher in an online environment than in a F2F group. When learning about relaxation techniques, some pwMS felt that without the F2F guidance from facilitators, the Web-based content would not be as engaging to view or easy to understand.

Feedback from pwMS suggested that they found the FACETS materials engaging—one of the reasons they continued to attend the program—and sometimes returning to the materials after the program had ended elicited changes in behavior or lifestyle adjustments. However, it was noted that digitization of the materials would require reformatting; for example, providing information in brief chunks and providing feedback following completion of sections and homework elements (which could then be used as a trigger to unlock new content).

It was acknowledged by pwMS and HCPs that not everyone would have the intrinsic motivation or self-efficacy to complete a self-guided Web-based version of the program. Being part of a group makes people feel a certain commitment to attend each week. It was felt that the key motivators of the FACETS program were the benefits experienced from attending the program and a sense of accomplishment from completing it.

Keeping in Touch/Reminders

PwMS generally thought that reminder and notification messages would be helpful in a Web-based version so long as there was choice over their format, configuration, and frequency. Reminders could prompt users to return to the materials at specific times, provide encouragement, and could also be used for personalized, responsive messages.

Homework

Homework is an important element of FACETS—enabling members of the group to try out aspects covered during sessions:

> *The more you put into your homework, the more you'll get out of the course as a whole. And over time, there's always the odd one that hasn't done stuff, but by the end of the group, even if people haven't written things down, they've been thinking about it during the week 'cause they know there isn't the pressure to write it down. And I don't know how you would do that online.* [HCP 3]

Both pwMS and HCPs felt the homework tasks would transfer well to a mobile device and that this could also provide opportunities for completion reminders and symptom monitoring and management.

Introducing the Cognitive Behavioral Model

HCPs felt that the gradual introduction of the cognitive behavioral model (CBM) in the FACETS program works well and noted it could have been too much to take on board had it been formally introduced in Session 1:

> *I think if it had been in the first session, I don't think I'd have liked that bit because it would have been just too much to take on board.* [Participant 2—CG3]
>
> *By the time they actually bring up the model, the person is actually familiar with all the terminology in that they've heard it in every week beforehand. So they've actually been talking about it the whole time, but they haven't, it hasn't been called that until, I*

> *think it is the 5th session. So, when it finally does come up, people are really open to it because they've heard it, they've worked with it, they understand it, it makes sense to them.* [HCP 4]

In a Web-based delivery format, the CBM could be presented via clickable content alongside video or audio content from HCPs and pwMS to provide further explanations and real-life examples. It was suggested that these sessions may require support from an HCP and a live element of peer interaction.

Rewards/Gamification/Goal Setting

Various forms of rewards and gamification were suggested such as obtaining a certificate or trophies; adding elements to a virtual interactive scene or pieces to a virtual jigsaw puzzle; and giving advice to an animated character. HCPs and pwMS held mixed views about gamification with many feeling that extrinsic motivators were not necessary:

> *I think the reward should be from having benefitted. I don't necessarily think that professionals should be rewarding people 'cause that kind of puts, feels almost a bit like a parent-child kind of relationship really.* [HCP 6]

One HCP suggested that it would be helpful if users receive some form of acknowledgment or feedback about the goals they set in any Web-based version:

> *If there was some way that they could continue to engage with the process and tick off when they feel they've achieved a goal or something, that would be quite nice.* [HCP 2]

PwMS noted that, in the F2F FACETS groups, attendees sometimes require additional explanations and support from the facilitators for the specific, measurable, achievable, and realistic with time for review (SMART) goal setting task in Session 3. They suggested it would be helpful to provide users with a variety of interactive examples of SMART goals in a Web-based version.

Progress Bar/Dashboard

Suggestions for ways to highlight progress included using tracking to document accessed sections and displaying progress on a central dashboard. Occasional user prompts and notifications could be incorporated to acknowledge progress and section completion:

> *It is useful to have that, how far you've gone.* [Participant7—CG1]

> *You might have people feeling that they can't proceed any further if they haven't got everything ticked...* [Participant6]

cFACETS: Interactivity

Flipcharts

Within FACETS, flipcharts are used frequently. HCPs noted they help to keep things *fluid* and maintain momentum. Flipcharts were seen to be an important means of adding variety to sessions, highlighting links between content and identifying patterns in behaviors and thinking, promoting focused discussions, and encouraging groups who may be quieter.

One HCP noted that although using real examples of flipchart content could be engaging, care would be needed to avoid this seeming scripted or formulaic. Forums were seen as possible alternatives to flipcharts or could be used in combination with flipcharts:

> *So I guess in an online bit, the discussion becomes the flipchart. Because, it will be where they write and see what other people are saying.* [HCP 2]

Technical Interactivity

The use of video and audio components within cFACETS, accessible on a number of different devices, was positively received by pwMS and HCPs. It was suggested that particular elements of FACETS might benefit from having different approaches in terms of the presenter—such as having HCPs and pwMS talking to the camera about a topic or, alternatively, a group being filmed in particular situations—for example, discussing a certain issue or feeding back about a homework task:

> *I'm wondering if there'd be any potential to have a video of a group speaking about different things...the way [XX] has just spoken about...that's very powerful.* [Participant 2—CG3]

Interactive tasks (including quizzes and polls) were also suggested by both HCPs and pwMS as engaging ways to communicate content and give the user a sense of *ownership*.

> *So I think with the tasks, just having more tasks, more click buttons, more things that they have to fill in so they're actually getting a bit more ownership of it.* [HCP 1]

Real or Virtual

There was much discussion surrounding the use of real people versus virtual characters. The consensus of pwMS tended toward using real HCPs or pwMS to convey key points, rather than using avatars or cartoons:

> *I won't trust them. I won't trust them 'cause I don't know them. They're not real, so. Personally, I don't respond well to avatars.* [Participant 5—CG1]

It was noted that having FACETS delivered by HCPs with a mix of professional backgrounds provides complementary perspectives and that pwMS could also be involved in delivering a Web-based version (or the choice of facilitator could be up to the user). It was considered important to include HCP support so that incorrect or problematic suggestions could be addressed.

Animations were considered useful but some pwMS felt they can feel patronizing and risk trivializing the subject matter. VideoScribe [19] was suggested as one example of a visual tool that could have a variety of possible uses (storytelling, conveying key concepts, and virtual flipcharts).

cFACETS: Health Care Professional Relationships

Health Care Professional Involvement

Reflecting on FACETS delivery, HCPs felt that their support would continue to be necessary to help achieve long-term behavior and lifestyle changes. Without some form of additional support and facilitation, there were concerns that the shifts and movements in people's thinking, integral to FACETS' success, might be less likely to occur. Several HCPs advised they could, in principle, be involved in an *Ask the Expert* component so long as there were prescheduled dates and time slots organized well in advance, and the role was shared among several HCPs.

Supporting Health Care Workers/Complementing Care

How cFACETS could complement existing care was also considered. It was felt by HCPs that any Web-based version should not replace the F2F programs being delivered, as the F2F format works well. However, giving pwMS the option of attending a group session or accessing a Web-based version could increase reach (though technical issues, such as low internet speeds in rural areas, would need consideration).

Discussion

Principal Findings

The consultation feedback highlighted the positive aspects of FACETS that have made it a successful program to date—including the group dynamics, CB approach, and sequential delivery model. Conclusions from the roundtable meeting were that a minimum viable Web-based version was the best starting point as it would allow for a digital solution to be implemented that could be added to over time. As potential app-based solutions were outside of the scope for digitizing FACETS in a minimum viable form, another recommendation was that a separate project should look to create a free, stand-alone digital toolkit focusing on the FACETS homework elements and possibilities for real-time symptom monitoring and management.

In their systematic review of MS apps present in US app stores [20], Giunti et al found that, compared with other long term conditions such as cancer and diabetes [21-23], there were relatively few apps available (n=25). Van Kessel et al [24] similarly noted that there is currently limited access to F2F cognitive behavioral therapy (CBT)–based interventions. Three authors of the current article (PK, ST, PT) have collaborated with van Kessel and others to create a self-guided CBT fatigue management app—*MSEnergise*—for iOS [25]. Usability and field testing are currently underway.

A complementary mobile solution enabling the FACETS homework elements to be made interactive and portable aligns closely with recommendations from the MS Society *Data and Technology* Report [16] and Action Plan [17] (specifically the areas of having more control over care and accessible and coordinated care). It would also help to meet the aims of the MS Society research strategy concerning self-management and implementation [26] and help address the third (fatigue) and fourth (self-management) James Lind Alliance research priorities for MS [3].

Giunti et al have called for much greater involvement of pwMS and HCPs before digital solutions are implemented [27,28]. In a number of health care implementations offered to date, user requirements, existing patterns of use, and HCP reflections have not been considered before or during the development of a solution [29,30]. It is imperative that consideration is given to the requirements of pwMS throughout the development, prototyping, and implementation of any digital solutions [16,17,31]. Feedback from this consultation has highlighted the opportunities and challenges of designing for an online audience of pwMS in terms of user requirements, design elements, and structural and pacing considerations.

A paced delivery format would mean that group members could work through the cFACETS program as a closed cohort. Although such a model could promote the idea of a group identity, it might undermine the flexibility and potential strengths of Web-based delivery. It was deemed key to design a Web-based version that could be accessed by, and have relevant content for, family members, friends, and work colleagues in addition to pwMS. Capturing the group element of FACETS in any digital solution was seen as a priority while at the same time not compromising on aspects of trust or safeguarding. However, it might not be possible to capture this aspect of the program fully online. Safeguarding issues were raised, including the importance of ensuring procedures were in place within any online group environment should significant disclosures be made or fake profiles be exposed [32].

Research is currently underway with French colleagues to develop and test the suggested concept of booster sessions [33]. Web-based booster sessions could offer cost and time efficiencies and be designed as a menu of key concepts and tools, incorporating a number of formats such as *Ask the Expert*, webinars, and chat forums.

Maintaining engagement with a Web-based program presents considerable challenges [34-38]. Responses highlighted the importance of considering the most effective ways of maintaining engagement. First, how configurable reminders, gamified elements, rewards and the use of progress bars and dashboard layouts might encourage engagement and adherence [28] and limit dropout [35]. For example, providing help buttons, linking goals via a mobile phone and providing real-life examples from pwMS could be ways to address engagement with SMART goal setting and completion. Second, how offering scheduled booster sessions digitally once the Web-based program has ended might improve long-term engagement [33]. Additionally, suggestions were made regarding how best to make use of the program's homework elements to ensure they are accessed, completed, and reflected upon and how best to exploit the strengths of a digital format when introducing complex elements such as the CBM [7,10]. In FACETS, those who have not completed the homework still obtain benefits from *check-in* discussions at the start of each session. On the Web this could take the form of videos of people discussing the homework or chat forums that focus on the homework. Diaries and completed homework tasks could feature in a dashboard—but design and functionality aspects would require careful consideration to ensure tracking features are not overbearing.

Although interventions using Web-based approaches have shown promise within health care and in the support of pwMS [39,40], one recommendation from Beatty et al's [41] study of an intervention for cancer-related distress was that future Web-based programs should be multi-platform in nature (so interventions could be used across the full range of smart devices and computers, enabling greater access). Findings from a recent RCT of a German CBT self-guided interactive Web-based intervention for MS fatigue were promising though dropout was relatively high in the intervention group (26% at postintervention follow-up) [42]. This again highlights the importance of considering issues of adherence and engagement when designing and developing digital solutions.

Interactive approaches were seen to be highly important to enhance and maintain engagement and enable personalization [16,17]. Examples were given from FutureLearn [43], where a number of short videos are located on different pages, with transcriptions available below. Suggestions were made regarding how session elements, such as flipcharts, could be made interactive in a Web-based delivery format. Metaphors and analogies presented visually could help to convey aspects of invisible symptoms [44]. Other suggested options for improving engagement included using video and audio elements to either replace or complement different program sections and using appropriately pitched interactive characters—animated therapists have been successfully used in other interventions [45]—and interactive quizzes and polls.

Participants also suggested how a Web-based solution could potentially link with HCPs in terms of delivery of and complementing existing care, alongside the continuation of the successful F2F program. There are potential benefits from enabling clinical teams to interface with an online solution—such as possibilities for remote monitoring and support. HCP involvement in cFACETS would vary depending upon the types of solutions suggested and their resource and workload implications. An online solution could be offered with optional support to accommodate differing preferences, needs and levels of patient activation [16,17]. If technology allowed, an enhanced support version could include an option for members of an individual's clinical team to check-in and see how they are doing and for progress alerts to be sent. This could allow pwMS to send questions to members of their own MS team or be able to view details of their MS team via a dashboard when invited to take part. It could also provide an information resource about fatigue for HCPs and other professionals supporting pwMS.

Providing a digitized version of FACETS opens up opportunities for different evaluation methods and ways to enhance and measure reach and impact. Thought should also be given to a wider evaluation of the current FACETS program than previously undertaken [12], as anecdotal evidence from this consultation suggested that the cumulative impact is under-reported.

Digitizing FACETS also presents challenges in terms of successfully replicating group dynamics—a key program component—and mirroring the pacing of the 6-session format where concepts and materials are introduced in a structured and staged manner allowing time for familiarization, reflection, and practice. Findings from the consultation suggested that consideration be given to the inclusion of a human support aspect to maintain adherence and increase the likelihood of behavior change [46-48].

Even acknowledging these challenges, the potential of a digital environment should not be overlooked. Relative to other long-term conditions, MS is currently under-served by health technology. New technology enhancements offer opportunities for personalized electronic health solutions relevant to pwMS and the management of fatigue [16,17] such as voice-activated speakers [49] and the ability to collect live biometric data by using plug-in oximeters and wearable monitoring devices (although accuracy still needs improving) [50]. There is also the possibility of exploring future integration with existing data streams, such as linking data recorded about FACETS attendance and from the homework tasks (such as goal setting and future plans) to a national MS register [51].

Limitations

The consultation discussions did not fully cover how pwMS were currently utilizing technology and the issues they had encountered. These limitations are being addressed via consultation groups with pwMS that will provide additional information for the initial design requirements of the digital toolkit. A further limitation was that no MS nurses were interviewed. Attempts to recruit MS nurses proved unsuccessful, but the majority of HCPs who have attended the FACETS training and delivered the program in clinical practice are occupational therapists. As the consultation did not include pwMS who have not attended FACETS, those who volunteered to participate in the consultation were likely to have relatively high levels of patient activation and hold a positive view of the program. This limitation can be addressed during the development of cFACETS and the digital toolkit by obtaining insights from a wider group of pwMS (including those who have not attended FACETS), using an online study and theory-led approach such as that piloted by Apolinario et al [52].

Conclusions

A minimum viable Web-based version of cFACETS was considered the best starting point, enabling a phased solution that could be added to over time. It was also suggested that creating a free, stand-alone digital toolkit focusing on the homework elements of FACETS could add value to cFACETS and fill a missing gap in mobile health for pwMS. Funding for an initial version of the digital toolkit has been obtained. The first version is in development with close involvement from pwMS during the design and build phases [53]. Meaningful involvement of pwMS is essential in all stages of development, prototyping, and implementation to achieve a user-centered solution.

Acknowledgments

ST and PT conceived and designed the study. SC carried out the interviews with HCPs. SC and ST conducted 2 consultation groups and ST conducted 1 consultation group. SC charted the data from the interviews and consultation groups. ST and AP conducted the data analysis. AP led the preparation of the paper. All authors critically reviewed and revised the paper and participated in the final approval.

The authors wish to thank all the pwMS and HCPs who took part in the consultation groups and interviews. Funding for the cFACETS consultation was provided by the MS Society of the United Kingdom.

Conflicts of Interest

None declared.

Multimedia Appendix 1

FACETS Delivery Comments.

[DOCX File, 27KB - formative_v3i2e10951_app1.docx]

Multimedia Appendix 2

FACETS Web-based Delivery Comments.

[DOCX File, 23KB - formative_v3i2e10951_app2.docx]

Multimedia Appendix 3

cFACETS Design Comments.

[DOCX File, 27KB - formative_v3i2e10951_app3.docx]

Multimedia Appendix 4

cFACETS Group Comments.

[DOCX File, 31KB - formative_v3i2e10951_app4.docx]

Multimedia Appendix 5

cFACETS Engagement Comments.

[DOCX File, 31KB - formative_v3i2e10951_app5.docx]

Multimedia Appendix 6

cFACETS Interactivity Comments.

[DOCX File, 24KB - formative_v3i2e10951_app6.docx]

Multimedia Appendix 7

cFACETS HCP Relationships Comments.

[DOCX File, 21KB - formative_v3i2e10951_app7.docx]

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Abbreviations

CB: Cognitive behavioral
CBM: Cognitive behavioral model
CBT: Cognitive behavioral therapy
cFACETS: Digitized version of FACETS program
CG: consultation group
FACETS: Fatigue: Applying Cognitive behavioural and Energy effectiveness Techniques to lifeStyle
F2F: face-to-face
HCP: health care professional
MS: multiple sclerosis
pwMS: people with multiple sclerosis
RCT: randomized controlled trial
SES: standardized effect size
SMART goals: Goals which are specific, measurable, achievable, and realistic with time for review

Edited by G Eysenbach; submitted 18.12.18; peer-reviewed by R Haase, J Apolinário-Hagen; comments to author 31.01.19; revised version received 01.03.19; accepted 04.03.19; published 22.05.19.

Please cite as:
Thomas S, Pulman A, Thomas P, Collard S, Jiang N, Dogan H, Davies Smith A, Hourihan S, Roberts F, Kersten P, Pretty K, Miller JK, Stanley K, Gay MC
Digitizing a Face-to-Face Group Fatigue Management Program: Exploring the Views of People With Multiple Sclerosis and Health Care Professionals Via Consultation Groups and Interviews
JMIR Form Res 2019;3(2):e10951
URL: http://formative.jmir.org/2019/2/e10951/
doi:10.2196/10951
PMID:31120021

Original Paper

Connecting Home-Based Self-Monitoring of Blood Pressure Data Into Electronic Health Records for Hypertension Care: A Qualitative Inquiry With Primary Care Providers

Sarah Rodriguez[1], BSN, RN; Kevin Hwang[2], MD, MPH; Jing Wang[3], PhD, MPH, RN, FAAN

[1]Cizik School of Nursing, The University of Texas Health Science Center at Houston, Houston, TX, United States

[2]McGovern Medical School, The University of Texas Health Science Center at Houston, Houston, TX, United States

[3]School of Nursing, The University of Texas Health Science Center at San Antonio, San Antonio, TX, United States

Corresponding Author:
Jing Wang, PhD, MPH, RN, FAAN
School of Nursing
The University of Texas Health Science Center at San Antonio
MSC 7851
7703 Floyd Curl Drive
San Antonio, TX, 78229
United States
Phone: 1 210 450 8561
Email: wangj1@uthscsa.edu

Abstract

Background: There is a lack of research on how to best incorporate home-based self-measured blood pressure (SMBP) measurements, combined with other patient-generated health data (PGHD), into electronic health record (EHR) systems in a way that promotes primary care workflow without burdening the primary care team with irrelevant or superfluous data.

Objective: The purpose of this study was to explore the perspectives of primary care providers in utilizing SMBP measurements and integrating SMBP data into the clinical workflow for the management of hypertension in the primary care setting.

Methods: A total of 13 primary care physicians were interviewed in total; 5 in individual interviews and 8 in a focus group. The interview questions were centered on (1) the value of SMBP in hypertension care, (2) needs of viewing SMBP and desired visual display, (3) desired alert algorithm and critical values, (4) needs for other PGHD, and (5) workflow of primary care team in utilizing SMBP. The interviews were audiotaped and transcribed verbatim, and a thematic analysis was performed to extract overarching themes.

Results: The primary care experience of the 13 providers ranged from 5 to 35 years. The following themes emerged from the individual and focus group interviews: (1) ways to utilize SMBP measurements in primary care, (2) preferred visual display of SMBP, (3) patient condition determines preferred scheduling of patient SMBP measurements and provider's preferred frequency of viewing SMBP data, (4) effect of patient condition on alert parameters, (5) location to receive critical value alerts, (6) primary recipient of critical value alerts, and (7) the need of additional PGHD (eg, emotional stressors, food diary, and medication adherence) to provide context of SMBP values.

Conclusions: The perspectives of primary care providers need to be incorporated into the design of a built-in interface in the EHR to incorporate SMBP and other PGHD. Future usability evaluation should be conducted with mock-up interfaces to solicit opinions on the optimal alert frequency and mechanism to best fit the workflow in the primary care setting. Future studies should examine how the utilization of a built-in interface that fully integrates SMBP measurements and PGHD into EHR systems can support patient self-management and thus, improve patient outcomes.

(JMIR Form Res 2019;3(2):e10388) doi:10.2196/10388

KEYWORDS

patient-generated health data; connected health; remote monitoring; electronic health record; hypertension; patient reported outcome; self-measured blood pressure; self-monitoring of blood pressure

Introduction

Poorly controlled hypertension has been shown to increase the risk for cardiovascular diseases and other related deaths. In the United States, approximately 1 in 3 adults and 2 in 3 older adults have hypertension, but only half of these patients have their blood pressure (BP) under control [1]. This presents a significant public health challenge, particularly in the primary health care setting. For this reason, effective intervention strategies that can help patients achieve optimal BP control have become a priority in health care [1]. Appropriately collecting and acting on patient-generated health data (PGHD), such as self-measured blood pressure (SMBP) data, has the potential to better engage patients in self-care, improve patient outcomes, and reduce health care costs related to readmission and emergency room visits. A recent study, implementing a 30-day program that utilized remote monitoring of SMBP measurements, showed significant reductions in the BP values of hypertensive patients [2]. A 2013 systematic review and meta-analysis previously demonstrated the use of SMBP was found to be effective with or without any additional support [3]. However, a more recent systematic review and meta-analysis shows strong evidence that the intensity of additional support combined with the self-monitoring drastically improved the effectiveness of SMBP on lowering BP in hypertensive patients when compared with self-monitoring alone [4]. Additional studies have explored patient and provider perspectives on using SMBP to identify best practices for using SMBP in a clinical practice. Although these studies explored the use of SMBP in clinical practice, no efforts have been made to integrate SMBP directly into the electronic health record (EHR) to fit workflow in the clinical setting. One study examined wirelessly transmitting SMBP measurements to an interactive Web-based system, which is then linked to clinicians' EHR system [5]. This 6-month pre- and postevaluation study showed promising results in patient BP control. Measuring SMBP with standardized machines that are wirelessly connected to EHR systems yields more objective data compared with the values reported by patients. Combined with other PGHD, including lifestyle behaviors and medication adherence, SMBP measurements can facilitate better behavior changes in patients by providing them with a clear picture of how medication and lifestyle play a role in BP control. The combination of PGHD and SMBP measurements also allows providers to see if the prescribed treatment regimen is having the intended effect. However, 1 challenge that remained from this study was how to further integrate SMBP data into EHR systems and standard clinical workflow. Our study is positioned to address this challenge. The purpose of our study was to explore how primary care providers currently utilize SMBP measurements in their practice and their preferences for a built-in system that integrates patient SMBP data and additional PGHD into the EHR to better facilitate workflow in the primary care setting.

Methods

Study Design

A qualitative descriptive study was conducted to explore the insights of primary care providers on the utilization of SMBP in the management of hypertensive patients in the primary care setting. A total of 5 individual interviews were conducted to obtain candid responses from the primary care providers without peer influence. One focus group, with 8 different primary care providers, was then conducted to seek insights from the providers and observe group interaction dynamic on their responses on this topic [6]. The same open-ended questions were utilized in the individual interviews and the focus group interview.

Participant Recruitment

The study participants were recruited from a local academic health center with multiple primary care sites. An invitation containing only the study purpose was sent by the senior author (JW) via email to solicit participant interest from the Departments of Internal Medicine and Family Medicine. Those who expressed interest were approached to schedule a phone call or face-to-face interview. No data were obtained from those who did not respond to the invitation email. Before this study, participants had no relationship with the senior author.

Provider Selection

A total of 13 primary care providers participated in the study. All providers specialized in internal medicine, and the primary care experience of the providers ranged from 5 to 35 years. The number of patients the providers saw each month ranged from 49 to 256 patients, with the average being 118 patients. One additional provider had expressed interest in the study but was unable to participate because of loss of follow-up.

Interview Protocol

Interview questions (Textbox 1) were open-ended and designed to illicit detailed information on how providers currently use SMBP measurements in the primary care setting and their preferences for how they might like to see SMBP data and PGHD integrated into the EHR to facilitate workflow in the primary care setting. The questions were centered on (1) the value of SMBP in hypertension care, (2) needs of viewing SMBP and desired visual display, (3) desired alert algorithm and critical values, (4) needs for other PGHD, and (5) workflow of primary care team in utilizing SMBP. Questions from a previous study that developed and tested the connection of mobile and wearable data to an EHR system for diabetes patients were used as a guide when developing our study's interview protocol [7]. When necessary, probing questions were used to encourage the participants to elaborate on their responses.

Textbox 1. Interview questions.

1. What is the value of viewing patients' home-based monitoring of blood pressure data?
2. How does it influence the care you provide?
3. What blood pressure monitor used—type of monitor, frequency, and time points used?
4. Would you prefer an alert? How should the alert be presented?
5. What do you think the algorithm of the alert should be? What are the parameters to be considered critical?
6. How would you prefer data to be displayed in the electronic health record (EHR)—graphs, charts, or tables?
7. What other patient-generated health data would you like to know?
8. How would you like it to work with the primary care team? Should the information to go to the team? How should they act on it?
9. What do you think would be the impact on workflow and care provided?

Interviews were held in person or over the phone to accommodate the providers' work schedules. All interviews were audiotaped using a digital recorder and held in an office at a university, including those held over the phone. The interviews lasted between 15 to 40 min. To ensure data consistency, all interviews were conducted by the senior author of this study [6]. During the interview process, no field notes were taken, and no other persons were present other than the moderator and the participant (or participants). Dr Wang's previous involvement in several focus group qualitative studies on patient self-management of diabetes and obesity using mobile and connected health technologies made her the most qualified of the researchers to conduct the interviews. She had training on focus group methodology. At the time of this study, she was an associate professor at University of Texas Health Science Center—Cizik School of Nursing.

Data Analysis

Field notes were made after each interview. The audio recordings of the individual interviews and focus group were then transcribed verbatim by a professional transcription service company. The transcripts were not returned to the participants for comment or correction, and no repeat interviews were conducted. A total of 2 members of the research team (SR and JW) utilized conventional content analysis to independently code and derive themes from the transcribed interviews [8,9]. Microsoft Excel was used to code provider responses based on the derived themes that were identified from analyzing the interview transcripts. Discrepancies in theme analysis or coding were resolved via discussion between the 2 members of the research team and verified by repeated cross-checking within and across all transcripts. Data saturation was reached, and the overarching themes that emerged from the individual interviews and focus group, along with supportive quotations, are presented in the Results section.

Results

Sample Characteristics

The participants were 13 primary care providers whose primary care experience ranged from 5 to 35 years; all providers specialized in internal medicine. The providers have currently been utilizing SMBP in the management and diagnosis of hypertensive patients and suspected hypertensive patients, respectively. A total of 7 themes emerged from the individual interviews and focus group. Each is discussed below and substantiated by quotes from the transcribed interviews.

Ways to Utilize Self-Measured Blood Pressure Measurements in Primary Care

The majority of the primary care providers consider home SMBP an important tool in differentiating between patients who suffer from sustained hypertension and those who have white coat hypertension. Providers also mentioned they use SMBP to initiate or titrate medication and monitoring patient condition. Though a few providers raised the issue of reliability or accuracy of SMBP data because of BP cuffs not being calibrated correctly, 2 providers stated this issue can be easily fixed by asking the patient to bring their home BP machine into the office for examination:

> *[SMBP] helps me to differentiate between an elevated blood pressure due to stress or*
>
> *white coat hypertension versus consistently elevated blood pressure so I get a*
>
> *better idea of whether my treatment is working.* [Provider 2]
>
> *[SMBP] influences it a lot because a lot of my patients have white coat hypertension, so they have very high blood pressures...But if I put them on medicines then they end up being hypotensive at home and getting sick.* [Provider 5]
>
> *To make sure we're on the same playing field, I do have my patients bring in their home blood pressure device and...compare it to what we may get here in the office.* [Provider 3]

Preferred Visual Display of Self-Measured Blood Pressure Data in Electronic Health Record

The majority of primary care providers preferred all SMBP measurements taken by the patient be displayed in the EHR as a table. However, they each wished to extrapolate different information from the table. One provider did not have a strong preference for how the data were presented in the EHR, whereas another provider wished to view the data as a graph. Other suggestions for the visual display included color-coding patients' SMBP measurements based on the Eighth Joint National Committee classes or by default parameters set by the provider:

Yeah, the date, the time for this, if they are checking it multiple times of the day I can correlate that. Then I'd probably want the numbers and then the weekly averages. [Provider 2]

Something like a run chart...where you have...the date and time and the blood pressure and it would show like a distribution and you would be able to see from the mean and the standard deviation...I think that would be the most useful to me. [Provider 5]

I don't have any strong preference [as long as the information is there]...and understandable. [Provider 4]

If we have the numbers, we can make a graph out of it. If they're entered as discrete data points. [Provider 8]

I was just going with the [Joint National Committee] eight classes and ranges and designating a color for that is a good idea. [Provider 3]

Patient Condition Determines Preferred Scheduling of Patient Self-Measured Blood Pressure Measurements and Provider's Preferred Frequency of Viewing Self-Measured Blood Pressure Data

The majority of primary care providers mentioned their preferences on how frequently and when patients should take their SMBP measurements. However, it was evident from their responses that the patient's condition significantly impacted the time of day the SMBP measurements should be taken, the number of SMBP measurements they wanted per week, and how often they wished to view the results of the patient's SMBP measurements. The preferred frequency of notifications for newly imported SMBP data into the EHR varied across providers and were dependent on the severity of the patient's SMBP measurements. Provider preferences for viewing SMBP data for well-controlled patients ranged from once every 2 to 3 weeks, once every 3 months, to once every 6 months. Opinions for monitoring uncontrolled or severe patients also varied. Provider views ranged from every couple of days, every week, to every 2 weeks:

Once a day is fine just as long as it's consistent. It may be even variant amongst times throughout the day...Most patients take their anti-hypertensives in the morning so maybe an hour after taking a blood pressure medicine one day and then the next day, maybe an afternoon or the following day, the evening, so we can get what the blood pressure is like across the day and try to get a better assessment that way. [Provider 3]

I would probably say like 3 times a week...at different times, like maybe twice, once in the morning and once in the evening, and once after a stressful day or something that they know was a stress trigger. [Provider 1]

Poor control, I said three times a week. If it's more controlled, I might want it twice a day for ten days, but then less after that. [Provider 4]

If it's not...out of range, I would probably say once in two to three weeks. [Provider 1]

If it's severe range and we're still working to get the blood pressure down, I actually wouldn't mind being tasked more frequently, like every two to three days. [Provider 3]

It depends on how well they're controlled...If it's severe range, asymptomatic blood pressure, I am seeing those patients every two weeks. If there's someone that is just a few points above...Maybe every visit when I am seeing them every 3 months or so. [Provider 3]

Effect of Patient Condition on Alert Parameters

The majority of providers had a set of general parameters for SMBP measurements that would trigger an alert in the EHR. However, the type of parameters and frequency of alerts varied from provider to provider. The suggested values for the alerts for hypertensive readings ranged from 160 to 180 for systolic BP and 100 to 110 for diastolic BP, whereas suggestions for hypotensive alert values ranged from 80 to 100 for systolic BP and 55 to 60 for diastolic BP. One provider did not set a critically high value, but rather, wished to receive a weekly alert if their patient's average BP readings were out of range of their individually set goal. During the focus group discussion, providers hesitated to provide any parameters for a critical value alert for fear of the possible legal implications they may face if they did not act on a critical alert and a patient were to suffer from an emergency condition such as a stroke. However, a recurrent theme among the focus group participants was how individual patient conditions impacted critical alert parameters:

If your blood pressure is below 100/60 on a consistent basis or above 170/100 please fax or send the information on your blood pressure details immediately. If they're between these parameters send them every week. But if they're less than these then once in two to three weeks, whatever we decide. [Provider 1]

If I've given them a blood pressure goal of less than 140/90 and their average is above that, then that information is tasked to me...A weekly alert if the average is out of range. [Provider 2]

It's hard to say what a critical value is. There's standards to say what maybe the ideal goal should be, and we can look at national guidelines and say, "This is the goal." But in terms of what's a critical value, it's really hard to say, it depends so much on the individual patient. [Provider 6]

Itdepends on how we fit in the consent form to the patients, about what's their expectations about how physicians or nurses will act on those data. I think as of right now we are trying to limit the liability of [the physicians]. [Provider 11]

[The button] is grey if it's someone that's not using it,...green if their averages are all within the parameter, [and] yellow or red if they've got values outside [the parameter]. [Provider 2]

Location to Receive Critical Value Alerts

The majority of providers preferred the alert for critical SMBP values appear in the task list of Allscripts, which is the EHR system for the study recruitment site. However, 1 provider requested the alert be sent to their pager instead of the task list because of alarm fatigue and concern about being able to identify, and thus, act upon the critical SMBP value alert in their already inundated task list:

> *I think the task is fine. I'm looking at that usually just a couple of times a day.* [Provider 4]
>
> *Task is the best way for me.* [Provider 3]
>
> *I would want a page though, not an Allscripts task...It's alarm fatigue. I have like 50 something messages in Tasks right now and most of them aren't urgent...* [Provider 5]

Team Access to Self-Measured Blood Pressure Data and Primary Recipient of Critical Value Alerts

All providers believed access to SMBP data in the EHR should be available to all members of the primary care team such as nurses, case managers, medical assistants, and other providers in the office. However, opinions differed regarding who should be the primary receiver of critical value alerts. Some providers preferred the alert be sent directly to them first, then they could decide if immediate action is required or if the nurse contact the patient. Others suggested the alerts should be routed to other personnel first, such a nurse, who would then evaluate the data and determine if the provider needs to be notified of the patient's condition:

> *I think our medical assistants would be very useful in pulling up the record in, you know, accessing it if it's in some different system and pulling it up in the patient's room so that it's available when we walk in.* [Provider 5]
>
> *I think it should be a part of the medical chart [and] everyone...that is treating the patient [has access to it].* [Provider 3]
>
> *Unless someone is covering for myself, I wouldn't expect anyone [to act on it]...If you're tasking me directly with highs...or [SMBP data] out of range...then I wouldn't expect anyone else to act on it.* [Provider 3]
>
> *Most likely what I would do...if get I these tasks...I would...forward [it] to the case manager and ask for their help.* [Provider 2]
>
> *I'm thinking that it should come to a central place and then the nurses look at it...before they route it to the appropriate provider.* [Provider 9]
>
> *Maybe it should go to a nurse who can call the patient. The nurse could easily triage the patient [to] see if they're symptomatic, [and] if they are, send them to the ER. If they're not symptomatic, get them to the clinic or call me.* [Provider 5]

Additional Requested Patient-Generated Health Data to Incorporate Into Electronic Health Record to Provide Context of Self-Monitored Blood Pressure Measurements

In addition to the BP measurements, the majority of providers wished to include additional PGHD to better understand SMBP measurements. They expressed how difficult it can be to evaluate SMBP data without context and how additional PGHD can provide a better picture of a patient's situation at the time a particular SMBP measurement was taken. Most providers wanted to include medication adherence with the SMBP measurements. Some providers also wished to include food diaries, weight, monitoring stressors such as any surgery or life events, emotional states of the patients, alcohol consumption if patients are drinking, heart rate, or the option for patients to include any symptoms they may be feeling if an SMBP measurement were above or below the preferred desired BP range. One provider stated he would like to incorporate additional PGHD but, because of concerns of information overload, he only wanted patient symptoms and BP measurements to be recorded:

> *I would definitely want to know whether they took their medicines.* [Provider 5]
>
> *The time in which they take the medication. Also, depending on certain anti-hypertensives, a heart rate would be good to coincide with the blood pressure. Some medications tend to lower the heart rate so that would be good to know as well.* [Provider 3]
>
> *If they could keep an intake log that includes their salt...and...water intake...what they're eating...and...a little thing to about their emotional state.* [Provider 5]
>
> *If there was any change in their regular pattern. They're going for surgery, or something, which could've impacted [their blood pressure].* [Provider 1]
>
> *I would also want, if possible,...a way for the patient to trigger if they have symptoms. That's one of the things that's super useful in an event [to] monitor.* [Provider 5]
>
> *Something else we might benefit [from is]...symptoms suggesting a blood pressure problem.* [Provider 4]
>
> *I guess in a perfect world, yes, [there is other data I would like to know], but...that...may be information overload. I'd rather go with the results.* [Provider 4]

Discussion

Principal Findings

Our study examined how primary care providers would utilize and incorporate SMBP measurements into EHRs to better facilitate workflow in the primary care setting. All the providers interviewed in this study acknowledged the benefits of utilizing SMBP data in the diagnosis, management and treatment, or monitoring of patients with hypertension. Patient condition had a significant effect on providers' responses in terms of determining both frequency of readings and critical alert parameters, which resulted in various responses from each provider. However, the majority agreed the critical value alert

should appear in the form of a task in the EHR, and all personnel caring for the patient should have access to the SMBP data and PGHD in the EHR. Though there was concern from 1 provider about information overload, the other providers stated PGHD, in addition to the SMBP measurements, would be beneficial in understanding the circumstances of an abnormally high or low reading. The majority of the providers also stated they preferred to view patients' SMBP readings in the form of a table. However, what information was included in the table and what they wished to extrapolate from the data varied among the providers. Additional differences were noted in whether the provider wanted to receive the critical value alert directly or if they thought it should be routed to a nurse first.

Comparison With Existing Literature

Similar to previous studies conducted on SMBP, the majority of primary care providers in this study typically utilize SMBP to differentiate sustained hypertension from white coat hypertension [10-13]. Additional scenarios for requesting SMBP from a patient, found in this study and in previous ones, included efficacy of antihypertensives or medication adherence and managing or monitoring of controlled hypertensive patients [10-12,14].

In our study, some providers wished to view individual readings, whereas others preferred to view averages. These variable preferences correlate to differences found among UK clinicians, where some clinicians disregarded the first of 3 readings and looked at the other 2 or eyeballed averages [15]. The responses from providers in our study suggest that despite American Heart Association (AHA) recommendations, individual patient condition greatly influences the number of daily and weekly SMBP readings they recommended to their patient. This, again, corresponds to the same UK study where clinicians in both primary and secondary care settings recommended different frequencies and durations of SMBP schedules based on whether the clinicians were trying to diagnosis a patient with hypertension or help manage an existing hypertensive patient [15].

In a previous study, glucose and SMBP data were uploaded to a telemonitoring system outside of the EHR. The nurses would then access the data from the website, transcribe or summarize it, and manually input the information into the EHR. The workflows of the practices in this study were not drastically impacted because they had critical care advanced nurse practitioner managers assigned to collect and evaluate the data. However, the authors of the study postulated practices without these designated nurse managers may find it difficult to implement the use of a telemonitoring system [16].

A recently published systematic review examined 221 studies reported on what factors contributed to the success and/or failure of the implementation of various electronic health tools. Ultimately, the review concluded workflow was the most important factor in determining whether the intervention of an electronic health tool would be successful [17]. Therefore, it is crucial to involve users in the design phase during the development of new electronic health tools such as the one discussed in our study.

Our study aims to address this issue by identifying provider preferences in an effort to design an application that will directly integrate SMBP measurements and PGHD into the EHR which, in turn, could help improve rather than impede workflow in the primary care setting. The participants in our study recognize that the health of a patient is multifaceted and, to provide each patient optimum care, they must consider more than just SMBP measurements. Additional PGHD in the EHR is important for providing context for SMBP data to assist providers in making more informative decisions and taking better actions. However, increasing clinician burden has been associated with the use of EHR [18]. Therefore, when attempting to add more PGHD into the EHR, it is necessary to carefully examine how members of primary care teams plan to share responsibility for responding to this additional data during different phases of patient care. In summary, the challenges in integrating SMBP data into EHR to facilitate hypertension care is 2-fold: (1) Providers must determine what PGHD is most pertinent in the management and treatment of hypertensive patients and (2) Designing a user-friendly patient application that can both obtain PGHD and SMBP measurements and seamlessly integrate that information into the EHR to make clinical workflow more efficient.

Strengths and Limitations

As more mobile and wearable devices enter the health care market, there is an inherent need to directly integrate PGHD from these devices into EHRs. This is the first study to examine the perspective of primary care providers in the development of a built-in interface that will fully integrate remote monitoring BP data and additional PGHD into EHR systems to fit primary care workflow. There are several limitations to this study. Providers interviewed in this study were primarily physicians; our next step will be to extend interviews to other health care providers or professionals serving hypertensive patients in the primary care setting. We did not collect demographic information of the providers, as we did not believe their demographic characteristics would significantly influence the study findings, but lack of this information may limit the understanding of our study participants to some readers. Furthermore, as mentioned in the Methods section, convenience sampling was utilized to seek participants for this study. Therefore, our sample was not random which, in turn, may limit the representation of primary care physicians in general. Another limitation is that the providers were recruited from 1 academic medical center. The discussion results from the sample regarding BP control values were not compliant with the current practice guidelines on BP measuring schedule, although the providers had a wide range of years in primary care practice (5-35 years).

Recommendations for Future Research

AHA guideline recommends beginning SMBP measurements 2 weeks after starting or changing a patient's treatment regimen. The guideline also recommends SMBP measurements be obtained at least 4 times a day; twice in the morning before taking medications and twice in the evening before supper [19]. On the basis of the findings of this study, we summarized a list of recommendations for the development of a built-in interface that fully integrates SMBP data into EHR systems, which

include (1) an initial education session to educate the providers about practice guidelines and recommendations regarding BP control; (2) visualization of SMBP in a simple format; (3) general parameters should be set according to AHA or other guidelines. Providers should have the ability to set individualized parameters based on patient condition; (4) a decision support system with a set mechanism to triage the patients based on their SBMP results need to be in place to reduce clinical burden in reviewing raw SMBP data; and (5) all team members should have access to the data. A team approach in integrating SMBP into primary care clinical workflow is favorable.

Conclusions

In summary, providers valued SMBP measurements in the diagnosis, treatment, and monitoring of patients. They also suggested additional types of PGHD that may provide contextual information of SMBP data which, in turn, would allow them to better manage their hypertensive patients. Provider preferences on SMBP frequency, provider monitoring frequency, and alert mechanisms varied based on patient conditions. Therefore, flexibility in a connected interface to fit the workflow of primary care teams should be explored in future studies. Future usability evaluation should be conducted with mock-up interfaces to solicit opinions on the optimal alert frequency, mechanism, and information flow coordination among primary care team members in proving patient-centered, team-based hypertension care in primary care.

Conflicts of Interest

None declared.

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Abbreviations

AHA: American Heart Association
BP: blood pressure
EHR: electronic health record
PGHD: patient-generated health data
SMBP: self-measured blood pressure

Edited by G Eysenbach; submitted 12.03.18; peer-reviewed by L Buis, S Omboni; comments to author 12.04.18; revised version received 04.06.18; accepted 23.04.19; published 23.05.19.

Please cite as:
Rodriguez S, Hwang K, Wang J
Connecting Home-Based Self-Monitoring of Blood Pressure Data Into Electronic Health Records for Hypertension Care: A Qualitative Inquiry With Primary Care Providers
JMIR Form Res 2019;3(2):e10388
URL: http://formative.jmir.org/2019/2/e10388/
doi:10.2196/10388
PMID:31124468

Original Paper

Utilization of an Animated Electronic Health Video to Increase Knowledge of Post- and Pre-Exposure Prophylaxis for HIV Among African American Women: Nationwide Cross-Sectional Survey

Keosha T Bond[1], MPH, CHES, EdD; S Raquel Ramos[2], MSN, FNP-BC, MBA, PhD

[1]Department of Public Health, New York Medical College, Valhalla, NY, United States

[2]Rory Meyers College of Nursing, New York University, New York, NY, United States

Corresponding Author:
Keosha T Bond, MPH, CHES, EdD
Department of Public Health
New York Medical College
40 Sunshine Cottage Road
Valhalla, NY, 10595
United States
Phone: 1 594 2830
Fax: 1 594 2049
Email: kbond@nymc.edu

Abstract

Background: Despite renewed focus on biomedical prevention strategies since the publication of several clinical trials highlighting the efficacy of pre-exposure prophylaxis (PrEP), knowledge of postexposure prophylaxis (PEP) and PrEP continues to remain scarce among women, especially among African American women who are disproportionally affected by HIV. In an effort to address this barrier and encourage uptake of PEP and PrEP, an electronic health (eHealth) video was created using an entertainment-education format.

Objective: The study aimed to explore the feasibility, acceptability, and preference of an avatar-led, eHealth video, PEP and PrEP for Women, to increase awareness and knowledge of PEP and PrEP for HIV in a sample of African American women.

Methods: A cross-sectional, Web-based study was conducted with 116 African American women aged 18 to 61 years to measure participants' perceived acceptability of the video on a 5-point scale: poor, fair, good, very good, and excellent. Backward stepwise regression was used to the find the outcome variable of a higher rating of the PEP and PrEP for Women video. Thematic analysis was conducted to explore the reasons for recommending the video to others after watching the eHealth video.

Results: Overall, 89% of the participants rated the video as good or higher. A higher rating of the educational video was significantly predicted by: no current use of drugs/alcohol (beta=−.814; *P*=.004), not having unprotected sex in the last 3 months (beta=−.488; *P*=.03), higher income (beta=.149; *P*=.03), lower level of education (beta=−.267; *P*=.005), and lower exposure to sexual assault since the age of 18 years (beta=−.313; *P*=.004). After watching the eHealth video, reasons for recommending the video included the video being educational, entertaining, and suitable for women.

Conclusions: Utilization of an avatar-led eHealth video fostered education about PEP and PrEP among African American women who have experienced insufficient outreach for biomedical HIV strategies. This approach can be leveraged to increase awareness and usage among African American women.

(JMIR Form Res 2019;3(2):e9995) doi:10.2196/formative.9995

KEYWORDS

eHealth interventions; heterosexual; African American women; HIV risk behaviors, HIV prevention; entertainment-education; postexposure prophylaxis; pre-exposure prophylaxis; internet; videos

Introduction

African American women are disproportionately affected by HIV in the United States, with 91% of new infections among this population being attributed to heterosexual transmission [1]. African American women account for 60% of all new HIV diagnoses among women, yet they do not engage in more sexual risk behaviors than their white and Latina counterparts [2]. Increased risk of HIV among African Americans is because of the high HIV prevalence within their sexual network and other structural factors, such as poor access to health care [3].

For sexually active individuals, the use of the male condom has remained the most cost-effective and readily accessible prevention tool since the start of the AIDS epidemic [4]. The use of condoms among African American women is exacerbated by the complex intersection of gender roles and power differentials between women and men, which may limit women's ability or willingness to negotiate male condom use or remain abstinent [5]. The inconsistency of condom use among African American women has been linked to their lack of control over sexual health decisions in relationships [3,6]. An option for addressing HIV risk among African American women is the initiation of biomedical prevention strategies such as postexposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) for HIV [7]. PEP prevents HIV infection in those who have been exposed by an infected partner within a 72-hour time frame [8]. PrEP consists of taking 1 pill daily to prevent HIV infection before any HIV exposure [8]. Despite FDA approval of PEP in 2005 and PrEP in 2012 [9], both biomedical prevention strategies have been scarcely used among African American women [10].

Little is known about the interest of biomedical prevention strategies among African American women [3,11], suggesting a need for innovative strategies to increase the knowledge and access among women in diverse settings [10,12]. The literature on the acceptability of oral antiretroviral medications as an HIV prevention method among HIV negative, ethnoracial minorities and heterosexual female community members in the United States is scarce [3]. The need to disseminate this information and expand awareness of female-controlled strategies for HIV prevention is limited by the shortage of implementation strategies that target the sexual health goals of heterosexual African American women [3,13-15]. An alternative to traditional methods of health education for expanding awareness and potentially impacting the uptake of these 2 HIV prevention options involves the diffusion of electronic health (eHealth) strategies that is tailored for a particular category of consumers [16].

Recent advances in eHealth have enabled the development of innovative HIV prevention strategies that have created a large number of opportunities for connecting to others to improve health and awareness about HIV prevention [17-19]. eHealth has strengthened in the field of HIV research as more interventions are adopting these techniques to address the barriers to participation in research that addresses sensitive topics [20-22]. Published reports suggested that individuals are more comfortable using computers while addressing sensitive topics such as HIV [23]. Several computer-based interventions have demonstrated efficacy in reducing HIV risk behaviors among African American women [24-26]. Lightfoot et al conducted a 3-arm trial (computer intervention, face-to-face group, and control) of a computer-delivered intervention for a diverse population of predominately African American and Latin youth aged 14 to 18 years [24]. At the 3-month follow-up, students who received the computer intervention were significantly less likely to engage in sexual activity compared with those in the small-group condition and had fewer sexual partners than those in the control condition [24].

Grimley and Hook tested a computer-delivered intervention with primarily African American females who were sexually transmitted infection (STI) clinic patients [27]. At the 6-month follow-up, the study found more consistent condom use and lower STI incidence, 32% for participants in the computer-delivered intervention versus 23% for the participants in the control arm [27]. A randomized controlled trial of Sisters Accessing HIV/AIDS Resources At-a-click (SAHARA), a 2-hour computer-delivered adaptation of the Centers for Disease Control and Prevention (CDC)-Diffusion of Effective Behavioral Intervention (DEBI) evidence-based Sisters Informing Sisters on Topics about AIDS program, found that women in the intervention arm (computer-delivered intervention plus a 20-min small-group discussion) reported a significantly higher percentage of condom-protected sex acts than those in the control arm [26].

Sisters Informing Healing Living and Empowering (SiHLE), a 4-session CDC-DEBI group-level HIV prevention intervention for teenage African American females aged 14 to 18 years, was translated into a 2-hour computer-delivered individual intervention called multimedia SiHLE [25]. The results of this study showed that the average condom-protected sex acts (proportion of vaginal sex acts with condoms in the last 90 days) for sexually active participants receiving multimedia SiHLE increased from 51% at baseline to 71% at 3-month follow-up, yet no statistically significant difference was found in the control group [25]. Nonsexually active intervention group participants reported a significant increase in condom self-efficacy, and there was no statistically significant difference found in the control group [25]. The study provided preliminary support for the efficacy of a computer-delivered adaptation of a proven HIV prevention program for African American teenage women [25]. This is consistent with meta-analyses that have shown that computer-delivered interventions, which can often be disseminated at lower per-capita cost than human-delivered interventions, can influence HIV risk behaviors in a positive fashion [28]. These studies suggested that computer-delivered interventions have the potential to be at least as effective as human-delivered interventions in influencing HIV risk behavior [22,28]. Unfortunately, African Americans and other marginalized racial/ethnic populations have not fully benefited from eHealth interventions [29].

Despite the fact that computer-based interventions have been efficacious among African American women [22], current Web-based HIV prevention research has been with predominantly white participants [30]. It has been suggested that African Americans have not been represented in Web-based

interventions because of disparities in internet access owing to lower socioeconomic status [31]; yet, research has shown that there is no distinguishable difference in social media use among ethnicities [32]. This may be due to the limited data on understanding their use of technology and willingness to participate in eHealth/mobile health research [33]. With African Americans' increasing use of the internet through mobile technology and African American women's frequent use of the internet to search for health information, there is an opportunity to engage African American women in research through an eHealth intervention for HIV prevention while minimizing some of the common barriers to community-based and clinical interventions [1,33]. To directly address the quandary of little to no awareness of biomedical prevention strategies for HIV prevention among African American women, our study sought to strengthen knowledge of PEP and PrEP using eHealth technology in an internet-based research study. Thus, the purpose of this study was to assess the feasibility and acceptability of the *PEP and PrEP for Women* video, which was designed to increase the knowledge of PEP and PrEP using entertainment-education format eHealth targeting African American women.

This study was guided by the social cognitive theory through the use of the entertainment-education communication strategy [34-36]. The social cognitive theory posits that individuals learn through the observation of others' attitudes, behaviors, and the outcomes of those behaviors [34]. In other words, behaviors are learned either by modeling the behavior of others or by direct experience [34]. Entertainment-education is a theory-based communication strategy that embeds educational and social narrative messages into a popular entertainment format such as media to achieve desired individual, community, institutional, and societal changes among the intended media user populations [36]. Previous research has shown that observing others enact a health behavior via entertainment-education narratives can significantly increase the viewer's health knowledge, attitudes, intentions, and behavior [37].

Entertainment-education narratives exert influence by reducing the audience's resistance to health messages [36]. The central constructs of the social cognitive theory are self-efficacy, the belief in the ability to implement the necessary behavior, and outcome expectancies [34]. It has been found that a strong sense of personal efficacy is related to better health, higher achievement, and more social integration [38]. The learning process is facilitated through combining storytelling and reflection [39]. This represents an active, purposive, contemplative, and deliberative approach where meaning is generated by the learning experience [39]. Entertainment-education through digital storytelling engages learners; organizes information; facilitates remembering; enhances discussion, problem posing, and problem solving; and aids understanding of the content [36,40].

In our application of the social cognitive theory framework and entertainment-education narratives, the *PEP and PrEP for Women* eHealth video study is intended to engage learners through digital storytelling and critical thinking on issues about (1) HIV risk, (2) sexual violence, (3) relationship dynamics, (4) patient-provider communications, (5) initiation of PEP and PrEP, and (6) female-controlled HIV prevention methods. A collaborative process among the research team members resulted in an initial 9-min and 3-second script that was based on a review of the HIV risk literature on African American women and their male sexual partners [5,15,41].

Methods

Recruitment

This study utilized data collected over a 6-week period (February and March 2015) for a cross-sectional health survey conducted on the Web. Participants were recruited through a social marketing campaign, which included Web recruitment via social media, flyers posted in community settings, and snowball sampling. Web-based venues used in Web recruitment included Facebook, Twitter, LinkedIn, and Craigslist. Flyers were posted in community venues that African American women frequent (eg, churches, hair salon, health centers, and colleges in the New York metropolitan area). As this is a historically difficult-to-reach population, snowball sampling was used to recruit African American women [42]. Study eligibility was as follows: (1) reported female identity, (2) self-identifying as black or African American, (3) aged 18 years or older, (4) ability to read English, and (5) willingness to participate. Those who clicked on the recruitment banner were routed to a screening survey on a secure study website. A total of 384 individuals consented to participate in the study. Of those, 34.3% (132/384) individuals were ineligible after not meeting the inclusion criteria. An additional 10.9% (42/384) of the surveys had missing data and, therefore, were also ineligible to be included in the sample. Furthermore, 7 eligible surveys were identified as duplicate responses based on identical IP addresses and were excluded from the sample (n=116). Moreover, per our original inclusion criteria, participants who did not watch the entire video were excluded from the regression model to ensure that the participants in the analysis received the same exposure during the study. As such, the final sample size was N=91.

Those who were deemed ineligible were thanked for their time and exited the site. Eligible participants were directed to the Web-based consent form, which outlined the study's purpose, risks, and benefits followed by a prevideo survey, a 9-min eHealth video (PEP and PrEP for Women), and a brief postvideo survey. Those who completed the study were entered into a random drawing to receive an Amazon gift card (US $100, US $200, or US $300) and asked to forward the link to potential eligible participants in their network. The institutional review board at Teachers College Columbia University reviewed and approved all study procedures.

Prevideo Survey Assessment

We assessed a comprehensive range of sociodemographic variables, including age, employment status (unemployed vs employed), annual income level (from "no income" to "more than $50,000" in increments of $20,000), education level (high school/GED or less vs some college vs college or more), current student (yes/no), relationship status (single vs partnered), and gender of current sexual partners (male, female, or both). We also assessed previous knowledge of both PEP and PrEP. Additional information related to sexual risk behaviors including

drug/alcohol use, drug/alcohol use during sex, HIV testing history, relationship dynamics [43], condom use, self-efficacy for condom use [44], history of adult and child sexual abuse, and sexual assault within their social network was collected in the prevideo survey and entered into the regression model but not reported in this paper. After the completion of the prevideo survey, participants were then directed to the 9-min *PEP and PrEP for Women* eHealth video.

Electronic Health Video

The 2-part *PEP and PrEP for Women* eHealth video was created using Goanimate Technology [45]. Goanimate is a software program used to create professional, animated, avatar-led videos with an entertainment-education style [45]. Research supports the premise of technology-based approaches [45] to facilitate learning and decision making.

Part 1 of the video addresses a storyline that warrants the initiation and use of PEP. In scene 1, the main character, Tania, informs her friend, Michelle, that she has been sexually assaulted (Multimedia Appendix 1). In scene 2, Tania is in the emergency room speaking with her physician after being examined. The physician explains how PEP could be used by women who may have been exposed to HIV. Tania decides to begin PEP treatment to prevent HIV from her possible exposure. In scene 3, Tania returns for a follow-up visit 28 days after she started her PEP regimen at the hospital clinic. This concluded part 1 of the eHealth video.

Part 2 addressed a storyline that warrants the use of PrEP to prevent HIV transmission. In scene 4, we introduce 2 new characters for this narrative, Kia and Jackie. The main character Kia has a discussion with her friend, Jackie, about her boyfriend Mike (Multimedia Appendix 2). Mike has not been monogamous in his relationship with Kia, and she is concerned. Jackie informs Kia about PrEP and suggests that she talks to a health care provider about initiating PrEP to protect her from possibly getting HIV. In scene 5, Kia's physician explains the history of PrEP and how PrEP can be used by women who are in a relationship with an HIV-positive partner or a nonmonogamous partner who may be at high risk of obtaining and transmitting HIV, such as in Kia's current situation. In addition, Kia's physician discusses some common concerns about using PrEP, such as cost, side effects, and the routine laboratory tests that are required as a part of treatment. Finally, Kia's physician empowers her with this information and lets her decide what is best for her—either starting prophylactic treatment now or considering its future use. This concluded part 2 of the eHealth video.

Postvideo Survey

After the participants watched the video, we conducted a brief survey to measure the participant's perceived acceptability of the video on a 5-point scale. First, we accessed their dose of exposure to the video to identify if the participants watch all, most, some, or none of the video. Second, we asked participants to rate the video with the following response anchors: poor, fair, good, very good, or excellent. Next, participants were asked if they would recommend the video to other women. A dialogue box was provided to ascertain why or why not they would share this video and information with other women. Finally, they were asked about their intentions to use PrEP and PEP in the future, if needed, and if they would recommend PrEP and PEP to other women.

Quantitative Data Analysis

Quantitative data were downloaded from SurveyMonkey, transferred to SPSS, and analyzed using SPSS 21 [46]. Descriptive statistics, including frequencies and proportions, were computed for all sociodemographic variables. Tabulations were performed for all responses. Bivariate correlations were calculated among the study variables using the Pearson coefficient of correlation (Pearson r). The outcome variable of interest was the participant's ratings of the *PEP and PrEP for Women* eHealth video. To refine our model to exclude insignificant or highly correlated variables, backward stepwise regression was used. The rationale for using this approach was based on the work by Mantel who explained that backward selection serves to reduce the degrees of freedom, has joint predictor capability, and removes noise caused by including unrelated variables or variables that may be highly correlated with each other [47]. This was conducted by including the full group of 22 predictor variables that were all entered into the equation regardless of their worth for the creation of the regression model. The backward stepwise regression analyses included 22 independent variables as potential predictors: (1) age, (2) level of education, (3) annual household income, (4) has a current partner, (5) is a student, (6) employed, (7) relationship status, (8) lifetime HIV testing, (9) tested positive for an STI, (10) current drug use, (11) have other sex partners, (12) had any unprotected sex with main/steady and any other partner(s) in the past 3 months, (13) heard of PEP before watching the video, (14) heard of PrEP before watching the video or not, (15) higher percentage of time had sex while using alcohol/drugs, (16) prevalence of exposure to sexual assault/rape before 18 years old, (17) prevalence of exposure to sexual assault/rape since 18 years old, (18) prevalence of sexual assault experiences, (19) prevalence of sexual assault in their social network, (20) self-efficacy for condom use [44], (21) better partner characteristics [43], and (22) more self-control in a relationship [43]. Next, the backward stepwise method involved the least significant variable (one with the largest *P* value) being removed when the model was refitted. Then, a new model is built in the absence of that 1 independent variable and the evaluation process is repeated again, removing the least significant variable. This removal process and the equation-reconstruction process were continued until only significant independent variables ($P<.05$) remained—as the final model reported for the backward stepwise regression.

Qualitative Data Analysis

Analyses of the open-ended questions were thematic, focusing on dominant themes that emerged and were organized by the question asked; attention was paid to the level of endorsement of a theme across the sample. For the qualitative analysis, a grounded theoretical approach was used, permitting the use of categorizing strategies to code and analyze the data [48,49]. First, the transcripts were summarized in a *digest* that identified the major themes of the responses. Using QSR International's

NVivo 9 qualitative software, the coding of the data was conducted in 3 steps. First, based on the transcripts of the responses, a list of analytic areas represented in the data was composed and given a code (ie, a *closed code*) derived from relevant literature pertaining to entertainment-education narratives [36]. Second, the primary analyst (principal investigator) reread the transcripts and identified blocks of text to be given a descriptive label (ie, either a label from the closed code list or an original one, termed an *opencode*). Next, the open-coded data were organized under and integrated into the closed code list. Third, the data under each thematic code (eg, *empowering*, *educational* / *informative*, *usability*, *suitability*, and *entertainment*) were reread, and, if needed, recoded into subcategories to refine the analytic categories used. As the themes of the responses emerged, special attention was paid to data that did not confirm emerging themes, noting these for exploration in future research. In addition to using these methods of analysis, we also ensured analytic rigor by engaging several peer reviews of early analytic claims [50]. For this analysis, we will focus on the questions related to recommendations for use of the video.

Results

Characteristics of Overall Sample

In our sample (N=116), the mean age was 34 years. Most women were born in the United States (109/116, 94%), identified as black or African American (115, 99%), were in a relationship (71, 61%), and were intimate with male partners only (110, 95%). Approximately one-third (30, 27%) of them had a high school education, and a similar proportion (38, 33%) of them were current students. The majority (83, 72%) of them reported either current full-time or part-time employment. Almost half (52, 47%) of them reported a household income of US $50,000 or more. Before watching the video, only 18% (21) of the participants reported that they heard of PrEP and 22% (26) reported that they heard of PEP (Table 1).

Table 1. Demographic characteristics of a Web-based sample of African American women.

Characteristic	Watched entire video			*P* value
	Total (N=116)	Yes (n=91)	No (n=25)	
Age (years), mean (SD)	34 (10.3)	34 (10.5)	33 (9.6)	.70
US born, n (%)				
Yes	109 (94.0)	84 (92)	25 (100)	.15
Education (n=111[a]), n (%)				**.15**
High school or less	30 (27.0)	21 (23.9)	9 (39.1)	
Trade school/associates	17 (15.3)	16 (18.2)	1 (4.3)	
College degree or more	64 (57.7)	51 (58.0)	13 (56.5)	
Income (n=112[a]), n (%)				**.20**
≤US $19,999	21 (18.8)	16 (18.0)	5 (21.7)	
US $20,000-US $39,999	29 (25.9)	27 (30.3)	2 (8.7)	
US $40,000-US $49,999	10 (8.9)	7 (7.9)	3 (13.0)	
US $50,000 or more	52 (46.4)	39 (43.8)	13 (56.5)	
Employment, n (%)				
Employed	83 (71.6)	63 (69.2)	20 (80.0)	.29
Student, n (%)				
Current	38 (32.8)	34 (37.4)	4 (16.0)	.04
Relationship status, n (%)				**.21**
Single	45 (39.0)	38 (41.8)	7 (28.0)	
Partnered	71 (61.2)	53 (58.2)	18 (72.0)	
Sex partners' gender, n (%)				**.19**
Male	110 (94.8)	85 (93.4)	25 (100.0)	
Both male and female	6 (5.2)	6 (6.6)	0	
PEP[b] and PrEP[c], n (%)				
Previous knowledge of PEP	26 (22.4)	19 (20.9)	7 (28.0)	.45
Previous knowledge of PrEP	21 (18.1)	17 (18.7)	4 (16.0)	.76

[a]The n value is different because of missing data.

[b]PEP: postexposure prophylaxis.

[c]PrEP: pre-exposure prophylaxis.

Dose of Exposure to Electronic Health Video

Overall, 78% (91/116) of the eligible participants watched all of the video (Table 2). In addition, 11% (13) of them watched most of the video and 3% (3) watched some of the video. Furthermore, 8% (9) of the eligible participants did not watch any of the video (Table 2). Analyses of the postvideo survey and regression model only included those who reported watching the entire eHealth video.

Table 2. Dose of exposure to the video (N=116).

Dose of exposure	n (%)
I watched all of the video	91 (78.4)
I watched most of the video	13 (11.2)
I watched some of the video	3 (2.6)
I watched none of the video	9 (7.8)

Rating and Recommendation of Electronic Health Video

Overall, 89% (81/91) of the participants rated the video as good or higher; 29% (26) of them rated the video as excellent, 32% (29) rated the video as very good, and 29% (26) rated the video as good. Only 10% (9) of participants rated the video as fair and 1% (1) rated the video as poor. The mean rating for the video was very good (mean 4.77, SD 1.01). Among the sample, 91% (83) of participants reported that they would recommend the video to others, whereas 9% (8) of them reported that they would not recommend the video.

After watching the video, 97% (88/91) of participants reported that they would seek out PEP if they felt that they might have been exposed to HIV, including taking the recommended oral medication for 28 days. In addition, 93% (85) of them reported that they would recommend to another woman to seek out PEP if they knew the woman might have been exposed to HIV. Regarding the use of PrEP, after watching the video, 76% (69) of them reported that they would seek out PrEP. In addition, 91% (83) of participants reported that they would recommend to another woman to seek out PrEP (Table 3).

Table 3. Rating of the video and acceptability (N=91).

Characteristics	n (%)
Video rating[a,b]	
Poor	1 (1)
Fair	9 (10)
Good	26 (29)
Very good	29 (32)
Excellent	26 (29)
Video acceptability	
Yes, I would recommend	83 (91)
No, I would not recommend	8 (9)
PEP[c] and PrEP[d] acceptability	
Would seek out PEP after watching the video	88 (97)
Would recommend PEP to other women	85 (93)
Would seek out PrEP after watching the video	69 (76)
Would recommend PrEP to other women	82 (90)

[a]Mean 4.77, min 2, max 6, SD 1.01.

[b]Percentages do not total 100 due to rounding errors.

[c]PEP: postexposure prophylaxis.

[d]PrEP: pre-exposure prophylaxis.

Backward Stepwise Regression

Regression analysis identified the best predictors for giving the PEP and PrEP video a higher rating (ie, good, very good, and excellent). The backward stepwise regression analysis showed that the 5 variables that best predicted a high rating of the video were not engaging in any current drug use (beta=−.814; *P*=.004), using condoms all the time in the past 3 months (beta=−.488; *P*=.03), a higher household income (beta=−.149; *P*=.03), lower education level (beta=−.267; *P*=.005), and less experience of sexual abuse as an adult (beta=−.313; *P*=.004). For this model, the adjusted R square was .224 (*F*=6.067; *P*<.001; df=5), meaning that 22.4% of the variance was explained by this regression model (Table 4).

Table 4. Backward stepwise regression predicting a higher rating of the PEP (postexposure prophylaxis) and PrEP (pre-exposure prophylaxis) for Women eHealth video.

Variable	Beta	Standard of error	*t* test	*P* value
Drug use	−.814	0.277	−2.939	.004
No condom use	−.488	0.214	−2.277	.03
Income	−.149	0.066	2.267	.03
Education	−.267	0.092	−2.887	.005
Sexual abuse	−.313	0.104	−3.005	.004

Qualitative Analysis of Video Recommendations

Thematic analysis was used to analyze the open-ended questions to identify reasons for recommending the video to other women. Overall, 91% (83/91) of the participants expressed that they would recommend the video to other women. Our analysis yielded 3 themes about the eHealth video, which were (1) educational, (2) entertaining, and (3) empowering (Table 5).

Under the first theme, educational, subthemes covered how the video provided awareness or knowledge of PEP and PrEP and how it was adaptable. The participants reported that they were not aware of PEP and PrEP before watching the video and that the video was informative and easy to follow. For the second theme, entertaining, subthemes covered how the video had characters that were relatable, and the information was provided via a video with a storyline and characters. The participants reported that they would recommend the video because the *at-risk* scenarios were relatable to women's current relationship situations, and it may encourage them to change their behaviors. Other participants commented that the video was nice to watch and entertaining. For the third theme, empowering, subthemes covered 3 areas: (a) female-controlled HIV prevention methods, (b) culturally relevant, and (c) heightened perception of risk. The participants reported that they would recommend the video because it provided information on an HIV prevention method that was female controlled. In addition, the video was considered to be culturally relevant based on the scenarios depicted in the video, and it was not judgmental. Finally, the participants reported that the video provides scenarios that would heighten women's awareness of their own risk because of their partner's behavior in sexual relationships.

In addition, 8 participants reported that they would not recommend the video to other women (information was excluded from the table). There were 3 emergent themes, including subthemes. First, participants expressed criticism of the script—with the subtheme of their identification with all of the characters. One participant wrote regarding the characters in part 2:

> *I would prefer more back and forth between women who are considering it, not a doctor promoting it.*

Participants stated that they would have preferred for the health information to not be delivered by the doctor character in the video. Second, participants reported problems maintaining attention because of the length of the video:

> *Although this video is very informative, it is too long. I doubt people will watch the whole thing.*

Third, participants expressed a preference for other modes of communication—with subthemes of age appropriateness and video format. The participants reported that the animated format was too cartoonish and would be more appropriate for younger women. As expressed by 1 of the participants:

> *While it was educational, I feel the avatar format is better suited for middle-older adolescent/college age women. The video was done very well though.*

Table 5. Reasons for recommending the PEP (postexposure prophylaxis) and PrEP (pre-exposure prophylaxis) for Women eHealth video.

Category, theme, subtheme	Sample quotes
Education: informative/accessible	
Awareness of PEP and PrEP	"As an 18-year-old still in high school and still currently learning about sexual education; I think it's important for the girls around me and myself to learn about these new drugs (at least new to me) so we can stay informed when engaging in sexual activities."
Adaptable	"Good conversation starter. I thought the video was extremely informative. It was easy to follow and can help any woman who may have questions regarding PEP/PrEP."
Entertainment: entertaining/engaging	
Relatable characters	"They were cute and personable."
Format: use of avatars	"Easy to understand and associate with the avatars."
Suitability: helpful/empowering	
Female-controlled prevention method	"It is important for all women because no man is going to be 100% honest with you if they are sleeping with other individuals."
Culturally relevant	"It is important that women are aware of the existence of preventive care for two distinctly different sexual situations…. I like the fact that this is culturally relevant and reflects a nonjudgmental approach.
Heightened perception of risk	"Good information about PrEP and PEP. Also may inspire women to leave unhealthy relationships after seeing how the PrEP candidate sounded in her justification of staying in her unhealthy relationship."

Discussion

Principal Findings

This intervention aimed to increase the knowledge and initiation of PEP and PrEP among African American women by modeling situations and discussions that would be relevant to the target population. The goal was to also make the video entertaining (ie, *edutainment*) and engaging, while having diverse characters suited for connecting to African American women [51]. More specifically, the intervention included personal narratives that were culturally tailored to the experience of HIV epidemic among African American women and provide information on PEP and PrEP [52]. For example, in *PEP and PrEP for Women*, the viewer learns through a conversation between 2 friends (Kia and Jackie) that the main character, Kia, does not have to rely

on her male partner to use condoms to prevent HIV. In this scene, Kia learns about PrEP from her friend, and she is referred to a clinic that provides PrEP. The video does not attempt to answer the question of personal responsibility or criticize complex relationship dynamics that influence HIV risk, but rather it increased the viewer's knowledge and awareness of an alternative HIV prevention option via involvement with the story characters [39]. Furthermore, the viewers may identify with the protagonists of the stories and thus might be better able to relate the scenario to their own lives while lessening the resistance to the health messages [40].

The participants reported a positive perception of the video, with 89% of those who watched all of the video reporting a video rating of good or higher. In addition to rating the video, 91% of them reported that they would recommend the video to other women. Moreover, 4 salient factors facilitated the recommendation of the video by participants. The high acceptability of the video could be attributed to its focus on providing educational messages in an entertainment content to raise awareness and increase knowledge of 2 novel HIV prevention strategies, PEP and PrEP. First, the information provided on PEP and PrEP increased their knowledge of novel prevention strategies [53]. Second, the format of the video was inclusive of phenotypically relatable characters [54]. Third, the animations and subject matter were entertaining using visual storytelling and the information was valuable [55]. Finally, the subject matter was culturally relevant [52] and focused on a topic about female-controlled HIV prevention methods [15].

Results from regression analysis showed that the major predictors of giving the video a high rating included not having unprotected sex in the past 3 months, lower education, higher income, less sexual abuse as an adult, and no current use of drugs. This could be interpreted that women who would be not considered at high risk for HIV or potential candidates with PEP or PrEP were more receptive to the video. Previous research has shown that people who are already receptive to or substantially aware of the issues were more inclined to adhere to the health message and evaluate it favorably [56].

It is important to acknowledge that African American women are disproportionately affected by HIV not only because of behavior but also because of vulnerabilities created by unequal cultural, social, and economic status [57]. Our sample represents an atypical Web-based sample of African American women with high socioeconomic status, including high levels of education, employment, and income [58]. The higher socioeconomic status is perhaps reflective of attributes of those who have access to computers and the internet or the impact of the snowball data collection method, resulting in a network of women with high incomes participating in the study. However, the high socioeconomic status of the sample may have important implications that are reflected in the body of data obtained. Very few studies have focused on HIV/AIDS risk among African American women with higher socioeconomic statuses and the challenges that they may face in their environment that are similar to women of color with lower socioeconomic statuses [59,60].

The content addressed in the video, information on HIV prevention methods that were female controlled, was provided as one of the reasons that the participants would be willing to recommend the video to other women. Among the sample, there was low awareness of both PEP and PrEP before participating in the study. This mode of eHealth videos that incorporate entertainment-education dramas can persuade individuals because they depict characters who changed their behavior by initiating PEP and PrEP to improve their lives [61]. Drama incorporates a component of emotional response to the informational content, and the combination of emotion and information works together to promote individual intentions to engage in prevention activities [61,62]. The participants reported that the characters were relatable and they had personal knowledge of similar situations experienced by the characters in the PEP and PrEP for Women video. After viewing the video, 88% and 69% of the participants reported that they would seek out PEP and PrEP, respectively, for themselves. This is reflective of the impact of entertainment-education used as a tool to change health behavior [63,64]. Bandura recommended that characteristics of the models should be similar to the viewers to increase the impact of educational modeling [64]. Perhaps the most important lesson is that although a Web-based intervention relies on audiovisual content, it is also important to tailor the intervention to the target population.

A generally positive response to eHealth as an innovation for disseminating HIV prevention was found in this study, but 22% of the participants reported that they did not watch all of the video. There are several possible reasons for why the individuals did not completely watch the eHealth video. Participants who were not able to watch the entire video expressed that they experienced technical problems with the video, which included not being able to watch the video on specific handheld devices. This issue could frustrate participants and cause them to skip over watching the video to complete the survey. An additional reason for not completing the video could be participant's fatigue because of the length of the video. In this study, some of the anticipated issues related to fatigue were addressed by creating 1 long video instead of 2 different videos for PEP and PrEP, but the length of the video was cited as a reason to not recommend the video. Participants reported that the video was informative, but the length of the video may make it difficult for viewers to maintain their attention. Other reasons cited for not recommending the video included the educator/health care provide character and the use of animation. Participants felt that the PEP and PrEP educator character should have been a peer and not a health care provider. Previous research reported that groups that have traditionally lacked power, such as African American women, may be more sensitive to an interventionist's physical characteristics [65]. Despite the fact that the doctor in the *PEP and PrEP for Women* video is an African American woman, the participants felt disengaged from the character. This may be reflective of the lack of cultural competence among medical providers, institutional racism, and personally mediated racism and sexism that have negatively affected the sexual and reproductive health of African American women [57]. Participants also stated that the animated format was not appropriate for all age groups. They reported that it was more suitable for teenagers or younger adults.

Although some consumers may criticize the limitations of the technology (eg, age appropriateness), the vast majority found the avatar video product to be informative, accessible, and engaging. Those individuals who have a positive response to the avatar video were willing to adopt the innovation and engage in the diffusion of it within their social networks, which includes disseminating on social media networking sites. Studies have shown that HIV prevention programs grounded in the diffusion of innovation theory can be useful for increasing HIV/AIDS risk reduction knowledge among early adopters and diffusing information throughout social networks; therefore, preventing HIV among vulnerable populations [66]. This study specifically demonstrated how programs may need to strive to incorporate social media technologies to disseminate information. In addition, prevention programs should also take relationship status into consideration during planning and implementation of effective programs to reduce women's HIV/AIDS risk.

Finally, this study offers recommendations and suggestions for Web-based research as well as Web-based recruitment using modern-day social networking. Although the sample may not be representative of all African American women in the United States with respect to socioeconomic status, this strategy allowed for rapid recruitment of the sample population with minimum resources, such as staff and funding. Furthermore, this strategy potentially provides opportunities not only for recruitment purposes but for eHealth intervention purposes. Researchers and practitioners should consider the benefits of not only Web-based survey research but also of Web-based health education, health promotion, and disease prevention to reach more diverse samples of subpopulations affected by the HIV epidemic. eHealth intervention has proven to be extremely useful in educating African American women on a number of topics related to HIV/AIDS or STI prevention. Web-based health education can be beneficial for African American women if they use the internet to access and share information with their peers. In addition, as previous research studies have shown, using eHealth interventions may help reach a subgroup of African American women who are not usually addressed in the literature pertaining to HIV risk and prevention [67].

Study Limitations

This study had some limitations. First, this was a small, cross-sectional, Web-based sample of African American women, thus making it difficult to reach generalizations from this data source. Second, internet access familiarity with Web-based technology may have influenced the decision to participate in the study. Women who use a different type of electronic device (eg, cell phones and tablets) to access the internet may be able to navigate websites easily and may encounter challenges with technical issues. Third, the video and script were not previously tested with different groups of African American women. Having focus groups or concept-mapping sessions before the launch of the study would have enhanced the script of the video for tailoring of the message. Future research should involve conducting focus groups with different age groups, socioeconomic statuses with regard to the scripting, video display, and avatar characters to reach a broader audience of African American women. Fourth, given that this is a feasibility and acceptability study, it is not possible to make any conclusion regarding the efficacy of the video. In addition, participants' responses to PEP and PrEP adoption intentions were based on a hypothetical situation rather than their actual experience. Increasing knowledge does not necessarily correlate with motivating behavioral changes. Finally, the results could have been influenced by social desirability bias [68]. To minimize bias, participants were able to anonymously take the survey on their 1 device. Despite these limitations, the results of this study have important implications for interventions targeting HIV risk behavior among African American women. In addition, it also has important implications for utilizing technology to disseminate HIV prevention information to this population [69].

Conclusions

This study has demonstrated that the *PEP and PrEP for Women* video using eHealth and entertainment-education health message narratives for a targeted, culturally centered, HIV/AIDS preventative education intervention for African American women can be readily adopted and diffused as an innovation, while still using low-cost technology in the public domain. Findings from this eHealth video study demonstrated that (1) a culturally tailored eHealth video could be used to increase awareness of HIV prevention methods and (2) it is feasible to recruit and engage African American women into an eHealth intervention that is delivered via the internet and social media. The *PEP and PrEP for Women* video was viewed as culturally centered Web-based content by the participants and capitalized on the widespread use of the internet to reach a population that is not only underserved in eHealth interventions but also in traditional HIV research targeting African American women, therefore, adding to the limited body of research on computer-mediated HIV interventions targeting African American women [1,67]. The eHealth video is an acceptable mode of education to address HIV prevention methods. It follows the CDC's recommendation to create health messages that are relevant, useful, and interesting to encourage the audience to interact and be engaged [52].

Given the disproportionate impact of the HIV epidemic on African American women, the lack of awareness of both PEP and PrEP [3], and poor participation rates of minority populations in prevention interventions [33], it is essential to develop strategies to reach underserved groups and reduce some of the challenges associated with face-to-face preventive interventions. eHealth technologies have the potential to reduce the gap between what is known about PEP and PrEP and its utilization among high-risk populations by increasing individuals' sexual health knowledge. Future research is warranted on improving the tailoring and design of the eHealth video by including African American women and other underrepresented groups, such as transgender individuals, to participate in the design of an updated PEP and PrEP for HIV video. This can be explored through formative qualitative research to first assess the cultural and structural factors that may influence uptake of both PEP and PrEP.

Acknowledgments

This research was conducted as part of the first author's (KTB) doctoral dissertation in the Health Education Program, Teachers College Columbia University. KTB was supported as a predoctoral and postdoctoral fellow in the Behavioral Sciences Training in Drug Abuse Research program sponsored by National Development and Research Institutes, Inc and New York University Rory Meyers College of Nursing, with funding from the National Institute on Drug Abuse (T32 DA007233). KTB and SRR are supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R25MH087217. The content is solely the responsibility of the authors and does not necessarily represent the official views, opinions, and conclusions of the National Institutes of Health, National Development and Research Institutes Inc, and New York University.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshot of postexposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) for Women eHealth Video Part 1-Post-exposure prophylaxis: Physician talking to Tania about the PEP treatment.

[PDF File (Adobe PDF File), 339KB - formative_v3i2e9995_app1.pdf]

Multimedia Appendix 2

Screenshot of the postexposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) for women eHealth Video Part 2-Pre-exposure prophylaxis: Kia and Jackie having a conversation about Kia's boyfriend's infidelity.

[PDF File (Adobe PDF File), 398KB - formative_v3i2e9995_app2.pdf]

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Abbreviations

CDC: Centers for Disease Control and Prevention
DEBI: Diffusion of Effective Behavioral Intervention
eHealth: electronic health
PEP: postexposure prophylaxis
PrEP: pre-exposure prophylaxis
SiHLE: Sisters Informing Healing Living and Empowering
STI: sexually transmitted infection

Edited by G Eysenbach; submitted 30.01.18; peer-reviewed by T Flickinger, KM Jackman; comments to author 31.03.18; revised version received 30.04.18; accepted 29.04.19; published 29.05.19.

Please cite as:
Bond KT, Ramos SR
Utilization of an Animated Electronic Health Video to Increase Knowledge of Post- and Pre-Exposure Prophylaxis for HIV Among African American Women: Nationwide Cross-Sectional Survey
JMIR Form Res 2019;3(2):e9995
URL: http://formative.jmir.org/2019/2/e9995/
doi:10.2196/formative.9995
PMID:31144667

Original Paper

A Peer-Led Electronic Mental Health Recovery App in a Community-Based Public Mental Health Service: Pilot Trial

Amelia Gulliver[1], BA, BScPsych (Hons), PhD; Michelle Banfield[1], BSc, BA (Hons), PhD; Alyssa R Morse[1], BPsych (Hons); Julia Reynolds[1], BA (Hons), MPsych; Sarah Miller[2], BA, PGradDipPsych, DPsych; Connie Galati[2], BA (Hons), MPsych

[1]Centre for Mental Health Research, Research School of Population Health, The Australian National University, Canberra, Australia
[2]Canberra Health Services, Canberra, Australia

Corresponding Author:
Amelia Gulliver, BA, BScPsych (Hons), PhD
Centre for Mental Health Research
Research School of Population Health
The Australian National University
63 Eggleston Road
Acton, ACT
Canberra, 2601
Australia
Phone: 61 261259472
Fax: 61 261250733
Email: amelia.gulliver@anu.edu.au

Abstract

Background: There is an increasing need for peer workers (people with lived experience of mental health problems who support others) to work alongside consumers to improve recovery and outcomes. In addition, new forms of technology (tablet or mobile apps) can deliver services in an engaging and innovative way. However, there is a need to evaluate interventions in real-world settings.

Objective: This exploratory proof-of-concept study aimed to determine if a peer worker–led electronic mental health (e-mental health) recovery program is a feasible, acceptable, and effective adjunct to usual care for people with moderate-to-severe mental illness.

Methods: Overall, 6 consumers and 5 health service staff participated in the evaluation of a peer-led recovery app delivered at a community-based public mental health service. The peer worker and other health professional staff invited attendees at the drop-in medication clinics to participate in the trial during June to August 2017. Following the intervention period, participants were also invited by the peer worker to complete the evaluation in a separate room with the researcher. Consumers were explicitly informed that participation in the research evaluation was entirely voluntary. Consumer evaluation measures at postintervention included recovery and views on the acceptability of the program and its delivery. Interviews with staff focused on the acceptability and feasibility of the app itself and integrating a peer worker into the health care service.

Results: Consumer recruitment in the research component of the study (n=6) fell substantially short of the target number of participants (n=30). However, from those who participated, both staff and consumers were highly satisfied with the peer worker and somewhat satisfied with the app. Health care staff overall believed that the addition of the peer worker was highly beneficial to both the consumers and staff.

Conclusions: The preliminary findings from this proof-of-concept pilot study suggest that a peer-led program may be a feasible and acceptable method of working on recovery in this population. However, the e-mental health program did not appear feasible in this setting. In addition, recruitment was challenging in this particular group, and it is important to note that these study findings may not be generalizable. Despite this, ensuring familiarity of technology in the target population before implementing e-mental health interventions is likely to be of benefit.

(JMIR Form Res 2019;3(2):e12550) doi:10.2196/12550

KEYWORDS

peer work; computers, handheld; pilot study; mental health recovery; mental health services, community; mental disorders

Introduction

Background

Technology-based mental health programs continue to gather a strong evidence base [1]. These programs are rapidly increasing in uptake as both frontline health care or to complement existing mental health care services [2]. Other advantages of electronic mental health (e-mental health) programs include that they are cost-effective, scalable, and accessible [1] and can be used to empower people to maintain some control over their own care [3]. However, although these programs have been determined to be effective in trials, there are significant challenges with their implementation in routine health care, including issues with engagement and uptake [4]. Peer support interventions have been proposed as a method of increasing consumer engagement and completion of e-mental health interventions [4]. In addition, there is evidence to suggest that community samples of people with serious mental illnesses use mobile phones, mobile apps, and social media at a similar level to the general population [5,6], albeit perhaps at a marginally lower rate [7]. However, there is currently insufficient knowledge on the most effective ways of using these e-mental health tools in community mental health care settings [8] and on the role peer workers may play in these processes.

Peer work

Peer work describes both voluntary and paid positions within consumer-operated and standard health care services [9]. Lived experience of mental illness informs the peer worker's practices in providing support to other consumers [10,11]. Recent reviews have demonstrated that peer workers can produce a range of benefits for both the consumers, including increased independence and confidence and fostering a sense of hope [10,12], and the peer worker, including improved self-esteem and a sense of empowerment [10,13]. Peer work is rapidly gaining traction in health care internationally [6-10]. Mental health treatment landscapes are changing, and workforce shortages are placing greater demands on an already overburdened system [11]. In addition, consumer needs and priorities for treatment are evolving [11,12], particularly for recovery-focused services [10,12,13]. Thus, there is growing demand for peer workers to work alongside consumers to improve outcomes and recovery [13,14].

International evidence shows that peer work produces meaningful change for mental health consumers [10,12], but implementation of peer work programs is fragmented, and the link between programs with research evidence and current practice is poor [14]. Peer work can be challenging to implement into health care teams [15], with issues noted including a perceived lack of role clarity, issues with self-disclosure and professional boundaries, and stigma [15]. These issues can present problems for the effective integration of peer workers into the workplace and may contribute to a lack of understanding of the importance and role of peer work [13,15,16]. It has been suggested that some strategies to overcome these issues include clearly defining the peer worker's role and the training of current staff on professional supervision and management of peer workers [15,16]. To ensure optimal delivery of peer work in the mental health system, it is vital to trial the implementation of peer recovery programs in existing health care settings.

This research examined a paid peer worker–delivered technology-based recovery intervention in a public mental health care setting.

Aim

The aim of this study was to determine if a peer worker–led e-mental health recovery intervention was a feasible, acceptable, and effective adjunct to usual community-based treatment for people with moderate-to-severe mental illness.

Methods

Ethics Approval

The ethical aspects of this research were approved by the Australian Capital Territory (ACT) Health Human Research Ethics Committee (ETH.2.17.028) and the Australian National University Human Research Ethics Committee (ANU HREC 2017/338).

Participants

The participants were 6 consumers and 5 health service staff. As per the protocol [17], because of the small sample and study location, no demographic data were collected to minimize the chance of identifying individuals. Consumer participants were people with moderate-to-severe mental illness attending a community-based public mental health service for treatment. Severity of mental illness was classified according to diagnosis, duration and intensity of symptoms, and degree of functional impairment [18]. The health professional staff participants were involved in the delivery of the program, including supervision, so they could provide valid insight into its delivery. This included 2 nurses, the peer worker's line manager at the health service, the peer worker's peer supervisor, and the peer worker.

Researchers

Overall, 3 researchers involved in this study (AG, MB, and ARM) have lived experience of mental health problems and are working currently in the field as consumer researchers. The collaboration of this group with a consumer and carer advisory group offered a unique perspective on the design of the survey questions and the evaluation study overall, ensuring that both content and wording were appropriate and acceptable for the target groups [19].

Recruitment

Participation in the e-mental health program and participation in the evaluation survey were treated separately. The peer worker and other health professional staff (ie, nurses) offered participation in the e-mental health program to attendees at the drop-in medication clinics during usual appointments at the

mental health service between June and August 2017. The peer worker would also then, at a mutually convenient time, offer participation in the evaluation survey separately with the researcher. The researcher would discuss the project with consumers who would then be free to participate or decline participation in the research. The consumers were explicitly informed that participation in the evaluation was voluntary and independent of their participation in either the recovery program or the services they received at the mental health service. Recruitment fell short of the intended target of 30 consumers. Overall, of the approximately 10 people who completed the program, almost half (n=6) were willing to complete the evaluation survey.

The research team invited the health professional staff involved in the trial of the peer worker–led e-mental health program to participate in a face-to-face interview with a researcher (AG or ARM) to discuss their experiences with the delivery of the program at a mutually convenient time. A total of 4 staff interviews were conducted in December 2017, and the final interview was conducted in January 2018.

Intervention: Peer Worker

A part-time (7 hours per week) peer worker who had completed the recognized Australian peer work qualification (Certificate IV in Mental Health Peer Work [20]) was recruited at the health service to deliver the current program. Consistent with a peer worker role, in addition to leading the e-mental health program, they were also expected to provide emotional support, develop trusted professional relationships, assist staff with recovery plans, and carry out other duties as appropriate. Key characteristics for the peer worker included (1) direct personal lived experience of using mental health services, (2) a positive experience of recovery, and (3) the ability and willingness to disclose their own personal experience of recovery to positively influence others. The peer worker was trained on the use of the e-mental health intervention, the Stay Strong app (see below), by a member of our research team (JR). In addition to their usual line management within the service, they also received professional supervision and support by an experienced peer worker supervisor.

Stay Strong Electronic Mental Health App

The e-mental health intervention used was the Aboriginal and Islander Mental Health Initiative (Stay Strong App, which was developed by Professor Tricia Nagel through the Menzies School of Health Research and Queensland University of Technology [21,22]. It was designed for use with Aboriginal and Torres Strait Islander service users and has some culturally specific imagery and content [22]; however, it has been approved by the authors for use in non-Aboriginal and Torres Strait Islander populations.

The Stay Strong app uses a simple, highly visual design that does not require literacy or a high degree of concentration. The app assists the person to identify their own worries and strengths and helps them to establish goals for themselves in personal areas they would like to change [23]. A visual and interactive representation of the strengths (including people and relationships) and worries (weaknesses) is created using a symbolic tree. The more strengths identified, the stronger and healthier the leaves grow; conversely, the more worries identified, the more the leaves on the tree wilt and change color. The app is specifically designed to focus on recovery and can be used by workers who have some mental health training but are not necessarily health professionals [22]. The app is a structured mental health and substance use intervention designed to be used as a collaborative tool between workers and service users. To deliver the app, the peer worker acted in a coaching role and assisted the person in applying the concepts to their personal situation. The program consisted of completing the Stay Strong recovery app on Apple iPads with the support of the peer worker in 1 of 4 sessions.

Evaluation Design

The evaluation of the current project was designed to be exploratory [17], examining the elements of the program that were useful and the barriers and facilitators to implementation in the service, and an investigation of the effectiveness of the program overall. The evaluation involved both the postintervention quantitative evaluation of a single cohort of participants and qualitative interviews with the peer worker and mental health service staff. A focus group to collect further qualitative data from participants was planned [17], but we did not proceed as no consumers from the participant pool agreed to participate. The protocol for the study has been published previously [17].

Evaluation Survey

The primary focus of the survey was on the acceptability of the program and its delivery for consumers. Multimedia Appendix 1 presents the evaluation survey questions. Overall, 6 questions, designed by consumer researchers in collaboration with the advisory group, assessed the acceptability of the peer worker, the e-mental health program, recovery, and self-efficacy. A seventh question addressing the participants' rating of the group delivery was dropped from the analysis; it was not feasible to conduct the intervention in groups because of the staggered appointment and wait times for consumers. The questions asked participants to rate their agreement with each statement about the peer worker and the program on a 4-point scale (1=*No, not at all*; 2=*No, not really*; 3=*Yes, to some extent*; and 4=*Yes, definitely*). The survey also measured a single recovery outcome, which was assessed using part A of the Self-Identified Stages of Recovery (SISR) [24]. The SISR part A is a single item that describes stages of recovery and asks the participant to select the stage of recovery with which they currently identify. Participants indicate which of the 5 statements describes how they have been feeling over the past month, with higher ratings indicating more positive perceptions of recovery. The SISR has demonstrated reliability and concurrent validity [25] and convergent validity for the staged model of recovery [26]. This single item measures a unique feature of recovery not assessed by continuous measures [26].

Staff Interviews

Staff were interviewed about their experience with the delivery of the program within the health service. Multimedia Appendix 2 presents the interview questions for the health care staff and

the peer worker. The peer worker interview focused on their experience with the delivery of the program, and the management and supervisory staff interviews focused on their observations of the feasibility of embedding a peer worker and e-mental health program within the service from an operational point of view. Interviews followed a structured protocol [17] and were recorded for accuracy.

Analysis Strategy

Mean scores for the 6 questions assessing the acceptability of the peer worker, the e-mental health program, recovery, self-efficacy, and SISR were calculated for the participants (n=6) at postintervention. The 5 health professional interviews were conducted by AG (n=4) and ARM (n=1). Owing to the very specific areas of interest for the evaluation, and the lack of focus group data collected as per the original protocol [17], a deductive approach was taken using highly structured interview questions to target themes of interest. Notes were taken during the interviews by the researcher and were reflected to the participants after each question to ensure accuracy. Corrections to any comments were made during interviews in response to this immediate feedback. In addition, the notes were emailed to participants to provide any further comments or alterations to the data. These changes were incorporated into the notes. Participant views on themes are presented below, quotes are taken from recordings.

Participant Codes

Participant codes are as follows: PW=Peer Worker, PWS=Peer Worker's Supervisor, LM=Line Manager (Health Service), HP1=Health Professional 1, and HP2=Health Professional 2.

Results

Participant Survey Results

Table 1 presents the results for the participant evaluation survey. There were no missing data. Participant ratings of specific aspects of the evaluation are reported below.

Table 1. Participant evaluation data for the peer-worker program.

Measure	Mean (SD)[a]
Self-identified stages of recovery	3.3 (1.5)
Delivery: "Did you like:"	
"that a *peer worker* was assisting you with the Stay Strong program?"	3.5 (1.2)
"completing the Stay Strong program on the *iPad (electronic device)*?"	3.2 (1.2)
"completing the Stay Strong program during *time that you normally wait* around at the Health Service?"	3.7 (0.5)
Program: "Did the Stay Strong program:"	
"give you a *sense of control over your life*?"	2.8 (1.2)
"help you *feel that you could recover*?"	2.7 (1.0)
"help you feel confident about your *ability to take care of yourself*?"	3.0 (1.1)

[a]The rating scale for the 6 evaluation questions was 1=No, not at all; 2= No, not really; 3=Yes, to some extent; and 4=Yes, definitely.

Recovery

Participant SISR scores (mean 3.33, range 2-5) indicated that, on average, participants at postintervention were between "*starting* to learn how to overcome the illness," and being able to manage their mental illness "reasonably well."

Delivery Evaluation

On average, participants were highly satisfied with (1) the peer worker assisting them with the program, (2) the iPad delivery, and (3) completing the app during their usual waiting time.

Program Evaluation

Participant ratings of the program overall were rated as somewhat helpful for (1) assisting them to feel that they could recover, (2) assisting them to feel a sense of control over their life, and (3) assisting them to feel confident about taking care of themselves.

Health Service Staff Interview Results

Advantages of the Program

Key advantages of the program that were noted by all of the health service staff were concerning the 2 key characteristics of the program: the *peer-led* aspect of the program and the *holistic and practical approach* of the Stay Strong program. These advantages are reported below.

Peer Worker

The health professional staff all agreed that the main benefit of the program was the unique utility of the peer worker. This was primarily because of their ability in *normalizing* mental health problems and connecting with consumers by engaging them in a meaningful way. For example, it was noted that it was helpful for consumers to have someone they could relate to who had similar experiences and could assist with coping skills and *nonclinical* tasks such as helping them to fill out forms (eg, social security). In addition, the peer worker observed that consumers appeared to enjoy working with her, a view that was overwhelmingly supported by all health service staff. This was because of 2 key reasons: the *specific personality of the peer worker*, which was noted to be warm, empathic, and engaging,

and the *validation and engagement* that people appeared to feel with having a peer worker with *authentic* lived experience working with them:

> *...she was able to engage with consumers like no clinician I've seen before.* [LM]

The peer worker was able to provide genuine empathy and assistance and also *validate* their experiences based on her own authentic experience, which was viewed as "...more relatable for people—more of an equal feeling" compared with when a clinician is asking the same questions [HP2]. Staff had observed participants enjoying the "...engagement and the one-on-one attention" [HP1].

Stay Strong Program

The program's strengths were seen to be predominantly the holistic approach of the program and the practical skills learned. It was praised for enabling people to look "at recovery in a holistic way" [PWS], giving them "...some time to reflect on what they considered important within their life" [PW]. It was also thought to be meaningful for people because it went through their strengths, weaknesses, and supports. The app itself was seen as easy to use and was bright and engaging, and the symbolism of the tree, which was able to be printed out for people to take home, was noted as an added benefit by the peer worker.

Challenges of the Program

There were several key challenges noted by the staff, including *engaging people in the Stay Strong program*, *the iPad delivery*, *integrating the peer worker into the health care team*, and the *target population*. These challenges are outlined below.

Stay Strong Program

The Stay Strong program itself was also considered a challenge within the overall program. Although it was noted as being holistic and meaningful, it was difficult to engage people in the app in this particular group. Staff believed that people appeared uncomfortable in providing the personal information needed to engage with the app. In addition, it was noted that the app was similar to completing other routine measurement tools within the service:

> *Many of the people we see are so regularly asked to do things like that...it's just another routine thing that they thought they'd have to do with us.* [PW]

Despite this, the peer worker thoroughly enjoyed delivering the app and found it a useful tool to bring about conversation and set meaningful goals with people.

Apple iPad Delivery

Overall, the view of the Apple iPad delivery was mixed but more negative than expected. All staff suggested that there was a lack of familiarity with tablet technology in this particular population. Generally, it was believed that this was up to individual preference; some enjoyed it, and others may have found the use of technology intimidating.

Integration of the Peer Worker Role

Overall, opinions differed on how the peer worker fit within the service across health service staff. The peer worker's line manager believed that the integration of the peer worker role was challenging, specifically, that there was some adaptation required to integrate the peer worker into the health care team:

> *Orienting my health professional staff around working with a peer worker...what we noticed was being ever so mindful of [any potentially stigmatizing] language that we used.* [LM]

However, the 2 health service staff involved in the program delivery believed that the peer worker fit into to the team well, though noting that this may have been because of qualities unique to this specific peer worker, including her warm personality and nursing background.

Target Population

Staff noted that there was very low uptake of the program. The peer worker's line manager believed that lower-than-expected levels of engagement may also have been because of the sedation of this particular population at this time: "...there's a tendency to feel quite tired postinjection, so I do wonder if that was a barrier" [LM]. In addition, perhaps, feeling self-conscious to go off in front of other people and do something *clinical* may have also contributed to lower uptake, that perhaps there was "a social kind of anxiety, around that they don't want to be the one to look like I'm going with the mental health clinician, outside to do a program on my mental health" [LM]. Alternatively, the line manager suggested that consumers may not have felt obliged to participate as it was a peer worker who was managing the program (as opposed to a clinician).

Dead Time Setting

Opinions about implementing the program within the 2-hour *dead time* after depot medication administration were mixed. The 2 health service staff working in the health service believed that for those who wanted to participate, it was an ideal time to engage this population compared with simply watching television or browsing the internet. However, the peer worker noted that there was a lot of individual difference in people's willingness to engage with the program during that time. Instead, some preferred to spend their time sitting and relaxing, and some felt tired and wanted to use it as their "down time" [PW].

Discussion

Principal Findings

Overall, the study findings indicate that a peer worker–led e-mental health recovery intervention was acceptable in this single-setting evaluation study and showed some evidence of effectiveness as an adjunct to usual community-based treatment for people with moderate-to-severe mental illness. However, the program, particularly the mode of delivery (Apple iPad), did not demonstrate feasibility in this population. This study was primarily conducted as a feasibility study; thus, given the study sample was small, the results may not be generalizable to other programs, populations, or settings.

Although only a small number of potential participants engaged with the program (n=10) and the evaluation (n=6), those involved in the research reported that they liked the program. Many consumers attending the health service in this study

experienced significant sedation following the administration of medication and, therefore, preferred to rest during the required wait time. Some were also unfamiliar with tablet technology; despite the ubiquity of mobile technology, especially mobile phones [27-30], the levels of familiarity and comfort with these technologies vary widely among individuals [31], and they may have been concerned about being watched or judged by others. Given that technology is increasingly being used to deliver mental health care [2], there are concerns that some people may experience digital exclusion. Service providers have been encouraged to support users to engage in services delivered electronically. In this study, the line manager noted that education for people in community-based health settings around tablet technology may be helpful for future programs using tablets.

Consistent with previous similar studies [10,12,31], health professional staff and consumers believed that the addition of the peer worker was highly beneficial. The peer worker fostered a sense of hope and provided positive role modeling for consumers, while also providing one-on-one support for tasks that were not otherwise able to be supported by health service staff. Although this is a good example of the unique elements a peer worker can add to a health care team beyond simple extra capacity, it does also raise additional considerations. As this study was part of a pilot of peer work within a public mental health service and was designed to inform role and guideline development, the scope and responsibilities of the role may have been somewhat unclear. The peer worker involved in the pilot also had nursing training; although this likely aided her integration into the health care team, it may also have blurred the boundaries of peer work versus other health care staff roles. A clear definition of the peer worker role and what they are expected to do, together with training on supervision and management of peer workers, is critical to the successful implementation of the role [15,16].

Strengths and Limitations

The principal strength of the study was that it evaluated the feasibility and acceptability of the intervention in a real-world setting, allowing participants to self-select into the program and research evaluation in their usual treatment setting. Further strengths of the study included the consumer input into the design of the evaluation and the exploration of all perspectives, including the peer worker, consumers, and the health care staff. However, it is possible that staff may not have felt comfortable offering their honest opinions to the researchers. The study had several limitations. First, the study design only evaluated a single app, the evaluation of which cannot be generalized to other app-based programs, particularly those that may have been more suitable for this population. In addition, the study did not allow clear separation of the concept of the peer worker and the app itself. To attempt to overcome this, participants were asked to rate the aspects of the program separately (the peer worker and the app), but attribution of outcomes was still unclear. Second, given that the study only used 1 peer worker, separating out the *concept* of the peer worker from the personal characteristics of this specific peer worker was difficult. It was clear from the interviews with the staff that this individual was highly skilled, and thus, the trial may have yielded different results with different peer workers. Third, only 1 method of recruitment was applied, and it was not particularly successful in this population. It is unclear whether this was because of the population, the type of intervention offered, or the recruitment method itself. However, the use of other methods of recruitment (ie, the researchers offering participation in the program) or offering incentives would have compromised the ecological validity of this proof-of-concept trial. In addition, demographic data were not collected because of the substantial risk of the identification of participants from such a small sample. Moreover, no qualitative data from consumers could be collected via focus groups as was initially planned. Finally, the small participant sample size and lack of a control group meant that the participant findings were limited.

Implications

This study provides a number of ways forward. First, it would be important to implement the addition of peer work or any new technology slowly and ensure adequate orientation to any new programs or changes. This includes a clear role definition for the peer worker and orientation for staff on the integration of the peer worker into the health professional team. The latter may include education on potential sensitivities and differences in language (eg, *person-first language* [32] referring to the person first and their diagnosis second) for both the peer worker and staff. Research on health professional staff attitudes toward peer work, peer workers, and any potential changes that may be reflected after the implementation of such trials would be a welcome addition to future research. Second, ensuring that a skilled and suitable peer worker is engaged in the position is vital. Careful attention to the peer worker's level of recovery, personality, degree of autonomy, and the skills required to perform the role within a specific setting are likely help them to perform to the top of their scope and successfully integrate into the health care team. Third, future implementation studies more broadly would benefit from careful co-design. In this study, the contrast between the consumers' and the staff's perceptions of *dead time* was highly apparent, that is, consumers saw it as *down time*, where they could rest or watch television, whereas staff saw it this time as idle. Finally, it would also be recommended that the implementation remain adaptive, as a key part of this process is to examine the core features needed for fidelity of an intervention versus the adaptation necessary for it to work in a particular environment. We note that in this study, the group delivery as originally planned was altered to individual delivery, emphasizing the importance of remaining flexible to best accommodate the population and setting.

Conclusions

Technology-based peer-led recovery has significant potential as an adjunct to usual treatment for people experiencing severe mental illness. The preliminary findings from this pilot trial suggest that in this setting, a peer worker was feasible and satisfactory in their role of providing the program for both health care staff and service users. However, the e-mental health program itself was not feasible in this population without modification, training, and support. The additional challenges to adoption of technology faced by this population should be borne in mind, but further large-scale research is now required

to differentiate the effects of technology-based recovery work from the effects of peer work more generally. This will inform the development of a range of peer-led programs that enable peer workers to maximize their unique scope of practice.

Acknowledgments

Funding for the Apple iPads to conduct the program was provided by the Canberra Hospital Foundation and funding to employ the peer worker was provided by ACT Health. This funding applied to the e-mental health program delivery only. The Menzies School of Health Research also provided the Stay Strong app for the current research cost-free. The research study was conducted using in-kind resources at the Centre for Mental Health Research. This includes funding provided by ACT Health for ACACIA: The ACT Consumer and Carer Mental Health Research Unit. The funding support for ACACIA is managed by a separate area from the one involved in program delivery, and the research was conducted independently of program implementation. MB is supported by Medical Research Future Fund fellowship 1150698.

Authors' Contributions

All authors approved of the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Evaluation survey - participants.

[PDF File (Adobe PDF File), 315KB - formative_v3i2e12550_app1.pdf]

Multimedia Appendix 2

Interview questions.

[PDF File (Adobe PDF File), 334KB - formative_v3i2e12550_app2.pdf]

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Abbreviations

ACACIA: Australian Capital Territory Consumer and Carer Mental Health Research Unit
ACT: Australian Capital Territory
e-mental health: electronic mental health
SISR: Self-Identified Stages of Recovery

Edited by G Eysenbach; submitted 19.10.18; peer-reviewed by D Hilty, D Fassnacht, D Kavanagh; comments to author 22.03.19; revised version received 01.04.19; accepted 29.04.19; published 04.06.19.

Please cite as:
Gulliver A, Banfield M, Morse AR, Reynolds J, Miller S, Galati C
A Peer-Led Electronic Mental Health Recovery App in a Community-Based Public Mental Health Service: Pilot Trial
JMIR Form Res 2019;3(2):e12550
URL: http://formative.jmir.org/2019/2/e12550/
doi:10.2196/12550
PMID:31165708

Original Paper

Independent and Web-Based Advice for Infertile Patients Using Fertility Consult: Pilot Study

Aleida Gerarda Huppelschoten[1], MD, PhD; Jan Peter de Bruin[2], MD, PhD; Jan AM Kremer[3], PhD

[1]Department of Obstetrics and Gynaecology, Radboud University Medical Center, Nijmegen, Netherlands

[2]Department of Obstetrics and Gynaecology, Jeroen Bosch Hospital, 's-Hertogenbosch, Netherlands

[3]Scientific Institute for Quality in Healthcare, Radboud University Medical Center, Nijmegen, Netherlands

Corresponding Author:
Aleida Gerarda Huppelschoten, MD, PhD
Department of Obstetrics and Gynaecology
Radboud University Medical Center
PO Box 9101
Nijmegen, 6500 HB
Netherlands
Phone: 31 615339787
Email: dana.huppelschoten@radboudumc.nl

Abstract

Background: Patient-centered care—that is, care tailored to personal wishes and needs of patients—has become increasingly important. It is especially relevant in health care areas where patients suffer from a high burden of disease, such as fertility care. At present, both diagnosis and treatment for infertile couples is provided at a single hospital. As a consequence, patients are not likely to receive optimal, independent advice regarding their fertility problems. Internet-based, independent advice could be feasible for large groups of patients because it is not limited by travel distance and overhead costs.

Objective: The aim of this study was to explore the experiences of both patients and professionals with an online platform using video consultations for patients with infertility seeking independent advice for their fertility problem.

Methods: This pilot study evaluated an online platform, Fertility Consult, where patients with infertility can get independent advice by a gynecologist through a video consultation, thus eliminating the need of meeting the doctor physically. Semistructured interviews were performed with 2 gynecologists and the chairman of the Dutch patients association. This information was used for a patients' questionnaire about their first experiences with Fertility Consult, including questions about the level of patient-centeredness and shared decision making, using the Patient-Centered Questionnaire-Infertility (PCQ-Infertility) and the CollaboRATE questionnaire, respectively.

Results: Of the first 27 patients enrolled at Fertility Consult, 22 responded (82%). Most patients (82%) visited Fertility Consult for a second opinion, seeking more personal attention and independent advice. The mean level of patient-centeredness on the PCQ-Infertility questionnaire was 2.78 (SD 0.58) on a scale of 0 to 3. For the CollaboRATE questionnaire (scale 0-9), patients provided a median score of 8.0 (range 7-9) on all 3 questions about shared decision making.

Conclusions: Patients were satisfied with independent, well-prepared, Web-based advice; health care professionals felt they were able to provide patients with proper advice in a manner befitting patients' needs, without any loss of quality. Future studies should focus more on the separation of advice and treatment and on Web-based consultations compared with face-to-face consultations to ascertain the possibility of increased patient involvement in the process to improve the level of patient-centered care.

(JMIR Form Res 2019;3(2):e13916) doi:10.2196/13916

KEYWORDS

patient-centered care; remote consultation; decision making; telemedicine

Introduction

In consulting rooms, health care professionals strive for a good relationship with their patients and want to provide them with the most optimal, person-centered advice and corresponding treatment. They are aware that more patient-centered care, which is focused on individual patients' wishes and needs, will increase patients' quality of life, improve health care professionals' satisfaction in their daily work, and lower the dropout rates [1-5]. However, previous studies have shown that this level of patient-centeredness has not yet been achieved. Especially in health care areas where patients suffer from a high physical and psychological burden, such as fertility care, improvement is needed. These patients are in need of more emotional support and health care professionals who will listen to them attentively, and they want to be more involved in the decision-making process [6,7]. In daily clinical care, it might be difficult to fulfill all the above-mentioned requirements because of, for example, time pressure and the somewhat impersonal setting of a hospital.

Several improvement studies have already been conducted to overcome these problems with varying results [8-11]. Thus far, these strategies have mainly focused at optimizing existing concepts in hospital care. However, there is a need to look from a different perspective for a greater improvement in patient-centered care. Similar to several health care areas, fertility care can be considered as existing of 2 separate entities: (1) the diagnosis and advice phase and (2) the treatment phase. Currently, the same organization or hospital provides both advice and treatment. Consequently, doctors may have conflicting interests, as the revenues of advice and treatment are tied within the business model of their hospital organization. Is it then always possible to be completely objective and focused on the patient's interests? In addition, patients' experience can be affected by their impression that the advice is not entirely objective. Other problems that can arise in our current clinical organizations are limited time for shared decision making, loss of continuity of care, excessive treatment, large overhead costs in hospital settings, and consequently less patient satisfaction.

Organizing advice independently, described in the study by Clayton Christensen as a *solution shop* [12], may solve a large part of these problems. Patients who are looking for the most optimal treatment for their unfulfilled wish for a child could benefit from optimal independent advice by a senior expert in the field. Nowadays, the internet offers an optimal opportunity to make such independent advice feasible for larger groups of patients without the limitations of long-distance travel and with low overhead costs.

Therefore, the main aim of this pilot study was to explore the experiences of both infertile patients and professionals with using an online platform, which involved video consulting for patients with infertility seeking independent advice about their current fertility problem, thereby eliminating the need to meet the doctor physically. Meanwhile, this study will explore the possibilities of introducing video consulting in fertility care, including its advantages and disadvantages.

Methods

Study Design and Participants

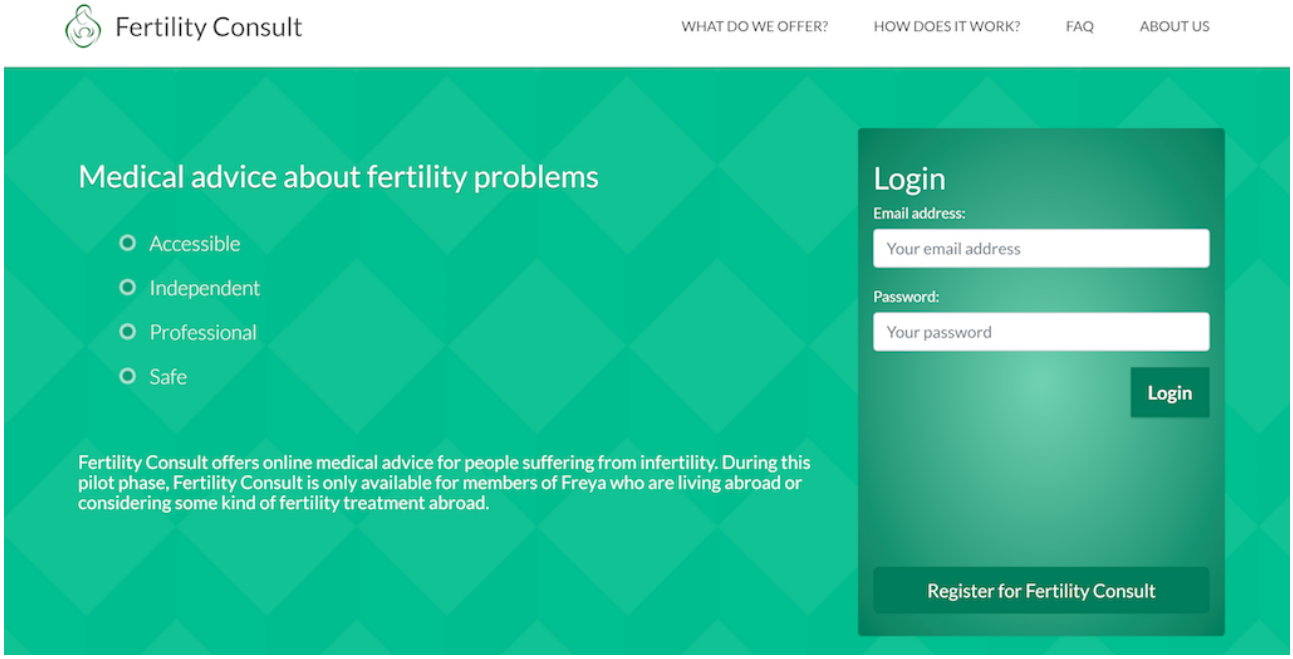
In this clinical pilot study, both qualitative and quantitative methods were used to evaluate Fertility Consult as an independent platform to provide advice for infertile patients with the use of video consulting. In the qualitative part, professionals were asked about their experiences with Fertility Consult using semistructured interviews. The results of these interviews were used as input for a patients' questionnaire—that is, the quantitative part of the study. To have more in-depth information about the level of shared decision making and patient-centered care, a modified version of the validated Patient-Centered Questionnaire-Infertility (PCQ-Infertility) and the validated CollaboRATE questionnaires were added to the questionnaire. Patients who were included in the pilot phase of Fertility Consult between February and April 2017 were asked to participate in the study.

About Fertility Consult

Fertility Consult was developed in 2016 by 2 Dutch gynecologists who had a special interest in patient-centered innovations. Fertility Consult is an independent and secured online platform that patients can use to get advice or a second opinion on their current fertility problem. The online platform was created following the Dutch quality standard "NEN 7510" for information security in health care. The target population for the study included Dutch patients living abroad and patients receiving fertility treatment in the Netherlands and who considered continuing their fertility treatment abroad. The reason behind this limitation was to avoid any negative impact to collegial relationships in this early pilot phase of this service. We excluded patients who received fertility treatment in our own hospital regions. Patients could join the online platform through the Dutch fertility patient's association "Freya."

For the gynecologists to be able to provide well-informed advice, patients had to upload their medical data and complete questionnaires about their history and previous fertility trajectory—that is, the results of previous fertility testing and the details and outcomes of previous fertility treatments, if any (see Multimedia Appendix 1). After this process, they were able to schedule a video consultation (Skype) with 1 of the gynecologists. In case medical information was not sufficient for the health care professionals to give proper medical advice, patients were asked for additional information. After the video consultation, patients received a summary of the conversation and personal, independent advice in their personal environment of the website. Figure 1 shows a screenshot of the home page of Fertility Consult.

Figure 1. Homepage of Fertility Consult.



Qualitative Part—The Interviews

For this part of the study, professionals were interviewed using semistructured interviews with a prospectively composed topic list. The professionals consisted of the 2 gynecologists performing the video consulting at Fertility Consult. In addition, the chairman of the Dutch fertility patients' association "Freya" was interviewed to include her opinion on this new online platform as well.

This list consisted of the 7 domains of patient-centered fertility care (ie, accessibility of care, information provision, communication, respect for patients' values, continuity of care, patient involvement, and professionals' competence) [11], complemented by questions about the technical part of Fertility Consult and its future perspectives. By using this design, we offered the professionals flexibility in discussing all experiences that were of importance to them.

Quantitative Part—The Questionnaires

For the quantitative part of the study, first, all patients who were eligible for participation were selected. Several patients subscribed for Fertility Consult once but never uploaded their personal information or requested for a video consult. Because of limited information being available about these patients, it was not possible to approach them for participation in the study. Therefore, only those patients were contacted who actually uploaded their medical file and had a video consultation with 1 of the 2 gynecologists.

The questionnaire consisted of questions about patients' background characteristics and questions that were derived from the semistructured interviews. To verify the content of the questionnaires, a short interview was performed with 5 randomly chosen patients, after which the questionnaire was adjusted on minor details accordingly.

To gather more in-depth information about the level of patient-centeredness and shared decision making patients experienced at Fertility Consult, we extended our questionnaire with questions of the *PCQ-Infertility* and the *CollaboRATE questionnaire*. The first questionnaire is a validated instrument assessing the level of patient-centeredness in fertility care by measuring the specific experiences of patients [13]. The original questionnaire consists of 46 questions covering 7 different subscales (eg, information provision, communication, or respect for patients' values). A higher score on the total PCQ-Infertility scale or 1 of its subscales (range 0-3) implies a higher level of patient-centeredness [13]. In our study, we used a modified version of the questionnaire as not all questions were suitable for our specific setting at Fertility Consult (eg, questions about the involvement of nurses in the fertility treatment). In total, we included 18 questions of the PCQ-Infertility covering 5 subscales.

The CollaboRATE questionnaire is a validated patient-reported measure of shared decision making, consisting of 3 questions following a clinical consult—that is, (1) "How much effort was made to help you understand your health issues?" (2) "How much effort was made to listen to the things that matter most to you about your health issues?" and (3) "How much effort was made to include what matters most to you in choosing what to do next?." All questions were scored on a 9-point Likert scale (0=no effort was made and 9=every effort was made) [14]. All patients were invited by email to complete the online questionnaire. Nonresponders were sent 3 reminders.

Data Analysis

All semistructured interviews were analyzed using a coding procedure in Atlas.ti (version 8, ATLAS.ti Scientific Software Development GmbH) to get an overview of the most important determinants. For the questionnaires, background characteristics and questions derived from the interviews were analyzed using descriptive statistics. Furthermore, the mean PCQ-Infertility

total and subscale scores as well as the median CollaboRATE scores were calculated. All results were analyzed using the SPSS, version 22.

Results

Qualitative Part—The Interviews

Both gynecologists did not find the video consults to be different from a regular face-to-face consultation at the clinic. Appointments could be scheduled quite fast, and patients seemed comfortable in their home environment, making it a very accessible situation. Especially because it is the first time that patient and gynecologist see each other, the nonverbal communication of a video consultation is considered of additional value when comparing it with a consultation by telephone. No major technical problems occurred during the video consultations, and both gynecologists felt they could properly prepare for the consults on account of having all the uploaded medical information from their patients. Both gynecologists felt comfortable by solely focusing on giving patients proper advice, without other interests to consider. A limitation is that Fertility Consult in this setting could not be performed by less experienced doctors or residents, as patients obviously want to speak to an "authority" in the field of fertility care to seek the best advice. In the Netherlands, in vitro fertilization and intracytoplasmic sperm injection treatments are mainly provided by larger public and academic hospitals where residents and younger less experienced doctors work as well. Consequently, as patient numbers would increase at the platform, an optimal combination of younger and more experienced support staff and a cost-effective business model are necessary to keep this platform working.

The chairman of "Freya" was very satisfied with an initiative such as Fertility Consult and found it especially important for patients with infertility who do not feel heard by their own gynecologist or for patients who want to go abroad but do not know exactly if and how this can actually increase their chances of getting pregnant. According to her, a point of interest should be how to reach low-literate patients.

Quantitative Part—The Questionnaires

The pilot group comprised 27 patients. Of these, 22 responded (response rate 81.5%). The median age was 37 years (range 29-48), and 16.7% (4/27) lived abroad. The characteristics of patients are summarized in Table 1.

After patients uploaded their medical information at Fertility Consult and asked for a consultation, the median waiting time before patients actually had a consultation was 5 days (range 2-28 days). The results of the second part of the questionnaire are summarized in Table 2.

Table 1. Background characteristics (N=22).

Characteristics	Values
Level of education, n (%)	
High[a]	91
Other	9
Living abroad, n (%)	17
Ethnic background, n (%)	
White	86
Other	14
Previous treatment, n (%)	
None	27
Non-ART[b,c]	9
ART[d]	64
Duration of infertility (years)	
<2	21
2-5	42
>5	37
Pregnant, %	16

[a]High level of education=higher professional education or university.

[b]ART: assisted reproductive technology.

[c]Included ovulation induction and intrauterine insemination with or without controlled ovarian stimulation.

[d]Encompassed in vitro fertilization intramuscular, intracytoplasmic sperm injection, cryopreservation, and testicular sperm extraction.

Table 2. In-depth questions per patient group (N=22).

Characteristics	Values
Reason visiting FC[a] , n (%)	
First opinion	18
Second opinion	82
How did you know about FC, n (%)	
Patient organization	82
Family	9
Google	9
Clarity website FC, n (%)	
Not at all	0
Little	0
Mostly	46
Absolutely	54
Comprehensibility questionnaire, n (%)	
Not at all	0
Little	0
Mostly	50
Absolutely	50
Time completing questionnaire (min)	
Median (range)	30 (10-60)
Satisfaction creating own medical file, n (%)	
Not at all	0
Little	10
Absolutely	90
Contact with other patients through FC, n (%)	
Yes	18
No	82
Recommend FC to others, n (%)	
Yes	90
Maybe	10
No	0
Total score for FC (0-10), median (range)	9 (7-10)
Willing to pay for FC	
Yes, n (%)	86
No, n (%)	14
Median (range), €	€60 (€10-250)

[a]FC: Fertility Consult.

Most importantly, 82% of patients visited Fertility Consult for a second opinion; they searched for more personal attention than they got at their own hospital and independent advice. Patients who wanted to go abroad were looking for advice on which hospital or doctor to go to. A total of 90.5% of patients would definitely recommend Fertility Consult to their family or friends. The median overall rate for Fertility Consult was 9 (range 7-10) at a scale of 1 to 10. Furthermore, 86% of patients were willing to pay a median amount of €60 for independent advice at Fertility Consult (range €10-250).

Table 3. Results of the modified Patient-Centered Questionnaire-Infertility and CollaboRATE questionnaire (N=22).

Characteristics	Values
Patient-Centered Questionnaire-Infertility, range 0-3 (mean, SD)	
Total score	2.78 (0.58)
Communication	2.88 (0.51)
Patients involvement	2.81 (0.50)
Respect for patients' values	2.81 (0.55)
Staff's competence	2.77 (0.55)
Organization of care	2.57 (0.74)
CollaboRATE, range 0-9 (median, range)	
Helping to understand health issues	8 (7-9)
Listen to things that matter most	8 (7-9)
What to do next	8 (7-9)

The results of the PCQ-Infertility and CollaboRATE questionnaires are summarized in Table 3. The mean total PCQ-Infertility score was 2.78 (SD 0.58) on a range of 0 to 3. The highest rating was provided to the subscale "Communication" (mean 2.80, SD 0.51) and the lowest rating for "Organization of care" (mean 2.57, SD 0.74).

For the CollaboRATE questionnaire, patients provided a median score of 8.0 (range 7-9) on a scale of 1 to 9 on all 3 questions about shared decision making.

Discussion

Principal Findings

This is the first pilot study exploring both patients' and professionals' experiences with an online platform using video consulting for infertile patients seeking independent advice about their fertility problem. In general, it was found that patients were satisfied with independent, well-prepared Web-based advice. Professionals felt they can provide patients with proper advice that caters to and fulfills patients' needs, without any loss of quality. As this was a small pilot study, caution should be exercised with respect to conclusions before the results can be generalized to larger groups or other health care areas.

Fertility Consult was developed to provide infertile patients with advice independently of other interests or benefits. This is not too common in health care yet but nonetheless, an interesting topic. Already about 2 decades ago, Christensen et al wrote that health care might be the most change-averse industry [12]. He found a resistance to several low-cost alternatives, which was not in the best interest of the patients. Doctors sometimes have difficulty with terms such as market force and innovations. A division between diagnosis and advice on the one hand and providing treatment on the other hand might be one of these difficult subjects as well. With this pilot study, it was shown that such independent advice is possible for a specific patient population in fertility care, with positive experiences of both participating patients and professionals. More research about this subject is, however, needed to provide more insight in the advantages and disadvantages of implementing the introduction of an independent treatment advice for patients in daily clinical care.

In this study, we provided independent advice in an online setting using video consulting. By making use of the internet, we expected to gain different advantages compared with a face-to-face consultation. It is, for example, an optimal tool to reach many patients from different areas in the Netherlands and abroad. Moreover, a Web-based discussion with a doctor in a neutral and safe environment for the patient (ie, at home or at work) prevents long-distance travel and immediately provides the appeal of an "independent counseling clinic" without the focus on therapy.

Comparison With the Literature

The literature on this subject is rather scarce, but some studies found that video consulting could account for different shortcomings in health care. In the Netherlands, the study by Schers et al showed that elderly patients in general practitioner (GP) practices were in particular skeptical to its use, and technical failures were mentioned as an important pitfall [15]. On the other hand, younger patients and patients who can handle computers might see benefits from video consulting. As patients with infertility are relatively young with a high demand of involvement in the decision-making process, fertility care could be a suitable field for video consulting. In other countries, especially those where patients have to travel long distances for access to specialist care, video consultation might provide a possibility to provide more medical services for these patients. In Australia, more than 100 GPs were asked to review video vignettes covering different patient scenarios. A total of 72% to 100% of the GPs agreed on the differential diagnoses of the scenarios, and GPs in larger practices especially were more positive toward video consulting [16]. In Sweden, similar results were found as GPs found video consultation an opportunity to provide education and ability for their patients to ask questions [17]. Furthermore, the safety of video consulting was studied, finding that good communication was essential for patients' perception of security during the consultation [18]. A study of Westra et al about the use of video consulting in plastic surgery found that patients who received a video consultation 6 weeks

after their surgery had a higher general satisfaction and less waiting time than patients with traditional in-person consultation. However, patients receiving Web-based consultation were less satisfied with the patient-physician communication [19].

Our study showed that the level of communication satisfied both patients and professionals. On the PCQ-Infertility questionnaire, the subscale communication even received the highest ratings. However, it remains interesting whether patients are really comfortable talking to the doctor through a computer or is it just a face-to-face contact they prefer as "the golden standard." On the basis of the literature, it seems like the latter is true, but video consulting could definitely overcome problems such as travel distance, waiting times, and impersonal hospital settings without a significant loss of quality of the consultation. This is especially important for patients with infertility, as not all kinds of fertility treatment are provided in all Dutch hospitals and require patients to travel large distances. Moreover, patients often suffer from psychological burden because of infertility and could, therefore, benefit from a doctor really listening to them in the safe and well-known environment of their own house.

Topics of safety and quality are obviously important when implementing an initiative such as Fertility Consult. As telemedicine is an upcoming way of providing health care, many national and international standards for video consulting and corresponding initiatives are already developed. For example, the American Telemedicine Association provides guidelines for managing patient safety [20]. Fertility Consult was developed following the Dutch quality standard "NEN 7510" for information security in health care, which is derived from the international ISO 27001 standard. Therefore, no safety and quality issues should be expected with the use of Fertility Consult.

Strengths and Weaknesses

The use of an online and secure platform and video consulting to provide independent advice for patients with infertility has never been studied before and is, therefore, one of the strengths of this study. As we used both qualitative and quantitative techniques, we were able to put the results of our questionnaires in a broader perspective and considered the opinions of patients, participating gynecologists, and the Dutch fertility patient association. Subsequently, we used 2 validated questionnaires to provide more information about the level of patient-centeredness and shared decision making patients experienced during their consultation. It is already known that patients in fertility care need more patient-centric care and shared decision making, so it is interesting that our pilot study seeks for a relationship with video consultation and the possibility of providing patients with independent advice.

Some limitations should be mentioned as well. First, because of the pilot setting, we used a small sample size. Although the response rate was quite high (81.5%), it would had been interesting as well to include patients who registered for Fertility Consult once but never uploaded their information and asked for a Web-based consultation. This might be a patient group without a strong need for a second opinion or independent advice. However, technical struggles for making an appointment or other difficulties in the process cannot definitely be ruled out, as we had no contact information to approach these patients for participation.

Furthermore, we used a modified version of the PCQ-Infertility questionnaire, as not all questions were applicable to the setting of video consultation. As the questionnaire is not validated and uses only some questions, we cannot compare our results with other studies using the PCQ-Infertility. However, by using these questions, we could provide a general overview of the degree of patient-centeredness that patients experienced when participating in Fertility Consult.

Finally, only the women of the infertile couple completed the questionnaires. This might have caused bias, although the literature shows that both women and their partners have comparable experiences with fertility care [21].

Conclusions

In conclusion, this pilot study explored the experiences of both patients and professionals with the online platform Fertility Consult providing patients with an independent advice about their fertility problem. This study shows a good satisfaction rate and a high level of patient-centeredness and shared decision making of patients who had a Web-based video consult. Patients appreciate the personal attention they received and independent advice. Professionals had positive experiences with the online platform as well, but they mentioned several areas for improvement. For them, the platform preferably should improve in terms of a more sophisticated and intuitive (mobile) interface for both patients and professionals. The process of scheduling appointments was bothersome, and it would further empower patients if they were able to schedule the appointment themselves. The platform should support the professional in generating written advice based on the answers from the patient questionnaires. Furthermore, it should be easier to track the flow of the patient population and to generate aggregated data for the population.

As this study showed positive experiences of patients and professionals with Fertility Consult, a next step would be to implement this pilot. We could, therefore, think of expanding the design of the website and adding an interactive mobile app with algorithms for evidence-based advice and coaching. As a next step, it would be interesting to compare quality of care of the online network versus standard care, focusing on lifestyle improvement, chance of spontaneous pregnancy, birth of a healthy child, psychological well-being, and patient-reported outcomes and experiences. Future studies should also focus on the interesting topic of the separation of medical advice and treatment and on Web-based consultations compared with face-to-face consultations to ascertain if patient involvement in the process can be further increased to improve the level of patient-centered care.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Fertility Consult questionnaires.

[DOCX File, 92KB - formative_v3i2e13916_app1.docx]

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Abbreviations

FC: Fertility Consult
GP: general practitioner
PCQ-Infertility: Patient-Centered Questionnaire-Infertility

Edited by C Eichenberg; submitted 05.03.19; peer-reviewed by L Lenzo, A Anazodo; comments to author 06.04.19; revised version received 21.04.19; accepted 21.04.19; published 04.06.19.

Please cite as:
Huppelschoten AG, de Bruin JP, Kremer JAM
Independent and Web-Based Advice for Infertile Patients Using Fertility Consult: Pilot Study
JMIR Form Res 2019;3(2):e13916
URL: http://formative.jmir.org/2019/2/e13916/
doi:10.2196/13916
PMID:31165714

Original Paper

Exploring the Potential for Use of Virtual Reality Technology in the Treatment of Severe Mental Illness Among Adults in Mid-Norway: Collaborative Research Between Clinicians and Researchers

Solveig Osborg Ose[1*], PhD; Hilde Færevik[1*], PhD; Jannike Kaasbøll[1*], PhD; Martin Lindgren[2*], MA; Kristin Thaulow[2*], MA; Stig Antonsen[3*], MA; Olav Burkeland[4*], MA

[1]SINTEF AS Digital, Trondheim, Norway

[2]Coperio AS, Trondheim, Norway

[3]Trondheim Municipality, Trondheim, Norway

[4]St. Olavs University Hospital, Trondheim, Norway

[*]all authors contributed equally

Corresponding Author:
Solveig Osborg Ose, PhD
SINTEF AS Digital
Klaebuveien 153
Trondheim,
Norway
Phone: 47 90728684
Email: solveig.ose@sintef.no

Abstract

Background: Virtual reality (VR) technology is not currently used in the treatment of severe mental health illness in Norway.

Objective: We aimed to explore the potential of VR as a treatment for severe mental health illness in Norway, through collaborative research between clinicians and researchers.

Methods: A collaborative research team was established, comprising researchers, the manager at a district psychiatric center, and the manager of the local municipal mental health service. An all-day workshop with eight clinicians—four from specialist mental health services and four from municipal mental health services—was conducted. The clinicians watched three different VR movies and after each one, they answered predefined questions designed to reflect their immediate thoughts about VR's potential use in clinical practice. At the end of the workshop, two focus group interviews, each with four clinicians from each service level, were conducted.

Results: VR technology in specialist services might be a new tool for the treatment of severe mental health illness. In municipal mental health services, VR might particularly be useful in systematic social training that would otherwise take a very long time to complete.

Conclusions: We found substantial potential for the use of VR in the treatment of severe mental health illness in specialist and municipal mental health services. One of the uses of VR technology with the greatest potential was helping individuals who had isolated themselves and needed training in social skills and everyday activity to enable them to have more active social lives. VR could also be used to simulate severe mental illness to provide a better understanding of how the person with severe mental illness experiences their situation.

(JMIR Form Res 2019;3(2):e13633) doi:10.2196/13633

KEYWORDS

virtual reality; severe mental illness; collaborative research; technology; social work

Introduction

A current challenge in the development of technology for mental health is that it is largely market-driven. This means that large target groups, such as people with less severe anxiety and depression disorders who are willing and able to pay, receive ready access to new supporting technology. People with severe mental disorders, lower levels of functioning, and poorer ability to pay often are not involved in commercial technology development; therefore, they receive little benefit from these technological advances.

In Norway, less severe, common mental illnesses must be regarded as public diseases because they have such a high incidence [1]. The sheer volume of these conditions indicates that treatment that can be delivered using commonly available technology such as smartphone apps will be a sensible option. More than 10,000 mental health–related apps are available for download. Because very few of these are evidence based, more transparency and trust through better oversight and a stronger commitment to research are needed [2]. Although some argue that greater patient and clinician involvement is needed to evaluate digital technologies and ensure they target unmet needs, maintain public trust, and improve clinical outcomes [3], the results of treatments using such technology have already shown some promise. A meta-analysis showed that psychological interventions delivered via smartphone devices can reduce anxiety [4], and a recent randomized controlled trial concluded that users of the mental health apps MoodMission and MoodKit experienced decreases in depression [5]. A survey aimed at exploring mental health stakeholders' knowledge, acceptance, and expectations of digital treatments for depression found that digital treatments were rated as more acceptable for milder forms of depression [6].

The use of technology in the treatment of severe mental disorders is less developed and has received less attention. One of the reasons for this may be the lack of interest from commercial developers because the market is smaller and those who might benefit have a lower ability to pay. Persons with serious mental illness are found to earn, on an average, one-third less than the median earnings, with no significant between-country differences [7].

Most digital treatments are forms of cognitive behavior therapy, that is, they are essentially existing treatments that have been converted into digital interventions. Truly novel digital treatments are infrequent [8]. Examples of novel digital treatments, according to Fairburn and Patel, include virtual reality (VR)–based treatments that are found to be effective for individuals with a range of severe mental health problems [9]. Valmaggia at King's College found that the innovative potential of VR is that it allows the measurement of real - time cognitive, emotional, physiological, and behavioral responses to a variety of real - life situations while enabling experimental control [10]. Preliminary findings suggest that VR can be applied to the delivery of cognitive rehabilitation, social skills training interventions, and VR-assisted therapies for psychosis [11]. A pilot validation study tested a new VR social situation paradigm (a party in a bar) with a subsample of participants who scored high or low in trait paranoia and found that the VR scenario could be used as a psychological assessment and treatment tool for people who experience paranoia in social situations [12]. Enthusiasm is growing among clinicians and researchers worldwide about the potential that VR offers for improving the assessment and treatment of mental and physical health problems [10].

However, while some clinicians explore the possibility of using new technology in the treatment of severe mental illness with good results, it may be difficult for other clinicians to introduce the technology into their own practice. If the barriers to the use of technology for behavioral health care, such as the characteristics of the technology, potential end users, organization structure and climate, and factors external to organizations [13], are to be overcome, a collaborate research methodology including managers and clinicians in mental health services might be warranted. Long-term collaborative research between researchers, managers, and clinicians was established with the aim of taking the first steps in exploring the potential for the use of VR technology in the treatment of severe mental illness among adults in Norway. Finance for a start-up project was provided by the Regional Research Fund for mid-Norway.

Methods

Collaborative research projects have emerged as a particular form of academia–industry interaction [14]. Our research plan included the following steps: (1) establish trust and robust personal relationships between main stakeholders, (2) obtain financing for a preproject, and (3) include clinicians to explore the potential for using VR in mental health services. If potential was found in step 3, we planned to establish a main project based on the same collaboration.

The collaboration began with several informal meetings between the researchers and the two management representatives from the district psychiatric center (DPC) and the municipal mental health care service. Three researchers were involved at the beginning: a social scientist with extensive mental health services research experience; a senior scientist who specializes in sensor technology, wearables, and physiology; and a scientist with a PhD in clinical medicine in mental health. The researchers also met with some of the clinicians at the DPC and discussed their thoughts and plans to establish a collaborative research group on VR in mental health treatment. A senior scientist who is a technical VR and augmented reality expert was involved from the beginning and will be further involved if the first step of the project shows potential among clinicians and managers.

The group was further expanded with two clinical psychologists experienced in creating and testing VR content in the commercial market outside health services. Their experience included working with the police (mental training using VR), a private bank (emotional intelligence training using VR), municipalities, and schools (using VR scenario training to assess risk in relation to violence) and biofeedback training in VR in the pain clinic of a university hospital. They were employed by a private local company called Coperio that provided management counselling services, innovation, occupational

health services, and outpatient mental health treatment for less severe problems.

A workshop with clinicians was planned to explore the potential of VR technology in the treatment of severe mental illness in adults in Norway. The 6-hour workshop was organized by the researchers and two clinical psychologists.

Eight clinicians, four from the DPC and four from the local mental health service, attended the workshop (seven men and one woman). The participants were recruited by the managers at the DPC and the local mental health service. Five of the participants had some experience in the use of VR privately, while three did not. All eight participants signed a written consent form.

The workshop started with an introduction to the research in the field, especially the research from the United Kingdom and Valmaggia. The local company then shared some of their experiences with the use of VR in the commercial market (ie, customers willing to pay for the use of VR in training and personal development, such as the private banking market). They also introduced the eight participants to the equipment and showed them how it worked. After a coffee break, we divided the participants into two groups and placed them in separate rooms. We showed them Movie 1 and then asked them to write down their immediate thoughts. After lunch, the participants watched Movies 2 and 3 and were asked to write down their immediate thoughts after each one. At the end of the day, the researchers conducted focus group interviews with both groups.

The study design was preapproved by the Norwegian Centre for Research Data (project number: 845033). The interviews were recorded and later transcribed. Thereafter, the research team members met to discuss the experiences of the day and plan further collaborations.

In this initial set-up, we used simple and affordable mobile VR equipment (Samsung Gear VR Oculus, Menlo Park, CA) provided by the local company.

The three short example movies were of (1) an angry man at the office, (2) a self-presentation to a small group in a work setting, and (3) mindfulness on the beach with biofeedback.

The first film was a VR scenario filmed by Coperio about an angry man coming into the participant's office. He gradually becomes more threatening and knocks his fist on the table. The film lasts 1 minute and 36 seconds and does not include biofeedback.

The second VR film was more advanced and included biofeedback. The film shows four people sitting at a round table in an office meeting setting. A man and a woman first present themselves in a relatively formal matter, following which the VR user presents himself/herself. A wristband measures and records the VR user's pulse as a measure of heart rate throughout the scenario. After the film, the VR users can see how their pulse rate developed during the session and thus train to reduce their nervousness in such situations. The VR users also received questions triggering self-reflection, including what they recalled about the content of the other meeting participants' presentations.

The third film showed an animated tropical beach with a bird on the water. When the viewer's pulse is calm, the waves will be calm and the bird will approach. When the viewer's pulse increases, the number of waves increases, the bird floats away from the shore, and the wind and sound increase [15].

The short questionnaire included one question to be answered before the participants watched any of the movies: "What are your expectations about the use of VR in clinical practice?" After each film, the participants answered the following questions: (1) "What are your immediate thoughts after watching the scenario?" (2) "What could be better?" (3) "What do you think was good?" and (4) "What are your thoughts about the potential use and application of VR in the treatment of severe mental illness?" At the end of the testing, they also answered the question, "Have you changed your mind about the use of VR in mental health care during the day?"

Results

In the following subsections, we combine the information given in the short questionnaires and the focus group interviews.

Expectations of Virtual Reality Before the Workshop

In general, the participants reported that they had mixed expectations of VR in mental health treatment. One participant argued that the technology has potential for creating and adjusting scenarios that may be important in patient training and that allow repetition in a safe environment. Another said that VR could be part of future mental health services and a new tool available to clinicians. A third participant thought that VR had a place in mental health treatment, but that it would take 10-20 years before this potential would be realized. Others thought that VR had potential in many different settings, including social training or learning to understand emotional expressions among persons with severe mental illness. Another participant made the point that it would be easier to get training started in VR because exposure to the real word is very hard for many of those with severe mental illness. Several participants mentioned that training in a safe environment had the potential to produce larger treatment effects.

Experiences with the Films

The films were used as examples of the types of films that could be developed and as a means of triggering the respondent's creativity in their thinking of ways that VR could be used to improve the lives of persons with severe mental illness.

Scenario 1: An Angry Man at the Office

The participants found the film realistic. Some of the participants thought the situation was uncomfortable and felt immersed in the situation. Others did not feel immersed. There were comments about the need to improve graphic and sound quality, which may increase immersion. Suggested areas of application included training employees in public services including mental health services, training in conflict management, and training in handling other peoples' extreme emotional reactions. Another suggestion was that such films could be used in the treatment

of anger disorder, where patients can see and feel how they affect other people with their anger behavior. It was suggested that situations that trigger the emotion of anger could be filmed, so that the patients could practice on specific problems and personal triggers as a form of personalized treatment.

Scenario 2: Self-Presentation

The participants also found this film realistic and thought the scenario was an example of a very common situation. In the film, one of the people in the meeting arrives late and one of the participants found himself to be slightly irritated by that person. Another commented that the feeling of going to a meeting without knowing the agenda was not common. All the participants found it interesting to see how their heart rate developed throughout the meeting, and for most of them, the pulse rate increased when it was their turn to present themselves. One of the clinicians reflected on the fact that his attention shifted toward himself and that he did not pay much attention to the others in the meeting. The participants all agreed that this was a realistic scenario that everybody could learn something from.

Suggested applications included training in similar situations to improve users' ways of presenting themselves and to learn to pay more attention to what other people communicate. It was also suggested that this could be used in couples therapy, the treatment of social phobia, and general training to reduce performance anxiety.

Scenario 3: Mindfulness on the Beach With Biofeedback

One of the participants thought this exercise was somewhat disturbing, as the bird floating in the water was big and spooky. This participant also felt that there was something behind the chair he was sitting on at the beach. One clinician suggested that the scenario could be used as part of the treatment for attention-deficit hyperactivity disorder and posttraumatic stress disorder (PTSD), because these patients often have a high pulse rate without being aware of it, and this mindfulness exercise could be a way of learning more about their own reactions. Another clinician thought it was funny that the image could be altered by thinking about situations that increased the pulse rate, while another found the exercise relaxing. Some said it would be better if the picture was real rather than animated and that the quality of the graphics and sound needed improvement. One observation was that the scenario focused on punishment rather than reward, as patients were punished with more waves and darkness if they could not control their pulse. All participants were fascinated by the interaction between biofeedback and the VR film.

Suggested applications included training to focus on the pulse and breathing and learning how to relax (mindfulness), autogenic training, and stabilization of overactivation in patients with PTSD. One of the clinicians suggested that this could be helpful for those with severe anxiety disorder:

> *Learning to control the heart rate can be useful for many patients who complain of strong anxiety and are very uneasy and afraid all the time. Perhaps the experience that it is possible to feel that one is becoming calm is useful.*

After Testing Virtual Reality

Six people were more positive about VR in mental health care after testing VR themselves, while two people who were initially positive had not changed their view during the day. All participants concluded that they could see opportunities for using VR in the treatment of mental health illness, especially in skill training and providing safe exposure to different situations. One of the participants said:

> *I am positive about using VR in mental health care. The day today has given me a glimpse into the opportunities this technology holds. This exciting technology should be developed further and applied to user groups that can make use of it.*

General Findings

In the interviews, we asked the participants about the general service attitude toward the use of VR in mental health care. Most of them observed a certain expectant attitude among their colleagues; for example, some cases presented about VR in the media (typically outside the health services), which may have contributed to a more positive attitude toward the technology. Few of the clinicians thought that the patients would be skeptical to try VR in treatment:

> *I do not think the patients in the future will be sceptical towards VR. And I also think that because the youth today get an iPhone almost at birth, VR may be an incredible opportunity in the treatment of future patients.*

At the beginning of the day, the participants had watched a film we received from Valmaggia, showing how VR technology was used in clinical practice at King's College. Several of the clinicians had started to think about the added value of using VR in clinical practice:

> *I see something valuable with this method, that you can sequentially put people into an actual situation. When I tried [VR today], I got a very strong experience of being in the situation, it was very realistic to me. And you can take the patient out of the situation again without stress to reflect. I think that the Valmaggia method is fantastic.*

They also added that being able to go back and see the same sequence and try to observe things that were not observed the first time was valuable.

One participant with extensive experience in mental health care said that about 20 years ago, he worked with persons with severe mental illness, training them on social skills such as how to keep a friendship, end a poor relationship, or a conversation:

> *Such social skill training was very demanding. Difficult with the setting, because how should we communicate to get people to contribute to this? It would have been much easier if you could use the VR technology.*

The clinicians also mentioned the need for social training for a large group of patients with different forms of avoidant personality disorder and provided examples of functionalities that they could build into a VR setting:

> *Small talk and situations of everyday life, such as taking the bus. Buying the bus ticket. Ordering a cup of coffee. Not very complicated things, but rather [things to] try to build up their social skills.*
>
> *It would be really good if someone got some practice in expressing their needs or disagreeing with some things. Yes, as training in taking up some space, and being conscious about what kind of space you take.*

We also discussed the situation for many people with severe mental illness who receive only acute treatment in specialist mental health services, because there is no other effective treatment available. These people often isolate themselves in their homes and have a poor social life. The effect of using VR to prevent isolation was suggested:

> *And being able to get out of the door, pick up the newspaper, nod to the neighbour and then go the next step, to make contact with someone on the sidewalk or a neighbour, to build something that can be anti-isolating. Because we know the specialist health service must contribute when the psychosis worsens.*

One of the participants working in the municipal mental health services added:

> *Training situations could be split into suitable sequences and we could simply achieve that they open the door when mental health carers were at the door.*

One of the psychologists from the local company had previously worked in specialist mental health services and told a story where he guided a person with severe mental illness in skills training. At first, the patient could only manage to put his head out of the door and look down the hallway before closing the door. The goal for the patient was to read the paper in a local café. He eventually reached the goal, but the process took 2 years. The clinician estimated that if he had VR equipment available at the time, the goal could have been reached in two months. Another clinician had a similar case:

> *I think VR is a tool for improving the life of some people with much suffering. I had a person who was terrified of going on bridges and when you live in this city with many bridges, this fear makes your life quite difficult, so we practiced by walking on bridges. If we had VR, we could have achieved our goals much faster.*

We also considered that many of those with severe mental illness lack the ability to read human signals correctly:

> *Misinterpretation of signals is quite widespread among persons suffering from severe mental illness. What they read as a rejection signal, do we read as others being a little questioning, perhaps? If the situation could be simulated and we had the ability to go back to reflect, what was it? Did he say he wouldn't see me anymore? No, he didn't.*

We also discussed how VR might be used to train patients that had never been working or had been outside the labor market for many years, to begin or return to work. A library of film jobs could be made, and the person could train in VR to increase their readiness to start working. Many of those with severe mental illness are not in employment, and it was suggested that VR training could be introduced into the individual placement and support efforts of the labor and health services.

We also discussed the possibility of simulating severe mental illness in VR so that, for example, relatives and others could gain a better understanding of how it felt to have this illness and thus improve the situation for those with severe mental illness. One participant said:

> *I think this would be very useful. Relatives are the ones who want the most and they need and are able to understand and take a role, a constructive role in this. And this is anti-isolating thinking. I think this is a pretty good focus.*

Another clinician added:

> *From being desperate and furious to desperate and furious all the time, parents could have a VR experience where they see what it looks like for their son or daughter. It would give a better understanding of the situation and perhaps be easier to comprehend.*

Discussion

Principal Findings

There is still a long way to go to promote investment, resources, and accountability in the mental health sector. It is suggested that the next steps include enhanced international co-operation and the creation of private–public partnerships, specifically with technology companies [16]. It is also argued that advancements in Web, mobile, sensor, and informatics technologies can help us better understand the very nature of mental illness and revise our fundamental assumptions about the structure, boundaries, and modalities of mental health treatment [17].

Long-term collaborative research groups between health care management representatives, clinicians, technology partners, and researchers are one way to increase innovation, dissemination, and adaption of new treatment forms in mental health services. This prestudy is the small beginning of such a long-term collaborative research group. The first aim of the research group was to explore the potential for the use of VR technology in the treatment of severe mental illness in adults. We conclude that there is potential in both specialist mental health services and municipal services in Mid-Norway.

A main concern is that individuals living with severe mental illness are often difficult to engage in ongoing treatment and show high dropout rates and poorer clinical outcomes, with symptom relapse and rehospitalization [18]. VR technology might be a new tool for the treatment of severe mental illness in specialist mental health services. Current research on mental health and the use of VR is related to social anxiety disorder or social phobia [19-23], psychosis [11,24], and high-functioning autism [25-27] and intellectual disabilities in young adults [28]. We found only a few studies that explored the use of VR in social skills training for persons with severe mental illness [29-31]. However, isolation, belonging, and social cognition are old problems that, despite new medicine, we do not have satisfactory answers to. The opportunity to train in virtual

scenarios without paying the social price in real-life situations can open the door to interesting studies.

Pure phobias such as arachnophobia or agoraphobia seem to be the easiest to cure using VR. However, many of the patients in mental health services have several diagnoses and a complex combination of different problems. In line with the thoughts of Kinderman (2014) and, in Norway, Aarre (2010), we found that modern mental health services must base their work on the fact that distress is usually an understandable reaction to life's challenges and that diagnoses should be replaced by descriptions of the individual's problems [32,33].

The research group has decided to continue the collaboration and has established a long-term regional collaboration to explore and test the use of VR, artificial intelligence, and other technologies in the treatment of severe mental illness. The region is known as Norway's technological capital, with Scandinavia's biggest research institution—SINTEF—located in Trondheim, Norway's third-largest city. A research collaboration has also been established between SINTEF, King's College, and Valmaggia.

Conclusions

We conclude that there is potential for VR in the treatment of severe mental illness in our region. One of the largest opportunities this collaborative research group identified so far was the use of VR technology to help individuals who have isolated themselves and need training in social skills and everyday activity to enable them to have a more active social life. We also believe that VR could be used to simulate severe mental illness, so that staff, relatives, and others could get a better understanding of how persons with severe mental illness experience their situation.

Conflicts of Interest

None declared.

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Abbreviations

VR: virtual reality
DPC: district psychiatric center
PTSD: posttraumatic stress disorder

Edited by G Eysenbach; submitted 05.02.19; peer-reviewed by A Campbell, K Davison, O Danilina; comments to author 20.03.19; revised version received 28.03.19; accepted 14.04.19; published 10.06.19.

Please cite as:
Ose SO, Færevik H, Kaasbøll J, Lindgren M, Thaulow K, Antonsen S, Burkeland O
Exploring the Potential for Use of Virtual Reality Technology in the Treatment of Severe Mental Illness Among Adults in Mid-Norway: Collaborative Research Between Clinicians and Researchers
JMIR Form Res 2019;3(2):e13633
URL: http://formative.jmir.org/2019/2/e13633/
doi:10.2196/13633
PMID:31199315

Original Paper

The Feasibility of a Using a Smart Button Mobile Health System to Self-Track Medication Adherence and Deliver Tailored Short Message Service Text Message Feedback

Rebecca J Bartlett Ellis[1], PhD, RN, ACNS-BC; James H Hill[2,3*], MS, PhD; K Denise Kerley[1], MSN, RN, CNRN, AG-CNS; Arjun Sinha[4*], MD; Aaron Ganci[5*], MFA; Cynthia L Russell[6], PhD, RN, FAAN

[1]Science of Nursing Care Department, Indiana University School of Nursing, Indianapolis, IN, United States

[2]Department of Computer & Information Science, Purdue School of Science, Indiana University-Purdue University, Indianapolis, IN, United States

[3]Center for Software and Innovation, Purdue School of Science, Indiana University-Purdue University, Indianapolis, IN, United States

[4]Richard L Roudebush VA Medical Center, Division of Nephrology, Indiana University, Indianapolis, IN, United States

[5]Visual Communication Design, Herron School of Art and Design, Indiana University-Purdue University Indianapolis, Indianapolis, IN, United States

[6]School of Nursing and Health Studies, University of Missouri-Kansas City, Kansas City, MO, United States

[*]these authors contributed equally

Corresponding Author:
Rebecca J Bartlett Ellis, PhD, RN, ACNS-BC
Science of Nursing Care Department
Indiana University School of Nursing
600 Barnhill Drive, E423
Indianapolis, IN, 46202
United States
Phone: 1 (317) 274 0047
Email: rjbartle@iu.edu

Abstract

Background: As many as 50% of people experience medication nonadherence, yet studies for detecting nonadherence and delivering real-time interventions to improve adherence are lacking. Mobile health (mHealth) technologies show promise to track and support medication adherence.

Objective: The study aimed to evaluate the feasibility and acceptability of using an mHealth system for medication adherence tracking and intervention delivery. The mHealth system comprises a smart button device to self-track medication taking, a companion smartphone app, a computer algorithm used to determine adherence and then deliver a standard or tailored SMS (short message service) text message on the basis of timing of medication taking. Standard SMS text messages indicated that the smartphone app registered the button press, whereas tailored SMS text messages encouraged habit formation and systems thinking on the basis of the timing the medications were taken.

Methods: A convenience sample of 5 adults with chronic kidney disease (CKD), who were prescribed antihypertensive medication, participated in a 52-day longitudinal study. The study was conducted in 3 phases, with a standard SMS text message sent in phases 1 (study days 1-14) and 3 (study days 46-52) and tailored SMS text messages sent during phase 2 (study days 15-45) in response to participant medication self-tracking. Medication adherence was measured using: (1) the smart button and (2) electronic medication monitoring caps. Concordance between these 2 methods was evaluated using percentage of measurements made on the same day and occurring within ±5 min of one another. Acceptability was evaluated using qualitative feedback from participants.

Results: A total of 5 patients with CKD, stages 1-4, were enrolled in the study, with the majority being men (60%), white (80%), and Hispanic/Latino (40%) of middle age (52.6 years, SD 22.49; range 20-70). The mHealth system was successfully initiated in the clinic setting for all enrolled participants. Of the expected 260 data points, 36.5% (n=95) were recorded with the smart button and 76.2% (n=198) with electronic monitoring. Concordant events (n=94), in which events were recorded with both the smart button and electronic monitoring, occurred 47% of the time and 58% of these events occurred within ±5 min of one another. Participant comments suggested SMS text messages were encouraging.

Conclusions: It was feasible to recruit participants in the clinic setting for an mHealth study, and our system was successfully initiated for all enrolled participants. The smart button is an innovative way to self-report adherence data, including date and timing of medication taking, which were not previously available from measures that rely on recall of adherence. Although the selected smart button had poor concordance with electronic monitoring caps, participants were willing to use it to self-track medication adherence, and they found the mHealth system acceptable to use in most cases.

(JMIR Form Res 2019;3(2):e13558) doi:10.2196/13558

KEYWORDS

medication adherence; medication compliance; behavior change

Introduction

Background

An estimated 30% to 50% of people with chronic conditions do not take medications as prescribed (eg, miss or skip doses, take medications late, or not at all), known broadly as medication nonadherence [1,2]. People who miss or skip taking medications or take them late are at risk for stopping their medications altogether [3]. Across all health conditions, medication nonadherence contributes to prescription-related morbidity and mortality, and nonadherence is estimated to cost around US $528 billion annually [4]. Despite the potential to improve patient outcomes associated with nonadherence, developing effective interventions relies on measuring medication adherence behaviors in a way that provides actionable information for behavior change.

Medication adherence measurement methods vary widely and include patient self-report (eg, questionnaires, interviews, and diaries), pill counts and claims data, direct observation, laboratory testing and monitoring by electronic technologies [5] (eg, packaging devices, digital medicines, ie, ingestible sensors), and video monitoring. Self-report and use of electronic technologies are traditionally and more frequently reported methods for measuring adherence in studies to improve medication adherence, as they offer insight into medication-taking behaviors useful for intervention [5,6]. Evidence suggests that electronic monitoring is better at detecting poor adherence compared with self-report [7,8], which often relies on recall. However, self-report is low cost and relatively easy to implement [6]. An advantage of electronic monitors is the ability to compile details about dosing history, as electronic monitors provide the time and date the medications were taken.

Currently used technologies that electronically compile dosing histories to determine adherence include packaging devices, digital medicines [9-11] (ie, ingestible sensors), and video monitoring [12]. Electronic packaging devices of pill caps, pillboxes, and blister packs differ by manufacturer, but they broadly use sensors to detect state changes in devices, for example, sensing cap or lid openings or closings, which indicate that medication has been taken. These “taking” events are associated with a date and time stamp to determine timing adherence, and these events have evidence of reliability for medication adherence both in clinical and research settings [13]. Although packaging devices can detect taking and timing adherence, using them requires disruption of already established medication-taking routines and organization systems, as users must store their medications in these devices for tracking [14,15]. Newer technologies, such as the ingestible sensor or video monitoring, overcome limitations imposed by packaging devices. The ingestible sensor allows users to keep their established routines, but it requires users to wear an adhesive patch attached to the abdomen to sense pill ingestion. The comfort associated with wearing the patch produced mixed reviews by patients [9]. In addition, ingestible sensors and video monitoring are intrusive and may be more appropriate for medications that require direct supervision to determine if medication was actually taken [16,17].

Specific Objectives

Capitalizing on the ease of self-report measures, allowing for end user flexibility with the methods already in use to manage medications and capitalizing on the dosing history that can be compiled through electronic technology, we investigated the feasibility of patients using a smart button to self-track medication adherence. The purpose of this study was to evaluate the feasibility of using a novel approach to measure medication adherence in a way that capitalizes on the ease of self-report and the ability to electronically compile dosing histories by having patients self-track medication taking using a smart button. The smart button is a component of our mobile health (mHealth) system that was field tested with the smart button in this study. In addition to describing our mHealth system in this paper, we (1) describe recruitment, enrollment and participant characteristics, (2) report the number of times we successfully set up the mHealth system in the clinic setting, (3) describe participants’ willingness to use the mHealth system and instances when they did not desire to use the system, and (4) evaluate concordance between self-report data acquired using the adherence self-tracking feature of our mHealth system compared with an established packaging device.

Methods

Study Design

In preparation for future studies, we conducted this small feasibility study in 3 phases over a 52-day period, with repeated daily measurements of medication adherence. Phase 1 lasted for 14 days, and it was designed to introduce participants to using the smart button to self-track medication taking and receiving standard short message service (SMS) text messages, whereas phase 2 comprised 30 days of tailored SMS text messages. Phase 3 lasted for 7 days, and participants again received the standard SMS text message when the button was pressed. As this was a feasibility study, the focus was on

understanding whether the smart button technology could be used by patients in their home environments. Our goal was to obtain 260 data points while minimizing the participant burden in the chance that the smart button technology did not work. As a result, we consecutively enrolled 5 participants. Data were collected between March 2018 and June 2018. Institutional review board approval was obtained, and all participants provided written informed consent before beginning the study.

Participants

Individuals aged 21 years of age or older, with a diagnosis of chronic kidney disease (CKD) and who self-administered at least one antihypertensive medication daily, were eligible for study participation. In addition, individuals needed to be able to speak, hear, and understand English, have the ability to open pill bottle caps, and be willing to use study devices. If participants were receiving dialysis at the time of screening, they were excluded because of the burden of dialysis treatment. Cognitive impairment was assessed, and only those with a score of 4 or greater on the 6-item Metal Status Screen Derived from the Mini-Mental Status Exam were included [18].

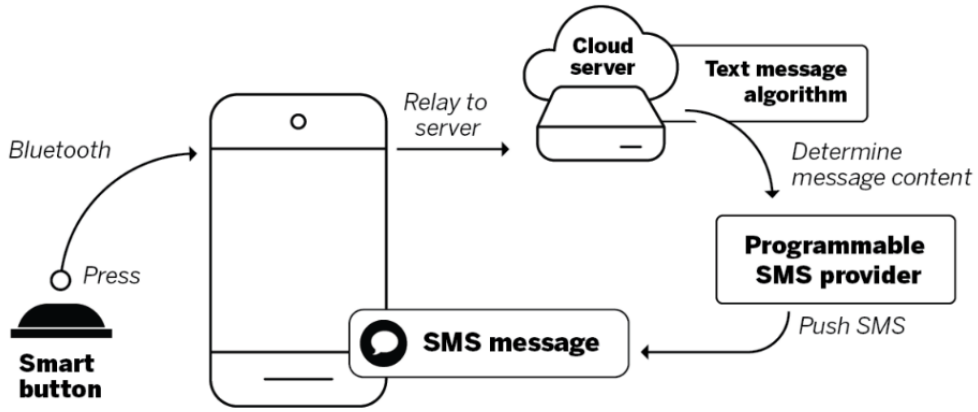
Setting

Participants were recruited from an ambulatory nephrology and hypertension clinic within the Indiana University Health system in Indianapolis, Indiana. Nephrologists prescreened patients taking antihypertensive medications and referred them to the research assistant (RA) for further screening.

Mobile Health System

The mHealth system capitalizes on Internet of Things technologies to deliver real-time SMS text messages on the basis of the time medications are taken and documented by the smart button press. The main elements of the mHealth system included a smart button and companion mobile app, a cloud-based server with a computer algorithm containing text messages, and an SMS text message platform (see Figure 1). We selected the smart button linked to a smartphone as the mHealth system, as we desired to develop an approach to measure medication taking and timing adherence without requiring users to store their medications in devices that were different from what they already used. Each of the mHealth system components is described below.

Figure 1. Components of the mobile health system. SMS: short message service.



Smart Button and Companion Mobile App

The first element of this system is a commercially available smart button named the Stone (Pebblebee). The smart button is a Bluetooth-enabled device that can be programmed using the companion smartphone-based app called Pebblebee, hereafter referred to as the app. The smart button can be easily programmed to perform a variety of tasks, such as tracking down a lost smartphone or using the smart button to control the volume on one's smartphone. The smart button is 0.9×0.8×0.5 inches in size, and it weighs 0.3 ounces. The battery life is listed as 1 year, and the battery is replaceable (retrieved from website). The smart button has a metal ring that allows it to be placed on a key chain. The smart button is compatible with iOS 8.3 or later and Android 5.0 or later, and it requires all phones to have Bluetooth Low Energy 4.0 (retrieved from website). The Bluetooth range is up to 150 feet, according to the manufacturer's product information. The smartphone app interacts with the smart button. For example, when the smart button is pressed, it sends a signal via the Bluetooth connection to notify the app it was pressed. The app can be programmed to react to button presses from the smart button to perform shortcuts for tasks using a smartphone. For example, the app can be programmed so that the smart button can be used to take smartphone photos from a distance or to find a phone with the push of a button. For our purposes, we programmed the app to send an event to a cloud-based server we set up for this study using a webhook. A webhook allows real-time transfer of information to other apps running at remote locations.

Smartphones

Smartphones are probably the most well-known and ubiquitous smart and connected devices. A total of 3 in 4 Americans own a smartphone [19]. Smartphone capabilities such as SMS text messaging, apps, and connecting other devices to them, make smartphones potentially useful technologies to support adherence [20]. The mHealth system and use of the smart button rely on the use of a smartphone. Participants were offered study smartphones to use during the study; however, all elected to use their personal smartphones. The RA assisted participants with device setup in the clinic, including downloading and setting up the app and webhook.

Cloud-Based Server With a Computer Algorithm to Deliver Short Message Service Text Messages

The cloud-based server acted as an endpoint for receiving events from the smart button app via the webhook. When the cloud-based server received a notification from the app, signaling that the smart button had been pressed, both the participant and the timing of the event were used as input data by the computer algorithm to deliver subsequent SMS text messages. The computer algorithm comprised decision rules that determined the type of text message to send to participants via SMS. This association is made by the algorithm extracting the unique ID from the event received by the server and by looking up the participant who was assigned that smart button. The server processed the events according to the algorithm in Textbox 1.

Textbox 1. Algorithm through which the server processed events.

If the event was received, then the algorithm determined study phase and day of study (phase 1: study days 1-14; phase 2: study days 15-45; phase 3: study days 46-52), and then subsequently the server sent an SMS text message to the participant, acknowledging they pressed the button correctly. These decision rules can be expressed as phase 1 of study={Study days 1-15}

IF participant linked with unique ID={confirmation message that system received button press notification}

If the event was received during phase 2, then the server sent a tailored SMS text message from Table N depending on the study day.

ELSE IF participant time associated with goal time={positive reinforcement message sent}

Programmable Short Message Service Provider

To push SMS text messages to participants, we used the SMS text platform provider Twilio, a platform as a service, which facilitates sending SMS text messages to mobile phones on behalf of an app. When the cloud-based server was ready to send an SMS text message to a participant, a request was sent to the SMS text platform, and an SMS text message was then sent to the specified participant's mobile phone number. The SMS text platform responded with either a unique ID for the request or an error message explaining why the request failed. We assumed that receipt of a unique ID for the request implied the participant eventually received the SMS text message on the mobile phone.

Short Message Service Text Messages

In preparation for future intervention research, we designed 2 types of SMS text messages for this study: (1) standard and (2) tailored, which were delivered in specific phases of the study. Evidence from systematic reviews of medication adherence interventions conducted across several chronic conditions shows promise for interventions that use SMS text messaging [21-23]. The use of SMS text messaging delivered via smartphone has been shown to improve medication adherence. A total of 2 recent reviews, 1 integrative and 1 meta-analysis of randomized controlled trials, suggest that use of SMS text messages improve adherence across a variety of patient populations by approximately 17% [21,24], and therefore incorporating SMS text messages in mHealth-based interventions to improve health behavior change interventions is warranted.

Standard Short Message Service Text Messages

Principles of interface design indicate that providing feedback to users so they understand the technology is working is a best practice of user-centered design [25]. Accordingly, the standard text message stated "thank you for pressing the button" for participants to know that their button press was recorded (ie, the technology worked).

Tailored Short Message Service Text Messages

Tailored SMS text messages were developed on the basis of systems thinking, which emphasizes habit formation using reliable systems (eg, routines) embedded in personal environments [26]. As systems thinking focuses on using established and reliable systems to support medication taking, it is an approach that moves away from "remembering." Evidence suggests that consistent medication-taking routines support medication adherence [14], and aligning behavior with individuals' personal environments, habits, and routines can support medication taking. Messages were tailored on the basis of whether medications were taken "On Time" or whether medications were taken "Outside Med Time." Both types of messages were designed to draw attention to the behaviors and environments that were supporting taking medication, with the "on time" messages designed to draw attention to the environments and routines working to support taking medication and the "outside med time" messages designed to encourage thinking about processes and routines that could be changed to support taking medications on time for the next scheduled dose. SMS text feedback messages were developed to be delivered in response to smart button presses. In phase 1 and phase 3, standard SMS text messages read, "Thank you for pressing the button" on the basis of user-centered design principles that indicate users require a mechanism to determine if the technology is working as intended [25]. During phase 2, tailored SMS text messages were sent to participants on the basis of medication timing. A total of 60 SMS text messages were developed in total, with 30 "on time" messages designed to be delivered if participants took medications within ±3 hours of their regularly scheduled time, and 30 "outside goal time" messages were designed to be delivered when participants took their medications outside this dosing interval (ie, outside the ±3-hour dosing interval). Sample SMS text message content and timing of delivery is shown in Figure 2.

Figure 2. Sample short message service text messages sent across study phases.

We set the ±3-hour window as taking a drug within 25% of the dosing interval maximizes drug bioavailability and effectiveness [27]. The SMS text messages were designed to be delivered in response to the smart button press, indicating the medication was taken. If participants pressed the button more than once daily during phase 2, the first message sent was the designated tailored medication adherence feedback based on the timing of the button press (described above), and subsequent presses on the same day triggered the same standard message participants received in phases 1 and 3.

Feasibility Measures

Recruitment and Enrollment

We tracked the number of patients seen in the clinic, screened for the study, and enrolled. Reasons for not participating in the study were tracked when provided.

Participant Characteristics

Demographics collected at study enrollment included gender, race, ethnicity, education, marital and employment status, annual income, CKD stage, and participant self-report of coexisting medical conditions. Data were collected and entered into a study-specific Research Electronic Data Capture (REDCap) database [28].

Mobile Health Setup in Clinic

We tracked the number of times the mHealth set up. Setup included the ability to download the companion app, set up the webhook, press the smart button, as well as receipt of the test SMS text message that indicated the system was operating as intended.

Willingness to Use the System

In addition to the data tracked about participant recruitment and enrollment, we tracked instances when participants did not desire to use the mHealth system and reasons why. Dropouts and technology problems reported by participants were noted and summarized. These were identified during the scheduled RA phone calls with participants.

Medication Adherence

We reported medication adherence (proportion of prescribed doses taken on time) to describe adherence in this sample and better interpret the results. To measure adherence, we used an electronic medication-event monitor (EMM) pill cap that measured adherence on the basis of the number of medication bottle cap openings recorded, as measured by the Medication Event Monitoring System TrackCap (MEMSCap, AARDEX Group), expressed as a percentage. The MEMSCap contains a microelectronic circuit in the cap that registers the date and time when the cap is removed from the bottle of pills. These time stamped events are stored and can be downloaded to the web portal medAmigo [29] using a Universal Serial Bus–reader device that transfers cap data to the platform. The medAmigo is a secure cloud-based software platform, with access provided to investigators with use of the MEMSCap. Medication adherence was measured by EMM using the medication adherence scores derived from the MEMSCap and that were

calculated automatically by medAmigo on the basis of the dosing history.

Concordance

There were 2 ways that concordance was measured. First, the number of events in which the recorded smart button events had a corresponding EMM event recorded on the same day was used. Second, we evaluated the number of these concordant events that occurred within ±5 min of one another and explored the timing in which the smart button press was activated and when the EMM device recorded a medication-taking event. The MEMSCap device was selected for the reference comparison, given its ability to measure timing adherence and evidence of its ability to estimate medication adherence [13,30-32].

Acceptability

Acceptability was based on qualitative feedback provided by participants. The RA documented comments made by study participants at each of 3 points of contact. The RA had 3 scheduled phone calls with participants during the study in which comments may have been documented, as well as during any points of contact when troubleshooting the mHealth system technologies may have occurred. The RA used a semistructured interview guide for phone calls. Following phase 2, the RA asked about participants' thoughts on whether the SMS text messages were helpful to support medication taking.

Procedure

At enrollment, all participants received study devices and in-person training by the RA on how to use the study devices. A unique ID was assigned to each button; therefore, our team could identify which participant had each button when a button was pressed. In addition, each participant received a unique study number that was used to set up the mobile app. The RA assisted participants with downloading and installing the app on their mobile phone. The app was required to run in the background of participants' phones to detect smart button presses. The RA instructed participants to ensure the Bluetooth on their mobile device was turned on and the app was open when pressing the smart button. Next, we sent an SMS text message with information needed to configure the app to communicate with the cloud server when the smart button was pressed by the participant. This critical step allowed us to (1) confirm we had the correct mobile phone number, as the cloud server could send the participant the SMS text message, and it allowed us to (2) remove potential errors caused by transcribing setup information into the app. We could easily copy and paste the setup information into the app directly from the received SMS text message on the participant's mobile phone. Before leaving the clinic, participants demonstrated use of the smart button, and each participant received a confirmation SMS text message indicating proper setup. To thank participants for their time in talking with the RA and using the study devices, they received an honorarium of up to US $50 in gift cards. For the purpose of this study, the RA selected 1 prescribed daily blood pressure lowering medication from participants' prescribed medication list, and participants were instructed to keep this medication in the MEMSCap bottle. The RA instructed participants to take this medication as prescribed and press the smart button when the medication was taken. The RA asked participants to identify a date on which they would start using the study devices, and this was recorded as the study start date. In addition, the RA asked participants to identify the time when they usually took the selected medication. The date and time were recorded as the study start date, and the time was used to calculate the dosing interval. Participants were instructed to place their supply of antihypertensive medication inside the MEMSCap bottle and begin taking it from the MEMSCap bottle on the selected start date. All enrolled participants were instructed by the RA on how to use the smart button to self-track their daily medication taking. Each day, the participants were to remove their selected medication from the MEMSCap bottle at the designated time, then press the smart button. Telephone calls were made by the RA at days 15, 46, and 52 to troubleshoot technical problems, determine if participants received SMS text messages, and provide instructions on returning devices to the study team at study end.

Data Analysis

Study data were collected and stored using REDCap electronic data capture tools, hosted at Indiana University [28]. Data were analyzed with descriptive statistics appropriate for level of measurement using IBM SPSS version 24.0 (IBM). Missing data for the smart button and EMM were coded as a failure to record data, with the exception of the days that participants reported not using the devices, and concordance analysis was adjusted appropriately. Frequency counts and percentages were used to summarize recruitment and enrollment, participant characteristics, the number of smart button press and MEMSCap events recorded, and concordance. Graphs were used to examine concordance between data acquired from self-tracking of medication adherence using the smart button and medication adherence recorded with the MEMSCap. Narrative analysis of comments made by participants was used to identify strengths and opportunities to improve the study for the future clinical trial.

Results

Overview

A total of 19 patients were prescreened for study eligibility in the clinic by physicians. Of these, 6 did not meet study eligibility criteria. Reasons for exclusion included the following: CKD stage >4 (n=3), no diagnosis of CKD (n=1), inability to self-manage medications (n=1), and not prescribed an antihypertensive (n=1). A total of 4 (21%) patients meeting prescreening criteria declined to participate. A total of 3 out of 4 patients provided reasons for their lack of interest in study participation. A total of 1 candidate used a flip phone, and the participant was not willing to carry another phone. The other 2 candidates were recruited for another study on day of clinic, and they were not willing to stay for recruitment discussion. Of the 3 remaining patients approached for further screening by the RA, 2 participants were willing to participate, but they were unable to stay in the clinic to obtain the study devices and be trained on setup, as they were dependent on prearranged transportation services. Of the 6 patients screened by the RA, 1 patient did not meet inclusion criteria, and the patient was

excluded, as this individual was not willing to use a smartphone. A total of 5 patients were enrolled in the study, 2 participants (40%) were women, and 3 participants (60%) were men. The mean age was 52.6 years (SD 22.49; range: 20-70). Table 1 lists the self-identified health conditions of the 5 participants; 4 participants (80%) had more than 3 conditions and 2 participants (40%) had 4 or more. The 5 participants took a mean total number of 8.6 (SD 5.02) medications (range: 3-14 medications), and out of those, a mean of 2.8 (SD 1.64) were antihypertensive medications.

Feasibility of Mobile Health System Technology Setup in the Clinic

The RA was successful in assisting all 5 participants (100%) with downloading the smart button app on their respective smartphones, setting up the webhook actions in the app, and testing the smart button device in the clinic setting. All 5 participants were able to press the smart button, and each participant received the test SMS text message while in the clinic setting, demonstrating the system was set up and operating correctly.

Technology Challenges

A total of 2 participants reported technology problems during the study. Troubleshooting included ensuring the phone app was open and Bluetooth was turned on, as well as confirmation that the smart button was pressed when taking pills. Although each participant gave confirmation, messages were still not received by these 2 participants. A total of 1 participant texted the RA study phone to troubleshoot, as SMS text messages were not received, but the phone number the participant texted from did not match the phone number provided by the participant at study enrollment. The participant validated that only 1 mobile number was used for both voice and SMS text messages. This problem remained unresolved.

Device Events Recorded Over Study Period

All 5 participants initiated the use of the EMM on the start day they indicated. Over the course of the 52-day study, with 5 participants, we expected to yield 260 data points (5 participants×52 days) per smart button and MEMSCap device. Over this monitored period, 36.5% (n=95) of the expected events were recorded with the smart button, and 76.2% of the expected events (n=198) were recorded with MEMSCap. There was 1 participant for whom no smart button events were recorded, although the system worked when tested in the clinic setting during enrollment.

Measurement Concordance

Concordance between events recorded on both devices (n=94) was achieved on an average of 47.4% (range 0%-81.3%) of the time. Event recordings and concordance for each participant across the study period in which participants reported using the devices are shown in Figure 3. Among the concordant events, on average, 58.5% of the events occurred within ±5 min of one another.

We also examined these concordant events to determine which event was recorded first or if the timing of the device activation occurred at the same time. There were 34 events in which the time recorded for the smart button preceded the MEMSCap time, indicating the smart button was pressed before removing medication from the bottle. The mean difference in time between these 2 event recordings was 55 min (median 8 min; minimum: 1 min, maximum: 17 hours 6 min). In contrast, 45 events were recorded first on the MEMSCap device, with a mean time difference of 29 min (median 1 min, minimum: 1 min, maximum: 9 hours 22 min). In 15 cases, the smart button time recorded was identical to that of the MEMSCap, indicating the button was pressed at the same time medication was removed from the MEMSCap bottle. A total of 1 participant noted that during the course of the study, a pill had been removed from the MEMSCap bottle and taken, but the participant received a phone call, and then, the participant did not press the smart button until remembering to do so at a later time. A total of 1 participant ended use of the study devices on day 48 because of travel and desire not to travel with the study devices. A total of 3 participants used the devices for longer than the 52-day study period. Feasibility and Acceptability of Text Messages

Of the SMS text messages delivered, correct messages in the algorithm were sent 100% of the time. However, in 1 case, a participant traveled to another time zone, and the algorithm responded on the basis of the server time zone. Owing to the time zone difference, the medication taking was outside the goal time of the server time zone, and, as a result, the algorithm sent the appropriate feedback message, but this did not match the participant's behavior on the basis of the new time zone. Overall, participants thought the idea of sending messages about taking medications via SMS text messages was a good idea; however, the participants shared different ideas about the timing and content of messages, as reflected in their comments below. Of the 3 participants that received the tailored SMS text messages, 2 of them found them helpful. One participant who was highly adherent to taking medications commented, "I did not find the messages helpful." This participant suggested sending messages "when medications are taken late" (ie, outside the dosing interval) instead of sending messages when people are adherent . Another participant indicated the messages were all helpful but suggested to "send messages every couple of days." This participant felt, "it was good to get encouragement when the messages came." This same participant also indicated that the participant forgot to press the button a couple of days. Similarly, another participant noted, "I felt messages were encouraging and helpful to know I was taking my meds [ications] on track." This participant stated that "the daily messages are helpful in motivating continued habits," and the participant further stated that there was not "any one message that was not helpful." Similar to the first participant comment, this participant also thought that sending a message to "prompt people who are usually late or way off" in taking medication might be helpful. The 1 participant who did not receive messages during the study commented about the helpfulness of receiving messages and indicated that "simple messages to remind to take meds would have been helpful with a timeline of when to take the medicine."

Table 1. Participant characteristics.

Category	Count
Gender	
Male	3
Female	2
Race	
White	4
American Indian or Alaska Native	1
Ethnicity	
Hispanic/Latino	2
Not Hispanic/Latino	2
Unknown	1
Education level	
High school graduate	2
Some college/no degree	1
Bachelor's degree	1
Doctoral degree	1
Marital status	
Never married	2
Married	1
Separated	1
Widowed	1
Employment status	
Full time	2
Retired	2
Not employed	1
Annual income	
US $20,000-$30,000	1
US $40,000-$50,000	2
>US $100,000	1
Prefer not to disclose	1
Chronic kidney disease stage	
Stage 2	1
Stage 3A	1
Stage 3B	2
Stage 4	1
Subject-identified medical conditions	
High blood pressure	5
Heart disease	3
Arthritis	2
Asthma	2
Back pain	1
Chronic obstructive pulmonary disease	1
Diabetes	1

Category	Count
Emphysema	1
Stroke	1
Congenital disorder	1

Figure 3. Concordance between smart button self-tracking and electronic monitoring of medication adherence. Gray boxes indicate event recorded on the device; white boxes indicate no event recorded. Type of Smartphone Operating Platform: 1Android, 2iOS; Wavy lines: participant travel, Dotted lines: refusal to use the device. Concordance determined by days participants reported using one or more of study devices. MEMS: Medication Event Monitoring.

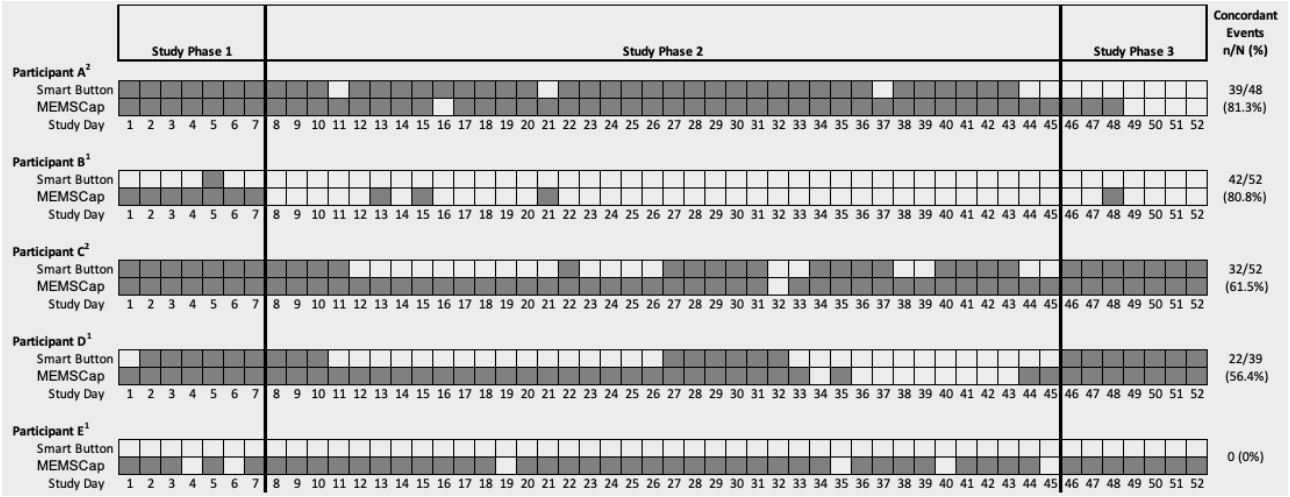


Table 2. Medication adherence acquired by electronic caps for each participant and study phase.

Participant	Overall adherence (Day 1-52), (%)	Phase 1 adherence (Day 1-14), (%)	Phase 2 adherence (Day 15-45), (%)	Phase 3 adherence (Day 46-52), (%)
A	98	100	97	100
B	22	57	6	14
C	98	100	97	100
D	95	100	91	100
E	88	86	87	100

Medication Adherence

The average medication adherence score across the study time frame was 80.2% (range 22%-98%) when recorded using EMM. Individual participant adherence scores are shown in Table 2.

Discussion

Principal Findings

Existing technologies used to measure medication adherence provide data about timing and taking adherence, but they can be disruptive and intrusive in patients' routines. This article focused on evaluating the feasibility of using a smart button to self-track medication adherence as part of an mHealth system to deliver subsequent SMS text messages on the basis of medication adherence timing. We examined the feasibility of recruiting and setting up this mHealth system in the clinic setting on participants' own phones, patients' willingness to use the self-tracker technology, and concordance between data acquired from the smart button and an established electronic packaging device. The main findings of this feasibility study are the lessons learned about the selected smart button and our mHealth system, which will serve to guide future studies.

Lessons Learned and Recommendations for Future Study

We demonstrated that it is feasible to recruit participants and set up the technology in the clinic setting, which we did for the 5 individuals participating in this study. However, our study procedures that included recruiting, enrolling, and setting up technology in the same clinic appointment may have deterred some individuals from participating because of the added time to their clinic appointment. We chose this approach as a pragmatic one, but for 2 people, this approach interfered with previous transportation arrangements and precluded them from participating. Future studies should ensure study procedures are flexible to meet patient needs and maximize participation, and letting patients know in advance about potential research opportunities may be beneficial. There are benefits and challenges to participants using their own smartphones. All 5 of our participants chose to use their own phones. This was helpful at the outset, as they were familiar with the functionality

of the phone. However, as Ling [33] points out, having expectations that mobile phones all provide the same level of access and functionality in designing and delivering mHealth interventions is often taken for granted. While troubleshooting technological problems, our team discovered that individual privacy settings were interfering with delivery of messages. A total of 2 iPhone users had a setting that if the SMS text message sender was unknown, the messages would be automatically deleted. On the basis of this finding, we recommend that in future research, phone numbers associated with the study be added to participant phone contact lists at study outset so that participants receive study messages and phone calls. One of the greatest challenges we encountered in our study was that the smart button only worked when the companion app was running in the background on the phone. Despite knowing this in advance and teaching our participants to keep the app open, there is a high likelihood that the app was closed, and it is the reason why smart button presses were not received. Smart button use for self-tracking medication adherence would be more useful if participants did not need to worry about the companion app. Moving forward with future research, we recommend exploring if other smart buttons on the market can operate without requiring the user to take this extra step or designing new systems that overcome this obstacle. We also learned that time zone changes posed challenges for our mHealth system, and time zone changes posed challenges for measuring medication adherence. As the determination of medication adherence is based on date and time, travel to other time zones can interfere with a regular schedule of medication taking. The smart button is connected to the phone, so the time zone of the user is the appropriate time zone, but if the server uses the time zone to send message algorithms, such as the one our team designed, then the messages may not appropriately match the medication-taking behavior. We found a study reported in the literature that encountered a similar difficulty with mHealth technology and medication adherence, and those researchers changed the programming code to ensure medication time was based on the mobile phone users' local time rather than the server or research teams' time zone [34]. We believe this a potential problem for all types of electronic measures of adherence, especially if the measurement device does not have the capability of sensing and responding to geographical changes. For example, the EMM MEMSCap device we used does not sense time zone changes autonomously; therefore, this is something that users would need to report to investigators to more accurately measure adherence if participants travel while having their medication taking monitored. On the basis of these findings, future investigations should ensure the programming of the mHealth system can respond appropriately to time zone changes. Investigators may wish to have patients keep a log of any time zone changes that occur during the course of their medication monitoring in medication adherence studies, including in studies using existing electronic medication monitoring devices. We also learned that the technology may not work outside of the United States; therefore, this is an important consideration for planning future research. Future research should explore the ideal conditions under which the smart button has utility both from a measurement and intervention perspective. In future research, there is a need to consider individual user characteristics, including gender, race, ethnicity, income, number and types of medications taken, and different chronic conditions, to determine if using a smart button self-tracker and mHealth system is feasible and then subsequently determine if using a smart button self-tracker and mHealth system can improve medication adherence. Future research will also need to further evaluate the content of tailored SMS text messages for content and face validity congruent with systems thinking and determine the best timing for delivering messages. Engaging patients in the participatory codesign of these messages may be a salient opportunity and best practice approach to engage the target end user [35,36].

Limitations

This is a small feasibility study focused on evaluating the technology components of the mHealth system and the ability to use a smart button to self-track medication adherence in the field. The sample size is small, but it was purposefully chosen to test feasibility of the smart button and mHealth system to operate according to plan in the patient home environment. Although the sample size limits generalizability, the study was useful in identifying opportunities to improve future iterations of the mHealth system components. Although we assessed medication adherence using an EMM bottle device and asked about self-reported adherence to devices, we do not have baseline medication adherence data for participants. Self-reported adherence, although likely to overestimate adherence, should be evaluated in future studies at baseline. Another limitation was that we relied on the SMS text message data to determine if the smart button was pressed. Participants reported pressing the button, yet no events were received on the server, and therefore no SMS messages were generated. Whether or not the participants pressed the button was not objectively evaluated in the study procedures; therefore, we do not have data on whether participants actually pressed the button. One of the challenges in medication adherence research is that there is no gold standard measure of adherence. The wide variability in measurement methods and ways of acquiring information on medication taking (self-report, indirect, and direct) are challenges in conducting this research. The smart button provided a self-report measure of medication taking, and we used the EMM bottle device to provide an indirect objective measure of adherence. We recognize that both of these methods come with limitations, which is why we used the concordance measure to make comparisons, but nonetheless, without direct observation, both of these approaches provide only an estimate of adherence. As the smart button is a self-report measurement approach, it is limited to patients' willingness to actually report their medication taking. However, our smart button approach is an innovative way to self-report medication adherence, as it allows for real-time self-report of medication adherence and does not rely on recalling if medications were taken, which is the basis for most self-report measures of adherence [6]. Among self-report measures that rely on recall, adherence is often overestimated by approximately 30% [37]. The smart button component of our mHealth system provides a novel self-report approach to measuring medication adherence, as it provides time and date data that are lacking from other common self-report methods for measuring adherence.

Conclusions

We demonstrated that it is feasible for participants recruited from the clinic setting to use a smart button device to self-track medication taking, although the selected device may not reliably work across smartphone operating systems and in participant home environments. Adherence was relatively high in this sample, although corresponding smart button presses were not consistently recorded, demonstrating poor concordance. We believe the discrepancy lies in the selected smart button technology and not in the ability of patients to self-track their medication taking, although this requires further study. Although there are some limitations to the use of the specific smart button used in this study, we were able to identify opportunities to improve the system to support testing in future studies.

Acknowledgments

This project was supported in part with funding from Sigma Theta Tau International Alpha Chapter.

Conflicts of Interest

None declared.

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Abbreviations

CKD: chronic kidney disease
EMM: electronic medication-event monitor
MEMSCap: Medication Event Monitoring System TrackCap
mHealth: mobile health
RA: research assistant
REDCap: Research Electronic Data Capture
SMS: short message service

Edited by G Eysenbach; submitted 10.02.19; peer-reviewed by P Chai, M Mileski, S Omboni, RJ Katz; comments to author 02.03.19; revised version received 27.04.19; accepted 29.04.19; published 25.06.19.

Please cite as:
Bartlett Ellis RJ, Hill JH, Kerley KD, Sinha A, Ganci A, Russell CL
The Feasibility of a Using a Smart Button Mobile Health System to Self-Track Medication Adherence and Deliver Tailored Short Message Service Text Message Feedback
JMIR Form Res 2019;3(2):e13558
URL: http://formative.jmir.org/2019/2/e13558/
doi:10.2196/13558
PMID:31237568

Original Paper

Feasibility of Using Short Message Service and In-Depth Interviews to Collect Data on Contraceptive Use Among Young, Unmarried, Sexually Active Men in Moshi, Tanzania, and Addis Ababa, Ethiopia: Mixed Methods Study With a Longitudinal Follow-Up

Francis Maganga Pima[1*], MPH; Martha Oshosen[1*], BSc, MPH; Kennedy Michael Ngowi[1,2*], BSc, MSc; Bruck Messele Habte[3], PhD; Eusebious Maro[4], MD; Belete Eshete Teffera[5], BSc; Godfrey Kisigo[1], MD; Iraseni Ufoo Swai[1], MD; Salim Semvua Msangi[1]; Amha Ermias[5], MSc; Blandina T Mmbaga[1], MSc, MD, MMed, PhD; Rosalijn Both[5], MSc, PhD; Marion Sumari-de Boer[1,6], MSc, PhD

[1]Department of Clinical Trials, Kilimanjaro Clinical Research Institute, Moshi, United Republic of Tanzania

[2]Department of Medical Psychology, University Medical Centre Amsterdam - Amsterdam Medical Centre, Amsterdam, Netherlands

[3]School of Pharmacy, Addis Ababa University, Addis Ababa, Ethiopia

[4]Department of Obstetrics and Gynecology, Kilimanjaro Christian Medical Centre, Moshi, United Republic of Tanzania

[5]SEGEL Research and Training Consulting PLC, Addis Ababa, Ethiopia

[6]Department of International Health, Radboud University Medical Centre, Nijmegen, Netherlands

[*]these authors contributed equally

Corresponding Author:
Marion Sumari-de Boer, MSc, PhD
Department of Clinical Trials
Kilimanjaro Clinical Research Institute
PO Box 2236
Moshi,
United Republic of Tanzania
Phone: 255 754331948
Email: m.sumari@kcri.ac.tz

Abstract

Background: Data on contraceptive needs and use among young unmarried men are limited. Conventional ways of data collection may lead to limited and unreliable information on contraceptive use due to sensitivity of the topic, as many young men feel ashamed to discuss their behavior of using contraceptives. As short message service (SMS) is anonymous and a commonly used means of communication, we believe that if deployed, it will create a promising user-friendly method of data collection.

Objective: The objective was to investigate the feasibility of using SMS to collect data on sexually active, young, unmarried men's sexual behavior and contraceptive preferences, practices, and needs in Addis Ababa, Ethiopia, and Moshi, Tanzania.

Methods: We enrolled men aged 18-30 years who were students (in Ethiopia and Tanzania), taxi or local bus drivers/assistants (Ethiopia and Tanzania), Kilimanjaro porters (Tanzania), or construction workers (Ethiopia). Young men were interviewed using a topic list on contraceptive use. They were followed up for 6 months by sending fortnightly SMS texts with questions about contraceptive use. If the young men indicated that they needed contraceptives during the reporting period or were not satisfied with the method they used, they were invited for a follow-up interview. At the end of the study, we conducted exit interviews telephonically using a semistructured questionnaire to explore the feasibility, acceptability, and accuracy of using SMS to validate the study findings in both countries.

Results: We enrolled 71 young unmarried men—35 in Tanzania and 36 in Ethiopia. In Moshi, 1908 messages were delivered to participants and 1119 SMS responses were obtained. In Ethiopia, however, only 525 messages were sent to participants and 248 replies were received. The question on dating a girl in the past weeks was asked 438 times in Tanzania and received 252 (58%) replies, of which 148 (59%) were "YES." In Ethiopia, this question was asked 314 times and received 64 (20%) replies,

of which 52 (81%) were “YES” (*P*=.02 for difference in replies between Tanzania and Ethiopia). In Tanzania, the question on contraceptive use was sent successfully 112 times and received 108 (96%) replies, of which 105 (94%) were “YES.” In Ethiopia, the question on contraceptive use was asked 17 times and received only 2 (11%) replies. Exit interviews in Tanzania showed that SMS was accepted as a means of data collection by 22 (88%) of the 25 interviewed participants.

Conclusions: Despite network and individual challenges, the SMS system was found to be feasible in Moshi, but not in Addis Ababa. We recommend more research to scale up the method in different groups and regions.

(JMIR Form Res 2019;3(2):e12657) doi:10.2196/12657

KEYWORDS

SMS; contraceptives; sexual behavior; feasibility; young unmarried men

Introduction

Data on contraceptive use is limited overall and often limited to use among girls or couples only. A study on the trends of contraceptive use from 1994 to 2014 showed that the levels of contraceptive use among women are as low as 20% in Western and Central Africa and up to 60% in Eastern and Southern Africa [1]. According to the latest Demographics and Health Surveys, in both Tanzania and Ethiopia, just over half of sexually active, unmarried women use a contraceptive method (54% in Tanzania and 55% in Ethiopia). In both countries, contraception is driven by the use of condoms, injectables, and oral contraceptive pills. In Tanzania, condoms are the most popular method used by young unmarried women (15%), while in Ethiopia, the most popular method is injectables (35%) [2,3]. The Tanzania National Family planning Research Agenda 2013-2018 reported that adolescents and young adults aged 15-24 years in Tanzania engaged in sexual activities before marriage [4], while in Ethiopia, the median age of the first sexual activity is 16-21 years [5]. Several studies have been performed in Tanzania and Ethiopia. In a study in Mwanza, Tanzania, many young men stated that they would be pleased to impregnate their partner because it demonstrates the man’s fertility [6]. In a study in an urban area in Northern Ethiopia, it was quite common among young men to frequent sex workers, and many expected their girlfriends to be virgins [7]. Nonetheless, these studies rarely touched upon the contraceptive needs and practices of these young men [8]. These studies show that there is limited information on contraceptive use and sexual behavior among young unmarried men. Collecting data through conventional ways such as face-to-face interviews or written questionnaires might not yield favorable results in this vulnerable young population.

In both Ethiopia and Tanzania, a gendered double standard allows young men much more sexual freedom than young women. Many young men in both countries claim that engaging in premarital sexual relationships prevents peers as well as women from questioning their manhood and enhances their reputation [9].

The majority of the limited existing data on contraceptive use come from demographic health surveys, other cross-sectional studies, and qualitative studies. However, due to the taboo on talking about sexual behavior and use of contraceptives, these data might be biased. Research among young, unmarried, sexually active men in countries where sexual contact before marriage is seen as a sin and is highly stigmatized needs less conventional and anonymous ways of data collection. Mobile phone usage and ownership among young men in Sub-Saharan Africa has rapidly increased in recent years [10]. Short message service (SMS) is a commonly used platform among young people for communication due to its low cost. This provides opportunities to introduce a mobile health (mHealth) app to collect or share information in order to promote knowledge on contraceptives among young men. The use of mobile phones for health is a promising way of increasing family planning knowledge and promoting a positive outlook toward contraceptive use. Furthermore, collecting data through mobile phones is possible, since access to mobile phones is relatively high. Using text messages for data collection is not expensive and unlike mass media, there is a possibility for two-way interaction. A text message with questions about contraceptive knowledge can be sent to a respondent for simple feedback, and the response can determine the follow-up question.

Several studies globally have shown the use of mobile phone surveys (MPS). A review performed by Gibson et al showed that limited information was acquired on the advantages and disadvantages of MPS, as the number of surveys using SMS is limited [11]. Another study showed that outcomes of remote data collection are too heterogenous to conclude on the feasibility of using such a tool. However, it is clear that more research is needed to investigate the feasibility of MPS [12]. Literature has shown that young people are the heaviest users of the mobile phones in their everyday life compared to other age groups [13].

To our knowledge, the SMS method has not been used to collect sensitive data about contraceptive use in our setting. As young men use mobile phones extensively, we believe SMS texts may be a promising way to generate much-needed data on the diverse and context-specific contraceptive needs, preferences, and behaviors of young men. Therefore, we conducted a qualitative study with the aim of exploring whether SMS, in combination with in-depth interviews, is a feasible method to collect data on contraceptive needs and use.

Methods

Study Design

This was a mixed methods study with a longitudinal follow-up. Sexually active, young, unmarried men were recruited and followed up for 6 months to collect data on sexual behavior and contraceptive use through SMS in combination with in-depth interviews. Ethical clearance for this study was obtained from

the Addis Ababa Regional Health Bureau and the National Research Ethics Review Committee in Ethiopia and the local institutional review board of Kilimanjaro Christian Medical University College and the National Health Research Ethics Committee in Tanzania.

Study Population

We recruited young, unmarried, sexually active men aged 18-29 years for our study. We involved groups of young men with diverse backgrounds regarding educational level, type of sexual partner, occupation and income, and religious affiliations. Young men recruited were students from universities (in Tanzania and Ethiopia), drivers and conductors of local transport buses (in Tanzania and Ethiopia), porters in Kilimanjaro Climbing Tourism (in Tanzania), and construction workers (in Ethiopia).

Study Procedures

Recruitment

For recruitment of participants, we used different methods including posting flyers on information boards at departments in universities (for students); snowball sampling, whereby we identified one informant through our personal and professional networks who we then asked to introduce us to others in their networks; and a screening list to assess whether participants were eligible. We provided participants information about the study in Kiswahili (in Tanzania) or Amharic (in Ethiopia). After the recruiter carefully explained the nature of the study to the participant, written informed consent was obtained in Kiswahili or Amharic.

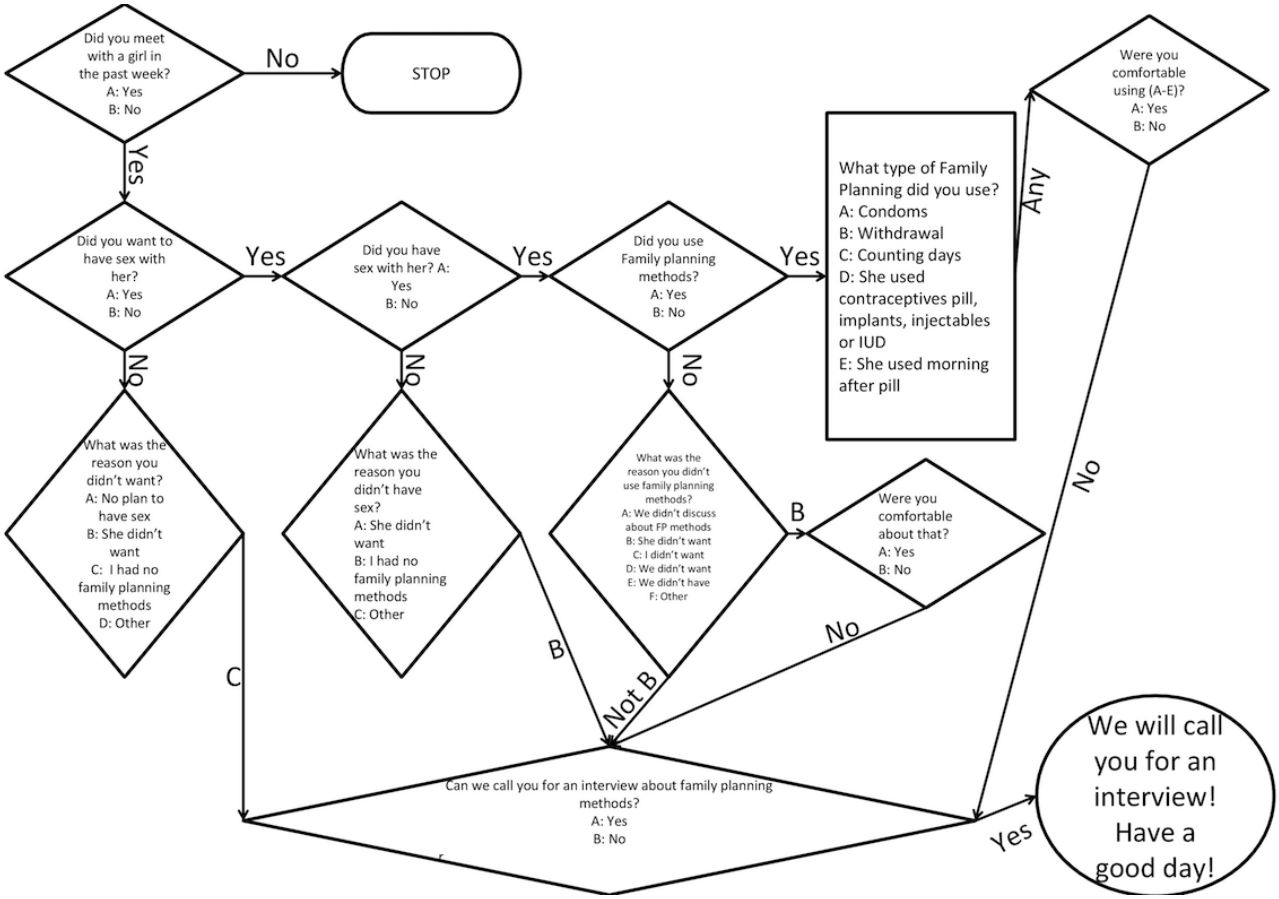
Informed Consent

Once a participant was recruited and signed the informed consent, we conducted an in-depth interview on his contraceptive needs and use. Participants were followed up for 6 months by sending SMS texts on a fortnightly basis to inquire about their contraceptive use in the past 2 weeks. If there was a need for contraceptives, the participants were invited for another in-depth interview that specifically focused on the instance of contraceptive need. Participants were asked about more in-depth information based on the first in-depth interview. At the end of 6-month follow-up, participants were called for exit interviews in which they were asked about the feasibility of using the SMS system.

Short Message Service Scheme

Participants received a fortnightly SMS message asking whether they had dated a girl in the past week. The keywords for responses were predefined, and the participants could reply via SMS. On receiving a reply, the SMS program scanned the replied message and matched it with the predefined keywords. When keywords were recognized, the program automatically sent a reply to the participant based on specified conditions and rules programmed to automatically receive another SMS. For example, if a participant replied “YES” to the question on having dated a girl, he automatically received a follow-up question on wanting to have sex with the specific girl. If he answered “NO” to the first question, he received the message, “Thank you, have a good day.” The keyword was “YES” if participant dated a girl, following which he received follow-up questions on whether he had sexual contact; whether he used contraceptives; and his reasons for not having sex, not using contraceptives, or not feeling comfortable with using contraceptives. The SMS flow is presented in Figure 1. Data from replies to the SMS texts were used to generate data about real-time sexual behavior and contraceptive needs in the past 2 weeks.

Figure 1. Scheme of short message service sent to participants. IUD: intrauterine device.



Data Collection and Tools

In-Depth Interviews

After enrolment, we conducted in-depth interviews to determine contraceptive use and needs of our participants. We used a topic list on sexual behavior and contraceptive use in the past 2 weeks, number and type of partners, reasons for (non)use of contraceptives, contraceptive decision-making, use of contraceptive services, and gender dynamics. More details about these in-depth interviews will be described in the future (manuscript in preparation).

Technical Feasibility of Using Short Message Service

We used Telerivet software (San Francisco, California, United States) for sending SMS texts. This software generates automatic SMS texts and triggers a flow of such messages based on replies from respondents. The system generates a database containing all data and contents of the sent SMS texts, delivery reports of the texts, and replies from respondents. The Telerivet software has a standard platform that integrates with most existing mobile phone technologies and allows routing of messages to and from any number of mobile devices. It also uses a basic internet connection. With a cloud-based management system, it supports the developer to adapt an external application platform interface using other platforms for monitoring and tracking activities. The system is only accessible through authorization. Data from the system were used to calculate the technical feasibility of using SMS.

Follow-Up In-Depth Interviews

In order to determine the reason for nonuse of contraception for the past 2 weeks, we invited the participants to a follow-up in-depth interview, wherein we focused on the need of contraceptives for the specific sexual encounter and discomfort with the used contraceptive method, as reported by SMS texts. We first asked the participant to elaborate about the specific sexual encounter using a topic list on sexual behavior, contraceptive use in the past 2 weeks, number and type of partners, reasons for (non)use of contraceptives, contraceptive decision-making, use of contraceptive services, and gender dynamics. We also discussed other issues that arose in the enrolment in-depth interview and seemed to be of interest for our study.

Participants' Perceived Feasibility

At the end of the study, we conducted exit interviews with our study participants in Moshi to inquire about their views on feasibility, acceptability, and accuracy of SMS as a data collection method. We used a semistructured questionnaire on the perceived experiences of receiving SMS, content of the SMS, difficulties in receiving the SMS, appropriateness of receiving SMS, and general views on the use of SMS to collect data on contraceptive use. We conducted exit interviews with the participants via phone calls. In Tanzania, we measured the feasibility by using a simple questionnaire on the basis of the responses obtained from those who were receiving the SMS texts on time, had experience of receiving SMS texts, were comfortable with receiving SMS texts, and thought the content

was friendly. Due to the study limitations, we were unable to conduct such structured interviews in Addis Ababa. However, we asked about half of the participants how they perceived use of the SMS system.

All in-depth interviews were tape-recorded with the approval of study participants and then transcribed and translated from the local language (Swahili/Amharic) to English.

Data Analysis

All data collected were treated confidentially and stored anonymously using code numbers in such a way that the records could not be traced back to the individuals. Code numbers (no names of participants) appeared in the database that was accessed through a secured internet account. The SMS system used was only accessible to authorized users. To avoid the risk of unwanted disclosure of sensitive information collected through SMS, we advised participants to use a password on their phones in order to avoid unwanted access. Moreover, the telecom laws of both countries maintain confidentiality of SMS texts sent through their systems.

Data from the SMS replies were analyzed using SPSS version 21.0 (IBM Corp, Armonk, NY). Descriptive analysis was conducted to explore the number of incoming and outgoing SMSs. Based on these SMS, we were able to evaluate the proportions of sent SMS texts and responses, sexual behavior, and use of contraceptives. As the focus of this study was on qualitative data, the power of the study was not adequate to make any inferential statistics. Qualitative data were analyzed through thematic framework analyses using NVivo version 11.0 (QSR International, Melbourne, Australia). After thoroughly assessing the data, codebooks were developed and refined through discussions with other study team members. Interview transcriptions were coded based on the codebook, and themes were developed in coding memos during and after completion of coding using both inductive and deductive theme extraction. These themes were linked together into larger topics that form the basis of our papers. More details will be published in the near future (manuscript in preparation). Recurrent themes will be described in more detail in our future paper on contraceptive use and knowledge, which is currently under preparation.

Results

Study Population

We enrolled 71 young, unmarried men—35 in Tanzania and 36 in Ethiopia. In Tanzania, we enrolled 12 porters who worked in assisting tourists climb mountain Kilimanjaro, 12 drivers of local buses (commonly known as “dala dala”), and 11 students of universities in Moshi. In Ethiopia, we enrolled 8 construction workers, 13 taxi drivers/assistants, and 15 students from different private and public higher educational institutes in Addis Ababa.

Technological Feasibility of Using Short Message Service in Tanzania

Table 1 shows the SMS traffic for both countries. In Tanzania, a total of 3327 SMS texts were recorded, of which 1426 (43%) were among porters, 1053 (32%) were among public bus drivers, and 848 (26%) were among students. A total of 1908 (57%) of the 3327 SMS texts were sent and delivered: 802 to porters, 601 to bus drivers, and 505 to students. Moreover, we received 1119 (34%) of the 3327 SMS texts, of which 512 were from porters, 325 were from drivers, and 282 were from students. Due to no availability of network, phones being out of network, and other unknown reasons, 193 SMS texts were not delivered, 78 were queued, and 3 were ignored. Over the period of 6 months, we sent 438 SMS texts to ask whether the participant had dated a girl and we received 252 (58%) replies, of which 109 (43%) were from porters, 69 were from drivers (27%), and 74 (29%) were from students. Follow-up questions obtained a better response rate of over 96%. There were no significant differences in response rates to follow-up questions from porters, drivers, and students.

Technological Feasibility of Using Short Message Service in Ethiopia

In Ethiopia, there was traffic of 782 SMSs, of which 525 (57%) were sent to the participants and 248 (32%) were received from the participants. Unfortunately, we have no data on whether our sent messages were received by the participants. A total of 314 SMS texts were sent to ask if the participants had dated a girl and 64 (20%) responses were obtained, of which 52 (81%) were “YES.” There was no specific information on contraceptives from the replies received from SMS texts in Ethiopia. Due to the limited feasibility of the SMS system, we decided to switch to phone data collection, and some of the participants were contacted for follow-up in this regard. There was, however, no recording of the number of phone calls made to these participants. A summary of the SMS questions sent are shown in the Table 1.

Table 1. Summary of the questions sent to participants via the short message service system and the responses received.

Questions sent to participants via SMS[a]	Tanzania	Ethiopia	*P* value
Total SMS traffic, n	3327	782	
Total questions delivered, n (%)	1908 (57.4)	N/A[b]	
Question 1 delivered: Regarding whether the participant dated a girl, n (%)	438 (22.9)	314 (40.1)	
Responses received	252 (57.5)	64 (20.4)	<.001[c]
Replied "YES"	148 (58.7)	52 (81.3)	.001[c]
Question 2 delivered: Regarding whether the participant wanted to have sex, n (%)	167 (8.8)	38 (4.9)	
Responses received	162 (97.0)	38 (100)	.60[d]
Replied "YES"	159 (98.1)	36 (95.0)	.20[d]
Question 3 delivered: Regarding whether the participant had sex with a girl, n (%)	133 (7.0)	24 (7.6)	
Responses received	127 (95.4)	24 (100)	.60[d]
Replied "YES"	126 (99.2)	24 (100)	>.99[d]
Question 4 delivered: Regarding whether the participant used a contraceptive, n (%)	112 (5.9)	17 (2.2)	
Responses received	108 (96.4)	2 (11.8)	<.001[d]
Replied "YES"	105 (97.2)	2 (100)	>.99[d]

[a]SMS: short message service.

[b]N/A: not applicable. There is no data on whether the messages sent were received by the participants.

[c]Chi-square test.

[d]Fisher exact test.

Participants' Perceived Feasibility

In Tanzania, we conducted telephonic exit interviews with 25 participants, as the others were not reachable. From the exit interviews, we found that 19 (76%) participants had a good experience with receiving SMS texts. In addition, 21 (84%) participants said they received the SMS texts on time and 22 (88%) participants had no difficulties with receiving SMS texts. A majority of the participants (n=21, 84%) found that the content of the SMS texts was good. Finally, 21 (84%) participants said it was appropriate to receive SMS texts, and 18 (72%) participants were able to respond to all the SMS texts sent to them (Multimedia Appendix 1).

In Ethiopia, based on the unstructured interviews, we found several reasons for the SMS system to be less feasible. At least five participants saw the messages but ignored them, mostly because they thought there were too many questions asked. One admitted that he responded with "NO" on purpose to the first question to avoid the next set of questions. Two men were lost to follow-up (lost their phone or did not respond to our phone calls after some time). Two taxi assistants told us they usually left their phone with others while working, while some of the construction workers had difficulties with reading Amharic and responding to the questions (although they reported being fluent in Amharic during enrolment). In addition, some participants said that the Amharic versions of the messages could not be displayed, which led to discontinuations. A couple of participants provided a phone number that was not theirs, which they only disclosed later; as such, both did not participate in the SMS system. Further, some participants responded in words instead of numbers, which were not recognized by the system. Other said they felt they received repeated messages or assumed that they were repeated messages and thus ignored them. Finally, receiving messages with errors such as jumbled order of questions or skipping of one question led to nonresponse.

Results From In-Depth Interviews

From the recruitment and follow-up in-depth interviews, we found that our participants mostly used condoms, emergency contraception pills, and the calendar method in Addis Ababa and condoms, withdrawal, and the calendar method in Moshi. Despite existing myths on condoms, it is the most frequently used contraceptive in these regions.

Generally, the use of contraceptives depended on the knowledge, availability, cost, and community perceptions. In both countries, the use of usual hormonal contraceptives was limited, because of concerns regarding their side effects, costs, and limited knowledge on the subject. In Tanzania, we found that many young men claimed the use of hormonal contraceptives to be confined to their partners. However, many reported to have discussions with their partners prior to making a decision on the choice and use of contraception method. In most discussions, men seemed to lead the decision-making process. In Ethiopia, however, young men reported the use of emergency contraception (postpill) to be common. The majority of men reported that their partner used the postpill at least once, and it was among the most well-known methods. Textbox 1 shows a few quotations that underlie these major conclusions. Detailed results will be described in our upcoming paper.

Textbox 1. Example quotes from in-depth interviews.

> *People, especially in the villages don't know in details about contraceptive methods.* [24-year-old college student, Tanzania]
>
> *You know there are many shops in town and one can buy condoms or any other contraceptive even at night but in villages one has to walk to a distance place to search for them (condoms).* [26-year-old porter, Tanzania]
>
> *It is just that I fear HIV/AIDS and other STIs or else I wouldn't use them at all.* [28-year-old porter, Tanzania]
>
> *Condoms are not effective, most of time they burst during the action. I and my friends had such instances.* [25-year-old local town-bus driver, Tanzania]
>
> *Everyone knows about it, there is no one who does not know Postpill (emergency contraceptive pill.* [23-year-old student, Ethiopia]
>
> *The problem with withdraw method is that you pull it out at the moment pleasure high, for me I can't manage.* [23-year-old college student, Tanzania]

Discussion

Our results show that the use of SMS for data collection seems to be feasible among young unmarried men in Moshi, Tanzania. More than half of the SMS texts received responses. However, the feasibility of using SMS in Ethiopia is questionable, as only 20% of the participants replied to the first question via SMS. Furthermore, we found that SMS and phone calls were a good entry point for collecting data on more in-depth information on sexual behaviors and contraceptive use. According to the exit interviews in Tanzania, the system was perceived to be feasible by young unmarried men.

In Tanzania, 42% of the SMS texts delivered to young men did not receive any response. One explanation could be that porters and "dala dala" drivers are often not reachable or unable to reply during work. We found a difference in response rates to the first SMS: "Dala dala" drivers responded less often than porters and students. This could be due to the fact that drivers are on duty at the time of the day when they receive the SMS texts and therefore cannot reply. There was a large difference in the response rates between Tanzania and Ethiopia. Besides the differences in cultures and the level of SMS use, participants cited several reasons for the low feasibility of the SMS system in Ethiopia. In addition, due to the technical issues at start of the study in Ethiopia, SMS texts were not always sent correctly and the participants might have been demotivated to fully participate in the study.

Two reviews have provided an overview of the advantages and disadvantages of remote data collection including SMS [11,12]. However, both studies did not conclude on whether SMS use is a good method, as the number of published studies on the use of SMS is limited. Several original studies have collected data through SMS. In another study from Tanzania that focused on the feasibility of using SMS for collecting data on contraceptive use among youth, four questions were asked on the feasibility, and the response rate ranged from 33% to 63% [13]. In Kenya, studies showed that the response rates to the text message surveys on feasibility ranged from 13.5% to 51.8%, which is lower than our results from Moshi but comparable to the results from Addis Ababa [14,15]. Similarly, in Uganda, a study reported the feasibility of using SMS in the delivery of health-related SMS texts to adolescents [16].

SMS is also used extensively in disease management and health promotion and has been shown to be effective and feasible in several studies. One study in United States showed the effectiveness of using text message for preventive sexual health promotion. Text messages in other studies have shown to be effective in helping people adhere to the clinical care management plan for chronic disease care [17,18]. In New Zealand, text messages were effective in improving adherence in asthma patients [19]. Other studies in Asia and Sub-Saharan Africa found that text message reminders were effective in improving attendance in primary care [20-22].

Our study has a few limitations. First, this is a qualitative study; the sample size was not based on power calculations, but rather on expectation of data saturation. Therefore, it is not possible to generalize the findings to other areas in Ethiopia or Tanzania, but it is likely that similar issues occur in other urban areas of Ethiopia and Tanzania as well as urban areas of other Sub-Saharan African countries.

Second, the groups that we recruited our respondents from were rather specific. Therefore, extrapolation to other groups is not recommended. However, this study generated new and valuable data that can be used for studies using quantitative research methods in larger populations. Third, due to the sensitivity of the topic, it is possible that some young men underreported their sexual activity. Finally, evidence shows that in research on sexual behaviors, use of a mixture of data collection methods results in answers that are more truthful; this is the approach we followed. We believed that by collecting data anonymously through mobile phones followed by repeated in-depth interviews and exit interviews, we would be able to build a sufficient rapport, triangulate data from each participant, and follow-up on the possible inconsistencies.

Strengths and value of the data collection method lie in the combination of data collection methods including in-depth interviews, which will serve in informing context-specific contraceptive interventions as well as the design of larger quantitative studies. Based on our findings, modifications of the systems are needed, such as the number of questions asked, shorter time of data collection, different timing of SMS texts, and a good information and communications technology structure for sending and receiving SMS texts. We recommend larger studies targeting different groups but with a shorter duration of data collection. The type of questions could also be

revisited during consultation with members of the study target groups. The system that we have developed can be further modified during participatory action research, where participants can be involved in the design. Furthermore, the survey system on SMS use could be combined with educational messages on contraceptives. Other studies have also introduced use of mHealth for education and information on contraceptives [23-25]. Although in Tanzania, the mobile network coverage is high with >80%, connection to the internet is still limited. Therefore, we believe SMS, rather than a smartphone app, is an excellent way for data collection and education on contraceptive use.

In conclusion, despite network challenges and individual challenges, the SMS system for data collection was feasible in Moshi, but not in Addis Ababa; however, this system could be feasible in Addis Ababa after modifications. Therefore, in general, we believe SMS is a potential way to collect data on contraceptive use among young, unmarried men. This paper highlights the use of an innovative, client-centered way to engage young men and collect data via mobile phones, which will ultimately improve contraceptive use among young men. More evidence-based research on the use of SMS is warranted to accumulate data on the potential impact on knowledge, sexual behavior, practices, preferences, and service utilization among young men and to determine the optimal communication model for mobile phone use regarding sexual behavior and contraceptive use, which can be integrated into the national health management information system. The system should also be used to inform pharmaceutical industries on the development new contraceptive methods that meet young men's preferences.

Acknowledgments

We thank the participants for the valuable information they shared with us. Furthermore, we thank the interviewers for the extensive work of interviewing, transcribing, and translating the data. We thank the Bill & Melinda Gates Foundation for their financial support to this study through the Grand Challenges Explorations Programme.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Feedback on SMS (Short Message Service) system from Tanzanian participants.

[PDF File (Adobe PDF File), 80KB - formative_v3i2e12657_app1.pdf]

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Abbreviations

mHealth: mobile health
MPS: mobile phone surveys
N/A: not applicable
SMS: short message service

Edited by G Eysenbach; submitted 31.10.18; peer-reviewed by Z El-Khatib, K Shanaube; comments to author 31.03.19; revised version received 09.04.19; accepted 09.04.19; published 26.06.19.

Please cite as:
Pima FM, Oshosen M, Ngowi KM, Habte BM, Maro E, Teffera BE, Kisigo G, Swai IU, Msangi SS, Ermias A, Mmbaga BT, Both R, Sumari-de Boer M
Feasibility of Using Short Message Service and In-Depth Interviews to Collect Data on Contraceptive Use Among Young, Unmarried, Sexually Active Men in Moshi, Tanzania, and Addis Ababa, Ethiopia: Mixed Methods Study With a Longitudinal Follow-Up
JMIR Form Res 2019;3(2):e12657
URL: http://formative.jmir.org/2019/2/e12657/
doi:10.2196/12657
PMID:31244476

Original Paper

A New Tool for Public Health Opinion to Give Insight Into Telemedicine: Twitter Poll Analysis

Josep Vidal-Alaball[1,2*], MD, MPH, PhD; Luis Fernandez-Luque[3*], PhD; Francesc X Marin-Gomez[1,2*], MD; Wasim Ahmed[4*], PhD

[1]Health Promotion in Rural Areas Research Group, Gerència Territorial de la Catalunya Central, Institut Català de la Salut, Sant Fruitós de Bages, Spain

[2]Unitat de Suport a la Recerca de la Catalunya Central, Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, Sant Fruitós de Bages, Spain

[3]Qatar Computing Research Institute, Hamad Bin Khalifa University, Doha, Qatar

[4]Newcastle Business School, Northumbria University, Newcastle upon Tyne, United Kingdom

[*]all authors contributed equally

Corresponding Author:
Josep Vidal-Alaball, MD, MPH, PhD
Health Promotion in Rural Areas Research Group
Gerència Territorial de la Catalunya Central
Institut Català de la Salut
Carrer Pica d'Estats, 36
Sant Fruitós de Bages, 08272
Spain
Phone: 34 936 93 00 40
Fax: 34 936 93 00 40
Email: jvidal.cc.ics@gencat.cat

Abstract

Background: Telemedicine draws on information technologies in order to enable the delivery of clinical health care from a distance. Twitter is a social networking platform that has 316 million monthly active users with 500 million tweets per day; its potential for real-time monitoring of public health has been well documented. There is a lack of empirical research that has critically examined the potential of Twitter polls for providing insight into public health. One of the benefits of utilizing Twitter polls is that it is possible to gain access to a large audience that can provide instant and real-time feedback. Moreover, Twitter polls are completely anonymized.

Objective: The overall aim of this study was to develop and disseminate Twitter polls based on existing surveys to gain real-time feedback on public views and opinions toward telemedicine.

Methods: Two Twitter polls were developed utilizing questions from previously used questionnaires to explore acceptance of telemedicine among Twitter users. The polls were placed on the Twitter timeline of one of the authors, which had more than 9300 followers, and the account followers were asked to answer the poll and retweet it to reach a larger audience.

Results: In a population where telemedicine was expected to enjoy big support, a significant number of Twitter users responding to the poll felt that telemedicine was not as good as traditional care.

Conclusions: Our results show the potential of Twitter polls for gaining insight into public health topics on a range of health issues not just limited to telemedicine. Our study also sheds light on how Twitter polls can be used to validate and test survey questions.

(JMIR Form Res 2019;3(2):e13870) doi:10.2196/13870

KEYWORDS

telemedicine; Twitter messaging; health care surveys

Introduction

Telemedicine

Telemedicine draws on information technologies in order to enable the delivery of clinical health care from a distance [1,2]. Telemedicine has been utilized around the world and a recent World Health Organization survey found that 38% of countries worldwide had some kind of telemedicine system and 30% had agencies that managed telemedicine services [1]. Telemedicine is particularly attractive in rural health areas as well as across long distances where it can be difficult to reach patients [2]; it has also been shown to increase the resolution of primary care teams, reducing referrals to face-to-face dermatology services [3]. There have been positive and unsuccessful implementations of telemedicine around the world [4]. This has likely led members of the public to have varying views and opinions toward the technology. It is important to gain an understanding of perceptions toward telemedicine before implementing an order to ensure it is received positively.

Twitter for Public Health–Related Research

Twitter is a social networking platform that has 316 million monthly active users and its potential for real-time monitoring of public health has been well documented [5]. Anyone over the age of 13 with an Internet connection can register with Twitter. Upon registration, Twitter users can select a user handle, which begins with the "@" symbol (eg, @jmirpub). Once users are registered with the platform, it is possible to send short, 280-character text updates known as *tweets*; 500 million tweets are posted per day [5]. Twitter users can also follow other users and share their tweets, which is known as a *retweet*. One of the differences between Twitter and Facebook is that the majority of Twitter accounts are completely public. Twitter also has the concept of hashtags, expressed by placing the "#" symbol at the start of a word and allowing users to categorize a topic and form discussions around it. For instance, it is possible to search Twitter for the hashtag "#telemedicine," which will display all tweets that have used the hashtag.

Twitter has been used previously as a platform to disseminate guidelines and perform polls by the European Association of Urology [5,6]. Twitter contains discussions related to a vast number of health topics, and a recent study noted that there were discussions on Twitter related to at least 379 different health conditions [7]. The study stated that the top-20 health communities, by number of tweets, included autism, diabetes, dementia, and AIDS. Moreover, a recently published systematic review examining Twitter as a tool for health research found that Twitter has been used for public health surveillance, recruitment, and intervention [8].

However, there is a lack of empirical research that has critically examined the potential of Twitter polls for providing insight into public health. Twitter is a platform with a demographic that is college educated and where users are likely to be aware of new forms of technology. This makes examining opinions toward telemedicine an interesting case.

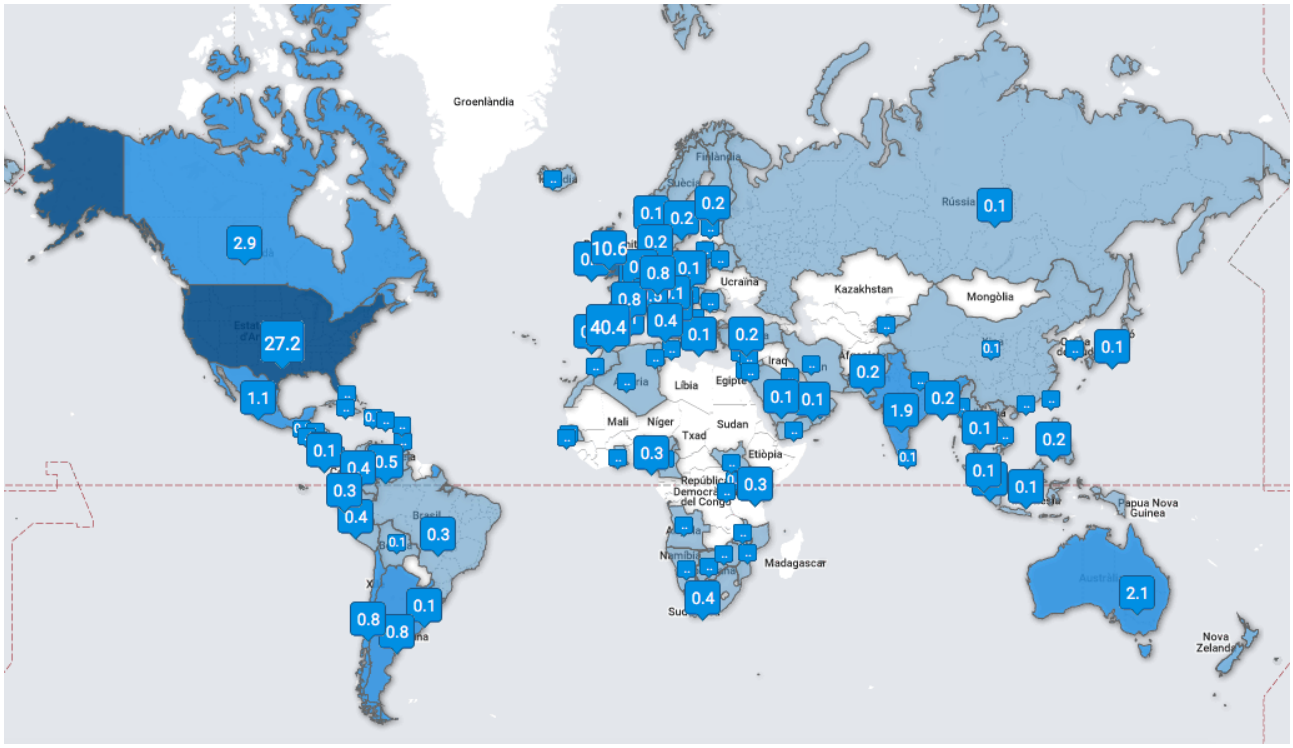
One of the benefits of utilizing Twitter polls is that it is possible to gain access to a large audience that can provide instant and real-time feedback. Moreover, Twitter polls are completely anonymized and it is not possible to learn the identity of a user completing a poll, nor is it possible for one user to vote on more than one occasion. However, it must be noted that Twitter users could hold several accounts that could allow a single user to vote several times. Our results will be of interest to health authorities, policy makers, and academics interested in telehealth. They are also likely to be of interest to health authorities around the world seeking low-cost, real-time survey methods, as well as researchers interested in a critical examination of Twitter polls.

The overall aim of this study was to better understand opinions related to telemedicine on Twitter and to assess the potential of Twitter polls to validate and test survey questions.

Methods

In this study, we devised two Twitter polls using questions from previous questionnaires to explore acceptance of telemedicine among Twitter users. We distributed the polls on the Twitter timeline belonging to one of the authors and asked the followers of the account to answer the poll and retweet it to reach a larger audience. The Twitter handle that we used for this study, @jvalaball, has more than 9300 followers. The followers of the Twitter account that was utilized had a worldwide audience that mainly derived from Spain (40%), the United States (27%), and the United Kingdom (11%). Figure 1 displays the percent distribution of Twitter followers by country; the map was generated using the Web application TweepsMap [9]. Ethical approval was not required because Twitter polls are completely anonymized.

Figure 1. Map showing the percent distribution of Twitter followers by country.



Results

Our first Twitter poll was distributed in May 2016 and was *pinned* to the top of the Twitter timeline used in the project for 7 days. By pinning a tweet, it will permanently be placed at the top of a Twitter user's account, such that any new visitor will see the tweet appear at the top of a user's timeline.

We used a question from the telemedicine satisfaction questionnaire, a validated questionnaire developed by Yip et al in 2002 [10]. The question posted was as follows: "I find telemedicine an acceptable way to receive health care services. Do you agree?" For the responses, only two answers were allowed, which were *Yes* or *No*. Figure 2 displays how the tweet was constructed as well as the responses submitted by Twitter users.

The poll was retweeted 51 times and had 6698 impressions (ie, number of views). It received a total of 108 votes, 89.8% (97/108) of which were positive and 10.2% (11/108) negative.

The second poll was posted during November 2017, and it was also pinned to the top of the timeline for 7 days. For this Twitter poll, we used a question from the physician questionnaire in the European Union project Health Optimum [11]. The question posted was as follows: "How do you rate the quality of care delivered by telemedicine when compared to the quality of traditional care?" Four answers were allowed: *Better*, *About the same*, *Not as good*, and *Not sure*. The poll was retweeted 49 times and had 4364 impressions. Figure 3 provides insight into how the tweet was constructed as well as the responses submitted by Twitter users.

Overall, the poll received a total of 113 votes. A total of 38.9% (44/113) of the respondents stated that they rated the quality of care delivered by telemedicine as *Not as good* as traditional care, 18.6% (21/113) found the quality of care to be *About the same*, 22.1% (25/113) rated the quality of care as *Better*, and 20.4% (23/113) responded that they were *Not sure* about the level of care.

Figure 2. First Twitter poll (screenshot). RT: retweet.

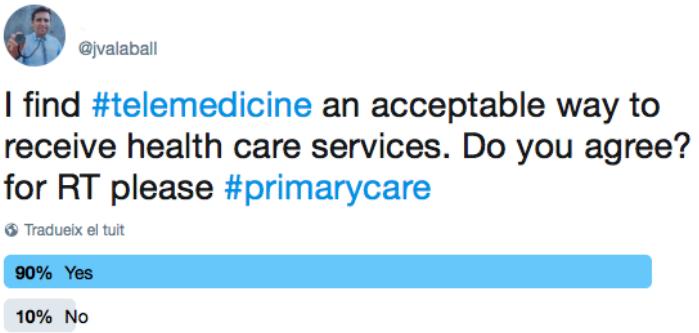
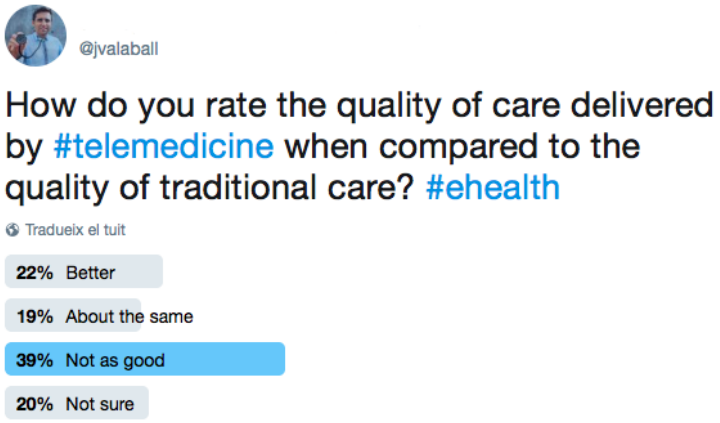


Figure 3. Second Twitter poll (screenshot).



Discussion

Our study provided an overview of a novel experiment where targeted Twitter polls were used to assess acceptance of telemedicine among Twitter users. We argue that this tool could be used to quickly perform surveys to assess the opinion of users regarding acceptance of telemedicine in order to obtain rapid feedback of new questionnaires before validating them. An advantage of using Twitter polls is that many can be created and disseminated in very little time as opposed to traditional questionnaires and surveys, which can become resource heavy. One of the key benefits of utilizing social media platforms such as Twitter is the very low cost when compared to traditional survey-based methods. In certain departments with low budgets, Twitter could be used as a tool to gain initial public opinion feedback before a survey could be devised. The first poll showed an overwhelming support toward telemedicine as an acceptable way to receive health care services. In the second poll, which asked Twitter users to rate the quality of care delivered by telemedicine when compared to the quality of traditional care, the majority of users found that telemedicine was not as good as traditional care. This highlights how the design of a question can potentially influence the results of a survey. Our method could be used to conduct testing on survey questions and to compare the answers to ensure they are consistent. Although the two Twitter polls received a very high number of impressions—6698 and 4364, respectively—the response rates were comparatively low. This could be due to the fact that the questions were not attractive enough to the audience for them to feel compelled to reply. It must be noted that one of the limitations of using Twitter for gauging public opinion through the use of Twitter polls is that its users are not representative of the general population in terms of demographics [12]. A further limitation of Twitter polls is that users with multiple accounts can vote on more than one occasion. Moreover, users with malicious intentions could attempt to manipulate the poll by using multiple accounts to repeatedly vote. However, a growing body of literature is noting the potential of social media data for providing unfiltered public opinion [13-15]. This is because one of the potential strengths of using social media data has been the ability to avoid the risk of interview bias [13]. Furthermore, due to the ability of social media to set agendas in mainstream media [16,17], it can be argued that it has become important to study content and public opinion held by social media users.

Our study has demonstrated the potential of Twitter polls for gaining insight into public health topics such as telemedicine and for shedding light on how Twitter polls can be used to validate and test survey questions. Twitter polls could be utilized by health authorities to gain early real-time feedback on public views and opinions on a range of health issues not just limited to telemedicine. Key strengths are the speed at which Twitter polls can be formulated as well as their low cost.

Acknowledgments

The authors thank their respective institutions.

Conflicts of Interest

None declared.

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Abbreviations

RT: retweet

Edited by G Strudwick; submitted 03.03.19; peer-reviewed by F López Seguí, T Schopf; comments to author 21.03.19; revised version received 28.03.19; accepted 29.03.19; published 28.05.19.

Please cite as:
Vidal-Alaball J, Fernandez-Luque L, Marin-Gomez FX, Ahmed W
A New Tool for Public Health Opinion to Give Insight Into Telemedicine: Twitter Poll Analysis
JMIR Form Res 2019;3(2):e13870
URL: http://formative.jmir.org/2019/2/e13870/
doi:10.2196/13870
PMID:31140442

Original Paper

Implementing Web-Based Interventions in HIV Primary Care Clinics: Pilot Implementation Evaluation of Positive Health Check

Camilla Harshbarger[1], PhD; Olivia Burrus[2], MPH; Brittany A Zulkiewicz[2], BA; Alexa M Ortiz[3], RN, MSN; Carla A Galindo[1], MPH; Bryan R Garner[4], PhD; Robert D Furberg[3], PhD; Megan A Lewis[2], PhD

[1]Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention, Atlanta, GA, United States

[2]Center for Communication Science, RTI International, Durham, NC, United States

[3]Digital Health and Clinical Informatics, RTI International, Durham, NC, United States

[4]Behavioral and Urban Health Program, RTI International, Durham, NC, United States

Corresponding Author:
Camilla Harshbarger, PhD
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd, MSE-37
Atlanta, GA,
United States
Phone: 1 404 639 4267
Fax: 1 404 639 0944
Email: uzz9@cdc.gov

Abstract

Background: Web-based interventions can help people living with HIV achieve better clinical outcomes and behaviors, but integrating them into clinical practice remains challenging. There is a gap in understanding the feasibility of implementing these interventions in HIV clinic settings from the clinicians' perspective.

Objective: The goal of the research was to determine whether Positive Health Check (PHC)—a Web-based, tailored video counseling tool focused on increasing patient adherence and retention in care and reducing HIV risk among HIV-positive patients—was acceptable, appropriate, and feasible for HIV primary care clinic staff to implement in clinic workflows.

Methods: A multiple-case study design was used to evaluate the pilot implementation. Four primary care clinics located in the southeastern United States implemented PHC over a 1-month period. Nine clinic staff across the clinics participated in structured interviews before, during, and after the implementation. In total, 54 interviews were conducted. We used a framework analysis approach to code the data and identify themes related to implementation outcomes, including acceptability, appropriateness, and feasibility. We also analyzed patient intervention use metrics (n=104) to quantify patient intervention completion rates (n=68).

Results: Overall, clinicians viewed PHC as acceptable and appropriate. Themes that emerged related to these implementation outcomes include the ability for PHC to increase provider-patient communication and its ability to engage patients due to the tailored and interactive design. While generally feasible to implement, challenges to the clinic workflow and physical environment were areas that clinics needed to manage to make PHC work in their clinics.

Conclusions: Findings from this pilot implementation suggest that clinical staff viewed PHC as acceptable and appropriate, especially as more patients used the intervention over the pilot period. Feasibility of implementation was challenging in some cases, and lessons learned from this pilot implementation can provide information for larger scale tests of the intervention that include assessment of both implementation outcomes and clinical outcomes.

(JMIR Form Res 2019;3(2):e10688) doi:10.2196/10688

KEYWORDS

internet; patient care; attitudes; vulnerable populations; public health practice

Introduction

Interventions are being developed for clinical settings to retain and support patients in HIV care [1,2]. However, the clinical context presents barriers to implementing new HIV retention and adherence interventions [3-7]. These barriers need to be addressed before widespread adoption of clinic-based interventions can occur [8].

Computer-based HIV adherence interventions appear to be feasible and acceptable from the patient perspective [9], but they have not been studied from the perspective of the clinic stakeholder implementing such interventions. The benefit of understanding implementation is that strategies can be designed to facilitate integration of evidenced-based interventions into care. Positive Health Check (PHC) is a brief, interactive Web-based video counseling tool to reduce HIV transmission and improve health outcomes for people living with HIV (PLH). The video tool was developed based on evidence that computer-based counseling tools can reduce sexual risk behaviors and improve antiretroviral therapy adherence [1,2,10-13] and viral load suppression [12]. PHC is grounded in the information-motivation-behavior model [14], assuming that providing information and building motivation and skills for medication adherence, appointment keeping, and other behaviors will result in PLH correctly practicing behaviors needed to manage HIV and improve health outcomes. We used principles of motivational interviewing [15] to guide the scripting of empathic language. The transtheoretical model [16] informed tailoring scripts, for example, around the extent to which individual HIV patients choose to interact with PHC intervention modules, ask questions of their provider, or select and practice behavioral strategies.

The making of PHC was a dynamic 3-year endeavor involving many stakeholders. The goal was to build a Web-based intervention that would support and be adopted by HIV clinics, be easily updated and scaled up, and improve patient health outcomes. We engaged a user-centered approach and gathered detailed and iterative feedback on the many steps taken to design, develop, and implement PHC from prospective HIV-patient users and HIV providers, including both implementers and gatekeepers. This process is described in Harshbarger et al [17]. To film, manage, program, use feedback, and fine-tune PHC from the database of 700 video clips, the PHC team employed an agile development process [18]. We worked with many contributors, including infectious disease researchers, app developer, videographer, graphic artist, and closed captioning specialist.

The purpose of the pilot implementation evaluation of PHC we describe here was to understand the barriers and facilitators to implementing the intervention in busy clinic settings. Specifically, we were interested in how clinic stakeholders managed the implementation. We examined their perceptions of implementation outcomes including (1) appropriateness (ie, the perceived fit, relevance, or compatibility of PHC to support clinic efforts to improve patient viral load suppression and well-being), (2) acceptability (ie, the perception among implementation stakeholders that PHC is agreeable, palatable, or satisfactory and supports the mission of the HIV clinics), and (3) feasibility (ie, the extent to which clinic staff can successfully administer or use PHC within the busy workflow of HIV clinic settings) [19,20]. Relying on data from the tool itself, we also aimed to determine if staff could provide patients with sufficient time in waiting rooms to complete the tool. This paper aims to address a gap in the literature to better understand staffer implementation of Web-based interventions in their complex clinical settings and workflows [21].

Methods

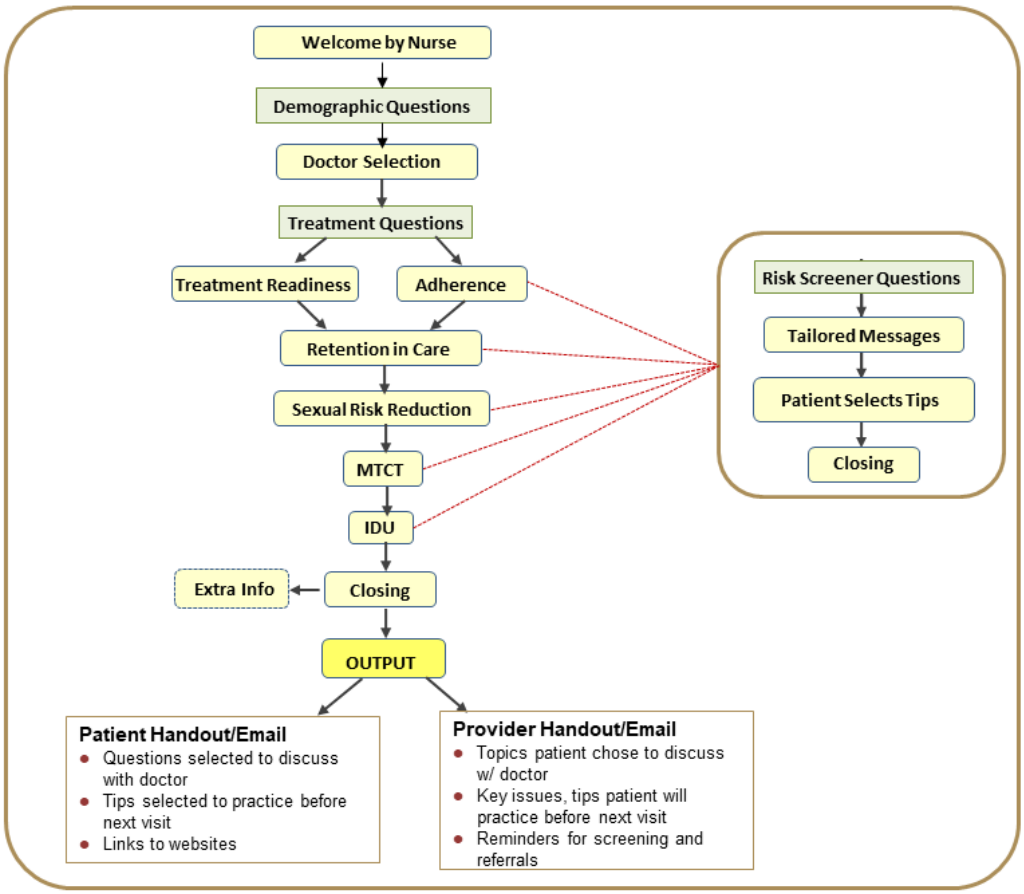
Positive Health Check Intervention and Pilot Implementation Evaluation Procedures

An overview of PHC is shown in Figure 1. PHC is introduced to patients by a designated clinic staffer, referred to as an onboarder, who offers an eligible patient in the waiting room the opportunity to use the Web-based intervention. The onboarder accesses the PHC clinic Web application (CWA) to generate a user ID and password. Based on responses to questions about clinic attendance, medication use, and HIV risk behaviors, each patient watches individually tailored videos addressing HIV treatment readiness, antiretroviral therapy adherence, retention in HIV medical care, sexual risk reduction, prevention of mother-to-child transmission, and safer injection drug use practices. Patients can select questions to ask their clinic doctor during their scheduled appointment, and they are provided behavioral strategies, called tips, to practice. A patient handout featuring this information is automatically printed and delivered to the patient, and a truncated version is delivered to the provider at the request of the patient. At the end of the intervention, patients can also click on “Extra Info” to view supporting resource materials. The onboarder uses the CWA to track process data, including the number of patients who logged on, completed the intervention, or requested that a link to PHC be sent to their private email. PHC does not collect any personal identifying information or patient data, and no email addresses are stored.

Study Design

This implementation evaluation pilot was conducted from May to July 2015, and each of the four participating clinics implemented PHC for 1 month during that period. A multiple case-study design [22] was used to gather process evaluation data from clinic staff to examine and describe the contextual and implementation issues that might help other clinics adopting PHC prepare for implementation [23]. We also analyzed de-identified tool use data to understand patient navigation, use, and completion of the intervention.

Figure 1. Positive Health Check patient experience flow diagram. IDU: injection drug use; MTCT: mother-to-child transmission.



Clinic Eligibility

Four HIV clinics were located in rural, urban, and suburban areas across the southeastern United States. All clinics were required to (1) provide primary HIV care to at least 200 HIV-positive patients annually; (2) use the PHC CWA on a secure, networked Windows desktop, workstation, or server; and (3) have broadband internet access that supports wireless access for iPad and Android devices. The characteristics of the four participating clinics are summarized in Table 1.

Patient Eligibility

HIV-positive English-speaking patients who were at least 18 years old were eligible to use the intervention during the pilot implementation evaluation. Onboarders invited patients to use PHC after they checked in to see their provider. One clinic contacted patients by telephone before appointments and issued invitations.

Preparing Clinics for Implementation

We provided each clinic with three tablets equipped with high-impact protective cases, privacy screens, and headphones for individual patient use. Additionally, we trained clinic staff how to use PHC and the CWA to onboard patients and generate summary reports. Staff also received user guides covering all aspects of intervention implementation.

Data Collection

We collected feedback from clinical staff (N=9), including the intervention onboarder and one primary care provider, at each clinic. At one site, an additional HIV primary care provider participated. We also collected data from the CWA to understand patient use of the intervention (eg, whether the patient completed the intervention; Table 2).

Pairs of interviewers conducted a series of semistructured interviews with each key informant. Each informant participated in 6 interviews: 1 face-to-face preimplementation interview, 4 weekly telephone interviews, and 1 telephone wrap-up interview, for a total of 54 interviews across all 4 clinics. Preimplementation questions focused primarily on perceptions of clinic preparedness and satisfaction with trainings and training materials. During the weekly interviews, we asked participants questions related to the implementation of PHC, including barriers and facilitators; contextual factors; and acceptability, appropriateness, and feasibility of the intervention. For example, we asked, “What types of patients do you think will most benefit from the intervention?” (appropriateness); “As a provider, what do you like the most/least about Positive Health Check?” (acceptability); “Describe to me how the tool is typically incorporated into your workflow, from the beginning to the end of a patient’s appointment” (appropriateness); “What aspects of your clinic environment do you think were an issue for how PHC was implemented? Why?” (feasibility); and “How, if at

all, has implementing Positive Health Check affected the workflow of the doctors at your clinic?" (acceptability/feasibility). Wrap-up interviews touched on these same topics and asked for suggested changes to the intervention and perceptions of sustainability. Development and pilot implementation of the tool was approved as nonresearch by the Office of the Associate Director for Science in the Division of HIV/AIDS Prevention at the US Centers for Disease Control and Prevention (CDC).

Analysis

Interview notes were entered into NVivo 10.0 (QSR International Pty Ltd). Notes were tagged by clinic, key informant type, and implementation phase (preimplementation, implementation weeks 1 through 4, and postimplementation). Notes were checked against audio recordings as needed for clarification and to ensure the accuracy of direct quotes used in reporting. A team of four trained staff coded the interviews using a topical codebook that operationalized concepts from the interviews. Concepts included barriers and facilitators, contextual factors, acceptability, appropriateness, feasibility, and sustainability.

Table 1. Characteristics of HIV primary care clinics in the pilot implementation evaluation (percentages may not add to 100% because of rounding).

Characteristics	Clinic A[a]	Clinic B[a]	Clinic C	Clinic D
Clinic demographics				
Type of service area	Rural	Urban	Suburban	Urban/suburban
Type of clinic	Nonprofit clinic	Ambulatory clinic, multispecialty practice, nurse-managed clinic	Ambulatory clinic, public hospital, academic medical center	Ambulatory clinic, primary care practice, specialty care practice
Patient visits per year	1000	800	4617	7400
Patient visits per day, average	10	15-20	50	8
Patient demographics				
HIV-positive patients, n (%)	257 (100)	140 (100)	1927 (90)[b]	1166 (100)
Sex, n (%)				
Male	(60)	(60)	1360 (70.6)	825 (70.8)
Female	(40)	(40)	557 (28.9)	332 (28.5)
Transgender	(0.1)	Unknown	10 (0.1)	Unknown
Race, n (%)				
White	(13)	(39)	610 (31.7)	301 (25.8)
Black or African American	(87)	(60)	1133 (58.8)	824 (70.7)
American Indian or Alaska Native	(0)	(0)	23 (1.2)	1 (0.1)
Asian	(0)	(1.0)	15 (0.8)	6 (0.5)
Other/unknown	(0)	(0)	145 (7.4)	34 (2.9)
Ethnicity, n (%)				
Hispanic or Latino	(2)	(15)	140 (7.3)	117 (10.0)
Not Hispanic or Latino	(98)	(85)	1787 (92.7)	1049 (90.0)
Age (years), n (%)				
<13	(0)	(4)	0 (0)	0 (0)[c]
13-24	(4)	(96)	81 (4.2)	14 (1.2)[c]
25-44	(31)	(0)	727 (37.7)	280 (24.0)[c]
45-64	(59)	(0)	1028 (53.3)	672 (57.6)[c]
>65	(6)	(0)	91 (4.7)	199 (17.1)[c]

[a]Clinics A and B reported demographics in rounded percentages only (except for number of HIV-positive patients); actual values are not available.

[b]Clinic C was not an HIV exclusive clinic; 90% of their patients were HIV positive.

[c]Age ranges for Clinic D were reported in different ranges than other clinics: <18, 18-21, 22-35, 36-55, and 56-80 years.

Table 2. Use information generated from the clinic Web application for Positive Health Check.

Category	Clinic A		Clinic B		Clinic C		Clinic D	
	n (%)	N	n (%)	N	n (%)	N	n (%)	N
Total approached[a]	17 (100)	—	16 (100)	—	91 (100)	—	21 (100)	—
Declined[b]	1 (6)	17	1 (6)	16	34 (37)	91	5 (24)	21
Onboarded[c]	16 (94)	17	15 (94)	16	57 (63)	91	16 (76)	21
Complete[d]	15 (94)	16	14 (93)	15	29 (51)	57	10 (63)	16
Incomplete[e]	1 (6)	16	1 (7)	15	22 (39)	57	5 (31)	16
Assigned[f]	0 (0)	16	0 (0)	15	6 (11)	57	0 (0)	16
Refused[g]	0 (0)	16	0 (0)	15	0 (0)	57	1 (6)	16
Patient handouts generated[h]	11 (73)	15	8 (57)	14	10 (35)	29	8 (80)	10
Patient handouts delivered[i]	10 (91)	11	5 (63)	8	5 (50)	10	8 (100)	8
Provider handouts generated[j]	7 (47)	15	4 (29)	14	6 (21)	29	3 (30)	10
Provider handouts delivered[k]	5 (71)	7	2 (50)	4	3 (50)	6	0 (0)	3

[a]Onboarder asked the patient whether he or she wanted to use Positive Health Check (PHC).

[b]Patient declined to use PHC. Percentages calculated based on N approached.

[c]Patient agreed to use PHC and was assigned a study ID. Onboarded percentages calculated based on N approached.

[d]Patient completed the entirety of the PHC tool. Percentages calculated based on n onboarded.

[e]Patient did not complete the PHC tool. Handouts were not generated. Percentages for incomplete calculated based on n onboarded.

[f]Patient agreed to participate and was assigned a study ID but did not log in to the PHC tool. Percentages calculated based on n onboarded.

[g]Patient agreed to participate, was assigned a study ID, and logged in to the PHC tool but did not accept at the consent screen. Refused percentages calculated based on n onboarded.

[h]Handouts were generated only for patients who completed the PHC tool and selected tips and/or questions for their providers. Percentages calculated based on n complete.

[i]Patient handouts were delivered directly to the patient. Percentages calculated based on n handouts generated.

[j]Provider handouts were generated and printed only for patients who completed the PHC tool, selected tips and/or questions for their providers, and agreed to share the handout with their provider.

[k]Provider handouts were delivered in person to the patient's provider by the onboarder, to the patient's medical chart, or on the exam room door, depending on the clinic's implementation protocol.

We conducted two rounds of test coding to establish consistency between coders.

We then used the framework analysis method [24] to identify themes within and across sites, generating theme-based charts to organize the data by code, clinic staff position, site, and time point. To complete the framework analysis, team members completed one round of thematic analysis on the same topical code to ensure consistent interpretation of the data. Discrepancies were reconciled, and team members then worked independently to identify themes in each code. A theme was deemed important when multiple interviewees echoed the same idea within the same site, across sites, and over time. Quotes from interview participants illustrating themes are included in Results. We summarize descriptive statistics about tool use generated from the CWA in Table 2.

Results

Patient Consent and Completion Rates

A total of 145 patients were approached to use PHC across the 4 clinics, and 104 (71.7%) patients agreed to participate. Although 68 (65.4%) of those 104 patients completed PHC, 29 (27.9%) did not complete the intervention, with Clinics C and D having particularly high patient incompletion rates of 39% (22/57) and 31% (5/16), respectively.

Acceptability and Appropriateness

Facilitating Provider-Patient Communication

We asked key informants to what extent clinicians perceived that PHC was acceptable and appropriate and what factors shaped these perceptions. Overall, clinicians reported that the intervention was acceptable and expressed support for its use and enthusiasm about its potential to support patients and providers.

> *This tool gave me an opportunity to understand that I probably need to do a better job of communicating with patients. In retrospect, the tool is good for the provider and if they look at what their patient's concerns are and think it may change or may enhance the conversation they have with the patient.* [Provider, Clinic D]

> *Typically patients are so overwhelmed with their diagnosis that the tool could really help them break things down and see the information in a different way.* [Provider, Clinic C]

Clinicians at each of the four sites indicated that providers also would benefit from PHC because it supports interactions during the clinic visit, as facilitated largely by the tailored handouts. For example, several providers said that the handouts empowered patients to ask questions and identify information gaps that needed to be addressed. The handouts also gave providers a starting point for discussions with patients. In one case, the handouts led a patient to reveal an undisclosed sexually transmitted infection. A provider in Clinic A said, "I did use the handouts to see what their concerns were or what they wanted to know more about, and that changed my conversation."

Providers at two clinics expanded their notions of who would benefit from the intervention over the course of the implementation period. One saw the potential benefits expand by adapting the intervention for loved ones and by conducting group sessions. Initially, developers perceived PHC as a way to support the patient when interacting with their provider. Yet over the course of implementation, providers in three clinics increasingly viewed PHC as helping them understand patient concerns. One provider learned she had been inadequately addressing medication adherence with her patients. Before implementation, this provider stated the following:

> *It is a great tool for patients, and also helps providers who don't necessarily take the time to have conversations with patients that they should have. This may be the way for patients to get the information to start the conversation.* [Provider, Clinic A]

After implementation concluded, this provider was asked if her impression had changed.

> *I still think the tool is great for patients to initiate a conversation. I still think this is a good way for patients to open up. Now, I think it's actually an opportunity for providers to be a little more interactive and to dig a little deeper in conversations with the patient.* [Provider, Clinic A]

Engaging Functionality and Interactive Design

At each of the four sites, clinicians and administrators reported PHC was an appropriate and acceptable intervention for helping PLH. In particular, the clinics liked the interactive components, such as patient selection of doctor and presentation of information in audio and video formats; the tailored messages based on patient responses; and information being presented in a clear and concise manner.

> *What I really liked the most about the tool was the fact the patient could select who they wanted to hear... If they wanted to have a female provider, if they wanted to have a provider of color, if they wanted to have a male versus a female...* [Provider, Clinic A]

These are important intervention features because electronic, tailored, and interactive interventions have been shown to be effective as they provide more appropriate information to patients, compared with interventions that are not tailored [25]. However, we also noted concerns about the length of PHC (at two of the clinics); ability to deliver the patient and provider handouts; and ease of navigation, with the exception of password generation.

Challenges to Acceptability

Relatively low computer literacy diminished the extent to which PHC was deemed to be appropriate for the population served by one rural clinic. Because of provider concerns about patient literacy in general and computer literacy specifically, during the first 2 weeks of implementation in this clinic, PHC was offered only to patients who were able to use the intervention without assistance. PHC was then offered to all patients during the last 2 weeks of implementation. At this point, it became clear that patients with lower computer literacy required more assistance, primarily due to the complexity of password generation, which required more of the onboarder's time:

> *This [the tool] was very easy to use, but in rural areas like these many patients have no experience with the computer, at all. Many homes here don't have Internet access...I think for people who don't have any experience with computers, that they may not have really understood how the tool can be used...* [Provider, Clinic A]

Feasibility

We also asked clinicians whether it was feasible to implement PHC as intended and what factors affected feasibility. Their responses revealed two main themes: clinic workflow and physical environment.

Clinic Workflow

Several factors related to clinic workflow presented implementation barriers. Respondents reported the challenge of scheduling patients to complete PHC without compromising tightly managed clinic workflows. Onboarders at Clinics A and B mentioned that PHC added 15 to 20 minutes to the time that patients spent in the clinic before seeing the provider, which caused delays. Additionally, onboarded patients were often interrupted to attend their provider appointments. Clinics C and D reported that clinic workflow processes interrupted patients engaging with the intervention. At Clinic C, patients were often called back to their appointment before the onboarder could deliver the handouts to the patient or provider. The onboarder from Clinic B described the experience fitting PHC into clinic workflow: "Possibly to try to get them [the patients] when they first come in the building as opposed to waiting for them to come into...the waiting room so they can view it [the tool] out there."

Three of the clinics onboarded patients into the intervention before their appointments. Two of these clinics had patients complete the intervention in exam rooms, and the third clinic had patients complete it in the waiting room, with the option of finishing in the exam room. Conversely, the fourth clinic onboarded patients after their appointments, in a room designated specifically for intervention use, which key

informants said was arranged because of possible workflow disruptions if delivered before the visit.

> *Sometimes patients can do the tool before they go back, but that's if they are pretty early, not if they are right on time or late.* [Onboarder, Clinic A]

> *It would be much better if the clinic could have gotten the patient to use the tool before the visit... But the patients would need to come in early for their appointments.* [Onboarder, Clinic C]

Physical Environment

The clinic physical environments also posed barriers that affected implementation feasibility. Two clinics were challenged by finding private space for patients to complete the intervention. At one clinic where patients were completing the tool in exam rooms, there were not enough rooms on particularly busy days.

> *There were some cases during implementation where there was no space to complete the tool. If there was anything that hindered use of the tool, it would be the fact that it was very busy and there was overflow of patients.* [Onboarder, Clinic C]

Another challenge for three clinics was inconvenient locations for picking up handouts from the clinic fax printers. The location of the fax machine at the clinics, coupled with printing delays, led to handouts not being delivered consistently to patients or providers. To address some of these issues during implementation, we substituted the fax machines with wireless printers.

Handout delivery methods and success rates differed across clinics. Three clinics delivered handouts to patients in exam rooms, and this approach worked relatively well for two of the clinics, where they delivered 91% (10/11) and 63% (5/8) of handouts; however, it posed challenges for the third, where they delivered only 50% (5/10) of handouts. In the fourth clinic, the printer was in the same room where patients completed the tool; consequently, they typically would retrieve their own handouts (8/8, 100%) when generated. These findings suggest that patient handout delivery is feasible, but delivery methods call for refinement.

> *They would finish it [PHC] right before the provider came in, and once the provider is in there, I can't give either patient or provider the handouts.* [Onboarder, Clinic A]

Discussion

Principal Findings

This pilot implementation evaluation demonstrated that in four clinics, HIV providers reported that the Web-based video tool PHC is an acceptable and appropriate intervention to supplement the support clinicians currently provide patients. They reported that PHC presents information in new ways that could strengthen patient-provider communication and help patients manage HIV. Clinicians indicated that provider handouts were useful because they increased their ability to address patients' highlighted issues.

Feasibility, or the ability to embed PHC in clinic workflow without disruption, proved to be more complex. PHC onboarders had to gain the support of other clinic staffers, manage scheduling patient tool use and the performance of digital tablets and Wi-Fi printers, assign patients passwords to log into the tool, and deliver PHC-generated handouts to patients and providers prior to scheduled appointments. Two clinics (A and B) facilitated patients' completion of the tool at relatively high rates (approximately 93%), but they reported that implementation increased patient wait time by 15 to 20 minutes and users were sometimes interrupted in order to minimize delays in workflow. Two clinics (C and D) reported more struggles with implementation, as reflected in the lower tool completion rates (51% and 63%, respectively). These clinics reported that PHC users were often interrupted in order to attend their provider appointment. To solve this problem, Clinic C started onboarding patients after their provider appointment, which undermined timely use of the patient and provider handouts.

PHC onboarders experienced difficulty in delivering patient and provider handouts as demonstrated by inconsistent delivery rates across clinics. The delivery of the provider handout was especially problematic due to the short amount of time between PHC completion and the start of the appointment. Onboarders had more success with the delivery of the patient handout due to the physical accessibility of the patient. We addressed two of the unanticipated barriers that slowed implementation efforts. The first was simplifying patients' overly complex passwords requirements. The second was finding the correct technology to print patient handouts; consequently, during the pilot we provided wireless printers instead of fax printers.

Clinic preparation to implement digital interventions requires extensive strategizing, trial and error, and coordination across many clinic staff. We believe that the 1-month time frame was an insufficient period of time for clinics to practice and finely hone these preimplementation strategies. In addition, there was insufficient time to pilot offsite PHC features that can alleviate some of the described barriers to implementation, where patients can finish the tool at home or request that their handout be emailed to them.

Importantly, qualitative interview data show that clinic staffers presented solutions to many of the noted implementation barriers. These suggestions that can inform future PHC implementation include simplifying overly complex password requirements, meeting patients early in hallways by waiting rooms or asking patients to come to clinic early in order to engage with PHC. One suggestion requires more flexibility than was practical for the pilot—administering PHC after provider appointments where the handouts could be delivered at the next clinic appointment or sent to the user's email address.

Aspects of the intervention design that resonated with the clinic staff included the interactive video format presenting information tailored to each user. These are important intervention features: electronic, tailored, and interactive interventions have been shown to be effective because they provide more appropriate information to patients compared with interventions that are not tailored [25].

This study underscores the concrete challenges of implementing digital interventions in complex and dynamic clinic environments, even when clinic stakeholders describe potential advantages and endorse the intervention. Pilot testing is critical to generate feedback from clinical stakeholders and produce implementation outcomes that will inform future implementation strategies in clinics.

Limitations

Several limitations pertain to this implementation pilot. First, we were able to include only the viewpoints of select key clinic staff at each site. Future assessments that rely on clinic staff should include a larger number over a longer period to better understand their viewpoints on implementation. Second, patients were engaged in piloting the intervention; however, we did not obtain user feedback on experience and satisfaction, which would be critical to inform future efforts to implement Web-based interventions. Finally, although the four participating clinics varied in their type of service area and population base, PHC acceptability, appropriateness, and feasibility in other large urban clinics or those with extremely low resources require further study.

Despite these limitations, this pilot shows promise for the implementation of Web-based interventions like PHC. This work contributes to our understanding of clinic environments and strategies that support intervention implementation. Clinical settings are governed by complex workflow procedures and the need to follow regulatory guidelines and professional association best practices [26,27]. To facilitate the implementation of Web-based interventions that improve patient outcomes in clinical settings, clinicians need to address organizational workflow issues [28-32] and determine how these interventions can become a best practice. To close the gap in the HIV continuum of care for vulnerable populations, it is vital to understand and systematically study the implementation of Web-based interventions in clinical settings.

Acknowledgments

This work was supported by the CDC contract 200-2007-20016, task order 0025, to RTI International. PHC was developed and piloted by RTI International in partnership with the CDC under this contract. During the time of this contract, all authors were employees of either RTI or the CDC. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC. We would like to thank the clinical sites that participated in this pilot implementation.

Conflicts of Interest

None declared.

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Abbreviations

CDC: US Centers for Disease Control and Prevention
CWA: clinic Web application
PHC: Positive Health Check
PLH: people living with HIV

Edited by G Eysenbach; submitted 04.04.18; peer-reviewed by C Lelutiu-Weinberger; comments to author 09.10.18; revised version received 25.01.19; accepted 26.01.19; published 18.04.19.

Please cite as:
Harshbarger C, Burrus O, Zulkiewicz BA, Ortiz AM, Galindo CA, Garner BR, Furberg RD, Lewis MA
Implementing Web-Based Interventions in HIV Primary Care Clinics: Pilot Implementation Evaluation of Positive Health Check
JMIR Form Res 2019;3(2):e10688
URL: http://formative.jmir.org/2019/2/e10688/
doi:10.2196/10688
PMID:30998219

Review

Predisposing and Motivational Factors Related to Social Network Sites Use: Systematic Review

Elisa Mancinelli[1*], BSc (Hons); Giulia Bassi[2*], PhD; Silvia Salcuni[3*], PhD

[1]Department of General Psychology, University of Padua, Padua, Italy

[2]Human Inspired Technology, Department of Developmental and Socialization Psychology, University of Padua, Padua, Italy

[3]Department of Developmental and Socialization Psychology, University of Padua, Padua, Italy

[*]all authors contributed equally

Corresponding Author:
Elisa Mancinelli, BSc (Hons)
Department of General Psychology
University of Padua
Via Venezia 8
Padua, 35219
Italy
Phone: 39 3342799698
Email: elisa.mancinelli@studenti.unipd.it

Abstract

Background: Social network sites (SNSs) have been defined as Web services that involve creating a private or semiprivate profile. Through these services, adolescents and adults can maintain and create new relationships. Adolescents, in particular, can be considered the main users of these sites as they spend a lot of time on SNSs. In using SNSs, individuals can exert greater control over the conversation and on the information shared, which is associated with a desire for self-presentation. Moreover, the need for self-presentation is related to personality traits such as those of the Big Five, namely extraversion, neuroticism, openness to experience, agreeableness, and conscientiousness, as well as emotional stability, introversion, narcissism, and motivational aspects. The latter are usually linked to an underlying social purpose that might predispose an individual to using SNSs, with the intent of satisfying particular needs, such as belongingness and interpersonal competency.

Objective: Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) method, this study aimed to present a systematic review of the scientific literature regarding the predisposing factors related to the Big Five personality traits and motivational aspects associated with the use of SNSs, for both adolescents (12-19 years) and adults (>20 years).

Methods: A search ranging from 2007 to 2017 was conducted through the academic database of Google Scholar and PsycINFO, in which the following terms and their derivatives were considered: *predisposing factors*, *personality traits*, *Big Five model*, *self-esteem*, *self-presentation*, *interpersonal competency*, *social network site*, *Facebook*, *motivation*, *five-factor model*, *use*, *abuse*, and *addiction*. Based on a defined list of inclusion and exclusion criteria, a total of 9 papers were finally included in the review.

Results: Our findings identified 3 main personality traits to be of greater value: extraversion, neuroticism, and openness to experience. Extraversion was a good predictor of motivation and SNS use, whereas the latter trait showed relevance for age differences. All 3 features further played a role in gender differences. Apart from extraversion, the self-presentational motive was also related to narcissism, whereas the need to belong presented an association with agreeableness and neuroticism. Further underlining the social value behind SNS use, people perceived interpersonal competency as being related to Facebook use intensity.

Conclusions: Extraversion was recognized as the main forerunner for SNS use and motivation for use. Neuroticism seems to be related to an attempt at compensating for difficulties in real-life social contexts. Openness to experiences has a strong valence for both adults and older adults since SNSs are still perceived as a novelty. Moreover, gender differences in SNS usage were observed to be the product of differences in motivation. Implications and limitations of the study were discussed.

(JMIR Form Res 2019;3(2):e12248) doi:10.2196/12248

KEYWORDS

social networks; individual differences; motivation; adolescents; adults

Introduction

Background

Social network sites (SNSs) have been defined as Web services that allow creating a private or semiprivate profile, a list of contacts, and that gives the possibility to scroll down the list of one's Web friends and to communicate with them [1]. Through these services, adolescents as well as adults can maintain and create new relationships. In particular, adolescents can be considered as the main users of these sites as they spend a lot of time on SNSs. Indeed, it is possible to affirm that such sites (eg, Facebook) have a great impact and role on youngsters' lives and, as affirmed in the study by Brown [2], this population can thus be defined as *the new media generation*. For example, these Web services allow individuals to think longer about their own answers while also pondering more on how to express themselves, therefore, exerting greater control on the conversation and on the information shared, which is all associated with a desire for self-presentation [2]. Moreover, the need for self-presentation is related to personality traits such as those of the Big Five, namely extraversion, neuroticism, openness to experience, agreeableness, and conscientiousness, together with emotional stability, introversion, and narcissism. Personality traits are important also for the motivational aspects, usually related to an underlying social purpose that might predispose an individual to using SNSs with the intent of satisfying their particular needs (eg, self-presentational motives, belongingness needs, and interpersonal competency) [2,3]. Furthermore, in relation to individual predispositions in the frequency of SNS use, an additional role is played by gender and age. Indeed, a relation between gender differences, motivation, personality traits, self-esteem, and specific SNS usage patterns was observed, thus not only considering the broader frequency of SNS use.

Self-Presentation and the Big Five Personality Traits

Self-presentation is a process through which individuals present themselves to the social world, and it is usually motivated by a desire to please others [3]. Self-presentation can be used as a means to manage the impressions of others relatively to oneself while also behaving in different ways, thus creating the desired impressions [3]. For example, an individual can interact with many people *vis-à-vis* throughout the day and create different impressions on each person. In particular, considering personality, neuroticism refers to a state of negative emotionality characterized by feelings of anxiety, depression, vulnerability, and angry hostility, whose counterpart is emotional stability. As a second factor, openness to experience describes a person that is fantasy prone, who values curiosity, and who shows behavioral flexibility. A subsequent dimension is that of conscientiousness, representing an individual that is achievement striving, self-disciplined, and conscientious. Agreeableness is instead associated with altruism, compliance, and tender-mindedness. Finally, the trait extraversion defines an individual that is assertive, highly sociable, and who shows positive emotions and impulsivity, whose opposite dimension is introversion [4]. Nowadays, impressions on people can also be transmitted through the use of SNSs in which individuals can control the conversation and the information shared, thus appearing to be related to a desire for self-presentation. In particular, it could be interesting how this desire for self-presentation might be associated with personality traits, as the above-mentioned dimensions, thus those of the Big Five personality traits, when mediated by the use of SNSs or in the context of SNSs interactions. However, greater empirical support is needed to better understand the link between self-presentation, the Big Five personality traits, and SNS use.

Motivational Aspects: The Need for Self-Presentation, Need to Belong, and Interpersonal Competency

Motivation can be defined as *a reason or reasons for acting or behaving in a particular way*, thus, as something energizing one's behavior toward a specific action, independently from one's character, highlighting its value when trying to comprehend a certain demeanor [5]. Through motivation, it is possible to observe that individuals, all with specific characteristics, present certain needs, which are then satisfied by employing them as motivators [5]. Furthermore, this factor is of even greater value as it might be more easily assessed than the broad category of personality traits as described by the Big Five with consequences on treatment and clinical interventions. Specifically, motivation will be investigated in relation to the Big Five personality traits and narcissism, particularly considering interpersonal competency motivation, which focuses on individuals' ability to interact on the Web and in real-life with others, the need of belongingness, and the self-presentational motive. In particular, the *need for self-presentation* specifies a behavior aimed at continuously monitoring the impression we would like to give on to people, whereas the *need to belong* refers to an individual necessity to affiliate with others and to seek social contacts [3]. However, greater empirical support is needed to better understand the 3 motivational components considered.

The Role of Gender and Age in Social Network Sites Use

The relation between motivation, personality traits associated with the interpersonal competency, the need to belong, the need for self-presentation, and to age-gender differences in real life, is widely provided [6-8]. For example, it has been shown that generally females, in respect to males, confer greater priority in creating a positive self-impression, whereas males are less worried about the image they present in face-to-face interactions [6]. Indeed, during such real-life encounters, women have been recognized to show, on average, a more agreeable and nurturing demeanor than men do [7]. A similar dynamic can also be observed in self-presentational behavioral differences among people of different age groups when communicating with others *vis-à-vis*. In line with the above considered gender differences example, adolescents and young adults are reported to be less agreeable and conscientious than older adults, which is probably because of the specific developmental stage the formers are going through [8]. As a matter of fact, both traits of conscientiousness and agreeableness tend to increase throughout early and middle adulthood. Still, considering SNS use in this context, its role as defined by past literature is not always clear. Furthermore, in such instance, as for age and gender differences are concerned, self-esteem could be otherwise speculated of

being of greater value in SNS use. Indeed, self-esteem showed a relationship with life satisfaction, academic success, social relationships, and mental and physical health; thus, self-esteem could also be an important motivator for SNS use [9]. Therefore, the variables considered in the analysis of data are the cause of the great variation in the results obtained, leading to the inconsistent results observed.

The aim of this study was to conduct a systematic review of the scientific literature concerning the predisposing factors related to the Big Five personality traits and motivational aspects associated with SNS use in general, and therefore, trying to define a comprehensive outline of the past literature on the matter. The intent is to understand on SNSs *who* and subsequently *how* behaves in a certain manner, instead of another, particularly as these sites have become increasingly salient in people's life experiences already from a young age.

Methods

Search Process

Following the PRISMA Group workflow [10], a systematic literature review from 2007 to 2017 has been conducted through the academic database of Google Scholar and PsycINFO, in which the following terms and their derivatives were considered: *predisposing factors, personality traits, Big Five model, self-esteem, self-presentation, interpersonal competency, social network site, Facebook, motivation, five-factor model, use, abuse,* and *addiction.*

Inclusion Criteria

The articles selected for the subsequent analysis were in line with the following inclusion criteria: (1) specificity to SNS use (with a focus on Facebook); (2) predisposing features related to the Big Five personality traits as reported by the five-factor model (FFM) or Big Five and narcissism; (3) motivational aspects connected to the need for self-presentation, need to belong, and interpersonal competency; (4) the role of self-esteem; and (5) the role of gender and age (adolescents, 12-19 years; adults, >20 years) in self-esteem for SNS use.

Exclusion Criteria

Studies that met any of the following criteria were excluded: (1) internet use in general and blogging; (2) the consequences of SNSs and internet use; (3) the relation between attachment style and SNS use; and 4) the association between psychological disorders and the type of SNS use. Independently, 2 rates judged the papers on inclusion-exclusion criteria (PRISMA workflow; [10]).

Results

Study Characteristics

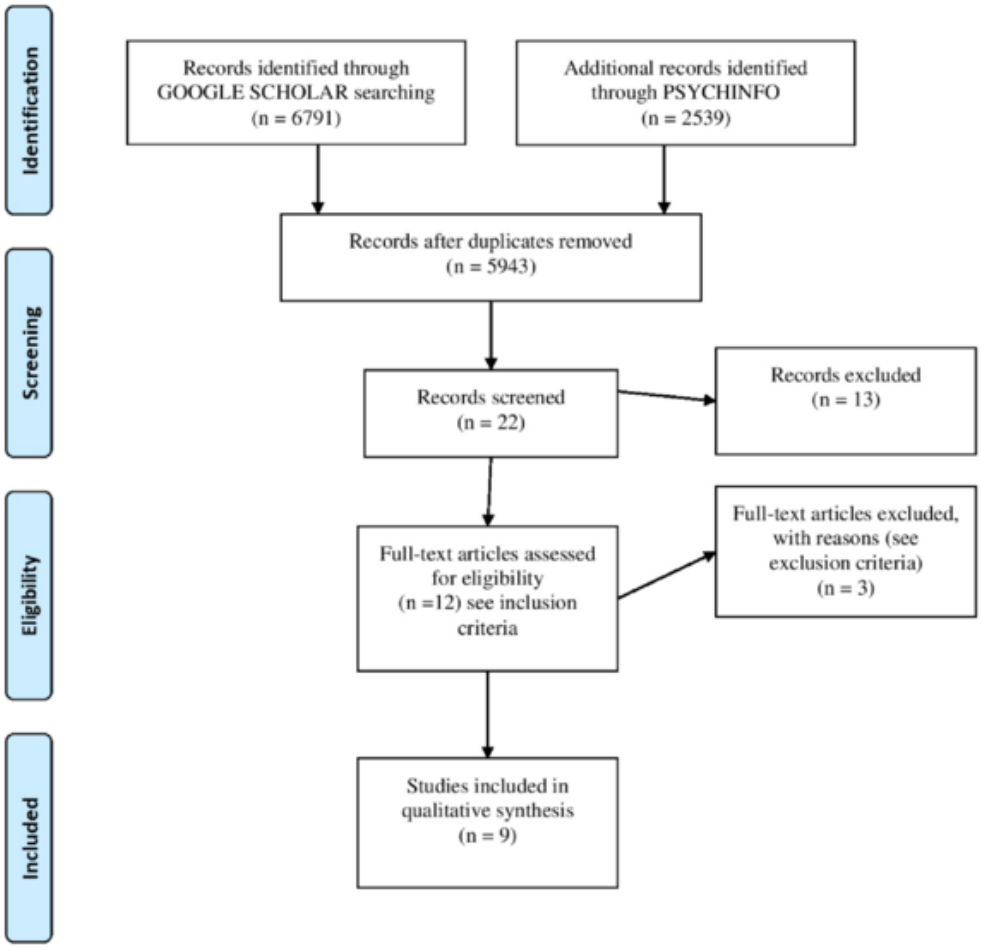
As shown in Figure 1, final results highlighted 9 studies (2 reviews and 7 types of research) regarding adolescents (12-19 years) and adults (>20 years). Gender and age differences have been considered as fundamental in SNS use particularly, considering the predisposing features related to the Big Five personality traits and analyzing the need for self-presentation, the need to belong, and interpersonal competency. Moreover, Multimedia Appendix 1 summarizes the main characteristics of the included studies. A total of 2230 participants were included in five studies [11-15], of which were conducted on young adults. As for the review [1], it took into account 42 articles concerning young adults. Two papers [16,17] considered both young adults and adolescents, one study [16] was carried out on 463 subjects whereas the other [17] reviewed 42 articles. The remaining one [18] was conducted on 275 adolescents. Four of the studies [12,13,16,18] focused on the Big-Five personality traits; 3 [11,14,17] on the relation between Big-Five and motivational factors for Social Networks use; and 1 study [1] targeted the relation between Big-Five, motivational factors and self-esteem. The remaining one [15] only considered self-esteem and motivation. All studies used and referred to self-reports to measure the outcomes.

Social Network Sites Use and the Big Five Personality Traits

As already stated, of greater relevance is the personality trait extraversion, as it has been widely recognized as the dimension better accounting for SNS use; still, results are contradictory. Indeed, no association was reported between extraversion and the amount of *time spent on Facebook* [11], whereas later research [16] observed that such trait was associated with the intensity of Facebook use over and above all other Big Five personality factors and gender. Thus, supporting the previous study in which extraversion was found to be the strongest predictor of SNS use in general [12].

One research [11] highlighted that extraversion was related to greater group membership but not significantly related to the *number of friends on Facebook*. This was explained by suggesting that extraverts use SNSs as an addition to their social life and not as an alternative to it. Different results were although reported, where extraversion was observed, together with gender, to significantly predict the number of friends on SNSs, where females presented more friends than the male counterpart [13]. Moreover, results assessed that once age, gender, and school grade were controlled for, the analyzed personality trait accounted for the number of friends over and above narcissism [18]. However, only extraversion accounted for the influence on the *frequency of SNS use*, whereas neuroticism seems not to be particularly predictive [16].

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses chart summarizing the selection process.



Contradictorily, in previous findings [12] considering emotional stability (low neuroticism), it was reported that those on this side of the continuum used SNSs less frequently, implying that the more anxious and worrisome individuals (thus, high on neuroticism) are those more drawn to the use of SNSs. A study [11] considering the amount of *personal information shared* on SNSs observed neuroticism to be unrelated to the posting of such information as explained by findings in which neurotic individuals were reported to be more controlling of the information shared [14]. Results further showed that those high on neuroticism preferred posting on their personal wall as compared with sharing photos, probably because of the possibility of better manipulating the content shared. Contrarily, another study [11] hypothesized and confirmed for neuroticism to be positively related to different self-aspects (*actual-self*, *hidden-self*, and *ideal-self*), together with *general* and *emotional self-disclosure*, with the latter being mediated by all the self-aspect and thus supporting past literature stating the value of self-presentation in the sharing of personal information and emotions [13].

As for what conscientiousness is concerned, these individuals being highly duty focused, most research considering its relation with SNSs proposed a negative association, assuming that SNSs would be perceived as a distraction. However, differently from past literature, the negative relation was not supported, and instead, no relation was reported [10,12]. Therefore, extraversion appears to be the strongest predictor of SNS use and motivation for use in general, over and above all other Big Five personality traits, followed by neuroticism, and then by openness to experience, for which age differences are glaring. Regarding the other personality traits, further research could be prompt so to better understand the role of agreeableness and conscientiousness in relation to SNS use. Particularly, these last 2 seem to have been only partially considered or not considered at all, which might be because of the marginal association reported with SNSs by past literature.

The Need to Belong and Social Network Sites Use

A study related to the dual-factor model, with a sample of American young adults (mean age=19.51 years), showed that for the *need to belong* its best predictors are high agreeableness and high neuroticism, for antipodal reasons [1]. In particular, the latter expresses a difficulty in social contacts and relations, leading neurotic individuals to try and fulfil their cohesion needs in Web platforms, whereas the former defines a person that is friendly and compliant and that, as such, shows great belonging motives, explaining why this trait is a strong predictor of belongingness on SNSs, being particularly associated with belonging to groups. Supporting this, it has been observed that individuals high in group identification and positive collective self-esteem felt as the most important motivator for SNS use the maintenance of contacts with their close group of friends [15]. Such a difference between findings can be explained by the way in which the need to belong is defined and assessed. In

line with belongingness needs, the value of neuroticism in this instance lies in neurotic people attempt of compensating for their inability to optimally self-present themselves in a face-to-face encounter, thus, allowing them to show also their hidden and ideal self-aspects. Low conscientiousness is instead straightforwardly explained by the fact that those high on this dimension exert greater cautiousness when presenting themselves, especially on the Web, preferring an authentic self-presentation.

Self-Presentational Motives and Social Network Sites Use

Considering the dutifulness encompassing the trait conscientiousness, the effort of better presenting themselves on the Web could be expected to be perceived as un unnecessary waste of time, reason for which individuals lacking on such trait tend to self-present themselves more. Indeed, it was observed that high neuroticism was predictive of *self-presentational needs*, together with low conscientiousness [14]. One study regarding self-presentational needs showed narcissism to be of greater relevance but only for self-generated content (ie, rating of one's profile pictures and frequency per week of status updates) compared with system-generated content (ie, the number of Facebook friends and photos) [18]. Past research [17,18] reported that narcissists have a larger Web social network, which in the study was instead accounted, together with photo count, by extraversion; thus, it allows to assume that people high on narcissism may have not yet started using such features as self-presentational means. This contradiction between findings can be explained by the age of the sample [18]. Adolescence is a period in which social life is yet to be fully developed, as opposed to university students for which social life is usually at its highest [18]. Such observation considers age as a limitation, although fostering the idea of comparing samples of different ages, with the aim of observing how narcissism translates on SNSs in different periods of life.

Interpersonal Competency and Social Network Sites Use

A further motivational element that needs to be reported is that of *interpersonal competency.* From past literature, a study by Jenkins et al [16] identified 2 domains relevant in Web social behavior used to define *interpersonal competency* (together with disclosure, negative assertion, and conflict management, which were not considered as variables): *initiating relationships* and *emotional support*. This same study [16], concerned with the relevance of personality and self-esteem in one's felt interpersonal competency and its subsequent impact on the frequency of Facebook use, underlines the importance of the previously mentioned research [18], as "the new media-generation" [2,16] has transported on the Web the developmental stages related to social behavior and cohesion once held in real-life [16,19]. In this regard, results showed that the intensity of Facebook use was related to perceived interpersonal competency. Specifically, individuals used this element as a motivator to compensate for their felt lack in relation to the initiation of relationships, although not accounting for emotional support. Interestingly, the 2 domains of interpersonal competency were not related to neuroticism, which could be intuitively associated with being shy and interpersonally incapable, together with the fact that neurotic individuals, as also previously discussed in relation to belongingness, were observed to use Web platforms to compensate for their lack of real-life contacts [14].

Age Differences in Social Network Sites Use

In a 2010 experiment, extraversion, emotional stability, and openness to experiences were adopted as personality variables, further accounting for life satisfaction in age differences [13]. The young cohort (from 18-29 years) frequency of SNS use was only predicted by extraversion, whereas the other 2 traits were found to be not significantly related with it, with life satisfaction never playing a significant role especially after accounting for personality.

As for the older ones (older than 30 years), all 3 personality dimensions showed a predictive value. In particular, extraversion and openness to experience reported a positive relation with SNS use, whereas emotional stability a negative one, implying that those showing negative emotionality, in general, tend to rely on SNSs more. Indeed, life satisfaction remained a strong negative predictor even after accounting for personality. As previously discussed, of particular relevance is openness to experience, as the role of this dimension is limited to the older cohort. As with emotional stability [12], other differences with the young media generation could be expected, further speculating on the novelty valence that SNSs might have for older adults as they need to learn to live with such tools, while being the normal mean of interaction for the youngsters.

Gender Differences in Social Network Sites Use

Concerning gender differences, females were reported to have more friends on SNSs as compared with males. In addition, a study observed that for females, extraversion and openness to experience showed a positive relation and no association with emotional stability, with life satisfaction never of relevance [12]. As for males, the latter personality trait presented a negative relation with SNSs frequency of use, whereas extraversion a positive one, and openness to experience showed no significant relation. Further supporting the relation between gender and SNS use, 1 study reported, even thought of no particular significance, women to be more likely to post photos and update their status [4]. Life satisfaction did not play any predictive role, only after accounting for personality variables. These differences in SNS usage are because of the different motivations expressed by females and males. Still, considering belongingness need, women reported using SNSs to satisfy closeness and relational needs by showing a greater amount of connections with friends [15]. Particularly, females both with negative and positive collective self-esteem used SNSs to communicate, entertainment, and passing time [15]. Differently, males with negative or positive collective self-esteem used SNSs as an attempt at social compensation, using them to learn about others, for social identity gratification, and to seek social companionship [15].

Discussion

Principal Findings

SNSs are increasingly becoming of great relevance in people's social life as in today's society these kinds of platforms have crept into many daily activities, with almost everybody using it, still not in the same manner and for different reasons, for which of value has been the consideration of the FFM personality traits and motivation. This systematic review aimed to develop a cohesive outline of the past literature in relation to SNS use through the consideration of the factors influencing it, specifically motivation and personality traits as well as personal variables such as age and gender. Regarding personality traits, extraversion has been recognized as the main forerunner for SNS use and motivation for use by recreating on the Web real-life social dynamics; still, SNSs offer advantages also for the *socially awkward* [2]. Examples of such benefits are the asynchrony in communication, the lack of direct feedback, and the chance of acquiring information about others in an indirect and passive manner and the possibility of " *manipulating* " one's own image [19]. Indeed, another relevant dimension is neuroticism, whose value has been speculated to be related to an attempt of compensating for their difficulty in real-life social contexts. In addition to individual differences, gender and age differences have been investigated. For the latter, openness to experiences has shown the greatest relevance as for adults and older adults SNSs are still perceived as a novelty. Differently, gender differences in SNS usage were observed to be the product of differences in motivation. Specifically, males use SNSs as social compensation tools, further supported by the negative relation with emotional stability, whereas females show as stronger motivator that of satisfying relational needs by seeking closeness [12]. Such findings can be considered also in relation to the dual-factors model of Facebook use in which authors identify 2 basic needs related to SNS use: the *need to belong* and the *need for self-presentation* [1,9]. Their value can be logically explained, as SNSs are indirect means of contact and communication, thus favoring both the sociable and the *socially awkward* individuals [1]. Throughout this review, what has been analyzed is SNS use and not abuse or addiction. Indeed, research on these 2 latter topics is inconsistent. As for *psychopathology* and its relation with SNSs, as for addiction, further explorations are required, also focusing on the age differences possibly mediating the relation between SNS use and/or abuse and psychopathology. For example, the older population might present a greater risk for psychopathological repercussions of excessive SNS use, particularly for those already presenting a diathesis (eg, for anxiety disorders or depression), which could be even more drawn toward these new social tools. Moreover, future investigations should further consider the role of narcissism, whose relevance exceeds that of extraversion in regard to self-presentational motives [18]. It was hypothesized that SNSs are highly egocentric platforms reflecting an individualistic focus, and in this respect, it was underlined that such narcissistic tendencies and SNS use fuel each other in a way that requires further investigation, particularly as narcissism has been associated with poor impulse control and a lack of empathy [18]. Being this latter study conducted in Singapore, a quite westernized city-state, there appears to be the need for supplementary research on the differences between individualistic and collectivistic countries in SNS use, the motivation for use, and in the role and value of narcissism in the 2 societies. In this second decade of the 21st century, together with Facebook, the use of other platforms, such as *Twitter*, *Instagram*, *Snapchat*, and *Tumbler* and so on have become widespread. Still, they have not been considered by past literature, to the exclusion of Facebook, and as a consequence, not mentioned in this review. Indeed, this remains a limitation of many past studies and as such a suggestion for future research can be prompt for the consideration of the varied types of SNSs specifically, as offering a different possibility of use. For this reason, they attract different people, thus resulting in different motivations for use, to associations with different personality traits, and potentially with different psychopathologies.

Conclusions

These results obtained through the systematic review of 9 articles, showed that, among the Big Five personality traits, extraversion appears to be the one better accounting for SNSs and motivation for use, favoring from an already satisfying real-life social network and competences, by transforming real-life relationships into Web ones. Indeed, SNSs are indirect means of contact and communication, encouraging both the sociable and the *socially awkward* individuals, such as to achieve information concerning others in a passive way and the possibility to manipulate of one's own image. Thus, to counteract social passiveness, neuroticism was observed to be of great relevance. Differently, openness to experience was reported to be related to age differences, being of value only for the older cohort. The role of conscientiousness and agreeableness, on the other hand, was not sufficiently investigated. As for gender differences, results showed differences in the motivation for SNS use, with females reporting the need of seeking closeness, whereas males for social compensation purposes. In conclusion, SNS use seems to be associated to different motivations for use and to different personality traits, for which findings are still inconsistent. Therefore, future studies are still needed to further explore our conclusions.

Acknowledgments

The Department of Developmental Psychology and Socialization and the Department of General Psychology supported this research. GB is grateful to the Fondazione Bruno Kessler (Trento, Italy) for a PhD grant.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Articles used in the literature review.

[DOC File, 45KB - formative_v3i2e12248_app1.doc]

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Abbreviations

FFM: five-factor model
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SNS: social network site

Edited by G Eysenbach; submitted 20.09.18; peer-reviewed by K Sedig, G Fontaine; comments to author 27.01.19; revised version received 23.03.19; accepted 13.04.19; published 09.06.19.

Please cite as:
Mancinelli E, Bassi G, Salcuni S
Predisposing and Motivational Factors Related to Social Network Sites Use: Systematic Review
JMIR Form Res 2019;3(2):e12248
URL: http://formative.jmir.org/2019/2/e12248/
doi:10.2196/12248
PMID:31199318

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org