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Original Paper

Cultural Adaptation of a Scalable World Health Organization E-Mental Health Program for Overseas Filipino Workers

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Abstract

Background: Electronic mental (e-mental) health interventions can address mental health needs of different populations. Cultural adaptation of these interventions is crucial to establish a better fit with the cultural group and to achieve better treatment outcomes.

Objective: This study aimed to describe the cultural adaptation of the World Health Organization's e-mental health program Step-by-Step for overseas Filipino workers. We used a framework which posits that cultural adaptation should enhance (1) relevance, wherein the cultural group can relate with the content; (2) acceptability, where the cultural group will not find any element offensive; (3) comprehensibility, where the program is understandable; and (4) completeness, wherein the adapted version covers the same concepts and constructs as the original program. We aimed to have English and Filipino and male and female versions.

Methods: Overall, 3 experienced Filipino psychologists provided their perspectives on the program and how it might be adapted for overseas Filipino workers. We then adapted the program and obtained feedback from 28 overseas Filipino workers from diverse industries through focus group discussions. We conducted 7 and 9 focus group discussions with male and female participants, respectively. Per discussion, cognitive interviewing was used to probe for relevance, acceptability, comprehensibility, and completeness of illustrations and text. Participant feedback guided iterative program adaptations, which were again shown to participants for validation and improvement.

Results: Several issues were raised by participants about the generic version of Step-by-Step. There were elements deemed irrelevant, like unfitting characters, lack of Filipino values, and unsuitable problems and activities. There were unacceptable components that were stigmatizing, political, inappropriate to context or subgroups, and too feminine for male users. Some elements were incomprehensible, unclear, or complicated. To address these issues, we made key adaptations. To enhance relevance, we adapted the narrative to match the experiences of overseas Filipino workers, incorporated Filipino values, and illustrated familiar problems and activities. To increase acceptability, our main characters were changed to wise elders rather than health professionals (reducing mental health and help-seeking stigma), political or unacceptable content was removed, and the program was made suitable for overseas Filipino workers from different sectors. To increase comprehension, we used English and Filipino languages, simplified the text to ease interpretation of abstract terms, and ensured that text and illustrations matched. We also used Taglish (ie, merged English and Filipino) when participants deemed pure Filipino translations sounded odd or incomprehensible. Finally, we retained the core elements and concepts included in the original Step-by-Step program to maintain completeness.

Conclusions: This study showed the utility of a 4-point framework that focuses on acceptance, relevance, comprehensibility, and completeness in cultural adaptation. Moreover, we achieved a culturally appropriate adapted version of the Step-by-Step

program for overseas Filipino workers. We discuss lessons learned in the process to guide future cultural adaptation projects of e-mental health interventions.

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KEYWORDS

cultural adaptation; migrant workers; e-mental health; overseas Filipino workers

Introduction

Background

The use of technology to deliver mental health interventions proliferated in recent years, with electronic mental (e-mental) health interventions providing accessibility to needed mental health interventions [1,2] for more people [3] and at greater frequency [4]. The use of e-mental health interventions is especially promising for vulnerable and marginalized populations such as migrants. They help reduce the stigma associated with help-seeking and minimize treatment barriers such as geographical distance and culture, religion, and language differences between users and providers [2,5].

E-mental health interventions that undergo cultural adaptation are more effective. Cultural adaptation is “the systematic modification of an evidence-based treatment (EBT) or intervention protocol to consider language, culture, and context in such a way that is compatible with the client’s cultural patterns, meanings, and values” [6]. Cultural adaptation is warranted when an intervention developed for one cultural group will be implemented within a different cultural group. When an intervention is adapted, a better fit between the program and the cultural group is expected, which in turn leads to better treatment outcomes [7].

Culturally adapted interventions are effective. A meta-analysis [8] of 78 studies revealed that culturally adapted face-to-face interventions performed better than the comparison conditions (another active intervention or no intervention), with an average effect size of $g=.67$. Furthermore, culturally adapted interventions are more effective than their original unadapted versions, with a medium effect size of $g=.52$. Another meta-analysis [9] of e-mental health interventions found that cultural adaptation resulted in a greater reduction in depression and anxiety symptoms. Essential elements for adaptation according to the Bernal and Saez-Santiago framework [10] include language, persons, metaphors, content, concepts, goals, methods, and context. Every additional element adapted resulted in a 14% increase in intervention efficacy.

It should be noted, however, that cultural adaptation does not equate with completely rewriting the program. In fact, a systematic review [11] on cultural adaptation of interventions for depressive disorders showed that all the studies included in the review preserved the original treatment’s framework and core principles that were deemed acceptable. The adaptations were made to establish cultural relevance, improve treatment acceptability, and remove barriers to care (eg, lack of trained professionals and limited literacy). Inclusion of barriers to care could be considered as implementation rather than a cultural

aspect and suggests that in some studies what counts as a cultural adaptation may be poorly defined.

Cultural adaptation involves an integration of top-down and bottom-up approaches [12]. The original program (top-down) is modified based on feedback from the intervention target population (bottom-up), that is, the original program is adapted based on input from the cultural group to be responsive to the cultural group’s context and specific mental health concerns [8].

The World Health Organization is developing several evidence-based interventions—including transdiagnostic programs—designed to be scaled up to reach populations globally that lack access to needed mental health services [13]. We adapted one of these, the Step-by-Step program, an e-mental health program based on the principles of behavioral activation treatment for depression, along with additional strategies such as psychoeducation, stress management, and help-seeking [14]. Following the internet- and mobile-based intervention categorization [1], Step-by-Step is considered a minimally guided self-help program, wherein a nonspecialist *eHelper* may provide technical support and assistance in accomplishing program activities through phone calls or text messaging for up to 20 min a week.

In places with more established services, Step-by-Step may be suitable for use within a stepped-care structure, where users who show mild-to-moderate levels of symptoms could be referred to higher-intensity services should they require it on completion of the program. The program contains text and stories with corresponding illustrations and 2 main characters. The first character is an expert who helps the second character by sharing behavioral techniques to overcome problems and by explaining the concepts behind the problems and the techniques offered in the program. The second character narrates their experience of using the Step-by-Step techniques to overcome depression, reporting their previous encounters with typical problems and psychological symptoms of the target population and explaining how they employed the program to reduce these problems.

The original version already has 3 of the 4 desired features of effective e-mental health interventions, as it is based on the empirically tested theory of behavioral activation, it is structured, and it is interactive or experiential [15]. The last desired feature of being targeted for a specific group [15] must be addressed through cultural adaptation. To ensure high-quality adaptation of Step-by-Step, we followed the approach used by Manson [16] and van Ommeren et al [17]. Manson [16] theorized that the end product needs to be (1) acceptable, with nothing in the program offensive or potentially offensive to the cultural group; (2) relevant, in that the program’s content is

related to the cultural group and does not contain unrelated phenomena; (3) comprehensive or understandable by the cultural group; and (4) complete, in that the program covers the same semantics, concepts, and theoretical constructs as the original version.

In this study, Step-by-Step was adapted for overseas Filipino workers (OFWs). There are 2.24 million OFWs around the world [18]. The majority (85%) work in Asian countries such as Saudi Arabia, United Arab Emirates, Qatar, Singapore, and China (ie, Macao and Hong Kong Special Administrative Regions, SARs). There are roughly the same number of male and female OFWs, but occupational differences exist between the groups. Male OFWs are mostly plant and machine operators and assemblers (24.7%) and craft and related trade workers (23.1%), whereas female OFWs are mostly employed as household service workers and cleaners and in other low-skilled occupations (56.2%). In Macao SAR of the People's Republic of China, OFWs are the second largest migrant group at 29,426 [19]; roughly half of them are household service workers, more commonly referred to as domestic workers, followed by hotel and restaurant workers.

Previous studies focused on the risks and challenges that OFWs and other labor migrants experience. OFWs' primary reason for working abroad is the desire to escape poverty or to achieve socioeconomic mobility, mainly for their family, rather than individual aspirations [20,21]. However, while abroad, and similar to other labor migrants, OFWs are at higher risk of experiencing mental health-related issues such as loneliness, stress, anxiety, depression, and serious mental illness [21,22]. However, resolving these challenges is problematic as labor migrants tend to have poor access to mental health services [23-25] and poor support systems [26]. E-mental health interventions are a way to address their mental health needs as more than 90% are smartphone users, and there is high potential uptake as 68% are likely to use a Web-based program when one is available [27].

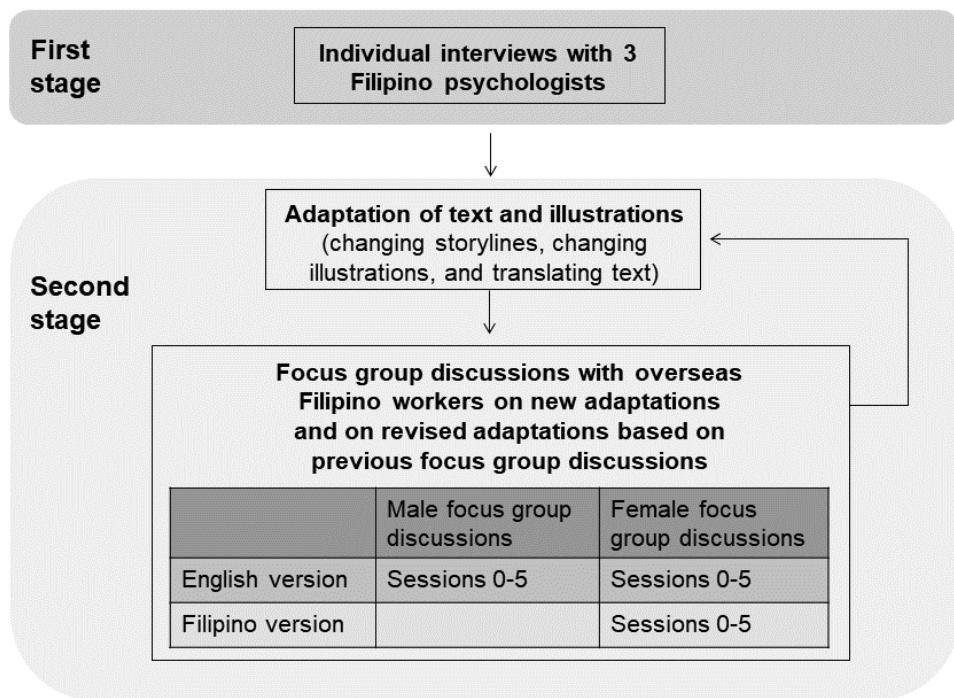
Objectives

This study aimed to culturally adapt the WHO Step-by-Step program for overseas Filipino labor migrants. We made English and Filipino and male and female versions. It was intended for use by OFWs engaged in different occupations.

Methods

Participants

There were 31 participants, all of whom were selected through purposive sampling. We used a 2-stage approach (refer to Figure 1), first interviewing 3 Filipino psychologists with considerable experience and expertise in psychological practice and in working with OFWs, using Zoom video conferencing (each approximately 120 min long). The second stage consisted of focus group discussions (FGDs) with 28 OFWs in Macao. Of the FGD participants, 16 were women, aged 24 to 52 years (mean 36.31, SD 9.44), and employed as domestic workers, caregivers, and food and beverage workers. In addition, 9 of them were married, 6 were single, and 1 was widowed. The length of time working in Macao ranged widely, from 1 month to 12 years (mean 4.28 years, SD 3.46). Furthermore, 12 participants were men, aged 23 to 47 years (mean 30.58, SD 7.66), and employed in hotel and casino, food and beverage, and facilities management industries. Half of them were single and half were married. They had been working in Macao for an average of 1.63 years (SD 1.12), with a range of 6 months to 4 years. FGDs were conducted separately for male and female participants, with each FGD covering 1 to 3 sessions of the program. Due to scheduling difficulties, participants were not able to join all FGDs to discuss all the sessions of the program. Each participant joined at least 1 FGD and at most 6 FGDs. There were 7 male and 9 female FGDs in all, with 2 to 11 participants per FGD. The FGDs lasted between 2 and 3.5 hours and were conducted in private rooms in a local nongovernmental organization (NGO) or in a university. The FGDs were held on Saturday nights and Sundays, either after participants' work or during their day off. The participants were remunerated MOP \$100 or roughly US \$12 per FGD.

Figure 1. Flow of the adaptation process.

Materials

The intervention material was a generic version of the Step-by-Step program. The program starts with registration and introduction (session 0), followed by sessions 1 to 5. Each session is meant to be completed on the Web by the user once per week, with each session lasting between 30 and 40 min.

In advance of the interviews with expert Filipino psychologists, we provided a summary of the program's content, the complete intervention content, and examples of possible illustrations with instructions to review all materials before the interview. For the FGDs with OFWs, we made Microsoft PowerPoint presentations that showed the entire initial adapted texts and illustrations (after Filipino psychologist interviews). Each slide consisted of about 3 to 5 sentences, most with simple illustrations. We started only with the intervention text for sessions 0 to 2, as the illustrations were not yet ready. Eventually, we showed both texts and illustrations to the participants side by side for the remaining 3 sessions.

We also utilized interview and FGD guides. The interview guide for the psychologist interviews consisted of questions about their opinions on whether or not the Step-by-Step program can address OFWs' mental health needs, the type of OFWs that the program will be most or least suitable for (ie, hotel staff and domestic workers), appropriateness of the content of the program, considerations we had to make with regard to Filipino culture and OFW culture, and challenges they foresaw in using the program. We added questions on which specific groups we needed to consider for content tailoring (eg, younger or older OFWs), suggestions on the characters in the story, and opinions with regard to the characteristics of the eHelpers.

For the FGDs with OFWs, we started *cognitive interviews* (a technique whereby participants *think aloud* [28]) with a broad

question on what participants thought about each of the PowerPoint slides. We then probed, using open-ended questions, if the content is relevant or relatable, understandable, or acceptable and the ways by which we can improve the text or illustrations. We also asked if the text and illustrations on each of the slides match, and if not, how we can change the text or illustrations to ensure they correspond with each other. When asking these questions, we told participants to think about all OFWs globally (eg, Would all or most OFWs understand this text?) and not just themselves or just OFWs in Macao to increase generalizability to OFWs across ages, marital statuses, occupations, and countries where they are employed.

Procedure

FGDs were conducted in English to adapt an English-language version and in Filipino to adapt a Filipino-language version. We matched the sex of the facilitator with the sex of the participants (ie, male facilitator during male FGDs).

We first gave participants consent forms to read and sign, and then, we introduced the interview or group discussion and the Step-by-Step program. We then proceeded with the interviews or FGDs. The first FGDs concerned developing the illustrations of the main characters. After this, once illustrations had been developed, further groups were conducted based on the remainder of the stories and activities. The entire adaptation process was thoroughly documented. We used note-taking, wherein we wrote participants' feedback for each slide. We also used audio recording to review the sessions if any of our notes were unclear. After an interview or FGD, we (MRG and BJH) discussed what transpired and reviewed our notes. We decided on pertinent changes that needed to be made on each slide. Throughout the process, we used the approach of Manson [16] and van Ommeren et al [17] in that we focused on adaptations that would better ensure relevance, acceptability, and

comprehensibility to as many OFWs as possible, while retaining completeness of the Step-by-Step program. When participants' opinions differed in terms of whether to make changes or not (ie, a sentence was understandable to some participants but others suggested to simplify or provide more explanation), we decided to make adaptations to ensure the content was appropriate to the broadest possible audience, and these modifications were then brought back to the community for any further comment and approval. When there were varied suggestions on how to adapt text and illustrations (ie, different suggestions on what words to use or how to change illustrations), we chose what the majority preferred and what was applicable to most OFWs (ie, applicable to the majority of male and female OFWs, young and old).

All changes in text and illustrations were documented using standard forms developed by the World Health Organization. We deemed making changes based on our notes sufficient because participant feedback on the slides was simple and straightforward (ie, participants mentioned which sentences were confusing, and they shared which part of the illustrations did not match the text), and participants provided us with concrete suggestions on what changes to make (ie, they suggested words to use and what to add or omit in the illustrations). Furthermore, each slide contained relatively short text and simple illustrations to begin with. The questions we asked them were also direct (ie, Can most OFWs understand the text? How might we improve the text to make it more understandable? Can you relate to the character? How might we make the character more relatable?).

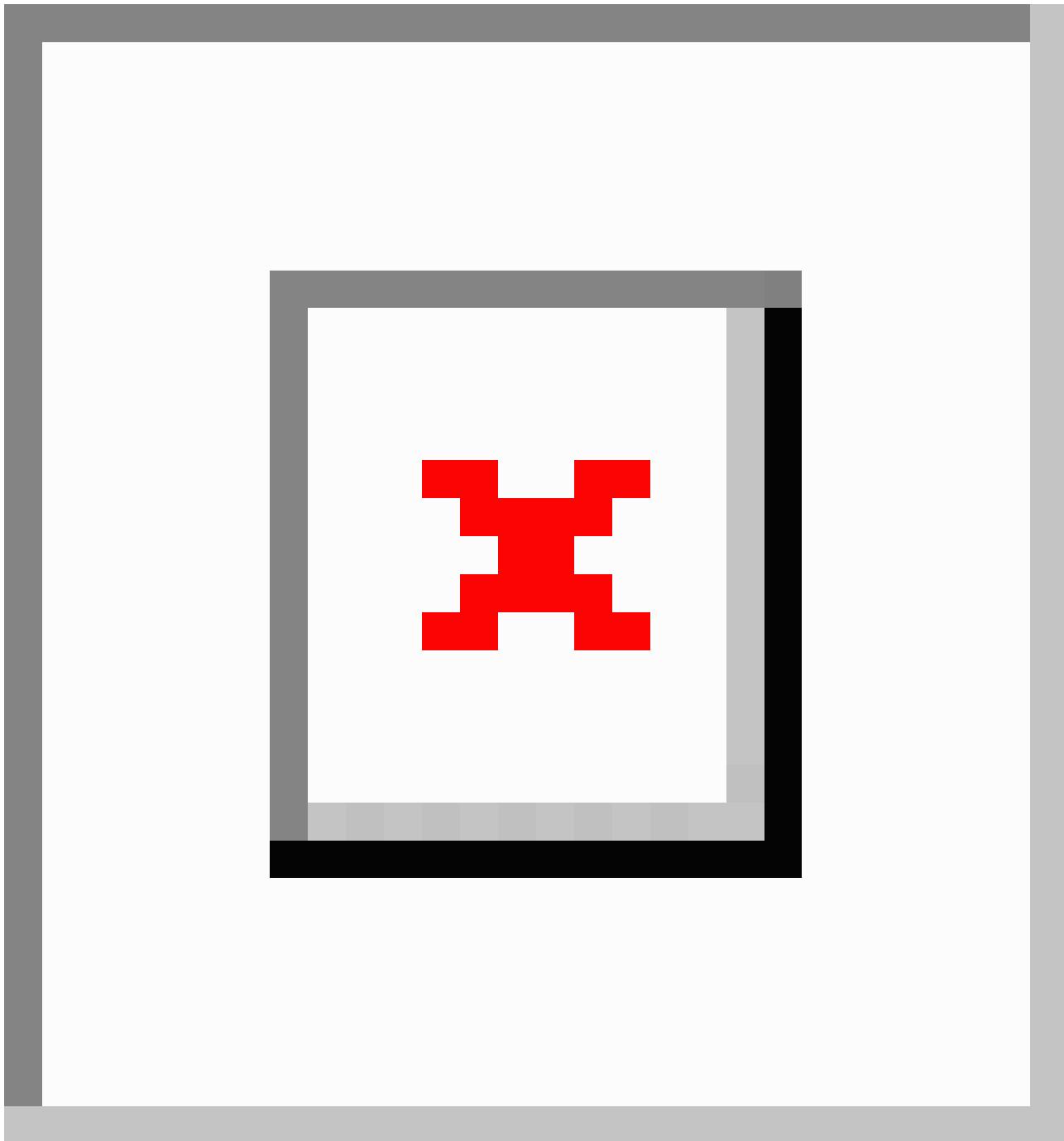
Suggested changes to the illustrations were sent to a professional illustrator. He was the same illustrator who made the illustrations for the original Step-by-Step program and was familiar with the program and cultural adaptation process. Using the original

illustrations as the starting point, we gave instructions on what changes to make (ie, character's facial expression should be happier or omit certain hand gestures) and at times accompanied instructions with sample photos taken from the internet to guide the development of new illustrations.

Changes in illustrations and in stories were then shown to participants during subsequent FGDs. We reminded participants of their comments on the past illustrations and text and showed them the revisions made. We asked for their feedback on the changes and then their approval (ie, Is this what you meant? Anything else that is unrelated, unacceptable, or hard to understand?). If the changes were still unsatisfactory, we asked for more input from them, made necessary revisions, and then showed them the newly revised slides in the next FGD. For example, it took 3 FGDs to finalize the appearance and get participants' approval for one of the characters (refer to [Figure 2](#)).

After we conducted all the FGDs on the English and female versions and after revising the texts, we sent the texts to a professional translator. The translator was a Filipino fluent in both Filipino and English, with a BA in *Malikhaing Pagsulat* or Filipino creative writing. We gave her a background of the adaptation process and informed her of the desired tone of the story and personality of the characters as per the interview and focus group feedback. We then edited the translated text to capture the OFW experiences better (ie, words they often used in FGDs to describe their experiences). The edited translations were then shown to female FGD participants during subsequent cognitive interviewing. Their comments and suggestions to simplify the texts, especially words that were too difficult to understand or lines that were too long, were then used to make additional translation edits. We then showed the revised slides during the next FGD for feedback and approval.

Figure 2. Character adaptations. In focus group discussion (FGD) 1, two sample illustrations of the main character were presented to participants for feedback with regard to appearance. Participants gave vivid descriptions on how they wanted her to look (ie, short hair with bangs, with jewelry, etc). In FGD 2, revised illustration based on FGD 1 feedback was shown to participants who gave partial approval. They liked how the character looked but not her personality. Participants suggested making her appear warm and happy. In FGD 3, revised illustration based on FGD 2 feedback was shown to participants, who then gave full approval.



Reflexivity and Procedures for Verification

This study was conducted by a research group that aimed to improve the health of migrants globally and within the Macao SAR. As such, the implementing researchers (MRG and BJH) were familiar with the OFW context, through prior knowledge and interactions with the study population, and worked with organizations providing support to this community (eg, Philippine Government, churches, and NGOs) for years, including those based in the Macao SAR. MRG is a native Filipino who speaks the Filipino language fluently and has a

similar cultural background as the participants. During data collection, MRG was an OFW herself but was only involved in the project as an investigator but not a participant. BJH is from the United States of America and emigrated to China over 5 years ago. However, neither researcher is employed in the same sector as the participants. We also had higher educational attainment, occupational prestige, and socioeconomic status. Although we are migrants ourselves and have a rich understanding of the OFW context, our experiences are different from the participants' and other typical OFWs. With this acknowledgment, we attended to our own beliefs by assuring

participants their feedback on the materials were crucial in improving the program and that they were the experts when it came to OFW experiences. We also probed participants' answers to get more information and asked them to confirm our understanding of their input. Furthermore, we presented to them the interim changes we made on the stories and illustrations for validation. They verified many of the changes, but at times, they provided clarifications and more details for additional changes. We also presented the findings to a group of stakeholders, which included Philippine Government staff (Consul General, Labor Attaché), NGO workers, a Macao government official, Macao mental health professionals, and Filipino priests and nuns, for their feedback. They did not suggest changes in the adapted program and instead raised concerns regarding logistics and eHelpers.

Results

Acceptability

On the basis of key informant interview data and FGD data, there were 3 main issues with regard to the acceptability of the generic version of Step-by-Step. This includes stigma regarding mental health problems and mental health help-seeking in the Philippines. On the basis of interview data with experts, the use of a doctor pathologizes the users' experiences and connotes there is something wrong with them. This would then serve as a barrier for the OFW population to use the program. This opinion is also backed by previous research [29]. Another issue was, from the participants' viewpoint, that some of the original content was politically charged or socially unacceptable to all OFWs. For example, the initial illustrations included hand gestures that reminded participants of political parties. The text also mentioned drug use as a negative coping strategy, but participants shared that this was reminiscent of the popular but polarizing drug war campaign of the current administration in the Philippines. Another example was illustrations that depicted the characters doing household chores, which leaned too much toward domestic work. Although many OFWs are skilled workers, there are many professionals such as nurses, managers, and teachers as well, which makes doing household chores unsuitable for all OFWs. Other instances were coping strategies originally depicted as negative but are normative or even positive coping strategies in the OFW context. For example, an illustration and text were about a character staying in bed all day, but participants shared that for OFWs in physically demanding jobs, this is a good strategy to recover from stress at work. Another was *drinking alcohol* because it is culturally normative for Filipinos to drink, especially when they are with

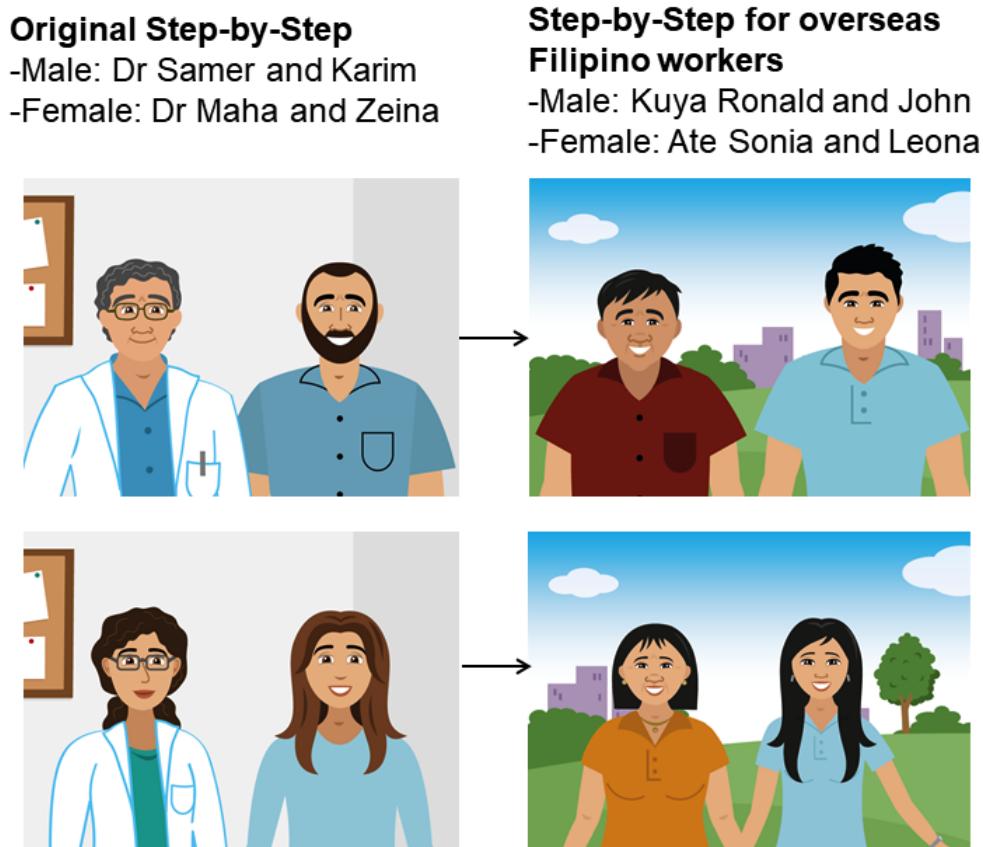
their friends. Finally, some male participants mentioned that some text and illustrations looked too feminine (ie, crying in bed). Due to strong traditional gender roles, it was important for them to maintain a masculine stance or at least not exude femininity, including emotional weakness.

To address these issues raised by participants, adaptations were then made to make Step-by-Step acceptable. These include reducing content that may increase the stigma associated with mental health and help-seeking, changing content that appeared political or potentially unacceptable to an OFW subgroup and depicted as negative when it is socially acceptable in the OFW's context, and making considerations for the male version. These are explained below.

To address the issue of stigma, we made 3 modifications. First, instead of stating the original program goal of "helping the user cope with difficult emotions and problems" explicitly, we changed it to "helping the user become a successful OFW, for their families' sake." The latter deemphasizes the focus on mental health and increases emphasis on positive goals and outcomes. The latter also still addresses the original goal but focuses on a common and integral OFW experience and value of working abroad to contribute to family's expenses, at times as the family's sole provider. Second, we developed the character that explains Step-by-Step concepts to the user (ie, stress and sadness) into an older OFW who has been successful in his or her work rather than a medical or mental health professional (refer to Figure 3). Changing the character to a fellow OFW normalizes the experience of problems and removes the stigma. Furthermore, interview and FGD data showed that making the character successful incorporates the aspirations of the target group. Third, we changed text such as "suffering at the moment" to "stressed at the moment" to make them sound less grave and more normative, as advised by FGD participants.

Some of the content was removed from Step-by-Step or changed. We removed certain hand gestures and drug use as a negative coping strategy to make the program apolitical. We removed the illustration and text about a character staying in bed all day as a negative coping strategy because this is an acceptable, even helpful, coping strategy for OFWs. We changed the illustration on characters doing household chores to sending remittances in a bank and filling up a package or what Filipinos call *balikbayan box* (literal translation: back to country) to the Philippines and preparing to go to work (refer to Figure 4) to be more neutral and suitable across occupations. These are ubiquitous OFW experiences, regardless of job or socioeconomic status.

Figure 3. Illustration of characters in the original Step-by-Step version and in Step-by-Step for overseas Filipino workers.



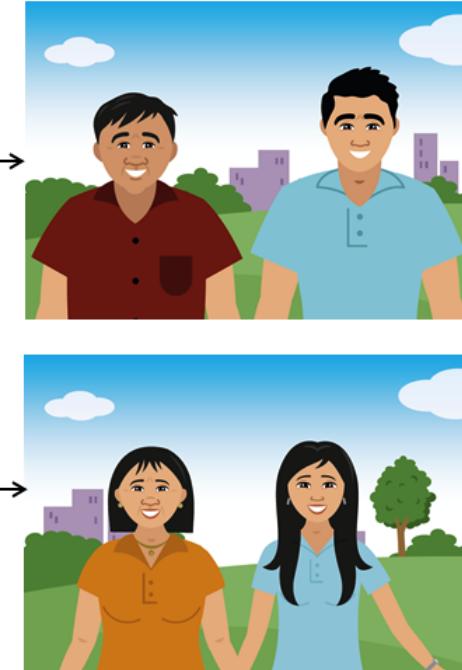
Another is “drinking alcohol,” which we changed to “drinking too much alcohol.” Participants recommended adding the term “too much” to make it a negative coping strategy.

We also made considerations for the male version. As much as possible, we ensured that female and male versions had similar storylines, activities, and illustrations so as to limit gender stereotyping as much as possible. However, for some illustrations, we made them slightly different to appeal to male OFWs by avoiding what male FGD participants believed to look too feminine. For example, in a scene that shows the character is isolated from others, the male character is in his bedroom looking lonely, with legs in v-position, elbows resting on his thighs, and hands clasped together. In the female version, the character is still alone in her bedroom but is in fetal position and hands covering her face (refer to [Figure 5](#)).

Relevance

There were 4 issues with regard to the relevance of the original text and illustrations of Step-by-Step. The first issue was in terms of the characters. The generic version used Lebanese and Muslim characters (ie, characters had names like Zeina and Karim, females wore hijab, and males had thick beards; refer

Step-by-Step for overseas Filipino workers
 -Male: Kuya Ronald and John
 -Female: Ate Sonia and Leona



to [Figure 3](#)), which were different from typical Filipino names and appearance. The second issue was in terms of the lack of relatable values in the stories. For example, participants found the tone of the stories and personality of the characters to be too serious and robotic, which they felt were not attuned to the Filipino value of showing warmth and hospitality. The third and fourth issues were in terms of the lack of relatable problems and activities. Some of the problems in the generic version included destruction of one’s home and community. Although these happen to some OFWs, participants felt these were not the most pertinent problems in their community. Moreover, participants deemed some of the activities in the generic version atypical or unfeasible, such as planting herbs and spending time with family. These were irrelevant to OFWs because while abroad, there is no ample space to plant herbs, and OFWs cannot be physically together with their families. Participants added that planting herbs would not come across as a fun activity for many OFWs.

To increase relevance, we made the following adaptations: (1) choosing appropriate names and appearance of main characters, (2) highlighting Filipino values, (3) using relatable problems, and (4) using relatable activities.

Figure 4. Illustration of providing support to others in the original Step-by-Step version and in Step-by-Step for overseas Filipino workers.

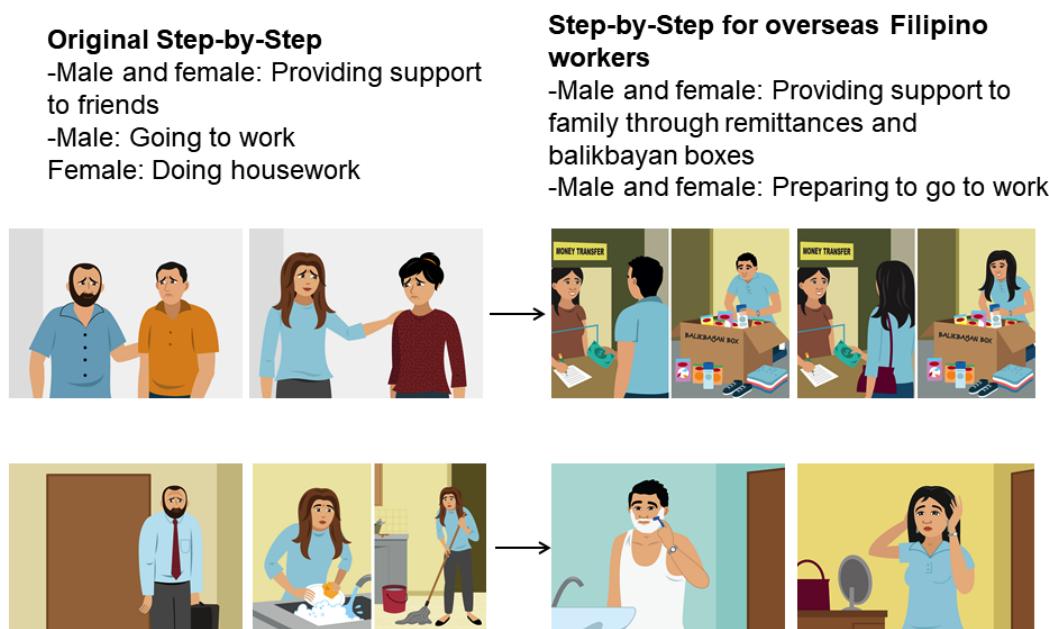
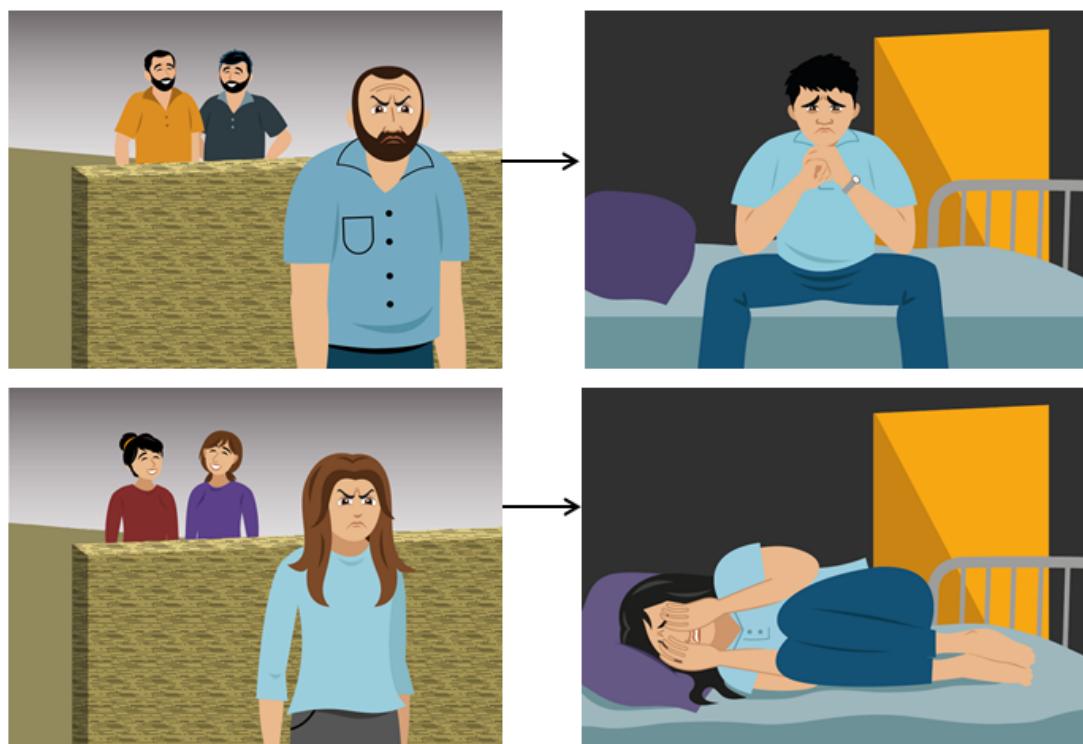


Figure 5. Illustration of isolating oneself from others in the original Step-by-Step version and in Step-by-Step for overseas Filipino workers.

Original Step-by-Step
Male and female: Facing away from friends and looking angry

Step-by-Step for overseas Filipino workers

- Male: Sad and alone, sitting on bed
- Female: Sad and alone, lying in bed in fetal position



We first developed the characters' names and appearances to make them sound and look Filipino. The older characters had Spanish-sounding names (Kuya Ronald and Ate Sonia), whereas the younger characters had more modern and American-sounding names (John and Leona), both of which are common naming practices that are related to the colonial and changing cultural context of the Philippines. We also ensured that the names had positive meanings (ie, a wise person and a fighter) and were approved or chosen by the participants. For the older characters, we added the terms *Ate* or *Kuya* before their names, which mean respected older sister or older brother in Filipino, often associated with being sensible and experienced. For the characters' appearances (refer to [Figure 3](#)), participants wanted their hair straight and black and their skin color warm or olive in tone. The participants also wanted the characters to look successful as they link being a migrant for years to having saved money and made investments but added that they needed to dress comfortably as they are busy at work. They proposed making their clothing simple, comfortable but modern, and adorned with jewelry such as watches for the male characters and earrings, necklaces, and watches for the female characters.

We highlighted Filipino values in 3 ways. First, experts and participants advised adapting the personality of the program and characters to exude desirable Filipino values of family orientation, showing warmth and care for others, sociability, and positive thinking. Participants added changing the tone of the text to become more conversational and story-like to sound more engaging and realistic such that the characters seem to be talking to the users. Participants also recommended that the characters addressed the user as *kabayan* or countryman, a common term used among OFWs, which denotes similarity and familiarity with fellow Filipino migrants. The older characters also acted as mentors or coaches to the younger characters and user. The younger characters called the user *sis* or *bro* to denote kinship. They showed eagerness to share their stories and emotions with the users and to learn and become better. Participants advised for all characters to offer encouragement or reassurance to the user, with lines such as "Keep up the good work!" and "You can do it!" They recommended matching these with illustrations where the characters gave warm smiles to welcome and bid the users goodbye and thumbs-up sign to show approval.

Second, the texts were changed to highlight that OFWs consider their family as motivation for going abroad and working hard, even making sacrifices for them. Participants suggested matching the illustrations by showing OFWs thinking of their families often and missing them. Furthermore, participants wanted to emphasize being with friends and family as crucial to one's mental health and as culturally appropriate and expected. Participants proposed matching the text with illustrations of characters spending time and having fun with friends who were also OFWs and with family through Web-based communication.

Third and last, as suggested by all 3 experts during individual interviews, we mentioned additional Filipino values such as *bayanihan* and *utang-na-loob* in the stories. *Bayanihan* means

working together to help someone, which we added in an activity where an OFW helped a main character in a task. *Utang-na-loob* means debt of gratitude, which we mentioned as a motivator for a main character to reach out to a friend who helped them in the past.

We adapted the content in terms of the problems the characters experienced to make them more typical, based on interview and FGD data. Examples of problems included leaving their family behind, having personal conflicts, and having too much work or having no break or day off.

We likewise adapted the content in terms of the activities the characters engaged in to make them enjoyable and doable to as many OFWs as possible. On the basis of FGD data, examples include eating *merienda* or afternoon snacks with friends, visiting nearby historic sites, celebrating events with family using Web-based communication, and singing videoke (video karaoke) with friends (refer to [Figure 6](#)). These are typical fun activities that Filipinos engage in. Filipinos are fond of eating meals together, exploring new sites when abroad, connecting with families back home, and listening to music and singing. These activities are also relatively inexpensive and not that time-consuming, which make them feasible to do during days off and even with limited finances.

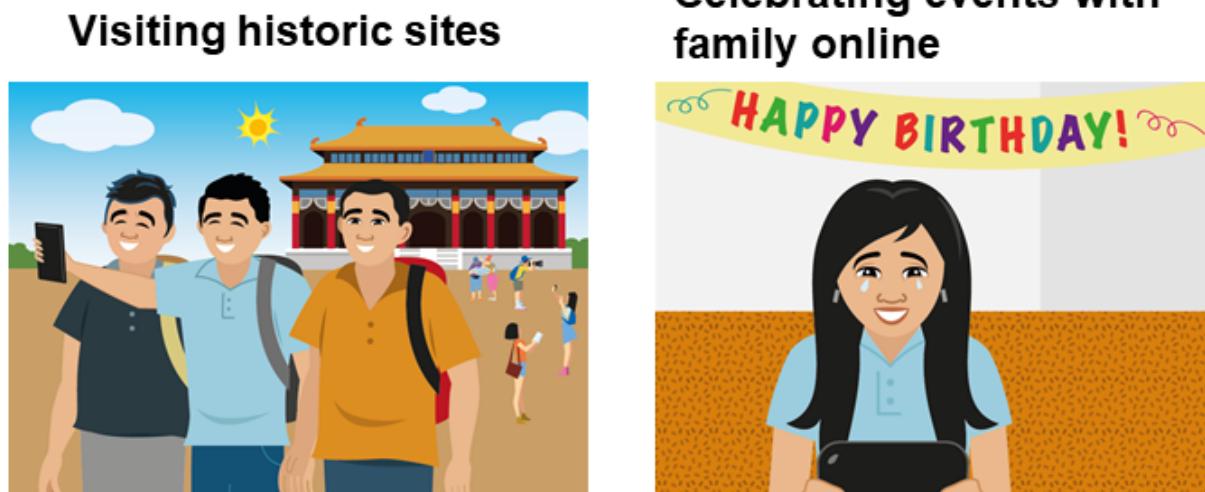
Comprehensibility

The generic version of Step-by-Step had elements that were incomprehensible, unclear, or too complex. In the text, there were sentences that participants deemed too long or repetitive and, therefore, difficult to understand. Some participants expressed finding some terms (ie, *peers*, *pace*, and *social support*) complicated. Finally, participants found that some texts and illustrations were not clearly linked. For example, one passage in the text was about isolating oneself from other people when one feels sad. Although participants understood the text, they mistook the illustration where the character is facing away from 2 other characters as friends gossiping about the character (refer to [Figure 5](#)).

To make the adaptation comprehensible, we used Filipino and English languages. Filipino is the national language in the Philippines. Both Filipino and English are official languages and are widely spoken by OFWs as primary mediums of communication, that is, Filipino with fellow OFWs who come from different regions in the Philippines and English with their employers. Filipino is derived from Tagalog, the main language of 35.1% of households in the Philippines [30].

On the basis of FGD data, we also simplified the text in 3 ways to boost comprehension: shortening long sentences by removing words, dividing long sentences into 2 sentences, and using simplest words and phrases (ie, changed the word *peers* to *friends* and *pace* to *speed*). When a term or an idea was too abstract, we changed the words or added extra words or lines to clarify what they meant. For example, instead of the abstract concept of *social support*, we used *helping hands* as suggested during an FGD because although participants understood what social support meant, they could not verbalize their understanding of the term.

Figure 6. Illustration of enjoyable activities in Step-by-Step for overseas Filipino workers.



For the Filipino version, participants suggested simplifying text by removing sentences when paragraphs sounded repetitive and confusing. We retained those lines in the English version as they did not sound repetitive in English. Moreover, some English words or phrases when translated to Filipino sounded awkward; hence, we retained the original words in English. For example, we retained the word *congratulations* because its Filipino translation of *binabati kita* or ‘I compliment you’ sounded odd to participants. We removed English words or phrases that did not translate well into Filipino, as suggested by participants.

We adapted texts and illustrations that were not clearly linked, following participants’ recommendations. For example, for the illustration about isolating oneself, we had the illustration changed so that the character is in bed alone (refer to Figure 5).

Completeness

All key concepts in the original version are intact in the adapted Step-by-Step for OFW. We also made sure that the English and Filipino versions were as similar as possible, so that if an OFW chooses to use the English version, they would have an equivalent program to the Filipino version and vice versa. For the Filipino version, instead of translating all English words to Filipino, we retained some English words because OFWs use these words to describe their experiences. The combination of Filipino and English (ie, Taglish) is an unofficial language [30] that is normative and accepted among Filipinos. An example is being *homesick* as they are away from their family. Participants recommended retaining the English word *homesick* instead of using the Filipino translation of *hinahanap-hanap ang pamilya* (yearning for family) because the word *homesick* is a common OFW term and is deeply tied to working abroad far from one’s family.

Discussion

Principal Findings

To our knowledge, this is the first study that culturally adapted an e-mental health intervention for the OFW population and

Filipinos generally. We illustrated how the 4-point framework to improve acceptance, relevance, comprehensibility, and completeness is useful in navigating the process of culturally adapting the Step-by-Step program. It was a practical guide to both us, the researchers, and the participants as it enabled us to capture and flesh out crucial elements to make the finished product attuned and sensitive to the context and experiences of OFWs. In turn, we were able to make the program culturally specific for this group, which is essential among the 4 features of effective e-mental health interventions [15].

Lessons Learned

For future cultural adaptations, we recommend that all illustrations and content be adapted at the same time. In our experience, participants were more engaged in the presence of visual stimuli (recall that we were not able to present illustrations for sessions 0-2). Furthermore, it was easier for them to understand the texts and key concepts while being able to see the illustrations.

We recommend that the same set of participants be part of the FGDs from start to finish to avoid spending time explaining the program, the mechanics of the cognitive interviews and discussion, and details from previous sessions. We were able to do this with the majority of our FGDs, but scheduling limitations hindered participants from attending all sessions. Therefore, to accommodate the realities of the population, we allowed the FGDs to be open to newcomers. Some participants were more able to provide input than others. As in any FGD, it is important to select participants who are more open, less shy, and comfortable to freely share their thoughts. In the context of this adaptation study, norms of social hierarchy and harmony within the cultural group may have influenced how much people shared within the groups.

Another limitation is the lack of standard and systematic evaluation on whether the inputs from members of the FGD represent the entire community. Further investigation is also recommended to determine which elements were most salient

to the participants to more clearly know when adaptations are good enough for the cultural group.

Relevance of the Research

The methods and detailed results of formative adaptation work as described in this study are often not shared by researchers or program implementers in mainstream literature [9,11]. As it is such a crucial step in planning and care provision, we hope that this study will not only highlight the importance of cultural

adaptation but also provide the audience a replicable account of how to conduct such formative research.

Following the Medical Research Council Guidelines for Complex Interventions and the WHO scalable psychological interventions program [31,32], this adapted program will be rigorously evaluated. The initial feasibility trial and subsequent full-scale randomized controlled trial both include process evaluation components. Subsequent changes to the illustrations, content, and program story will be made, if needed.

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Conflicts of Interest

None declared.

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Abbreviations

EBT: evidence-based treatment

e-mental: electronic mental

FGD: focus group discussion

NGO: nongovernmental organization

OFW: overseas Filipino worker

SAR: Special Administrative Region

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Original Paper

Community Engagement in the Development of an mHealth-Enabled Physical Activity and Cardiovascular Health Intervention (Step It Up): Pilot Focus Group Study

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Abstract

Background: Community-based participatory research is an effective tool for improving health outcomes in minority communities. Few community-based participatory research studies have evaluated methods of optimizing smartphone apps for health technology-enabled interventions in African Americans.

Objective: This study aimed to utilize focus groups (FGs) for gathering qualitative data to inform the development of an app that promotes physical activity (PA) among African American women in Washington, DC.

Methods: We recruited a convenience sample of African American women (N=16, age range 51-74 years) from regions of Washington, DC metropolitan area with the highest burden of cardiovascular disease. Participants used an app created by the research team, which provided motivational messages through app push notifications and educational content to promote PA. Subsequently, participants engaged in semistructured FG interviews led by moderators who asked open-ended questions about participants' experiences of using the app. FGs were audiorecorded and transcribed verbatim, with subsequent behavioral theory-driven thematic analysis. Key themes based on the Health Belief Model and emerging themes were identified from the transcripts. Three independent reviewers iteratively coded the transcripts until consensus was reached. Then, the final codebook was approved by a qualitative research expert.

Results: In this study, 10 main themes emerged. Participants emphasized the need to improve the app by optimizing automation, increasing relatability (eg, photos that reflect target demographic), increasing educational material (eg, health information), and connecting with community resources (eg, cooking classes and exercise groups).

Conclusions: Involving target users in the development of a culturally sensitive PA app is an essential step for creating an app that has a higher likelihood of acceptance and use in a technology-enabled intervention. This may decrease health disparities in cardiovascular diseases by more effectively increasing PA in a minority population.

KEYWORDS

cardiovascular health; community-based participatory research; health behaviors; mHealth; mobile phone; physical activity; qualitative data

Introduction

Cardiovascular disease remains the leading cause of death in the United States, and African Americans bear a disproportionate burden, leading to significant and excessive morbidity and mortality [1,2]. Cardiovascular disease risk factors are more prevalent among both low-income and racial or ethnic minority populations, emphasizing the need to design interventions that address these risk factors and, ultimately, reduce health disparities [1]. A major factor contributing to poor cardiovascular health is the lack of sufficient physical activity (PA). The Centers for Disease Control and Prevention reports that 24% of US adults do not engage in leisure-time PA. National averages for women and African Americans are higher, at 29.5% and 26.4%, respectively [3]. A systematic review conducted by Joseph et al found that African American women face unique barriers to PA, including neighborhood safety concerns, financial costs, and hair maintenance, among others [4]. Culturally tailored community-based interventions that combine education, support, and tools to improve cardiovascular health are especially useful when addressing disparities in resource-limited settings [5].

Mobile health technology (mHealth) is a potentially effective and widely accessible platform for community-based interventions seeking to improve health outcomes in areas of lower socioeconomic status. Approximately 72% of African Americans in the United States own a smartphone, and they are more likely to depend on smartphones for internet access than other racial groups. Thus, smartphone apps are a realistic target for interventions among African Americans [6]. As 62% of all smartphone users access health information via their mobile phones, capitalizing on apps to deliver health interventions may facilitate access to communities with lower health care utilization, such as African Americans [7]. This is substantiated by the finding that African American women are willing to participate in mHealth research that uses technology, such as fitness trackers and smartphone apps [8]. To date, there have been no studies that use community-based participatory research (CBPR) methods to engage urban, low-income, African American women as end users in the development of a smartphone app for PA promotion.

In order to understand the potential impact of an app on health behavior, such as PA, it is helpful to rely on an existing theoretical framework. The Health Belief Model (HBM) consists of six relevant constructs related to behavioral change: perceived benefits, perceived barriers, perceived susceptibility, perceived severity, self-efficacy, and cues to action [9]. HBM allows for the systematic exploration of beliefs and attitudes through these well-defined constructs, while other theories [10] do not. Therefore, we propose that HBM will be a strong theoretical basis upon which to analyze the role of an app in facilitating a behavioral change.

Typical CBPR methodology includes working alongside a community advisory board (CAB) to develop a relevant, tailored intervention that is appropriate for the community in question. CBPR, which is focused on the intentional engagement with minority populations, has been a validated approach for eliminating health disparities [11]. Focus groups (FGs) are an effective CBPR methodology for eliciting feedback and gaining a comprehensive understanding of mHealth features preferred by a population. FGs are also at the core of user-centered design processes. Thus, we employed community-based FGs to facilitate user-centered design and develop a smartphone app that promotes PA by addressing the unique needs and barriers of African American women. The primary aim of this pilot study was to employ FGs to qualitatively gather the perspectives of low-income, African American women on a PA-promoting app prior to use in a future, larger mHealth-enabled intervention in the Washington, DC metropolitan area. Applying HBM as a theoretical framework in the thematic analysis of FGs allowed us to effectively explore the utility of the app for improving health behaviors in this population.

Methods

Overview of Study Design

A convenience sample of African American women participated in 2 FGs assessing their views on the use of mHealth tools. Immediately following the preintervention FG session, the study app was downloaded onto participants' mobile phones, and participants were given study-associated Fitbit accounts and a Fitbit Charge 2 device (Fitbit, Inc, San Francisco, CA, USA). Therefore, all participants began both study components—using the app and wearing the Fitbit—simultaneously. After completion of the 20-day study period, participants took part in the postintervention FG interviews to share their experiences with the study app and Fitbit device. The pilot study was conducted for 20 days to accommodate the 18-day push-notification message scheme, plus 1 extra day on each end. Findings of the postintervention FG are described in this manuscript. The study was approved by the National Heart, Lung, and Blood Institute (National Institutes of Health, NIH) institutional review board, and all participants provided written informed consent (NCT 01927783).

Study Population

African American women aged 19–85 years and residing in low-income areas of Washington DC (wards 5, 7, and 8) and Prince George's County, MD, were invited to participate. Participants were recruited from a convenience sample of communities in Washington, DC metropolitan area between August 2017 and October 2017. Participants learned about the study through local health education events, flyers at churches, and peer recommendations. Participants were required to own a smartphone device, be proficient in written and spoken

English, be physically able to engage in study activities, and be either overweight or obese (body mass index, BMI, $\geq 25 \text{ kg/m}^2$) by self-reported height and weight. The study criteria and convenience sampling resulted in the recruitment of 20 possible participants and, ultimately, enrollment of 16 participants.

Developing the Smartphone App

The app was developed in partnership with Vibrent Health (Fairfax, VA, USA), a health technology company. The app was designed to deliver motivational messages via push notifications, educational content about PA, and a daily self-assessment of stress and participants' opinions of the message content of that day. The app featured a welcome video of the Principal Investigator (TP-W) explaining the purpose of the study and encouraging participants to increase their PA. The app was tested by the study team and app development group prior to distribution to study participants.

Community-Based Participatory Research for Push Notification Message Development

Using the Communication, Awareness, Relationships, and Empowerment Model [12], we engaged our community partners through our previously described CAB, the DC Cardiovascular Health and Obesity Collaborative [13,14]. These community partners provided feedback and input on study design and implementation, including a review of the recruitment and data collection methods.

A questionnaire was emailed to the CAB to identify local and culturally relevant barriers to PA and to solicit suggested motivational push notification messages that promote PA. Follow-up telephonic interviews were then conducted based on a prewritten script to further ascertain and clarify their suggestions (see [Multimedia Appendix 1](#), which illustrates the CAB interview script for suggested messages). Both the questionnaire and interview asked CAB members to provide messages applicable to 1 of the 4 motivational constructs: self-efficacy, self-esteem, goal setting for increasing motivation, and goal setting for those with motivation but limited time. These categories were chosen based on prior work identifying barriers to PA for African American women [15] and the proposed theoretical framework for a community-based, mHealth-enabled PA intervention in development [16]. During the interview, respondents were given examples of messages from each category consecutively to prompt message suggestions relevant to that category. Additionally, CAB members were asked to tailor their suggestions to the population of interest, African American women, in order to generate the greatest impact on PA [17]. These messages were compiled, reviewed, selected, modified, and reorganized into the 4 categories prior to consulting a health communications expert (SE-T) for approval. The final messages were incorporated into a database for use in community-based PA interventions (see [Multimedia Appendix 2](#), which illustrates the process of

engaging the CAB for the push notification message development).

Motivational Push Notification Message Dissemination

The app was designed to deliver 3 motivational messages daily via push notifications, which included photos of African American women of all body sizes and ages participating in PA. The app also allowed participants to review past messages by storing all received messages on a "wall" within the app. Motivational messages were disseminated via the app according to a programmed order (see [Multimedia Appendix 3](#), which shows the programmed order of message dissemination; arrow represents 1 individual, N=16). Participants were scheduled to receive a specific sequence of motivational messages over an 18-day period split into six 3-day blocks. During each 3-day block, participants were scheduled to receive daily messages from 1 motivational category or to review educational modules. Each participant would, therefore, receive a unique sequence of messages over the testing period to control for sequencing effects, while allowing them to see examples from each motivational category and the educational modules. During the final 3-day block, participants were randomized to receive daily messages from a single motivational construct in combination with the educational modules.

Educational Modules

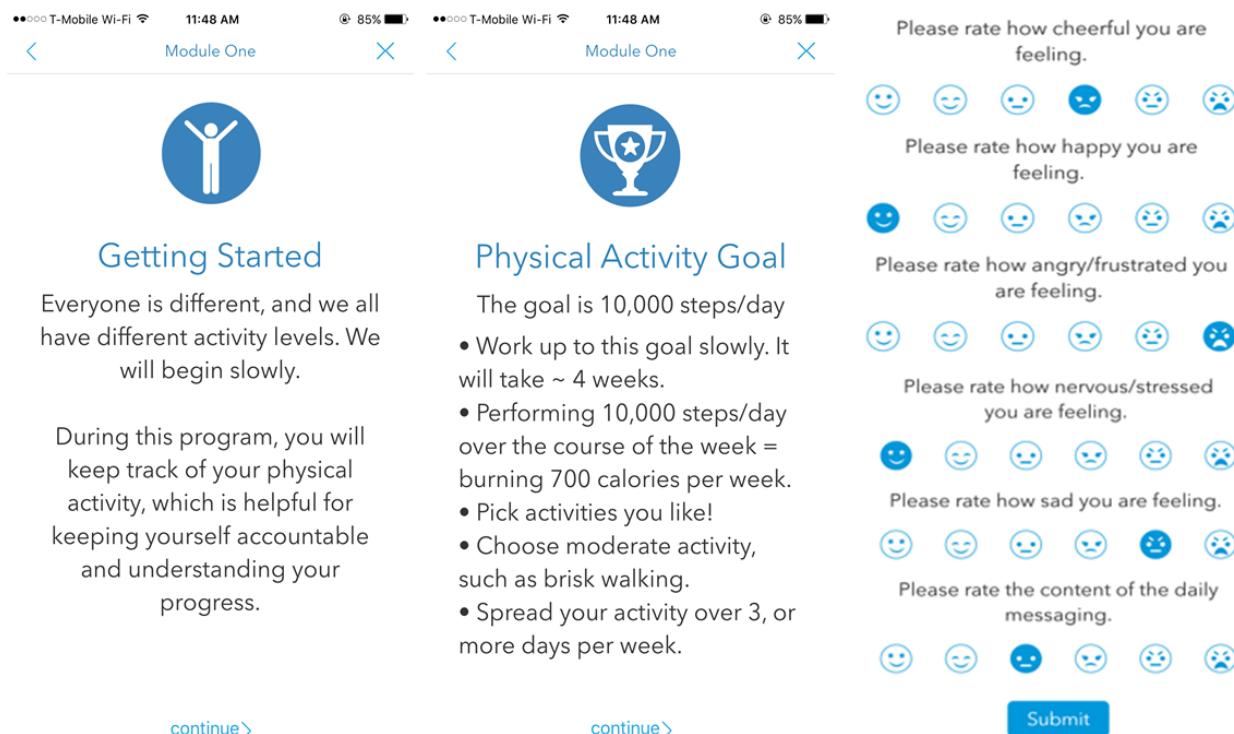
Information about PA was distributed via 2 educational modules, adapted from the Diabetes Prevention Program ([Figure 1](#)) [18]. Module 1 covered goal setting and benefits of PA. Module 2 covered safety, stretching, and how to integrate PA into a busy life. Both modules were interactive, allowing participants to enter their current PA levels and goals for the following week. Upon completion of both modules, participants received further positive reinforcement (a "prize") within the app, which consisted of 2 simple, heart-healthy recipes.

Daily Self-Assessment

Participants were asked to complete a 6-item self-assessment every evening that evaluated their stress and cognitive affect ([Figure 1](#)). The first 5 questions were derived from prior ecological momentary assessment tools [19,20]. Participants were asked to rate their levels of cheerfulness, happiness, anger or frustration, nervousness or stress, and sadness on a 6-point scale. For the 6th question, participants were asked to rate the content of the daily motivational push notification messages on a 6-point scale.

Wearable Physical Activity Tracker

Participants wore Fitbit Charge 2 devices 24 hours per day for the 20-day study period, with the exception of water-based activities. The wrist-worn activity monitor recorded minute-by-minute amount and intensity of PA achieved by each participant as well as sleep duration and quality. As the study app did not sync with the PA tracker, participants were able to view their activity via the commercially available Fitbit app.

Figure 1. Screenshots of the study app which show Educational Module 1 and the Daily self-assessment.

Focus Groups

Immediately following the 20-day study period, all participants met at a local partnering church to discuss their experiences with the PA-promoting app, fitness tracker and associated app, and resulting changes in PA. Then, 2 simultaneous FGs, which included 8 participants each, were conducted to allow all 16 participants greater opportunity to speak. The FGs were conducted using a semistructured interview process. Each FG was led by 2 study team members, a moderator and a facilitator, with additional note takers present to document nonverbal responses. Both moderators followed a Moderator's Guide, which included preselected questions and probes but allowed for open discussion based on the comments raised (see [Multimedia Appendix 4](#), which illustrates the Moderator's Guide). During FG, the facilitator's role was to manage the equipment (ie, name cards and tape recorders), take notes, make observations, and ask follow-up questions when deemed necessary. The FGs were audiorecorded and transcribed verbatim by an independent clinical research organization (Social Solutions International, Inc, Silver Spring, MD, USA).

Data Analysis

Descriptive statistics were assessed from demographics and Fitbit data using SAS 9.4 (SAS Institute, Cary, NC, USA). A behavioral theory-driven thematic analysis based on the HBM was used to analyze FG data. The transcripts were reviewed,

and a preliminary codebook of themes was developed based on theoretical constructs of the HBM. Each theme was accompanied by an operational definition that allowed 3 coders to systematically and independently identify quotes from the FGs that represented each theme. The coding process was iterative, with a total of 6 codebooks developed until consensus was achieved. An intramural NIH qualitative research expert (GW) validated the final coding and corresponding themes.

Results

Sample Characteristics

The study sample consisted of 16 African American women with a mean age of 62.1 (SD 6.6) years ([Table 1](#)). Mean BMI was 35.5 (range 25.6-54.6) kg/m², with 75% (12/16) of the women classified as obese (BMI \geq 30 kg/m²). About 63% (10/16) of the women were retired or unemployed. Educational attainment varied and ranged from high school level to graduate or professional degree although most participants (12/16, 75%) had, at least, a college education. Income information was only available for 8 participants, with the majority of participants having a household income \geq US \$60,000. Participants had an average step count of 7359 steps per day, with a valid day defined as 10 or more hours of Fitbit wear time. There were 292 valid days for analysis. Step data were averaged over valid days for the 20-day period.

Table 1. Sample characteristics (N=16).

Characteristic	Values
Age (years), mean (SD)	62.1 (6.6)
Sex, n (%)	
Female	16 (100)
Race, n (%)	
African American	16 (100)
Employment status, n (%)	
Employed	6 (37)
Retired or unemployed	10 (63)
Income (US \$), n (%)^a	
<60,000	6 (37)
≥60,000	5 (63)
Education, n (%)	
Some college or below	4 (25)
Technical degree	2 (12)
College degree	7 (44)
Graduate or professional degree	3 (19)
Marital status, n (%)	
Single, divorced, or widowed	12 (75)
Married	4 (25)
Location of residence, n (%)	
Maryland	7 (44)
Washington, DC	9 (56)
Body mass index (kg/m ²), mean (SD)	35.5 (8.29)
Weight parameters	
Overweight ^b , n (%)	4 (25)
Obese ^c , n (%)	12 (75)
Physical activity parameters, mean (SD)	
Steps per day ^d	7359 (2201)
Sedentary minutes per day	1174 (54)
Light intensity minutes per day	236 (50)
Moderate intensity minutes per day	12 (8)
Vigorous intensity minutes per day	18 (10)

^aIncome information was only available for 8 participants.

^bBody mass index ≥ 25 kg/m².

^cBody mass index ≥ 30 kg/m².

^dValid day defined as ≥ 10 hours of wear time (step data averaged over valid days during the 20-day study period).

Focus Group Themes and Subthemes

The HBM includes 6 constructs, of which the following 5 were germane to the data: perceived benefits, perceived barriers, perceived susceptibility, cues to action, and self-efficacy. Perceived severity was not identified in the transcripts. Additional, emergent themes were identified, including technical

difficulties, generational differences, and relationship with the community (Textbox 1). Themes, subthemes, and illustrative quotes can be found in [Multimedia Appendix 5](#). As the app was designed to provide multidimensional behavioral support, instances of overlap between themes arose during the analysis, for example, between perceived benefits and cues to action as well as perceived barriers and technical difficulties. However,

many quotes succinctly and fully illustrated a single theme, such as the following perceived benefit:

I didn't lose weight, but it showed in my blood tests; the results of my blood tests. So, I did show some improvement with the increasing of the exercise.

This participant is highlighting the benefit she perceived from using the app to increase her PA (improved laboratory tests), in the absence of achieving her personal goal (weight loss).

Textbox 1. Themes and subthemes.

Health Belief Model

- Perceived benefits
 - Impact on nonphysical activity health behaviors (mood, sleep, healthy eating, etc)
 - Goal setting
 - Education or new information
 - Safety of global positioning systems tracking
- Perceived Barriers
 - Difficulty of use (ie, lack of automation)
 - Ambiguity over goals of daily self-assessment
 - Accuracy of physical activity tracking or ambiguity over physical activity goals
 - Technology literacy
 - Community or historical distrust of research
 - Safety as a barrier to physical activity
 - Insufficient data plan or memory
- Perceived Susceptibility
- Cues to action
 - Push notification messaging
 - Expanding the definition of "exercise"
- Self-efficacy

Emergent Themes

- Technical difficulties
 - Check-ins or IT support
- Generational differences
- Relationship with community
 - Connection to fellow participants
 - Connection to the research team
- Social support
- Preferred features

Participant Suggestions for the App Improvement

During the FGs, participants shared their opinions of the app and provided suggestions for further improvement (Table 2). Participants strongly expressed a desire for increased educational content, more tailored location-specific recommendations for outdoor PA, and in-app connection to existing community resources that may assist in overcoming barriers to PA. They also suggested that the app show PA data from the Fitbit device (rather than on the separate, Fitbit app), include personalized step goals, and have a redesigned daily self-assessment tool.

Table 2. Participants' suggestions for the app improvement.

Suggestion	Illustrative quotes
Increased automation	
Water intake	"So if I drank the water and it automatically like it does my sleeping. It counts the sleep. It needs to count the water."
Food intake	"The food intake. I put in one thing and then I said, 'Oh wow, this is just, I don't know how much this is.' [...] But I looked at that and I said, 'This is a little too much [work].'"
Increased relatability	
Redesign the daily self-assessment	"We not no children, get rid of them [smiley faces]." "I'd definitely get rid of them smiley faces. I didn't like the smiley faces. I thought [they]made me feel like I'm in the elementary with my grand[daughter]." "I couldn't quite relate to the daily self-assessment, the rating scale, the happy faces. I think it was more like giving each segment stars, I could have understood that better. I couldn't relate to [the smiley faces]." [Speaking about revising the scale in the self-assessment] "Like on a scale from 1 to 10, on a scale from 1 to 10, I'm like a 7 or..."
Including photos of heavier women	[Speaking about the photos that accompanied the messages] "Have a person that's heavier than these people. They look like they're already fit." "I liked, well, when I read I like to see people that look like me." "It's really important that I see somebody with some gray hair..." "Weight." "Heavy!"
Ease of use	
Saving or printing the recipes	"And then you're on your phone and you don't have a printer see you're not putting it on your iPad or anything. If you had that you'd print it out. I couldn't print it out and I wasn't going to handwrite it."
Increased educational material	
Diet and nutrition	"Even add a few more modules." "About I guess they could talk about, because I know a lot of people don't like calorie counting and different things but the health coach that I'm working with, or the program that I'm working with, we have measurements and they show you what your size is you know, protein your palm of your hand, the grain your first, or different things like that and they do a lot of visuals and so on like that so that we don't have to worry about counting and how to prepare healthy nutritious meals you know with a protein, a carb I mean your grain, your vegetable. Things like that."
Stretching, including an instructional video	"If there's a video like there the pictures may show you someone exercising, how to exercise. Maybe if there is a video if the video shows you how to do that exercise or proper technique for that exercise or the benefit of that particular exercise. If the video was to be included I think that would be helpful." "I agree because I remember...they were saying roll your flatten your back to the floor and I kept trying to visualize what they were saying. So, maybe a video would have helped." [Discussing stretching techniques shared in the educational module.]
Sleep hygiene	"Maybe in the future since there are some of us that have sleeping issues. Maybe I didn't see anything at any of the questions, like suggestions about either going to bed early, turning the T.V. off, you know those kinds of suggestions to help us."
Connection to community resources	
Group exercise or dance classes at existing facilities	"I'm thinking maybe you know safe places to exercise in the community, places where we can get food, you know just whatever. Any kind of resources that I think would pair well with exercising and eating well and taking care of yourself." "[I] think you could maybe add somewhere, I don't know where but maybe somewhere more information about resources." "A cooking class." [Speaking about community resources she would like to see included in the app]
Community walking groups and ability to create them in the app	"Yeah, group exercise and stuff like that. And you'd get more people motivated and doing this cause so far that's what we're doing at the [Recreation Center]. We're spreading the word and we're getting a lot of people coming in now...The classes are free and they giving them four days a week. You could do stuff up there, and the most time they got line dance, hand dance, jazz you know all these classes." [Speaking about the benefit of having a group or competition component within the app] "Yeah, I know and that's what made me think within the study maybe they could do something like that. Even if it's to link up with some of those that is already in existence." "You don't like to walk alone because it's not safe nowadays. But, if there was some kind of information that would say like, 'Look, we would like a group to walk, a start off group to walk at five o'clock in the morning in a certain area."

Suggestion	Illustrative quotes
Safe places to walk or exercise outside	"Yes, and I think we just did a thing on, what they call it? Geographical information systems where they show you know they map out areas where you can go to get physical activity and different things like that. Because you know health information is being done through a lot of technology and that would be one because sometimes people in the community need to know where can I go, you know how can I get there? For children through adults. Different things like that."

Discussion

Principal Findings

This study demonstrates the effectiveness of community engagement techniques, such as CBPR and FGs, in developing and refining culturally tailored smartphone apps for use in a community-based, mHealth-enabled PA intervention. Introducing a user-centered mHealth intervention in a low-income, African American population at risk for cardiovascular disease increases the likelihood of adoption and, therefore, may be an effective method for addressing health disparities.

Despite the purported potential of technology to alleviate health disparities, little research has been done to evaluate the feasibility and effectiveness of mHealth in minority populations. Consistent with recent studies, we show that both wearable technology and smartphone apps are well received among urban, community-dwelling African American women [8,13]. Location-based tracking was not perceived as a significant barrier for the adoption of technology-based interventions in this population. Rather, it was seen as a benefit due to the possibility of locating an individual in the event of safety concern (ie, abduction). In summary, mHealth may be a useful tool for promoting PA among minority and low-income populations, and future work to evaluate its efficacy is warranted.

Community-Based Participatory Research for User-Centered Design

Involving community members at the earliest stage of the study design upholds the essence of true CBPR methodology. We were able to incorporate the community perspective directly into the intervention through the process of developing tailored motivational messages with the CAB. The majority of CAB members share residence and demographic characteristics with the study participants. This allowed us to overcome a strong barrier to effective health disparities research, namely, the predominating influence of an “outsider” perspective. Previous research demonstrates the effectiveness of culturally relevant persuasive messages for PA promotion among African American women [21,22]. Effectively engaging the community through CAB allowed us to generate culturally tailored messages, which also highlighted unique barriers to PA for this population, such as safety and hair maintenance. The success of this collaboration allowed us to better address the needs of the study population, while simultaneously empowering the target population as a mutual partner. Therefore, we see the formation of CAB to work alongside health disparity researchers as a necessity.

Focus Group Interviewing for User-Centered Design

Using FGs to inform the development of our PA app was an effective method to facilitate end user tailoring and, potentially, satisfaction. Although prior studies have used FGs for mHealth interventions, most explored end user satisfaction and feasibility only after the final app development and immediately before commencing a randomized control trial. Very few studies have used FGs as a means of collaborating with the target population to obtain feedback for the enhancement of a PA app at its inception [23-28].

Focus Group Interviewing and the Health Belief Model

Grounding our qualitative data analysis within HBM allowed us to identify how the app acted as both a promoter and barrier to behavioral changes. Specifically, HBM elements showcase the app’s potential to facilitate a behavioral change by means of educating users on the benefits of PA, promoting self-efficacy, and providing cues to action. Although discussion on perceived severity did not arise during the interviews, that particular construct has been shown to be less influential in facilitating a sustained health behavioral change [29,30]. Conversely, the concept of perceived susceptibility was raised during the discussion and has been shown to play a significant role in developing health behaviors [31]. A concern that often arises in the dialogue surrounding minority health and research participation is the historical and pervasive mistrust of the scientific community [32]. Indeed, participants discussed the potential of community distrust to act as a barrier to app adoption. However, they also highlighted and reinforced CBPR as a means of reducing hesitancy and enhancing trust. In summary, HBM constructs were especially useful in informing the development of an mHealth-based intervention, which aims to increase PA as a preventive health behavior in limited-resource minority communities.

Tailoring the App to User Needs and Preferences

While the primary focus of the intervention, PA, was well received by participants, the qualitative data demonstrate a need for a significant secondary impact on nonPA health behaviors. Participants expressed a strong desire for additional information regarding other beneficial lifestyle modifications. For example, they spoke frequently about increased awareness of their sleep patterns and need for improved sleep hygiene. Discussion on diet and nutrition was also extensive, including a desire for increased information on portion size, healthy choices, and water intake. Participants also discussed their novel awareness of the connection between mood and activity. They expressed a realization that exercise can improve mood and discussed the benefits of engaging in relaxation and mindfulness techniques. Increased awareness of benefits of PA, including mood, may generate an additional, novel reinforcing mechanism that increases the probability of future PA.

Similarly, social support was a recurrent theme, and the participants' comments suggest a relationship wherein social support is a vehicle for increased self-efficacy. Improved self-efficacy has been shown to substantially increase the probability of successful maintenance of health interventions, including smoking cessation [33], PA [34,35], and weight loss [36,37]. Participants' social networks, including accountability of partners, family, and key community members, were repeatedly juxtaposed with expressions of self-efficacy. Therefore, incorporating social networks in future interventions may improve self-efficacy and encourage sustained behavioral changes. Participants also referenced several opportunities for increasing social support from within the app, including the formation of competition and walking groups. They expressed the desire to be able to communicate and share resources with fellow community members, which was not an available feature within the app. Additionally, they described the relatability of the app content (ie, photos of heavier and older women engaging in PA) as a form of social support. Finally, they viewed the technology itself (Fitbit) to be a common ground around which they could form groups and connections within the broader community, for example, at local recreation facilities. Capitalizing on the broad impact of social support on motivation, self-efficacy, and adherence may further promote sustained behavioral changes among urban African American women.

Our findings affirm that using FGs to identify values, goals, experiences, and definitions of PA may result in more informed and, therefore, more effective strategies for PA promotion [28]. Having engaged the population of interest early in the process of app development allows us to incorporate key suggestions into future iterations of the app and, therefore, build the most accessible, efficacious platform for increasing PA within this community. As a result of participants' feedback, we will modify the app to increase user satisfaction by incorporating information about local parks and fitness classes. We will also increase the user relatability by redesigning the daily self-assessment and adding additional photographs that reflect the cohort's demographics and physical appearance. Finally, we will incorporate additional educational modules that reflect participants' desire for information on nonPA health behaviors.

Limitations

As this was a pilot study, the duration of the intervention was short, and the sample size was small. The study population was a convenience sample of middle-aged, African American women who were recruited from communities within Washington, DC metropolitan area. Although our findings may not be generalizable to other populations, they may be generalizable to other African American female residents of urban

environments. The use of the Fitbit PA app may have influenced participants' perceptions of the study app, but this was not assessed. Finally, due to technical difficulties, some participants were not able to access the entire app content, and we were unable to objectively evaluate the influence of the push notification message dissemination protocol on PA.

Comparison With Prior Work

Previous work has explored smartphone usage and willingness to participate in mHealth weight management research via quantitative data collection [6]. However, this study is the first to employ FGs for qualitative data collection of such information. Furthermore, this study is the first to employ FGs to guide the development of a culturally tailored app for a community-based, mHealth-enabled PA intervention among African American women. The findings from this FG reaffirmed previously cited barriers for African American women for engagement in PA [4].

Future Directions

Although culturally tailored push notification messages were the focus of this study, we plan to expand this approach to include geographically and personally tailored push notification messages as well. For example, the use of geographic information systems can provide suggested locations for safe sites for outdoor PA and increased awareness of existing community PA resources, such as recreation centers. Incorporating personally tailored step goals and push notification messages based on the real-time activity may further promote sustained PA as it has been shown that personalized, adaptive goal setting improves adherence to PA interventions [38,39]. It is thought that fixed, nonpersonalized PA goals can be discouraging to participants as goals may be either unrealistically high or, conversely, not adequately challenging [40-42]. Personalized PA goals can be accomplished through machine-learning techniques, as recently demonstrated by Zhou et al [42]. Incorporating these techniques in the future app development may strengthen user satisfaction and effects of the intervention.

Conclusions

This pilot study demonstrates that the development of mHealth-enabled interventions based on the qualitative CBPR methodology and community member engagement may improve future PA and cardiovascular health interventions. The resulting enhancements to the app may be useful in ameliorating health disparities and improving health outcomes of underserved, minority communities by increasing the likelihood of acceptability and utilization of mHealth by target users.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Community Advisory Board interview script for suggested push notification messages.

[[PDF File \(Adobe PDF File\), 39KB - formative_v3i1e10944_app1.pdf](#)]

Multimedia Appendix 2

Diagram of the motivational push notification message development process.

[[PPTX File, 39KB - formative_v3i1e10944_app2.pptx](#)]

Multimedia Appendix 3

Diagram of the pilot study push notification messaging strategy with educational modules.

[[PPTX File, 51KB - formative_v3i1e10944_app3.pptx](#)]

Multimedia Appendix 4

The Moderator's Guide.

[[PDF File \(Adobe PDF File\), 65KB - formative_v3i1e10944_app4.pdf](#)]

Multimedia Appendix 5

Focus group themes, subthemes, and quotes.

[[PDF File \(Adobe PDF File\), 64KB - formative_v3i1e10944_app5.pdf](#)]

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Abbreviations

BMI: body mass index

CAB: community advisory board

CBPR: community-based participatory research

FG: focus group

HBM: Health Belief Model

mHealth: mobile health

NIH: National Institutes of Health

PA: physical activity

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Original Paper

Use of a Biofeedback Breathing App to Augment Poststress Physiological Recovery: Randomized Pilot Study

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Abstract

Background: The speed of physiological recovery from stress may be a marker for cardiovascular disease risk. Stress management programs that incorporate guided breathing have been shown to moderate the stress response and augment recovery.

Objective: The aim of this study was to examine the effectiveness of an app-based brief relaxation intervention (BioBase) for facilitating physiological recovery in individuals exposed to a brief psychological stressor.

Methods: A total of 75 participants (44 women) completed a stressor speech task and were randomly assigned to one of three conditions: control, rumination, or an app-based relaxation breathing (BioBase) conditions. Heart rate variability (HRV) was assessed as a measure of autonomic function at baseline (6 min), during stress (6 min), and during recovery (6 min).

Results: There was a significant increase in subjective stress following stress exposure, but the ratings returned to baseline after recovery in all three groups. In addition, there was a significant decrease in vagally mediated HRV in the poststress period. During recovery, the root mean square of successive differences ($P<.001$), the percentage of successive interbeat (RR) intervals that differ by >50 ms (pNN50; $P<.001$), and high-frequency ($P<.02$) HRV were significantly higher in the BioBase breathing condition than the rumination and control conditions. There was no difference in HRV values between the rumination and control conditions during recovery.

Conclusions: App-based relaxed breathing interventions could be effective in reducing cardiovascular disease risk. These results provide additional utility of biofeedback breathing in augmenting physiological recovery from psychological stress.

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KEYWORDS

biofeedback; breathing; heart rate variability; recovery; rumination; stress

Introduction

Cardiovascular disease is one of the leading causes of premature death and disability in most westernized countries and accounts

for approximately 30% of deaths worldwide [1]. Its risk factors include genetic and congenital defects as well as behavioral factors such as diet, exercise, and smoking [2]. Another major risk factor for cardiac disease is mental stress [3,4]; mental

stressors are known to cause physiological and psychological changes due to the activation of the sympathetic nervous system and parasympathetic withdrawal [5]. These changes include increased heart rate; respiration; and production of various biological stress markers including adrenaline, cortisol, and alpha-amylase. Prolonged stress exposure or delayed recovery from stress responses (ie, how quickly an individual returns to a specified resting baseline), is thought to contribute to cardiovascular disease risk, as it causes wear and tear of the cardiovascular system [6]. Growing research evidence suggests that recovery from stress may be more predictive of cardiovascular health than cardiovascular reactivity to the stressor itself [7-9].

Stress is a part of life and cannot be completely avoided. Therefore, it is crucial to identify and develop techniques that can augment recovery from stress in order to prevent the development of chronic health problems such as cardiovascular disease. One effective method for the management of stress is the use of biofeedback systems [10]. Biofeedback is a mind-body self-regulation practice, wherein individuals learn how to regulate their thoughts, feelings, and behavior to modify their physiology through continuous physiological feedback. For example, by instantaneously translating heart rate onto a visual display, an individual can quickly learn how slow breathing can be used effectively to reduce the heart rate. Biofeedback training has beneficial effects on many symptoms of stress, including anxiety and depression, and improves the overall health [11].

There are many different physiological stress markers such as elevated blood pressure, heart rate, and cortisol levels, but this study focused on heart rate variability (HRV). Changes in HRV have been shown to reflect levels of stress induced by a mental stressor [12,13]. In addition, HRV is a marker of autonomic dysfunction, and a reduced HRV has been associated with an increased risk of cardiovascular disease and mortality [14-16]. HRV is considered a nonintrusive, objective, discrete measure of vagally mediated cardiac regulation. Vagally mediated HRV refers to the beat-to-beat variability in heart rate that is controlled by the parasympathetic nervous system via the vagus nerve. Regulating emotions is a key life skill, and emotional changes appear to occur simultaneously with changes in HRV. Thus, HRV may be a marker of emotional regulation, which is activated when individuals are under mental stress [13,17-20]. The heart rate increases slightly during inspiration and decreases slightly during expiration; slow breathing evokes respiratory sinus arrhythmia, through which the heart rate and breathing synchronize, thereby increasing oscillations within the heart. Respiratory sinus arrhythmia is used as an index of cardiac vagal tone (referring to the activity of the vagus nerve) and contributes to HRV. Deep, slow diaphragmatic breathing stimulates the vagus nerve, thus improving HRV and reducing stress responses. By slowing down breathing, an individual can learn to control his/her heart rate and, ultimately, the HRV by increasing parasympathetic activity [21].

HRV biofeedback has resurfaced in recent years, and biofeedback interventions have been effective after an emotional disturbance [22]. In addition, interventions that include breathing exercises have been shown to reduce stress responsivity in both the

laboratory and real world [23-25], although these interventions are time consuming and typically developed as part of a suite. For example, the body scan breathing exercise, which forms the basis of most mindfulness programs, requires repeated practice with typical sessions of ≥30 min [25], whereas some studies that incorporate breathing routines require attendance in 10 treatment sessions, each lasting 90 min [24]. Such interventions, although effective, require investment of a lot of time from users, and many people feel time starved. Therefore, easy-to-use parsimonious interventions that mitigate the effects of stress are clearly advantageous. It is now possible for mobile health interventions to incorporate biofeedback breathing exercises in order to help people regulate their emotions during acute periods of stress.

Technology has paved the way and provided an easy and accessible method to engage with and monitor stress levels. Breathing techniques and biofeedback can now be easily combined to create an effective coping tool for stress management. Mobile technology can be used to effectively deliver stress-management techniques [26,27]. Through consumer-grade sensors, mobile phones provide an excellent avenue for collecting continuous biometric data such as those on heart rate and HRV. Such applications allow people to access their HRV biofeedback and modify their breathing, thereby gaining better control over stress [28]. Deep-breathing mobile phone apps are easy to use and inexpensive and have the potential to reach a large population; thus, they have far-reaching implications for long-term health.

This study aimed to examine a commercial breathing app called BioBase [29] as a potential intervention to reduce poststress activation. The BioBase program reduces stress responsivity by coaching users through Papworth breathing exercises, both audibly and visually. The regulation of breathing triggers a vagal response to aid parasympathetic activation, leading to relaxation.

To test the efficacy of the BioBase app, we subjected participants to a standard psychological stressor task and then randomly assigned them to one of three conditions: the BioBase breathing app, rumination, and control conditions. The rationale for using a rumination condition was amplification of possible differences in HRV between the three conditions. We hypothesized that compared to the rumination and control conditions, the BioBase breathing app would enhance recovery following exposure to a stressful speech task.

Methods

Participants

A total of 75 participants were recruited to the study, including 44 (59%) women and 31 (41%) men, with an average age of 23.5 years (SD 6.39; range, 18-55 years). The sample predominantly identified themselves as white British (n=55, 73%) and the remainder, as Asian (n=8, 11%), white other (n=4, 5%), African (n=2, 3%), black British (n=1, 1%), Greek (n=1, 1%), Hispanic (n=1, 1%), mixed Hispanic (n=1, 1%), and Mauritian (n=1, 1%). All participants received a £15 gift voucher for their time. The study was approved by the ethics committee

of the University of Surrey, UK, and written informed consent was obtained from all participants (identifier: 1190-PSY-16).

Speech Task

During the stressor phase of the study, participants listened to a 2-min audio recording that described a situation where they had been falsely accused of stealing a purse and had to defend themselves to the police; this stressor has been used in previous studies (eg, [30]). The participants were instructed to imagine themselves in the scenario and were given 2 min to mentally think and prepare a statement for their defense in front of a video recorder. The recording stated that their speech would be evaluated and marked by the experts for fluency and confidence. This aimed to instill a social evaluative threat that has been shown to increase stress and rumination and induce physiological reactivity [31,32]. However, in reality, the speeches were not evaluated, as the performance ratings were not relevant to this study.

BioBase App

Participants in the BioBase condition were guided through a clinically validated version of the Papworth-Benson breathing exercise [33]. Originally developed at Papworth Hospital in Cambridgeshire, UK, more than 5 decades ago, this breathing method focuses on diaphragmatic breathing to use the full lung capacity and slow down breathing as well as trigger vagus nerve stimulation and consequently, the relaxation response. Through the process of photoplethysmogram and the use of the camera and flash on the mobile phone, the app measured changes in the user's heart rate during a guided breathing exercise and displayed their heart wave on the mobile phone screen in real time. Participants in the control and rumination conditions used a modified version of the Biobase app during the intervention period, which measured their heart rate, but did not guide them through the breathing exercise.

Self-report measures

Thoughts Questionnaire

Following a stress-exposure task, individuals may spontaneously ruminate [34] and therefore confound the results. To assess poststress rumination, we used a modified version of the Thoughts Questionnaire [35]. Items were rated on a 5-point scale, from 0 (*never*) to 4 (*very often*), on how often they thought about each item during the intervention period (eg, I made a fool of myself and how awkward I felt). The Thoughts Questionnaire has good internal consistency [36] and has been used in many previous studies to assess postevent rumination following the delivery of a speech task [32,37,38]. Cronbach's alpha for this measure was .81 in the present study.

Heart Rate Variability

HRV was captured during baseline, the speech task stressor, and poststress recovery by using a Biopac ECG100C amplifier (Biopac Systems Inc, Santa Barbara, CA). The electrocardiogram was recorded with a sampling rate of 1000 Hz.

Procedure

After entering the laboratory, participants were asked to read the information sheet explaining the study. After providing written consent, the participants completed a demographic questionnaire. They were subsequently fitted with electrodes and acclimatized to the Biopac amplifier. The Biopac amplifier recorded heart data continuously throughout the experiment. All participants then relaxed for 6 min while the experimenter left the room to minimize distraction. On resuming the exercise, the participants rated their level of stress using a 7-point visual analogue scale (1, *very little pressure* to 7, *extreme pressure*). Thereafter, the participants listened to the audio stressor recording for 2 min, as described above in the Speech Task section, and were given 2 min to prepare a statement for their defense. They then presented their statement for 3 min in front of the experimenter and a video camera. Subsequently, the participants rated their level of stress using the 7-point stress scale. Following the speech task, participants were randomly assigned using a random number-generator program [39] to one of the three groups (control, BioBase, or rumination) for 6 min. As this study was not a preregistered randomized controlled trial, it was considered a pilot study.

Participants assigned to the breathing condition used the BioBase app on the mobile phone and followed the guided breathing instructions. Individuals in the rumination condition were asked to think and reflect about their speech and focus on performance-based thoughts and were guided during this task by a modified version of the Thoughts Questionnaire [35]. Participants in the control condition were asked to sit passively. At the end of the intervention period, participants rated their level of stress. All participants then completed the original Thoughts Questionnaire [35] to measure the actual levels of rumination during the intervention phase. Finally, participants were disconnected from the equipment, fully debriefed, and given a gift voucher.

Data Analysis

All data were screened for measurement artifacts using the ARTiiFACT software [40] by one of the authors (SS) who was blinded to the conditions. Artifacts were identified using the algorithm developed by Berntson and colleagues [41], and a distribution-based threshold value calculated individually for each participant. Flagged beat intervals were visually checked and, if confirmed as artifacts, deleted and substituted by means of cubic spline interpolation of neighboring intervals. HRV analysis is typically performed in time or frequency domains. The time-domain measure root mean square successive difference (RMSSD) is considered to indicate vagally mediated HRV; values < 50 ms are considered unhealthy, values > 100 are considered healthy, and values in between indicate risk. The frequency-domain analysis high frequency (HF), which is considered to depict parasympathetic regulation, was also calculated for each person. Measurements and analyses followed established guidelines [42]. For the analysis, we grouped the HRV data into baseline, stressor, and intervention groups and analyzed 6-min segments, which are sufficient for HRV analysis [43]. Following the standard procedure, data were screened,

outliers above and below 3 SDs were excluded, and data were transformed where necessary.

Results

There was no significant difference between the groups with regard to demographic variables (gender, physical fitness, smoking status, general stress, and age), any baseline measures of subjective stress, or HRV. Ratings of perceived stress significantly increased from baseline (mean=2.01, SD 0.97) following completion of the stressor (mean=5.05, SD 1.37; $t=18.68$, $P<.001$), demonstrating successful experimental manipulation. Perceived stress returned to baseline levels in all three groups at the end of the recovery period. From the baseline period to the stress period, there was a significant increase in the heart rate (mean=78.59, SD 10.90 to mean=88.10; SD 13.25; $t=-8.60$; $P<.001$) and a significant decrease in the RMSSD (mean=44.13, SD 22.84 to mean=40.09, SD 15.56; $t=1.72$; $P=.04$), percentage of successive interbeat (RR) intervals that differ by >50 ms (pNN50; mean=17.75, SD=15.56 to mean=13.46, SD=11.18; $t=3.35$, $P<.001$), and HF (mean=2.77, SD=0.42 to mean=2.67, SD=0.37; $t=2.42$; $P=.01$; one-tailed), demonstrating autonomic activation in response to stress. There were no main effects of interaction or group. However, there was a significant difference between groups ($F_{1,2}=10.46$;

$P<.001$) in poststress rumination: The rumination group reported greater rumination (mean=1.97, SD 0.58) than the BioBase (mean=1.44, SD 0.79) and control (mean=1.37, SD 0.43) groups. There was no significant difference between the BioBase and the control groups in terms of poststress ruminative thoughts. Thus, the intervention manipulation was successful.

Cardiac Analysis

To examine the effects of the intervention on cardiac recovery in the poststress period, a between-subjects analysis of covariance for group (BioBase, rumination, and control) was conducted using the recovery measures as the outcome and the reactivity change score as a covariate. As individual differences in stress response could influence the findings, following previous research [9], we treated reactivity as a covariate to statistically remove the influence of reactivity on recovery. Apart from heart rate, a significant effect of group, with medium-to-large effect size, was found for RMSSD, pNN50, and HF. In addition, in all cases, the recovery rate was higher in the BioBase group than in the rumination and control groups. There were no significant differences between the rumination and control groups. Thus, individuals who used the breathing app demonstrated enhanced recovery from stress. The results of the analysis are presented in Table 1.

Table 1. Results of the data analysis. Values on each line with an asterisks (*) or dagger (†) were not significantly different from one another.

Parameter	BioBase group, mean (SD)	Control group, mean (SD)	Rumination group, mean (SD)	F value	P value	Effect size, partial eta squared
Heart rate, bpm	74.02 (9.25)*	78.52 (9.32)*	79.53 (10.40)*	2.58	.08	.07
RMSSD ^a	65.9 (20.51)	39.88 (20.73)*	43.77 (27.46)*	9.25	.001	.22
pNN50 ^b	30.14 (10.89)	16.26 (15.34)*	18.14 (15.34)*	9.17	.001	.21
High frequency ^c	2.97 (0.37)*	2.74 (0.39)*,†	2.65 (0.37)†	4.15	.02	.11

^aRMSSD: root mean square successive difference.

^bpNN50: percentage of successive inter-beat RR intervals that differ by >50 ms.

^cLog transformed.

Discussion

Principal Findings

As stress is an unavoidable part of life and the workplace becomes increasingly pressured, providing fewer opportunities for recovery, it is important to identify easy-to-use practical aids that can help individuals unwind and recover after the stressful period. The main finding of this study was that physiological recovery following stress exposure was enhanced in individuals who were guided through the BioBase breathing condition. This is an interesting finding because higher HRV is associated with reduced cardiovascular risks and other health outcomes [18,20,44].

We examined the effects of rumination on recovery in this study. Cognitive rumination has been defined as repetitive and intrusive negative thinking about past stressor(s) [45], and rumination is one of the main contributing factors that disrupts poststress recovery [46,47]. We were successful in manipulating

rumination in the laboratory; however, rumination in the present study was not associated with reduced HRV, as there was no significant difference in poststress recovery between the rumination and control groups (as compared to [48]), although both groups showed reduced HRV as compared to the BioBase group.

Although there was a difference between the groups with respect to physiological parameters during recovery, there was no difference in subjective stress, as the levels of perceived stress returned to baseline for all groups in the recovery period. This finding is intriguing and suggests that perceptions of and actual physiology are not always in accordance. Individuals may think they have recovered from the effects of stress but may be unaware of their actual physiological state. This may not be an issue in the short term, but a mismatch between one's psychological and physiological state could lead to long-term health issues over time, especially in individuals who are exposed to high levels of stress or work in demanding jobs.

Interventions aimed at increasing sensitivity to one's internal body state—perhaps, by enhancing interoceptive awareness—are needed. Somatic, or interoceptive awareness, could be defined as one's perceptual awareness of signals from the inside the body, such as heartbeats, breathing, bowel movements, and higher-order processes including beliefs and attitudes as well as emotions regarding those perceptions [49-51]. Interoceptive awareness can be measured and trained. Such training might rely on the fact that simply noticing feelings, particularly bodily sensations associated with particular feelings, can foster emotional regulation. This is an aspect of mindfulness training that has been previously explored in studies of meditation training on interoception [52,53]. In the future, studies should focus on the integration of multimodal systems such as digital screen-based devices (mobile phones) and multidimensional theoretical models of interoception that take into account measurement of autonomic nervous system disruption using HRV data in order to build multimodal, digital therapeutic systems that measure interoception as well as offer training experiences that might help manage anxiety-based disorders embedded in apps such as BioBase.

Limitations

There are some caveats with this present study. Heart rate monitoring was stopped after 6 min; therefore, we do not know how long the actual effect on HRV lasted. It will be of interest for future studies to establish the benefits of guided breathing

over time and examine whether the effect fades, stabilizes, or increases with repetition. Repeated use of the guided breathing app may help individuals who chronically experience stress to recover more quickly physiologically and improve their health outcomes and functioning. Although physical fitness has been associated with enhanced physiological recovery from stress [7,54], we did not assess the levels of physical fitness in this study, which could be perceived as a limitation. However, there was no significant difference between the groups in terms of self-reported physical activity, and therefore, it seems extremely unlikely that physical fitness could account for the difference between the conditions in HRV recovery. Nonetheless, future research should control for levels of fitness to completely rule out the possibility that fitness played a key role in our findings.

Conclusions

Given the ubiquitous nature of stress and the documented evidence associating stress with cardiovascular disease and mortality, it is important to identify affordable and practical aids that help individuals unwind and recover after the stressful period. To our knowledge, this is the first study to examine the effects of the BioBase breathing app on HRV under controlled conditions and provide evidence for its efficacy in aiding poststress recovery. These findings also provide evidence of the utility of biofeedback breathing in augmenting physiological recovery and suggest that app-based breathing interventions are effective in reducing cardiovascular disease risk.

Acknowledgments

Editorial notice This randomized study was non-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, guiding the development of the application. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness.

Conflicts of Interest

DP, DM, and LO are employees of a commercial company, BioBeats Group Ltd, London, UK. The other authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Abbreviations

HF: high frequency

HRV: heart rate variability**M:** mean**RMSSD:** root mean square successive difference

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Original Paper

A Virtual Reality Food Court to Study Meal Choices in Youth: Design and Assessment of Usability

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Abstract

Background: Regular consumption of take-out and fast foods with sugary drinks is associated with poor quality diets and higher prevalence of obesity. Among the settings where such food is consumed is the food court typically found in shopping malls prominent in many countries.

Objective: The objective of this research was to develop a virtual reality food court that could be used to test food environmental interventions, such as taxation, and ultimately to facilitate the selection of healthier food choices.

Methods: Fourteen food courts in Sydney, Australia were selected to include those in the city center and suburbs of high and low socioeconomic status. Researchers visited the courts to collect information on number and type of food outlets, all menu items for sale, cost of foods and beverages and sales promotions. This information was used to assemble 14 food outlets typically found in food courts, and representative menus were compiled. The UNITY gaming platform was used to design a virtual reality food court that could be used with HTC VIVE goggles. Participants navigated the virtual reality food court using the head-mounted display, keyboard, and mouse and selected a lunch meal, including food and beverage. A validated questionnaire on presence within the virtual reality food court and system usability was completed at the end of the session. The constructs for presence included a sense of control, sensory fidelity, realism, distraction, and involvement. Questions were rated on a scale from 1 (worst) through 7 (best) for each of 28 questions giving a maximum total score of 196. The systems usability scale (SUS) that gives a final score out of 100 was also assessed.

Results: One hundred and sixty-two participants with a mean age of 22.5 (SD 3.1) years completed the survey. The mean score for total presence was 144 (SE 1.4) consisting of control: 62.1 (SE 0.8), realism: 17.5 (SE 0.2), involvement: 9.6 (SE 0.2), sensory fidelity: 34.9 (SE 0.4), and distraction: 24.0 (SE 0.3). The mean SUS was 69 (SE 1.1).

Conclusions: Virtual reality shows promise as a tool to study food choice for test interventions to inform practice and policy.

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KEYWORDS

virtual reality; nutrition promotion; food policy; take-out food; obesity; young adults

Introduction

The world is currently experiencing an obesity epidemic [1]. An association between transactions for fast food meals per capita and population body mass index has been demonstrated

in the member countries of the Organization for Economic Cooperation and Development (OECD) [2]. Policies that aim to limit the consumption of these foods are recommended. Among the suggested approaches are energy and nutrition

labeling, regulation of food advertising, incentives for healthier choices, taxation, and reformulation [3].

Adolescents and young adults show the highest rates of weight gain [4], have the poorest quality diets [5] and are more likely to eat meals out including take-out meals [6]. They are an age group vulnerable to advertising [7] and they are sensitive to price, [8] so that cheap and tasty meals hold considerable appeal. Clearly, among the actions to be taken to curb obesity rates in this demographic must be intervention in the fast and take-out foods sector. One venue where young people congregate in many OECD countries is the shopping mall and its food court. Conducting experiments in this setting is met with many barriers and food outlet owners may require evidence that any measures imposed on them will achieve the intended aim of changing rates of overweight and obesity. A number of countries have enforced the display of calorie counts on fast-food menu boards [9]. While these have led to greater awareness of energy contents and better choices by those who use them, only about 30% of people do so [10]. We propose that virtual reality may offer a means to test the potential efficacy of different policy approaches before they are implemented in real-world trials.

Previous research with virtual reality supermarkets in the Netherlands, New Zealand, and United Kingdom (UK) and a virtual reality buffet in the United States has shown high acceptability of such a platform and report that behavior is similar to that in the real world [11-15].

The aim of this study was to develop a virtual reality food court (VRFC) and to test its usability, and factors associated with presence in a sample of young adults. Presence in virtual reality is the phenomenon of being present in the computer-generated environment rather than the real world around oneself [16]. Establishing presence was believed to be an important step if the virtual food court environment will be used to predict food choices in the real world.

Methods

Development of the Virtual Reality Food Court

Fourteen food courts that included those in the central business district and across the suburbs of a major global city with a population of five million were visited. Food courts in suburbs of both higher and lower socioeconomic status were selected. Information was collected on the number and type of food outlets, all menu items for sale and cost of foods and beverages. Photographs of all displays were taken. The nutritional composition of foods and beverages for sale was compiled into a database. Nutrition information was obtained from both the

Australian Food, Supplement and Nutrient Database (AUSNUT) 2011-13 [17] and the commercial outlets' websites. This included both macronutrients and micronutrients of interest because of potential deleterious effects (ie, energy, protein, total fat, saturated fat, carbohydrate, total sugars, dietary fiber, and sodium). The database values included a nutrient composition for the serving sizes for sale as well as the composition per 100g.

The similarities in food outlets across all food courts allowed compilation of menu items into 14 representative stores. As an example, there were typically three major chains of stores selling chicken fast-food products and a menu incorporating food items for all three was used for one store. This meant it sold chicken burgers, chicken wraps, and rolls, chicken salads, whole chicken, portions of chicken and nuggets that were fried, roasted and grilled as well as side dishes such as vegetables, salads, and sauces. The names selected for the stores were purposely different to any commercial names so as not to infringe any registered trademarks. These were a burger outlet (My Burger), a fried and barbecued chicken outlet (Clucky Fried Chicken), a sandwich chain outlet (Sandwich King), an independent sandwich outlet (Sandwich House), doughnut outlet (Donut World), muffin outlet (Muffin Mania), café outlet (Glory Coffee), salad bar outlet (Salad Soul), juice bar outlet (The Juice Team), seafood outlet (The Fish Net), sushi outlet (Sushi Besuto), an outlet selling Asian cuisine (Little Asia), a kebab outlet (Turkish Kebabs) and an outlet selling Indian cuisine (Taste of India). The menu boards were made to resemble those in the real-world food court using the photo images collected as a reference point. The pricing of food items was based on the prices collected during the initial visits to the real food courts and confirmed on the outlet's websites. Screenshots of the overview of the VRFC and an individual outlet with menu boards are shown in Figures 1 and 2. In total 515 foods and condiments and 219 beverages were available for sale across the 14 food outlets.

The gaming development platform, UNITY 5.4.0, was used to construct the VRFC which was made compatible with an HTC VIVE head mounted display (HMD). The Asus G751JY was used to host the VRFC. The VRFC was developed to allow various menu boards and promotional posters to be uploaded so that modified versions of the same outlets with the same menus can be used in randomized controlled trials of the court under varied conditions. For example, boards that have taxed conditions on sugar-sweetened beverages can be loaded; posters that show the public health dangers of excess sugars can be displayed within the court.

Figure 1. Overview of the virtual reality food court.**Figure 2.** An individual food outlet within the virtual reality food court.

Study Procedure

Once developed the food court was tested in a sample of young adults recruited in the real food court of a large urban university (>60,000 students). The venue was selected as it provided the sounds and smells that one encounters in a real food court. Researchers distributed recruitment flyers to participants at the food court during typical lunch hours of 11 am until 2 pm. To be included in the study, subjects had to be aged 18 to 35 years of age. Those who regularly experienced motion sickness were excluded. All subjects gave informed consent. The study was approved by the Institutional Human Research Ethics Committee (Project 227).

Subjects received instructions regarding the HTC VIVE HMD and navigation in the virtual reality food court. They were asked to select a lunch meal, including food and beverage, up to the

value of Aus \$10 that was adequate to cover the costs of a sandwich, burger or hot meal choice and beverage or a meal deal with beverage included. After they had made their choice the participants were asked to complete questionnaires regarding the system usability and presence in the food court. Participants received Aus \$10 as compensation for their time.

Study Measures

Presence and System Usability

Each subject had their age, gender, and meal purchases (ie, food and beverage) recorded. All participants completed an online questionnaire that included questions on usability and presence. The presence questionnaire was based on the 32 item Presence Questionnaire developed by Witmer and Singer [16] which has been demonstrated to have high internal validity and repeatability. The factors contributing to presence are control

in the activities of the virtual experience, realism of the environment, the sensory fidelity of the environment and distraction in the virtual environment. Items 6,15,16 and 17 of the questionnaire were excluded in this study because no sound and touch were offered by the virtual reality game with sound and food smell restricted to those within the chosen real food court where the experiments were conducted. All 28 questions were scored on a seven-point scale.

Nine items on system usability from the scale originally developed by Brooke [18] (question 2 to 10) were included and participants rated questions on a scale with strongly disagree at one end and strongly agree at the extreme end. The item concerning frequent use of the court was excluded as it was not expected this virtual reality experience would be used in the same participants on repeated occasions.

Statistical Analysis

For each of the questionnaire items measuring presence, the response for each score of 1 to 7 was calculated and tabulated. These were then grouped and analyzed according to the factor it measured: control (items 1, 2, 3, 7, 12-14, 21, 25-27, 29, 31), realism (11, 12, 14, 22), sensory fidelity (4, 5, 10, 14, 18-20), and distraction factors (8, 9, 24, 28-30). A subscale item of involvement was also scored (23, 32). For responses to items 8, 9, 11, 22, 24, 25, 28, and 29, a higher score is actually a negative outcome for the VRFC. Thus, to calculate the total score and mean for each factor the scales have been reversed so that score 7 would now correspond to score 1 and score 1 would now be score 7. Usability was assigned an overall score out of 100 in accordance with the scoring method. The number

of foods and beverages purchased from each outlet were compiled. All statistics were conducted using Microsoft Excel.

Results

Participant Characteristics

A total of 162 young adults gave consent to participate in the study and completed the presence and the usability questionnaire and all of these results were included. However, only 157 (96.9%) completed their purchase of food. Failure to complete was due to feeling uncomfortable wearing the HTC VIVE HMD and nausea.

Food and Beverage Purchases

All 14 food outlets were visited for lunch. Flavor of India was the most popular outlet for food and beverages. The fish burger (5.1%) from The Fish Net was the most common food item purchased. Canned regular cola was the most commonly purchased drink (19.1%) followed by all types of fruit juices (15.3%). [Table 1](#) shows the number of purchases from each outlet.

Presence

[Table 2](#) shows the results for each of the presence questions. [Table 3](#) shows the mean total presence and the scores for the factors (ie, control, sensory fidelity, realism, distraction, and involvement).

Usability

The second section of the VRFC questionnaire measured system usability and the mean systems usability scale score was 69.0 (SE 1.1) out of a possible 100.

Table 1. The frequency of food and beverages choices in the virtual reality food court.

Outlets	Food, n (%)	Beverage, n (%)
Clucky Fried Chicken	20 (12.7)	8 (5.1)
Donut World	2 (1.3)	5 (3.2)
Flavor of India	30 (19.1)	35 (22.3)
Glory Coffees	1 (0.6)	17 (10.8)
Juice Team	1 (0.6)	3 (1.9)
Little Asia	8 (5.1)	9 (5.7)
Muffin Mania	9 (5.7)	13 (8.3)
My Burger	16 (10.2)	9 (5.7)
Salad Soul	5 (3.2)	5 (3.2)
Sandwich House	1 (0.6)	3 (1.9)
Sandwich King	11 (7.0)	8 (5.1)
Sushi Besuto	18 (11.5)	13 (8.3)
The Fish Net	22 (14.0)	21 (13.4)
Turkish Kebabs	13 (8.3)	8 (5.1)

Table 2. Presence questionnaire items with the percentage of respondents for each of the seven scores.

Questionnaire items	Score responses, n (%)						
	1	2	3	4	5	6	7
1. How much could you control events	0 (0)	4 (2.5)	10 (6.2)	27 (16.7)	59 (36.4)	50 (30.9)	12 (7.4)
2. How responsive was the VRFC ^a to your actions	3 (1.9)	4 (2.5)	16 (9.9)	27 (16.7)	51 (31.5)	47 (29.0)	14 (8.6)
3. How natural were your interactions in the VRFC ^a	2 (1.2)	16 (9.9)	31 (19.1)	40 (24.7)	39 (24.1)	25 (15.4)	9 (5.6)
4. How completely were all your senses engaged	0 (0)	5 (3.1)	26 (16.1)	29 (17.9)	45 (27.8)	44 (27.2)	13 (8.0)
5. How much did the visual aspects of the VRFC ^a engage you	1 (0.6)	4 (2.5)	19 (11.7)	20 (12.4)	47 (29.0)	55 (34.0)	16 (9.9)
7. How natural was the mechanism controlling movement	2 (1.2)	15 (9.3)	26 (16.1)	40 (24.7)	50 (30.9)	24 (14.8)	5 (3.1)
8. How aware were you of events in the real world around ^b	15 (9.3)	25 (15.4)	25 (15.4)	29 (17.9)	35 (21.6)	23 (14.2)	10 (6.2)
9. How aware were you of the display and controls ^b	0 (0)	3 (1.9)	19 (11.7)	30 (18.5)	53 (32.7)	37 (22.8)	20 (12.4)
10. How compelling was your sense of objects moving	0 (0)	6 (3.7)	19 (11.7)	46 (28.4)	53 (32.7)	27 (16.7)	11 (6.8)
11. How inconsistent was the information from your senses ^b	8 (4.9)	24 (14.8)	37 (22.8)	43 (26.5)	32 (19.8)	15 (8.6)	4 (2.5)
12. Consistency of experiences in VRFC ^a with those in real food court	1 (0.6)	13 (8.0)	24 (14.8)	34 (21.0)	56 (34.6)	28 (17.3)	6 (3.7)
13. Could you anticipate happenings in response to actions	1 (0.6)	5 (3.1)	16 (9.9)	25 (15.4)	58 (35.8)	34 (21.0)	23 (14.2)
14. Completeness of searching of VRFC ^a with your vision	0 (0)	2 (1.2)	12 (7.4)	23 (14.2)	54 (33.3)	53 (32.7)	18 (11.1)
18. How compelling was your sense of movement in VRFC ^a	2 (1.2)	7 (4.3)	23 (14.2)	29 (17.9)	50 (30.9)	34 (21.0)	17 (10.5)
19. How closely could you examine objects in the VRFC ^a	2 (0.6)	2 (1.2)	15 (9.3)	19 (12.3)	39 (24.1)	55 (34.0)	31 (18.5)
20. How well could you examine from multiple viewpoints	0 (0)	3 (1.9)	16 (9.9)	35 (21.6)	59 (36.4)	33 (19.8)	17 (10.5)
21. How well could you manipulate objects in VRFC ^a	20 (12.4)	11 (6.8)	20 (12.4)	31 (19.1)	43 (26.5)	28 (17.3)	9 (5.6)
22. Degree of confusion at end of VRFC ^a experience ^b	24 (14.8)	33 (20.4)	31 (19.1)	16 (9.9)	38 (23.5)	16 (9.9)	4 (2.5)
23. How involved were you in the VRFC ^a	0 (0)	5 (3.1)	13 (8.0)	26 (16.1)	57 (35.2)	43 (26.5)	18 (11.1)
24. How distracting was the control mechanism ^b	12 (7.4)	26 (16.1)	41 (25.3)	37 (22.8)	29 (17.9)	12 (7.4)	5 (3.1)
25. How much was the delay between actions and outcomes ^b	51 (31.5)	47 (29.0)	25 (15.4)	19 (11.7)	13 (8.0)	6 (3.7)	1 (0.6)
26. How quickly did you adjust to the VRFC ^a	1 (0.6)	3 (1.9)	19 (11.7)	20 (12.4)	36 (22.2)	52 (32.1)	31 (19.1)
27. How proficient in movement and interaction did you feel at the end	0 (0)	4 (2.5)	11 (6.8)	41 (25.3)	50 (30.9)	38 (23.5)	18 (11.1)
28. How much did the visual display cause distraction from activities ^b	10 (6.2)	30 (18.5)	25 (15.4)	30 (18.5)	45 (27.8)	19 (11.7)	3 (1.8)
29. How much did the controls interfere with activities ^b	11 (6.8)	26 (16.1)	25 (15.4)	36 (22.2)	45 (27.8)	16 (9.9)	3 (1.9)
30. How well could you concentrate on tasks rather than the mechanisms	2 (1.2)	5 (3.1)	17 (10.5)	23 (14.2)	51 (31.5)	40 (24.7)	24 (14.8)
31. Did you learn new techniques to improve performance	6 (3.7)	13 (8.0)	14 (8.6)	24 (14.8)	54 (33.3)	36 (22.2)	15 (9.3)
32. Were you so involved in the VRFC ^a tasks that you lost track of time ^b	7 (4.3)	11 (6.8)	24 (14.8)	34 (21.0)	41 (25.3)	31 (18.5)	15 (9.3)

^aVRFC: virtual reality food court.^bHigher scores are better except for items marked with superscript a lower score is better.

Table 3. Total presence and presence factor scores for each factor.

Presence factor	Range ^a	Mean (SE)
Total presence	28-196	144.0 (1.4)
Control	13-91	62.1 (0.8)
Sensory	7-49	34.9 (0.4)
Realism	4-28	17.5 (0.2)
Distraction	6-42	24.0 (0.3)
Involvement	2-14	9.6 (0.2)

^aThe range indicates the minimum and maximum score possible.

Discussion

Effective policies and regulation around food and beverages are needed to reverse the obesity epidemic [19]. There are numerous suggestions such as restricting promotions of unhealthy foods and instead promotion of healthy foods in retail outlets, energy and nutrient labeling on menu boards, increased taxes on unhealthy foods and drinks and subsidies for healthy foods [19]. Among the reasons that stakeholders may be resistant to legislation is the lack of proof of effectiveness such changes produce the desired outcomes on food consumption. Virtual reality might afford the opportunity to simulate experiments to produce evidence to enable real-world experiments. The results from the current study encourage the further development of the VRFC in order to enable a future study of food choice when conditions are manipulated in order to encourage healthier choices.

The similarities between the take-out outlets across 14 food courts simplified the process of constructing a representative VRFC. Furthermore, there were usually one or more similar chain stores such as different burger franchises or fried or barbecued chicken outlets that enabled the compilation of food and beverage products offered into a single menu for one outlet to represent these. There is considerable overlap in menus of these fast food outlets in many countries so that minimal change might be needed to use the VRFC, however, in terms of serving size and the nutritional formulation, there are noted differences for the same product between countries [20]. This would mean that country-specific nutritional databases would be needed to replace the current one developed for Australia. When the VRFC is used in future experiments to test the impact of nutritional labeling or taxation of a nutrient, such as fat or sugars, on improved diet quality, it is essential to have the appropriate nutrient database.

Participants purchased foods and drinks from every outlet indicating all were recognized and reasonable usability of the VRFC system was confirmed. Factors for control, sensory, realism, and involvement indicated the presence in the VRFC but the distraction was centered on neutral ratings. Realism measures the consistency of information from an individual's senses and vision in the court as well as the consistency of the experience with the real world and confusion after leaving the VRFC. Distraction measures how much the mechanisms of using the VRFC interfere with the experience. However closely a virtual reality experience mimics the real world, wearing

goggles and using controls are reminders this is not the real world but this does not necessarily negate the utility of virtual reality environments for food choice decisions. It has been stated that one of the most important attributes of a virtual reality environment is that the participant feels that objects in the environment are immediately actionable [21]. Our assessment demonstrated participants mostly felt in control and they experienced little delay between actions and outcomes.

Others researchers have used virtual reality to study food selection in a variety of settings and with different populations. Waterlander and colleagues have developed and validated 3-dimensional virtual reality supermarkets [12-14]. Using the UNITY platform (used in the current research) a Dutch virtual reality supermarket was designed with initial testing indicating 83% of participants found it easy to use and 79% reported their virtual purchases resembled those in the real world [14]. A recent adaptation of the software to simulate a UK supermarket was similarly tested with 83% finding it easy to use and 89% reporting it resembled their purchases in the real world [12]. The researchers provided further evidence of the validity of the virtual reality supermarket by conducting an experiment whereby they had virtual shoppers collect their till receipts at a subsequent shop at a real supermarket [13]. Seventy-four of the 123 (60.2%) completed 3 shopping experiences in this manner. The mean budget participants set for the Virtual Supermarket was NZ \$121.19 (SD 65.01) but they only spent 71.4% (SD 25.6%) of their budget. Their expenditure for the four most expensive food groups (ie, fruit and vegetables, bakery goods, dairy and meat and fish in the real world) was similar to the expenditure in the virtual world.

Presence in the virtual supermarket was assessed using the Presence Questionnaire Items Stems examining the domains of sensory fidelity, focus, immersion, involvement and interface quality. Overall the participants rated their presence as medium but high scoring was noted for the interface quality [13]. One difference between the current research and the supermarket is that the experiments are conducted on a computer screen and not with headsets. One might expect that the addition of headsets would lead to greater presence. The questionnaire used in the supermarket study has some differences to that used for the VRFC but overall the ratings for factors seem comparable with moderate to high scoring.

Van Herpen et al [11] compared the effects of a real supermarket, 3-dimensional virtual supermarket and 2-dimensional photographs with an experiment on spending in

3 food categories: fruit and vegetables, milk and biscuits. As for the other supermarkets cited above, the simulation was viewed on a computer screen with keyboard and mouse navigation. Interestingly, they found similarities and differences between the real and virtual environments for the different product categories (ie, virtual reality more closely approximated the viewing), selection of products, and spending in the milk category than photographs. However, for the other 2 food categories the virtual supermarket and photographs were similar and both differed from the real supermarket. The researchers caution that while virtual reality may be useful for studying food selections and food environment interventions that the inclination to buy more foods and varieties must be accounted. However, in the current VRFC experiment subjects were only asked to purchase the food and beverage for one meal and given a fixed budget. This is a much less complex activity than completing shopping at the supermarkets which in some cases had more than 600 items on sale. It has also been reported that assigning a budget in a virtual supermarket leads to purchases closer to reality and this is why we selected an appropriate amount of money to spend, for these young adult participants who were mostly students, in the VRFC [13].

Another experiment using virtual reality environments for food choice may more closely approximate the conditions in the current study. Persky et al [15] created a virtual reality food buffet to assess how parents feed their young children. Fifty-two parents of children aged three to seven years participated in an experiment to validate the buffet by serving portions of juice and a pasta dish in the virtual and real-world settings. Both demonstrated a high correlation of virtual and real selections for the serving size. Parents also used the whole buffet to select a meal for their child and reported they were able to select a meal typical of what they might feed to their child [15].

Another use of virtual reality for food choice in differing food environments has been in the area of emotional response to foods. Gorini et al [22] have studied the differences in emotional responses in exposure to real food, virtual reality food and food photographs in patients with eating disorders. They found that the self-reported and monitored physiological responses to virtual reality food were comparable but food photographs failed to elicit the same response. Ferrer-Garcia et al [23] extended this concept to healthy subjects. They designed 4 different virtual reality scenarios to study the effects of high and low-calorie food environments in restaurant and kitchen settings on food cravings in a group of female college students. They found that the food craving elicited in the virtual environment, high-calorie food scenarios evoked stronger cravings and was the same as reported in real-world scenarios. Body mass index or self-reported subclinical eating disorder symptoms did not alter the findings. Together these two experiments validate the

use of virtual reality environments to study reactions to food although not necessarily food selection in a virtual environment.

VR food environments have strengths as discussed above but it must be stated that their validity has limitations. Validity testing in two studies cited has used self-report as to whether the choices are like those in their real world [12,15]. Obviously, some reporting bias might be expected and we decided not to ask such a question in this study. It is acknowledged the Persky et al [15] study validated the serving sizes but only for one dish and beverage which may be a relatively simple exercise. The incongruent findings for different product categories in the 2 supermarket validations show we cannot be certain that when an intervention is conducted in a VR setting a positive finding can be extrapolated to the real world [11,13]. Further research on congruence between settings is required but conducting a randomized controlled trial in both virtual and real-world settings for validation simultaneously is not suggested. Rather testing in the virtual followed by the real-world is a better approach.

There are several strengths of using the VRFC over the real-world food court. Firstly, the cost of running interventions in complex real-world experiments may be prohibitive. Secondly, it removes potential conflicts of interest in collaborating with food retailers. Thirdly, we visited 14 food courts in the city and suburbs and in areas of differing socioeconomic status. As little difference in the food outlets across areas was found the virtual food court is a realistic compilation of stores and menus complete with a nutritional database of foods and prices and lastly, the participants reported an acceptable level of presence.

A limitation of the current VRFC is that we used the computer keyboard for navigation that confined them to a desk and we are unable to directly simulate sensory aspects associated with food choice such as smell and perhaps touch. Further improvements to the system are indicated and will be actioned before the VRFC is used in different experimental conditions. These include improving movement within the VRFC to make it more natural. Hand controls will be used instead of a keyboard to enable participants to move around to examine objects. Improvements in the ability to close in on the menu boards of the food outlets to examine all aspects more closely such as price and calorie labels will be enabled.

In summary, after some improvements to usability to enhance presence, the VRFC may prove useful in the conduct of experiments testing effects of taxation, pricing and promotions on food choice within this popular food environment. Obtaining such evidence is a step forward in understanding consumer behavior when changes are made to the food environment. If virtual reality studies provide positive results, the experiments must be duplicated in real-world settings to establish validity.

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Authors' Contributions

MAF, RAC, KI, LWC, SR, and HP contributed to the conception and design of the research. HT and JL conducted the data collection. HT, JL, and MAF analyzed the data and MAF drafted the first version of the manuscript. All authors read and approved the final manuscript.

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Abbreviations

AUSNUT: Australian Food, Supplement and Nutrient Database

HMD: head mounted display

OECD: Organization for Economic Cooperation and Development

UK: United Kingdom

VRFC: virtual reality food court

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Original Paper

Evaluation of a Mobile Device Survey System for Behavioral Risk Factors (SHAPE): App Development and Usability Study

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Abstract

Background: Risk factors, including limited exercise, poor sleep, smoking, and alcohol and drug use, if mitigated early, can improve long-term health. Risk prevalence has traditionally been measured using methods that now have diminished participation rates. With >75% of American citizens owning smartphones, new data collection methods using mobile apps can be evaluated.

Objective: The objective of our study was to describe the development, implementation, and evaluation of a mobile device-based survey system for behavioral risk assessment. Specifically, we evaluated its feasibility, usability, acceptability, and validity.

Methods: We enrolled 536 students from 3 Vermont State Colleges. Iterative mobile app development incorporated focus groups, extensive testing, and the following 4 app versions: iOS standard, iOS gamified, Android standard, and Android gamified. We aimed to capture survey data, paradata, and ambient data such as geolocation. Using 3 separate surveys, we asked a total of 27 questions that included demographic characteristics, behavioral health, and questions regarding the app's usability and survey process.

Results: Planned enrollment was exceeded in just a few days. There were 1392 "hits" to the landing page where the app could be downloaded. Excluding known project testers and others not part of the study population, 670 participants downloaded the SHAPE app. Of those, 94.9% of participants (636/670) agreed to participate by providing in-app consent. Of the 636 who provided consent, 84.3% (536/636) were deemed eligible for the study. The majority of eligible respondents completed the initial survey (459/536, 85.6%), whereas 29.9% (160/536) completed the second survey and 28.5% (153/536) completed the third survey. The SHAPE survey obtained 414 participants on the behavioral risk items in survey 1, which is nearly double the 209 participants who completed the traditional Vermont College Health Survey in 2014. SHAPE survey responses were consistent with the traditionally collected Vermont College Health Survey data.

Conclusions: This study provides data highlighting the potential for mobile apps to improve population-based health, including an assessment of recruitment methods, burden and response rapidity, and future adaptations. Although gamification and monetary rewards were relatively unimportant to this study population, item response theory may be technologically feasible to reduce individual survey burden. Additional data collected by smartphones, such as geolocation, could be important in additional analysis,

such as neighborhood characteristics and their impact on behavioral risk factors. Mobile tools that offer rapid adaptation for specific populations may improve research data collection for primary prevention and could be used to improve engagement and health outcomes.

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KEYWORDS

mobile phone; demographic characteristics; health surveys; risk behaviors; mobile apps

Introduction

Monitoring risk behavior prevalence is critical for public health planning and interventions. Early mitigation of specific risk factors for poor health, such as limited exercise, poor sleep, mood disorders, smoking, and drug and alcohol use, can prevent serious long-term health consequences in the general population. Across the United States, 25% of adults smoke [1]. With only 21% of US adults meeting the recommended levels of physical activity [1], it is not unexpected that over a third (35.8%) are overweight [2]. Alcohol abuse and dependence are highly prevalent [3-5], as are serious mood disorders [6] and illegal drug abuse [7]. Although there are smartphone apps that measure many risk factors [8-12], there is currently no ability to rapidly collate the results of these measurements to determine the population-specific risk prevalence that can be used for public health planning and interventions.

Risk prevalence is currently measured through telephonic surveys using methods such as random digit dialing (RDD) that now faces ever-diminishing participation rates among eligible subjects and bias because of migration from landlines to mobile phones [13]. The Behavioral Risk Factor Surveillance System [14] is the largest RDD survey in the United States with 500,000 annual respondents, but it has suffered a 20% drop in response rates during the past decade [15]. Nonresponse can vary significantly across different demographic and geographic groups. Although procedures to adjust for this nonresponse can be utilized, they may result in diminished statistical precision [16]. As in many other fields (including preelection polling), telephone surveys are increasingly unreliable, and the search for a modern-day alternative is justified to ensure the continuity of valid measurements. Collecting survey data using smartphone apps may offer many advantages, including the potential to collect geolocation, scanning, photo, and video data. Over 75% of American citizens now own a smartphone [17], and underrepresented groups have often been quick to adopt this technology and forgo landline telephones [18].

Web surveys have been used to collect information on sensitive behaviors. However, the mode of survey administration was found to affect responses for about one-third of variables in one study (the British National Survey of Sexual Attitudes and Lifestyles), which compared a Web survey interview design with computer assisted personal interview and self-interviews [19]. Other criticisms of Web surveys include the lack of research on the effects of format or design on the levels of unit and item response or data quality [20] and the lack of representativeness compared with the general population [21].

Although surveys have been conducted to determine how mobile phone owners use health apps [22,23], few papers provide detail on how to develop a survey app specifically designed to administer a variety of surveys [24]. A framework for developing the survey apps was proposed by Buskirk and Andres [25] who presented an outline of app-based smartphone survey approaches. Davis and Oakley-Girvan [26] provided strategies to improve testing and validation of mobile apps, including iterative testing, enhanced user engagement, reduced burden, and appropriate infrastructure to reduce downtime and meet Health Insurance Portability and Accountability Act (HIPAA) privacy and confidentiality of personal health information requirements.

This study focuses on developing, implementing, and pilot-testing a mobile survey system to collect behavioral risk data from college students and addresses the following questions:

- Feasibility: Can the target population be recruited to download and use the app?
- Usability: Can an app be developed that is easy for people to understand and quick to use?
- Acceptability: Will respondents allow access to phone-captured ambient data?
- Validity: How well do the app data correspond to traditionally collected data from the target population?

The hypothesis was that utilizing an iterative development and testing approach would yield an effective app with low burden and high acceptability to collect behavioral health and demographic characteristics consistent with previous benchmarks. This paper presents the results of this pilot study that addresses the 4 questions provided above.

The objective of this paper was to describe the development and evaluation of a mobile app to administer behavioral health-related surveys on iOS (Apple) and Android platforms with at least 500 pilot users from 3 small northeastern colleges and at least 20 behavioral health-related survey questions. We chose a college population because the characteristics of the entire population were already known through other survey mechanism. Similar survey questions had already been collected on this population through traditional RDD telephone and Web surveys which provided a comparison for our mobile phone app survey results. The evaluation was developed to include a process to encourage individual enrollment by downloading the mobile app, providing a mechanism to invite users to respond to consecutive short surveys within the mobile app, and capitalizing on the ability to pull location from users' mobile phone.

Methods

Study Protocol Summary

The study population included students enrolled in 3 Vermont State Colleges (Castleton University, CU; Lyndon State College, LSC; and Johnson State College, JSC). In the summer of 2016, we conducted a focus group with a convenience sample of CU students (n=9) to elicit suggestions concerning branding, color scheme, and a name for the app (ultimately named “SHAPE”). Based on this input, the study team created 4 versions of the SHAPE app (iOS standard, iOS gamified, Android standard, and Android gamified) to collect behavioral health data. Survey questions focused on the demographic characteristics and behavioral health items consistent with available benchmark data. A multipronged approach was used to recruit student participants during a 22-day period in October 2016. Additional details on recruitment methods are included in the “Participant Recruitment” section. Similar to traditional

telephone surveys, where the informed consent is administered after potential study subjects answer the phone, SHAPE participants were administered the informed consent process and institutional review board approved consent materials embedded within the mobile app download and eligibility determination process. Eligible participants (aged ≥ 18 years with an email domain at a participating institution) who consented were administered the first survey. Two additional surveys were administered by utilizing a push out mechanism within the app over a period of several weeks. A total of 27 questions were asked across 3 surveys, the last of which included questions regarding the SHAPE app functioning and the survey process.

A focus group with selected mobile app participants was conducted after app data collection to understand how students liked the app and why they did or did not respond to the surveys. Students (n=7) were recruited in person by the on-campus recruiter, and 8 open-ended questions were discussed.

App Development

To design and build this multiple component platform, our app development team included user interface (UI) designers, user experience (UX) designers, iOS and Android Developers, Web and backend developers, and Quality Assurance analysts. Utilization of the nimble mobile app platform by Medable and app development team was essential because the rest of the multidisciplinary team did not need to be familiar with the platform and programming language. We were able to successfully create the Council of State and Territorial Epidemiologists SHAPE app on both the iOS and Android operating systems. To meet the objectives of the project, it was necessary to develop an app for each platform (iOS and Android), each having 2 versions—the standard version (only the survey items) and a gamified version (the survey items plus a point system). All 4 versions of the SHAPE app were developed using the native programming languages of each platform, Swift (for iOS) and Android Studio (for Android), and were compatible with iOS 8+ and Android 4.x+.

Native components for both platforms were used to improve the performance and user experience for conducting research. Research Kit was used for iOS, and Research Stack was used for Android; these kits provided a user experience in compliance with the iOS and Android standards as required when submitting research that is included as part of an app. The gamified version was a slightly modified variation of the standard version, which allowed the reuse of substantial portions of app code for both gamified and nongamified versions, enabling the adherence to the time and budget limitations of this project. Owing to the use of native technologies, there were minor visual design differences between the 2 operating systems. The differences were based on typical design displays for each operating system; for example, Android answer options are displayed with a radio button that is filled in when tapped, whereas iOS users see a checkmark appear to the right of an answer option when tapped. Appendices provide screenshots of both operating systems for comparisons. Of note, any potential differences in subjects’ responses because of these visual design features were not explored.

The backend, the technology component where the data are managed and stored, was another key component of the solution. The backend functionality was provided by Medable and, in particular, by its Axon product, aimed at facilitating the execution of studies using mobile apps. From the backend, the researchers were able to manage users and create studies (surveys) as well as questions and response options. The backend can seamlessly be integrated with the mobile app through the iOS and Android Software Development Kits provided by the Medable platform. As described above, an additional feature implemented in the Medable platform is HIPAA compliance.

Another important aspect of the SHAPE app was the availability of push notifications as a way to notify users that a survey was available and to remind them to participate. These push notification scripts were developed in Medable and executed through the Medable platform to the apps. The Medable backend platform captured responses to the survey items as well as all data related to the game (points) and all paradata (date and time of starting a survey, date and time of ending a survey, geolocation, etc).

Design of the App

The design of the app was driven by a process that was developed in stages with each stage resulting in the identification of the best intermediate product based on the needs of the overall project and included the development of wireframes, definition of use cases, UI design, and user experience testing.

Development of Wireframes

The start of the development process involved the creation of wireframes and a clear definition of the end product. To gather ideas and get the team discussion moving, it was necessary to first lay out the basic structure and flow of the app, initially with low fidelity paper sketches, followed by digital interactive sketches available on the internet for user testing with the use of Invision (www.invisionapp.com). Through this tool (Invision), the UI/UX team was able to share the progress of

the design process and receive feedback and comments directly in the tool from the team members located in different US cities.

Definition of Use Cases

In parallel with the wireframes and product specification process, use cases were defined; this development technique was used to explore the potential needs of the end users of the app. As identified through the use cases process, the app brand was an important and challenging requirement of the process. The branding included name creation, logo, and a complete brand guideline that was used across the different components of the platform—apps, dashboard, marketing materials, etc.

User Interface Design

Once the flow of both apps (standard and gamified) was defined and wireframes were approved by all team members, we moved to the final UI design stage. For this stage, an interactive prototype was built, and users tested it with the help of Lookback (www.lookback.io), a research tool that captures how users experience the app. The SHAPE brand was tested through interviews with Castleton students. Lookback records user interactions with the product—their screen touches, clicks, and their face and voice. With this information, the UI/UX team was able to observe how users engage with the app, including facial and voice reactions to the app while they are using the app; this gave powerful insight into ways to improve the overall user experience.

User Experience Testing

The final stage of the development involved a series of continual tests in which every internal release delivered by the development team was reviewed by the UI/UX team. Improvements were made to UI, obtaining continual feedback to allow the detection of any usability issues that we were unable to test on the prototype. In the final phase of our UI/UX process, the UI/UX designers reviewed the quality of the developed apps, ensuring that the final user experience matched the intended design.

Survey Questions

Survey questions for which benchmark data were already available from the traditionally administered Vermont College Health Survey (VCHS) [27] included questions related to general health behavior (physical activity and sleep), mental health (depression and stress), and substance use (alcohol, marijuana, tobacco, cocaine, and methamphetamine use). In addition, demographic items (age, gender, race or ethnicity, year in school, and residence) were selected from VCHS. Supplemental questions were developed regarding how respondents learned about the SHAPE app, motivation for participation, evaluation, and “adoptability” of the app [28]. The questions were divided into 3 surveys. Demographic, mental health, and health behavior items (15 items total) were asked in the initial survey. The second survey included questions on substance use (7 items). The final survey asked questions related to evaluating and providing feedback about the app (5 items).

Marketing or Branding

Student employees of the Castleton Polling Institute created some preliminary names and logos for the app to present to the

preapp focus group; this focus group provided information to guide the logo, color scheme, and name selection of the app. Polling Institute student employees helped create general marketing messages and recruitment materials. Prior to the app launch, additional iterative usability research was conducted within the research team and 6 CU students to gather feedback on the app prototype as well as the draft marketing strategy, messages, and recruitment materials.

Participant Recruitment

A website landing page was created to facilitate easy app download and ensure that participants were randomly assigned to receive either the gamified or standard versions of the app. The landing page included links to the SHAPE app in both Apple’s and Android’s app stores, a frequently asked questions section about the project, a link to the consent form, and contact information for questions or assistance. In addition, Google Analytics and unique links were created to track traffic to the page for each of the recruitment methods. At the launch of the project, approximately 1000 full-color flyers were placed at the 3 campuses in varying locations. Student recruiters were hired at all 3 campuses to encourage participation. Student recruiters were provided leaflets with the landing page link and bookmarks as recruitment aids. CU and JSC published advertisements for the app in their school newspaper, 3 emails were sent to all CU students with links to the landing page, and LSC included recruitment materials in their electronic weekly student newsletter. In the final week of recruitment, targeted Facebook ads were purchased for 5 days at CU. A lunchtime pizza giveaway at JSC and LSC campuses was hosted.

Implementation: Security and Data Collection

The SHAPE project pilot test was approved by the Institutional Review Boards of Castleton University, Lyndon State College, and Johnson State College, as well as all 3 institutions’ Presidents and the Vermont State College Systems legal counsel. Medable, a medical software development company, provided a HIPAA-compliant backend platform that allowed secure storage and transmission of data and a business associate agreement that meets US Department of Health and Human Services requirements for the protection of human subjects.

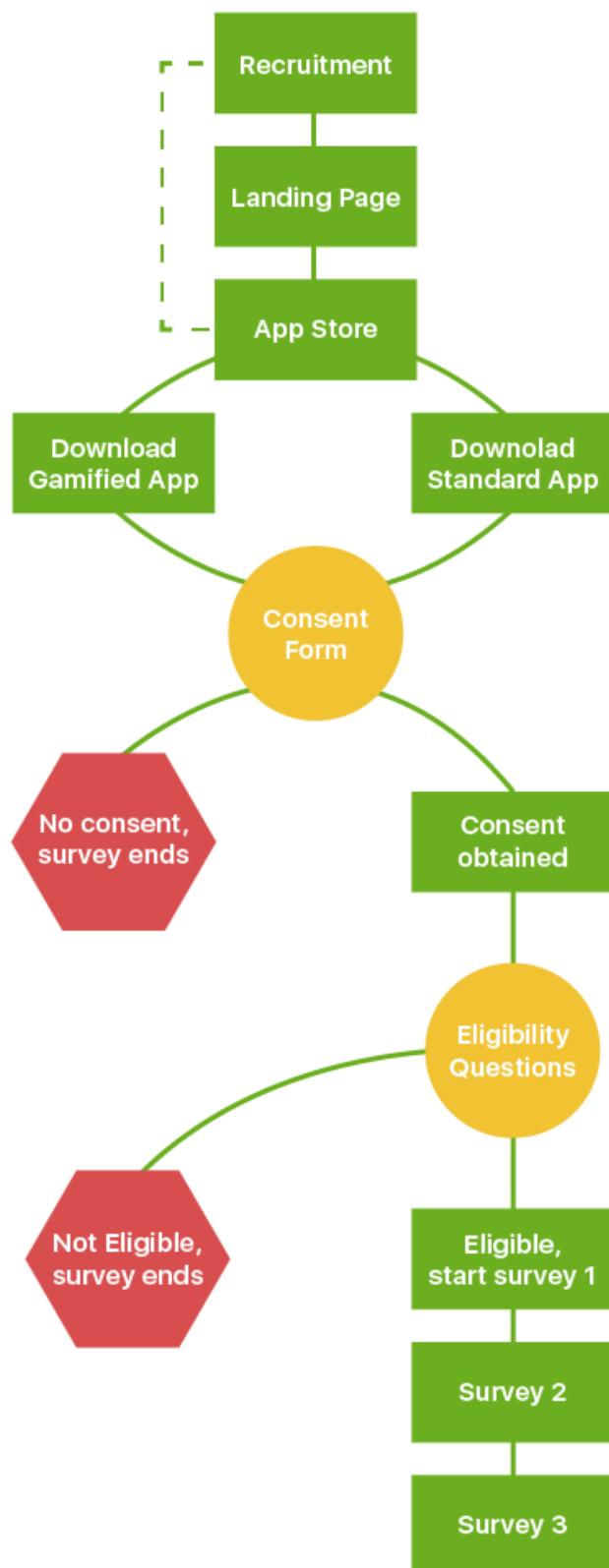
As part of the eligibility and consent process, participants were asked their age and institutional email address. A respondent was eligible if they were 18 years of age or older and provided an email address that used a participating institution’s domain. Eligible respondents were asked if they would allow push notifications (messages sent by the SHAPE app to the device but not required) and then given the option to begin the first survey or resume at a later date and time. The first survey remained open during the enrollment period. Any enrolled participant who did not fully complete Survey 1 received push notifications (if they had allowed the notifications on their device) as reminders to complete the survey. A total of 4 push notifications were included during Survey 1’s field period (October 10, 2016–October 31, 2016).

All eligible respondents, regardless of completion of Survey 1, received a push notification at the start of Surveys 2 and 3 followed by additional reminder push notifications. Because of

low initial response to Survey 2 with only push notifications, 3 reminder emails were sent during the second field period (November 17, 2016–November 27, 2016). Survey 3 was launched on November 30, 2016. All enrolled participants, regardless of previous survey completion, were asked to

complete Survey 3. The notification protocol included an initial survey push notification, 3 reminder push notifications, and 3 email reminders. Survey 3 closed on December 8, 2016. **Figure 1** shows the study protocol from recruitment, consent, eligibility, and survey administration.

Figure 1. The study protocol schematic.



Evaluation of Feasibility, Usability, Acceptability, and Validity

Iterative testing of apps for each platform (iOS and Android) was conducted over 16 weeks. Each app had 2 versions—the standard version (only the survey items) and a gamified version (the survey items plus a simple point system)—with acceptance on the iOS and Android app stores. The SHAPE app was developed using Swift (for iOS) and Android Studio (for Android) and was compatible with iOS 8+ and Android 4.x+. Medable's Axon product for Research Kit was used for iOS, and Research Stack was used for Android.

From the Medable HIPAA-compliant backend, the researchers were able to manage users, create questions and response options, and push notification scripts. The Medable backend captured real-time responses to the survey items as well as all data related to the game (points) and all paradata (date and time of starting a survey, date and time of ending a survey, geolocation, etc).

Qualitative data (eg, focus groups, UI/UX testing, and interviews) were audiorecorded and reviewed by the project team [29]. Data from the VCHS 2014 survey were compiled in aggregate for the population of interest. Several paradata measures were collected and analyzed [30-33].

Results

Feasibility: Participants' Characteristics

There were 1392 “hits” to the landing page where the app could be downloaded. Excluding known project testers and others not part of the population of study, 670 apps were downloaded. Of those 670, 636 participants (636/670, 94.9%) agreed to participate by providing in-app consent. Of the 636 who consented, 536 (536/636, 84.3%) were deemed eligible for the study. The majority of eligible respondents (459/536, 85.6%) completed Survey 1. Similar to longitudinal studies, the highest rate of attrition occurred between Survey 1 and Survey 2. Retention between surveys 2 and 3 was high because almost equal numbers of respondents to Survey 1 completed Survey 2 (160/459, 34.9%) as well as Survey 3 (33.3%, 153/459). As reported by Miller et al (Survey Research, In Press 2018), 88.1% (472/536) of eligible respondents were from the primary location (CU), the majority were iOS system users (438/536, 81.7%), and the sample was deemed representative of the target population (Castleton University).

The distribution of years in school was significantly different between completers (those completing all 3 surveys) and noncompleters (those completing only 1 or 2 surveys) with 12.1% more third-year students completing all 3 surveys. The rate of completion between enrolled and eligible participants for all 3 surveys among gamified (76/277) and standard app (77/259) respondents was similar (27.4% vs 29.7%), indicating that the pilot-tested gamified design did not reduce the attrition rate.

Validity: Comparison to the Benchmark Survey (Vermont College Health Survey)

The data collected from the SHAPE mobile app were compared with the results for CU students obtained from the 2014 VCHS because results from the 2016 survey were not yet available for analysis. Because not all 2014 survey items were the same as the items asked in 2016 (and thus repeated in this project), analyses were restricted to comparisons when the 2016 questions were either identical or had minor differences in wording compared with the 2014 questions. This analysis focused on respondents from the primary site (CU) because of small numbers of participants from JSC and LSC. The SHAPE app items had low item nonresponse rates, similar to response rates from the 2014 VCHS.

A total of 209 CU students responded to the 2014 VCHS. In comparison to enrollment numbers, the age distribution was similar in both VCHS and SHAPE. Women were overrepresented in VCHS data by 22% compared with the 2014 enrollment data, whereas women were only minimally overrepresented (279/536, 2.1%) in the SHAPE app survey respondents. VCHS data included a slightly higher proportion (by 4%) of international students than in total enrollment compared with slightly lower participation in the SHAPE app (−3%). Interestingly, the app improved upon capturing race or ethnicities other than white and had almost double the number of anticipated respondents to survey 1 compared with the 2014 VCHS.

Some examples of health and behavior items that were included in both the 2014 VCHS and the SHAPE app project were as follows:

- On how many of the past 7 days, did you perform moderate-intensity exercise for at least 20 minutes?
- On how many of the past 7 days, did you perform vigorous-intensity exercise for at least 20 minutes?
- On how many of the past 7 days, did you perform exercises to strengthen your muscles (8-10 exercises each for 8-12 repetitions)?
- How often have you used cigarettes?
- How often have you used alcohol?
- During the last [reference period], how many times have you had 5 or more drinks of alcohol at a sitting? (The reference period is 2 weeks in the VCHS and 30 days in SHAPE)
- How often have you used marijuana?
- How often have you used cocaine (eg, crack, rock, blow, and freebase)?
- How often have you used methamphetamine (eg, meth, crystal, ice, and crank)?

Except the first two, response options for the other questions were not the same but were collapsed into comparable categories for analysis.

The mean number of days in the past 7 days that subjects engaged in moderate or vigorous physical activity was slightly higher among SHAPE app respondents compared with VCHS participants (Table 1). The median for all 3 physical activity items in the VCHS data was 1 day less than that in the SHAPE

app data. Compared with the 2014 VCHS data (Table 2), fewer app respondents indicated smoking cigarettes in the past 30 days (11/143, 7.7% vs 33/206, 16%) and more app respondents selected the “never used” category (106/143, 74.1% vs 139/206, 67.5%).

The same percent of respondents in both surveys (11.9%, 17/142 and 11.7%, 24/205) selected the “never used” alcohol category (Table 2). VCHS subjects (Table 2) had a larger proportion of

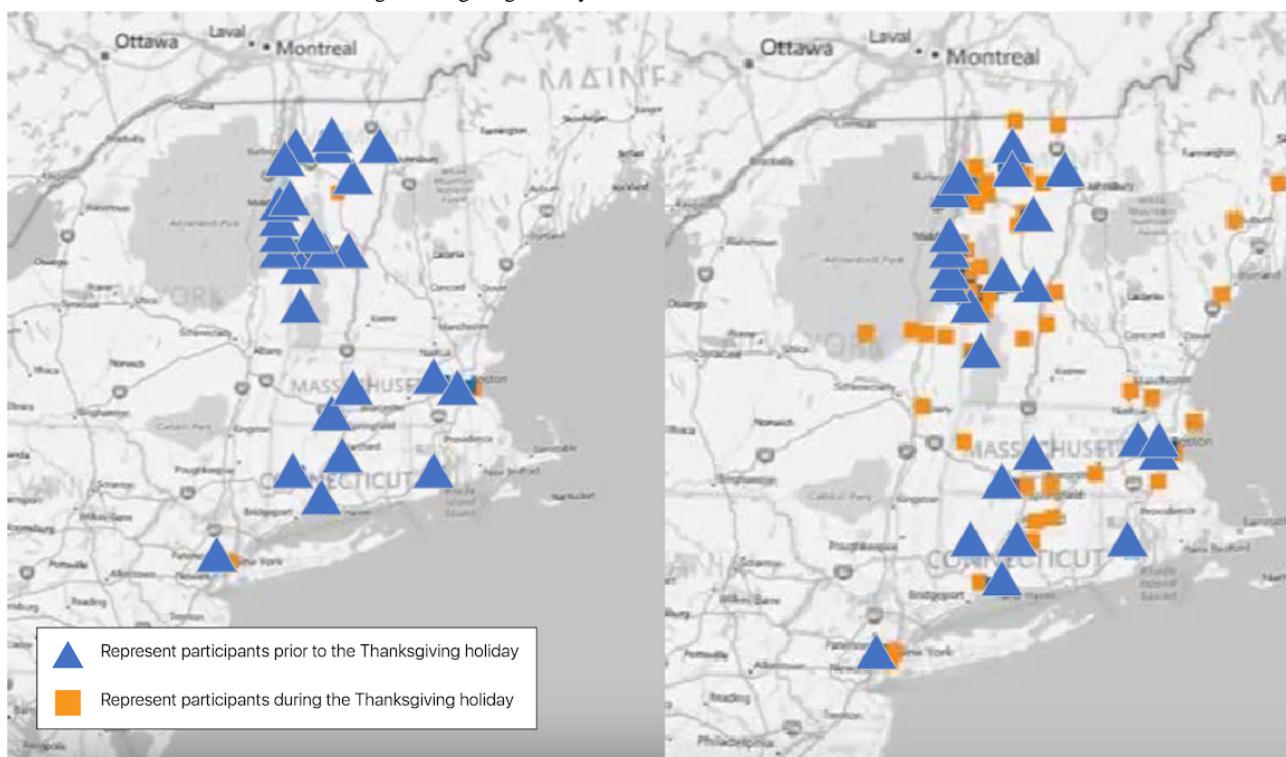
respondents, indicating alcohol use in the previous 30-day period compared with app respondents (76.1%, 156/205 and 69.0%, 98/142, respectively). The reference period for the binge drinking item was different in the 2 surveys—the previous 30 days for the app and the previous 2 weeks for VCH Survey. As noted in Table 1, app respondents had a higher mean (1.87) compared with VCHS (1.02). Given the longer reference period (30 days vs 2 weeks), it is reasonable to expect an increase in mean days reported for app respondents.

Table 1. Behavioral health characteristics of Castleton SHAPE app participants compared with results from the Vermont College Health Survey (VCHS) administered in 2014.

Physical activity, past 7 days	2016 Castleton SHAPE app respondents (n=414 survey 1, n=143 survey 2)		2014 Castleton VCHS participants (n=209)	
	Mean (SD)	Median	Mean (SD)	Median
Moderate-intensity exercise for at least 20 min (number of days)	3.11 (2.38)	3	2.56 (2.18)	2
Vigorous-intensity exercise for at least 20 min (number of days)	2.54 (2.41)	2	1.90 (1.98)	1
Performed exercises to strengthen muscles (number of days)	1.88 (2.07)	2	1.71 (2.01)	1
Number of times had 5 or more drinks of alcohol at a sitting (SHAPE last 30 days, VCHS last 2 wk)	1.87 (2.67)	0	1.02 (1.58)	0

Table 2. Behavioral health characteristics of Castleton SHAPE app participants compared with results from the Vermont College Health Survey administered in 2014.

Characteristics	2016 Castleton SHAPE app respondents, n (%)	2014 Castleton Vermont College Health Survey participants, n (%)
Frequency of cigarette smoking, n (%)		
Never used	106 (74.1)	139 (67.5)
Used, but not in last 30 days	26 (18.2)	34 (16.5)
Used in last 30 days	11 (7.7)	33 (16.0)
Frequency of alcohol use, n (%)		
Never used	17 (12.0)	24 (11.7)
Used, but not in last 30 days	27 (19.0)	25 (12.2)
Used in last 30 days	98 (69.0)	156 (76.1)
Frequency of marijuana use, n (%)		
Never used	53 (37.1)	108 (52.7)
Used, but not in last 30 days	47 (32.9)	42 (20.5)
Used in last 30 days	43 (30.1)	55 (26.8)
Frequency of cocaine use, n (%)		
Never used	129 (90.8)	191 (92.7)
Used, but not in last 30 days	10 (7.0)	8 (3.9)
Used in last 30 days	3 (2.1)	7 (3.4)
Frequency of methamphetamine use, n (%)		
Never used	142 (100)	199 (97.5)
Used, but not in last 30 days	0 (0)	4 (2.0)
Used in last 30 days	0 (0)	1 (0.5)

Figure 2. Geolocation data before and during Thanksgiving holiday.

A larger proportion of app respondents (Table 2) reported marijuana use than VCHS respondents (90/143, 62.9% and 97/205, 47.3%, respectively). The pattern in responses for cocaine use between the 2 datasets is similar with slightly lower frequency of “never” and “last 30 day” users among app respondents and a slightly higher rate in the “used but not in the last 30 days” category (10/142, 7.0%) compared with 3.9% (8/206) in the VCHS results. All respondents indicated that they had “never used” methamphetamine in the app compared with 97.5% (199/204) in VCHS.

Acceptability: Paradata Findings

For Survey 1, 38.3% (176/459) of respondents completed the survey when the app was launched. Another 30.3% (139/459) completed it after the third push notification. For Surveys 2 and 3, the highest survey completion rate came with the arrival of the first reminder email. The overall time to project completion was an average of 37.6 hours for Survey 2 and an average of 11.6 hours for Survey 3. Nearly 90% of users (400/459, 87.1%) completed Survey 1 in <5 minutes with the median and modal response time of only 2 minutes. Surveys 2 and 3 were completed in 1 minute or less by the overwhelming majority of respondents.

Ambient data, such as geolocation, were easily captured for all users. There were 3 large data clusters centered near the 3 institutions that participated in the study. Two smaller clusters appeared in Manhattan and Connecticut during Survey 1, but these were likely nonglobal positioning system information. Survey 2 was fielded over the Thanksgiving holiday. By utilizing the geolocation data, we could see how much more dispersed the physical location of respondents was pre- and postholiday (Figure 2). Each triangle on the map indicates the geolocation of a survey respondent before the Thanksgiving

holiday (diagram on the left) and each square represents the respondent during the Thanksgiving holiday (diagram on the right) with the before triangle also displayed. A few students appeared to have left “early” for the holiday because a few squares can be seen in the diagram on the left.

Feasibility and Usability: Study Participant Feedback

In Survey 1, respondents were asked, “How did you hear about this project” and were given a list of options to select all that applied. The most frequently selected category (54%) was from someone else, followed by 28% indicating a flyer on campus, 15% via email, 14% a flyer in the bathroom, 11% somewhere else, and 1% via Facebook.

In addition, respondents were asked an open-ended question, “What is the primary reason you decided to download this app?” Overall, 37.9% (174/459) of respondents’ responses were categorized as “told about it by someone” with the “altruistic motivation” category closely following with 35.1% (161/459) of responses. The “personal reward” category had 10.9% (50/459) of responses, “general interest/curiosity” had 10.0% (46/459), “other” 5.0% (23/459), and “marketing materials” was at 2.2% (10/459).

The final survey was designed to gather evaluation data about the app. Results indicated that the app experience was positive. The majority of respondents (122/153, 79.7%) indicated that they would prefer to participate in surveys with an app on their phone compared with other modes of survey participation. Respondents were asked, “How much do you think you should be paid for downloading the app and answering the survey?” The results indicated nothing or a small amount under US \$5 is preferred. Furthermore, 28.1% (43/153) of respondents were categorized as “promoters” based on their response to the

question “How likely would you be to recommend this app to a friend?”

Usability: Focus Group Post App Follow-Up

Participants in a focus group and interviews held after the close of all 3 surveys frequently stated that the app was easy to use and was intuitive. Those who completed the surveys and those who only partly completed them expressed that they expected more frequent surveys. When asked about the number of questions per survey, participants were satisfied with the length. Nearly all respondents wanted, at least, the option of seeing the results of the surveys after completing them and understand how they “compared” with their fellow students.

Discussion

Principal Findings

In this study, we were successful in rapidly recruiting participants with an initial group of 536 eligible participants. Notably, the number of participants for CU on the behavioral risk items was 414 for Survey 1, almost double the 209 CU participants who completed the VCHS in 2014. The survey app resulted in higher than usually observed response rates for longitudinal surveys [34].

Multiple technical successes were achieved throughout the app development process, indicating excellent feasibility for rapid development. Guidelines for successful mobile app development were followed [26], including the involvement of the study population in the development process through focus groups and interviews, iterative UI and UX, field testing, and postfield testing follow-up through user focus groups. Medable removed multiple barriers (cost, time, technical knowledge, and HIPAA requirements) as a rapid mobile app development tool and a backend platform focusing on data security.

In addition, we were able to capture GPS data from participants’ phones; this highlights the exciting future potential to include additional sensor data to add richness to a dataset instead of just relying on self-report. Geocoded information combined with health information could open up the potential for additional analyses, such as the impact of the place or the neighborhood where people live on physical activity, diet, and drug use. The neighborhood environment has been shown to have an additional and distinct effect from individual characteristics [35-37].

Participants in the postsurvey focus groups viewed the app as being easy to use, engaging, and low burden. However, this information was gathered from those who completed all 3 surveys, and we do not have data from participants who completed just Survey 1 or Surveys 1 and 2. In the future work, we plan to assess the experience at the end of each survey with a few simple questions.

This project successfully demonstrated that one-fifth (472/2,342) of a college population (CU) would download, consent and be deemed eligible to participate in the SHAPE app and that researchers could make the survey experience low burden while maintaining the validity that is comparable with more expensive and burdensome efforts. Once study subjects downloaded the app, they were impressed with the speed and ease of entering

their survey responses. Every indication suggests that the data collected were of good quality because both the correspondence between the app survey responses and the available benchmark comparisons were nearly identical and there was a low item nonresponse in all surveys. A limitation of this work is that we were unable to compare raw VCHS data to our mobile app survey data because of limited release of the VCHS data and because the samples were not entirely independent (although approximately 50% of the college population would likely have graduated); as a result, we did not conduct specific statistical testing of means and proportions or other summary measures.

Although the population selected for this study is not representative of the general US population, it is a well-defined and enumerated population. The study population closely mirrored the entire college population on which this study was focusing. However, because this app survey mechanism relies on voluntary download, the requirement of downloading an app could potentially introduce a selection bias in other populations and deserves further study in other scenarios. In addition, multiple recruitment methods were used that required in-person efforts, which may be difficult in larger communities. Gamification, which was one of the controlled variables, was underdeveloped and did not result in any difference in the survey response. The mobile app survey mechanism that this project developed has great potential for future research but requires further evaluation of potential barriers in broad population groups, particularly those that may be difficult to reach through current telephone and paper-based methodologies.

Recruiting a broad community-based population sample of subjects to download an app and consent to a data collection protocol will require additional methodological investigation, particularly because it relates to branding and social media marketing. Ideally, we would like to identify additional strategies to increase engagement, uptake, and retention.

Behavioral health assessment surveys collected by smartphone apps have great potential; very few respondents were lost during the consent and registration processes following download and most were likely the result of addressable technical and log-in challenges. The ability of smartphone users to “turn-off” notifications may have resulted in lower participation numbers for Surveys 2 and 3 and should be addressed.

A Cochrane review assessing the equivalence of data gathered through smartphone apps compared with other alternative delivery modes found that apps did not affect the data equivalence as long as the clinical application of the survey questions, the intended frequency of administration, and the setting remained unchanged [38]. Future extensions of this methodology include the ability to capture passively collected background data, such as accelerometer, and other ambient information; this information could proactively inform health providers, provide optimal resource allocation at the state and national agency level, and personalized information for a wide variety of health needs and health improvement objectives such as exercise, weight, and sleep. Moreover, the SHAPE app could be rapidly adapted to include additional surveys and other health metric outcomes of interest in either the college population or the general community. A value of native mobile apps is the

ability to easily update them and encourage additional health survey data gathering for building projects and new data.

Conclusions

This paper describes developing and pilot-testing a mobile app to administer behavioral health-related surveys on iOS and Android platforms targeting college students in Vermont.

The three key findings are as follows:

1. It was feasible to engage a large proportion of the target study population to download the SHAPE app, complete consent and eligibility determinations, and complete behavioral risk survey items. The first survey was completed by 459 participants and retention without incentives or other engagement tools was approximately 33% over time. Furthermore, the SHAPE mobile device survey system was very effective at including typically underrepresented groups.
2. Survey responses on behavioral risk items were valid because they were consistent with more expensive, larger survey efforts conducted using time-consuming methods. This paper compares CU app respondents with CU VCHS participants on 7 major behavioral risk items [27]. The data were valid and SHAPE was also deemed acceptable because it also captured ambient and real-time data that is not possible using conventional survey methods.
3. Mobile app survey systems can be used with low burden and quick response rates that includes ambient data such as geolocation. The average time for the overall project completion was 37.6 hours with an average of 11.6 hours from survey launch to completion response for Surveys 2 and 3, respectively. Once participants engaged in a survey, nearly 90% completed the survey in <5 minutes. Based on the data from questions in Survey 3 and postsurvey focus groups and interviews, participants found that the surveys were low burden, welcomed more engagement and questions, felt motivated by civic-mindedness, and were

generally not concerned about being paid to participate. Moreover, students preferred to do a survey through an app on their phone compared with other modes of survey administration.

In summary, new techniques are emerging in survey methodology for public health and research. The private sector has moved ahead of the public sector on survey innovations. The internet and social media have become powerful methods of gathering information from consumers; voice recognition software allows businesses to offer rewards to consumers who call in to respond to surveys throughout the day. At the same time, participants are becoming resistant to cold calls in the evening as telemarketing has increased its pressure on the public. The goal of this pilot study was to determine if early adopters of smartphone technology would be likely to download an app to participate in a behavioral health survey. From this pilot study, we learned that the mobile app survey is a methodology that users of smartphone technology can employ with relatively low burden. The next step in the evolution of this technology and the methodology is to test this on a broad general population. This method alone will likely not be the sole means of collecting general population health data but rather a supplement. Currently, there is no one mode of data collection that can be used to conduct general population surveys. Even in-person only studies, which are prohibitively expensive for most researchers and government agencies, are limited in capturing data during daily life activities and suffer from erroneous self-report for certain sensitive information. As public health research evolves, leveraging current technologies to supplement data collection modes will be essential to capture rich and meaningful datasets and address nonresponse bias and coverage issues. The mobile app titled "SHAPE" developed in this project could be utilized in the future with the rapid addition of new surveys and new health content areas either in the college population or the general population in specific communities when warranted.

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Conflicts of Interest

IO-G is employed part-time by Medable Inc, but did not receive any funding from Medable for her role on this project nor did she engage with Medable app development staff during the app development.

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Abbreviations

CU: Castleton University
HIPAA: Health Insurance Portability and Accountability Act
JSC: Johnson State College
LSC: Lyndon State College
RDD: random digit dialing
VCHS: Vermont College Health Survey
UI: user interface
UX: user experience

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Original Paper

Feasibility of a Therapist-Supported, Mobile Phone–Delivered Online Intervention for Depression: Longitudinal Observational Study

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Abstract

Background: Depression is a very common condition that impairs functioning and is often untreated. More than 60% of the treatments for depressive disorder are administered in primary care settings by care providers who lack the time and expertise to treat depression. To address this issue, we developed Ascend, a therapist-supported, mobile phone–delivered 8-week intervention administered at the Meru Health Online Clinic in Finland.

Objective: We conducted two pilot studies to examine the feasibility of the Ascend intervention, specifically, dropout rates, daily practice, weekly group chat use, and changes in depression symptoms. We also explored whether daily practice and weekly group chat use were associated with changes in depression symptoms.

Methods: A total of 117 Finnish adults with elevated depressive symptoms enrolled in Ascend, a program that included daily cognitive behavioral and mindfulness meditation exercises delivered through a mobile phone app, anonymous group chat with other users, and chat/phone access to a licensed therapist. Eight weekly themes were delivered in a fixed, sequential format. Depression symptoms were measured at baseline, every second week during the intervention, immediately after the intervention, and 4 weeks after completion of the intervention. Data were analyzed using intent-to-treat repeated-measures analysis of variance and linear regression models.

Results: For studies 1 and 2, we observed dropout rates of 27% and 15%, respectively, decreasing daily practice and group chat use, and decreased depression symptoms from baseline to immediately and 4 weeks after the intervention ($P<.001$). We found that both more daily practice and chat group use predicted the occurrence of fewer depressive symptoms at 4 weeks postintervention (Study 1: $\Delta R^2=.38$, $P=.004$ and $\Delta R^2=.38$, $P=.002$, respectively; Study 2: $\Delta R^2=.16$, $P<.001$ and $\Delta R^2=.08$, $P=.002$, respectively).

Conclusions: This therapist-supported, mobile phone–delivered treatment for depression is feasible and associated with reduced depression symptoms. Design features that enhance daily practice and group chat use are areas of future investigation. Validation of these results using a controlled study design is needed to establish the evidence base for the Ascend intervention.

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KEYWORDS

cognitive therapy; depression; digital health; digital therapeutics; mindfulness; online intervention

Introduction

Background

Depression is one of the most common mental disorders, impacting more than 300 million people worldwide according to the World Health Organization (WHO) [1]. In addition, depression carries the heaviest burden of disability among all mental and behavioral disorders [2]. People who suffer from depression often experience significant problems with employment, physical health, interpersonal functioning, suicidal ideation, and suicidal attempts. Thus, depression inflicts a significant burden on the individual, the network of family and friends, and society at large.

There are several effective psychological [3,4] and pharmacological interventions [5] for depression. However, the WHO estimates that less than 50% of people with major depression receive any care for their symptoms. Many people with depression do not have access to effective clinical care and are not willing to use antidepressant medications. Others are hesitant to obtain mental health treatment due to individual and social stigma [6]. Furthermore, when treated with antidepressants, roughly one-third of patients do not experience significant alleviation in symptoms [7]. In primary care settings, only 20% of patients who are referred to psychotherapy follow up, and of those, more than 50% drop out of treatment [8]. Thus, from a public health perspective, there is a need to examine other ways of delivering interventions for depression that bypass these obstacles.

Online interventions for mental disorders, especially depression and anxiety, have gained increasing popularity during the last decade. These online interventions can be delivered in many different formats including psychoeducation, self-help programs, chat support groups, interactive health coaching, and professional-led online therapy [9]. Online interventions have the advantage of being accessible to patients who previously did not have access to such mental health care. Further advantages include their ability to be self-paced, be programmable to record practice, and have a flexible sequence of clinical content and exercise that can be tailored to the individual patient. Importantly, they are also able to support clinical techniques such as cognitive reappraisal and mindfulness meditation practices in real-time and natural contexts. Furthermore, there is evidence that web-based interventions that include human support or coaching increase adherence and produce better outcomes [10].

There is a growing body of evidence for the beneficial effect of online interventions for depression. A recent meta-analysis [11] of controlled trials from a 10-year period (2006-2016) showed that therapist-supported online cognitive behavioral therapy (CBT) and in-person CBT were equally effective in reducing depressive symptoms and superior to treatment as usual, waitlist controls, and attention controls. Furthermore, this meta-analysis did not find an interaction between depression severity and CBT efficacy, suggesting that therapist-supported online CBT may be helpful for patients at all levels of depression severity. A meta-analysis [12] of 15 randomized controlled trials (RCTs) demonstrated a significant impact of online

mindfulness-based interventions on depression symptoms. Studies also suggest the cost effectiveness and cost utility [13,14] of online interventions for depression over traditional treatment modalities. Improved cost effectiveness combined with high scalability makes online interventions a promising area for development and dissemination of empirically supported interventions, especially for traditionally underserved patients.

More recently, the increased use and flexibility of mobile phones has presented a more promising route to extend the reach of clinical interventions. A recent meta-analysis involving 3414 participants across 18 RCTs of mobile phone-based interventions for depression [15] showed a small reduction in depression symptoms compared to an active control group ($Hedge g=.22$) and a moderate reduction compared to an inactive control group ($g=.56$). This study also found no statistical difference between the effect of mobile phone only and mobile phone plus human/computerized components for the treatment of depression. Furthermore, apps focused on mental health produced a greater reduction in depression symptoms than apps focused on cognitive training. Interestingly, the integration of specific features, including mood monitoring, CBT, and mindfulness, did not alter the observed effects sizes. In addition, a more conservative subanalysis of studies (n=16) that used intention-to-treat analyses or reported complete outcome data showed a moderate effect of these treatment methods on depression symptoms ($g=.40$). This meta-analysis suggests that mobile phone apps may be a potentially effective tool to introduce self-management skill training for adults with depression. However, we need to better understand the potential mechanisms (ie, mediators) and pretreatment patient features (ie, moderators) that predict outcome and help us refine mobile phone-delivered interventions for depression.

To address the public health need for more accessible interventions for depression, we developed a new mobile phone-delivered intervention that includes self-help modules, support from a personal remote therapist, and chat group access to an anonymous patient peer-group support.

Present Study

The goal of this pilot study was to examine the feasibility of a newly developed mobile phone-delivered, therapist-supported 8-week intervention for depression in self-referred depressed individuals. We examined dropout, number of days of practice, and weekly use of an online group chat. For symptom reduction, we examined intervention-related changes in depression symptoms and whether daily practice and weekly group chat use predicted a reduction in depression symptoms. We proposed three hypotheses. First, we expected a dropout of $\leq 30\%$ among all participants, daily practice on at least half of the days (ie, 28/56 days), and weekly group chat use for at least half (4/8) of the weekly group chat sessions. We also examined the pattern of change in daily practice and weekly group chat over the 8-week intervention. Second, we expected the Ascend program to be associated with significant decreases in depression symptoms. In study 1, we used the Beck Depression Inventory-II (BDI-II) [16] to measure depression symptoms. In study 2, we shifted to the Patient Health Questionnaire 9-item version (PHQ-9) [17], because it is more commonly used than BDI-II

in primary health care. Third, we expected that greater amount of daily practice and weekly group chat use during the 8-week intervention would predict reductions in depression symptoms.

Methods

Recruitment

For studies 1 and 2, participants were recruited from March to September 2017 in Finland via online Facebook advertisements for the Meru Health Online Clinic, a national remote health care provider approved by the Finnish National Supervisory Authority for Welfare and Health (Valvira approval number V/25535/2017). Meru Health operates under HIPAA (Health Insurance Portability and Accountability Act); legislation and all protected health information is stored in a HIPAA-compliant cloud storage hosted by a company called Datica [18]. All data are encrypted in transit, end to end, and at rest.

Participants were offered a free online intervention for depression that included mobile phone-delivered content, anonymous weekly chat group, and private phone/chat access to therapists. All participants were required to have a mobile phone. To enter the study, participants had to demonstrate some depression symptoms based on the BDI-II (>9) in study 1 and at least mild depression symptoms based on the PHQ-9 (>4) in study 2. We increased the depression symptom cut-off in study 2 to match the validated score of PHQ-9 for screening mild depression. Other inclusion criteria included the perceived ability of the participant by both the participant and therapist to commit to an 8-week online intervention with a minimum of 20 minutes of practice 6 days per week. The exclusion criteria included previous suicide attempts, severe suicidal ideation with a specific plan, severe self-harm, active substance abuse, and a history of psychotic disorder.

Procedures

We informed participants that the goal of the study was to examine an online intervention for depression, delivered through a mobile phone app. Participants provided informed consent through the Ascend mobile phone app for their anonymous data to be used for further intervention refinement and research purposes. Participants were not compensated for their participation. They enrolled in the program at no cost. Institutional review board exemption was granted by Pearl IRB (Indianapolis, IN) for analyses of previously collected and deidentified data.

We provided participants a link to download the Meru Health Ascend app on their mobile phone to access the intervention content. Participants used a unique identification number to record depression symptoms at baseline, during the intervention, immediately after the intervention, and 4 weeks after the intervention. We trained participants on how to access an anonymous chat group and converse with the study therapist via direct one-to-one chat messaging or, in few exceptions, phone calls.

As part of the standard treatment procedure at the Meru Health Online Clinic, Ascend study therapists conducted phone interviews to examine inclusion and exclusion criteria before enrollment and determine participant suitability for the online

intervention. After the program, the study therapist spoke to participants via phone calls to assess the participant's experiences and address any further needs. In addition, participants had an opportunity to speak directly with the therapist via phone calls during the program. This occurred in only a few cases when a participant had a specific concern or question that could not be properly communicated by chat messaging with the study therapist.

Ascend Program

The Ascend program consists of 8 modules delivered in a fixed order through a mobile phone app over an 8-week period, including practices derived from mindfulness-based stress reduction [19], mindfulness-based cognitive therapy [20], CBT [21], and behavioral activation therapy [22] treatment protocols. Modules are delivered each week in the following sequence: Introduction to mindfulness, Low mood and motivation, Self-compassion, Managing worry, Overcoming thinking traps, Rethinking your life values, Being aware of your relationships, and Relapse prevention. The content was designed to teach participants skills based on mindfulness meditation and cognitive behavioral therapy. The content for each week unlocked automatically during each of the 8 weeks of the Ascend intervention without the need to view prior content and complete prior exercises. The Ascend program has high standards of data security and adheres to the European Union General Data Protection Regulation requirements (EU 2016/679). If there were any signs of mental state deterioration during the intervention, the study therapist conducted an additional phone-based assessment of the participant's condition. For emergencies such as severe suicidality, the Ascend intervention includes a written security plan that all participants reviewed with the therapist before starting the program.

The Meru Health therapists provided ongoing individual support as needed and curation of the group chat during the Ascend intervention. The interaction took place primarily via chat messaging and, in a few instances, phone calls. Therapists included one medical doctor and two master's-level clinical psychologists, each of whom had training in mindfulness-based stress reduction or mindfulness-based cognitive therapy. The patients could reach out to their therapist whenever they wanted. However, more than 50% of the communication was initiated by the therapist, not the patient. The therapist would normally check in with the patient via chat at least 2-3 times/week to see how the patient was doing. On an average, the therapist spent 20 minutes on each patient per week, including time spent chatting with the patient and reviewing the patient's data and progress.

Study therapists used a Professional Dashboard (Meru Health Inc, CA), which is a secure web-based tool to monitor participant progress and chat with participants. The mobile phone app hosted all the weekly program content, including text, video, audio, and graphics. The intervention included video lessons every week, audio-guided mindfulness-meditation practices, visual graphics that illustrated cognitive-behavioral principles, and journaling prompts.

The mobile phone app consisted of the following components: a "Me" screen to access the daily practices and learning

materials; a “Program” screen to view the structure of the whole Ascend program, identify where on the timeline one is currently located, and access already completed modules and practices; a “Group” screen to view other anonymous participants’ written reflections on different practices and lessons (the Group screen did not allow any commenting, but rather only reading of therapist’s and other participants’ comments); a “Notifications” screen to track therapists’ messages and newly available lessons or practices; and an “Other” screen to view the Emergency Plan, Privacy Policy, Terms of Use, and a single button to contact the therapist via chat messaging.

Measures

We used multiple measures to assess the feasibility of the Ascend intervention. We measured dropout from the intervention, operationally defined as less than 4 weeks of active participation during the 8-week intervention. We also measured completion of mobile phone-delivered practices (number of days during the 8 weeks) and participation in the once-weekly chat group (a binary yes/no measure). As stated above, we shifted from the BDI-II in study 1 to the PHQ-9 in study 2 to measure depression symptoms, because it became clear that the latter self-report measure is more commonly used across a wide variety of health care settings.

Depression Symptoms

Beck Depression Inventory-II

Depressive symptoms were measured using the BDI-II, a scale containing 21 items rated 0-3 points in terms of intensity, with total scores ranging from 0 to 63. BDI-II scores of 14-19 points suggest mild depression; 20-28 points suggest moderate depression, and 29-63 points suggest severe depression. To enter the Ascend intervention, the participant had to score a minimum of 10 points at baseline. The BDI-II has demonstrated high internal consistency (Cronbach alpha=0.9) in outpatient samples [23].

Patient Health Questionnaire-9

The PHQ-9 is the 9-item depression scale extracted from the full PHQ. Because each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day), the PHQ-9 score can range from 0 to 27 points. PHQ-9 scores of 5-9 points suggest mild depression, 10-14 points suggest moderate depression, 15-19 points suggest moderately severe depression, and 20-27 points suggest severe depression. To enter the Ascend program, the

participant had to score a minimum of 5 points at baseline. Prior large-scale studies have shown that the PHQ-9 has excellent internal reliability, with Cronbach alpha of 0.89 in primary care settings, and excellent test-retest reliability [24].

Therapist Rating Questionnaire

To assess the patient-therapist interaction, we used a single-item question: “How valuable has the therapist interaction been for you?” This rating ranged from 1 to 5, with higher values indicating greater value. The patient-therapist interaction was assessed at weeks 1, 3, and 6 and after the intervention.

Statistical Analysis

We computed descriptive statistics for different indicators of intervention engagement. We plotted the number of days per week of practice during the intervention and the number of weeks of chat group use and used a repeated-measures analysis of variance (ANOVA) with Huynh-Feldt correction for autocorrelation of adjacent time points to examine whether there was significant change over time in the number of days of practice completed and online chat group use.

We used an intent-to-treat analysis that included all participants regardless of whether they completed or dropped out of the intervention. We used the more conservative method of last observation carried forward to insert missing data immediately postintervention and during the 4 weeks of follow-up. We implemented repeated-measures ANOVA and reported effect size as partial eta-squared (η^2_p) using SPSS, version 25 (IBM Corp, Armonk, NY). We also computed a depression-change score from the baseline to the 4-week follow-up to be used as the dependent variable in subsequent linear regressions.

Using linear regression analysis controlling for baseline levels of depression, we examined whether change in depression symptoms from baseline to 4 weeks postintervention was predicted by the number of days of practice during the intervention or the number of weeks of group chat use.

Results

Participant Characteristics

As shown in Table 1, participants were primarily female, young adults, and college educated and all Caucasian. Thus, the samples in studies 1 and 2 were similar and uniform.

Table 1. Characteristics of participants.

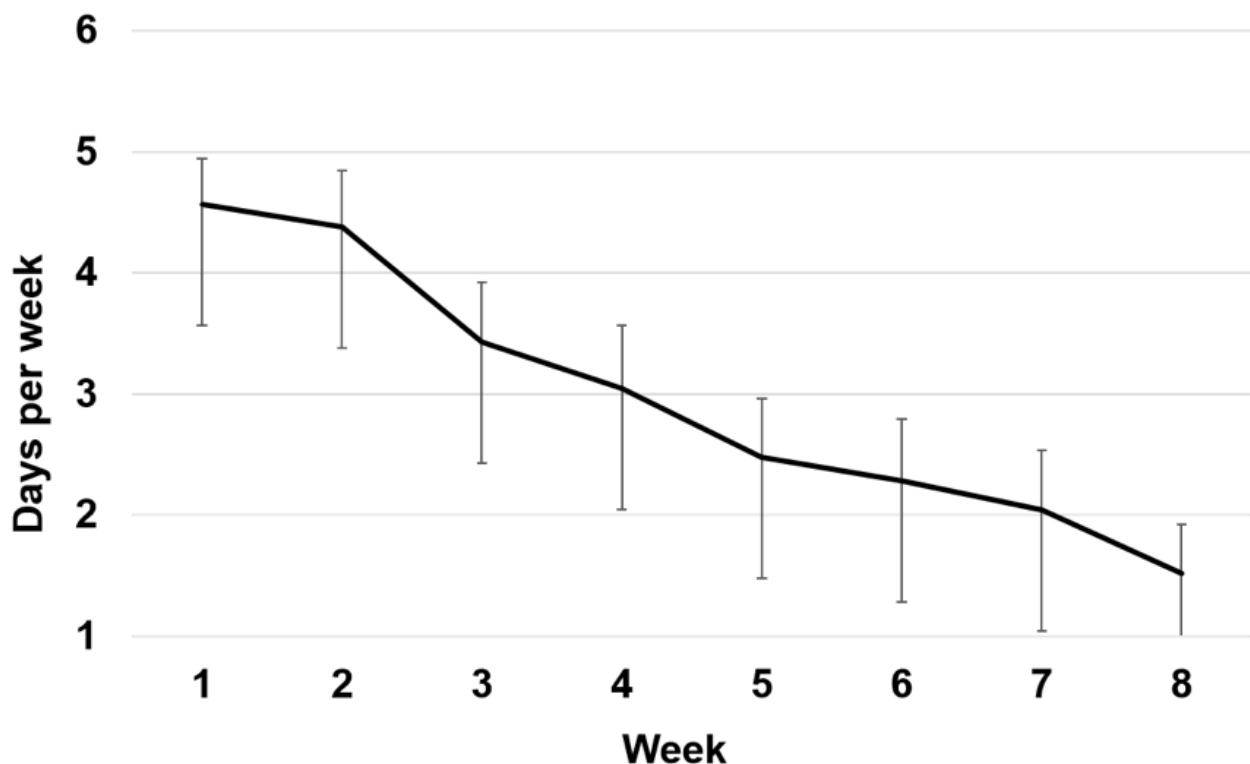
Characteristic	Study 1 (n=22)	Study 2 (n=95)
Women, n (%)	22 (100)	76 (80.0)
Age (years), mean (SD)	23.2 (1.1)	32.0 (9.85)
Education (years), mean (SD)	17.4 (3.3)	16.3 (2.1)
Ethnicity (Caucasian), n (%)	22 (100)	95 (100)

Study 1

Dropout, Daily Practice, and Weekly Group Chat

Dropout from the 8-week Ascend intervention was observed in 6 of the 22 participants (27%). For mobile phone-delivered exercises during the Ascend intervention, participants completed daily practices on 42% of the 56 days (mean 23.8 days; SD 14.2; range 1-49 days). A repeated-measures ANOVA, with Huynh-Feldt correction for autocorrelation of adjacent time points, showed that the mean number of days per week of practice decreased significantly ($F_{4,02}=15.02$, $P<.001$, $\eta^2_p=.43$) from week 1 (mean 4.57 days [SD 1.72]) to week 8 (mean 1.52 [SD 1.83]) of the intervention (Figure 1). For the once-weekly group chat, participants participated for an average of 4.87 weeks (SD 3.12; range 0-8 weeks). Repeated-measures ANOVA, with Huynh-Feldt correction for autocorrelation of adjacent time points, showed that the percentage of participants who used the online chat group per week decreased significantly from week 1 (78%) to week 8 (52%; $F_{5,21}=2.65$, $P=.03$, $\eta^2_p=.11$, $g=.68$). Participants reported a high and consistent level of the participant-therapist interaction across four time points during the 8-week intervention (mean 4.12).

Figure 1. Number of days per week of mobile phone-delivered practices completed during the 8-week Ascend intervention during study 1. Error bars indicate standard error of the mean.



Depression Symptoms

We used an intent-to-treat analysis that included all participants. Repeated-measures ANOVA for depression symptoms measured with the BDI-II revealed a significant reduction from before to after the intervention (mean delta=-8.55, SD 9.17; $F_{1,21}=19.11$; $P<.001$; $\eta^2_p=.48$) as well as from before to 4 weeks after the intervention (ie, week 12 assessment; mean delta=-10.91, SD 10.35; $F_{1,21}=24.44$; $P<.001$; $\eta^2_p=.54$; Figure 2).

Predictors of Change in Depression Symptoms

Using a linear regression controlling for baseline depression symptoms, we found that greater number of days of practice significantly predicted a reduction in depressive symptoms from the baseline to 4 weeks postintervention (BDI-II; $\Delta R^2=.38$; $\Delta F_{1,20}=11.14$; $P=.004$; unstandardized coefficient beta=-0.45, standard error of beta=0.14, 95% CI=-0.74 to -0.17; Figure 3). Similarly, we found that higher number of weeks of group chat use predicted a reduction in depressive symptoms from baseline to 4 weeks after the intervention (BDI-II; $\Delta R^2=.38$; $\Delta F_{1,20}=12.30$; $P=.002$; unstandardized coefficient beta=-2.06, SE of beta=.59, 95% CI=-3.29 to -0.83).

Figure 2. Depression symptoms during study 1 of the Ascend intervention. Error bars indicate standard error of the mean.

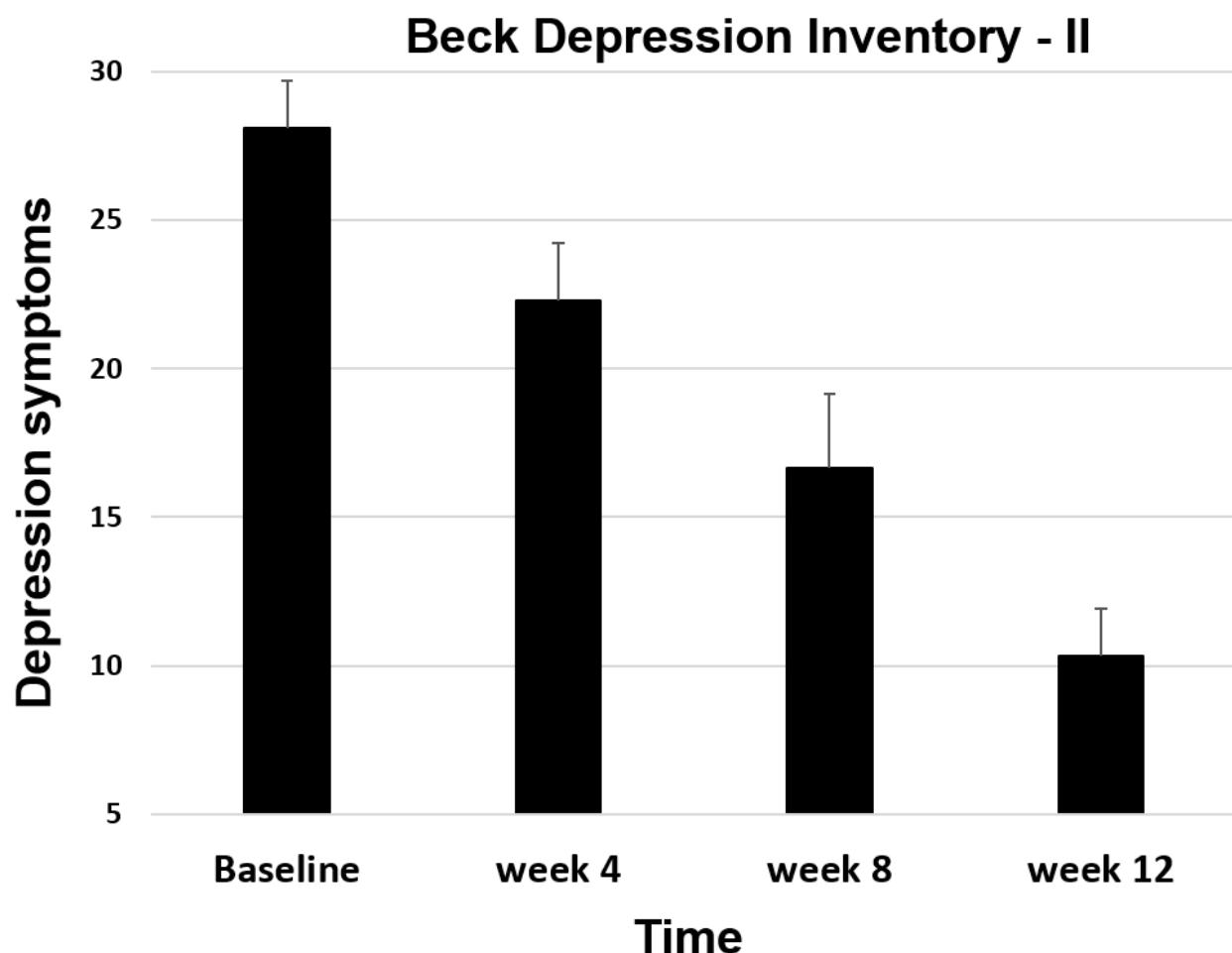
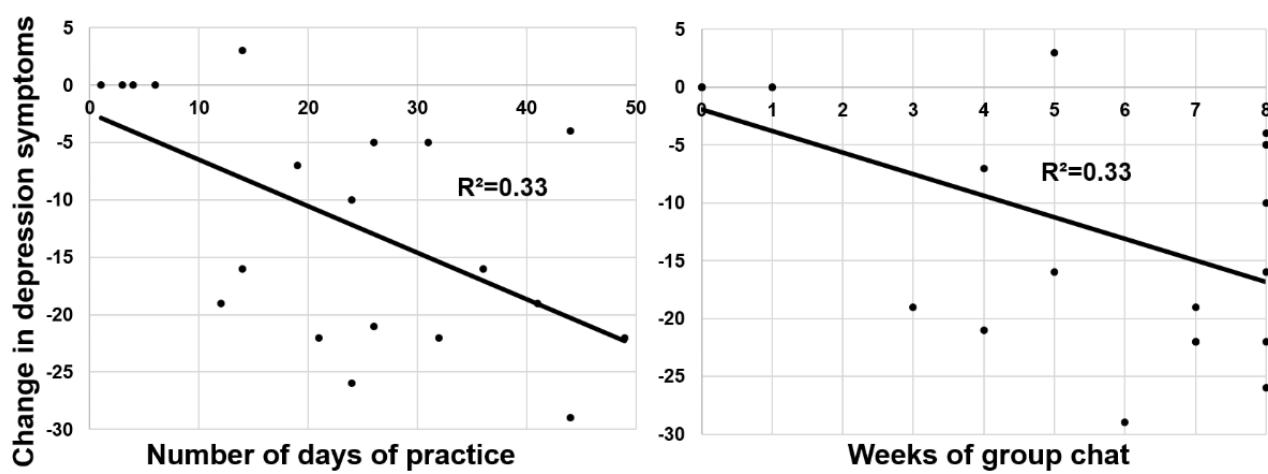


Figure 3. Daily practice and weekly group chat use during Ascend intervention predict pre-to-post change in depression symptoms in Ascend in study 1.



Study 2

Dropout, Daily Practice, and Weekly Group Chat

Dropout was noted in 14 of the 95 participants (15%). Participants completed the mobile phone-delivered exercises during the Ascend intervention on 55% of the days (mean 30.9

days; SD 14.1; range 1-56 days). A repeated-measures ANOVA, with Huynh-Feldt correction for autocorrelation of adjacent time points, showed that the mean number of days per week of practice decreased significantly ($F_{6.02, 535.33}=38.4$; $P<.001$; $\eta^2_p=.30$) in a linear trajectory from week 1 (mean 5.04 days [SD 1.71]) to week 8 (mean 2.63 [SD 2.31]) of the intervention

(Figure 4). For the once-weekly group chat, participants participated in an average of 5.81 weeks (SD 2.63; range 0-8 weeks). A repeated-measures ANOVA, with Huynh-Feldt correction for autocorrelation of adjacent time points, showed that the percentage of participants who used the online chat group per week decreased significantly from week 1 (85%) to week 8 (59%; $F_{5.59, 514.50}=6.09$; $P<.001$; $\eta^2_p=.06$). Participants reported high and consistent levels of participant-therapist interaction across four time points during the 8-week intervention (mean=4.13).

Depression Symptoms

A repeated-measures ANOVA of depression symptoms measured with the PHQ-9 revealed a significant reduction from before to after the intervention (mean delta=−4.39, SD 5.07; $F_{1,94}=71.20$; $P<.001$; $\eta^2_p=.43$) as well as from before to 4 weeks

after the intervention (ie, week 12; $F_{1,94}=71.88$; $P<.001$; $\eta^2_p=.43$; Figure 5).

Predictors Of Change in Depression Symptoms

Using linear regression, we found that higher number of days of practice significantly predicted lower residual depression symptoms at 4 weeks postintervention ($\Delta R^2=.16$, $F_{1,89}=16.46$, $P<.001$; unstandardized beta=−0.028, standard error of beta=0.01, 95% CI=−0.041 to −0.014; Figure 6).

We also found that higher number of weeks of group chat use predicted reduced depressive symptoms at 4 weeks postintervention ($\Delta R^2=.08$, $\Delta F_{1,91}=9.92$, $P=.002$; unstandardized coefficient beta=−0.63, standard error of beta=0.20, 95% CI=−1.03 to −0.23; Figure 6).

Figure 4. Number of days per week of mobile phone–delivered practices completed during the 8-week Ascend intervention during study 2. Error bars indicate standard error of the mean.

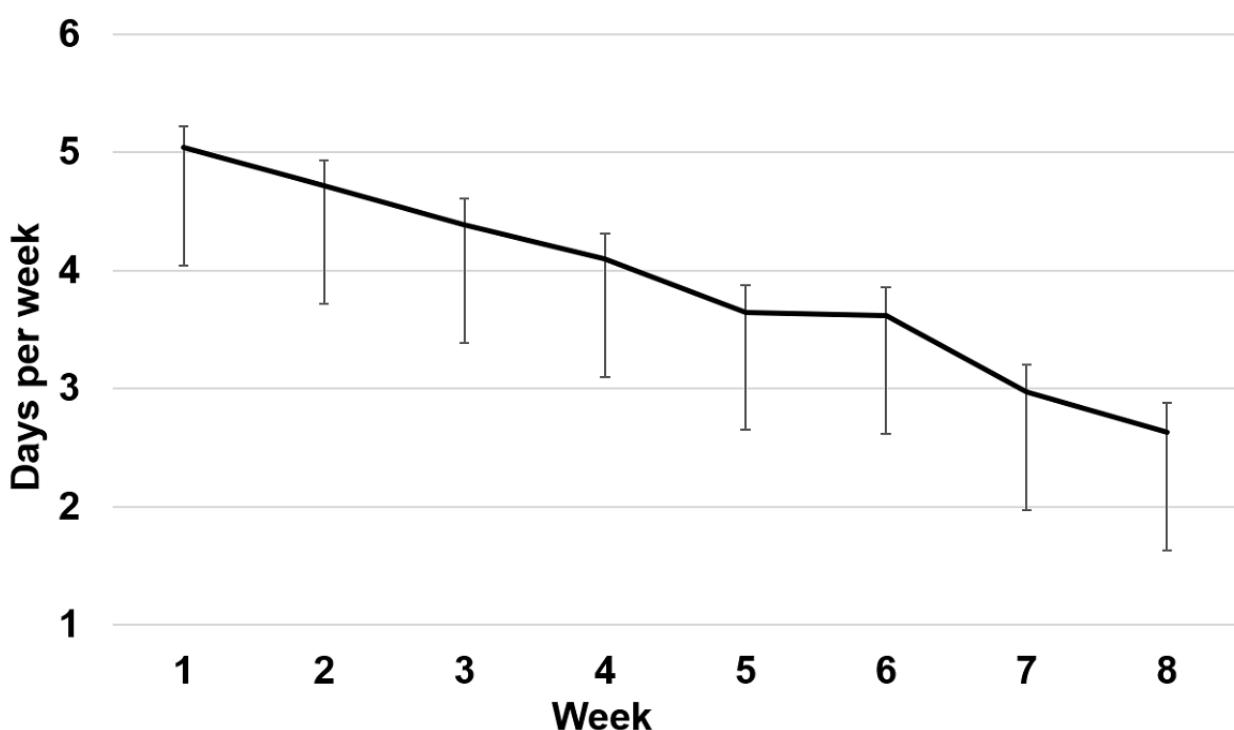


Figure 5. Depression symptoms during study 2 of the Ascend intervention. Error bars indicate standard error of the mean.

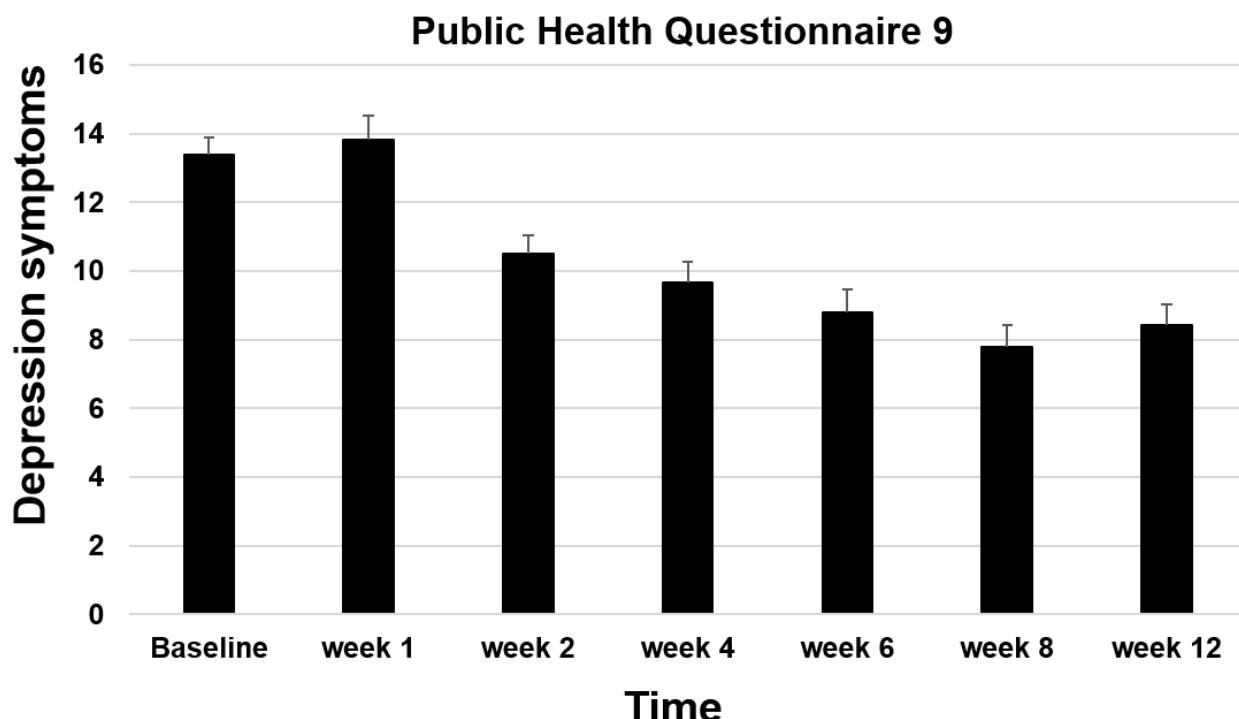
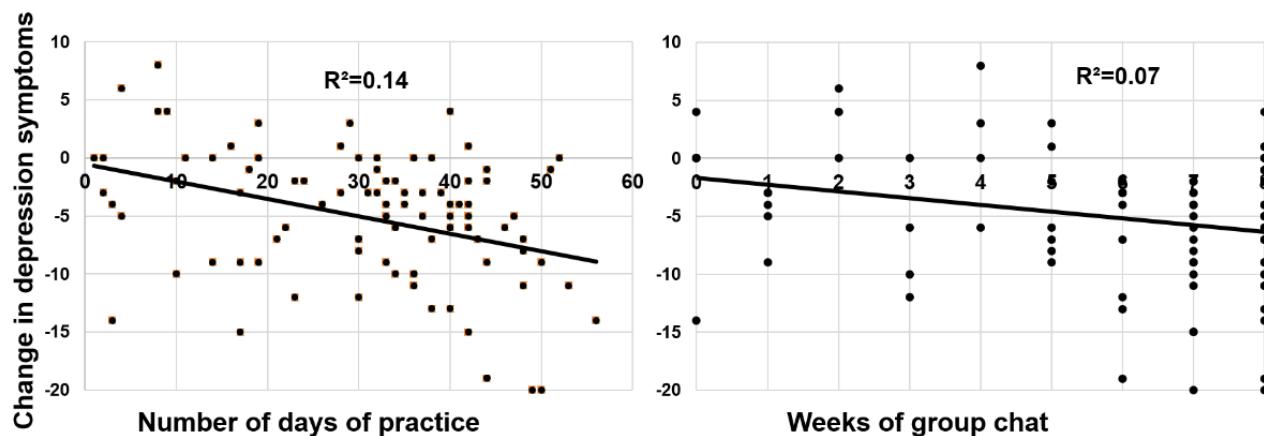


Figure 6. Daily practice and weekly group chat use during Ascend intervention predict pre-to-post change in depression symptoms in Ascend in study 2.



Discussion

Principal Findings

Findings from this study suggest that the mobile phone-delivered, therapist-supported Ascend intervention was associated with acceptable levels of dropout, linear decreasing daily practice, and weekly group chat use as well as significant decreases in depression symptoms in a sample of self-referred depressed individuals. Furthermore, the amount of daily practice and weekly group chat use during the intervention were associated with a reduction in depression symptoms from baseline to 4 weeks postintervention.

Comparison with Prior Work

A recent RCT of CBT for major depression reported 33% dropout from mobile-delivered CBT (mobile phone or iPad) versus 30% dropout from computer-delivered CBT [25]. For comparison with nonmobile phone internet-delivered intervention for depression, a recent study [21] that employed a coach to guide people through online therapy for depressed patients reported a 37% dropout rate. Thus, the dropout rate observed in our pilot study (17%, 20/117 participants) was comparable to both other mobile phone- and internet-delivered interventions.

Daily practice of mobile phone-delivered exercises decreased linearly over the course of the 8-week Ascend intervention in both pilot studies. Given that the amount of daily practice

significantly predicted a reduction in depression symptoms in each of the two pilot studies, this finding is disconcerting and strongly suggests that further effort is needed to investigate methods to support sustained practice, as it may lead to greater clinical improvement. This may involve introducing more novel types of practices or different modes of delivery of practices to maintain the participant's attention and sustained engagement. Ongoing measurement of engagement during the intervention and tailoring the delivery to individual participants may help increase sustained practice. This could involve the use of individual participant feedback after each practice to direct what type of practice and modality is to be used when delivering subsequent practices. A brief motivational interview by the therapist may also identify and overcome obstacles to engagement. This is a component of internet interventions that would benefit from further research. Sustained engagement may likely increase the effect of the Ascend intervention and possibly reduce the probability of depression relapses.

Group chat, often referred to as synchronous text-based dialogue, is an increasingly important component of online mental health interventions. In our studies, the number of weeks of chat group use decreased significantly over the 8-week intervention. Like daily practice, group chat use was a significant predictor of a reduction in depressive symptoms. A recent review [26] found that interventions using one-on-one synchronous chat reduced clinical symptoms more than waitlists, but not more than treatment as usual (face-to-face and telephone counseling). Research has found that text-based chat communication involves approximately 50% fewer words than oral conversation [27]. In our study, however, the chat group, which included intervention participants and curation by the therapist, was only one component of the intervention. More research is needed to better understand the factors that encourage and inhibit group chat use in mobile phone-delivered interventions for depression.

The Ascend intervention was associated with a reduction in depression symptoms across two pilot studies. However, because we did not incorporate a comparison control group, we cannot rule out regression to the mean as a reason for the reduced depression symptoms. Nonetheless, our intent-to-treat analysis revealed a moderate effect ($g=.43$ to $.54$) for reduction of depression symptoms across the two pilot studies. Our findings are in line with the results from a recent meta-analysis [15] of mobile phone-delivered interventions for depression that found moderate effect sizes for intent-to-treat or complete outcome data trials ($g=.40$), CBT-based interventions ($g=.53$), and interventions that included mindfulness practices ($g=.49$). Importantly, subanalyses in this meta-analysis that focused on diagnosed mood disordered samples showed that mobile phone-delivered interventions were most effective for patients with self-reported mild-to-moderate levels of depression symptoms ($g=.52$). This is important because individuals with mild-to-moderate depression symptoms are most likely to have the capacity to use mobile phone and other online interventions.

Identification of predictors of better outcomes is essential for determining how to refine and optimize a clinical intervention. We found that higher number of days of completing mobile phone-delivered practices predicted a greater reduction in

self-reported depression symptoms. Variance in the reduction of depression symptoms explained by practice during the 8-week Ascend intervention ranged from 7% to 38%. Additionally, in both pilot studies, we found that greater chat group use predicted reduced depression symptoms. Although these findings are promising, they also suggest that there likely are other factors that predict outcome and may interact with subgroups of patients. It will be important to determine which specific practices and what amount of group chat use are most effective for reducing depression symptoms.

Identifying patient characteristics that predict the impact of online interventions on depression symptoms is essential. A well-controlled study comparing self-guided internet-delivered interpersonal psychotherapy, CBT, and MoodGYM found that female gender, lower mastery, and lower dysfunctional attitudes predicted lesser depression symptoms following 4 weeks of treatment and 6 months of follow-up regardless of the intervention type [28]. Understanding how these patient characteristics interact with daily practice and group chat use should be examined in future studies.

Given that novelty captures attention, one approach is to explore on an individual participant level whether introducing new modalities of delivery of didactic content and practices might recapture attention and dedication to practice. An algorithm could be used to detect when the number of days of practice begins to decrease and then introduce new videos, practices, or communication from other participants and psychotherapist to buttress against further reduction in practice. Another method would be to show each individual their own week-to-week relationship between practice and depression symptoms to further motivate engagement with the Ascend program.

Limitations

Participants in this study were self-referred, and thus, there may be a sampling bias in that these individuals were more motivated to participate than the normative population of depressed individuals. Furthermore, the sample consisted of 80%-100% women, which is also not representative of the population of individuals with depression in clinical settings or the community. This pilot study did not include any control group with or without an active comparison intervention, which limits the inferences that can be made regarding the efficacy or comparison of the effect sizes between the Ascend program and other interventions. Future studies will benefit from comparison of Ascend to gold-standard psychosocial (eg, CBT) and pharmacological interventions as well as a control group without an active intervention. Although this study provides initial evidence of a reduction in depression symptoms, future studies should include diagnostic assessment of participants. In addition to changes in clinical symptoms, it will be important to measure putative mediators of the Ascend intervention related to mindfulness meditation (eg, mindfulness skills) and CBT (eg, cognitive reappraisal). Future studies might consider determining whether the amount (eg, duration in minutes and frequency of events) or type of therapist-patient interaction (eg, chat, phone, and email) predicts intervention outcome.

Conclusions

The overall finding from this pilot study is that the 8-week online Ascend intervention was associated with reduced

depression symptoms. However, more rigorous controlled trials that compare the Ascend intervention with both other online mental health interventions and gold-standard clinical interventions for major depression are needed.

Acknowledgments

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Conflicts of Interest

PRG owns options of Meru Health Inc. RL serves as the chief operating officer of Meru Health Inc, owns a large share of the company's stocks, and receives a salary from the company. KR serves as the chief executive officer of Meru Health Inc, owns a large share of the company's stocks, and receives a salary from the company. OH is employed as a chief therapist by Meru Health Inc, owns stocks and options, and receives a salary from the company. At the time of the study, TH was employed as a therapist by Meru Health Inc and received a salary from the company. AR is employed as a medical director by Meru Health Inc, owns stocks and options, and receives a salary from the company.

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Abbreviations

ANOVA: analysis of variance
BDI-II: Beck Depressive Inventory-II
CBT: cognitive behavioral therapy
HIPAA: Health Insurance Portability and Accountability Act
PHQ-9: Patient Health Questionnaire 9-item version
RCT: randomized controlled trial
WHO: World Health Organization

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Original Paper

Impact of Food Preparation Video Exposure on Online Nutrition Education in Women, Infants, and Children (WIC) Program Participants: Retrospective Study

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Abstract

Background: The impact of integrating video into health education delivery has been extensively investigated; however, the effect of integrating video on a learner's subsequent performance in an online educational setting is rarely reported. Results of the relationship between the learner's online video viewing and subsequent progression toward health behavior change in a self-directed online educational session are lacking.

Objective: This study aimed to determine the relationship between viewing a Health eKitchen online video and key engagement performance indicators associated with online nutrition education for women, infants, and children (WIC).

Methods: This study involved a retrospective cohort of users grouped on the basis of whether Health eKitchen exposure occurred before or after completing a nutrition education lesson. A two-sample test for equality of proportions was performed to test the difference in the likelihood of progression between the groups overall and when stratified by lesson type, which was defined by whether the lesson focused on food preparation. Welch two-sample *t* tests were performed to test the difference in average link depth and duration of use between groups overall and stratified by lesson type. Logistic regression was conducted to validate the impact of video viewing prior to lesson completion while controlling for lesson type and factors known to be associated with WIC key performance indicators.

Results: A greater stage of change progression was observed for both food preparation ($\chi^2=12.6$, $P<.001$) and non-food preparation ($\chi^2=62.8$, $P<.001$) lessons among early stage users who had viewed a Health eKitchen video before completing a lesson. Time spent viewing educational learning resource links within the lesson was also significantly longer for both food preparation ($t=7.8$, $P<.001$) and non-food preparation ($t=2.5$, $P=.01$) lessons. Logistic regression analysis corroborated these results while controlling for known confounding factors. The odds of user progression were nearly three times greater among those who viewed a Health eKitchen video prior to lesson completion (odds ratio=2.61; 95% CI=2.08-3.29). Type of lesson (food vs non-food preparation) was the strongest predictor of progression odds (odds ratio=3.12; 95% CI=2.47-3.95).

Conclusions: User access to a Health eKitchen video prior to completion of an online educational session had a significant impact on achieving lesson goals, regardless of the food preparation focus. This observation suggests the potential benefit of providing an application-oriented video at the onset of online nutrition education lessons.

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KEYWORDS

internet; online video; WIC; engagement

Introduction

The federally funded Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) provides qualified program participants who are at nutrition risk due to insufficient financial access to nutritious foods to supplement diets, information on healthy eating, and referrals to health care. Many positive health outcomes have been associated with the program, including improved diet, infant feeding practices, and preconceptual nutrition status [1]. Wichealth.org [2] is an online educational framework in which clients engage to meet the educational requirements in order to be eligible for the WIC program. People who complete wichealth.org lessons demonstrate very high rates of positive movement with belief in their ability to engage in various health-promoting nutritional and physical activity behaviors [3,4]. Over the last decade, many enhancements have been made to wichealth.org to provide continuous improvement with respect to various key performance indicators. These enhancements indicate the value of education for the client, including both engagement extent and duration, as well as the subsequent impact to the client's current readiness to change behavior. One of these enhancements was the Health eKitchen curated library of existing internet-based food preparation and cooking videos available to users of wichealth.org. Videos consist of short segments (eg, 2-3 minutes in length) that demonstrate how to prepare and cook recipes using specific foods associated with the WIC food package. A recent review of Health eKitchen usage patterns suggested a positive relationship between video access and wichealth.org user lesson progression.

The impact of integrating video into health education delivery has been extensively investigated to determine whether learning objectives can be achieved more effectively and with greater learner satisfaction than interventions that do not use any technology [5-10]. This is also true for other educational disciplines that do not focus on health [11-14]. Typical investigations concerning the use of video, whether integrated into a face-to-face or online educational setting or not, aim at comparing the use of one or more modalities on the learning outcome of interest [15-17]. However, the effect of integrating video on a learner's subsequent performance in an online educational setting is scarcely reported [18]. Further, to our knowledge, no study has specifically reported on the relationship between learner online video viewing and the learner's subsequent progression toward health behavior change in a self-directed online educational session. Studies that focused on the effect of video use within the context of an online educational setting tended to focus on user satisfaction and knowledge recall, where online learner satisfaction has been demonstrated to be strongly associated with learner engagement in the educational content [19-21]. Furthermore, inclusion of videos can increase learner motivation to learn and subsequent engagement with online course content [16].

Typical studies concerning the impact of video use in an online learning environment focus on comparing various educational modalities that include video with those that do not or those that have varying levels of interactive video integrated [14,16,22]. Choi and Johnson conducted similar work, wherein

various online learning environments that included or did not include the use of video instruction were compared [23]. Most reports identified a significant improvement in learners' motivation when online videos were integrated. Increase in online learner engagement through the use of videos has also been demonstrated physiologically: Using electrodermal activity and heart rate measurements, van Bruinessen and colleagues showed that a moderate level of increased arousal is ideal to increase learning capacity in an online self-help intervention [18].

The purpose of this study was to determine the relationship between viewing of a Health eKitchen online video and key engagement performance indicators associated with WIC online nutrition education.

Methods

Participants

The sample used for this study was derived from WIC clients across 21 US states, who completed a wichealth.org lesson during a 34-month period in the government's 2014-2016 fiscal years. Participating subjects chose to complete a wichealth.org lesson as a means of meeting secondary contact requirements associated with the WIC program. Data-collection protocols using wichealth.org were approved for use by the Western Michigan University's Human Subjects Institutional Review Board. Online informed consent was provided prior to completion of the online survey.

Data Collection

Data utilized in this study were collected from 4460 wichealth.org uses from the system database for WIC clients who started an English-based lesson in one of the first three stages of the Transtheoretical Model (ie, precontemplation, contemplation, and preparation), completed the lesson, and viewed at least one Health eKitchen video during their session. Only the individuals who began a lesson in the early stages of readiness to change, not those in the active change stages, could have measurable progression at the time of lesson completion.

All lessons were completed using the wichealth.org website application. Data consisted of six system-collected measures (links viewed, link view time, device type, beginning stage of change, ending stage of change, and lessons completed), four profile items (ethnicity, race, pregnancy status, and age), and time at which the Health eKitchen video was viewed. The staging algorithms used to identify the beginning and ending stages were based on criteria previously used to determine stages of change and progression, which have been described in detail elsewhere [3,4].

Statistical Analysis

Binary progression—irrespective of whether a subject advanced in stage of change intent—was the dependent variable used. The primary independent variable of interest was subject exposure to a Health eKitchen video prior to completion of a wichealth.org lesson. Over the past decade, program evaluations conducted every 6 months demonstrated the importance of other variables currently collected from users of wichealth.org. These

include user demographic characteristics of race, ethnicity, pregnancy status, and age as well as system access characteristics including device type (fixed, such as a desktop or laptop, vs mobile), lesson type (feeding behavior focus vs other), number of internet resource links accessed (depth), and duration of all resource links used. Each of these variables was considered a possible effect modifier or confounder of the relationship of interest. Depth and duration of link use are key performance indicators for wichealth.org previously demonstrated to be strongly associated with users' stage of change progression [24]. Lesson type was also assigned based on whether the wichealth.org lesson content focused on feeding behaviors that would be relevant to Health eKitchen videos about food preparation and recipes. Lesson type was included in the model to determine whether the impact of a video view on a lesson is associated with whether the lesson addresses content related to food preparation and recipes.

In order to control for motivation bias potentially confounding the positive relationship between lesson engagement and viewing a Health eKitchen video prior to wichealth.org lesson completion, users who chose to view a Health eKitchen video after completing a wichealth.org lesson were used as the comparison group. Similar to users who viewed a Health eKitchen video prior to their lesson, these individuals were motivated to view a video, but they viewed the video after their lesson. As users access Health eKitchen by their own choice and motivation, it is likely they are motivated to be engaged to a greater extent and subsequently more likely to progress in the stage of readiness change compared to users that opt not to access Health eKitchen at all.

A two-sample test for equality of proportions was performed to test the difference in the likelihood of progression between comparison groups. Likewise, this difference was tested for each of the covariates: Welch two-sample *t* tests were performed to test whether link depth and duration were associated with user progression and each of the covariates. The Welch *t* test adjusts the number of degrees of freedom when the variances are not equal between groups. A logistic regression was conducted to evaluate the odds of progression for users who viewed a Health eKitchen video prior to subsequent completion of a wichealth.org lesson compared to those who did not. All data were analyzed using the R statistical package [25].

Results

Approximately half (2301/4460, 51.59%) of the subjects included in this investigation reported that they were of Latino ethnicity, and 58.5% of subjects belonged to a race other than white. Most (4206/4460, 94.30%) subjects were mothers of the child who was receiving WIC benefits. In addition, 2655 of the subjects (59.53%) completed the lessons using a fixed device. As expected, device type and lesson type were both significantly associated with the outcome of interest or at least one of the wichealth.org key performance indicators ($P<.001$; [Table 1](#)). Further, age group was associated with the outcome of interest and both wichealth.org key performance indicators presented. None of the other demographic variables were significantly associated with progression, link use depth, or link use duration ([Table 1](#)).

The wichealth.org stage of change progression (one or more stages) was significantly associated with whether a user accessed a Health eKitchen video prior to their lesson ($\chi^2=127.2$, $P<.001$; [Table 2](#)). Further, the average time spent by users on links during the lesson was significantly more for users who viewed a Health eKitchen video prior to the lesson ($t=8.2$, $P<.001$). In addition, both food preparation ($\chi^2=12.6$, $P<.001$) and non-food preparation ($\chi^2=62.8$, $P<.001$) lessons demonstrated significantly greater progression among early stage of change subjects who viewed a Health eKitchen video prior to the lesson. Similarly, the average time spent was significantly longer for both food preparation ($t=7.8$, $P<.001$) and non-food preparation ($t=2.5$, $P=.01$) lessons among users who viewed a Health eKitchen video prior to the lesson.

Only predictors significantly associated with the odds of stage progression were included in the model ([Table 3](#)). Although age group was associated with the outcome of interest, it was not a significant contributor to the model and was therefore not included. Viewing of a Health eKitchen video prior to completion of a lesson was associated with nearly three times the odds of progression as that for subjects who did not view a Health eKitchen video until after lesson completion (odds ratio=2.61; 95% CI=2.08-3.29). Lesson type was the strongest predictor of progression odds (odds ratio=3.12; 95% CI=2.47-3.95).

Table 1. Characteristics of early beginning-stage users who accessed Health eKitchen.

Demographic	Early state users (N=4460)	% Progression in stage of change	Average link views	Average link minutes
Device type				
Fixed	2655	91.1	2.8 ^a	5.7 ^a
Mobile	1805	91.3	1.1	1.7
Lesson type				
Non-food preparation	1557	81.5	1.9	3.2
Food preparation	2903	96.3 ^a	2.2	4.6 ^a
Race				
White	1853	91.3	2.2	4.0
Non-white	2607	91.1	2.1	4.1
Latino ethnicity				
No	2159	89.7	2.2	4.0
Yes	2301	92.5	2.0	4.1
Pregnancy status				
No	3694	91.4	2.1	4.1
Yes	767	89.8	2.2	4.1
User age group				
<31 years	2404	90.1	2.0	3.5
≥31 years	1972	92.5 ^a	2.3 ^a	4.8 ^a

^a*P*<.001.**Table 2.** Key performance indicators according to Health eKitchen video viewing.

Health eKitchen video viewed prior to lesson	Early state users (N=4460)	% Progression in stage of change	Average link views	Average link minutes
Overall				
No	913	81.7	2.08	2.69
Yes	3547	93.6 ^a	2.14	4.45 ^a
Non-food preparation				
No	470	71.7	1.9	2.5
Yes	1087	85.7 ^a	1.9	3.5 ^b
Food preparation				
No	443	92.3	2.3	2.9
Yes	2460	97.1 ^a	2.2	4.9 ^a

^a*P*<.001.^b*P*=.01.

Table 3. Results of independent samples study group logistic regression model.

Predictor of model feature	Estimate <i>B</i>	SE <i>B</i>	<i>z</i>	Pr(> <i>z</i>)	Odds ratio	95% CI
Intercept	0.39	0.12	3.24	0.00121 ^a	1.47	1.17-1.87
Health eKitchen view prior to the lesson	0.96	0.12	8.22	0.00000 ^b	2.61	2.08-3.29
Lesson type	1.14	0.12	9.53	0.00000 ^b	3.12	2.47-3.95
Device type	0.49	0.12	4.07	0.00005 ^b	1.63	1.29-2.07
Link views	0.28	0.04	6.30	0.00000 ^b	1.32	1.22-1.43
Link minutes	0.05	0.02	2.59	0.00967 ^a	1.05	1.01-1.09

^a*P*<.01.^b*P*<.001.

Discussion

Principal Findings

Video use has been well demonstrated as a valuable and impactful tool in the online educational setting. This study evaluated the effect of video viewing on intent to change parent-child feeding behavior when the video was viewed before beginning the educational lesson. Potential for confounding caused by motivation or volunteer bias associated with learners who chose to view a Health eKitchen video prior to their lesson was minimized, as the comparison group also chose to view Health eKitchen videos but did so after completion of their educational session.

The results of this study are important, because even though online nutrition education programs have been found to have an impact on various aspects associated with nutrition behaviors among WIC clients, including belief in ability and intent to positively impact parent-child feeding, knowledge and behaviors surrounding eating breakfast, and reduction in salt intake [3-5,26,27], the specific effect of video viewing on achieving online educational objectives when viewed by learners before engaging in a lesson of interest is not well reported in the literature, especially in the WIC setting. To our knowledge, only one published study deemed the use of a training video on how to access a WIC online nutrition education program as helpful in reducing challenges with online access [5]. However, examining the usefulness of instructional video on tasks associated with logging in and negotiating a website is very different from determining the relationship between video viewing and key performance indicator engagement, which was the basis of the current study.

Findings from this investigation suggest that early stage *wichealth.org* users were more successful in progressing in stage of behavior change intent when the session focusing on that behavior was preceded by a Health eKitchen video view as compared to when it was followed by video viewing while controlling for other key predictors of progression. It was expected that if an effect was identified, it would be limited to lessons focusing on meal-preparation behaviors, as Health eKitchen videos would mostly be relevant to such behaviors, rather than lessons focusing on, for example, behaviors such as physical activity or dental hygiene. However, users of non-meal

preparation lessons benefited to a similar extent as users of meal preparation lessons when they used Health eKitchen before completing their lesson, suggesting that the content of the video may be less important than the arousal or level of engagement that may be incited in the learner following video viewing. A previous study on the use of video and its ability to enable deep learning that touched on the subject reported that the relevance of the video with a learning objective should be carefully considered and clear to the user [28]. In contrast, the current study indicated that the use of video may have a positive impact regardless of whether it is specifically related to a behavior change focus. Here, the degree of relevance may be important. In addition, the fact that the Health eKitchen videos are related to personal health choices may be relevant enough to stimulate the user's motivation and interest in learning more about different, yet related, topics.

Limitations

Subjects chose whether they wanted to use *wichealth.org* as the method for completing secondary contact requirements, which limits the ability to generalize the results of this study to the entire WIC population. In addition, Health eKitchen is a separate feature that does not qualify for secondary contact credit. As such, the two groups compared in this study may differ in how they approach educational learning. Nonetheless, the use of video prior to initiating an online learning session appears to be an important strategy to employ in e-learning environment designs in order to maximize user engagement and subsequent achievement of learning objectives.

Recommendations

We recommend that a more rigorous study be conducted to confirm our findings and allow generalization of the results to a broad audience of WIC participants. Additional studies could focus on introducing video learning in other online education and behavior change programs used by WIC to determine if our findings are applicable to any online learning approach with WIC clients or specific to the Health eKitchen feature available within the *wichealth.org* nutrition education platform. The use of video prior to the use of other traditional educational formats available within WIC clinics, such as information malls and one-on-one nutrition counseling, could be explored as a means for potentially impacting client engagement. Many clinics provide kiosks or looping videos in clinic waiting areas where

nutrition-related videos could be shown. Although not the same as an online format, the implication that the use of video may, to some degree, influence client engagement warrants exploration of this method of learning.

Conclusions

This study is useful to nutritionists and WIC staff for developing or adopting online nutrition education and behavior change interventions, especially for WIC populations. This study showed that viewing a video prior to lesson completion was positively related to subject engagement in the online educational session.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

WIC: Women, Infants, and Children

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Original Paper

A Digital Modality Decision Program for Patients With Advanced Chronic Kidney Disease

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Abstract

Background: Patient education regarding end-stage renal disease (ESRD) has the potential to reduce adverse outcomes and increase the use of in-home renal replacement therapies.

Objective: This study aimed to investigate whether an online, easily scalable education program can improve patient knowledge and facilitate decision making regarding renal replacement therapy options.

Methods: We developed a 4-week online, digital educational program that included written information, short videos, and social networking features. Topics included kidney transplant, conservative management, peritoneal dialysis, in-home hemodialysis, and in-center hemodialysis. We recruited patients with advanced chronic kidney disease (stage IV and V) to enroll in the online program, and we evaluated the feasibility and potential impact of the digital program by conducting pre- and postintervention surveys in areas of knowledge, self-efficacy, and choice of ESRD care.

Results: Of the 98 individuals found to be eligible for the study, 28 enrolled and signed the consent form and 25 completed the study. The average age of participants was 65 (SD 15) years, and the average estimated glomerular filtration rate was 21 (SD 6) ml/min/1.73 m². Before the intervention, 32% of patients (8/25) were unable to make an ESRD treatment choice; after the intervention, all 25 participants made a choice. The proportion of persons who selected kidney transplant as the first choice increased from 48% (12/25) at intake to 84% (21/25) after program completion ($P=.01$). Among modality options, peritoneal dialysis increased as the first choice for 4/25 (16%) patients at intake to 13/25 (52%) after program completion ($P=.004$). We also observed significant increases in knowledge score (from 65 [SD 56] to 83 [SD 14]; $P<.001$) and self-efficacy score (from 3.7 [SD 0.7] to 4.3 [SD 0.5]; $P<.001$).

Conclusions: Implementation of a digital ESRD education program is feasible and may facilitate patients' decisions about renal replacement therapies. Larger studies are necessary to understand whether the program affects clinical outcomes.

Trial Registration: ClinicalTrials.gov NCT02976220; <https://clinicaltrials.gov/ct2/show/NCT02976220>

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KEYWORDS

chronic kidney disease; end-stage renal disease; online social networking; patient education; renal dialysis

Introduction

An important part of care for patients with moderate to advanced chronic kidney disease (CKD) is education about treatment options for end-stage renal disease (ESRD) including in-center

or in-home renal replacement therapies as well as nondialysis treatment options including kidney transplant or conservative management with no dialysis. Unfortunately, rather than planning ahead for ESRD, up to 50% of patients have emergent starts or undergo unplanned, urgent starts to dialysis [1,2].

Circumstances associated with such unplanned or crash initiation of dialysis, such as hyperkalemia, and the higher infection rates associated with hemodialysis catheters place patients at high risk for frequent hospitalizations and death [3] and impose a high cost on the medical system [1,4]. Furthermore, of the 500,000 patients who have ESRD and receive dialysis, less than 10% utilize in-home dialysis therapies such as peritoneal dialysis or home hemodialysis [5]. Surveys of patients with ESRD on hemodialysis suggest that low patient awareness may be a barrier to choosing self-care in-home dialysis (such as peritoneal or home hemodialysis) compared with in-center dialysis [6].

Studies have shown that predialysis education may increase the likelihood of patients undergoing planned, elective dialysis starts [7]. Predialysis educational programs have been shown to increase the likelihood that patients choose self-care dialysis or in-home dialysis rather than in-center dialysis [8], and they have been shown to increase the likelihood of patients choosing peritoneal dialysis rather than hemodialysis [9-11]. Successful programs have included one-on-one contact with a clinician educator [10]; patient group sessions to allow for discussion [8]; and multidisciplinary education involving an integrated team of doctors, nurses, and social workers [12]. These approaches to dialysis education are effective but may not be accessible to a broad spectrum of CKD patients because of cost and geographic restrictions. Digital technology has the potential to integrate these diverse educational approaches, facilitate communication between patients and clinicians in one-on-one or group forums, and afford better scalability to generate educational programs for a larger range of CKD patients.

We conducted a feasibility and preliminary efficacy study of the Modality Decision Program, a digital online educational program designed by specialty kidney care provider, Cricket Health, to prepare patients with advanced CKD for choosing a plan of care in the event that they reach ESRD [13]. We hypothesized that the program would have high usability and feasibility as well as high rates of program engagement. We also hypothesized that patients would have increased knowledge, self-efficacy, and confidence in choosing a treatment plan after completing the program and that the proportion of patients choosing in-home dialysis modalities would be higher after completion of the educational program.

Methods

Recruitment

Study participants were recruited in person, by mail, and by physician referral from the University of California, San Francisco (UCSF) Nephrology and Hypertension Clinic and the San Francisco Veterans Affairs Medical Center (SFVAMC) Renal Clinic. Patients at these clinics were first screened for eligibility using electronic health records and then mailed a letter explaining the study and providing contact information of the study coordinator. Screening of the medical record was primarily done manually by the study coordinator in the research team; additional efforts to enroll patients were made by enlisting the Clinical Research Services at UCSF to send out letters via their Recruitment Service. Two weeks after the recruitment letter was sent, the study coordinator called to inquire if they

would like to join the study and to further evaluate eligibility. Participants were offered US \$300 for completing the 2-month study. Flyers were also posted at UCSF and SFVAMC for eligible patients to contact the study team.

The study coordinator screened medical records, and the principal investigator confirmed the patient's eligibility for the study based on the inclusion and exclusion criteria. Eligibility criteria included an estimated glomerular filtration rate (eGFR) $<30 \text{ ml/min/1.73 m}^2$ in the 6 months before enrollment, attendance at the renal clinic at least twice within the 18 months before enrollment, and documented discussion between patient and nephrologist about the potential need for dialysis in the future. Any 1 of the following resulted in exclusion: currently on dialysis, eGFR $\geq 10 \text{ ml/min/1.73 m}^2$ over the past 6 months, age greater than 90 years, homelessness, inability to speak English, lack of phone or computer or internet access, lack of email access, dementia, severe cognitive impairment, blindness, deafness, or more than 2 hospitalizations during the last 6 months. All participants gave written informed consent. All procedures were in accordance with the Declaration of Helsinki (World Medical Association Declaration of Helsinki, 2000). The study was approved by the UCSF Human Research Protection Program Institutional Review Board (IRB study #16-19626), including waivers of written consent and Health Insurance Portability and Accountability Act authorization, and was registered on ClinicalTrials.gov (NCT02976220).

The Modality Decision Program

The main objectives of the educational program were to (1) increase patient knowledge of ESRD treatment options, (2) help patients to prioritize options based on their lifestyle and values, and (3) build patients' confidence in their treatment choice. The program design was informed by prior successful education programs [8]. The program was supplied as a responsive website accessible through a smartphone, tablet, or computer. Online digital content included 9 videos, consisting of one-on-one interviews with patients with ESRD; each patient describes how ESRD has affected his or her life and family and what factors influenced his or her choice of care for ESRD. The digital content also included answers to 129 frequently asked questions (FAQs), direct messaging, and individualized advice via online video from the study nurse, peer mentors (patients with ESRD who could share their experiences about treatment options), and a moderated patient discussion group. Samples of FAQs, nurse chat, and discussion board are shown in [Multimedia Appendix 1](#).

Following the intake visit, participants were asked to engage with the educational program over a period of 4 weeks. During the 4 weeks, the study nurse followed up with the patient via messaging on the website and the participant had the opportunity to read educational materials and interact with the nurse and peer mentor group. For a participant to be considered adequately engaged with the program, the participant had to send at least one message to the nurse, mentors, or discussion board and also view at least one video or FAQ. These metrics of engagement were monitored by Cricket Health, and if a patient's engagement was less than adequate on the online study platform during the 2 weeks following the intake visit, the study coordinator

reminded the patient to engage with the platform. Program completion was marked by the end of the 4-week period or by the achievement of adequate engagement when not achieved by the end of the 4-week period. Upon completion of the educational program, participants discussed their preferred treatment option with the study nurse and addressed any remaining questions or open topics. On the basis of these discussions, the study nurse compiled an insights report summarizing the education the patient had received and any major concerns the patient expressed about their plan of care. After completion of the program, an insights report was sent to the patient and, if requested, their nephrologist.

Study Visits

Each participant attended 3 study visits over a period of 2 months at the UCSF Nephrology and Hypertension Clinic. At the first study visit, the study coordinator conducted intake interviews, administered baseline surveys, took a medical history, verified eligibility, and obtained written informed consent. Participants were informed that completion of the study would require 8-14 hours over 2 months (2 hours for visit 1, 4-10 hours of engagement with the online program over 1 month, 1 hour for visit 2, and 1 hour for visit 3). The coordinator helped the participants log on to the website and gave them a tour of the program. The study nurse was present via online video during the intake visit. After participants completed the 4-week education program, they returned for a second study visit during which they repeated the survey administered at baseline. Participants attended a third study visit 1 month after completion of the intervention and were administered the same survey to evaluate whether the educational program had a durable effect. The third study visit occurred 1 month after the second (2 months after intake). During both the second and the third visits, participants were given the opportunity to provide qualitative feedback on the program.

Survey Instruments

The study survey was developed specifically for this pilot study according to the educational content of the instructional materials. Cricket Health gave the research team access to the online subject matter so that we could ensure our surveys covered topics included in the educational program. We conducted a literature review of relevant surveys for patients with CKD to assess the content, vocabulary, and complexity of such surveys. CKD knowledge was assessed by 18 multiple-choice questions about knowledge of dialysis and treatment options modeled on those found in the Kidney Knowledge Survey [14], the ESRD Questionnaire [15], and the Chronic Hemodialysis Knowledge Survey [16]. Confidence in treatment choice was assessed by the Likert scale with the statement “I feel ready to choose a treatment option that would be best for me if I experience kidney failure.” CKD self-efficacy was assessed by 5 Likert items, including 1 from the CKD-Self Efficacy Survey (“I can actively share my experience of managing CKD with other patients”) [17] and 4 centered on self-care dialysis. A final question assessed the patient’s preferred treatment option should they reach ESRD based on a ranking of 5 choices. The survey also included 5 questions

assessing patient satisfaction with the program. The complete patient survey is shown in [Multimedia Appendix 2](#).

We contacted each patient’s nephrologist to inform them of the patient’s participation in the study and obtained consent from each nephrologist to contact him or her after the patient completed the study. To evaluate provider perspectives on the usefulness of the educational program for their patients’ individual care, we surveyed study participants’ nephrologists after each patient completed the final visit. The survey included 5 questions assessing whether the program helped the patient and the physician prepare for ESRD care ([Multimedia Appendix 3](#)).

Statistical Design and Analysis

Initial analyses described the multistep enrollment into the study. For participants who completed the study, we describe engagement with the 4-week educational intervention program and demographic and clinical characteristics at baseline. In this single-group, pretest-posttest study design, patients served as their own control. On the basis of the results of a previous pretest-posttest study of a self-management education program among patients with CKD that evaluated changes in self-efficacy using a survey totaling 250 points [18], we calculated that a minimum sample size of 26 patients was needed to detect a change of 15 points on such a survey using a 2-tailed test and alpha level of .05.

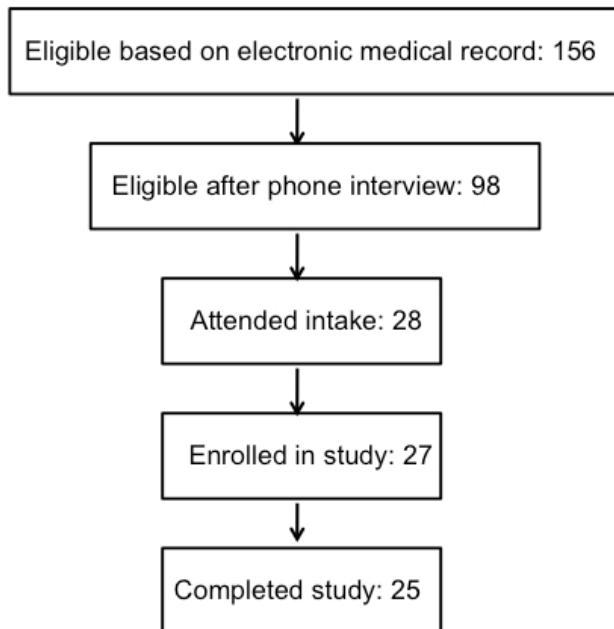
We designed this study to include 2 posttest surveys to allow the primary evaluation of program effects immediately following program completion as well as a secondary evaluation of the durability of the effects of the educational intervention 4 weeks after program completion. Each participant’s CKD knowledge was scored as the percentage of answers correct out of the 18 CKD knowledge questions from the survey. Confidence in treatment choice and CKD self-efficacy were measured by participants’ responses on individual items according to a 5-point Likert scale. Additionally, scores from all 5 CKD self-efficacy questions were averaged to calculate an overall CKD self-efficacy score. In the main analyses, differences in scores on the survey completed before participating in the online program and after 4 weeks of participating in the program were evaluated by the Wilcoxon signed-rank test. For each measure, we also calculated the number and percentage of patients who improved their score. We described the number and percentage of patients choosing a specific preferred treatment option pre- and postintervention and used McNemar exact test to evaluate differences.

Results

Study Enrollment

Overall, out of 2617 patients screened for eligibility, 156 were potentially eligible after screening the medical chart. After contacting these 156 patients, 98 were deemed eligible after the phone interview. Among 98 eligible patients, 48 were interested in the study and 39 scheduled an intake visit. Of these, 28 attended an intake visit and 25 completed the study ([Figure 1](#)).

Figure 1. Recruitment and enrollment. A total of 2617 patients who had been seen at the University of California, San Francisco and San Francisco Veterans Affairs Medical Center renal clinics were either sent letters to notify them of the study or screened via the electronic medical record for eligibility. A total of 156 patients were potentially eligible based on initial screening; of these, we found 98 of those that responded to be eligible after the phone interview. Moreover, 27 of these enrolled into the study and 25 completed the study.



Baseline Characteristics

Characteristics of the 25 study participants who completed the study are summarized in [Table 1](#). The mean age of participants was 65 years, 13 (13/25, 52%) were of non-white race, 17 (17/25, 68%) were male, and 13 (13/25, 52%) were retired. The average annual income among participants was US \$45,000, and 9 (9/25, 36%) had college degrees. Moreover, 7 (7/25, 28%) had received dialysis in the past and 12 (12/25, 48%) reported having received education on ESRD treatment options before the study. A total of 20 (20/25, 80%) patients had been in the care of a nephrologist for over a year.

Program Engagement

According to metrics collected by Cricket Health, each patient engaged with the program for a median of 5 (interquartile range: 2-6) hours over a mean of 32 (SD 14) days. Most participants used their own devices, although 3 participants (3/25, 12%) accessed the program using a shared or public computer. All participants viewed at least one FAQ, 24 (24/25, 96%) watched at least one video, and 21 (21/25, 88%) chatted with a nurse. Four participants needed more than 4 weeks to demonstrate adequate engagement with the online program and make a modality decision on the month 1 survey. Further details about patient engagement with the videos, FAQs, and discussion are summarized in [Table 2](#).

Preferred Treatment Option

At intake to the study, 32% (8/25) of the participants were unable to make a choice in the treatment plan; after completing the program, 100% (25/25) of the participants made a choice. The most commonly preferred treatment choice was kidney transplant, and the proportion of patients choosing this option increased from 12 (12/25, 48%) at intake to 21 (21/25, 84%) after program completion ($P=.01$). In a post hoc analysis, we

determined patients' preferred treatment choice in the case that a kidney transplant was not available or feasible (eg, with that answer option excluded). At intake, 4 (4/25, 16%) participants chose peritoneal dialysis if transplant was not available, compared with 13 (13/25, 52%) participants after program completion ($P=.004$). At intake, 2 (2/25, 8%) participants chose in-home hemodialysis if transplant was not available, compared with 4 (4/25, 16%) participants after program completion ($P=.50$). These proportions remained similar after program completion and 4 weeks later at the month 2 survey ([Tables 3](#) and [4](#)).

Knowledge, Confidence, and Self-Efficacy

Mean scores for CKD knowledge and confidence in treatment choice improved significantly between surveys at intake of each study participant and program completion (P values $<.03$). The mean (SD) of all individual self-efficacy scores also increased significantly after the intervention, from 3.2 (1.4) to 4.1 (1.0; $P<.001$). Self-efficacy scores on 3 of the 5 individual Likert items improved, specifically: "My treatment would be just as good if I was responsible for my dialysis," "I understand self-care dialysis," and "I understand in-center dialysis" (P values $\le.005$). In contrast, there was no statistically significant difference between intake and postintervention scores on the following statements: "I can actively share my experience of managing CKD with other patients" and "I could learn how to do self-care dialysis" (P values $\ge.06$). Furthermore, most patients improved their scores between surveys performed at intake for each participant and program completion: 19 (19/25, 76%) on CKD knowledge, 15 (15/25, 60%) on confidence in treatment choice, and 20 (20/25, 80%) on overall CKD self-efficacy. Month 2 scores on assessments of CKD knowledge, confidence in treatment choice, and self-efficacy were similar to those from immediately after program completion ([Table 5](#)).

Table 1. Baseline characteristics of participants (N=25).

Characteristic	Statistics ^a
Age (years), mean (SD)	65 (15)
Female, n (%)	8 (32)
Latino, n (%)	2 (8)
Race, n (%)	
Black	5 (20)
White	12 (48)
Other	8 (32)
Employment status, n (%)	
Employed full- or part-time	6 (23)
Retired	13 (52)
Unemployed	3 (12)
Disability, n (%)	2 (8)
Annual income US \$, n (%)	
<25,000	9 (36)
25,000-49,999	4 (16)
50,000-99,999	4 (16)
>100,000	6 (24)
Highest level of education, n (%)	
High school diploma or general education diploma	4 (16)
Associate's degree	1 (4)
Bachelor's degree	9 (36)
Master's degree	4 (16)
Doctorate	3 (12)
Uses the internet on shared or public computer, n (%)	3 (12)
Diabetes, n (%)	17 (68)
Prior or current tobacco use, n (%)	14 (56)
Time since CKD ^b diagnosis (years), median (IQR ^c)	10 (4-23)
Estimated glomerular filtration rate (ml/min/1.73 m ²), mean (SD)	21 (6)
CKD cause, n (%)	
Glomerulonephritis	5 (20)
Diabetes	4 (16)
Hypertension	3 (12)
Medication adverse effect	2 (8)
Vasculitis	1 (4)
Polycystic kidney disease	1 (4)
Unknown	9 (36)
History of dialysis, n (%)	
Peritoneal dialysis	1 (4)
Hemodialysis	6 (24)
Vascular access, n (%)	3 (12)
Evaluated for transplant, n (%)	13 (52)

Characteristic	Statistics ^a
Active on transplant list, n (%)	7 (28)
“How long have you been seeing your current nephrologist?” n (%)	
5-8 months	2 (8)
9-12 months	3 (12)
>12 months	20 (80)
“I have received education about treatment options for chronic kidney disease prior to participating in this study,” n (%)	
Agree or strongly agree	12 (48)
Neutral or unsure	7 (28)
Disagree or strongly disagree	6 (24)

^aCategorical data are shown as n (%); continuous data are summarized as mean (SD) or median (IQR). All data were collected via self-report.

^bCKD: chronic kidney disease.

^cIQR: interquartile range.

Table 2. Participation and engagement during the 4-week educational program (N=25).

Measure	Statistics ^a
General	
Days required to complete program, mean (SD)	32 (14)
Hours active on program, median (IQR ^b)	5 (2-6)
Videos	
Viewed at least one video, n (%)	24 (96)
Number of unique videos viewed (out of 9), median (IQR)	8 (5-9)
Total number of video views, median (IQR)	10 (8-21)
Frequently asked questions	
Viewed at least one frequently asked question, n (%)	25 (100)
Number of unique frequently asked questions viewed (out of 129), median (IQR)	24 (10-98)
Total number of frequently asked question views, median (IQR)	32 (15-118)
Chat communication	
Number of messages sent to nurse, mentors, or discussion board, median (IQR)	11 (4-19)
Number of conversations viewed on discussion board, median (IQR)	27 (13-47)
Chatted with nurse, n (%)	21 (84)
Chatted with mentor, n (%)	6 (24)
Chatted with group, n (%)	11 (44)

^aCategorical data are shown as n (%); continuous data are summarized as mean (SD) or median (IQR). Data were collected by Cricket Health.

^bIQR: interquartile range.

Table 3. Preferred treatment modality choice, if transplant is a feasible choice.

Treatment choice	n (%) ^a
Intake survey (N=25)	
Kidney transplant	12 (48)
Conservative management	2 (8)
Peritoneal dialysis	1 (4)
Home hemodialysis	1 (4)
In-center hemodialysis	1 (4)
None/unsure	8 (32)
Month 1 survey (N=25)	
Kidney transplant	21 (84) ^b
Conservative management	2 (8)
Peritoneal dialysis	1 (4)
Home hemodialysis	1 (4)
In-center hemodialysis	0 (0)
None/unsure	0 (0)
Month 2 survey (N=24)	
Kidney transplant	19 (79)
Conservative management	2 (8)
Peritoneal dialysis	1 (4)
Home hemodialysis	2 (8)
In-center hemodialysis	0 (0)
None/unsure	0 (0)

^aCategorical data are shown as n (%). Data obtained from surveys conducted at intake of each study participant, after 4 weeks of engagement and completion of the Modality Decision Program, and then 4 weeks after completing the Modality Decision Program.

^b*P* value for tested differences in proportions between initial and month 1 survey, using McNemar exact test was .01.

Table 4. Preferred treatment modality choice, if transplant is not a feasible choice.

Treatment choice with transplant option removed	n (%) ^a
Intake survey (N=25)	
[removed: Kidney transplant] ^b	— ^c
Conservative management	6 (24)
Peritoneal dialysis	4 (16)
Home hemodialysis	2 (8)
In-center hemodialysis	5 (20)
None/unsure	8 (32)
Month 1 survey (N=25)	
[removed: Kidney transplant]	—
Conservative management	6 (24)
Peritoneal dialysis	13 (52) ^d
Home hemodialysis	4 (16) ^e
In-center hemodialysis	2 (8)
None/unsure	0 (0)
Month 2 survey (N=24)	
[removed: Kidney transplant]	—
Conservative management	3 (13)
Peritoneal dialysis	12 (50)
Home hemodialysis	6 (25)
In-center hemodialysis	3 (13)
None/unsure	0 (0)

^aCategorical data are shown as n (%). Data obtained from surveys conducted at intake of each study participant, after 4 weeks of engagement and completion of the Modality Decision Program, and then 4 weeks after completing the Modality Decision Program.

^bIn a post hoc analysis, we determined patients' preferred treatment choice in the case that a kidney transplant was not available or feasible (eg, with that answer option excluded).

^cNot applicable.

^d*P* value for tested differences in proportions between initial and month 1 survey, using McNemar exact test was .004.

^e*P* value for tested differences in proportions between initial and month 1 survey, using McNemar exact test was .50.

Table 5. Chronic kidney disease knowledge, confidence, and self-efficacy.

Measure	Statistics ^a	P value ^b
CKD^c knowledge (% correct from 18 CKD knowledge questions)		<.001
Initial survey, mean (SD)	65 (56)	
Month 1 survey (main effect), mean (SD)	83 (14)	
Month 2 survey (durability), mean (SD)	86 (11)	
Patients who improved after program, n (%)	19 (76)	
Confidence in treatment choice (Likert scale 1-5): “I feel ready to choose a treatment option that would be best for me if I experience kidney failure”		.03
Initial survey, mean (SD)	3.2 (1.4)	
Month 1 survey, mean (SD)	4.1 (1.0)	
Month 2 survey, mean (SD)	4.3 (0.7)	
Patients who improved after program, n (%)	15 (60)	
CKD self-efficacy (Likert scale 1-5)		
Average CKD self-efficacy score		<.001
Initial survey, mean (SD)	3.7 (0.7)	
Month 1 survey, mean (SD)	4.3 (0.5)	
Month 2 survey, mean (SD)	4.3 (0.6)	
Patients who improved after program, n (%)	20 (80)	
“I can actively share my experience of managing CKD with other patients.”^d		.12
Initial survey, mean (SD)	4.1 (0.6)	
Month 1 survey, mean (SD)	4.2 (0.6)	
Month 2 survey, mean (SD)	4.1 (0.9)	
Patients who improved after program, n (%)	5 (20)	
“My treatment would be just as good if I was responsible for my dialysis.”		.002
Initial survey, mean (SD)	3.6 (0.8)	
Month 1 survey, mean (SD)	4.3 (0.6)	
Month 2 survey, mean (SD)	4.3 (0.6)	
Patients who improved after program, n (%)	14 (56)	
“I could learn how to do self-care dialysis.”		.06
Initial survey, mean (SD)	4.2 (0.6)	
Month 1 survey, mean (SD)	4.4 (0.7)	
Month 2 survey, mean (SD)	4.5 (0.5)	
Patients who improved after program, n (%)	6 (24)	
“I understand self-care dialysis.”		<.001
Initial survey, mean (SD)	3.1 (1.2)	
Month 1 survey, mean (SD)	4.2 (0.8)	
Month 2 survey, mean (SD)	4.2 (0.6)	
Patients who improved after program, n (%)	16 (64)	
“I understand in-center dialysis.”		.005
Initial survey, mean (SD)	3.4 (1.3)	
Month 1 survey, mean (SD)	4.2 (0.6)	
Month 2 survey, mean (SD)	4.2 (0.7)	
Patients who improved after program, n (%)	12 (48)	

^aCategorical data are shown as n (%); continuous data (scores) are summarized as mean (SD). Data obtained from surveys.

^bP value calculated by Wilcoxon signed-rank test for the difference between initial values and values at month 1 study visit.

^cCKD: chronic kidney disease.

^dSelf-efficacy statement drawn from CKD Self-Efficacy instrument developed by Lin et al [17].

Patient and Physician Satisfaction

Overall, both patients and physicians were satisfied with the educational program. All patients responded with a score of ≥ 4 (out of 5) that they would recommend the program to a friend or family member, that the program was valuable in making a treatment choice, and that the website was easy to use. Among 22 nephrologists of program participants, 21 (21/25, 95%) indicated that the program helped their patients prepare for ESRD care, 18 (18/25, 82%) indicated that the program helped the patient choose a care plan for ESRD, and 21 (21/25, 95%) indicated that the program helped the physician learn about the patient's lifestyle and care preferences and also made it easier for the physician to care for the patient. Only 1 (1/25, 5%) indicated that the program could be improved by including more information on management.

Discussion

In this study, we found that delivering digitally enabled ESRD education to patients in clinical care is feasible using the Modality Decision Program developed by Cricket Health. Patients demonstrated a high level of engagement, and they were able to complete the program and make a choice in the plan of ESRD care. Kidney transplant was the most common first choice for ESRD care. Among choices for dialysis modality, we observed that patients were more likely to choose self-care, in-home dialysis options (particularly peritoneal dialysis) after completing the education program. The Cricket Health program increased patients' knowledge of ESRD treatment options as well as their self-efficacy regarding self-care, in-home dialysis modalities.

The importance of predialysis patient education is well established [19]. Prior research has shown that educational interventions in predialysis patients may delay the need for dialysis [20], encourage patients to agree to early vascular access for hemodialysis [21], and even have long-term survival benefits [22]. Manns et al conducted a randomized controlled study of an educational program that included written materials, a video, and small group sessions and found that it improved awareness and preference for in-home, self-care dialysis [8]; additional programs centered around in-person education have been shown to increase the likelihood of patients choosing peritoneal dialysis rather than hemodialysis [9-11]. Such in-person programs are labor- and personnel-intensive and may not easily be scaled up to reach a larger number of patients. Online media is a rapidly expanding topic of research for self-management of patients with a number of chronic diseases, including CKD [23-25]. Several internet-based self-management programs have been developed for patients with ESRD [26-28]. Few internet-based educational programs for CKD have been tested for the specific purpose of educating patients with predialysis CKD on options of care for ESRD.

The Modality Decision Program developed by Cricket Health builds on these prior educational programs and also addresses the need for education that can be digitally distributed to a wider audience of CKD patients. The online, digital format increases accessibility, addresses individual lifestyles and preferences, and allows the patient to learn about modality options at his or her own pace. Throughout the educational materials, patients are encouraged to choose a treatment option that fits into his or her own lifestyle. This individualized approach likely contributes to the success we observed in improving patients' knowledge of ESRD, willingness to choose peritoneal dialysis when transplant is not an option, and to enhance patients' confidence and self-efficacy regarding treatment choice.

In addition to the quantifiable effects on patient knowledge and treatment choice, the Modality Decision Program may have an emotional impact. The educational program incorporates emotional support for patients by integrating peer mentors who already have ESRD and facilitating one-on-one communication with the study nurse. During the program, these sources of emotional support are available through email and chat, which is likely to be more convenient and accessible than conventional in-person support groups. As other researchers have noted, a patient's effort to learn about CKD can be undermined by uncertainty and fear [14]. Although most patients' confidence and self-efficacy improved after the program, multiple patients commented on an emotional response to it, and 1 study participant interrupted his participation in the program because of the emotional burden imposed by learning about CKD. Prior researchers have recognized the therapeutic potential of patient-centered educational programs that emphasize support and community, discuss the emotional aspects of CKD, and teach coping skills [29]. Subsequent programs developed by Cricket Health aim to give patients additional emotional support as they learn about CKD and ESRD. For example, the current Wellness Management Program developed by Cricket Health integrates a social worker into the educational team for further emotional support.

Patients with kidney disease often have other comorbidities that complicate their plan of care. Educational programs should take into account the complex medical condition of many CKD patients and provide educational content addressing the intersections of comorbid diseases, such as diabetes and CKD. Subsequent programs developed by Cricket Health have focused on disease-specific aspects of CKD management, including blood pressure management, congestive heart failure, diet, and nutrition.

Enrolling patients with CKD into clinical trials is challenging. Reasons for low enrollment of CKD patients into clinical trials may include their high comorbidity burden, necessitating frequent doctor visits or hospitalizations that make the patient unable to attend study visits, and their high rates of disability [30]. We observed that out of over 2000 screened patients, 98 were eligible for the study after the phone interview. About

50% (49/98) of eligible patients were interested and about 50% (49/98) of these interested participants enrolled in and completed the study. This low response and participation rate is consistent with prior literature; taking this into consideration, if further studies are planned to evaluate this or other educational programs for patients with advanced CKD, they would likely have to be multicenter to enroll more patients.

This study has several limitations. The patient survey we developed to evaluate changes in patient knowledge and self-efficacy used items from validated surveys but was not validated in our population. The study design involved a single group of patients, and the results might be less conclusive than if it were structured as a randomized controlled trial. Specifically, it is possible that the observed improvement may have occurred for reasons unrelated to the program, although there are no other known potential sources of improvement. Our geographical focus in the San Francisco Bay Area and the requirement that participants be screened for eligibility by phone may have selected a higher proportion of affluent, tech-savvy participants that might not be representative of the broader US population. However, our sample of participants was racially diverse and represented a relatively broad socioeconomic spectrum. One of our inclusion criteria was that the patient must have had a documented discussion of dialysis with his or her nephrologist during a clinic visit. We felt it was important for

ethical reasons to make sure the patient was not informed for the first time by the study team about the possible need of dialysis in the future; however, these criteria did limit the number of patients in the study and could result in a more informed sample with greater knowledge of ESRD treatment options than the general US population of patients with advanced CKD. We also felt that excluding patients with more than 2 hospitalizations in the past year or no internet access would help expedite timely completion of the study, but these criteria did also limit generalizability as well as our sample size.

In conclusion, we have conducted a pretest-posttest study among 25 patients with advanced CKD to evaluate the potential impact of the Modality Decision Program developed by Cricket Health for increasing patients' CKD knowledge, self-efficacy, ability to make a choice in ESRD treatment modality, and preference for in-home therapies. After completing the Modality Decision Program, patients had improved knowledge, confidence, and self-efficacy; were able to make a choice of treatment modality for ESRD; and were more likely to choose self-care, in-home dialysis therapies as their preferred dialysis modality. In summary, implementation of a digital ESRD education program is feasible and may be effective in facilitating patients' decisions about renal replacement therapies. Larger studies are necessary to understand whether the program affects clinical outcomes.

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Authors' Contributions

RD designed the study, collected the data, assembled and analyzed the dataset, and drafted the manuscript. AR assisted with analyses, contributed to interpretation of the data, and provided critical revisions to the manuscript for important intellectual content. Both authors read and approved the final manuscript.

Conflicts of Interest

Cricket Health Inc contributed to the conception and design and collected limited data on study engagement and enrollment, but was not involved in the analysis or interpretation of survey results. Cricket Health Inc approved the manuscript, but the final content was determined by the authors. The views and opinions expressed in this paper are those of the authors and should not be construed to represent the views of the sponsoring organizations, agencies, or the US Government.

Multimedia Appendix 1

Example of the online digital content of the educational program.

[[PDF File \(Adobe PDF File\), 824KB - formative_v3i1e12528_app1.pdf](#)]

Multimedia Appendix 2

Patient survey.

[[PDF File \(Adobe PDF File\), 1MB - formative_v3i1e12528_app2.pdf](#)]

Multimedia Appendix 3

Provider survey.

[[PDF File \(Adobe PDF File, 1MB - formative_v3i1e12528_app3.pdf](#)]

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Abbreviations

CKD: chronic kidney disease

eGFR: estimated glomerular filtration rate

ESRD: end-stage renal disease

FAQ: frequently asked question

IQR: interquartile range

SFVAMC: San Francisco Veterans Affairs Medical Center

UCSF: University of California, San Francisco

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Original Paper

Digital Gaming for Nutritional Education: A Survey on Preferences, Motives, and Needs of Children and Adolescents

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Abstract

Background: Use of novel information and communication technologies are frequently discussed as promising tools to prevent and treat overweight and obesity in children and adolescents.

Objective: This survey aims to describe the preferences, motives, and needs of children and adolescents regarding nutrition and digital games.

Methods: We conducted a survey in 6 secondary schools in the southern region of Germany using a 43-item questionnaire. Questions referred to preferences, motives, and needs of children and adolescents regarding nutrition and digital games. In addition, knowledge regarding nutrition was assessed with 4 questions. We collected self-reported sociodemographic and anthropometric data. Descriptive statistical analyses were performed using SPSS.

Results: In total, 293 children and adolescents participated in the study, with ages 12-18 years (137 girls, 46.8%), weight 30.0-120.0 (mean 60.2 [SD 13.2]) kg, and height 1.4-2.0 (mean 1.7 [SD 0.1]) m. A total of 5.5% (16/290) correctly answered the 4 questions regarding nutrition knowledge. Study participants acquired digital nutritional information primarily from the internet (166/291, 57.0%) and television (97/291, 33.3%), while school education (161/291, 55.3%) and parents or other adults (209/291, 71.8%) were the most relevant nondigital information sources. Most participants (242/283, 85.5%) reported that they regularly play digital games. More than half (144/236, 61.0%) stated that they play digital games on a daily basis on their smartphones or tablets, and almost 70% (151/282, 66.5%) reported playing digital games for ≤ 30 minutes without any interruption. One-half of respondents (144/280, 51.4%) also stated that they were interested in receiving information about nutrition while playing digital games.

Conclusions: This survey suggests that nutrition knowledge in children and adolescents might be deficient. Most children and adolescents play digital games and express interest in acquiring nutritional information during digital gameplay. A digital game with a focus on sound nutrition could be a potential educational tool for imparting nutrition knowledge and promoting healthier nutrition behaviors in children and adolescents.

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KEYWORDS

adolescents; children; communication; motives; mobile phone; needs; nutrition; obesity; overweight; preferences; serious games; survey

Introduction

Overweight and Obesity in Children and Adolescents

Overweight and obesity are major public health concerns worldwide [1]. In Germany, 15% of children and adolescents aged 3-17 years are overweight, while 6.3% are obese [2]. The number of children and adolescents with obesity, aged 5-19 years, has increased in most regions and countries from 1975 to 2016 [3]. The major cause of overweight and obesity is an energy imbalance between caloric intake and energy expenditure. An obesogenic environment, dominated by a Western diet high in energy-dense foods, is linked to obesity [1]. In addition, there is a growing trend toward a sedentary lifestyle [1,4]. Overweight and obesity require effective prevention and treatment strategies, especially in children and youths. At present, there is growing interest in exploring the potential of new information and communication technologies (ICTs), for example, mobile apps, for tackling the obesity epidemic. These novel tools are low cost, ubiquitous, and almost unlimitedly scalable. Studies have already demonstrated that young people prefer health information through ICTs rather than through printed materials [5,6].

Prevention and Treatment Strategies—Serious Games

A novel ICT approach is “serious games,” which is a term used for digital games that are designed for educational and training purposes [7]. Serious gaming is a promising method to convey health-related information and promote change in health-related behaviors because of its exciting, enjoyable, and intrinsically motivational nature [8-13]. Several studies have investigated the effects of serious games on health-related outcomes like nutrition knowledge, dietary behavior, physical activity, and body mass index [14-20]. A randomized controlled trial observed that 10-12-year-old children who played video games significantly increased fruits and vegetable consumption compared with the control group, who played serious games on websites [21]. A systematic review showed that most studies achieved positive results using video games in the prevention and treatment of obesity in children and adolescents. The authors emphasized that video games provide an additional and supporting element in preventing and treating obesity along with the potential to increase treatment compliance and to promote success [22]. The “Alien Health Game,” a nutrition instruction game, increased short-term nutrition knowledge among primary school children [13]. Owing to the high acceptance and widespread usage of digital games, children and adolescents seem to be a suitable target group for the serious gaming approach. Nevertheless, exposure to electronic gameplay may be associated with overweight and obesity because of its potential to increase sedentary behavior and consumption of energy-dense foods and beverages [23,24]. In addition, general and especially excessive use of digital devices is associated with negative effects such as school difficulties, sleep disturbance, depression, and Attention-Deficit/Hyperactivity Disorder [24-26]. Nowadays, serious and exergames are developed to overcome the adverse effects of gameplay by education combined with entertainment, known as “edutainment” [11,27]. Serious games may enable health

educators to integrate health education into already existing game-based activities.

Aim

The objective of this survey was to gather information about the preferences, motives, and needs of children and adolescents regarding nutrition and digital games. The results of this survey are intended to be used for the development of a serious nutrition game tailored to children and adolescents.

Methods

Design and Protocol

The Ethical Committee of the Faculty of Medicine at the Technical University of Munich and the Rosenheim School Board approved this survey, which was conducted in 6 secondary schools in the city and administrative district of Rosenheim (Bavaria, Germany) between June 2016 and July 2017. We obtained written consent from parents or legal guardians of each participant.

Recruitment and Procedure

The Rosenheim School Board invited 23 secondary schools to participate in the survey. Children and adolescents were recruited by school teachers. We conducted the survey under standardized conditions according to a detailed survey protocol, which was executed by the study team. Each participant received a hard copy of the questionnaire. The study team read the introduction aloud, after which participants completed the questionnaire on their own. Children and adolescents who were not given parental permission to participate received a nutrition quiz. The maximum time for completing the questionnaire was 45 minutes, which corresponds to 1 classroom hour.

Questionnaire: Development and Design

An interdisciplinary team of nutritionists, economists, sociologists, and computer scientists developed a target group-specific questionnaire. The preliminary questionnaire was pretested for ease-of-use and understandability by a subset of 26 individuals aged 14-17 years. The final questionnaire was designed using EvaSys V7.0 (2101). The introduction included information regarding the research project, data protection, voluntary participation, and contained instructions for completing the questionnaire. The main part consisted of questions referring to 3 different subjects—nutrition (16 questions), digital games (21 questions), and personal characteristics (6 questions). The nutrition questions referred to nutritional communication, behavior, and knowledge and focused on preferences, motives, and needs. The area on digital games consisted of questions on preferences, motives, and needs regarding gaming behavior in general and digital gaming behavior in particular. To design a target group-tailored serious game, questions concerning the design of a digital game were also asked. In addition, we obtained sociodemographic (age, sex, and home environment) and self-reported anthropometric data (weight and height). The mean value for weight and height was calculated for participants who provided ranges for these values. The literature indicates that self-reporting of weight and height is an appropriate and reliable assessment method among

adolescents and young adults compared with measured anthropometric data [28,29]. To maintain the attention and motivation of respondents, introductory questions were used. In addition, the filter question “Do you play digital games (smartphone, computer, console, apps)?” was asked to ensure that subsequent questions were answered only by participants who actually play digital games. The majority of the questions were closed and semiended with single or multiple-choice answer options; however, the questionnaire also contained a few open-ended questions. The questions were short, unidimensional, and easy to understand. To avoid influencing the response behavior, questions were designed to be neutral and target group-specific. Furthermore, a “do not know” or “no answer applies” option was mostly provided to prevent incorrect responses and remove pressure. Furthermore, questions were formulated in a way to avoid social desirability.

Statistical Analyses

Data were initially checked for integrity and plausibility. Respondents with ≥ 8 unanswered or invalid questions were excluded. Therefore, the number of respondents varied from question to question. Furthermore, the statistical analysis was focused on selected questions, which are directly associated with the game development. In total, 21 questions were considered for the underlying analysis (Multimedia Appendix 1). The descriptive data analysis (frequencies and percentages) was performed using Microsoft Excel 2013 (Microsoft Corp) and SPSS version 24 (IBM Corp).

Results

Participants’ Characteristics

In total, 293 German-speaking children and adolescents (137 girls and 156 boys) from the 7th to 8th grade who were not affected by writing disabilities participated in this study. Table 1 presents participants’ demographic and anthropometric characteristics. Children and adolescents (137/293, 46.8% girls) aged, on average, 14.7 (SD 1.2) years. Weight ranged 30.0-120.0 (mean 60.2 [SD 13.2]) kg, while height varied between 1.4 m and 2.0 (mean 1.7 [SD 0.1]) m. Most respondents (278/293, 94.9%) reported that they live “at home.”

Digital and Nondigital Sources of Nutritional Information

Table 2 shows sources of digital and nondigital nutritional information that are currently used, as well as additionally desired by respondents. More than one-half of the participants (166/291, 57.0%) reported using the internet as a digital information source. In total, 71.8% (209/291) participants indicated obtaining nondigital nutritional information from parents and adults in general. In contrast, most participants wanted to receive additional nutritional information through apps (49/274, 17.9%) and school education (108/274, 39.4%). Fewer than 10% (23/291, 7.9%) of participants reported currently using or wanting to use additionally (19/274, 6.9%) digital games to familiarize themselves with nutrition knowledge. Twice as many boys (16/156, 10.3%) as girls (7/137, 5.1%) used digital games for nutritional information; however, this gender-specific difference was not observed for any other currently used information source.

Table 1. Participants’ characteristics (N=293).

Variable	Participants, n (%)	Participants, mean (SD)	Minimum, maximum
Age (years)^a			
12-14	148 (50.5)	N/A ^b	N/A
15-17	134 (45.7)	N/A	N/A
18	11 (3.8)	N/A	N/A
Sex			
Girls	137 (46.8)	N/A	N/A
Boys	156 (53.2)	N/A	N/A
Anthropometric data			
Weight (kg)	276 (94.2)	60.2 (13.2)	30.0, 120.0
Height (m)	289 (98.6)	1.7 (0.1)	1.4, 2.0
Home environment			
At home	278 (94.9)	N/A	N/A
Alone	2 (0.7)	N/A	N/A
Other	13 (4.4)	N/A	N/A

^aParticipants: mean 14.7 (SD 1.2); minimum 12, maximum 18.

^bN/A: not applicable.

Table 2. Sources of nutritional information.

Nutritional information source ^a	All, n (%)	Girls, n (%)	Boys, n (%)
Currently used^b			
Digital			
Television	97 (33.3)	39 (28.7)	58 (37.4)
Internet	166 (57.0)	79 (58.1)	87 (56.1)
Social networks	78 (26.8)	42 (30.9)	36 (23.2)
Apps	33 (11.3)	15 (10.9)	18 (11.5)
Digital games	23 (7.9)	7 (5.1)	16 (10.3)
Nondigital			
School	161 (55.3)	76 (55.5)	85 (54.5)
Parents and adults	209 (71.8)	100 (73.0)	109 (69.9)
Friends	54 (18.6)	32 (23.4)	22 (14.1)
Books & newspapers	74 (25.4)	44 (32.1)	30 (19.2)
Other			
Unconscious	51 (17.5)	19 (13.9)	32 (20.5)
No answer applies	13 (4.5)	4 (2.9)	9 (5.8)
Additionally desired^c			
Digital			
Television	45 (16.4)	19 (14.5)	26 (18.2)
Internet	46 (16.8)	22 (16.8)	24 (16.8)
Social networks	34 (12.4)	15 (11.5)	19 (13.3)
Apps	49 (17.9)	29 (22.1)	20 (14.0)
Digital games	19 (6.9)	10 (7.6)	9 (6.3)
Nondigital			
School	108 (39.4)	43 (32.8)	65 (45.5)
Parents & adults	46 (16.8)	23 (17.6)	23 (16.1)
Friends	17 (6.2)	12 (9.2)	5 (3.5)
Books & newspapers	31 (11.3)	22 (16.8)	9 (6.3)
Other			
Unconscious	29 (10.6)	15 (11.5)	14 (9.8)
No answer applies	74 (27.0)	30 (22.9)	44 (30.8)

^aMultiple responses allowed.^bWhere are you informed about nutrition?/Where do you inform yourself about nutrition?; n (%)=291 (100).^cWhere do you want to be additionally informed about nutrition?; n (%)=274 (100).

Knowledge About Nutrition

In total, 4 questions were asked to evaluate the participants' nutrition knowledge (Table 3). Less than one-fourth of respondents (66/290, 22.8%) answered the question regarding the daily recommended fruits and vegetable consumption according to the German Nutrition Society (DGE) correctly. The common response to the question "Do you know what a food pyramid is?" was "Yes" (260/293, 88.7%). Almost three-fourths (210/291, 72.2%) of the survey population

correctly indicated that fish should be eaten once or twice per week. In total, 24.7% (72/291) participants responded incorrectly regarding the calorie content of 100 g of sugar; almost one-half of children and adolescents (145/291, 49.8%) replied with "I don't know." Moreover, 10.3% (30/290) and 18.2% (53/291) reported not knowing the correct answer regarding recommendations of daily fruits and vegetable or fish consumption. Overall, only 5.5% (16/290) of participants correctly answered all 4 questions regarding nutrition knowledge.

Table 3. Nutrition knowledge in children and adolescents.

Question ^a	n (%)	Correct answer			Incorrect answer			Answer “I don’t know”		
		All, n (%)	Girls, n (%)	Boys, n (%)	All, n (%)	Girls, n (%)	Boys, n (%)	All, n (%)	Girls, n (%)	Boys, n (%)
How many portions of fruits and vegetables should be eaten (portion = a handful) each day?	290 (100)	66 (22.8)	31 (23.1)	35 (22.4)	194 (66.9)	87 (64.9)	107 (68.6)	30 (10.3)	16 (11.9)	14 (9.0)
Do you know what a food pyramid is?	293 (100)	260 (88.7)	129 (94.2)	131 (84.0)	33 (11.3)	8 (5.8)	25 (16.0)	N/A ^b	N/A	N/A
How often should fish be eaten each week?	291 (100)	210 (72.2)	101 (73.7)	109 (70.8)	28 (9.6)	11 (8.0)	17 (11.0)	53 (18.2)	25 (18.3)	28 (18.2)
How many calories [kcal] are in 100g of sugar?	291 (100)	74 (25.4)	24 (17.7)	50 (32.3)	72 (24.7)	34 (25.0)	38 (24.5)	145 (49.8)	78 (57.4)	67 (43.2)

^aSingle response allowed.^bN/A: not applicable.

Digital Gameplay: Preferences, Motives, and Needs

Multimedia Appendix 2 presents motives, behavior, and preferences regarding digital games. More than 80% (242/283, 85.5%) of the survey population reported playing digital games. Children and adolescents primarily play digital games if they were in the mood (209/282, 74.1%) or if they are bored (164/282, 58.2%), while 8.5% (24/282) reported happiness or sadness (15/282, 5.3%) as motivators for digital gameplay. More boys than girls indicated playing digital games when they felt like gaming or when they were happy. Children and adolescents often play digital games if they were alone at home (117/282, 41.5%) or stay with friends (54/282, 19.2%), while boys reported this behavior 2-3 times more often than girls. Playing time was observed to be dependent on the digital device. While most participants play digital games continuously for up to 30 minutes on a smartphone or tablet (151/227, 66.5%), less than half (57/209, 27.3%) play for up to 30 minutes on a personal computer (PC) or console. Participants reported playing digital games \geq 1 hour on PC or consoles (116/209, 55.5%), which was 3 times more often than those playing digital games for the same amount of time on smartphones or tablets (41/227, 18.1%). Compared with female participants (6/79, 7.6%), male children and adolescents were far more likely to play digital games for >1 hour (47/130, 36.2%). A similar trend could be detected for a gaming duration lasting 1 hour. The most common answer regarding gaming frequency on any device was daily, with differences observed between girls and boys. In addition to the motives behind digital gameplay and the behavior itself, the questionnaire also asked about gaming preferences. More than one-half of the survey population preferred that teammates in a digital nutrition game are friends (191/286, 66.8%) or individuals with similarities, such as hobbies or eating behaviors (203/286, 71.0%); however, some participants 7.4% (21/286) favored playing without a team. Almost one-half of children and adolescents reported enjoying digital gameplay with \leq 5

players (116/255, 45.5%), and 22.8% (58/255) of participants liked playing alone. Close to one-half of participants (119/277, 43.0%) preferred an older or same-aged human as a game character, while 19.1% (53/277) preferred a fantasy character. The main proportion of the survey population reported that they prefer learning about nutrition through a quiz (157/287, 54.7%) or by solving tasks (123/287, 42.9%). Some participants 12.9% (37/287) did not want to learn anything in a digital nutrition game, with boys about 3 times more likely to report this answer (29/151, 19.2%) than girls (8/136, 5.9%).

Discussion

Nutrition Knowledge in Children and Adolescents

This survey suggests that nutrition knowledge in children and adolescents may be limited. Only 6% (16/290) correctly answered the 4 questions regarding nutrition knowledge. Moreover, one-fourth (66/290, 22.8%) of participants knew that eating fruits and vegetables 5 times per day is recommended, and nearly the same number (74/291, 25.4%) correctly answered questions about the calorie content of sugar. These findings are consistent with the results of a recent study by the German Nutrition Society, which indicated that around 50% of German adolescents are inadequately informed about the components of a healthy diet [30]. The National Pupil Survey (2013) revealed that only one-half of children and adolescents aged 11-16 years correctly answered a question regarding the recommendation for daily fish intake [31]. This survey indicates that >70 % of participants knew that fish should be eaten once or twice per week. As evidenced by the National Pupil Survey, 88% of adolescents know that 5 portions of fruits and vegetables should be eaten each day [31]. Epidemiological data have demonstrated that knowledge about nutritional recommendations as well as the intake of fruits and vegetables has to be improved in German adolescents. A German survey revealed that only 25%-29% of girls and 16%-18% of boys met the fruits or vegetable intake

recommendation [32]. It should be mentioned that this survey provides no representative data of nutrition knowledge among children and adolescents. Furthermore, it cannot be ruled out that respondents affirmed the question without even having knowledge of it. Hence, the 4 questions about nutrition knowledge can only provide a small impression about respondents' nutrition knowledge. In addition, it is noteworthy that many factors have an impact on children's and adolescents' nutrition knowledge. According to this survey, the majority of children and adolescents (72%) consult their parents or adults regarding nutrition. Wansink stated that a "home's nutritional gatekeeper is the biggest food influence in the nutrition life" of all family members [33]. The findings of Qian et al showed that children with low parent education level tend to have a less comprehensive nutrition knowledge than children from parents who are more highly educated [34]. As the survey was only conducted in secondary schools, it could be assumed that the education level of parents might have been rather low. Further literature indicates that nutritional education of parents can be effective in improving children's diet [35,36]. A recent systematic review of parent-targeted, in-home interventions resulted in a small but significant increase in fruits consumption in children [35]. These facts need to be considered, as nearly 95% of children and adolescents in this survey lived at home. Findings regarding the effectiveness of nutritional education programs on dietary knowledge and food behaviors are controversial [37]. A study showed that students aged 14-19 years significantly improved their nutrition knowledge after attending a nutritional course at school [38]. A 5-day physical activity and nutritional intervention program in children with overweight and obesity resulted in higher rates of physical activity, as well as in a reduction of consumed sugar and sweets [39]. Moreover, reviews demonstrated that nutritional education could be effective in improving healthy eating behaviors [40]; in contrast, a cross-sectional survey revealed that the "knowledge of healthy foods does not translate to healthy snack consumption" [41]. By improving nutrition knowledge and health attitudes children and adolescents may develop a healthier lifestyle and, thus, would be at lower risk of becoming overweight or obese [38].

Implications for Game Design

This study shows that more than one-half of children and adolescents would like to receive nutritional information through digital games. The majority stated that they would like to learn about nutrition in a digital game by playing a quiz (55%) or by solving tasks (43%). Therefore, different types of quizzes should be considered in the development of a nutrition game [42]. A recent study in children investigated the delivery of nutritional information through a gaming app and demonstrated that learning of nutritional information was improved with repeated exposure [43]. To convey knowledge effectively through a game, different elements should be considered in the game design [42]. Many participants (43%) reported preferring a fantasy character as a game character. These findings are similar to the results of a survey about serious games conducted among 465 Asian pharmacy students; most participants (60%) preferred a fantasy, medieval, and mythical setting, while 41% wanted an adventure storyline [44]. For example, the "Move2Play"

game contains an avatar which can be personalized by users. A small study showed that adolescents enjoyed customizing their avatar [45]. It is also worth mentioning that children and adolescents in this survey preferred playing digital games with friends (191/286, 66.8%) and only one-fifth of participants (58/255, 22.8%) played digital games by themselves. The literature confirms that digital gaming has a great social value. In a survey on video gameplay among 1254 US 7th- and 8th-grade students, only 18% of male and 12% of female children and adolescents indicated that they always play alone [46]. In addition, digital gaming as a social activity was confirmed in a focus group of 42 male adolescents [46]. Considering these findings, players should be given an opportunity to create social groups in a game [42]. Furthermore, social components, such as chat interaction, group profiles, and social games or challenges, should be implemented [42].

Digital Gameplay—Preferences, Motives, and Needs

This survey data show that >85% of children and adolescents play digital games. According to the survey by Olson et al, only 6% of children and adolescents did not play any digital games in the 6 months prior to the survey [46]; these results confirm that children and adolescents are frequent users of digital devices [47]. Adolescents aged 15-18 years spend on average 22 minutes per day on video gaming on cell phones, and 31 minutes per day on consoles [47]. Furthermore, a German survey showed that two-thirds of participants aged 12-19 years (n=1200) played digital games (smartphone, PC [offline], console, online, and tablet) regularly (daily or several times a week), whereas only 8% never played digital games [48]. Regarding the frequency of digital gameplay, these results are similar to the current findings. Almost two-thirds of participants specified playing digital games daily or weekly on smartphones or tablets, and more than two-thirds played on a PC or console. The use of educational games as a viable teaching strategy can promote enjoyment and, therefore, may enhance the retention of information in the long-term [12]. In contrast, excessive use of digital games can generate negative health effects in children and adolescents [23]. Consequently, there is an ongoing debate as to whether electronic gameplay is a "health hazard" or a "health promoter" [49]. The question of why young people play digital games is also addressed in this survey. Most children and adolescents have an emotionally induced digital gameplay experience and primarily replied to the question "When do you often play digital games?" with "pleasure" and "boredom." Olson et al showed that 45% of male and 29% of female participants said that they played to "To get my anger out," while 25% of boys and 11% of girls selected the answer "cope with anger" [46,50]. Negative emotions, such as "sadness," were only reported by around 5% of young people in this survey, whereas the answer option "anger" was not present within this questionnaire. The fact that most young people play digital games when they are in a positive mood could be exploited to transfer knowledge playfully and entertainingly through digital games.

Serious Games—Serious Design

Although there are a growing market supply and demand for health-related games, little is known about game design aspects

and preferences, motives, and needs of children and adolescents regarding digital nutrition games [51]. It is important to emphasize that qualitative research (eg, interviews) prior to game design is critical [52]. Consideration of the “needs, interests, perspectives, and preferences” of the target group in the development of health games may result in better targeted games [52]. Furthermore, collaborations with health professionals from an early design stage are necessary, both to ensure that the content is accurate and to have the game validated from a clinical viewpoint. The target group needs to be involved, especially to improve the usability. It is well known that health promotion and disease prevention programs suffer from poor adherence and compliance by participants, often because they are designed without addressing the target group [14,53]. This also applies to the field of health games. In their recently published review, Lu and Kharrazi examined almost 2000 health-related games (from 1983 to 2016) for usability and concluded that one of the main limitations is the lack in customization and feedback [54].

Digital Games for Nutritional Education at Schools

Furthermore, it has to be noted that most children and adolescents like to receive additional nutritional information through apps or at school. According to a study of 505 American teachers, more than one-half (55%) reported using games as an educational element in school teaching [55]. The advantage of serious games is to educate the target group through entertaining, enjoyable, and intrinsically motivating game elements and experiences [11,27]. Therefore, a serious nutrition game may be a suitable, educative method to impart nutrition knowledge and to promote healthy dietary behaviors in children and adolescents.

Limitations

This survey revealed findings about digital nutrition games among children and adolescents, yet it has some limitations. The survey was conducted in one school area and type. Therefore, it is limited by sample size and homogeneity. Moreover, present findings are not representative, especially concerning nutrition knowledge, which was assessed on the basis of 4 questions. Furthermore, it cannot be ruled out that the participation rate, which cannot be calculated owing to missing data (invited vs participated children and adolescents), is biased by the motivation and engagement of teachers, parents, and participants themselves. The nonvalidated questionnaire used in the survey was internally generated to obtain all the relevant information for a target group-specific game design. As the age of participants is only available as life years without months, no appropriate weight classification for children and adolescents (percentiles/z-scores) could be calculated. The results are further limited owing to missing information about parental education level. Future research should address more diverse survey populations across entire Germany, providing further insights and expanding the generalizability.

Conclusions

Results revealed that children and adolescents are interested in nutritional information. Present findings support previous surveys that there is a lack of nutrition knowledge in this target group. Children and adolescents stated a preference for apps and school education in order to receive additional nutritional information. Furthermore, the target group was interested in digital games as well. Therefore, such preferences and interests could be implemented in an educational app, for example, for schools to increase nutrition knowledge and to improve dietary behavior.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire excerpt from Holzmann et al (Digital Gaming for Nutritional Education).

[[PDF File \(Adobe PDF File\), 193KB - formative_v3i1e10284_app1.pdf](#)]

Multimedia Appendix 2

Table from Holzmann et al (Digital Gameplay: Motives, Behavior, and Preferences).

[[PDF File \(Adobe PDF File\), 115KB - formative_v3i1e10284_app2.pdf](#)]

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Abbreviations

ICT: information and communication technology

PC: personal computer

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Original Paper

Using Mobile Technology to Improve Bone-Related Lifestyle Risk Factors in Young Women With Low Bone Mineral Density: Feasibility Randomized Controlled Trial

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Abstract

Background: Poor bone health in adolescent and young adult females is a growing concern. Given the widespread use of mobile phones in this population, mobile health (mHealth) interventions may help improve health behaviors related to bone health in young women.

Objective: The goal of the study was to determine the acceptability and feasibility of an mHealth intervention called Tap4Bone in improving health behaviors associated with the risk of osteoporosis in young women.

Methods: The Tap4Bone mHealth intervention comprised the use of mobile phone apps, short messaging service (text messaging), and Web emails to encourage health behavior changes. The education group received osteoporosis prevention education leaflets. Changes in the bone health-related behaviors exercise, smoking, and calcium intake were assessed. User experiences and acceptance of the app were collected through focus group interviews.

Results: A total of 35 (22 completed, mean age 23.1 [SD 1.8] years) were randomized to either the mobile phone (intervention n=18) or education (control n=17) group. Although there were trends toward improvement in calcium intake, sports activity, and smoking behaviors in the mHealth intervention group compared to the education group, these were not statistically significant.

Conclusions: The Tap4Bone mHealth intervention was shown to be acceptable and feasible in subsets of the participants. The intervention should be improved upon using participant feedback to improve functionality. Findings from this study may aid in the development and modification of health care apps to reduce participant attrition.

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KEYWORDS

behavior therapy methods; mobile phones; health behavior; primary prevention methods; self-care methods

Introduction

The major adverse outcome of poor bone health is osteoporosis with associated fragility fractures [1]. Bone mineral density (BMD) is a clinically useful predictor of fragility fracture risk [2]. During adolescence, young people may be influenced to push boundaries and experiment with risky behaviors that may have an impact on future health trajectories [3]. Many of these lifestyle changes in young women can have an adverse impact on their bone health, increasing the risk of poor outcomes in later life.

There are several identified risk factors that affect peak bone mass accrual and maintenance and may result in the development of this skeletal disorder. Nonmodifiable risk factors include age, female sex, onset of menopause, and genetic predisposition to poor bone health. There are other proposed risk factors that are potentially modifiable such as smoking, high alcohol intake, inadequate physical activity and calcium intake, vitamin D deficiency, and long-term use of corticosteroids [3]. The fact that there is no known cure for osteoporosis and that the risk can be substantially reduced makes it crucial that preventive measures are identified and adopted to reduce the prevalence of this disorder that causes significant morbidity and high economic burden [3].

Findings from prospective longitudinal studies in young female twins (aged 15 to 30 years) highlighted the extent of lifestyle changes in young women [4]. It was found that participation in sports activity decreased with age, with only 23.5% of women aged 27 to 29 years participating in 4 or more hours per week of sports compared to 47.5% of women aged 15 to 17 years [4]. Conversely, sedentary behaviors and smoking habits significantly increased with age, with 14% of women aged 15 to 17 years reporting ever smoking at least one time and by age 27 to 29 years, 51% had smoked [4]. These considerable changes in lifestyle may not have an immediate impact on the skeleton. However, adverse effects are likely to be gradual in onset and accumulate over the life span [3]. Therefore, these adverse lifestyle changes should provide a strong impetus to develop effective interventions to improve risky but modifiable lifestyle factors and improve long-term bone health in young women.

Mobile health (mHealth) is the use of mobile devices to support medical and health practices. Over the past decade, use of mobile phones that include internet and other data packages has grown dramatically. Approximately 81% of the Australian population owns a mobile phone [5]. Of particular interest, the highest ownership and use of mobile phones is found in the 18 to 34 year age group [5]. Approximately 74% to 78% of people in this age group own at least one mobile phone. Therefore, this technology offers a promising tool for health interventions in young people.

In this study, we conducted a 12-week randomized trial to determine whether it is acceptable and feasible to use an mHealth intervention in establishing behaviors known to have favorable influences on bone health, in a sample of young women with relatively low BMD.

Methods

Ethics

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and was approved by the Royal Women's Hospital Human Research Ethics Committee on July 1, 2013.

Recruitment and Consent

Participants for this study were recruited via telephone from the Young Female Health Initiative (YFHI) study between October 14, 2013, and February 7, 2014. In the YFHI study, a sample of young women were recruited using targeted advertisements on Facebook from May 19 to September 30, 2010, the detailed methodology of which has been reported elsewhere [6].

Clicking on the advertisement directed respondents to secure websites containing more information and where expressions of interest were registered. Prospective participants were then contacted by investigators and consented into the study.

Participation included the completion of a Web-based questionnaire using SurveyMonkey (www.surveymonkey.com) covering demographics, mental health, lifestyle, and reproductive health. Existing participants from the YFHI study who had consented to be contacted for future studies and met the inclusion criteria for this pilot study were contacted by phone to obtain consent. Trained research staff assessed whether the potential participant could be considered a mature minor (if under age 18 years) and that she fully comprehended the purpose, methods, demands, risks, and potential benefits of the study and was capable of giving informed consent to participate. She was required to understand that participation was voluntary and there were no consequences for discontinuing study participation. Staff followed instructions from the Medical Practitioners Board of Victoria "Consent for Treatment and Confidentiality in Young People" on how to define a mature and competent young person.

Bone Density Assessment

In the YFHI study, participants had their BMD at the total body, lumbar spine, and hip measured at the Royal Melbourne Hospital using dual-energy x-ray absorptiometry (DXA) (QDR 4500A densitometer, Hologic Inc). Participants who had relatively low (z score ≤ -0.5 at the total hip, femoral neck, or lumbar) or otherwise abnormal (z score < -1.0) bone density results were informed via postal letter including advice on appropriate follow-up. A copy of the participant's BMD report was enclosed with the letter. Participants were advised to discuss the result and any necessary further management with their usual doctor. Only participants who met the bone density cutoff values specified below were contacted for this study.

Inclusion and Exclusion Criteria

Inclusion criteria were met if individuals were female aged 16 to 25 years, residing in Victoria, Australia, and having a BMD z score ≤ -0.5 at the total hip, femoral neck, or lumbar spine region from DXA. According to the World Health Organization, a z score unit represents 1 standard deviation above or below

the age- and sex-matched mean BMD for a specific skeletal site, and a z score higher than -1.0 (equivalent to a T-score of -1.0 in young adults as defined by the World Health Organization) is considered normal [7]. However, for inclusion in this study we wished to define a sample with relatively low, but not necessarily abnormal, BMD. It was considered that such a group may be motivated to undertake a lifestyle-oriented intervention to improve their bone health. Selecting this cutoff also enabled us to achieve the desired sample size.

Participants were excluded if they had a BMD z score >-0.5 at all measured sites, current or history of any significant medical conditions, including eating disorders, or were pregnant or breastfeeding. Individuals were also excluded if they did not own iPhones or Android phones or were not willing to use them for the study.

Randomization Detail

Participants were randomized 1:1 to either the education or mHealth intervention group after completing a baseline questionnaire on current calcium intake, physical activity levels, and smoking habits if applicable. Participants were not aware of which intervention was of interest and which one was the comparator.

Randomization Sequence Generation

An independent researcher generated the randomization sequence and provided the principal investigator with each treatment allocation. The allocations were sealed in white opaque envelopes with only the randomization sequence numbers written on the front of the sealed envelopes. This ensured that the researchers conducting the study were blinded to the treatment groups to which each patient was randomized.

Participants were randomized into the 2 intervention groups by stratified block randomization in blocks of 2, 4, 6, and 8. Participants were stratified by tertiary education (yes/no) and z score.

- No tertiary education and z score ≤-0.5 to -1.0 at any region (total hip, lumbar spine, or femoral neck)
- No tertiary education and z score <-1.0 to -2.5 at any region (total hip, lumbar spine, or femoral neck)
- Currently completing or completed tertiary education and z score ≤-0.5 to -1.0 at any region (total hip, lumbar spine, or femoral neck)
- Currently completing or completed tertiary education and z score <-1.0 to -2.5 at any of region (total hip, lumbar spine, or femoral neck)

Interventions

Education Intervention

Participants were emailed educational leaflets on osteoporosis prevention downloaded from the US National Institutes of Health website [8].

Participants were then asked to complete an assessment of understanding that evaluated their knowledge of bone health and osteoporosis. The assessment comprised 10 true/false questions based on the educational leaflets. Participants were

required to answer 6 out of the 10 questions correctly to proceed with the study.

mHealth Intervention

The Tap4Bone mHealth intervention included using mobile phone apps and sending and receiving short messaging service (SMS) text messages and web emails. In addition to the educational leaflets, participants in the mHealth group received suggestions for other mobile phone apps to be used as behavior change techniques (BCTs), including the following:

- Self-monitoring of diet and exercise using mobile phone app
- Encouragement and motivations from text messages
- Goal-setting and checking forms via the survey tool Limesurvey (www.limesurvey.org)
- Progress feedback via emails

Additionally, they were emailed a guidance document on how to download and use other mobile phone apps. Participants in the mHealth group also received 5 questions in the assessment to determine their understanding of the guidance document and how to properly use the mobile phone apps.

Other Mobile Phone Apps

Participants were asked to download and use 3 recommended mobile phone apps: MyFitnessPal, Nike Training Club, and QuitBuddy. MyFitnessPal is a free calorie counter app that helps people track their diet and exercise. Nike Training Club is a free app comprising more than 100 full-body workouts. This app also tracks the overall amount of workout time completed by the users but it does not take into account when the exercise was completed. Therefore, for the purpose of tracking and providing feedback on participant progress, we encouraged them to track their physical activities in MyFitnessPal. QuitBuddy is a smoking cessation interactive app developed by the Australian National Preventive Health Agency to help smoking cessation efforts.

Participants also received motivational text messages that were sent out randomly using an automatic system (SMS Broadcast) during the study. Various text messages providing suggestions on how to change participant behaviors or giving them encouragement were sent. Suggestions included tips on how to increase dietary calcium intake and improve physical activity. Participants received one text daily for the first 3 weeks, and subsequently, 3 texts per week for the next 9 weeks.

Participants were also asked to set behavior goals on day 1 of week 1, week 3, week 6, and week 9. They could set dietary goals, exercise goals, or smoking cessation goals or a combination of all 3 types. The behavioral goals they selected were emailed to them to remind them of the goals they aimed to attain. At every goal-setting time point, participants were asked to check against the goals that they had achieved during the previous 3 weeks.

Finally, participants received biweekly feedback reports on their behavior change progress. We used the diet and exercise diaries entered by them in MyFitnessPal and smoking habits provided via SMS to provide individual progress feedback on their calcium intake and exercise progress. The data were collated

and sent via email to the participants for personal monitoring of their progress.

Exit Survey

Participants in both groups were asked to complete an exit survey at the end of week 12. The purpose of this survey was to find out whether they had self-initiated changes to their lifestyle in response to the intervention they received. In addition, participants were asked for their initial perceptions of a mobile phone app to help improve young women's bone health and the potential for implementation in their daily lives.

Participants in the mHealth intervention group also completed a usability questionnaire in which they were asked about their experience with the mobile phone intervention. The usability questionnaire covered the use of the different components such as the app, goal-setting, motivational text messages, and progress reports as well as the overall perception of the future use of a bone health mobile phone app. See [Multimedia Appendix 1](#) for an outline of all study activities.

mHealth Focus Group

Participants from the mHealth group who completed the week 12 questionnaires and exit survey were invited to a focus group. The focus session of 30 minutes' duration was conducted within 2 months after completion of the week 12 questionnaires and exit survey.

One investigator conducted a qualitative semistructured interview using responses from the mobile focus group to explore participant perceptions of Tap4Bone and whether it might be implemented into their everyday lives. The topics covered during the interview included (1) how the intervention was used, (2) what components were useful, and (3) how the intervention affected their behaviors. The focus groups were conducted using a free mobile phone app called WhatsApp Messenger as described elsewhere [9]. The semistructured mobile focus group interview data were analyzed the same way as described in the Calci-app study [9].

Study Outcomes and Measurements

Primary Outcome

The primary outcomes was the percentage and direction of change (either a positive or negative behavioral change) in individual health behaviors at week 12.

- Number of cigarettes smoked per day
- Daily calcium intake (measured in milligrams per day)
- Weekly physical activity score (measured in metabolic equivalent of task: minutes per week)

An overall cumulative risk factor score will be reported from the net percentage change, which is calculated by combining the percentage change in each individual risk factor.

Secondary Outcome

The secondary outcome was the feasibility of the intervention in young women. We measured the feasibility of the mobile phone-based intervention using study completion rate and responses to the usability questionnaire and semistructured interview.

Sample Size Calculation

The sample size was calculated based on the anticipated number of participants from the YFHI study who would fulfill the required bone density parameters. We estimated that 150 participants would have completed the YFHI study's site visits from October 2012 to November 2013. From this sample, we estimated that 33% (with a mean of 0 and standard deviation of -2.5 in a normal distribution) would have z scores between -0.5 and -2.5 . Taking into consideration that 20% of the recruited participants might decline participation, withdraw consent, or be lost to follow-up, we aimed to recruit 40 participants in total for this study.

A target of 40 to 50 participants was determined to be an appropriate size to determine the effect of the intervention. This number was not powered to measure outcomes at 12 weeks as this is an exploratory study. Post hoc power analysis will be done to determine the study's statistical power and effect size for further potential studies.

Statistical Analysis

Statistical analysis was performed with Stata version 15 (StataCorp LLC). Descriptive statistics were used to summarize participant experiences with results reported as frequency and percentage. A Student *t* test was used to investigate significant differences between groups. Thematic analysis was undertaken to analyze qualitative data [9].

Results

General

Of the 74 young women who met the inclusion criteria, 44 agreed to participate, while the other 30 subjects were either not contactable or declined participation ([Figure 1](#)).

Of the 44 participants recruited into Tap4Bone, 9 withdrew prior to randomization and 35 were randomized into either mobile phone (intervention $n=18$) or education (control $n=17$) groups. Reasons given for participant withdrawal included lack of time and being away overseas. Participants who could not be contacted after 3 attempts via different modes of communication (phone, email, or SMS) were considered lost to follow-up.

Efficacy of Intervention in Overall Study

We were unable to detect significant differences between a change in calcium and lifestyle behaviors for participants in each group across the 12 weeks ([Table 1](#)).

Figure 1. Flowchart for recruitment of participants. YFHI: Young Female Health Initiative, mHealth: mobile health, BMD: bone mineral density, DXA: dual-energy x-ray absorptiometry.

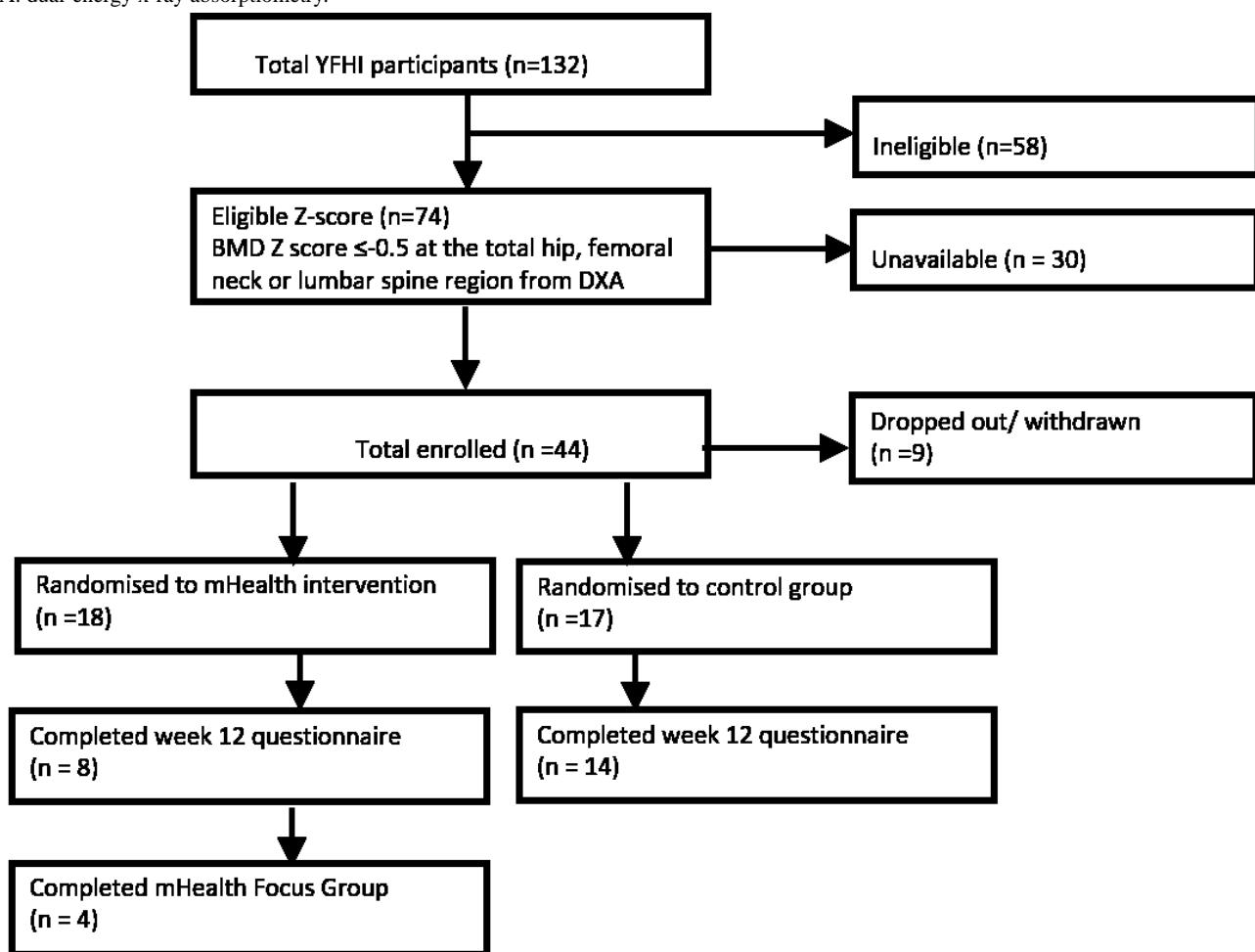


Table 1. Demographic and lifestyle characteristics of participants (N=35).

Characteristics	mHealth intervention (n=18)	Control group (n=17)	P value
Age in years, mean (SD)	23.3 (2)	22.3 (2)	.08
Body mass index (kg/m ²), mean (SD)	22.6 (3)	24.1 (5)	.28
BMD^a category, n (%)			
Normal (-0.5 to -1.0)	8 (44)	6 (35)	.58
Osteopenia (-1.0 to -2.5)	10 (56)	11 (65)	
Calcium intake (mg/d), mean (SD)	618.5 (472.2)	645.0 (309.2)	.85
Physical activity (hours per week), mean (SD)	12.5 (15)	15.56 (19)	.60
Smoking (pack-years), mean (SD) ^b	2.8 (2)	1.5 (1)	.46
Change in calcium intake over 12 weeks, % ^c	3.34	0.17	.29
Change in physical activity over 12 weeks, % ^c	0.41	0.07	.42
Change in smoking over 12 weeks, % ^d	0	-0.74	—
Net change in risk factors (%)	3.76 (9)	0.24 (1)	.25

^aBMD: bone mineral density.

^bData available for 4 participants from the mHealth intervention group and 6 participants from the control group.

^cData available for 7 participants from the mHealth intervention group and 9 participants from the control group.

^dData available for 4 participants from the control group.

Qualitative User Experience

Thematic Analysis

Thematic analysis of the focus group interviews (n=4) was used to summarize mHealth participant experiences with Tap4Bone and the feasibility of such an intervention in young women. Four distinct themes were identified: (1) need to target the right audience, (2) increased lifestyle awareness, (3) experience with integrating BCTs into lifestyle, and (4) need to maintain focus on bone health.

Need to Target the Right Audience

When asked how other young women would perceive such an intervention, all participants identified that targeting the correct audience was the first and most critical step in the intervention uptake. Participants in the study proposed that young women who know that they have low bone density would be more interested in the intervention than those who have normal bone density and those who do not know of their bone density status. Besides targeting the intervention at young women with low bone density, one participant expressed that the information also needs to be relevant for young women in this age group.

Absolutely. If your bone density results were perfect you would continue doing what you're doing. If you know they're bad you'd happily download the app to improve your own health. [Participant A]

And knowing your bone density would be crucial to your interest in an app. [Participant D]

Telling other female friends about this study, none were particularly interested. [Participant C]

Increased Lifestyle Awareness

The intervention was successful in raising daily awareness of participant lifestyle behaviors. However, implementation of changes in their lifestyles was restricted mostly to increasing dietary calcium intake and not physical activity. One of the likely reasons could be that the exercise app contained irrelevant workouts and lacked a reward and recognition system to motivate participants. Moreover, 3 out of 4 participants had a regular exercise routine and were already using other exercise apps (such as MapMyRun and Lorna Jane) before they started Tap4Bone. Almost all felt that monitoring their diet and comparing it with recommended daily calcium intake had significantly helped them increase their dietary calcium intake.

I suppose that having reminders, and the requirements to record them, meant that you were aware all the time. [Participant B]

I am more aware of my calcium intake as well, because of the study. [Participant C]

However, it was unanimously agreed that the heightened lifestyle awareness, particularly from keeping a food diary, could be confronting and it inevitably stimulated bad eating thoughts. They acknowledged that young women put a lot of pressure upon themselves to look good and are often worried about body image and weight control. As the app also tracked calories, participants felt that they eventually became used to caloric counting.

If it's any interest to you, I have actually stopped using MyFitnessPal as I felt I was becoming quite consumed by my kilojoule intake which was frustrating! [Participant D]

On a positive note, half of the participants felt that the intervention had helped ignite a focus on health and fitness and also shifted their focus on exercise for weight loss to exercise for preventative health, in this case, for building bone density.

I was already using MyFitnessPal before starting the program. I was using it for weight loss it was good to help track calcium consumption. [Participant C]

I think that young women have a lot of pressure on them to eat well and exercise to look good, but providing them with information about long term benefits of eating a lot of calcium and encouraging them to exercise for a preventative measure would be well received. This was one thing I got from this study, I re-jigged my concept of exercise as being about healthy bones and healthy body rather than about weight loss. [Participant D]

Experience With Integrating Behavior Change Techniques Into Lifestyle

Participants did not find the respective BCTs (texts, goal setting, or progress feedback) particularly useful on their own. However, they found the prospect of having an all-in-one app that connects each of the BCTs in a relational way very favorable. For example, text messages could be personalized with the goals they have set, instead of random motivational texts that most of them found artificial and patronizing. The texts could also be more informative and serve as reminders to help them attain their goals.

Although, also a record of goals set on the actual App would be helpful. It needed to be more centralized because there were components all over the place, email, MyFitnessPal, Nike, the online survey etc. [Participant B]

If the texts could have been more focused on your individual goals I think that would have been better. So if you said you would have 1 slice of cheese a day a text daily that said "have you had your cheese slice today?" Might have been more useful. [Participant A]

The main priorities participants looked for in a bone health intervention app were motivation, relevance, and usefulness. Also, the extreme preferences for text messages (ranging from very negative to very positive) meant that participants preferred a flexible app in which they could adjust their preferences. The need for flexibility was also reflected in their request for more personalized and practical goals that they could implement into their individual lifestyle. Therefore, although the BCTs were not useful in isolation, integrating them into a holistic app was well received.

The text message reminders were great, made you really think about what you needed to eat/drink each day. [Participant A]

Sorry to say I would be happy not to receive them at all. I think that's more specific to me though. [Participant C]

A bit more freedom in the goal setting, too, would help. For example, I don't like drinking whole glasses of milk, and I don't like hard cheese, so those weren't things I was going to ever do. [Participant B]

Need to Maintain Focus on Bone Health

An interesting observation raised by one participant was that young women are willing to overlook bone health for body image reasons and weight management. As a result, participants felt that they became distracted with the caloric measurements in MyFitnessPal while monitoring their calcium intake.

Also some advice that tied between exercise and calcium. I've found a lot of personal trainers get you to stray away from lots of cheese and milk, which confuses the hell out of me because I know you need those things for calcium. [Participant A]

Participants felt that the intervention seemed to continue for too long; consequently, they lost focus on the overall goal of building bone density.

Yeah it did go for a long time and I have to admit I lost site of the overall goal of building bone density. [Participant D]

Agreed D. By the end of it I was really more focused on exercise than bone density. [Participant A]

With me I was more concerned with KJ intake. [Participant C]

Hence, it was quite possible that the combination of distraction from caloric counting and lack of visible progress (ie, bone density change measurements) contributed to the shift in focus from bone density building to caloric management.

To bring the focus back to bone health, participants wished that there were more bone-related information and emphasis on relevant consequences of suboptimal bone health. However, it is a challenge to shift the focus on bone density and sustain it since bone-related consequences are only visible many decades later.

I must admit the study got me onto a health and fitness kick, but not focused on calcium. I think more information about calcium intake throughout the study would have helped. More case studies, more Q&A's, facts for us to read along the way to remind us WHY we were taking part and the benefits to us. [Participant A]

I actually learned I was extremely vitamin D deficient and it wasn't calcium intake that was my problem, so maybe some more info about how the body uses calcium to build bones and reminders about that rather than just simply about eating cheese. [Participant D]

Discussion

Principal Findings

In this study, the acceptability and feasibility of an mHealth intervention, Tap4Bone, was trialed in young women with below average bone health measures, with some features working well within subsets of the participants. Participants perceived value in the mHealth intervention and did not indicate that it caused them additional burden. When asked about their interest in a mobile phone app with all the Tap4Bone functions, 3 out of 4 users said that they would be likely to use it in the future to improve their bone health. Importantly, participants reported that the prospect of having an all-in-one app that connects each of the BCTs in a relational way was optimal. Participants also believed that the intervention would be more useful with the involvement of health professionals. The critical function of health care delivery would be to provide support and encouragement to patients to help them achieve healthier behaviors and self-manage chronic illnesses. However, support and encouragement rendered to patients are limited within existing health care infrastructures and even traditional informational media (brochures, posters, etc). This would be where the far-reaching capabilities of mobile technologies can be tapped into to allow low-cost interventions and support interactivity, hence allowing patients to "obtain extra help when needed" [10-12].

Although there are many dietary mobile phone apps available commercially, to our knowledge this is the first study investigating the feasibility of using mobile technology to improve calcium intake and other bone-related lifestyle behaviors in young women. Further, for this study we selected suitable BCTs taken from a taxonomy [13] that has been proven to be effective in lifestyle behavior change interventions. Previous meta-analyses have identified a specific set of BCTs that have been shown to be effective in interventions to promote healthy eating, physical activity, and smoking cessation, most of which have been included in this study [14,15].

Limitations

This study had several limitations. While the sample was randomly recruited through Facebook and was representative of the general population in the same age range in terms of socioeconomic factors and country of birth, those with greater education levels and older participants were slightly overrepresented [6]. Also, in the absence of a placebo control group that receives no active intervention, the ability to uncover the true effects of the mobile technology intervention was limited. However, in other randomized controlled trials in which education was used alone, investigators found no changes in lifestyle behaviors [16]. Therefore, we considered that the education group in our study provided a reasonable control for comparison with the mHealth group. We also had a number of participant withdrawals and a small sample size which may have reduced the likelihood of our detecting significant differences in behaviors between the two groups. However, it should be noted that the primary aim of this study was to evaluate the feasibility of implementing an mHealth intervention. Last, a longer period of follow-up would be needed

to ascertain long-term adherence to the intervention and the effects of persistent lifestyle changes on BMD outcomes.

As we have demonstrated that an mHealth intervention targeted at young women with below average bone health measures has shown some aspects of acceptability, the next phase of this study will involve taking on board participant feedback and creating Tap4Bone as one mobile phone app comprising the different online methods of communication we have discussed in this paper. By trialing this stand-alone mobile app with a larger cohort of young women, we will also then have adequate power

to investigate the changes in behaviors we looked at in a preliminary fashion in this study.

Conclusion

We have demonstrated that an mHealth intervention is an acceptable and feasible method of engaging young women with suboptimal bone health. To further improve the functionality and purpose of Tap4Bone, we will use constructive feedback provided by participants to develop a single mHealth app in which input from health professionals will be integrated.

Acknowledgments

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Conflicts of Interest

None declared.

Editorial note: This randomized study was not prospectively registered, justified by the authors as it was a pilot acceptability and feasibility study. The editor granted an exception of ICMJE rules for prospective registration of randomized trials because the risk of bias appears low. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to their primary outcomes or effectiveness, as the lack of registration means that authors could change their outcome measures retrospectively.

Multimedia Appendix 1

Study activities for participants.

[[DOCX File, 16KB - formative_v3i1e9435_app1.docx](#)]

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Abbreviations

BCT: behavior change technique

BMD: bone mineral density

DXA: dual-energy x-ray absorptiometry

SMS: short message service

YFHI: Young Female Health Initiative

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Original Paper

Using Exploratory Trials to Identify Relevant Contexts and Mechanisms in Complex Electronic Health Interventions: Evaluating the Electronic Patient-Reported Outcome Tool

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Abstract

Background: Designing appropriate studies for evaluating complex interventions, such as electronic health solutions to support integrated care, remains a methodological challenge. With the many moving parts of complex interventions, it is not always clear how program activities are connected to anticipated and unanticipated outcomes. Exploratory trials can be used to uncover determinants (or mechanisms) to inform content theory that underpins complex interventions before designing a full evaluation plan.

Objective: A multimethod exploratory trial of the electronic patient-reported outcome (ePRO) tool was conducted to uncover contexts, processes and outcome variables, and the mechanisms that link these variables before full-scale evaluation. ePRO is a mobile app and portal designed to support goal-oriented care in interdisciplinary primary health care practices (clinical-level integration). This paper offers evaluation findings and methodological insight on how to use exploratory trial data to identify relevant context, process, and outcome variables, as well as central (necessary to achieving outcomes) versus peripheral (less critical and potentially context dependent) mechanisms at play.

Methods: The 4-month trial was conducted in 2 primary health care practices in Toronto, Canada. The patients were randomized into control and intervention groups and compared pre and post on quality of life and activation outcome measures. Semistructured interviews were conducted with providers and patients in the intervention group. Narrative analysis was used to uncover dominant mechanisms that inform the intervention's content theory (how context and process variables are linked to outcomes).

Results: Overall, 7 providers, 1 administrator, and 16 patients (7-control, 9-intervention) participated in the study. This study uncovered many complex and nuanced context, process, and outcome variables at play in the intervention. Narrative analysis of patient and provider interviews revealed dominant story lines that help to tease apart central and peripheral mechanisms driving

the intervention. Provider and patient story lines centered around fitting the new intervention into everyday work and life of patients and providers and meaningfulness of the intervention. These themes were moderated by patient-provider relationships going into and throughout the intervention, their comfort with technology, and the research process.

Conclusions: Identifying dominant story lines using narrative analysis helps to identify the most relevant context and process variables likely to influence study outcomes. Normalization process theory emerges as a useful theory to uncover underlying mechanisms because of its emphasis on the social production and normalization of technological, processual, and social aspects of work; all found to be critical to our intervention. The number of complex, overlapping influencing variables suggests that complex interventions such as ePRO require us to pay careful attention to central versus peripheral mechanisms that will influence study outcomes. The narrative methods presented here are shown to be useful in uncovering these mechanisms and help to guide subsequent larger evaluation studies.

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KEYWORDS

eHealth; mHealth; multiple chronic conditions; clinical trial, phase III; health care evaluation mechanisms; quantitative evaluation; qualitative evaluation; narrative analysis

Introduction

Background

Designing rigorous and appropriate evaluation studies for complex interventions, such as electronic health (eHealth) solutions to support integrated care, remains a methodological challenge. Although it is difficult to draw the line between simple and complex, complex interventions tend to include multiple interacting components that might occur across multiple individuals, teams, or organizations. These interventions can have numerous and variable expected and unexpected outcomes, which occur through multiple potentially challenging behavior changes by those delivering and receiving interventions. Contributing to complexity is the number of interacting components and degree of fidelity—degree to which a program is delivered as intended [1]—required of the intervention [2].

Interventions involving eHealth solutions are among those complex examples that make evaluation challenging. eHealth can be broadly defined as information and communication technologies used as part of health service delivery [3]. eHealth and mobile technology adoption is often viewed as a prime example of a complex health intervention, given the interaction of individual, contextual, and technological variables [4-6]. As such, evaluation methods used for complex interventions are recommended to assess eHealth interventions.

The Medical Research Council's framework on the evaluation of complex interventions includes attention to the stages of implementation from development to full-scale implementation [2,7]. Similarly, Parry et al [8] recommend adopting a 3-phase approach to evaluation of new complex models of care. These phased approaches seek to build an understanding of the intervention to inform evaluation designs. Common among the approaches are attention to the context in which interventions are implemented and the mechanisms (or content theory), which suggest how the intervention will lead to expected outcomes [7,8]. Moreover, common is a view to an end point of a randomized control design, which persists as the gold standard within the hierarchy of evidence [9,10].

Exploratory trials are recommended as a means to pilot test key components of a full trial including the control (or comparative)

group, the appropriate sample size, and suitable outcome measures relevant to patients and at the system level (ie, economic measures) [2,11]. Exploratory trials can also be used to refine content theory as well as for exploring the implementation of the model in terms of the satisfaction, experience, and learning among users (execution theory) [8]. However, a recent systematic review of the complex intervention evaluation literature found there is often insufficient reporting of detail in these evaluations, particularly around context of the intervention itself [12]. As such, there is a lack of methodological guidance in conducting these trials and using them to inform larger-scale evaluations.

This paper presents findings from our exploratory trial of the Health System Performance Research Network-Bridgepoint *electronic Patient-Reported Outcomes* mobile device and portal system—hereafter referred to as the electronic patient-reported outcome (ePRO) tool—designed to support goal-oriented care delivery in primary care settings. We adopted a developmental evaluation approach collecting quantitative and qualitative data to support the appraisal of the tool. In addition to testing the trial design, this exploratory trial sought to determine how we draw on multiple data sources to gain insight into the relevant contexts, processes and outcomes, and the mechanisms that connect these variables. This paper offers study findings as well as methodological insight with regard to how we answer 2 questions:

1. *What are the contexts, processes, and outcomes most relevant to the ePRO intervention?*
2. *What are the central (critical to achieving outcomes) versus peripheral (less critical and potentially context dependent) mechanisms that underpin the content theory of the ePRO intervention?*

The Intervention: The Electronic Patient-Reported Outcome Tool

The ePRO tool includes 2 features: (1) My Goal Tracker and (2) Health Status Scales and Outcome Measures. See [Multimedia Appendix 1](#) for screen shots of the portal and mobile app and Steele Gray et al [13] for a detailed overview of ePRO.

Table 1. Goal attainment scale monitoring.

Score	Goal achievement
+2	Much better than expected
+1	Better than expected
0	Goal (expected level specified by patient and, or caregiver and provider)
-1	Less than expected
-2	Much less than expected

Table 2. Monitoring protocols.

Symptom or outcome	Health status scales and outcome measures
Depression	Patient Health Questionnaire 9-item depression questionnaire [15]
Anxiety	Generalized Anxiety Disorder 7-item anxiety questionnaire [16]
Global health	PROMIS ^a Global Health Scale ^b
Pain management	PROMIS Pain Interference Scale ^b
Mobility	Improved Health Assessment Questionnaire ^a

^aPROMIS: Patient-Reported Outcomes Measurement Information System.

^bSee [17-20] validation of PROMIS tools and relevance to primary care.

Feature #1: My Goal Tracker

My Goal Tracker allows patients (their caregivers if interested) and providers to collaboratively create goal-oriented patient care plans. Once a goal is added to the patients' care plan, their mobile app prompts them to report on outcomes related to that goal on their mobile device (specifically on a smartphone). The ePRO tool uses goal-attainment scaling (depicted in **Table 1**) to capture standardized outcome measures across diverse patient groups, standardize goal attainment measures, and address the challenge of writing multiple goals [6]. Customizable monitoring questions can be added using question templates. Patients can include comments at each monitoring period to provide context and detail needed to understand why goals are achieved or are not achieved.

Feature #2: Health Status Scales and Outcome Measures

The Health Status Scales are intended to help patients, their caregivers, and providers track and monitor symptoms and outcomes identified as important by patients with complex care needs [14]. This type of monitoring is also helpful for patients not yet ready to goal set, as it provides a starting point to the self-monitoring process. Similar to the *My Goal Tracker* feature, patients will be prompted when symptom reporting is due. **Table 2** identifies monitoring protocols that can be added to patient health journals.

Methods

Evaluation Framework

As recommended for exploratory trials and complex interventions, we sought to capture context, process, and outcome measures to provide early evidence of effectiveness (or ineffectiveness) of the tool and to identify likely *mechanisms of action* to build on what was learned in piloting [7,11].

Consistent with the developmental evaluation approach, informed by our overarching user-centered design methods, data from this study are also used to inform design changes to the technology—see prior publications on development and usability testing [21,22]. **Table 3** summarizes outcome, process, and outcome variables of interest to our study, and the tools and methods used to capture data.

Outcome Measures

Patient and provider level outcomes were collected as part of this study. The primary patient outcome measures included the following: (1) Quality of life, measured using the Assessment of Quality of Life Scale (AQoL-4D) [23] and (2) self-management, measured using the 13-item Patient Activation Measure (PAM) [24]. Patient experience measures were collected using a modified version of the Patient Assessment of Chronic Illness Care (PACIC) tool, a 20-item measure of patient centeredness [25]. Provider-level effectiveness was captured using provider interviews informed by the Assessment of Chronic Illness Care tool (the provider partner assessment to the PACIC), which has been used to help health care teams improve care delivered to patients with chronic illness [26].

Process Measures

The Post-Study System Usability Questionnaire (PSSUQ) was used to assess experience and usability of the tool. The PSSUQ is a 19-item usability questionnaire comprising 3 subscales (system usefulness, information quality, and interface quality) [27]. The PSSUQ has demonstrated reliability and validity [28] and has been used to assess satisfaction and experience with similar mobile health technologies [27]. Postintervention patient and provider interviews were used to capture additional information regarding user experience and probed tool impact on provider workflow. Although ethnography and observation methods can be used to assess these process measures [29,30],

these approaches were not feasible for this study. Instead, we used targeted probes in the interviews to capture data.

Context Measures

Context measures are captured at the patient, provider, organizational, and system level. At the patient and provider level, demographic and characteristic information such as age, gender, chronic illness profile, socioeconomic status, and information technology (IT) skills are collected. These contextual factors have been found to impact the adoption and implementation of eHealth tools [31]. At the organization and system levels, we used postimplementation interviews with providers and clinic managers to identify barriers and facilitators to ePRO adoption. Factors such as appropriate supportive resources (ie, IT support), logistical issues (ie, integration of the tool into provider workflows), appropriate training and time to learn new systems, and organizational-level support have been found to be pivotal in adopting new eHealth systems [31-33]. System level contextual issues such as noncentralized systems, lack of standardization of data systems, legal requirements, financial incentives (or disincentives) have also been found to impact eHealth adoption [32].

Study Design

We conducted a 4-month trial in 2 Family Health Teams (FHTs) in Toronto. To study outcomes, we randomized patients into either control or intervention arms of the study at the 2 sites. To explore process and context measures, we adopted a case study approach, which is appropriate for complex interventions given the need to explore phenomena in their natural settings [34]. These types of naturalistic designs are recommended when evaluating telehealth and eHealth interventions [4].

Table 3. Data collection for electronic patient-reported outcome tool exploratory trial.

Concept and measurement level	Variable	Tool and method	Data collection
Outcome			
Patient	Self-management	Patient Activation Measure	Baseline; 4 months
	Quality of life	Assessment of Quality of Life Scale	Baseline; 4 months
	Person-centered care delivery	Patient Assessment of Chronic Illness Care	Baseline; 4 months
Provider	Delivering patient-centered care	Provider interviews	Postintervention
Process			
Patient	Tool experience	Post-Study System Usability Questionnaire	4 months
Patient	Tool experience	Patient interviews	Postintervention
Provider	Tool experience	Provider interviews	Postintervention
Organization	Provider workflows	Provider interviews	Postintervention
Context			
Patient	Patient demographic and characteristics	Electronic medical record extraction Patient information sheet	Preintervention
Provider	Provider demographic and characteristics	Provider information sheet	Preintervention
Organization	Resources, support, and training	Provider and manager interviews	Postintervention
System	Structure, data standards, legal requirements, and funding	Provider and manager interviews	Postintervention

Although the length of time from end of trial to interviews was a bit longer for providers, this was unavoidable because of challenges faced while booking interview times with busy clinicians. Given it was a unique experience for most providers, they were able to recall the experience and provide in-depth feedback. Only 1 provider explicitly noted some challenges in recalling the intervention.

Patients and providers were asked to tell us the story about how they used the tool over the 4 months, what (if anything) changed because they used the tool, the challenges and benefits that were experienced, and then more directed questions and probes around the usability of the tool. Providers and managers were additionally asked to reflect on enablers and barriers from a clinical and organizational perspective as they told the story of using the ePRO tool. Interviews were audio-recorded and transcribed verbatim. As is consistent with qualitative analysis methods [36], postinterview memos were written by researchers who conducted the interviews and included in the dataset to guide analysis.

Data Analysis

Patient outcome data were analyzed by calculating overall and domain scores of the AQoL-4D (standardized scores of Independent Living, Mental Health, Relationships, Senses, and total), PACIC (Patient Activation, Delivery System Design and Decision Support, Goal Setting, Problem-solving and Contextual Counseling, Follow-up and Coordination, and total), and PAM, including changes in scores between baseline and 4-month follow-up periods within groups and between intervention and control groups. Due to the small sample size, the Wilcoxon signed-rank test was used to compare paired survey data means between pre and post for both control and intervention groups, and the Mann-Whitney test was used to compare the change in scores from pre and post between the Control and Intervention groups. Quantitative data on tool experience captured through the PSSUQ were analyzed using standard descriptive statistics across subdomains. Data were analyzed using SPSS version 25 (SPSS Inc).

Qualitative data collected through patient, provider, manager, and administrator interviews were analyzed using qualitative description [37] to first categorize and identify dominant themes in the data. Overall, 3 coauthors engaged in the iterative inductive coding of transcripts to identify codes. The coauthors double coded a subset of interviews to validate the codebook. Codes were identified at the patient, provider, organization, and system levels, as well as codes relating to the technology. Through this process, descriptive codes were categorized into thematic groupings. Once the authors agreed upon the descriptions and application of the codes, all interview transcripts were coded using NVivo 11 (QSR International). A summary of findings was shared with patient and provider participants for member checking. No suggested modifications, concerns or issues were raised by participants.

Results

Participants

A total of 201 patients were identified and mailed invitations (113 at site 1 and 88 at site 2). Overall, 16 patients (21 consented, 5 withdrawals) participated in the study across the 2 sites. Of them, 9 were randomized into the intervention arm and 7 to the control arm. In total, 11 of the patients were female, most of whom were in the age group categories of 55 to 64 years (n=7) or 65 to 74 years (n=5), and 9 patients reported having 3+ chronic conditions. A total of 15 patients reported either comfortable or very comfortable with a computer; 14 reported either comfortable or very comfortable with a smartphone or tablet.

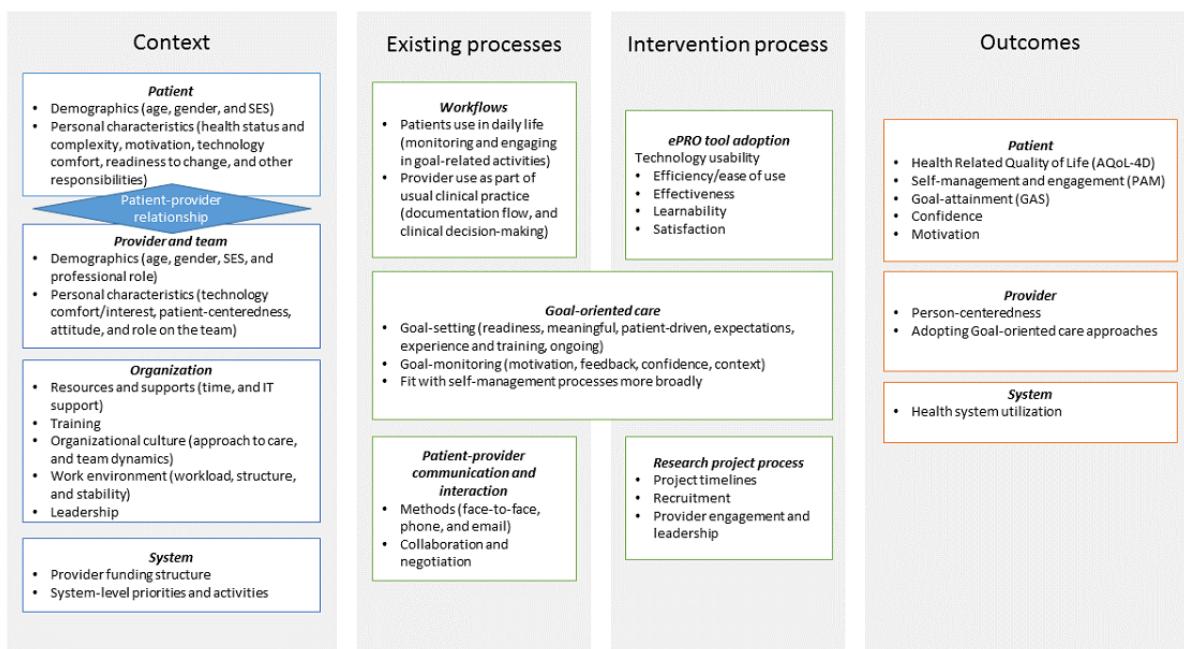
The vast majority of patients who were contacted simply did not respond to our emails and follow-up phone calls. For those we were able to speak to directly, the main reasons they did not wish to participate were: (1) they were already overwhelmed with managing their health needs and did not want to add another responsibility, (2) they were not sure they had health goals they could work on, (3) they did not self-identify as having a *chronic condition* (eg, some patients did not consider hypertension or even diabetes as a chronic condition) and therefore felt they did not meet the inclusion criteria, and (4) they had concerns about using technology (they did not have much experience using technology).

A total of 6 providers participated in this study, including 2 physicians (1 of whom held a managerial role), 1 nurse practitioner, 2 registered nurses (1 a diabetes educator), 1 social worker, and 1 dietitian. A total of 6 providers reported they were comfortable with computer and tablet technologies. An administrative staff member involved in the implementation of the study was also interviewed. Interviews were conducted with all 9 intervention patients, all 6 providers (1 of whom was also a clinical lead), and the 1 member of the administrative staff. All interviews were conducted at one time.

Electronic Patient-Reported Outcome Contexts, Processes, and Outcomes

Quantitative and qualitative data from the exploratory trial were mapped onto a context, process, and outcome framework. Although some of this mapping came directly from our design (see variables described in Table 3), we pulled data from interviews to identify additional variables perceived as having an impact on the intervention. Variables extracted from our interviews include the following: the patient-provider relationship, patient motivation, confidence and responsibilities, provider attitudes and beliefs, organizational culture and work environment, patient use in daily life, the process and adoption of the goal-oriented care process (beyond just the use of technology), additional outcomes including patient goal-attainment, and perhaps most notably the research project process. Figure 1 offers a comprehensive descriptive list of all identified constructs.

Figure 1. Context, process, and outcome constructs present in the electronic patient reported outcome exploratory trial. AQoL-4D: Assessment of Quality of Life Scale; GAS: goal-attainment scale; PAM: Patient Activation Measure; SES: socioeconomic status.



Electronic Patient-Reported Outcome Context

As depicted in Figure 1, contextual variables at patient, provider, organization, and system level were all found to play a likely role in the ePRO intervention. Not only are there multiple components to consider at each level but these levels also intersect. In particular, the patient-provider relationship was found to be a critical context for this intervention, which also drove some key mechanisms of change (described in our Content Theory section).

Electronic Patient-Reported Outcome Process

Process variables can be broken into existing processes as compared with new processes introduced by the ePRO intervention. Existing processes provide an indication of the types of work conducted by providers (eg, clinical work as usual) and patients. For clinicians, work as usual includes seeing patients, engaging in decision-making activities, documenting encounters, following-up, and referring as required. For patients, usual work involves engaging in their everyday lives, which often involves managing their complex health and social care needs. The intervention process introduced *new* work for both patients and providers who were asked to engage with a novel technology as part of care. Notably, although FHTs had adopted goal-oriented care as part of usual practice, this study showed that the tool introduced new ways of engaging in this approach,

making it both an existing and new process. Finally, the research project process itself played an important role (see Content Theory section).

Electronic Patient-Reported Outcomes

Patient pre- and postsurvey results are presented in Tables 4 and 5. No statistical differences were seen for pre versus post means of overall or subscale scores of AQoL, PACIC, and PAM in both control and intervention groups, nor between control and intervention; however, the sample is not sufficiently powered to pick-up change. As exploratory trials are often used to help determine sample size for larger trials, effect size estimates were calculated using Cohen *d*. As can be noted in Table 5, the confidence interval ranges are quite large, which is unsurprising given the small sample, and make it difficult to generate meaningful effect sizes.

Interestingly, control patients had a lower reported quality of life at baseline as compared with intervention patients, who scored above the norms reported in the literature [38]. Interestingly, the SDs are smaller than those reported norms, suggesting less variability in our relatively small sample. The greater homogeneity of the sample might be connected to some of the reasons patients chose to decline the participation described above, resulting in a group that looks a bit more similar than the broader complex patient population.

Table 4. Pre/postsurvey means and standard deviations of control and electronic patient-reported outcome intervention groups.

Measures	Control, mean (SD)		Intervention, mean (SD)	
	Pre	Post	Pre	Post
Assessment of Quality of Life Scale (standardized scores)^a	69.05 (17.23) ^b	65.48 (17.56) ^b	83.33 (5.38) ^c	84.57 (11.96) ^c
Independent living	74.60 (33.16) ^b	77.78 (22.22) ^b	95.06 (8.07) ^c	92.59 (18.43) ^c
Relationships	63.49 (25.43) ^b	61.90 (30.67) ^b	83.95 (12.56) ^c	85.19 (11.11) ^c
Mental health	55.56 (18.14) ^b	44.44 (22.22) ^b	65.43 (17.07) ^c	65.43 (21.11) ^c
Senses	82.54 (24.73) ^b	77.78 (21.28) ^b	88.89 (9.62) ^c	95.06 (8.07) ^c
Patient Assessment of Chronic Illness Care^d	3.25 (0.88) ^b	2.57 (1.31) ^e	3.61 (0.98) ^c	3.39 (1.16) ^c
Patient activation	3.33 (1.00) ^b	2.87 (1.58) ^e	4.19 (0.88) ^c	3.81 (1.31) ^c
Delivery system Design and decision support	2.86 (0.96) ^b	2.50 (1.36) ^e	4.11 (0.90) ^c	3.67 (1.19) ^c
Goal setting	2.97 (1.15) ^b	2.29 (1.26) ^e	3.31 (1.30) ^c	3.22 (1.20) ^c
Problem-solving and contextual counseling	3.50 (1.36) ^b	2.85 (1.75) ^e	3.78 (1.16) ^c	3.44 (1.35) ^c
Follow-up and coordination	3.49 (0.81) ^b	2.52 (1.33) ^e	3.16 (1.13) ^c	3.09 (1.26) ^c
Patient Activation Measure ^d	55.91 (10.15) ^b	54.96 (22.34) ^f	68.90 (15.72) ^c	68.15 (17.16) ^c
Post-Study System Usability^g Questionnaire^a	— ^h	—	—	3.83 (1.84) ^c
System usefulness	—	—	—	3.78 (2.24) ^c
Interface quality	—	—	—	3.46 (1.95) ^c
Information quality	—	—	—	3.92 (1.51) ^c

^aHigh scores indicate lower functioning.^bn=7.^cn=9.^dHigh scores indicate higher functioning.^en=5.^fn=6.^gPSSUQ scores were only collected post study for intervention patients who used the technology.^hNot applicable.

Table 5. Effect size and change scores for control and electronic patient-reported outcome intervention groups.

Measures	Control			Intervention			Mann Whitney test (P value)
	Cohen <i>d</i>	95% CI of difference	<i>P</i> value	Cohen <i>d</i>	95% CI of difference	<i>P</i> value	
Assessment of Quality of Life Scale (standardized scores)^a	-0.23	-10.86 to 18.01	0.31	0.12	-9.37 to 6.9	0.48	0.21
Independent living	0.17	-20.69 to 14.34	0.71	-0.12	-13.95 to 18.89	>.99	0.54
Relationships	-0.04	-34.71 to 37.88	0.68	0.07	-14.36 to 11.89	0.89	0.76
Mental health	-0.36	-17.34 to 39.56	0.48	0	-12.08 to 12.08	0.89	0.84
Senses	-0.19	-18.11 to 27.63	0.5	0.63	-13.7 to 1.36	0.1	0.09
Patient Assessment of Chronic Illness Care^b	-0.59	-0.38 to 1.09	0.23	-0.23	-0.52 to 0.96	0.77	0.52
Patient activation	-0.24	-1.7 to 2.5	0.47	-0.34	-0.46 to 1.2	0.2	0.9
Delivery system design and decision support	0.02	-1.9 to 1.83	0.89	-0.34	-0.56 to 1.45	0.39	0.7
Goal setting	-0.29	-0.63 to 1.01	0.59	-0.07	-0.95 to 1.13	0.95	0.7
Problem-solving and contextual counseling	-0.25	-1.2 to 1.8	0.58	-0.43	-0.29 to 0.93	0.26	0.9
Follow-up and coordination	-1.09	-0.1 to 1.54	0.07	-0.05	-0.92 to 1.05	0.91	0.52
Patient Activation Measure ^b	-0.15	-8.08 to 10.89	0.89	-0.04	-12.07 to 13.56	0.57	0.86

^aHigh scores indicate lower functioning.

^bHigh scores indicate higher functioning.

Qualitative interviews point to additional outcomes beyond those anticipated in the original design. Patients reported gaining confidence and an increased motivation to engage in the behavior change needed to help achieve goals. Patients and providers also reported attaining and exceeding goals such as regularly attending health and wellness programs, improved sleep, weight loss, and improved blood pressure. Providers reported improved person-centered care delivery by having a tool to help guide collaborative conversations and better engage in goal-oriented care as a process.

The qualitative data thus provide us with a more in-depth understanding of the impact of the intervention than the quantitative data alone. These varying pictures of impact offered by quantitative and qualitative data require us to better understand what is driving the changes we are seeing. This better understanding of *why* we observe these changes can be achieved through an exploration of the mechanisms that link contexts and processes to observed outcomes. The following section offers our analysis of the mechanisms that are likely informing these outcomes.

Using Narrative Analysis to Uncover Central and Peripheral Mechanisms

Our findings suggest a range of potentially applicable theories and frameworks that might be influencing outcomes. Theories of patient self-management and individual behavior change are likely applicable given the intention of the ePRO tool supporting goal setting and attainment. However, identifying which is most applicable can be challenging. A recent scoping review of theories of behavior change in the social and behavioral sciences

literature found 82 behavior and behavior change theories available [39], dozens of which could be applicable in this intervention. In addition, usability, organizational behavior, and technology use theories, such as the Fit between Individual, Task, and Technology [33], could also apply.

Rather than identifying all possible applicable theories, frameworks, and relevant disciplinary approaches and then engaging in concept mapping, often unfeasible in tight study timelines, we decided to draw on narrative methods. Narrative and ethnographic methods are being increasingly adopted in the evaluation of complex eHealth interventions [29,40-43], and they can help capture contextual variables as a means to illuminate complexities and tensions [44]. Although we did not explicitly conduct a narrative study as part of our exploratory trial, the interviews with patients, providers, and administrative staff provide us with shared stories of technology use, thereby offering the opportunity to adopt a narrative analysis approach to illuminate dominant constructs likely to be influencing our outcomes.

Using a descriptive narrative approach [45], coded transcripts were reviewed to search for common themes, and short summaries were written for each transcript. Saturation of dominant themes occurred by the fourth provider and manager interview. A summary memo was written on these themes, which was shared with coauthors for review and discussion. The same method was repeated for patient interviews; saturation of themes was similarly achieved. We present dominant themes from provider and patient narratives below and use these to update Figure 1 with a visual pathway to link contexts, processes, and outcomes.

Provider/Manager Narrative Themes

Overall, 2 dominant themes were found across the provider, manager and administrator transcripts reviewed: (1) research versus real-world and (2) meaningfulness. Each theme has a slightly different tone and nuance across the different interviews and was moderated by context variables.

Research Versus Real World

Every provider discussed how the adoption of ePRO was different in the context of research than what would be expected in real-world practice. Particularly concerning to providers was timing constraints of the research study, meaning that patients had to be identified and on-boarded in a particular window, which did not fit into the way things *usually work*. Providers reflected goal-oriented care should happen organically and take into account patient readiness and the relationship between the patient and provider. Simply put, a strict research timeline did not resonate with the iterative nature of the goal-oriented care process:

I think because health coaching or change processes is such an iterative ongoing process that in the longer term, it would sort of come in and out of being useful for me, I think. In times when someone was really willing to work on a goal and really wanted to progress, then being able to track that change would have been really helpful. [Nurse]

Even though the tool had been codesigned with providers to fit their usual clinical workflow, adopting ePRO in a research environment was perceived as a new process, which was challenging in a busy clinic environment where providers experience competing demands. Among the recommendations for improvement was the suggestion to integrate the technology into the practice EMR, a tool already highly used as part of the clinical workflow of providers. The clinical leader at site 1 reflected on the tension between a busy clinic and the research process; later in their story, they suggested how better alignment to clinical priorities (context) would improve adoption:

Sometimes research studies are as they are—just a little bit clunky to fit into regular life. But it was a bit of a round peg, square hole situation [...] [Providers] were making it work into the work flow as opposed to just sort of fitting into the work flow. And so I think that they got kind of stuck at that level as opposed to kind of moving on and moving forward with the patient goal.

...there's all these layers of things [the teams] have to do [...] So we all have to have a quality improvement plan. We all have to have matrix that we need to report on [...] there's eventually an opportunity to say, look, [ePRO] is part of either a patient satisfaction matrix or a complexity management matrix or kind of actually making it into the work, making it what people are about, they will likely, again, be a bit more engaged and use it more. [Physician and Clinical Lead]

Meaningfulness

The second dominant theme in the providers' stories was about the meaningfulness of the ePRO tool to themselves, their patients, and to their organization. Providers often reflected on what they felt the role of technology should be: desiring a tool that would provide actionable information to assist with clinical decision-making, in addition to improving workflow efficiencies resulting in less work" (Nurse), meaning fewer clinical activities needed to meet patient needs. Meaningfulness to the organization was often around meeting performance metrics, as identified by the clinical leader of the FHT.

In almost all stories, providers discussed how important it was that the ePRO tool be meaningful to patients. Interestingly, for most providers, the challenges regarding fitting the tool into their practice were mitigated when they felt their patients benefitted from using ePRO:

It would definitely be adding work, I would say, because it takes up that time in the appointment. It would take up more time than just having a discussion about SMART goals. But that being said, if it's beneficial to the patients then I'm willing to do that. [Registered Dietitian, Diabetes Educator]

Some competing stories emerged regarding how patient contexts would change whether the tool was meaningful to patients or not. For instance, several providers noted that patients were not ready to goal set or had needs that were too complex to engage in goal setting, stating that it would "only work for those super motivated patients" (Registered Dietitian, Diabetes Educator), whereas other providers suggested patients were *too* capable to see benefits from the tool:

[the patient] was already quite an active 70-something year old woman, that maybe she needed less sort of pushing, motivating and prompting than maybe if she was like a smoking cessation person where it is a very hard thing to change and to do which might require a lot more checks and check-ins. [Nurse Practitioner]

An interesting reflection from 1 provider (and resonated with patient stories discussed below) is how the collaborative nature of the tool increased the meaningfulness of the tool for patients and helped to motivate them toward their goals:

Now, when they've had their own apps or their own journals, they didn't stick to it. And I think maybe [ePRO] made them feel more responsible in a sense. Maybe because I was involved or someone else was involved, and so they felt they had that responsibility to do it. So someone did definitely lose weight using the application just because of keeping him more mobile and active. The majority said they found it useful for sure. [Physician]

Patient Narrative Themes

The narrative analysis of patient stories revealed, 2 dominant themes, 1 around goal reminders and progress monitoring, and the other regarding the crucial role of the provider. The expression of these themes varied in terms of whether patients

were techno-savvy (identifying greater technological experience and comfort) or techno-timid (reporting less experience and comfort with technology).

Goal Reminder and Progress Monitoring

Both patient groups talked about how useful the tool was as a reminder and as a way to monitor their progress (or lack of progress) toward achieving their goals. Reporting was perceived as either positive or negative depending on how well the goal had been defined and measured. A techno-timid participant shared her thoughts:

Having to report that I didn't do what I was [supposed] to be doing made me think, "OK, well I'll try to make that up on [another day] when I wasn't supposed to exercise" ...So I think it was useful for me as a guilt thing sitting on my shoulder. [Female patient, 65-75 years]

If patients found the goal meaningful and realistic, then the feedback from the tool was reinforcing, resonating well with the providers' reflections on meaningfulness. However, sometimes setting goals incorrectly meant that they achieved the goal quickly; therefore, continuing use had little point. A techno-savvy participant shared his thoughts:

The goal was pretty simplistic and I set the goals probably too low. So it wasn't really a challenge at all and I didn't get a heck of a lot out of it. [Male patient, 75+ years]

The Crucial Role of the Provider

The patients echoed the physician's reflection that the collaborative nature of the goal-oriented approach was an important motivating factor. Both techno-savvy and techno-timid groups emphasized the importance of working with their health providers during the goal-setting process. Participants with positive experiences worked with their providers to identify relevant goals, and they negotiated meaningful levels of goal attainment. A patient added her suggestion:

Make sure the goal is stated in a way that is meaningful and can be tracked in a meaningful way. I would say the most important part of the whole thing for a patient would be working with the provider to

get those goals just right. [Female patient, 45-54 years]

The patient participants perceived the role of the provider in helping to narrow and focus the goal as encouraging and helped to identify areas that need work. For example, 1 techno-savvy participant described having set 3 goals. Progress was evident for 2 of the goals, but it became clear that more focused work was needed on the third goal. The participant independently came to this realization as she monitored her own progress on the tool:

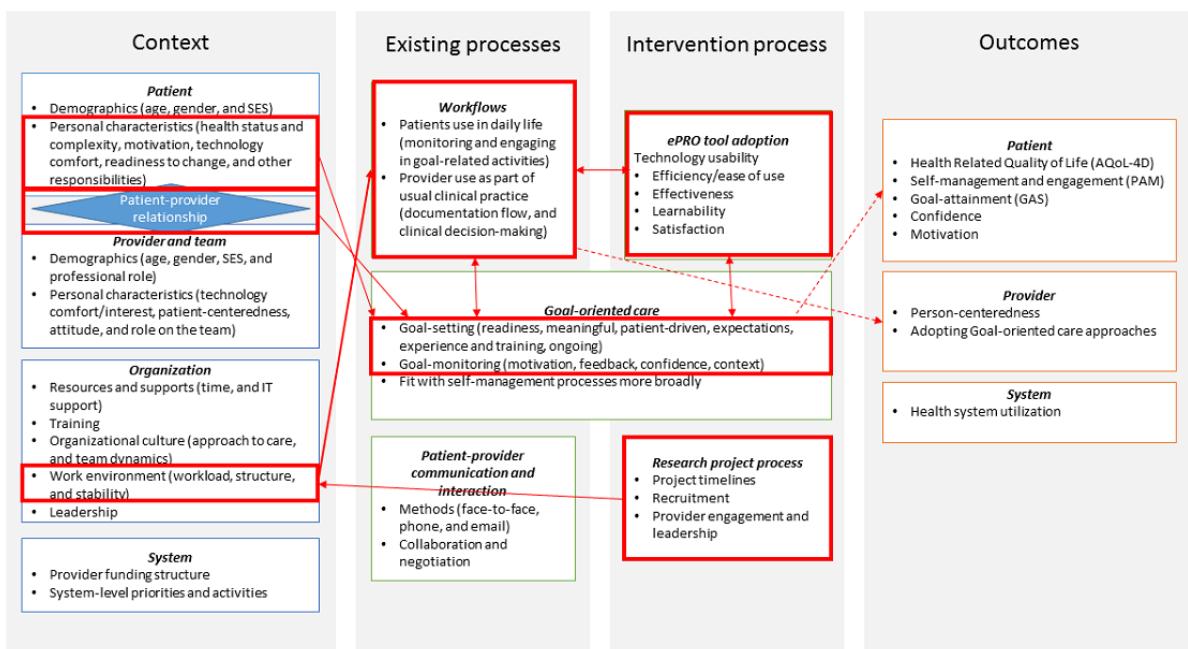
I found the question related to how confident are you that you will reach your goal...was a really good question because as it went on, I could just see I went from I'm sure I can do this to Oh, it's hopeless (laughs). [Female patient, 45-54 years]

Bringing It All Together to Generate a Content Theory

The narrative themes point to core mechanisms that are likely driving ePRO intervention outcomes. Most important are the notions of *meaningfulness* for patients and providers, which were influenced by key contexts including the patient-provider relationship (which enables collaborative goal setting), participant comfort with technology, the providers' work environment, and the research process itself. These contexts moderate patient and provider adoption of the ePRO tool, which we expect will impact patient and provider outcomes. Most interesting is the role of the research process in relation to these contexts and how patients and providers assign meaning to intervention activities. For instance, stringent research timelines prevented more natural use of the tool in delivery of care, which forced participants to fit to the tool rather than incorporate it into their work and daily lives.

We offer a visual representation of how these mechanisms map onto our context, process, and outcome variables in [Figure 2](#). Unidirectional arrows show how contexts and the research process influence the intervention process. Bidirectional arrows indicate processes that interrelate with each other over the course of the intervention. The dashed-line arrows indicate how we expect the processes to influence the outcomes collected at this stage, which would be tested in the next larger trial. Our discussion offers a likely theory to explain the nature of these mechanisms.

Figure 2. Dominant mechanisms driving electronic patient reported outcome trial outcomes. AQoL-4D: Assessment of Quality of Life Scale; PAM: Patient Activation Measure.



Discussion

Principal Findings

Outcome data alone suggest little change occurred for either control or intervention groups from pre to poststudy across any of our outcome measures. Intervention patients appeared to have a lower reported quality of life but higher levels of activation as compared with control groups. Notably, patient-centeredness seemed to go down for intervention patients according to the PACIC survey. Although the sample size is too low to capture real change, the narratives shed light on what variables might have an impact on these outcomes and point to areas that might be missed in looking at outcome data alone.

The narrative themes suggest fitting the ePRO tool into regular provider clinical work processes and patient daily activities is a critical mechanism and it points us in the direction of Normalization Process Theory (NPT) to uncover the nature of the mechanisms of our intervention. NPT's emphasis on the social production and normalization of *work* helps us understand participant interactions with all aspects of the intervention, technological, processual, and social [46-48]. The theory suggests that new processes take hold through 4 generative mechanisms: coherence, cognitive participation, collective action, and reflexive monitoring. Through these mechanisms, new activities or practices become normalized and part of the everyday routine of actors.

We can see examples of all 4 generative mechanisms driving participant actions in the case of the ePRO tool. In terms of coherence (sense-making work), our narratives show how the perceived meaningfulness of the ePRO tool was crucial to overcoming contextual barriers (the research process) to adoption. Cognitive participation (relational work) and collective

action (operational work) drove perceived meaning through patients and providers interacting with each other around the intervention, allowing them to legitimate tasks and assign roles and responsibilities when using ePRO. Engaging in these tasks effectively (setting up appropriate goals, patients remembering their goals and monitoring, and then following up together) was essential to meet outcomes reported in qualitative findings. When patients and providers saw the value of ePRO, through patients achieving and exceeding goals, meaningfulness increased and supported ongoing appraisal (or the reflexive monitoring mechanism) of the tool.

Many of these positive procedural changes are not captured in quantitative outcome data. The qualitative data provide a richer picture of outcomes that could be captured over the shorter term, such as patient motivation (related to empowerment), which can have a positive impact on outcomes [49]. Using narrative analysis, we are able to more clearly see the mechanisms of change needed to move the outcome dial over the longer term in a full-scale trial. For this trial we will need to do the following: (1) collect data on the perceived meaningfulness of ePRO to all participants (capturing coherence and relational work), (2) adopt a more pragmatic trial approach to better fit the research into the real-world environment (addressing operational work), and (3) pay careful attention to the process of goal-oriented care, particularly the patient and provider interactions and relationships (capturing relational work and reflexive monitoring). Critical to addressing all 3 aims is the adoption of an embedded ethnography that includes patient-provider interaction observations, interviews at multiple time points that probe on key areas, and an iterative analysis method that supports building interpretation of findings as we go. We will adopt Greenhalgh and Swinglehurst's [29] approach

to ethnographic information communication technology evaluation as a methodological and analytic guide.

Limitations

One of the most important limitations in this study is that we did not explicitly aim to collect patient and provider narratives; therefore, our method had to be modified to look at shared stories on how participants used technology. One potential limitation is that we only conducted interviews with participants once, whereas narrative approaches often suggest multiple interviews to craft participant stories [36]. Instead of thorough additional interviews, we collected additional data regarding the stories of adopting ePRO through reflective memos and in team meetings. The team was engaged with the sites weekly, often daily, memoing on the exchanges and experiences, which allowed us to iteratively analyze and interpret the story of the intervention as we went. As noted previously, this type of iterative analysis is consistent with many qualitative method approaches including narrative [36].

Although the small sample meant we could not engage in more advanced statistical methods, it did allow us to do a much more in-depth qualitative analysis, which is perhaps more important at the stage of an exploratory trial. As noted in our findings section, the sample was also more homogenous than we expected, potentially reducing generalizability of findings to broader complex patient populations. However, it is possible that the goal-oriented care approach is more appropriate for a particular subset of patients with complex care needs; it is a

new question we are exploring through another project in our current research program. However, the adoption of a theoretical framework and in-depth qualitative analysis does support transferability [50] of findings to other settings.

Finally, we were missing ethnographic observation, which potentially limited our ability to generate additional insights into the role of the patient and provider relationship and could have shed some light on some of the contradictions found in this study. Our full trial of the ePRO tool will include an embedded ethnography with more explicit use of narrative interview methods as a means to address these gaps.

Conclusions

Evaluating complex interventions marks a significant methodological challenge, which may be especially crucial in interventions that incorporate technology as an added layer of social complexity. Simply identifying all likely contexts, processes and outcomes, and underlying mechanisms might be unwieldy, leading to more questions than answers with regard to findings from our studies. Furthermore, this might make it difficult or impossible to clearly identify the content theory driving the intervention. We suggest studies of complex interventions, particularly those that incorporate eHealth technologies, adopt phased and integrative evaluation methods as we have done here. Using narrative analysis as a part of exploratory trials offers a useful methodological approach to help identify more central mechanisms underlying our complex interventions that drive outcomes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The electronic Patient Reported Outcome (ePRO) mobile app and portal screenshots.

[[PDF File \(Adobe PDF File, 108KB - formative_v3i1e11950_app1.pdf](#)]

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Abbreviations

AQoL-4D: Assessment of Quality of Life Scale

eHealth: electronic health

EMR: electronic medical record

ePRO: electronic patient-reported outcomes

FHT: Family Health Team

IT: information technology

NPT: Normalization Process Theory

PACIC: Patient Assessment of Chronic Illness Care

PAM: Patient Activation Measure

PSSUQ: Post-Study System Usability Questionnaire

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Original Paper

Co-Design of a Consultation Audio-Recording Mobile App for People With Cancer: The SecondEars App

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Abstract

Background: Many patients choose to audio-record their medical consultations so that they can relisten to them at home and share them with family. Consultation audio-recordings can improve patients' recall and understanding of medical information and increase their involvement in decision making. A hospital-endorsed consultation audio-recording mobile app would provide patients with the permission and means to audio-record their consultations. The Theory of Planned Behavior provides a framework for understanding how patients can be encouraged to appropriately audio-record consultations.

Objective: The aim of this study was to use a co-design process to develop a consultation audio-recording mobile app called *SecondEars*.

Methods: App development began with stakeholder engagement, followed by a series of 6 co-design workshops and then user acceptance testing. Stakeholder engagement included advice from legal, information technology (IT), clinical and allied health leads; digital strategy; and medical records. The co-design workshops were attended by: patient consumers, members of the research team, IT staff, the app designers, clinicians, and staff from medical records. During workshops 1 to 4, the purpose and scope of the app were refined, possible pitfalls were addressed, and design features were discussed. The app designers then incorporated the results from these workshops to produce a wireframe mock-up of the proposed *SecondEars* app, which was presented for feedback at workshops 5 and 6.

Results: The stakeholders identified 6 requirements for the app, including that it be patient driven, secure, clear in terms of legal responsibilities, linked to the patient's medical record, and that it should require minimal upfront and ongoing resources. These requirements informed the scope of the co-design workshops. The workshops were attended by between 4 and 13 people. The workshop attendees developed a list of required features and suggestions for user interface design. The app developers used these requirements and recommendations to develop a prototype of the *SecondEars* app in iOS, which was then refined through user acceptance testing.

Conclusions: The *SecondEars* app allows patients to have control and autonomy over audio-recording and sharing their consultations while maintaining privacy and safety for medical information and legal protection for clinicians. The app has been designed to have low upkeep and minimal impact on clinical processes. The *SecondEars* prototype is currently being tested with patients in a clinical setting.

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KEYWORDS

referral and consultation; adult; humans; cancer; audiovisual aids; mobile apps; community-based participatory research; health behavior; psychological theory

Introduction

Background

Facilitating Patient-Centered Care

Shared decision making and patient participation are essential elements of patient-centered care [1]. However, patient participation is reduced when patients do not understand or remember information given to them by their health care team [2]. Patients' ability to retain health care information can be compromised if the patients have low health literacy or language barriers or if the information is complex or distressing [3-5]. Consultation audio-recordings are an effective method to improve patients' recall and understanding of medical information and subsequently increase their involvement in decision making [6-10].

Smartphones for Consultation Audio-Recording

With the increase in smartphone ownership, patients are taking the initiative to audio-record their medical consultations themselves [11]. Recording of consultations is predominantly undertaken because of a desire to increase understanding and to facilitate discussions with family [12], but only a few health care systems have recording policies in place and patients sometimes audio-record consultations without their clinician's knowledge [13,14]. Patients have therefore self-identified a problem in their care—namely, their lack of understanding and recall of medical information—and a solution to this problem: mobile health (mHealth) technology. Furthermore, patients have expressed a desire for health care providers to institute clear, permissive strategies to facilitate consultation audio-recording [12]. Previous studies have also emphasized the patients' desire to control which consultations are audio-recorded [5]. Clinicians and health care providers must now work with patients to implement official systems of consultation audio-recording to facilitate an environment where audio-recording is openly encouraged. Medico-legal and trust concerns may be a barrier for some clinical staff regarding participation in consultation audio-recording [15]. An official consultation audio-recording system, such as a suitable smartphone app, may mitigate any potential fear or mistrust that could emerge between the patient and clinician as a result of audio-recordings. A suitable consultation audio-recording smartphone app would promote responsible use of consultation audio-recording, meet relevant legal requirements, and align with patient-centered care by placing control in the hands of the patient.

Previous consultation audio-recording studies have utilized digital recorders or Dictaphones operated by hospital staff, and a copy of the audio-recording was then given to the patient to take home on an audiotape, CD, or USB [16-19]. Dictaphones require resource-intensive setup and maintenance by staff. The administrative load of this system prohibits implementation into

usual care, and it prevents patient control over the audio-recording. Clinicians and hospital administrators understand that consultation audio-recordings are beneficial for patients, but they emphasize that successful implementation would require a system that (1) has low upkeep with minimal burden on clinical processes and resources, (2) addresses medico-legal concerns, (3) clearly defines who is responsible for the audio-recording once it is made, and (4) responds to patient preference by allowing the patients to control when they audio-record and with whom they share the audio-recording [11,15].

Co-Design of a Smartphone App

If a consultation audio-recording app is to meet the needs of patients, family, clinicians, and hospital administrators, all stakeholders must be involved in the app design and development [20]. Experience-based co-design is the process whereby future end users and other stakeholders draw on their experience and work with designers to design a product or service [21,22]. The experience-based co-design approach applies the key tenets of patient participation. Patients, as experts in their care, are involved in all facets of the project from solution generation, project design and oversight, through to design and testing. Patients have already identified smartphones as a means to audio-record their consultations [11,13,14]. The aim of this study was to use experience-based co-design to design a consultation audio-recording mobile app called *SecondEars* that utilizes this patient-identified solution while working to meet the implementation requirements identified by clinicians and hospital administrators.

Objectives

The objectives of this co-design study were to:

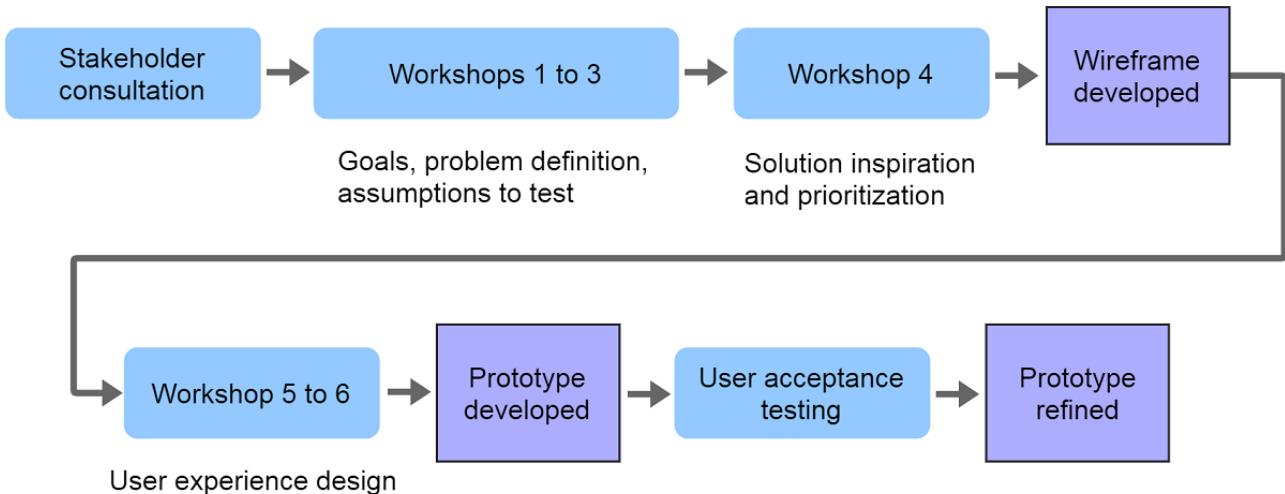
1. Identify and engage the stakeholders integral to implementation of mHealth technology within a hospital.
2. Facilitate co-design workshops to identify the necessary features of the app.
3. Develop a wireframe of the app.
4. Conduct user acceptance testing of the app.
5. Complete a prototype of the app.

Future publications will report on the piloting and implementation of the *SecondEars* app into usual care.

Methods

Study Design

This study was conducted at the Peter MacCallum Cancer Centre (Peter Mac) in Melbourne, Australia, and was approved by the relevant ethics committee (reference number: 16/07L). Objectives 1 to 5 were met via the co-design process outlined in [Figure 1](#). All workshop attendees provided written informed consent.

Figure 1. The co-design process for the SecondEars consultation audio-recording app.

Theory of Planned Behavior

The Theory of Planned Behavior provided a framework for the design and future implementation of the SecondEars app. The Theory of Planned Behavior posits that a person's behavior is directly related to the person's intentions, which in turn result from subjective norms, beliefs, and perceived control over the behavior [23]. If the patients are to be encouraged to responsibly audio-record consultations, the following should be addressed in the design of the SecondEars app:

1. Clinicians', hospital administrators', and patients' beliefs about consultation audio-recording
2. Patients' perceived control over audio-recording
3. The subjective norms of consultation audio-recording

Apps are user-controlled; it would be up to the patients to download and use an app on their own device, thereby supporting perceived control. An app can be promoted by the hospital, giving patients permission to audio-record openly, thereby developing a subjective norm. An app could also link audio-recordings to the hospital's medical record or information technology (IT) systems and allow patients to share the audio-recording with family or friends, indicating the safety and utility of audio-recordings, which may change clinicians', hospital administrators', and patients' beliefs about consultation audio-recording.

A well-designed consultation audio-recording mobile app could therefore positively influence behavioral, normative, and control beliefs and, according to the Theory of Planned Behavior, change intentions and encourage responsible audio-recording behavior.

Stakeholder Engagement

Initial consults with key stakeholders began in 2016 and continued throughout the development process. This early engagement informed the legal and technical requirements of the app before commencing the co-design process (see the Results section for a summary of these requirements). The following 16 stakeholders were consulted: 2 members of the hospital's legal department, 4 members of the IT department, including the head of department, 5 clinical and allied health

leads, the director of digital strategy, the head of the medical records department, and 3 consumer advocates. These stakeholders were kept informed throughout the development process and some attended workshops. The consumer advocates also took a formal place within the project steering committee as associate investigators. The proposed requirements of the app were reviewed and approved by the New Technology Review Committee at Peter MacCallum Cancer Centre in December 2016.

Developer Engagement

A local mobile app development company, Wave Digital, was contracted in February 2017 to create the SecondEars app. Wave Digital readily embraced the co-design approach and used elements of the Design Sprint methodology to structure the design process [24].

Co-Design Workshops and Activities

A total of 6 co-design workshops were held between April and June 2017 (see Figure 1). Some of the methods used to elicit information during the workshops included frequently asking open and obvious questions such as "Why." In addition, rephrasing assumptions or problems as questions was critical to accurately capture the goals for the product and identify the problem the product was attempting to solve.

Stage 1: Goals, Problem Definition, and Assumptions to Test (Workshops 1-3)

Before the first workshop, the attendees were briefed on the rationale for developing the SecondEars app, the proposed primary functions of the app, and the requirements and constraints that had been identified by the key stakeholders. The following 3 questions were addressed in workshops 1 to 3:

1. What do we want the app to do?
2. How can we imagine the app failing?
3. Who will be involved in using the app?

To address question 1, the attendees brainstormed a list of functions that the app should be able to do; this list was iteratively added to and refined throughout workshops 1 to 3. To address question 2, the attendees identified possible reasons that the app may fail and then reframed these potential pitfalls

as knowledge-seeking questions. These knowledge-seeking questions were used as starting points to generate strategies that could be employed to prevent the potential pitfalls. To define who would be involved in using the app (question 3), a technique called Journey Mapping was used, and the attendees mapped out the pattern of use for the app in the broader context of the patient's journey through Peter Mac. This included how and when a patient may become aware of it; how and when they may download it; who may encounter the app before, during, or after the patient's hospital consultation; and who may listen to the audio-recording.

Stage 2: Solution Inspiration and Prioritization (Workshop 4)

During workshop 4, attendees compiled a list of existing apps that they believed were well designed, intuitive, or provided a unique experience. These apps were then used to provide inspiration for the user interface design of the SecondEars app.

The co-design team used the MoSCoW method [25] to prioritize the desirable functions that had been identified during workshops 1 to 3. MoSCoW stands for the following: must-haves (Mo), should-haves (S), could-haves (Co), and won't-haves (W). This method allowed the attendees to reach a common understanding of the scope of the project and the relative importance of each of the functions that were listed during workshops 1 to 3.

Following workshop 4, the app developers used a technique called wireframing to do the following:

1. Structure the composition of the features and functions of the app (as prioritized during workshop 4).
2. Prioritize the content on those interfaces.
3. Connect the interfaces into a logical user flow.

Stage 3: User Experience Design (Workshops 5 and 6)

In workshop 5, the proposed designs for the app were presented in paper form using a series of interfaces cut to size. The feedback from this workshop informed the wireframes of the app. These wireframes were presented on an iPhone in workshop 6. The app developers conducted one-on-one user experience feedback sessions with each of the attendees to gauge each attendees' thought process and responses to using this wireframe design. Each attendee was given the wireframe app on an iPhone and asked to complete the following 4 tasks without prompting:

1. Make an audio-recording and then listen back to it.
2. Write a note on one of the recordings.
3. Read previously made notes while recording a consultation.
4. Log out of the app.

User Interface Design

The final stage of the design process was to create a visual identity for the SecondEars app. The combination of a logo, color, typography, and iconography was developed during the design process. Those brand elements were then applied to the interfaces of the SecondEars app, incorporating all feedback gathered during the sixth co-design workshop.

Development and User Acceptance Testing

Wave Digital used the finalized visual designs to develop a prototype of the app. Immediate feedback from the research team was incorporated and, in September 2017, the refined prototype was released to the co-design team for user acceptance testing so that any bugs could be identified. All faults were then rectified before the SecondEars app was made available in Test Flight mode on the Apple App Store.

Results

Iterative Refinement

Each stage of the development process resulted in requirements and refinements that were incorporated into the final design of the SecondEars app. The outcomes of each stage of the development process are outlined below.

Requirements Identified Through Stakeholder Engagement

The requirements identified by the stakeholders are outlined in Table 1. These requirements established the design profile and constraints of the SecondEars app and provided a foundation for the workshops.

To meet requirement 6 (see Table 1), the research team chose to develop a minimum viable product and assess its success before making additional financial investment. For this reason, some aspects of requirement 5 were not addressed in this version of the app. Specifically, the research team decided not to automate the app's connection to the medical record until the app had been piloted within clinical care. If piloting indicates high uptake of the app, then the investment in the IT infrastructure necessary to securely and automatically upload the audio-recordings to the medical record would be justified. In the interim, the audio-recordings would be securely hosted through a cloud solution (Amazon Web Servers) with an interface to allow the medical record staff to access the audio-recordings and manually upload them to the patient's medical record if necessary, thus meeting requirement 3. The research team identified a potential tension between requirement 1 and requirement 3: if the app is entirely patient driven, then the responsibility of uploading the audio-recording to the medical record falls to the patient. This process could not be automated; therefore, the research team introduced a requirement that all audio-recordings must be uploaded before they can be played back or shared by the patient.

In response to requirement 6, the research team decided to further reduce upfront costs by initially creating the app in iOS for iPhone, not Android. App development in Android is more complex and costly as the app design must be tested on a larger number of Android devices, whereas iOS can be developed for 1 platform only. Developing for iOS first enables more feedback to be gathered from users and any issues addressed before investing in an Android version. It was therefore pragmatic to delay releasing the app in Android until it had been piloted in iOS.

Workshop Attendees

Each workshop was attended by between 4 and 13 people who together comprised the co-design team. The co-design team included the following: patient consumers, members of the research team, representatives from IT, app designers, clinicians, hospital volunteers, and a representative from the medical records department. **Table 2** shows the number and type of attendees at each workshop. One consumer attended 4 of the

workshops (female, 56 years of age, previous experience as both a patient and a carer, and self-identified as having intermediate technology skills). Another consumer attended 2 of the workshops (male, 66 years of age, previous experience as both a patient and a carer, and self-identified as having intermediate technology skills). The third consumer attended the final workshop (female, 64 years of age, previous experience as a carer, and self-identified as having beginner technology skills).

Table 1. The requirements of the app identified through stakeholder engagement.

Requirement	Description of requirement	Suggested means to meet the requirement
1. Patient-driven	The app should be used by patients, not hospital staff; If the patient's clinician has given permission to be audio-recorded, the patient should have ultimate control over when and how the patient uses the app; This is not only important in terms of patient participation but also for practicality and financial feasibility of the app (see requirement 5)	The patient must be able to source, download, and use the app independently, with minimal input from hospital staff
2. Secure	The audio-recordings saved on the app and shared from the app must be secure as they will contain identifiable information	Access to recordings should be given only to users of the system via Secure Sockets Layer; The actual recording files should never be sent via unsecure means (eg, short message service, email); Strong password policy for Admin access
3. Linked to medical record	Consultation audio-recordings should be considered a part of the patient's medical record; Saving original copies of the audio-recordings on the patient's medical record may help guard against tampering or misrepresentation in the case of a malpractice lawsuit	An original copy of all audio-recordings made on the app should be stored in the appropriate patient's electronic medical record, or in a secure location that is accessible by medical record staff
4. Clear legal responsibilities	Patients using the app must be aware that they are legally responsible for the safety of the audio-recordings that are saved on and shared from their mobile, just as they are responsible for any copy that they are given of any component of their medical record	Include statement of responsibility on the opening screen of the app and in all app promotion material
5. Minimal upkeep	Once developed and implemented into usual care, the app should require minimal input from the staff and minimal ongoing financial costs	Integrate the app into existing hospital procedures; Automate processes where possible (eg, automatic upload of recordings from the app to the medical record); Use the latest secure cloud infrastructure to keep ongoing costs down
6. Minimal upfront costs	Additional funding could not be sought until the app had been piloted in a clinical setting and evidence was obtained about the usability of the app, whether it met requirements 1 to 5, and the extent of uptake among patients	Develop a minimal viable product. Results of the pilot can then be used to refine the product and support further, ongoing funding; Develop in iOS only (not Android); Delay investing in automating processes until after piloting

Table 2. The number and type of attendees at each workshop.

Category	Workshop 1	Workshop 2	Workshop 3	Workshop 4	Workshop 5	Workshop 6
Researcher	2	2	2	2	2	2
App developer	2	2	2	2	2	2
Consumer	2	1	1	0	0	3
Information technology	1	0	0	0	0	1
Oncologist	0	0	0	0	0	1
Nurse	0	0	0	0	0	1
Allied health	0	0	0	0	0	1
Medical records	0	0	0	0	0	1
Hospital volunteer	0	0	0	0	0	1
Total	7	5	5	4	4	13

Outcomes From Workshops 1 to 4

In answer to question 1 (“What do we want the app to do?”), the attendees took a blue sky thinking approach and articulated an ultimate aim for the app, as well as a list of all possible functions. The ultimate aim of the app was unanimously decided and described as “Improve the quality of patients’ care,” that is, improving the quality of patients’ participation, understanding and support during treatment, diagnosis, decision making, and support during their cancer journey. This was used as a keystone upon which to design the app and guide decision making regarding design, functionality, and utility. The possible functions identified by the attendees included the following: audio-record, share audio-recordings, listen back to audio-recordings, use without help, secure, categorize and label

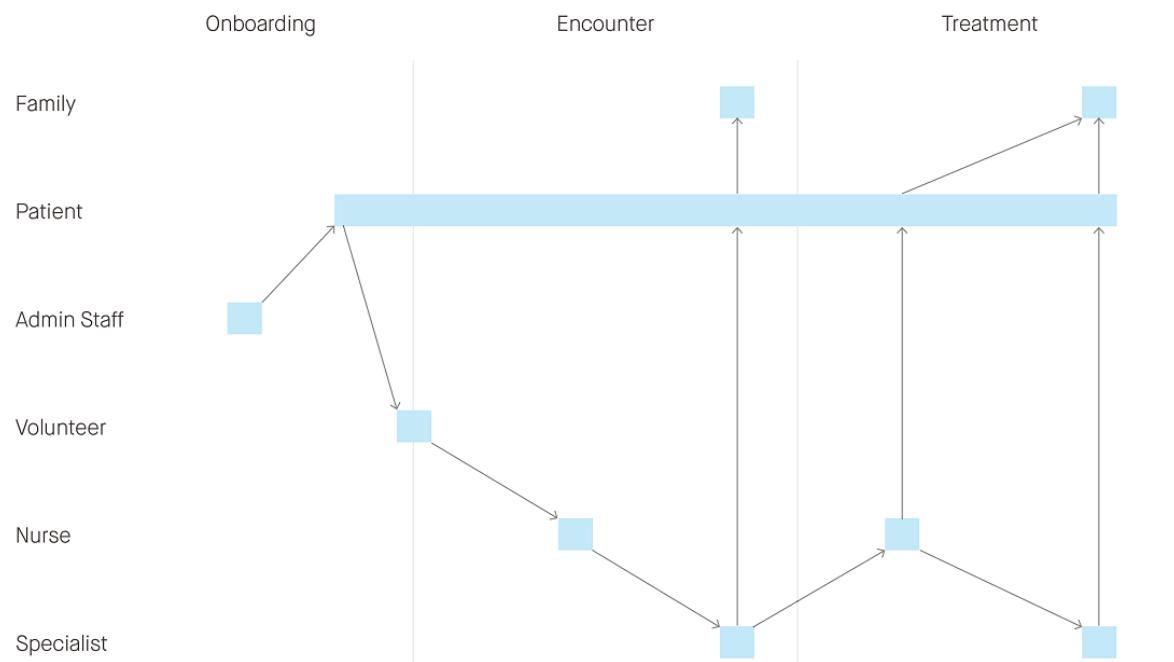
audio-recordings, send audio-recordings to Peter Mac, make notes, and read notes.

Table 3 summarizes the potential pitfalls and corresponding preventative strategies that were identified by the workshop attendees in answer to question 2 (“How can we imagine the app failing?”). This exercise indicated that, to be successful, the app would need to be paired with a promotion and education strategy to teach patients how and when they should use the app, their rights and responsibilities regarding use and sharing of audio-files, and to build trust with clinical staff.

In answer to question 3 (“Who will be involved in using the app?”), the attendees mapped out a typical patient journey within the hospital, identifying the key interactions that all personnel would have with each other and the app (see [Figure 2](#)).

Table 3. The potential pitfalls, knowledge-seeking questions, and preventative strategies outlined in workshops 1 to 3.

Potential pitfalls	Knowledge-seeking question	Preventative strategy
1. The app is too difficult to use	How do we make the app intuitive to the patient, the carer, and the health care community?	User-friendly, simple design; Education on how to use (provided with appointment booking information); Volunteer assistance in clinic
2. The app leads to incidents of personal damage (eg, security breaches)	How do we gain and maintain trust?	Appropriate security infrastructure; Education on responsible sharing (presented at app log-in); Upload to medical record required before play back or sharing
3. Patients do not download the app	How do we support appropriate and wide distribution?	Promotion (notification with appointment booking, signs in waiting room, and encouragement from the staff)
4. Patients forget to use the app	How do we let everyone know when it is the right time to use the app?	Promotion (notification with appointment booking, signs in waiting room, and encouragement from the clinical staff)
5. Patients do not find the app useful	How do we align the service to the benefits of audio-recordings that have already been established through research?	Draw on existing research; Include consumers in development

Figure 2. A journey map representing the envisaged pattern of use of the SecondEars consultation audio-recording app.

Textbox 1. The features that could be included in the SecondEars app and their corresponding prioritization according to the MoSCoW (Must have, Should have, Could have, and Won't have) method.

Must have

- Record consultation
- Upload required before playback
- Playback recording
- Patient identification number required for log-in
- Explain legal context and provide instructions
- Delete recording
- Share recording
- Recording library (list)
- Peter Mac access to data (list of recordings to download and attach to medical record)

Should have

- Notes on playback (editable)
- Notes while recording (view only)
- Categorize recordings (colors or tags)
- Ability to associate each recording with the relevant clinician (ie, tag recording as Physio, doctor, and nurse)

Could have

- Capture next appointment
- Reminder notification of next appointment

Won't have

- Authenticate and user management
- Booking system integration
- Push notifications and reminder emails
- Upload over 3G, Wi-Fi setting (user controlled)
- Barcode or quick Response code scan
- Access recording and share recording without device

Figure 2 shows that the initial promotion of the app would need to be undertaken by the administration staff. Information about the app would be provided to the patients by the administration staff when their first appointment is booked. The patients would then download the app before their first consultation (or “encounter”) at the hospital. Hospital volunteers, who are a regular presence at Australian hospitals, would be made aware of the app and be available to assist patients in downloading it while the patients wait for their appointment. The patients may then use the app to audio-record the nurse and/or specialist during their first consultation and at subsequent consultations. The pattern of use also shows that the patients may share the audio-recordings with their family members or friends after their hospital encounter. According to the Theory of Planned Behavior, integrating the app into the clinical process could influence subjective norms and therefore influence the patients’ behavior.

During workshops 1 to 3, additional features were suggested as complements to the audio-recording functionality in the app, and suggestions were made regarding how patients could label,

categorize, store, share, and search for audio-recordings once they are made. These features are listed in **Textbox 1** along with their priority according to the MoSCoW exercise that was completed in Workshop 4. The features classified as “Must have” or “Should have” were considered within the scope of the app. These features were included in the wireframe of the app, which was trialed in workshops 5 and 6.

Outcomes of Workshops 5 and 6

Feedback from workshop 5 informed the development of the wireframe, which was presented on an iPhone in workshop 6. The members of the co-design team attended workshop 6, and decisions from workshops 4 and 5 were reviewed at the start of the workshop. A total of 9 members of the co-design team trialed the wireframe of the app in workshop 6 (see **Table 2**). The 2 researchers and the 2 app developers did not trial the wireframe in this workshop as they had viewed the designs in workshop 5 and were not the intended users of the app. The wireframe contained all app content but without the colors, etc, of a final version. All attendees completed the 4 tasks without prompting.

Their feedback suggested that the app was “quite straightforward” to use (consumer). Suggestions were also made to further improve usability. A clinician suggested that the font size be increased (“I couldn’t read that without my glasses on”); therefore, the app was adjusted to automatically match the font size settings on the user’s phone. Another clinician suggested placing the *play* symbol (a triangle) inside a circle so that it looked more like a button. Moreover, 1 clinician and 1 consumer suggested that app users should be able to navigate back to the instructions page if they want a reminder of how to use the app (the wireframe displayed the app-use instructions only once, immediately after log-in). The representative from medical records suggested an amendment to the terms and conditions. Several attendees suggested adding an open category in the labeling function so that patients can assign their own labels to recordings or note if more than 1 clinician was present at the appointment.

Some extra features were also suggested, which were shelved for later iterations. A clinician suggested allowing patients to attach photos to audio-recordings; she often draws pictures to explain medical procedures to patients or shows them scans that they may want to photograph. Several people suggested changing the notes feature so that the user could create notes that were not related to a specific audio-recording or, conversely, to link notes to a particular section (ie, minute and second) of an audio-recording.

After prioritizing all the feedback generated from workshops 5 and 6, the wireframes were adjusted to enhance the navigation and layout. The hierarchy of the individual recordings screen was reconsidered to place a stronger focus on the core feature of listening to an audio-recording. Additional smaller changes were made to increase the overall accessibility of the app, resulting in an experience that was more intuitive and easier to navigate.

User Acceptance Testing

Wave Digital incorporated the feedback from workshops 5 and 6 into the visual interface design of the app to develop a prototype for user acceptance testing. Unlike the wireframe, this prototype contained all the design features and was, in essence, a complete app. Overall, 7 people tested this prototype: 2 clinicians, 4 researchers, and 1 consumer. Feedback included the following: bugs or defects (eg, typos or unexpected error messages), design-related feedback (eg, recommendations for consistency of the *exit* and *back* buttons), suggestions for changes to written content or copy, and feedback relating to the user interface for the Amazon Web Server (eg, allowing audio files to be deleted by the administrator).

The Final App Design

The feedback from user acceptance testing was incorporated into a final version of the app. The design of this version of the app is included in [Multimedia Appendix 1](#) and its functionality is listed in the *Must have* and *Should have* sections of [Textbox 1](#).

Discussion

The SecondEars App

The SecondEars consultation audio-recording app for cancer patients was successfully co-designed and a prototype was developed in iOS. This mHealth patient-identified solution has been designed to facilitate its implementation in a clinical setting and has been developed within a framework of the Theory of Planned Behavior. The app enables a copy of each audio-recording to be saved on the appropriate patient’s medical record, thereby allowing the hospital to retain access to the original recording for medico-legal reasons. This balance between patient autonomy and clinician security was achieved through stakeholder engagement, co-design workshops, and user acceptance testing to ensure that SecondEars was designed to meet the requirements of all users. Furthermore, the app was designed to have low upkeep and minimal burden on clinical processes.

Principal Findings

Most of the requirements identified through stakeholder engagement echo the findings from Moloczij et al [15] and van Bruinessen et al [11] regarding barriers and facilitators to implementation (summarized in the Introduction of this paper). Stakeholders in this study emphasized the importance of minimizing upfront costs. This requirement led to the development of a pragmatic, minimum viable product comprising only the essential core features. The first co-design workshop confirmed that the aim of the app is to “improve patient care.” This impetus, and the MoSCoW session in workshop 4, worked to focus the app development on the most important features: audio-recording and sharing the audio-recording securely and confidentially. Paring back the app to contain only essential features ensures will help to minimize upkeep and keep the app cost-viable for a public health care setting. Further features can be adapted and expanded in the future as the feasibility and efficacy of the app become established through the evaluation of implementation in a clinical setting.

SecondEars was designed to strike a balance between 2 imperatives that, at times, could come into conflict: patient autonomy over the audio-recording and legal protection for the clinician. Our stakeholders identified that medical information provided by the doctor would form a part of the medical record, which prompted a solution that met both of these imperatives: compulsory uploading of audio-recording before playback and sharing would provide the clinician with a measure of security while maintaining the patient’s control over the creation and distribution of the audio-recording.

Furthermore, useful data were generated regarding practical recommendations to facilitate implementation after piloting. The second and third co-design workshops confirmed that the app would need to be distributed with publicity and education information to ensure timely uptake of the app, which is in line with the Theory of Planned Behavior. The patient journey map revealed how many different types of people would encounter the app, suggesting that an app can be a means to change subjective norms.

A recent systematic review found that health care apps are more likely to be effective if they are user-friendly and require minimal time investment [26]. This is in line with the perceived behavioral control aspect of the Theory of Planned Behavior; people will be more likely to take up a behavior if they feel that they do not have external time pressures and if they believe that they are capable of the behavior. User acceptance testing demonstrated that testers found the app easy to use. The app is currently being piloted in a wider patient population in a clinical setting to determine feasibility and ease of use.

Limitations

This study's strength lies in its theoretical basis and the extent of stakeholder and consumer engagement. The researchers chose to include multiple stakeholders and not just consumers. This had benefits in terms of practical recommendations and requirements for the app. However, the inclusion of multiple stakeholder groups meant that the number of people in each group had to be limited to maintain a manageable number of attendees for the workshops. The contributions of consumers were emphasized throughout (there was a higher proportion of consumers on the co-design team compared with the other stakeholder groups); unfortunately, because of scheduling conflicts, the MoSCoW session in workshop 4 was attended by only the researchers and app developers. Future co-design research should ensure that the entire co-design team is involved when features are prioritized. Future studies could also choose to repeat workshops to provide more opportunities for consumers to be involved. This approach would increase the number and diversity of the consumers in the co-design team (eg, wider range of ages, ethnicities, and time since diagnosis), but it may result in each consumer individually having less input overall.

Financial and pragmatic constraints identified through stakeholder engagement mean that the app was developed for iOS only, not Android. This may introduce a perceived external control for patients who do not have the necessary equipment to use the app, which, according to the Theory of Planned Behavior, may negatively affect behavior change. The number of patients who are ineligible to participate in piloting because of not having an iPhone will be recorded. The drawbacks of having the app on only 1 platform will be temporary as the app will be adapted for Android once the current design has been piloted in a clinical setting.

Although the Theory of Planned Behavior is generally a well-accepted theory of behavior change and has been used to design many behavior change interventions, there have been inconsistent results regarding its effectiveness, [27,28] and debate continues around the use of the theory in this context [29,30]. Future researchers can refer to a recent report to consider the full suite of options for behavior change frameworks for intervention development [31].

Comparison With Previous Work

To the authors' knowledge, no other consultation audio-recording apps have been developed via a co-design approach. Previous research has successfully used the Theory

of Planned Behavior as a guide for developing health care interventions [32], and other apps have successfully been developed following a behavior change theory [33].

Some of the desired features, such as the app's automated integration with the medical record, are very complex. Other studies have also encountered similar problems when trying to integrate an app with the medical record [34]. The pragmatic choices made in this project will allow the app to be piloted in a clinical setting before significant investment is made to integrate it with the medical record.

Future Research

The SecondEars app is currently being piloted with patients in a clinical setting. Feedback from patients and clinicians will inform any further design changes that need to be made before implementing the app as part of usual care at Peter Mac. Piloting will also inform the education and promotion strategy that was identified as important during the development process. Upon implementing the app, data could be collected regarding behavior change (uptake, use, etc) to evaluate the success of the app.

Clinical staff have expressed concern regarding potential changes in communication caused by the act of recording a consultation, such as loss of rapport-building, and reduced personalization of information delivery, as fear of litigation may drive information delivery rather than patient need [6]. Longitudinal evaluation of SecondEars implementation could identify whether these changes occur and whether they are sustained as the app becomes a familiar and routine component of care. Longitudinal evaluation could also provide opportunities to study the impact that the SecondEars app has on patients' recall and understanding of medical information and their participation in clinical decision making.

Future versions of the app should include interface options for specific patient groups, such as translations and adaptations for culturally and linguistically diverse patients, and text-to-voice options for patients who are visually impaired. Furthermore, there are potential, unexplored benefits to the SecondEars app that could be investigated in future studies. For example, the consultation audio-recordings could provide professional development opportunities for clinicians or teaching opportunities for clinical students. Other studies have also discussed the potential cross-professional use of consultation audio-recordings as a helpful mechanism of information transmission between primary and tertiary settings [6].

Conclusions

The SecondEars app has been designed to be a viable and cost-effective means of integrating consultation audio-recordings into an oncology setting. The app embraces existing technology as a patient-driven solution to improve patient-centered care. Engagement of stakeholders and consumers in the co-design process ensured that barriers to implementation were addressed and facilitators were leveraged. The SecondEars prototype is currently being piloted with patients in a clinical setting before implementation.

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Conflicts of Interest

GC and GP-B are employees of Wave Digital, and RL-S and AH are employees of Peter MacCallum Cancer Centre. Wave Digital and Peter MacCallum Cancer Centre may benefit financially if the SecondEars app is commercialized in the future.

Multimedia Appendix 1

Screenshots of the SecondEars app design.

[[PDF File \(Adobe PDF File, 3MB - formative_v3i1e11111_app1.pdf](#)]

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Abbreviations

IT: information technology

mHealth: mobile health

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Original Paper

The Development of an Arabic Weight-Loss App Akser Waznk: Qualitative Results

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Abstract

Background: Obesity and its related illnesses are a major health problem around the world. Saudi Arabia has one of the highest national obesity rates globally; however, it is not easy to intervene to prevent obesity and becoming overweight owing to Saudi Arabia's cultural and social norms, and linguistic barriers. In recent years, there has been an exponential growth in the usage of smartphones and apps in Saudi Arabia. These could be used as a cost-effective tool to facilitate the delivery of behavior-modification interventions for obese and overweight people. There are a variety of health and fitness apps that claim to offer lifestyle-modification tools. However, these do not identify the motivational features required to overcome obesity, consider the evidence-based practices for weight management, or enhance the usability of apps by considering usability attributes.

Objective: This study aimed to explore the opportunity and the need to develop an Arabic weight-loss app that provides localized content and addresses the issues with existing apps identified here. This study has explained the steps taken to design an Arabic weight-loss app that was developed to facilitate the adjustment of key nutritional and physical activities and behaviors, which considers the social and cultural norms of Saudi Arabia.

Methods: Qualitative studies were conducted with 26 obese Saudi Arabians, who tested the level of usability of 2 weight-loss apps and then provided feedback and recommendations. The app Akser Waznk is an interactive, user-friendly app designed primarily for iPhones. It has several features intended to assist users to monitor and track their food consumption and physical activities. The app provides personalized diet and weight loss advice. Unique features such as *Let's Walk* are designed to motivate users to walk more. An augmented reality function is implemented to provide information regarding fitness equipment, fruits, and vegetables. The app uses behavior-change techniques to increase activities and healthy behaviors and evidence-informed practices for weight-loss management. The Akser Waznk app considers user privacy and data security by applying a number of guidelines and procedures.

Results: The development of the app took 26 months. In all, 7 experts (5 dietitians, and 2 physical activity professionals) evaluated the app's contents. Moreover, 10 potential users (5 men and 5 women) tested the app's level of usability, its features, and performance during a pilot study. They reported that the app's design is interactive, and the motivational features are user-friendly.

Conclusions: Mobile technology, such as mobile apps, has the potential to be an effective tool that facilitates the changing of unhealthy lifestyle behaviors within the Saudi community. To be successful, the target group, the usability, motivational features, and social and cultural norms must be considered.

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KEYWORDS

weight loss; mobile app; obesity; physical activity; smartphone; mHealth; motivation

Introduction

Background

Obesity refers to the process of storing extra energy in the body in the form of fat [1]. It is estimated that 39% of adults globally are deemed overweight and a total of 13% of the entire world's population are obese [2]. Obesity is increasing at a rapid pace in Saudi Arabia, and it is believed that more than one-third (35.5%) of the population experiences this problem [3]. Obesity causes health problems and raises the risks of hypertension, cancer, and diabetes as well as cardiovascular and other diseases [4,5].

Some critical local factors have been identified that have caused the growth of this problem in Saudi Arabia. These include the increase in wealth and greater development in the country that has brought with it changes in lifestyle, with easier access to cars, international fast food chains, and the increased acceptance of processed food leading to a change in diet [6]. In addition, people lack nutritional knowledge, such as information about the calories in traditional and local foods [7]. Other significant factors are a lack of exercise and the country's climate, which forces people to limit outdoor activities and stay indoors [8].

Furthermore, cultural aspects, beliefs, and restrictions, especially for women, could contribute to increasing the rate of being overweight and obese. In some local traditions, being overweight or even obese is considered a sign of high social status, beauty, prosperity, and fertility. In addition to this, women are encouraged to stay inside their homes and must be accompanied by their male guardians if they go out. Moreover, a male family member must agree and give permission to women to participate in physical activities [9]. Despite the widespread occurrence of obesity and overweight in Saudi Arabia, there is little treatment currently available. Gastric and bariatric surgery is the most popular way to reduce weight in Saudi Arabia as it is seen as the fastest and most effortless method; however, there are a number of risks and side effects related to it [10].

The use of smartphones and apps is common in Saudi Arabia, and the country is ranked as having the third largest global smartphone usage [11] penetration at 73% [12] as well as the largest global Twitter usage [13]. Smartphones can help people, especially women, to virtually interact publicly and socially when they would not normally be able to do so owing to cultural restrictions. Social media websites and apps, for example, Instagram, Facebook, and Twitter, are used by Saudi Arabians to start home-based businesses [14] and contribute to social solidarity [15]. Therefore, based on the growing ubiquity of the use of smartphones and apps, developing an Arabic app that can be used as a tool to treat and stop obesity in Saudi society is seen as vital.

Previous Work

To ensure the developed app was suitable for its intended use, 4 significant aspects were examined. First, it was important to identify what features would help and encourage people with

obesity to be active, change their lifestyle, and keep them motivated to overcome obesity. It was stated that goal-setting, monitoring, reminders, gamification, and rewards are features that can have a positive effect on overcoming obesity [16]. The second aspect to consider was the availability of effective weight loss apps, particularly in the Arabic language. For weight management, 13 evidence-informed practices are required, and the existing English [17,18] and Arabic [19] apps do not fulfill them. The third aspect involved consulting potential Saudi users of weight-loss apps regarding their use and requirements. After using such apps, these users reported language barriers, low usability levels, bad user experience, and cultural insensitivity. They recommend developing an Arabic weight loss app that is culturally sensitive [20-22]. The fourth aspect concerns the usability of the app. Recent studies found that, as of 2017, there were no Arabic weight-loss apps available that are designed with the aim of enhancing the level of usability of the app by addressing usability attributes to motivate users to lose weight [21,22]. The important usability attributes expected in any mobile app include effectiveness, satisfaction, efficiency, learnability, errors, and memorability as well as cognitive load [23,24]. The result from recent experimental usability testing for 2 weight-loss mobile apps built specifically to help Saudi users lose weight was that both apps had a low level of usability as they were developed without considering usability attributes and thus, users reported that both apps are difficult to use [21,22].

Objectives

Given the information outlined in this section, the development of an Arabic weight-loss app that considers all 4 aspects is justified. This study aimed to describe the development process of the Akser Waznk app, the tools used to design the app, the obstacles faced by the designers, and the lessons learned through the process.

Methods

The Development

The Akser Waznk app is developed for iPhones. It is a user-friendly, interactive app that helps users to monitor and track their daily physical exercise and food consumption. It gives personalized advice for losing weight. The app took 26 months to develop, mainly owing to the need for professional information regarding motivational features to overcome obesity and the decision about what usability attributes should be considered while developing and designing the fitness mobile app. During the development of the app, we reviewed and explored the content of Arabic weight-loss apps and then chose 2 apps (Twazon and Aded Surat) and tested their level of usability with a group of 26 obese Saudi citizens (13 men and 13 women). We used their feedback to develop a fitness app which responded to their needs.

What is Akser Waznk?

The Arabic term *akser waznk* means *lose your weight*. This term was selected as the name for the designed app as it refers to the app's main goal. The app aims to assist and motivate users to overcome obesity in a healthy way by helping individuals who are experiencing obesity to change their lifestyle. An initial focus group and participants from the local community were consulted to develop the app's name, logo, and slogan (Figure 1).

Users begin using the app with membership and social networking features (Figure 2). They have the option to create a new account by completing a 2-step registration process involving creating a user profile and inputting their information and body measurements or to sign in via their Facebook, Twitter, or Instagram account and then complete a 1-step registration process of inputting their information and body measurements. Creating a user profile requires users to input basic information such as their name and email address and to select a password. The information and body measurements step requires users to input their gender, age, height in centimeters, weight in kilograms, and, if known, the circumferences of their waist, buttocks, and hips.

In addition to these compulsory steps, an optional step—*health information*—can be completed, which requires users to provide information regarding 4 aspects: whether they use any

medication permanently; if they have a chronic disease; whether they experience vitamin D deficiency; and if they are allergic to certain foods. Diet specialists will contact users in case 1 or more of the reported answers means the user requires a specific diet. First, they will provide users with a customized diet based on their needs and then help users to plan their future diets. This step was added based on recommendations from diet specialists as such factors affect users' diet and weight-loss progress. After submitting the required information, users' ideal weight and current body mass index (BMI) are displayed on the app screen.

There are a variety of different approaches that can be used to guide health promotion interventions. Social cognitive theory [25] forms the theoretical base of the Akser Waznk app because this theory addresses the importance of social systems relative to an individual's behavior and considers the value of both self-efficacy and regulation. Moreover, this theory considers the dynamic interaction among personal, behavioral, and environmental factors, and the importance of observational learning that is established on observing others' consequences and experience is confirmed.

The app contains numerous tools and features to address all the 13 evidence-informed practices for weight-loss interventions [17] (Table 1). The development of the app also considers the results and recommendations of both the experimental usability testing for 2 weight-loss apps [21,22] and the study that determines the motivational features to overcome obesity [16].

Figure 1. The logo and slogan of the Akser Waznk app.



Figure 2. Membership and social network feature.



Table 1. The tools used in Akser Waznk to address evidence-informed practice for weight-loss management.

Practice	App information
Assessing and reaching an ideal weight	The waist circumference and BMI are calculated to assess each individual's weight. The app provides a target weight and a date for individuals to use as their objective.
Healthy diet	On the basis of the users' target weight, a daily calorie count required is calculated. Provides the recommended daily portions of food items and beverages. Provides the recommended daily amount of water. Generates and distinguishes recommendations based on the score of the weekly self-assessment. Helps users to understand and read labels on food products. Suggests substitutions of healthy foods for unhealthy food options. As an educational tool, the app shows users examples of nutritionally poor meals and diets to help them to plan their healthy meals. Users can plan healthy meals via a specific tool. The app will send notices if the calorie consumption and exercise deviate from the recommended level based on the score of the weekly self-assessment. The user's consumption report helps to create a tailored healthy lifestyle circle.
Physical activity	The app suggests a minimum of 6 exercises from a list of physical exercises for the individual to do for a minimum of 45 min at least five times per week. The users are able to analyze their physical activity at the end of every week. The app provides videos and detailed information regarding all physical exercises in the app list for the users so that they execute the exercises in the proper manner. If physical activity is not achieved or the recommended level is not met, the app will send a reminder to the users. The <i>Let's Walk</i> feature encourages the users to walk together every week. There is an added feature that provides directions so that users can walk to their nearest Mosque (place of worship). Gamification features encourage users to reach/achieve the daily count of steps goal, with the app donating money to charity every time the goal is met. Set an initial aim of 5000 steps, with this number gradually rising over time. A pedometer is offered to users so they can count the steps taken.
Self-monitoring and assessment	The app tracks the daily consumption of water, food (calories), performed exercise, and counts the daily steps taken. The users can perform the self-assessment regarding their physical exercise, food, and water consumption at the end of the week. The weight-loss tracker allows users to keep track of their weight-loss progress, offers their current weight in kilograms, and shows how they are meeting their weight-loss goal.
Social support	The users can use the built-in social network feature to communicate with other users, share their experiences, and provide useful tips and support. The users can have a 1-to 1-conversation with a qualified fitness trainer and diet specialists so that the users can raise any queries with professionals. The app can merge with social media platforms including Facebook.

Assessing and Reaching the Ideal Weight

The app assesses users' current weight based on the information that they input while creating their user profile. Lemmens et al's [26] equations were used to determine users' current BMI and ideal weight. The app allows users to set up a goal to lose either 0.5 or 1 kilogram per week [27], and users will be encouraged to have at least a moderate loss of their original weight (between 5% and 10%) because this amount of weight loss is significantly associated with significant changes in

chronic disease risk [28]. The duration (in days or weeks) that is required to reach the ideal weight is calculated, allowing users to set realistic and appropriate goals. The Mifflin-St Jeor equation [29] for men and women was used to determine the daily calorie intake, as it was the most accurate and reliable calorie calculator equation available at the time of conducting this research [30].

The Diet

The app uses a diet template developed by the Clinical Nutrition Department at the Ministry of National Guard Health Affairs, Saudi Arabia, to help users to plan their daily meals (Figure 3). The template recommends users have 6 meals a day: breakfast, morning snack, lunch, afternoon snack, dinner, and bedtime snack. The template contains 6 food groups: vegetables, fruits, milk, grains, protein, and oil. The food portions for meals are determined according to the individual's daily calorie needs. The app suggests meal times based on the recommendation of diet specialists.

The app requires users to add the exact amount of their food portions from each food group for each meal. Users cannot exceed the daily requirement of calories or the calories recommended for each meal. The app has an interactive screen

Figure 3. Clinical Nutrition Department's diet template.



that makes planning or adding a meal easy for users (Figure 4). In the top part of the screen, users can see a number of circles that represent the different kinds of food groups that are displayed at the bottom of the screen. When users add a food item, its related food group circle turns on and, once users add all the required amount from a particular food group, the food group icon turns as well. If the user does not do this, a notification appears that asks users to follow the diet requirements to add a meal. In case the users consumed food that is not on the app's food list, they can suggest their food items, and the app's supporting team will address these foods to determine whether they should be added or not (Figure 5).

The app also determines the recommend daily amount of water based on a specific equation [31] and describes the right way to read food labels (Figure 6) and how to determine a food serving size using the user's hands (Figure 7).

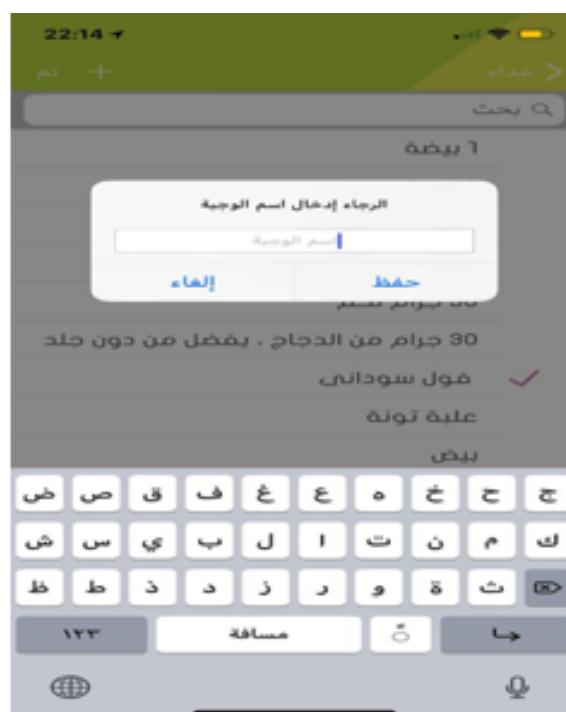
Figure 4. App implementing diet template.**Figure 5.** User suggests food item.

Figure 6. Description of how to read a food label.**Figure 7.** Determining food serving size by using hand.

Customized Saudi Food Database

It was important to create a food composition caloric information database that included Saudi Arabian food varieties. The database uses the Clinical Nutrition Services Diet Manual from King Abdulaziz Medical City and Saudi food composition tables [32] as a base to offer both caloric information and serving size for more than 100 food items. However, as the caloric count of many traditional food items, for example, Shawarma and Mandee, were not available, we had to use common recipes from local restaurants and then calculate the nutrient values of

different ingredients to determine the caloric count. The existing Saudi food databases use grams for measurement; yet, considering the traditional social norms, we were required to convert the quantity of food ingredients from measuring in grams to measuring with spoons, cups, or hands so that users could easily understand the quantities required. Furthermore, the app allows users to suggest new food items to be added to a specific database, with the app support team evaluating items before adding them to the official food database.

Self-Assessment

There is a self-assessment feature in the app that allows users to keep track of their activities, performances, and progress during the week. Numerous studies have shown that eating a Mediterranean diet is helpful for reducing the obesity ratio [33,34]. Therefore, the app's self-assessment technique is developed based on the Mediterranean diet assessment instruction [35]. However, as alcohol consumption is prohibited in the religion and culture of Saudi Arabia, alcohol was excluded. On the basis of both the Saudi Healthy Food Palm Guide [36] and Clinical Nutrition Department, Ministry of National Guard Health Affairs Guide, 5 extra questions were added, which cover an additional 4 aspects: the consumption of dairy, the consumption of whole grains, the consumption of water, and physical activity. The total score of the self-assessment is 18, with each question holding a value of 1 point (Multimedia Appendix 1). These questions help to analyze

the level of consumption of different food items, and users' responses are calculated to determine if their consumption is meeting the advised level or not.

To make the results easy for users to understand, the results of the assessment will be presented in a graphic, user-friendly interface (Figure 8). When answers meet the recommended level, the graphic format will change from gray to a unique color in each aspect.

Users' responses that do not meet the suggested level will be addressed by sending a notification to them that provides customized advice obtained from the Saudi Healthy Food Palm Guide [36] and international government health sources [37-39]. The app will also send a notification in the event that the performed activities, food and water consumption rates did not meet the recommended level according to the weekly self-assessment score.

Figure 8. Graphic display regarding self-assessment results.



Physical Activities

The app's physical exercise section was developed keeping in mind exercises that Saudi Arabians will be able to do. Exercises that are not available or possible for some users, for example, tennis and swimming, were substituted with different exercises that can be performed easily at home. This is a great benefit especially for female app users, who are not permitted to go outside unlike men. Each of the physical activities has information that describes the goal of the activity as well as a video to show the correct way it should be performed (Figure 9).

A qualified trainer will contact users once a month through the app's chat feature to discuss the daily exercises. Users will also be able to talk to the trainer if they have a query. The app will recommend the user do 6 physical exercises from the provided exercises list for approximately 45 min at least 5 times a week.

The Akser Waznk app has 3 unique features that will inspire users to walk more. The first one is named *Let's Walk*. With this feature, users can vote between 2 footpath locations to determine a place to gather with other users and walk as groups (Figure 10). The vote takes place weekly. At present, this feature works in 2 cities in Saudi Arabia (Makkah and Jeddah). The nominated places to be the starting point will be determined according to the footpath availability. The administration team will send a notification to users regarding the footpath that has been chosen each week based on the voting results.

Saudi Arabia is a nation where more than 92% of the population believe and follow the Islamic religion [40]. In Islam, believers are required to pray 5 times in the day, and most men go to mosques to practice their prayers daily. Therefore, a second unique feature was developed, called *Walk to Mosque*. The app gives users the option to turn on notifications or alerts when it is a time of prayer that show the mosques nearest to the user's

location (Figure 11). If the users choose this option, the app will guide them. The app will give the users a choice of mosques so the user can walk to a more distant mosque if they want to increase their walking distance.

Several studies state that adding rewards to goal-setting features is a very useful way of increasing motivation and task performance [16] because they give a sense of achievement and satisfaction to the user and that leads to improved motivation

and the achievement of fitness goals. Therefore, the gamification feature was implemented in this app. The app provides a pedometer that allows users to track their daily number of steps (Figure 12). Users have a daily goal of a certain number of steps to achieve and when it is achieved, they can donate a small amount to a charity. All the new users will have a credit of few cents at the beginning that can be used for the donation. Over time, the daily goal will then increase to the next level in increments of 500 steps until they reach a total of 10,000 steps.

Figure 9. Physical exercise example.



Figure 10. Voting screen.

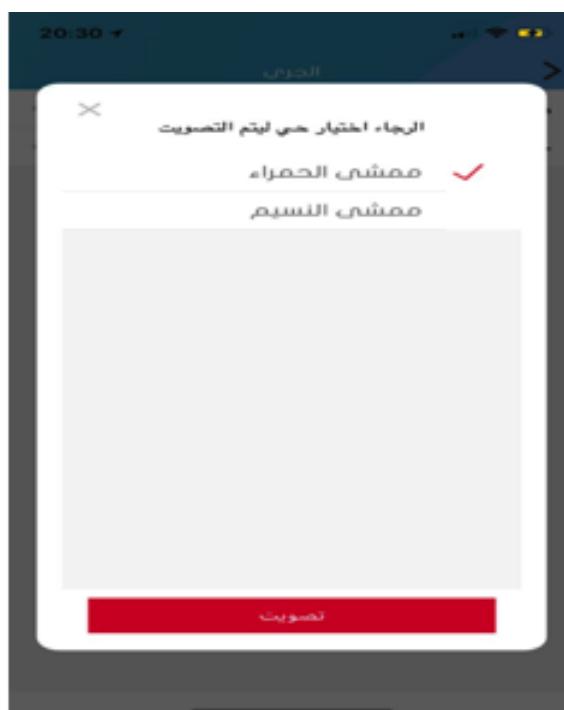
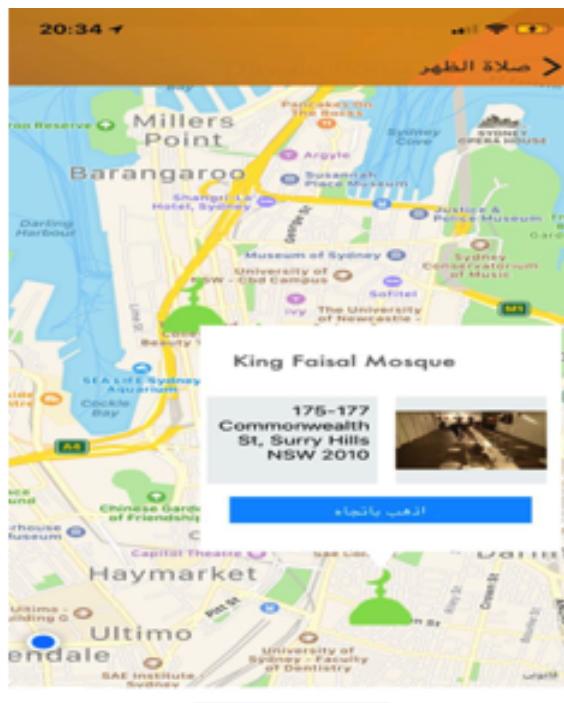
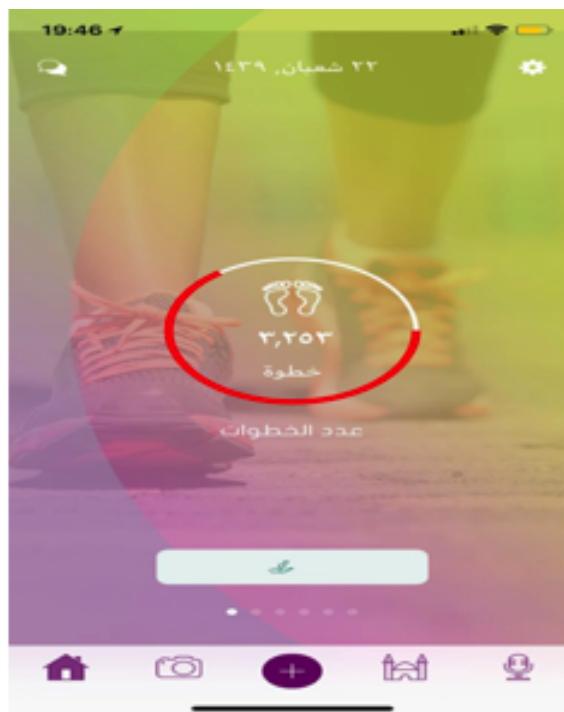


Figure 11. Mosques nearest location.**Figure 12.** Tracking daily number of steps.

Self-Monitoring, Tracking, and Feedback

Self-monitoring is an essential part of the app because of the strong association between both physical exercises and a healthy diet with weight loss [41,42]. Thus, users will be able to self-monitor their daily intake of energy, for example, food (kCal), drinks and water consumption (in), the amount of physical exercise (out), and weight-progress tracking.

As it is important for the users to track and monitor their daily balance in the form of calories (in) versus exercise (out), the Akser Waznk app provides a customizable database for that

purpose. By using this database, users have the ability to store their daily food intake and physical exercise performed and view their previous day's history.

The home page has 6 horizontally scrolling sliding screens that provide information regarding the step count, exercise, meals, water consumption, weight-loss progress, and the summary of the day to allow easy access for tracking and goals. In addition to this, the app enables users to report their daily consumption of food and drinks and then calculates the number of calories eaten, so that it can inform users about the calories left to consume before the end of the day. Thus, the Akser Waznk app

tracks the daily calorie consumption, steps taken, water consumption, and performed physical exercises.

Users cannot exceed the required amount of daily food and drink consumption (kCal) for weight loss, but if they do not consume the daily required amount of calories, drink enough water, or perform the recommended amount of physical exercise, the app will send a notification to remind them to engage more (see [Multimedia Appendix 2](#) for a full list of the Akser Waznk app's feedback and prompts). The app also allows users to monitor and track their weight development ([Figure 13](#)) by providing their starting weight, current weight, ideal weight, current BMI, and remaining duration (days or week) to reach their ideal weight. The app allows users to update their weight weekly and provides a graph that shows users their progress toward overcoming obesity.

Social Communication

The app allows users to connect to Web-based social media platforms and has a built-in chat feature ([Figure 14](#)) so that the users can share their experiences and tips with each other, which positively affects users' health behavior [[43](#)]. This also enables users to get to know each other and then view each other's progress, chat and post photos, and share them on several social media platforms, for example, Path, WhatsApp, and Twitter. This real-time communication allows users to get answers to various questions instantly, and users can answer queries by talking to each other. Many other weight-loss apps in both

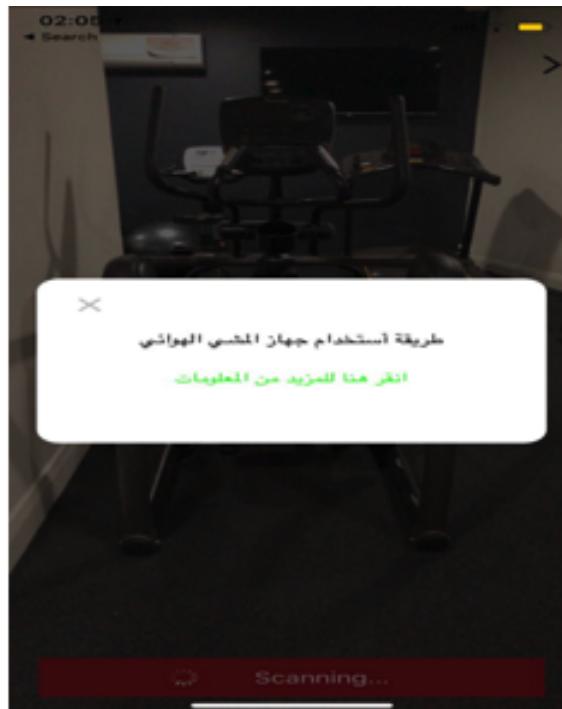
English [[17,18](#)] and Arabic [[19](#)] lack this feature, and the ability to do this will motivate the users of Akser Waznk. The decision to include this feature was based on usability testing and users' recommendations to design the chat interface to be similar to other widely used messenger apps such as WhatsApp [[21,22](#)].

Augmented Reality

There are several technologies that have emerged recently and have been used widely in mobile apps as motivational tools, for example, augmented reality (AR) [[44](#)]. In AR, physical reality can become improved via the extra information that computers can produce in real time [[45](#)]. AR technology has been used in several mobile apps. In addition to this, it has been used in different fields, for example, education [[46](#)]. Such technology can even enable the better use of mobile devices for those with declining cognitive ability, such as people affected by Alzheimer's disease [[47](#)]. As AR technology has proven that it can be used successfully in different fields by various groups of people and based on the users' recommendations, the AR feature was implemented in the Akser Waznk app. The app allows users to scan fitness equipment to identify it and then the app will provide information regarding the benefit of using that type of equipment and the correct way for it to be used ([Figure 15](#)). The app identifies several fruits and vegetables common in Saudi Arabia and provides information regarding their average energy (kCal). For that purpose, a specific database was created to offer information for fitness equipment and food items.

Figure 13. Weight loss progress.



Figure 14. Chat between users.**Figure 15.** Scanning fitness equipment.

App Themes

After the app's functionality and features, an app's colors are arguably its most vital aspect. They assist an app's users to see and interact with its contents, elements, and better understand actions [48]. Thus, they are seen as one of the most significant design features that strongly affect users' evaluation and the perception of apps in general. However, selecting the color schema is a challenge, because it affects the level of usability of an app [48,49].

In this app, the traditional color scheme patterns (monochromatic, analogous, and complementary) were implemented. The app currently has 5 different themes that users can choose from. These themes were developed and tested with end users and experts from the initial focus group, and it was reported that they facilitate interaction with the app's contents. According to the results of the usability testing and based on the users' recommendations [21,22], an interactive design is seen as a vital tool that motivates users to keep using an app and hence improve the usability of an app. Therefore, a variety of app themes was presented.

Figure 16. Voice commands.

Voice Recognition

To ensure a user-friendly experience, the app supports voice commands for easy interaction [50]. This function allows users to add tasks or submit enquires using verbal commands (Figure 16). The app translates verbal command into written text on the screen and then performs what it is asked to do or answer the queries by either providing information on the screen or speaking to the user. At present, the app can do the following:

1. Navigate users to the *add meal* option.
2. Add the consumed amount of water.
3. Say the remaining amount of daily water consumption.
4. Say the consumed amount of water.
5. Say the remaining amount of daily calorie consumption.
6. Say the consumed amount of calories.

Reminders

Many researchers have examined the effect of reminders on health in different settings and found that reminders are an effective motivational intervention [13,14]. Research [13] measures the impact of reminder features in apps as weight-loss intervention among obese individuals. The study explored the 6-month efficacy of a weight-loss intervention by mobile apps and found that intervention through reminders can produce modest weight loss. Therefore, the Akser Waznk app allows users to set a reminder, with users being able to determine the date, time, repetition, name, and the ringtone for a reminder.

Behavior Change Techniques

The requirements and suggested features for an effective weight-loss app were based on both the feedback and recommendations gained from the target group [16,21,22] as well as all aspects of evidence-informed practices [17,18]. A number of existing weight-loss apps implement behavior change techniques (BCTs), and it is believed that BCTs can be helpful

in increasing activities and healthy behaviors [51]. Therefore, these techniques are implemented in this app by using Michie's taxonomy [52]. A total of 30 BCTs were incorporated into the following related goals: identity (1 code), goals and planning (4 codes), antecedents (3 codes), feedback and monitoring (4 codes), regulation (1 code), social support (3 codes), rewards and threats (3 codes), shaping knowledge (1 code), repetition and substitution (3 codes), natural consequences (2 codes), comparison of outcome (1 code), comparison of behavior (2 codes), and associations (2 codes). A reflection of the system prerequisites, BCTs, and relevant Akser Waznk app features are presented in the [Multimedia Appendix 3](#).

Data Privacy and Security

The Akser Waznk app provides accurate and personalized advice for weight loss through collection of users' personal data. Personal data can be defined as information regarding an identified or identifiable natural person [53]. Due to the nature of the app and its use of private and personal information, the Akser Waznk app utilizes a number of the guidelines that were included in the European Commission's Code of Conduct on privacy for mobile health apps [54] and the EU's General Data Protection Regulation [53] to guarantee users' security. These guidelines include purpose limitation, data minimization, and users' consent. Upon signing up to the app, users are given a set of questions and an explanation of the purposes and method of the app before they consent to provide the necessary personal information including their age, gender, and weight. This forms an important dataset utilized to measure the user's BMI, establish the target weight for the users, and provide the accurate diet plan. The app also requires users' consent after creating an account and before actually using the app to access users' health data via the iPhone Health option to retrieve data regarding steps and walking plus running distance. These data will be used to measure the daily walking steps and distance for users.

In simple Arabic language, the app provides a detailed privacy policy outlining the purposes behind the data collected, permissions, and privacy statements as well as provision of necessary details of the app developers. This privacy policy for the Akser Waznk app can be found through either the Apple Store or through the app in the Setting option.

Moreover, to protect the users' data, an advanced level of security procedure which is recommended by Martínez-Pérez et al [55] is performed, that is, encryption of the data. Encryption uses algorithms turning plain texts to unreadable text or jumbled code to ensure the security of the data and app. To decrypt this ciphertext, an encryption key is needed. Such a key is something which only authorized parties have in their possession [56]. The encryption protects 2 types of data: in-transit and at-rest data. In-transit data are data that are moving from 1 location to another, for example, when users input information on their mobile device, and the data are transferred to servers or databases. At-rest data refers to data that are not actively transferred and are instead stored, for example, in databases or clouds [57]. The Akser Waznk app considers both types of data and implements encryption techniques to ensure data protection.

Results

App Testing

During the testing phase for the Akser Waznk app, analysis was done by 2 groups: potential users and field experts living in Makkah and Jeddah, Saudi Arabia. Testers were given the app for testing, and they provided feedback and recommendations after using the app for 2 weeks.

Expert Testing

The expert testing group comprised 7 health professionals in total: 5 dietitians (3 females and 2 males) and 2 male physical activity professionals. These testers evaluated the level of accuracy of the app by analyzing the app's information, advice, and goals; and they confirmed that the information and advice provided by the app is accurate according to their professional experiences and knowledge. They had complete access to the app and its documentation. They stated that the Akser Waznk app meets all the required criteria, and its contents are effective and precise. The dietitians' criteria include assessing users' current weight, calculating current BMI, determining ideal weight, and allowing users to provide information regarding their health history and current status. In addition, this formula includes determining the daily calorie intake, providing 6 meals (3 meals and 3 snacks), encouraging users to eat from the 6 food groups, and determining the food portions for meals. Apart from this, the physical activity professionals' criteria include providing a variety of exercises attainable for people who suffer from obesity. This section includes showing the correct way for the exercise to be done, explaining the goals of each exercise, guiding users to perform a minimum of 6 exercises at least 5 times a week, and encouraging daily walking.

In all, 4 of the dietitians responded positively with the app being able to determine the recommended calorie intake and food portions. A female dietitian reported:

The app determines the daily calorie intake and the food portions for meals. It does not allow users to add more calories within meals and ensure that users eat from all the different groups of foods. This is important that patients eat fruits, vegetables and all other food groups and not only focus on eating protein and grains. This is what I liked most of the app; it helps patients to have a healthy diet.

All the dietitians stated that knowing obese patients' health history and current status is an important factor as it affects their diet and weight-loss progress. A male dietitian stated:

Users can report more information regarding their health status. Patients with chronic disease for example Diabetes do not eat some specific kinds of food. As a dietitian, it's important to know our patients' health status and history and the app helps in doing that.

The physical activity professionals liked the physical exercise section and how the app provides specific information regarding each kind of exercise such as the correct way to be performed and the goal of doing it. A physical activity professional pointed out that:

Through the app, people can see how exercises should be performed and know what is the benefit from them. I had several cases when people do exercises in the wrong way and then harm themselves and decides to stop practising.

Some enquiries were highlighted by the professionals regarding the use of voice commands as an input tool, the navigation to a mosque feature, and AR with the offline function and the gamification feature.

Potential Users Testing

The potential users group comprised 10 obese Saudi Arabians. There were 5 men and 5 women in the group (Table 2).

They inputted their personal data and then followed the app's goals, physical exercises, and recommendations as suggested so the testers could check the app's features, level of usability, design satisfaction, user experience, and any other issues with the app's performance.

Interview

After the trial, semistructured interviews that were audio-recorded were held with each of the potential users to gain their feedback and to respond to any queries. The testers were asked to provide feedback about what they liked and suggestions.

Visual aids such as word clouds were generated based on the data collected through extensive interviews [58]. Word clouds gather the amount and frequency of words and phrases used and display this through the size of the font [59]. In general, word clouds were utilized in social and commercial settings; however, they also have practical use in analysis because they provide rapid means to analyze textual data and reduce bias [60]. In the case of the interview data, 2 groups were formed with the answers (liked and suggestions), and 2 word clouds were generated showing common themes for each group.

Table 2. Demographic information about the potential users.

User	Gender	Age group (years)	Profession	iPhone model
1	Male	35 to 44	Self-employed	iPhone X
2	Male	25 to 34	Teacher at a high school	iPhone 7
3	Female	55 to 64	Retired	iPhone 6S
4	Female	25 to 34	Receptionist at a hospital	iPhone X
5	Male	45 to 54	Self-employed	iPhone 7
6	Female	Prefers not to say	Prefers not to say	iPhone X
7	Female	25 to 34	Accountant in a company	iPhone 7 Plus
8	Male	18 to 24	Student at university	iPhone 6
9	Female	45 to 54	Unemployed	iPhone 7 Plus
10	Male	25 to 34	Government employee	iPhone X

Table 3 displays the content of the original word cloud, and demonstrates that the majority of the users liked the app's color schema and the variety of themes that they can choose from. User 4 said:

I like the colours of the app and what I liked more is the ability to change the whole themes.

They also liked the gamification features and how they were contributing socially while walking toward the daily counting-steps goal. User 7 stated:

Every time I walk, I remember that there are other people who will benefit from such walking. It is a good feeling and even encourage me to walk more and more.

The ability to self-monitor weight-loss progress and the ease of tracking daily activity and the consumption of both food and water were appreciated by the majority of users. User 1 reported:

All the tracking screens are in the main screen, I just scroll right and left, and all the information is there. It is great to know how many calories I had and how much is left. The same thing for the water consumption as well. What I liked most is the weight

progress screen. When I updated my weight, I can see a chart that shows me the exact date of updating my weight and even in the screen there is my start, current and goal weight.

The AR feature and how it can help to provide information regarding fitness equipment was also appreciated. User 6 pointed out:

It is great and easy to use, this is the first app I used that has such a feature.

Suggestions for Future Versions of the App

Table 4 shows potential users' most-mentioned words regarding the suggestions to improve the app. User 4 suggested that it would be good for users to be able to customize the color schema as well as the app's themes. In addition to this, Users 1 and 5 wanted to receive notifications to remind them about meal times. Furthermore, User 3 mentioned that it would be good to have a tutorial on how to use the app. Another suggestion by Users 1, 4, 5, 6, and 10 was to make the app integrate with fitness and watch trackers such as Apple watches and Fitbits. Users 1, 3, 4, and 6 suggested that this app should have sponsors or that users should have the ability to donate to charities when they have achieved their daily steps goal.

Table 3. What potential users liked about the app.

Most common words	Frequency of use
Colors	8
Tracking	7
Goal weight	5
Donate	3
Loss	3
Augmented reality	2
Screen	1
Progress	1
Calories	1
Easy	1

Table 4. Potential users' suggestions for the app.

Most common words	Frequency of use
Apple Watch	7
Sponsors	5
Notifications	4
Themes	3
Colors	3
Remind	2
Times	2
Meal	2
Tutorial	1
Customize	1

Discussion

Principal Findings

The Akser Waznk app aims to facilitate the change of unhealthy lifestyle behaviors within the Saudi community by identifying and implementing the motivational features [16], considering both the Saudi social and cultural norms [20-22] and usability attributes [21,22]. As stated in previous studies, other Arabic weight-loss apps do not comply with the needed evidence-informed practices for weight-loss management [19,21], and the research and development of Akser Waznk app aim to effectively contribute to such an issue. The Akser Waznk app is different than other Arabic weight-loss apps in the following ways:

1. End-users and experts in the field of exercise and diets helped design the app, with their requirements, feedback, and recommendations incorporated into the beta version.
2. The app is in line with all 13 evidence-informed practices for weight-loss management.
3. Social network access for interacting with other app users is provided.
4. The app contains calorie counts of Saudi foods.
5. The app's design considers usability attributes.
6. The app considers the social and cultural norms of Saudi citizens.
7. Users can view the history of their calorie consumption and exertion via a customized database.
8. The app has a gamification feature to encourage users to walk more.
9. The app provides information regarding the correct use of a fitness equipment via an AR feature.
10. The app supports voice commands.
11. The app encourages group-walking via the *Let's Walk* feature.
12. The app can guide users to mosques near their location.

A group of 7 experts (5 dietitians and 2 physical activity professionals) and 10 potential users (5 men and 5 women) from the Saudi community tested the Akser Waznk app to evaluate the app for usability, performance, and motivational features. The app was also evaluated in terms of how accurate the

information it provides is. The testing found that the app assisted numerous potential users to understand their weight-loss goals and techniques. Moreover, the testers reported that the app's design is esthetically pleasing, and the majority of motivational features are user-friendly.

Following feedback from the testers, new users will be guided via a tutorial consisting of pop-up messages within the app for the first time that identifies the most significant points and steps. This will better clarify the app's functions and features. Notifications of meal-times and the ability to customize the color schema and the app's themes are features which will be worked on and integrated in a future version of the app. Moreover, the food database bank will be constantly updated to provide the nutritional data of additional foods.

Limitations

The current Akser Waznk app has some limitations. It is not available on smartphone platforms other than iPhone, for example Android and BlackBerry. The app also currently does not support virtual reality features and is not integrated with smartwatches, such as Apple watches, or fitness trackers, for example, Fitbit. It does not support the barcode-scanning feature for food items, and the app cannot work offline. There is no sponsor for the gamification feature, and the app does not allow users to donate to charities directly. In addition to this, the response time for the health information step might take up to a week as there are just 5 diet specialists participating as consultants. However, finding possible solutions to these limitations in the near future and updating the app regularly will further help to motivate and keep users engaged.

Strengths

The Akser Waznk app is different from its counterparts in a number of ways. It is built on all of the 13 evidence-informed practices for weight-loss management, and it addresses the initial focus group's feedback and recommendations, which allows the app to meet the specific requirements of obese Saudi people via a localized and tailored method. The Akser Waznk app is currently the only app in Saudi Arabia that has gamification, AR, voice command features, and it is the only app which encourages weekly walking groups via the *Let's Walk* feature and daily walking via *Walk to Mosque* feature.

The app offers local Saudi household measurement units, such as cups and spoons for local and traditional foods, which makes it easier for users to manage their daily portion control. The daily physical exercise suggested by the app meets the social and cultural norms of Saudis and suits users' physical status. The app provides a social media platform especially for the app's users, which allows them to share information and support and motivate each other. Finally, advice and recommendations to avoid specific foods and increase the consumption of others are sent by notification to users based on the results of their weekly self-assessments.

Potential Impact

Lacking nutritional knowledge, exercise, limitation for outdoor activities owing to Saudi Arabia's climate and restrictions especially for women are some of the critical local factors that contribute to increasing rates of obesity. Smartphones are becoming very popular in the country, and this is changing many dynamics of the conservative society. The Akser Waznk app aims to help people who suffer from obesity to lose weight and improve their overall lifestyle. The app is a low-cost alternative to traditional personal behavioral weight-loss programs as it considers the needs of Saudi obese users, unique living habits of the country, and provides several unique features that motivate users to monitor and track their food consumption and increase their physical activity. On the basis of the results of the experts' evaluation, potential users' usability testing, and feedback, it is believed that the usage of Akser Waznk app will decrease the obesity rate in the country.

Motivational features such as *Let's Walk* will encourage people to gather together to walk. As more than 92% of the Saudi population believe and follow the Islamic religion, the majority of people go to mosques 5 times a day. The *Walk to Mosque*

feature will, therefore, contribute, providing attainable exercise with the potential to make it communal. It will encourage and guide users by giving them a choice of mosques near their location, and users will have the ability to choose to walk to a more distant mosque if they want to increase their walking distance. The app also provides a pedometer, allowing users to track their daily steps and when users reach their daily goal of walking, they can donate a small amount to a charity. Users will be able to share their achievement with their peers within the built-in chat feature or with their friends on other social media platforms which will positively affect users' health behavior. The app will also encourage users to set up a goal to lose either 0.5 or 1 kilogram per week and will determine the daily calorie intake and the duration (in days or weeks) to reach their ideal weight. Including local food varieties and providing their ingredients and measurement in an easy way to be understood, such as spoons, cups, or hands, is another aspect that can motivate users to follow their diets. All of these and other features with the ease of use of the app will positively contribute in the acceptance of the app among the target group and help to decrease the rate of obesity in Saudi Arabia.

Next Steps

To better determine the usability level of the app and improve it, a quantitative study will be conducted with a group of 26 obese Saudi citizens (13 men and 13 women) from the cities of Jeddah and Makkah. Also, a 3-month pre- and postintervention study with the group will be done to determine the effectiveness of the app on weight-loss management. Users who lose at least 2.5% of their body weight will be the main endpoint for this study. In addition to this, developing the app in other popular mobile phone platforms, for example, Android, and integrating the app with smartwatches and fitness trackers are other objectives in the near future.

Acknowledgments

This research is approved by the University of Technology Sydney, Human Research Ethics Committee approval number: ETH16-0833, Informed Consent Form ([Multimedia Appendix 4](#)). The authors thank all the experts and potential users for their help.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Lifestyle self-assessment questions.

[[PDF File \(Adobe PDF File\), 60KB - formative_v3i1e11785_app1.pdf](#)]

Multimedia Appendix 2

Full list of the Akser Waznk app's feedback and prompts.

[[PDF File \(Adobe PDF File\), 78KB - formative_v3i1e11785_app2.pdf](#)]

Multimedia Appendix 3

A reflection of the system prerequisites, behavior change technique and relevant Akser Waznk app features.

[[PDF File \(Adobe PDF File\), 125KB - formative_v3i1e11785_app3.pdf](#)]

Multimedia Appendix 4

Informed Consent Form and approval.

[[PDF File \(Adobe PDF File, 212KB - formative_v3i1e11785_app4.pdf](#)]

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Abbreviations

AR: Augmented Reality

BCTs: behavior change techniques

BMI: body mass index

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Original Paper

The Learning Exchange, a Community Knowledge Commons for Learning Networks: Qualitative Evaluation to Test Acceptability, Feasibility, and Utility

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Abstract

Background: Learning Networks are distributed learning health systems that enable collaboration at scale to improve health and health care. A key requirement for such networks is having a way to create and share information and knowledge in furtherance of the work of the community.

Objective: We describe a Learning Exchange—a bespoke, scalable knowledge management and exchange platform initially built and tested for improving pediatric inflammatory bowel disease outcomes in the ImproveCareNow (ICN) Network—and assess evidence of its acceptability, feasibility, and utility in facilitating creation and sharing of information in furtherance of the work of the community and as a model for other communities.

Methods: Acceptability was assessed via growth in active users and activity. Feasibility was measured in terms of the percentage of users with a log-in who became active users as well as user surveys and a case study. Utility was measured in terms of the type of work that the Learning Exchange facilitated for the community.

Results: The ICNExchange has over 1000 users and supported sharing of resources across all care centers in ICN. Users reported that the Learning Exchange has facilitated their work and resulted in increased ability to find resources relevant to local information needs.

Conclusions: The ICNExchange is acceptable, feasible, and useful as a knowledge management and exchange platform in service of the work of ICN. Experience with the ICNExchange suggests that the design principles are extensible to other chronic care Learning Networks.

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KEYWORDS

quality improvement; knowledge management; community networks; intersectoral collaboration; database management systems; patient-centered care

Introduction

Background

In the US health care system, patients receive only 50% of recommended care [1,2] and only 50% of those patients are able or have the necessary support to follow the recommendations [3]. Mindful of this, the Institute of Medicine (now the National Academy of Medicine) has called for learning health systems [4] in which patients and clinicians work together to choose care based on best evidence and drive discovery as a natural outgrowth of every clinical encounter, ensuring innovation, quality, and value at the point of care. Learning Networks [5]—organizational structures that facilitate coproduction [6] to improve health and health care—are promising examples of such learning health systems [7]. However, to reach their potential, Learning Networks must be able to leverage the collective intelligence of large groups of stakeholders—patients, families, clinicians, and researchers—to distribute both the production and implementation of information, knowledge, and know-how [8].

Fjeldstad and colleagues [9] have described an organizational architecture that might enable large-scale coproduction in systems like Learning Networks. This actor-oriented architecture consists of (1) sufficient numbers of actors (people and organizations) with the values and capabilities to self-organize, (2) structures, protocols, and processes that make it easy for actors to form highly functional teams, and (3) a commons where actors create and share information, knowledge, and know-how. A recent scoping review of collaborative writing applications such as wikis suggests that such knowledge translation platforms are in increasing use [10], although evidence for their impact is still lacking [11]. However, the Learning Networks previously had no purpose-built knowledge commons platform that could engage large numbers of diverse stakeholders.

Below, we describe the design and use of such a platform, the Learning Exchange, within the setting of ImproveCareNow (ICN), a Learning Network whose mission is to transform the health, care, and costs for children and adolescents with inflammatory bowel disease (IBD) by enabling patients, families, clinicians, and researchers to work together to accelerate innovation, discovery, and the application of new knowledge [12,13]. When it formed in 2007, ICN consisted of 8 care centers from 7 states. Currently, more than 900 pediatric gastroenterologists from more than 100 ICN care centers in the United States, United Kingdom, Qatar, and Belgium care for more than 28,000 children with IBD. During this decade, the remission rate for patients cared for across the Network has increased from approximately 50% to 81%, 96% of patients do not take steroids, and 93% have satisfactory growth status [14].

ImproveCareNow uses the evidence-based chronic care model [15-19] as the framework for improving care. Participating care centers receive instruction and ongoing quality improvement (QI) coaching to build skills and capacity [12,13]. Clinicians enter data for patient encounters into their institution's electronic health record, from which it is then passed into the ICN2 registry where it populates measures and reports that drive care decisions

[20]. Local QI teams consist of clinicians, QI consultants, researchers, patients, and parents from each center. At monthly teleconferences and semiannual face-to-face meetings based on an adapted breakthrough series (BTS) method [21,22], the teams transparently share best practices, outcome data, and lessons learned from changes they are testing. There is also a robust, asynchronous communication infrastructure featuring a newsletter, blog, and social media platforms on Twitter, Facebook, and Instagram [23]. All ICN members are encouraged to continuously design and test network-wide, center-specific, and personal innovations to make collaborative and participatory care more efficient and effective, ultimately leading to improved outcomes. They also use communication structures to share the status of innovations with the network and learn from and apply the work from other centers to their own. Current QI projects focus on engagement, self-care and care management, and chronic illness care and sustainability.

In the adapted BTS model, care center QI teams, comprised of patients, families, clinicians, QI staff, and researchers, meet in person twice a year and participate in monthly webinars. These are synchronous and high-touch approaches that are vital but not sufficient as methods to scale and meet the needs of a large, growing, and geographically dispersed community. While attendees were aware of what was being done by others, the schedule of regular but infrequent meetings did not provide the structure needed to share information, tools, and ideas robustly throughout the Network or the access those things when the need arose. We needed a place where members of the ICN community could create a shared body of knowledge, tools, and processes and learn from each other about how to improve care and outcomes. We therefore developed the process and technology to create an online community commons, a Learning Exchange [24], and implemented this approach to improve the care for children and adolescents with IBD on a digital platform called the ICNExchange (icnexchange.org). More than a website, a Learning Exchange is community-focused rather than technocentric and can serve as a prototype for other Learning Networks addressing other conditions and a larger network of Networks.

Design Concept

Based on the principles of open innovation, in 2011 a design team began discussions on the needs of the Network with members of the ICN community. The result was an overall aim to create a learning resource to radically improve what people know about how to implement an effective and reliable care delivery system to treat and manage chronic disease, beginning with pediatric IBD.

The ICNExchange was conceptualized as a visually focused Web platform offering image-cued discovery, curation, and sharing. This choice was inspired by the success of Pinterest (pinterest.com), a platform that experienced substantial growth in a short period of time [25]. We hoped to take advantage of that velocity with a visual-style Learning Exchange. Also, like Pinterest, we envisioned the ICNExchange as a place to share ideas that others can then use or, in the words of the Pinterest CEO, “Our hope is that when we show you the right idea you go out and do that thing”[26].

Design Activities

Achieving the global aim was conceptualized as delivering on four key drivers: user interaction, technology, content management, and community engagement.

Interaction Design

We applied the principles of interaction design [27], including the development of personas and scenarios, to guide our work. Personas are detailed descriptions of users, and scenarios describe tasks that a persona performs with the technology to achieve a goal. The design team built on prior work with personas [28] and developed scenarios that described how a user persona would interact with the technology to achieve a specific goal. For example, a clinician at a care center who wants to track and improve patients' adherence with their prescribed treatment could log on to the ICNExchange and search for tools and processes implemented by other care centers and create a posting in a forum to which others can respond asking for ideas and resources. The clinician could then download the relevant tools that are attached to the pinned image. These attachments may be documents, spreadsheets, or presentations. Such scenarios, validated with community members, drove the development. In this scenario, the technology must allow search, file attachment, and access to the source files for downloading. In addition, the clinician's search also requires that content be discoverable. That is, the person who originally shared the resource must have categorized it into a preexisting taxonomy and tagged it with descriptors in their own words.

Technology Design

Drupal [29] was chosen as the prototype platform because themed distributions were available to implement the Pinterest-like visual model, a critical design requirement. Additionally, Drupal was open-source software, so the core software was free to use and numerous modules could be licensed to extend capability as user needs and preferences emerged. A key design requirement to encourage widespread use was for content uploading and tagging to be as effortless as possible. The pin motif served this purpose because it was a familiar approach to many members of the community and relatively easy. A pin is a picture that visually signals information. The information may be entirely contained with the image or in addition to the image; the visual may signal that the user has attached files to the pin. Self-contained pins might, for example, signal the availability of a resource at a Web location outside of the ICNExchange, such as a link to a video on YouTube. Pins with attachments might, for example, signal an attached document describing a shared process from a care center. Attached files could be documents, presentations, and worksheets that would be useful for other care centers wishing to implement or adapt that process.

Content Management

To be useful, content needs to be readily accessed through a variety of end-user navigational behaviors such as browsing (through visual cues) or searching by descriptors, tags, or categories. One approach is to create and apply taxonomic structure. Taxonomy is critical to ensuring a shared understanding of the organization of content contributed across

a diverse community. In this case, content was initially organized into categories that reflected the chronic care model [15-19]: population management, previsit planning, self-management, and data quality. In order to pin an item, the user was required to assign a taxonomic category. The design also allowed users to add their own descriptions or tags to resources to enable different views of content organization to emerge, a folksonomy. A folksonomy is user-generated and emerges from user perspectives about how content should be organized. The "...main advantage is that the [folksonomy] reflects the information structures and relationships that people actually use" [30]. The resulting hybrid taxonomy-folksonomy ontology provided multiple entry points for the user's discovery process. The tracking of the folksonomy over time also creates the opportunity for the community's own understanding of content organization to be formalized into a recognized taxonomic structure and navigational cues.

Individual users can curate their own content into boards—collections of resources or pins that a user creates and names (eg, "Good resources for teens" has pins related to self-management and IBD education for adolescents). Users create boards to manage content so that information they have accessed through targeted searching or browsing is readily available. These boards may be followed by other users who wish to learn what someone else finds useful. This feature opens the possibility for some users to demonstrate leadership by curating content and others to follow and observe what these other users find useful.

Content management becomes crucial as the number of resources grows and the network scales. By making resources visible to the care community and providing access to download, repurpose, and readapt content, all users in the community have ready access to the wealth of resources from all care centers. Sharing what exists can be seen as an early phase of a community, a place where shared resources make it easy to search for what you need and browse what is available.

Community Engagement

Leadership in online communities is critical to success. Actions by people "...who have the ability to trigger feedback, spark conversations within the community, or even shape the way that other members of a group talk about a topic..." [31] are necessary. To that end, the design team enlisted the commitment of key leaders in the community to actively contribute content, comment on contributions by others, and encourage this same behavior in other members of the community. We identified an activist to lead the community by example by posting pins, commenting on pins, and posting in the discussion forum. The activist was a well-respected member of the community in a leadership role focusing on QI and could call community attention to a particularly valuable or otherwise useful resource; advocate that other users view, download, and adapt a resource; and initiate a chat topic and encourage others to participate. In turn, this leadership was expected to enable and encourage three specific actions in the community: (1) adding resources to the ICNExchange that health care professionals in a care center find useful so these resources are available to the whole ICN community, (2) sharing resources adapted or improved by a

care center by pinning to a board so that improved resources are readily available for use in other care centers, and (3) identifying needed resources through collaboration among community members with common interests working across boundaries (role, location, etc) to cocreate them.

Deployment

We executed a low-fidelity prototype site based on the proposed design. As the prototype was socialized with selected key community leaders, features were implemented or removed based on response. For example, blogging capability initially seemed important but was removed from the ICNExchange because it was incidental to the collaborative information exchange that was evolving in the design. Key features retained included functionality that enabled uploading content, downloading content, and adding remarks such as questions, comments, and suggestions to pins. This latter functionality centered on the pin, allowing the pin to become the focus for new iterations of content and promoting the idea of coproduction within a collaborative community.

Pilot testing was opened to key leaders and selected users, representative of all community roles. Webinar training sessions were provided to give them the knowledge and proficiency to begin using the ICNExchange within their current work processes. In February 2013, five lead innovators, representing a cross-section of network roles and user experience levels (1 beginner, 2 intermediate, 2 experienced), participated in semistructured interviews to gain feedback on site features and develop an understanding of how different users interacted with the ICNExchange. Lead innovators were defined as community members who were likely early adopters and in a position to influence the community regarding adoption and worked closely with the development team to describe needs and test features. Interviews were designed to evaluate the areas of user experience, attitude, and behavior. Data from these interviews were organized according to these areas and synthesized, through comparison, into themes. Usability of the initial prototype was refined and the availability of the ICNExchange was announced with a live demonstration at the spring 2013 ICN Community Conference, an ICN-wide event.

Ongoing Design

The ICNExchange was not just a new resource; it suggested new ways of working in the community. As such, not all needs could be articulated in the design phase. Users needed to experience the ICNExchange before they could more fully identify needs that could be translated into technology features. Thus, design was considered an ongoing activity. As the community interacted with the commons, their needs emerged through both formal inquiry and informal conversations. These needs were reviewed by the design team and network leadership. Changes were developed and tested in a controlled environment and the revised ICNExchange was released to select users in their real environment before being released to the entire community.

Study Aim

The aim of this study was to assess the ICNExchange's acceptability, feasibility, and utility in facilitating the creation

and sharing of information in furtherance of the work of the community.

Methods

Overview

This project was reviewed by the Institutional Review Board at Cincinnati Children's Hospital Medical Center and designated as not human subjects research. We used existing data on the number and types of users, their activities, and the content of their posts. We also surveyed users about the ICNExchange and performed a success case evaluation [32].

Acceptability

We defined acceptability in terms of growth in active users and activity. The Drupal database was queried monthly to determine who was using the platform (ie, role and care center) and what they were doing (eg, adding content as a pin, commenting on a pin, commenting in a forum). In July 2015, we began tracking which files attached to pins were being downloaded by users and examining the popularity of available resources (ie, most downloaded). Activity, including how many people were using the commons, was reported to stakeholders each month to assess whether growth in users was keeping pace with the growth of the Learning Network.

Feasibility

We differentiated between users, who have an account only, and active users, who have done an action beyond logging in such as viewing a pin or entering a forum at any point in time. We defined feasibility in terms of the percentage of users with a log-in who became active users, as well as data around barriers to use from the user survey and case studies.

Utility

We defined utility in terms of the type of work that the ICNExchange facilitated for the community. We tracked user actions such as adding to the commons by pinning new resources; repinning an existing resource by, for example, selecting an existing resource and adding it to a personal board; adding comments to a pin, such as by advocating others review this resource; and creating or contributing to discussions in the chat forum. Other analyses examined users by role within the network and resources by type. Of particular interest was determining if other users emerged as leaders by mimicking the actions and activity of the activist.

In September 2013, a cross-section of potential users (n=51) including physicians, coordinators, and parents responded to a survey regarding use, barriers to use, and value. Respondents were also asked open-ended questions about how the ICNExchange has been useful in their work, making the ICNExchange more useful, and areas of additional feedback. Qualitative data from these were organized in lists by a research assistant and one of the authors (SM) and sorted into similar themes, with representative quotes selected to characterize the feedback. Disagreements were resolved by consensus.

In the spring of 2014, a success case evaluation [32], in which in-depth qualitative data are gathered on successful and

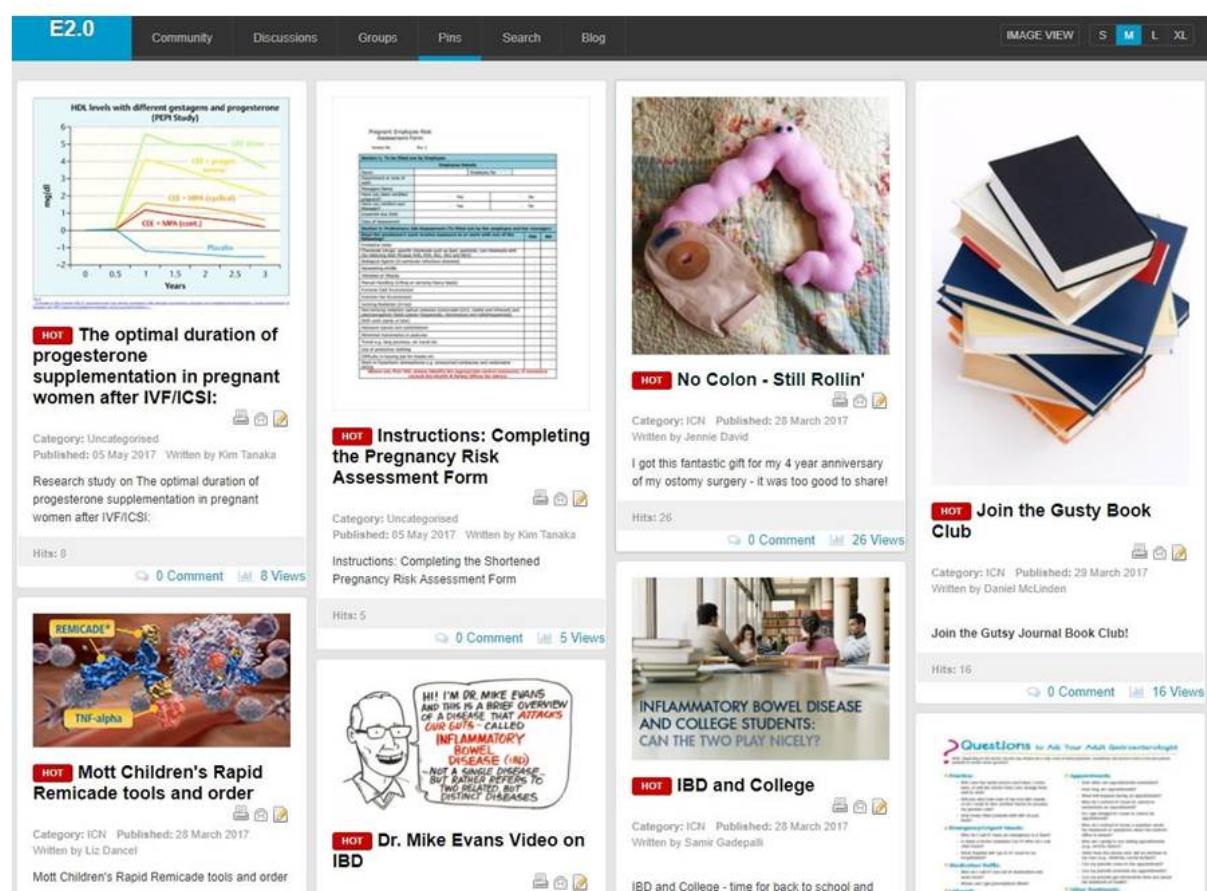
unsuccessful instances, was implemented with network members from the most (n=10) and least active (n=10) centers. We attempted to contact 35 of the most active Exchange users, mostly nurses or improvement coordinators but some physicians, from these centers via email. Of the 35 individuals contacted, 14 responded with a willingness to participate. We performed semistructured interviews via conference call lasting approximately 30 to 45 minutes with these individuals to determine successful practices and identify recommendations for revisions to improve impact.

Results

Acceptability

The ICNExchange (Figure 1) was launched at the April 2013 ICN Community Conference to approximately 200 initial users. By May 2017, there were 1098 users and over 4000 total actions consisting of pins, comments on pins, and posts in the discussion forum. Users worked in a variety of roles (Table 1). The approximately 100 original resources on the Exchange were, for the most part, existing resources taken from other repositories. Since then, the number of contributions has grown, and the content consists of pins and repins, comments on content, and contributions to discussion forums (Table 2).

Figure 1. Screenshot of the ICNExchange home page. The screen is dynamic; new resources are added to the top of the page and earlier postings move down.



Feasibility

While the number of users increased over 5-fold, 72.50% (796/1098) of users became active users. Table 1 shows the percentage of active users by type. As might be expected, improvement coordinators and QI consultants had the highest proportion of active users.

Utility

The results of the February 2013 interviews with lead innovators in the Network suggested that, while the ICNExchange overwhelmed these early users at first, most felt that the format was engaging, intuitive, and timely. A total of 51 people from 30 care centers responded to the September 2013 survey about use, barriers to use, and value. These included 11 improvement coordinators, 10 nurses, 5 parents, 13 physicians, and 9 other. Overall, 69% (35/51) of respondents had used the ICNExchange. While most improvement coordinators (8/11), nurses (10/10), parents (4/5) and other roles (6/9) indicated that they used the ICNExchange to upload content, download content, participate in a forum, or add a comment, most (7/13) of the physician respondents indicated that they were not likely to use the ICNExchange, citing time constraints (4/13) and usefulness (3/13) as barriers. Of the 35 respondents who used the Exchange, 89% (31/35) agreed that the Exchange is a useful resource for supporting QI activities.

Table 1. Breakdown of users of the ICNExchange by role.

User role	Registered users (n=1098), n (%)	Active (n=796), n (%)	Inactive (n=302), n (%)
Physician	264 (24.0)	192 (72.7)	72 (23.8)
Improvement/research coordinator	161 (14.7)	148 (91.9)	13 (4.3)
Parent	157 (14.3)	111 (70.7)	46 (15.2)
Nurse (RN ^a , LPN ^b)	138 (12.6)	96 (69.6)	42 (13.9)
Midlevel practitioner (NP ^c , PA ^d)	61 (5.6)	47 (77.0)	14 (4.6)
Dietician	54 (5.0)	44 (81.5)	10 (3.3)
Patient	39 (3.6)	27 (60.2)	12 (4.0)
Social worker	23 (2.1)	15 (65.2)	8 (2.6)
Psychologist/counselor	17 (1.6)	14 (82.4)	3 (1.0)
Quality improvement coordinator	14 (1.3)	12 (85.7)	2 (0.7)
Project manager	8 (0.7)	5 (62.5)	3 (1.0)
Other (researchers, data architects, hospital administrators, and pharmacists)	162 (14.8)	85 (52.5)	77 (25.5)

^aRN: registered nurse.^bLPN: licensed practical nurse.^cNP: nurse practitioner.^dPA: physician assistant.**Table 2.** Breakdown of activities by ICNExchange users.

Resource type	Value (n=4069), n (%)
Adding a resource by pinning content	526 (12.9)
Adding an existing resource to a personal board by repinning existing content	1906 (46.8)
Adding a comment to an existing pin	425 (10.4)
Creating a discussion forum	179 (4.4)
Adding comments to a discussion forum	1033 (25.4)

The 14 case interviews [32] conducted in the spring of 2014 showed that the work done by members from the most active centers was prompted or seeded by the activist. Recommendations for improvements included enhancing the search function and providing hands-on training at the next community conference.

An indication that the activist was modeling behavior for the community was evident in that the cumulative activity of this individual exceeded that of all other users (Figure 2). While this role was critical to community building it did create a weak link, namely the person and the role were synonymous. A necessary feature of a sustainable community was the emergence of other users taking a similar role and being encouraged to do so by the activist. More recent behavior on the ICNExchange (Figure 3) showed that some other users have emerged as activists. Their cumulative behavior in the past year showed a pattern similar to and in some cases exceeding the activity level of the original activist.

Three key elements emerged as candidates for improvement in a next version. First, while the pin motif was familiar to the early users due to their familiarity with Pinterest, more recent feedback has indicated that the home page, with its many pins, can be confusing. Second, although the original vision of the Exchange was to enable collaborative creation of new resources, the capability of the Web platform is not yet ideal for collaborative cocreation. The ICNExchange has been used as a vehicle to announce a call to action and then post the finished product. For example, the patient advisory committee used the ICNExchange to invite the community to develop a new resource for kids with ostomies and later to be a distribution channel for the work (Figure 4) [33]. However, the work to cocreate the resource took place outside of the Exchange. Third, we have heard from our users that the search function needs improvement, specifically the ability to search across multiple data fields (eg, author and full text of attached documents).

The types of activities summarized in Table 2 suggest that the ICNExchange was useful in its original aim of facilitating the management and exchange of knowledge.

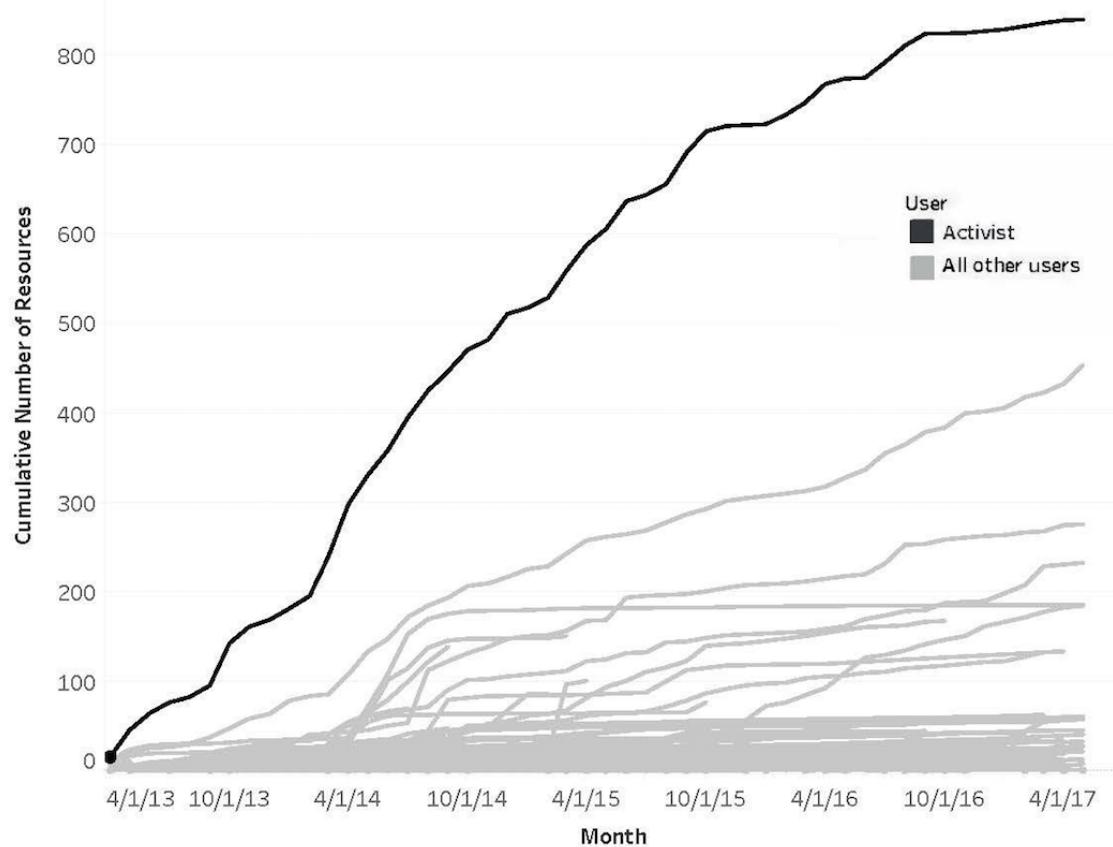
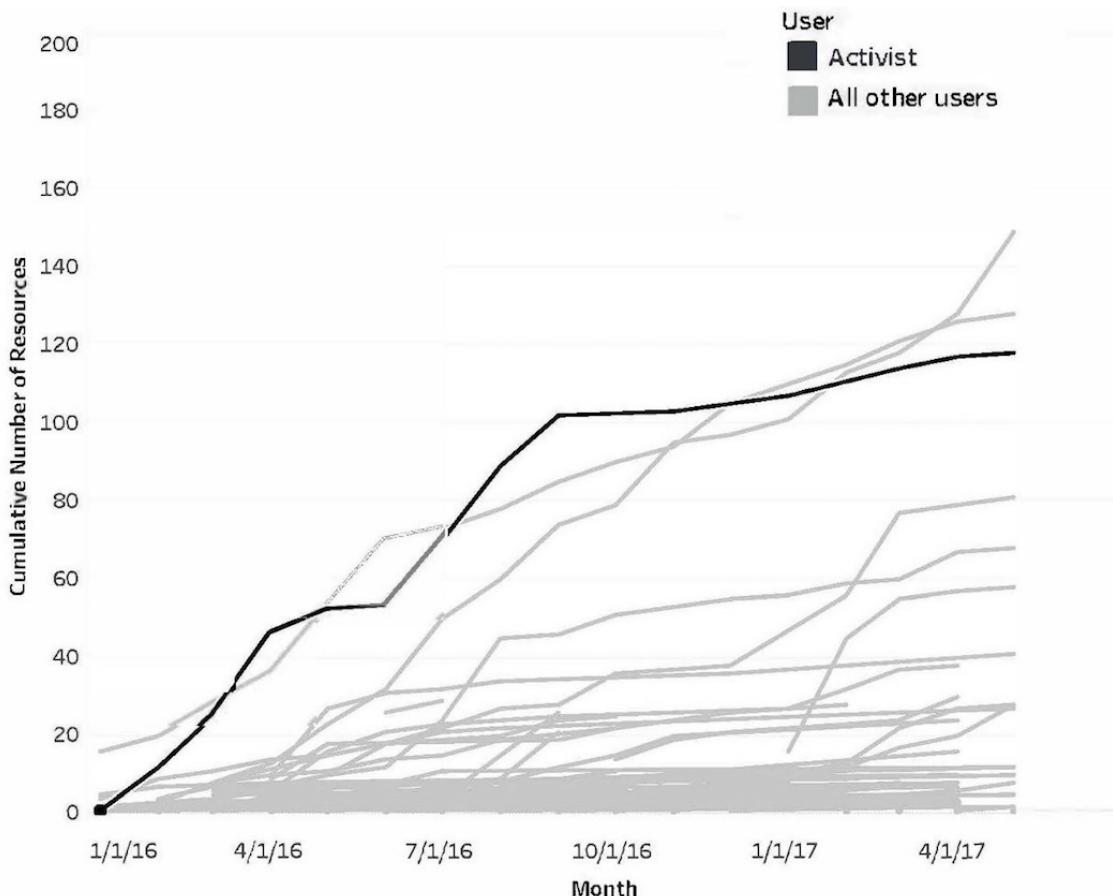
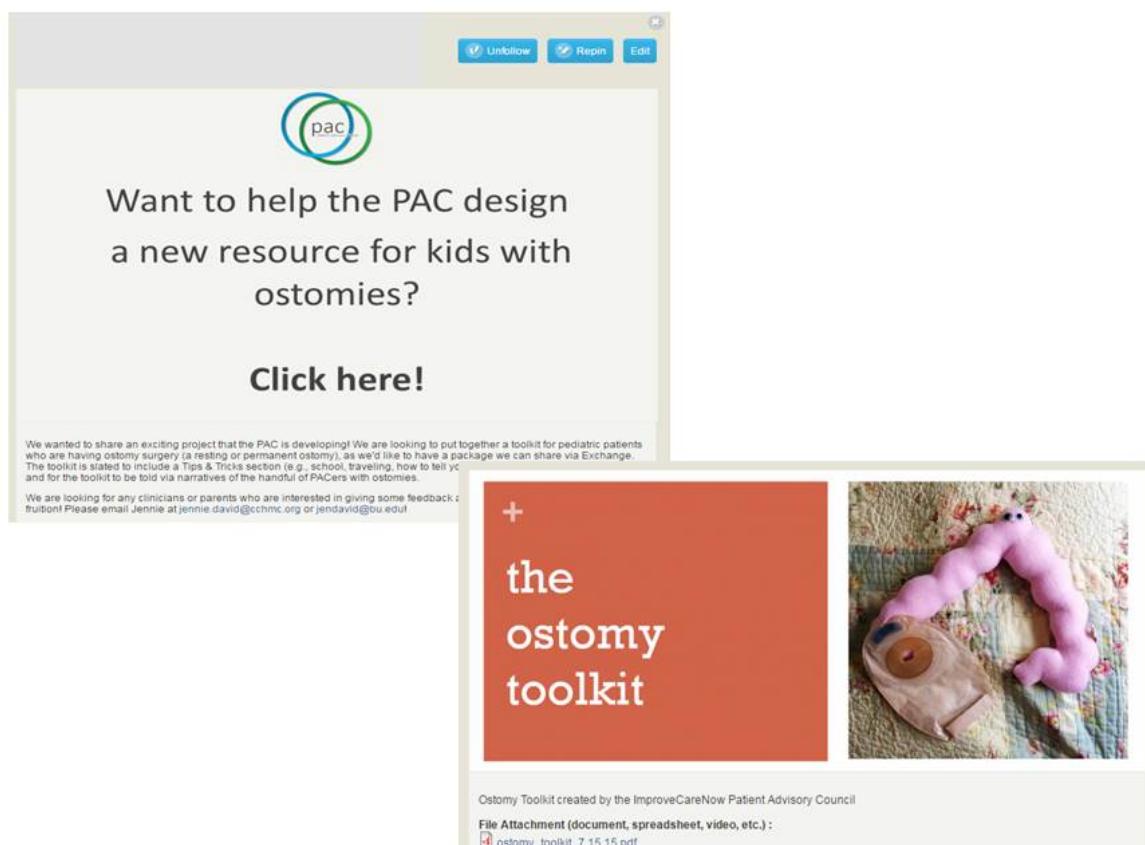
Figure 2. Activist user contributions compared to all other users over 4 years.**Figure 3.** Contributions of some community members (emerging activists) approach and surpass contributions of the activist in final 15 months.

Figure 4. Pins illustrating the call to action and the resulting product, the ostomy toolkit.



As the ICNExchange was used more, further utility was uncovered. One such use emerged from formal inquiry at the semiannual face-to-face meetings and led to making the distribution of meeting materials a function of the ICNExchange. Using the ICNExchange in this way was more efficient and reliable and reduced work for administrative staff. Adding Wi-Fi connectivity to in-person conferences allowed each user to access content on a laptop or tablet. As a result, the ICNExchange became a prominent feature of the network, and driving traffic to the commons increased the potential of further engaging users in making the Learning Exchange part of their individual work processes.

An additional enhancement made post release was the development of a visible database of the improvement goals established by care centers. The data entry and viewing functionality developed on the ICNExchange provides an opportunity for all care centers to see and share their goals and progress and identify those working to tackle similar issues.

Discussion

Principal Findings

The ICNExchange is a collaborative knowledge-sharing platform that allows members of an extended Learning Network to communicate and innovate across the globe. The various members of the community use it to share seamlessly, and it has extended the community's all teach/all learn focus. The

ICNExchange was designed and developed to be used by an ongoing community involved in improving outcomes for patients. The growth in active users and activities shows that it was acceptable as a first version of such a platform, use patterns and feedback show that it is feasible with room for improvement, and activity on the platform as well as additional uses attest to its utility.

Opportunities exist to continue the community-focused design process to meet the network's evolving needs. Barriers to use, such as lack of time, perceived irrelevance, and information overload, as well as facilitators, such as a community of practice, training, and a community facilitator, are similar to those found in the literature [10]. New ideas for using the ICNExchange emerged over time as the community learned more about its use and capabilities and the design team remained engaged in monitoring acceptability, feasibility, and utility. This illustrates the key benefits of a flexible platform and ongoing design process that remains community- versus technology-focused. These are facilitators not readily apparent in other literature [10].

In such a large network, keeping participants connected is daunting as is ensuring the best tools and ideas are shared equally. Before launching this innovation, tools, ideas, and knowledge generated by individual care centers were relegated to email attachments and file cabinet drawers. Centers connected on monthly webinars and twice yearly in-person meetings, but

little asynchronous collaboration or peer mentoring was possible. Our vision for the ICNExchange is continued evolution toward better curation and organization of health-improving ideas and best practices, leading to faster spread across more centers. We have the community of improvers and the will to collaborate using the ICNExchange but need to further cultivate the commons so everyone can easily find like-minded people, the tools they need, and the knowledge to implement shared tools well. While the ICNExchange has been an improvement in this vibrant community, as with any technology, with use, limitations and opportunities for improvement become apparent.

Looking to the Future

As we design the next version, our vision is for a home page that is less cluttered and can be personalized for the specific user; the pin motif will still exist but will be in the background. We also learned that the multiple steps needed to create a pin is considered a barrier. In a future version, we plan to reduce the steps needed to add a pin to a single step that only involves uploading a resource. We intend to improve search by enabling the search of content in attachments, something that is not currently possible, as an adjunct to searching by taxonomy and keyword. Our vision for a future Learning Exchange would support work inside of a community commons to develop new and needed resources. Collaborators can have one place for ideation, creation, storage, and version control so that the Learning Exchange facilitates the collaboration to create new assets, not just the sharing of assets.

Limitations

We framed this work as the development of an intervention to address the challenges of connecting people and their knowledge across a large and growing network. We engaged with the community regularly to understand what was useful and what was not useful and be aware of emergent and unanticipated needs. While necessary and important, such inquiry was driven

by efforts in design and development and not an overarching research strategy. While structured inquiry was undertaken through interview and survey methods, the value of this inquiry was limited by the fact that such inquiry was not undertaken more often. Additionally, we have noted the importance of community engagement and the crucial role of an activist to facilitate that engagement and have described those actions. While important, actions alone are not sufficient. As we noted, the activist was a respected member of the community and this phrasing implies psychosocial features such as mutual trust and understanding. These and similar concepts are not well documented here; future research should be directed to a better understanding of the psychosocial milieu that makes community engagement successful.

Conclusion

The scalability of the ICNExchange as a model for collaboration and information sharing is dependent on both extending the cocreation capability of the platform and transferring the model to new communities. Our vision for a Learning Exchange as a platform where network participants, made up of parents, patients, clinicians, and QI professionals cocreate resources to solve clinical improvement challenges depends on developing, extending, and enabling the creative commons of our collaborative network. The ICNExchange is a dynamic repository of solutions for chronic care across a spectrum of different conditions. Seamless sharing, applied to community-developed approaches to previsit planning, population management, self-management support, and QI, is an enabling strategy to improve health care delivery to chronic care patients. The ICNExchange fosters unique collaborations by allowing diverse and distributed groups to interact and share in collaborative spaces and share across the broader community. The Learning Exchange platform is now primed for rapid dissemination and transfer to other chronic conditions.

Conflicts of Interest

None declared.

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Abbreviations

BTS: breakthrough series

IBD: inflammatory bowel disease

ICN: ImproveCareNow**LPN:** licensed practical nurse**NP:** nurse practitioner**PA:** physician assistant**QI:** quality improvement**RN:** registered nurse

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Original Paper

What Is Being Used and Who Is Using It: Barriers to the Adoption of Smartphone Patient Experience Surveys

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Abstract

Background: Smartphones are positioned to transform the way health care services gather patient experience data through advanced mobile survey apps which we refer to as smart surveys. In comparison with traditional methods of survey data capture, smartphone sensing survey apps have the capacity to elicit multidimensional, *in situ* user experience data in real time with unprecedented detail, responsiveness, and accuracy.

Objective: This study aimed to explore the context and circumstances under which patients are willing to use their smartphones to share data on their service experiences.

Methods: We conducted in-person, semistructured interviews (N=24) with smartphone owners to capture their experiences, perceptions, and attitudes toward smart surveys.

Results: Analysis examining perceived risk revealed a few barriers to use; however, major potential barriers to adoption were the identity of recipients, reliability of the communication channel, and potential for loss of agency. The results demonstrate that the classical dimensions of perceived risk raised minimal concerns for the use of smartphones to collect patient service experience feedback. However, trust in the doctor-patient relationship, the reliability of the communication channel, the altruistic motivation to contribute to health service quality for others, and the risk of losing information agency were identified as determinants in the patients' adoption of smart surveys.

Conclusions: On the basis of these findings, we provide recommendations for the design of smart surveys in practice and suggest a need for privacy design tools for voluntary, health-related technologies.

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KEYWORDS

quality of healthcare; surveys and questionnaires; patient satisfaction; data collection; smartphone; mobile phone; risk; privacy

Introduction

Background

High-quality patient-centered care is widely recognized as a priority in health care [1] and has been shown to improve patient experience, patient safety, and accessibility to services [2,3].

Health care professionals engaged in patient-centered care focus on ensuring that patients' experiences at a physician, hospital, or rehabilitation facility meet basic standards of care, such as treating them with courtesy, informing them about their care, and minimizing pain during their visit. Standardized questions surrounding these aspects of a medical visit are widely used

within the health care industry to inform patient-centered care best practices and to improve governance, public accountability, and patient autonomy [4,5].

Paper-based collection of experience surveys remains time-consuming, expensive, and limited by factors such as nonresponse, recall bias, and inadequate sample size [6-8]. Although paper-based surveys may be advantageous in some circumstances, that is, to reduce startup costs or for nondigital natives such as the elderly, the use of smartphone-based survey apps, which we call *smart surveys*, provides new opportunities to improve data collection techniques. Mobile technology overcomes many of the limitations of paper-based surveys and enables collection of large quantities of real-time data over a broad geographical area. Exploiting this technology opens the possibility of private and public sector services, health care providers, and government bodies effectively engaging with the public, one-on-one, to better respond to their needs. However, at present, there is little guidance to help service providers understand when and where individuals are willing to disclose service experience data using their smartphones. In particular, there is a lack of understanding of users' beliefs, perceptions, and attitudes toward sharing of health service experience feedback using their smartphones.

Patient Experience Surveys

Patient experience surveys are validated questionnaires, which are developed by health services experts to understand patient perceptions of their health care experience and serve an integral role in patient engagement and service improvement [3]. For example, the WatLX patient experience questionnaire [9-11] determines agreement with statements such as "I was always treated with courtesy," "My physical pain was controlled as well as possible," or "From now on I know what to expect about my care." When such patient experience feedback is collected, collated, and interpreted, findings can drive critical and necessary improvements in service quality, patient safety, and clinical effectiveness [3,4]. In recent years, to increase the benefits yielded from such surveys, health service research has begun to shift from "traditional" paper-based methods of survey administration to the use of technology-enabled survey tools.

Yet there is little published research on the use of smartphone technology to collect individuals' experiences of health services.

The health care literature has found no significant differences in data equivalence or validity between paper- and Web-based surveys [12-14]. With mobile devices, researchers are able to collect large quantities of data over broad geographical areas. Furthermore, the use of smartphone-based apps provides access to functionality such as location-based activity detection [15,16] and notifications [17] that can help improve survey compliance and completeness of survey responses to improve the overall reliability of results [18]. In situ assessment of services, where data are collected during or immediately after a service encounter, may yield an even more immediate and insightful level of understanding of service quality [19]. However, the context in which these data are collected can also introduce new issues such as concerns around privacy [20].

Smart surveys, which we define as smartphone survey apps that use advanced functionality to provide more intuitive surveys or gather more contextual complementary data in addition to participant responses, introduce a number of unfamiliar behaviors for patients to undertake that may work as barriers to adoption. For example, they require users to download an app to their personal smartphone and to disclose potentially sensitive information via a digital channel that may be perceived as public or insecure. To better identify and understand how these barriers may impact the adoption of smart surveys, we turn to the theory of perceived risk [21,22].

Perceived Risk Theory

A user's perceptions of risk can have a negative effect on information system (IS) adoption [21,23,24]. Initially introduced in the context of consumer behavior research, perceived risk can be conceptualized as the subjective expectation of loss experienced by a consumer during purchase decisions [21]. Perceived risk describes risk as a multidimensional construct that comprises facets such as financial risk, performance risk, physical risk, psychological risk, social risk, time risk, and privacy risk. Our framework of perceived risk is adapted from studies by Jacoby and Kaplan [22] and Featherman and Pavlou [23] (Table 1).

Table 1. Seven dimensions of perceived risk framework.

Risk dimension	Definition
Performance	The possibility that a product or service is not performing the way it was designed or advertised, therefore failing to deliver the expected benefits.
Financial	The possibility that the use of a product or service will cause undesired financial loss (due to purchase and incurring fees or fraud).
Time	The possibility that a product or service will cause the consumer to lose time from researching the product, learning the use, or returning the product if it underperforms.
Psychological	The risk that the purchase or performance of a product or service will cause a negative effect on the consumer's mind or self-perception (eg, frustration or loss of self-esteem).
Social	The potential loss of the consumer's social circle due to the use of a product or service.
Physical	The possibility that the use of a product or service may be harmful or injurious to the consumer's health.
Privacy	The potential for personal information being shared without consent and/or used for purposes other than originally intended.
Overall	A general measure of perceived risk when all criteria are considered together.

Consumer behavior and IS research has found perceived risk and its antecedents to be key predictors of electronic service adoption; for example, perceived risk and its dimensions are inhibitors of technology acceptance model variables [19]. Of all the facets of perceived risk, privacy (security) risk is demonstrated to be the most important barrier in the adoption of e-services for consumers, having both direct and indirect influences on the intention to adopt [25]. Financial risk, the second most important inhibitor to adoption, also has a significant negative impact on attitude to technology adoption [26]. Time risk has a negative influence on attitudes, implying consumers are concerned about delays and length of time to complete a transaction.

Perceived risk impacts attitudes toward adopting mobile e-services [27-29] as well as the intentions of use among both frequent and infrequent users of mobile e-services. In these studies, results have consistently shown overall perceived risk to be mediated by privacy, financial, time, and performance risks. With respect to mobile health (mHealth) app adoption studies, perceived risk has significant and negative effects on attitudes toward adoption. For example, Schnall et al [30] identified patient concerns regarding security (eg, health information or location sharing) when referring to mHealth apps and smartphone devices, similar to Zhou [31].

Previous research has categorized users based on the intensity of their perceptions of privacy risk. Westin [32] separates technology users into 1 of the 3 risk groups based on their willingness to share personal information on the Web: (1) privacy fundamentalists (high privacy orientation and supports regulatory controls), (2) privacy pragmatists (weigh benefits to self or society and bases trust on context), and (3) privacy unconcerned (willing to share information and reject privacy concerns). These categories were developed over a series of more than 30 consumer surveys [33] and have been used extensively by the computer-human interaction community as a requirements engineering design tool to help anticipate user needs and design functionally relevant technology. However, in practice, this methodology has faced criticism, and research has found a lack of correlation between Westin's categories and user behaviors and attitudes (ie, willingness to share information), perhaps attributable to the development of the questions before the internet [34-36]. In response to this mismatch between Westin's categories and user behavior and to more fully account for the importance of privacy risk as a barrier to adoption of smart surveys, we turn to Dupree et al's work on privacy personas [37,38].

Privacy Personas

Dupree et al [37] developed privacy personas to add contextual information to participants clustered by their attitudes and behaviors related to security and privacy. The personas provide a better understanding of a user's proactivity and ability to act upon privacy risk concerns, better aligning their behavior with their attitudes. Dupree et al identify the following 5 clusters:

1. Fundamentalists (high knowledge and motivation): like Westin's privacy fundamentalists [33], these individuals are highly concerned with privacy and show distrust toward

corporate monitoring. They exercise extreme caution when handling their information, often encrypting their devices.

2. Lazy experts (high knowledge and low motivation): these individuals share the same technical knowledge as fundamentalists, but often choose convenience over security and socialization over privacy. They continue to put effort into protecting their privacy, however not to the extent where they would limit their interactions with society.
3. Technicians (medium knowledge and high motivation): have less technical knowledge compared with the fundamentalists and lazy experts. However, they show limited trust in privacy settings and are highly motivated to protect their privacy, often choosing privacy over being social. They tend to form their attitudes more intuitively but will change their behavior when provided with evidence.
4. Amateurs (medium knowledge and medium motivation): these individuals are just learning about security concepts. They are not nearly as motivated or knowledgeable as the other previously mentioned groups. Despite having limited knowledge, this group will still act to protect themselves from privacy threats.
5. Marginally concerned (low knowledge and low motivation): with limited knowledge about security concepts, they trust networks and websites which claim to be safe. They are aware of potential privacy threats but feel these threats are unlikely to happen to them.

Morton and Sasse [39], who performed their research concurrently with Dupree et al, also identify 5 clusters that closely correspond to those listed above but in the context of location disclosure.

The purpose of this study was to understand what beliefs, perceptions, and attitudes influenced patients' intentions to share health service experience feedback using their smartphones, in particular, what role perceived risk plays in this process. Health care providers are increasingly being held accountable for the quality of services they provide; however, data collection is expensive, response rates are low, and turnaround times can be long. Although mHealth apps are common in the sector, and smartphones have been used to collect experience data in other industries [40,41], there has been little research into the use of mobile apps to collect *in situ*, location-based experience data in health care.

Methods

Participant Recruitment and Selection

We recruited participants from a local university between January and February 2017 using posters, email, and snowball sampling techniques. Participants were classified according to their privacy persona and their dimensions of perceived risk, and their responses were sequentially analyzed to allow researchers to evaluate the breadth of our sample and to ensure that individuals with different technical backgrounds as well as varying degrees of privacy tolerance related to information sharing were included in the study. Recruitment and analysis proceeded until saturation [42,43]. Participants received Can \$10 for participating in the interview.

Figure 1. MetricWire's smartphone app served as a platform to administer the patient experience SmartSurvey.



Data Collection and Analysis

Participants were welcomed upon their arrival and were given an overview of the purpose of the study and the data collection process by a researcher. Participants reviewed and signed an informed consent form and provided demographic information. Data were collected from participants using short questionnaires followed by a semistructured, in-depth interview. The information gathered from the questionnaires and think-aloud technique provided information for classification of participants into privacy persona clusters as well as complementary data for further context.

In the first questionnaire, participants were asked to rate their perspectives on privacy and security (PAS) ([Multimedia Appendix 1](#)). The second questionnaire included Westin's privacy user questions [32] and questions that were related to their knowledge and motivation to protect their privacy ([Multimedia Appendix 2](#)) [37]. Before completing the final questionnaire and interview, participants were given the opportunity to learn more about the mobile app used for the survey distribution, analysis, and administration [44] and to evaluate its key features and user interface. The MetricWire app is a commercially available mobile phone and Web-based survey platform [44]. The app allows mobile completion of surveys, with functionality such as automatic alerts or triggers to prompt phone owners to respond to a survey based on factors

such as time of day or location of the device. Researchers loaded a modified standardized and validated patient experience survey [9,10] into the MetricWire platform using a smartphone provided by the researchers ([Figure 1](#)). Participants were asked to recall their last visit to a physician and fill out the survey. Completion of the survey ranged from 2 min to 5 min.

Using cognitive interviewing techniques [45] (think aloud), where questions are administered, and participants are encouraged to verbalize the reasoning behind their answers, a third questionnaire (including questions adapted from Jacoby and Kaplan's [22] perceived risk study), was used to assess participants' perceptions of risk ([Multimedia Appendix 3](#)). These semistructured participant interviews ranged from 20 min to 40 min. Throughout and at the end of the interview, the researcher summarized their interpretation of each participant's responses. Participants were encouraged to add any additional information that they felt was missing from the summarized interview responses. This process served as an informal method for member checking [46].

Upon completion of each participant interview, participant responses were transcribed manually from the digital recordings and thematically analyzed using QSR International's NVivo 11 [47]. Responses were used to inform subsequent interviews. We used constant comparison and content analysis to code and analyze the transcripts [48], with 3 researchers (DN, JM, and JW) reviewing the interview transcripts independently and using

consensus methods to iteratively discuss content and discrepancies to ensure coding consistency. Data were manually sorted using the perceived risk framework and then thematically analyzed to uncover the unique challenges facing smart surveys' adoption and use for patient experience sampling. Interview transcripts underwent initial open-ended coding where quotes were divided into 4 concepts and 12 subconcepts based on similarities in meaning or context. These concepts were then discussed among the researchers to further develop emergent themes. The themes were developed based on both the perceived risk typology (deductive reasoning) and open and axial coding of interview transcripts (inductive reasoning) [47,49].

To assign participants to 1 of Dupree's clusters, each participant's data were reviewed (DN), and the participant was preliminarily assigned. Following a process of discussion (JM, JW, and PM), participants were reassigned as necessary until each cluster remained stable. Participant data were collected until we had at least one participant from each of the Dupree clusters identified, and saturation was achieved, where no new themes or evidence emerged from the interview transcripts [42,43].

Ethics approval for this study was sought and obtained jointly from the ethics committees at Wilfrid Laurier University and the University of Waterloo (#4690). All participants provided written informed consent before participating in the study.

Results

Overview

We conducted 24 semistructured interviews with Canadian smartphone owners (7 male and 17 female) with varying educational backgrounds, technical knowledge, and motivations to protect privacy. All the participants were registered university students, half at the graduate level and, as such, are "digital natives" and thus confident using smartphones and mobile apps [50]. All had received some postsecondary or postgraduate education, were comfortable speaking English, and regularly used a smartphone. The average age of the sample was 23.9 years (minimum: 21 years, maximum: 56 years, and median: 22.5 years).

Perceived Risks and Privacy Personas of the Sample

Respondents were classified according to Dupree et al's [37] privacy clusters framework (Table 2). Participant 4 was rated with *low technical knowledge* yet *high motivation* to protect their privacy. Therefore, they did not fit any of the Dupree privacy personas, and we classified them as "Undefined."

To develop an understanding of the core issues facing smart survey adoption, we also categorized responses according to the dimensions of perceived risk [21,22] (Table 3). Participants were most concerned about PAS and performance risk; under the circumstances, that is, the introduction of a novel app for use in a contextually sensitive location, this result was predictable. None of the participants expressed concerns related to their psychological or social well-being as a result of using the app.

Table 2. Participants classified by privacy persona.

Privacy persona	Knowledge	Motivation	Statistics, n (%)
Marginally concerned	Low	Low	8 (33)
Technicians	Medium	Medium	7 (29)
Amateurs	Medium	Low	5 (21)
Lazy experts	High	Low	2 (8)
Fundamentalists	High	High	1 (4)
Undefined	Low	High	1 (4)

Table 3. Number of participants who classified dimensions of perceived risk as either "likely" or "very likely."

Type of perceived risk	Statistics, n (%)
Privacy and security	18 (75)
Performance	12 (50)
Time	4 (17)
Financial	2 (8)
Physical	1 (4)
Psychological	0 (0)
Social	0 (0)

Thematic Analysis

A number of themes emerged from our analysis of cognitive and in-depth interview transcripts: (1) perceived risks associated with smart survey use, (2) loss of information agency, and (3) trusted data collectors and altruistic intentions. These are organized according to the focus of this study: first, how perceived risk impacts the propensity to use smartphones to provide service feedback using our perceived risk framework, and second, the role of participants' key beliefs, perceptions, and attitudes in that process.

The Impact of Perceived Risk on Intentions to Use Smart Surveys

Performance Risk

Although performance risk was the most cited type of risk, participants perceived it to be minimal when downloading or using smart surveys. The likelihood of performance risk was rated by 25% (6 out of 24) participants as "Very Unlikely" and as "Unlikely" by 46% (11 out of 24) participants. Some participants attributed this lack of risk to smart surveys being more simplistic in design than other apps on their phone and others to functionality that allowed participant audit before data were submitted:

...from my point of view, it doesn't look too fancy or a gaming application with a lot of coding and stuff...I feel like chances of it not working...will be low. [P21, Amateur]

It's not quite as advanced as some other apps. And since it submits [data] all at once... I would be able to look at all the information before it's submitted. [P14, Lazy expert]

Time Risk

Some participants commented that smart surveys' voluntary nature mitigated any associated risks related to time. Others disagreed, saying time loss from downloading and using the app was "very likely"; as they perceived that only health care providers would ultimately benefit from the data, they saw no off-setting personal benefit to mitigate the time risk:

Very likely, because it does benefit just the company, not really yourself. And like I said, it already takes a long time as an app it downloads and all that stuff... [P4, Undefined]

Financial Risk

The majority of participants felt that the possibility of financial loss associated with the app was either "Very Unlikely" 71% (17 out of 24 participants) or "Unlikely" 21% (5 out of 24 participants). The perception of low financial risk was attributed to smart surveys' free download and lack of request for any financial information:

As a patient, would I have to pay money to download the app?...In this case, there doesn't seem like there's any chance that I would be losing money with Smart surveys. I don't think it's asking for credit card information or anything. [P22, Lazy expert]

Psychological Risk

When asked to judge their perception of psychological risk associated with smart surveys, nearly all participants 8% (20 out of 24) rated their perceived psychological risk to be "Very Unlikely." Participants were familiar with providing feedback and with using smartphone apps:

...it's voluntary if there was something I didn't want to say or discuss, I wouldn't have taken it. [P21, Amateur]

Social Risk

Overall, participants perceived a very low possibility of social risk, noting that completing surveys on a smartphone was sociably acceptable and could be completed privately:

I'm on my phone a lot anyways. I'm answering surveys. I don't think anyone would think of me differently because it's just surveys. [P7, Technician]

Physical Risk

There was little to suggest that participants perceived any physical risk associated with this technology and noted that it was comparable with any other app on their smartphone:

Well, it's just filling out buttons on a survey. I don't think there should be health issues any more than health issues from just using a smartphone. [P7, Technician]

Privacy and Security Risk

In line with the 6 dimensions of risk, participants rated the likelihood of "overall" risk associated with smart surveys as low. However, when discussing the overall risk, the predominant concerns related to PAS risk included the loss or misuse of sensitive information associated with their location and activity:

Personally, I don't like the idea of data being collected on me...If there's an app that could literally tell you physically where you're being, that's part of the metadata government can collect on you. [P12, Technician]

Similarly, participants displayed heightened sensitivity and apprehension about the possibility of the app being used to retrieve additional information unrelated to the research:

Maybe if I download some app, maybe someone can get your personal information on your phone. [P6, Marginally concerned]

Moreover, 1 participant was concerned that a third party, such as an employer or insurance company, could use the collected data to deny individuals employment or insurance claims:

If it's not associated with my insurance company in any way, and it's only for the health care to improve their staff's interaction with their patient. I don't think it would be likely [I would consider it a risk]. [P24, Technician]

Yes. I just think I would just want to know what is being used and who's using it. And if someone could tell me that, then it might change my mind from not

giving out that information to giving information. [P11, Marginally concerned]

I don't consider the information to be very sensitive. Even if it does go into the wrong hands, which would be weird, I probably wouldn't mind too much. [P7, Technician]

Another expressed a belief that mobile apps may be less secure than traditional desktops apps and that the use of smartphones introduces risks such as susceptibility to hackers, in-device vulnerability, and susceptibility to loss:

It's not 100% safe...I'm not sure apps interact with each other in a smartphone...if other apps can steal information from another app. It's not 100% safe. [P21, Amateur]

I think it's safe. It's not risky to share feedback. But you never know. Sometimes people can get your secure passwords, your bank passwords. [P23, Amateur]

...it's not really safe to send it through the smartphone...a smartphone can easily go into the wrong hands. It could get stolen, or even borrowed, maybe you just left it somewhere... [P7, Technician]

Location (Global Positioning System, GPS) data were an area of particular sensitivity. The majority of participants 71% (17 out of 24) were reluctant to disclose their location (GPS) data for service quality improvement. Many chose to not share location information for reasons of privacy, safety, and battery life:

If it's on all the time, I feel like someone's following me all the time or someone can see that they're following me and it probably drains out my battery too. [P13, Amateur]

Other issues included concern over the perceived lack of standards surrounding the handling and storage of patient experience data. The heightened sensitivity was not surprising given the considerable attention to PAS risks associated with mHealth apps [51] and frequent breaches of health ISs in the free press at the time. Finally, the overall usability of smartphones relative to desktops was also considered, reflecting limitations of a smartphone's display as part of their confidence in the device to live up to the task of completing a survey:

...I mean, it's kind of normal for me to do surveys on a computer but doing it on the phone is a little awkward. Another reason, I guess, I'm not too fond of reading too much on a smartphone 'cause I have a smaller screen and the text is small. [P7, Technician]

The Role of Participants' Beliefs, Perceptions, and Attitudes

Trusted Data Collectors and Altruistic Intentions

Importantly, the third-party mobile app for data collection using a smartphone was perceived as distinct from the health care facility requesting the data, which participants generally trusted to comply with ethical treatment of their data:

...because it's health care facility. I have complete trust in them. [P2, Amateur]

The identity of those who receive and interpret patient experience data was an important consideration for participants when deciding to complete a patient experience smart survey. More than half the participants 6% (14 out of 24) mentioned concerns over who received and viewed their information. Knowing who the users were and how the data would be used helped them decide whether or not to share feedback. Sharing experience data with their care providers was not a barrier, given its less sensitive nature, and thus diminished consequences if mishandled.

For some participants with altruistic intentions, the *impact* of their feedback was a significant factor in decision making, particularly where trusted care providers might directly or indirectly use that feedback to improve service quality for others:

I want my feedback to improve the service. I don't write my feedback for someone who can't change anything or improve anything. [P20, Marginally concerned]

If I share my data with the doctor, the administrator will not benefit me if they look into my data. Anyone who's not really involved with the service. If I want to share my information in my smartphone, I want to give it to the doctor directly...It's also the benefit of the smartphone, it can give it directly to the doctor. [P15, Marginally concerned]

Loss of Information Agency

Participants expressed concern that collected data may be used for purposes beyond what was initially intended or disclosed, specifically that it might affect their "information agency." This differed from their privacy concerns, where privacy risk is defined as the potential loss of personal information without the consumers' knowledge following the use of a service or a product [23]. The loss of information agency is the loss of control over the interactions after the information has been shared by the participant. An example of loss of information agency might relate to receiving marketing emails following a service encounter, using contact information a patient provided to an endorsed third party collecting a trusted provider's service quality survey data. In addition, 1 participant explained that the loss of agency can be apparent when seeing Web-based advertisements tailored to her daily life:

Maybe it's stuff you don't necessarily want a third party to know and they do know it because sometimes certain third party companies display ads based on what you've done if you see an ad that's something related to you in story that you've done. [P21, Amateur]

In general, the participants exhibited comments and knowledge consistent with their Dupree classification.

Discussion

Principal Findings

Mobile apps are increasingly being used to gather real-time clinical and ecological patient data and to help manage workload in the health services sectors [50-54]. Although smartphones are changing the way we deliver health care and engage patients [55], examples of their use in collecting in situ patient service experience data are scant. We explored perceptions and attitudes, which impact the adoption and use of smartphone-based apps to collect patient experience data, referred to as smart surveys. The theory of perceived risk [21,22] suggests there will be inhibitors to smart surveys adoption. Yet, although participants mentioned perceived risks normally associated with electronic commerce and other Web-based activities such as social, psychological, physical, financial, and time risks [23,56], these were considered minimal.

The study used an app that participants would have to download, retain on their phone, and manage alerts and the software app itself over time. The most commonly perceived risk was PAS, consistent with other mHealth and wearables literature [51,57,58]. Participants' PAS risk perceptions were related to connectivity, data sharing, encryption, and storage. Consistent with Dupree et al [37], we observed that not all digital natives have the same level of technical knowledge. Our thematic analysis revealed other factors indirectly related to risk that influenced participant's perceptions of smart surveys as a conduit for patient service experience data collection. In particular, participants trusted the data collectors and communication channel, thereby reducing perceptions of risk. Conversely, concerns over loss of information agency, evoked based on past social and personal experiences where they lost control of their data, served to amplify their PAS concerns. These themes have implications for the design and use of smart surveys apps in practice in 3 main areas. The 3 themes, with recommendations for developers are as follows:

Support Communication Between Providers and Recipients of Information

When individuals do trust their health care provider, the presence of trust reflects a belief that the provider has the ability and motivation to make changes that result in service improvements [59,60]. However, existing surveys often do not allow for participants to see the impact of their feedback or for providers to acknowledge its importance. Participants' concerns revealed a need to better communicate patient experience survey goals to patients and to ensure that feedback impacts service improvements. Only half of the participants believed their feedback was important, and some participants regarded feedback as a formality rather than a tool to improve services. Similarly, we found that participants wanted health care providers who receive their comments to have the authority to implement changes. Our results point to an opportunity for smart surveys' functionality to be expanded to include frictionless feedback loops where health care providers acknowledge the importance of participation and communicate when service feedback has been received and implemented. These

communications are essential in building trust between patients and providers and are poorly supported through paper surveys.

Furthermore, our results suggest a need to better identify any complementary uses and recipients of survey data. Research ethics standards of practice require that researchers inform participants how data will be used at the beginning of a survey; however, this is not necessarily the case for private or nonprofit health service providers. Outside of personal health information, the use and management of which is often governed by legislation, consumers have very little control over what data are stored and shared for commercial use [61]. Our results suggest that participants want health care providers to affirm who and how the feedback data will be used and its sequelae.

Recommendation Number 1

Smart surveys functionality should foster trust between patients and providers by identifying the recipients of feedback data and communicating when it is read and what improvements to care are made as a result.

Provide Transparency of Motives and Options

Participants perceived a lack of confidence in the security of smartphones and that they can be perceived as a second-class computing device when compared with desktop personal computers for completing surveys. For example, participants expressed concerns about installing apps on their personal devices and uncertainty about how data may be shared between different apps. This was notable among the amateurs and marginally concerned. For individuals with more in-depth technical knowledge such as the fundamentalists, disclosure of implementation details was equally important, such as the types of permissions the app required, the type and location of servers on which the data would be stored, whether information would be encrypted, and the length of time their information would be retained. However, it should be noted that this was the exception. As with Gkioulos et al, we found that digital natives tended to ignore or were complacent about privacy policies [50].

Recommendation Number 2

For technical users, provide optional information about where data will be stored, for how long, and whether it will be encrypted.

Recommendation Number 3

Where possible, smart surveys should provide optional modalities to complete experience surveys on devices other than smartphones.

Controlling Access to And Sharing of Information

Although there were disagreements about the sensitivity of feedback data, participants were consistently hesitant about unauthorized use of or access to data, particularly their location (ie, GPS) [16,62]. Participants believed that location data introduced a higher level of risk and loss of agency that could lead to subsequent inconveniences (eg, telemarketing interactions) or consequences (eg, identity theft). In some cases, participants believed that loss of information agency could lead to the loss of privacy, loss of finances, or physical harm.

The perceived risk of losing agency represents a significant barrier to adoption of “advanced” smart surveys features such as geofencing (use of technology to create a virtual geographic boundary that triggers or alerts when a mobile device enters or leaves the area). For example, smart surveys can reduce recall bias by prompting patients for feedback soon after they leave a physician’s office, instead of days or months later in traditional survey methods. The majority of participants found location-based prompts too intrusive and risky and had location services disabled on their phone. This finding is consistent with prior research that demonstrates concerns for privacy are higher when the service is based on tracking the user’s location [62]. Furthermore, participants were conscious of the consequences of their location being disclosed to third parties.

Recommendation Number 4

Smart surveys should support alternatives to location services for prompting patients for feedback, for example, quick response codes or calendar integration.

Limitations

The themes identified through our interviews helped to develop an understanding of barriers to smartphone-based patient experience surveys. Nevertheless, we are careful to acknowledge limitations to this study. First, the attitudes and perceptions of risk held by our participants were captured at 1 point in time, and attitudes toward adoption can change over time and as they become more familiar with technology [63,64]. Furthermore, participants were not asked to download and use the app on their own devices. Consequently, there may have been less consideration given to risk as participants did not actually surrender any personal information. Future work will address these limitations through data triangulation and a longitudinal validation that patient behaviors reflect their reported perceptions. Second, participants were mostly younger (average age: 23.9 years) and more educated, and as a result, they are not necessarily representative of the largest patient segment using health care services [65]. Although the results of this study may not be generalizable to the wider population, a majority of adults now own cell phones, 77% of them own smartphones, and a growing percentage of adults aged 50 to 64 years and over 65 years are smartphone users (73% and 46%, respectively)

[66]. These rapidly growing rates and the decreasing availability of cell phones without expanded digital capability and access to the internet suggest that adults across the life stage will soon experience similar issues as the study sample.

We used nonprobability convenience sampling and a nonsystematic recruitment process for this exploratory study; we did not anticipate our findings would be exhaustive; however, we believe that they add to the understanding of this emerging domain. On the basis of our findings, we believe that individuals with higher technical knowledge and motivation to protect their privacy were under-represented. Finally, the strength of qualitative research is its ability to describe and understand both obvious and latent phenomena contained within the “thick descriptions” provided by interview data. Although our interpretation of these exploratory data is nongeneralizable, the use of in-depth interview methodology provides researchers with an appreciation of the complexity and context of this relatively new research domain. It should also be acknowledged that with every new innovative technology, the patterns of risk and security concerns may differ from those of ostensibly similar legacy systems [24].

Conclusions

The use of smartphone-based patient experience surveys provides new and exciting opportunities for health care providers to assess and improve the quality of health services. We conducted 24 semistructured interviews with smartphone users to explore the types of perceived risks that may exist when using smart surveys in the context-sensitive health services sector. The results demonstrate that the classical dimensions of perceived risk raised minimal concerns for the use of smartphones to collect patient service experience feedback. However, PAS risk associated with trust in the doctor-patient relationship, the reliability of the communication channel, and the risk of potential loss of agency over shared information may inhibit adoption. Conversely, altruistic motivations to contribute to health service quality for others may facilitate patients’ adoption of smart surveys. We conclude that barriers and enablers of adoption of novel technologies may change from sector to sector and should be further explored.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire: participant perspectives on privacy and security.

[[PDF File \(Adobe PDF File, 56KB - formative_v3i1e9922_app1.pdf](#)]

Multimedia Appendix 2

Questionnaire: perceived risk associated with the use of smart surveys.

[[PDF File \(Adobe PDF File\), 64KB - formative_v3i1e9922_app2.pdf](#)]

Multimedia Appendix 3

In-depth interview (Think Aloud) prompts.

[[PDF File \(Adobe PDF File\), 69KB - formative_v3i1e9922_app3.pdf](#)]

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Abbreviations

GPS: Global Positioning System

IS: information system

mHealth: mobile health

PAS: privacy and security

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Original Paper

A Mobile App to Promote Adapted Exercise and Social Networking for People With Physical Disabilities: Usability Study

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Abstract

Background: People with physical disabilities (PWD) experience several unique challenges that prevent them from participating in onsite exercise programs. Although mobile apps can provide a ubiquitous channel for delivering convenient exercise services within the community, no exercise apps have been designed for people with disabilities who experience certain functional limitations.

Objective: The aim of this study was to examine the usability of a mobile exercise app in PWD.

Methods: A sequential explanatory mixed-method design was used to holistically test usability in 4 core areas: *effectiveness* (ie, ease of use), *efficiency* (ie, operation speed), perceived *satisfaction*, and *usefulness*. Participants completed 7 face-to-face usability tasks and 1 structured interview. Equipment included a computer tablet that came preinstalled with the exercise app. The app included exercise videos that focused on several components of fitness: aerobic capacity, muscular strength, functional strength or balance, and range of motion. The app contained 3 different versions of the exercise program: (1) a program for people with the ability to use the upper and lower limbs, (2) a seated program for people with the ability to use only upper limbs, and (3) a program designed for people with hemiparesis. The app also included educational resources in the form of infographics aimed at addressing key social cognitive theory constructs included social support, outcome expectancies, self-efficacy, and barriers or facilitators to exercising. Participant characteristics and quantitative usability data were descriptively reported. Qualitative data were analyzed using thematic analysis.

Results: A total of 12 PWD tested the usability of the exercise app and completed 96% (69/72) of the usability tasks on the first attempt. Operation speed varied among users, which prompted the development team to make minor revisions to the app. Qualitative results demonstrated 3 overarching themes: *facilitates exercise adoption*, *positive experiences of videos*, and *easy to learn*. Participants noted that the app circumvented several barriers to exercise associated with leaving the home (eg, inclement weather conditions, exacerbations of health conditions or disability symptoms, difficulties with transportation, and social support).

Conclusions: The mobile exercise app provided a simple platform that was effective, useful, and appreciated by PWD. Participants also perceived the app as easy to use and felt it was a valuable tool for assisting PWD to obtain regular exercise. Study findings also offered insight into the participants' preferences for mobile exercise apps that can aid future research and development projects. Future exercise trials are needed to determine the true impact of mobile app technology on lifestyle physical activity in people with disabilities.

Trial Registration: Clinicaltrials.gov NCT03024320; <https://clinicaltrials.gov/ct2/show/NCT03024320> (Archived by WebCite at <http://www.webcitation.org/75hNLgRFH>).

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KEYWORDS

exercise; telehealth; rehabilitation; mHealth

Introduction

According to the United States Census Bureau, 30.6 million people have mobility limitations (eg, difficulty with walking or climbing stairs and wheelchair or cane use) and 15.5 million experience problems with normal activities of daily living [1]. In addition to the direct physical impairments associated with the disability, systematic reviews have identified a multitude of structural and logistical barriers to onsite exercise participation. Some of the more egregious barriers include lack of transportation, extensive time commitment, lack of accessible facilities and equipment, and high cost of a fitness membership [2]. The diversity and number of barriers likely explains why adults with disabilities have higher rates of physical inactivity compared with adults without disabilities. National prevalence data have indicated that 57.4% of adults with mobility limitations living within the United States were inactive (ie, achieving <150 min of moderate-to-vigorous intensity aerobic exercise), compared with only 26.1% of adults without disabilities [3].

Mobile health (mHealth) apps can provide a ubiquitous channel for delivering convenient exercise services to people within their community [4]. In the general adult population, app-based interventions have been found to be efficacious for improving physical activity participation and reducing sedentary behaviors [5]. These apps appeared to be particularly beneficial when accompanied by behavior change techniques. Common examples of these techniques include goal setting, self-monitoring, performance feedback, and social networking [6,7]. Nevertheless, the viability of using mHealth apps for promoting exercise behavior will ultimately depend on participants' perceptions of their ease of use [8].

Although there are thousands of fitness apps that are commercially available for the general population, few have been developed specifically for people with physical disabilities (PWD) [9]. A survey of 377 people with functional limitations reported that exercise and activity apps were the most commonly used type of mHealth apps [9]. However, only 173 (173/377, 45.8%) of these individuals reported that they could easily locate a suitable app, and the same percent reported that they were satisfied with usability. Within this report, the respondents identified that commercial apps had issues with accessibility and usability and suggested that apps be created with disability-specific content. Although research studies have incorporated self-regulated mHealth apps or Web-based interventions to deliver streamed video content, one-on-one training, and activity tracking and monitoring in PWD, there are limited apps that include customizable exercise content and behavioral change techniques that are tailored to people with a range of functional limitations [10]. Therefore, the purpose of this study was to examine the usability of an inclusive mHealth fitness app that was developed specifically for PWD. The study had 2 aims: (1) quantitatively assess the app's effectiveness and efficiency and (2) qualitatively explore participants' satisfaction and usefulness of the app.

Methods

Study Design

This study used a nested mixed-methods design (QUAN ->qual) [11] to test the usability of an mHealth fitness app. The design incorporated a primarily quantitative usability study that was followed by a qualitative interview. The study included both quantitative and qualitative data collection to provide an *expanded evaluation of usability* in 4 core areas: *effectiveness*, *efficiency*, *satisfaction*, and *usefulness*. These components were selected based upon best practice recommendations for usability testing [8]. The study conformed to the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online Telehealth (CONSORT-EHEALTH) [12].

Recruitment

Twelve PWD were recruited for this study to satisfy best practice recommendations for usability testing [8]. Eligibility criteria included: (1) age 18 to 70 years, (2) documented physical mobility limitation, which we broadly defined as the use of an assistive device as a primary means of mobility or the presence of walking impairments (eg, hemiparesis or drop foot), (3) ability to speak and understand English, and (4) ability to operate an app on a mobile device. Participants were recruited through the network of an internationally recognized community fitness facility which specializes in adapted physical activity programs for PWD. This project was approved by the university institutional review board. Before enrollment, written consent was obtained from each participant.

Intervention

The mHealth app examined in this study is referred to as Trial #NCT03024320, Scale Up Project Evaluating Response to Home Exercise and Lifestyle Tele-Health (SUPER-HEALTH). This study aimed to test the usability of the SUPER-HEALTH app before evaluating its effectiveness in a randomized controlled trial. The primary component of SUPER-HEALTH was the exercise video content, which included movements that were adapted from a rhythmic movement-to-music (M2M) program for people with multiple sclerosis and stroke. M2M was created and implemented for 4 years at an internationally recognized fitness facility for PWD. SUPER-HEALTH (version 2.3) is a research tool that can be commercially downloaded at no charge, but does require a research team member to activate and tailor the program to meet the functional needs of a participant. The app includes the following features:

- a multicomponent fitness program using a set of videos that can accommodate a variety of functional abilities;
- educational papers with content framed within the social cognitive theory [13];
- the ability to sync and display exercise data from commercial activity monitors;
- achievement rewards (badges);

- social networking functions that include the ability to add other users as friends, communicate with other users via a newsfeed, and private message other users to facilitate social support.

Exercise videos included movements from the M2M program and focused on several components of fitness: range of motion, muscular strength, cardiorespiratory endurance, and functional strength or balance. To be inclusive of a wide variety of functional abilities, the app contained 3 different versions of the M2M program: a version for people with the ability to use the upper and lower limbs, which included movements in the seated and standing position (Level 1); a seated version for people with the ability to use only upper limbs (eg, wheelchair users; Level 2); and a seated and standing version designed for people with the ability to use 1 upper and 1 lower limb (ie, hemiparesis; Level 3). Examples of the movements in the different program versions are shown in [Figure 1](#).

The educational papers in the app included infographics that aimed to enhance self-regulated physical activity behavior and were based on strategies grounded in social cognitive theory [[13,14](#)]. These papers targeted 4 core constructs (self-efficacy, goal setting, outcome expectations, and barriers and facilitators), each of which has been recommended to increase physical activity behavior in people with neurologic disabilities [[14](#)]. Examples of content included understanding the benefits of physical activity participation in people with disabilities; learning how to monitor physical activity; setting SMART goals (Specific, Measurable, Attainable, Realistic, and Timely); and seeking social support.

Procedure

This study included 2 phases: usability testing and a qualitative interview. Usability testing included 7 tasks that were followed by a one-on-one semistructured interview, both of which took place at the research laboratory. After obtaining consent, written information including participant demographics (age, sex, race, and education), clinical characteristics (disability or condition and mobility limitation), mobile phone usage, and physical activity status were recorded. Participants were then instructed to login to the app with a standard user account and perform

the 7 usability tasks, which included: opening the app; locating and opening a paper; locating and opening a badge; locating, opening, and creating a one-word post on the newsfeed; adding a user as a friend; locating and viewing the leaderboard; and playing the videos and performing the adapted exercise routine. While performing the tasks, the participants used a think aloud approach [[8](#)]. A research assistant took written notes while observing participants during the tasks. The assistant also recorded the time it took participants to complete each task, except for the performance of exercise videos.

When instructed to play an exercise video, participants were asked to locate, play, and perform a single video that they felt was suitable to their functional ability. Participants were given access to an archive of videos that included the first 6 weeks of the SUPER-HEALTH 48-week program. The archive included a total of 33 videos that were categorized by the 3 program levels (11 videos per level). Within each program level, there were 4 videos for range of motion exercises, 3 videos for strength, 2 for cardio, and 2 for functional strength. The videos were accompanied by an image that represented the type of movement patterns and positions (seated or standing) that were included within each video. Participants were instructed to perform all movements at a comfortable pace.

After completing the user tasks, participants met with the study investigator and completed a semistructured interview. The interview was conducted in a private setting in the research laboratory. The interview was recorded by an audio device, which was later transcribed for qualitative analysis.

Measures

Summary

App usability was defined in terms of effectiveness (the ease at which individuals can use the product), efficiency (the speed with which an individual can accurately complete a task), usefulness (the extent a product can enable users to achieve their goals and willingness to use the product), and satisfaction (the users' perceptions and opinions of the product) [[8](#)]. Usefulness and satisfaction were explored through qualitative means, whereas effectiveness and efficiency were examined through quantitative metrics.

Figure 1. Examples of the 3 different program versions (Left: Version 1; Middle: Version 2; Right: Version 3).



Effectiveness

Research members evaluated the *effectiveness* of users' experiences with the app by recording the frequency of tasks that participants completed on the first attempt without error or issue. These observations were summed for all users and divided by the total tasks that were completed, which resulted in a single percentage value. The research team set an *a priori* benchmark of acceptable *effectiveness* at 95% [8].

Relative Efficiency

Relative efficiency was measured by the time required to complete each of the 6 tasks (video performance task excluded). As the research team anticipated that participants would include older adults, as well as individuals with neurologic and upper-limb impairments, the research team did not set an *a priori* benchmark to indicate an acceptable level of efficiency. Instead, these data were used to identify problem areas within the app for rectification.

Usefulness and Satisfaction

Researchers assessed *usefulness* and *satisfaction* through participants' qualitative feedback from face-to-face interviews. Each semistructured interview included open-ended questions that sought to gain insight into the participants' overall perceptions of the app, their likes and dislikes regarding app features and content, whether they would use the app at home, and whether they felt they could find a video that was suitable to their functional ability. The specific interview guide and questions are included in the [Multimedia Appendix 1](#). Two members of the research team conducted the interviews. One interviewer was a research staff member that was trained and supervised by the primary interviewer. The primary interviewer had 4 years of experience with qualitative interviews and had a background in adapted physical activity.

Physical Activity

Physical activity status was assessed with the Godin Leisure-Time Exercise Questionnaire (GLTEQ) [15]. The GLTEQ is a questionnaire that asks participants to self-report the number of exercise bouts in a typical week that last longer than 15 min. Bouts are counted for 3 different exercise intensities: light, moderate, and vigorous. Frequency counts for moderate and vigorous intensity exercises are multiplied by 5 and 9, respectively, and summed into a single health contribution score. Activity levels can be compared with the following cut-points: ≥ 24 sufficiently active, 23-14 moderately active, and < 13 insufficiently active [16,17]. This method of scoring has been validated in the general adult population with fair to substantial k coefficients for test-retest reliability (k coefficient for a 15-day period = .65; k coefficient for a 30-day period = .45). This scoring method has also been demonstrated to have a moderate correlation ($r=.46$) with moderate-to-vigorous physical activity (measured via accelerometer) in adults with multiple sclerosis [18].

Instruments

An example of the usability test setup is shown in [Figure 2](#). Equipment included a 10.5-inch Android tablet that came installed with the mHealth fitness app and was mounted to an adjustable floor stand (Standzfree Universal Stand, Standzout).

Analysis

The research team's philosophical assumptions aligned with dialectical pluralism [19]. Within this paradigm, the research team held separate theoretical perspectives for the quantitative and qualitative methods (positivism and interpretivism, respectively). Participant characteristics and quantitative usability data were descriptively reported.

Qualitative data were analyzed using thematic analysis [20], which was underpinned by an interpretivist philosophical approach. Specifically, the analysts' ontological beliefs aligned with ontological relativism (ie, reality is multiple and subjective) and their epistemological beliefs with subjectivism (ie, knowledge is socially constructed) [21]. In other words, the analysts acknowledged that participants can have multiple explanations for a phenomenon that can be shaped by their backgrounds and interactions with others. Accordingly, the analysts acknowledge that research staff are not blind-observers during the qualitative process: data collection is influenced by the presence and interaction of the interviewer; and themes are interpreted by the analysts and transformed beyond mere explicit statements reported by participants.

The 6 steps proposed by Braun and Clarke [20] were used to guide the thematic analysis process. A total of 2 analysts generated initial codes from segments of a transcribed interview. These codes were then refined into fewer subthemes. The analysts repeated this process for each transcription and evolved their subthemes. The analysts then met to discuss their subthemes, which they then integrated and refined into a single set of themes. These resultant themes were reported. Both analysts had training and experience in mixed-methods research and in developing exercise programs for PWD. One analyst was also the primary interviewer. The other analyst had a physical disability for 12 years.

To enhance the quality of the qualitative research, we adopted a relativist approach that aligned with the ontological and epistemological assumptions that underpinned the qualitative component [22]. First, the qualitative research was aimed at providing a *substantive contribution* [23]. This was demonstrated in the results by the efforts to provide meaningful findings that can be used by other investigators, who aim to understand how PWD interact with and respond to exercise technology. Second, *coherence* was sought by using qualitative study procedures throughout the methods and results that fit together and aligned with the goals of the study [24]. Finally, *transparency* was sought by receiving in-depth feedback from a *critical friend* [25], whereby the individual scrutinized matters such as the theoretical preferences, qualitative procedures, and results to encourage reflexivity and alternative explanations and interpretations of the data.

Figure 2. Example of an individual following an exercise routine through a computer tablet mounted to an adjustable stand.

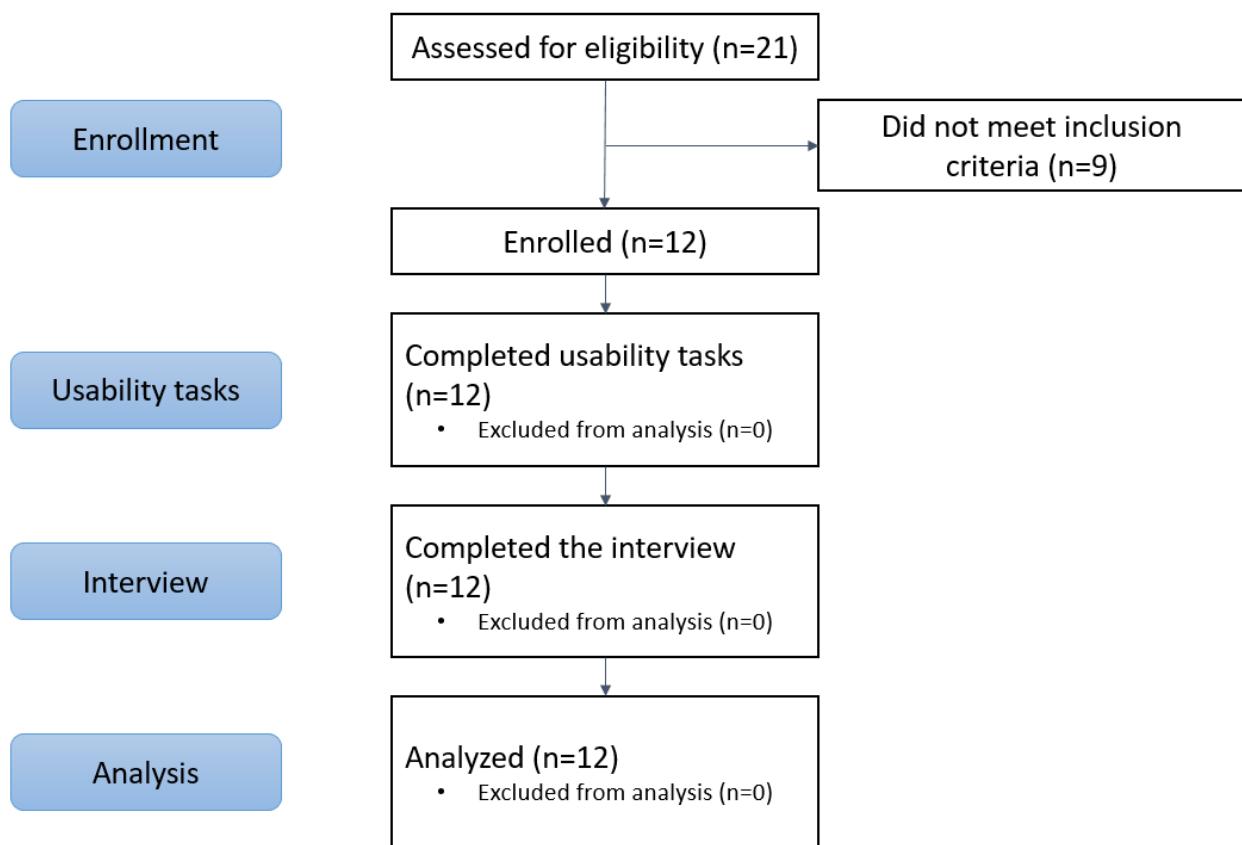


Results

Overall

Figure 3 displays participants' progression through each of the study phases. A total of 21 people with disabilities were contacted and screened. Of these, 12 individuals were eligible to participate in the study. Participants had a range of functional limitations.

The study occurred from October 2017 to February 2018. A total of 5 participants performed the standing video set (Level 1), 5 participants performed the seated video set (Level 2), and 2 participants performed the hemiparesis video set (Level 3). Participant demographics and clinical characteristics are shown in Table 1. Each visit took approximately 1.5 hours to complete, which included consent, usability testing and the interview.

Figure 3. Flow diagram.

Effectiveness and Efficiency

Effectiveness

Participants completed 96% of the usability tasks (69/72) on the first attempt. There were only 3 minor usability issues related to app features. One was because of confusion with wording on the paper's page and the other 2 were issues with visual cues on the Newsfeed page.

Efficiency

Results for the time required to complete each task are shown in [Table 2](#). Developers identified 3 of the 6 tasks that demonstrated substantial variability: locating an earned badge (task 3), locating the Newsfeed page and creating a one-word post (task 4), and adding another user as a friend (task 5).

Usefulness and Satisfaction

Qualitative results from the semistructured interviews ([Textbox 1](#)) demonstrated 3 themes: *facilitates exercise adoption*, *positive experiences of videos*, and *easy to learn*.

Facilitates Exercise Adoption

Participants perceived the app as a powerful and valuable tool for incorporating exercise behavior into the daily activities of individuals with disabilities by circumventing several barriers to exercise associated with leaving the home. Barriers such as

inclement weather conditions, exacerbations of health conditions or disability symptoms (eg, arthritis-related inflammation, severe fatigue, and pain), and, most notably, difficulties with transportation (cost, time, and accessibility) were reported by participants. In addition, participants reported that exercising at home could negate feelings of social judgment that occur in a group exercise setting at a fitness facility, such as feelings of conviction from missing an exercise class or embarrassment from poor or incorrect performance in the presence of other class members. To address a need for social support, participants reported that the social media functions within the app provided an opportunity for camaraderie, which could be beneficial for individuals with disabilities who are often isolated within their community. Due to these collective benefits, participants reported that the app was potentially valuable and innovative for inactive people with disabilities who needed to adopt a lifestyle that included regular exercise. As stated by participant 12:

I think that it [the app] is a way of introducing, a way of beginning, and a way of encouraging. My overall impression is that it is something that is needed and something that could lead people out of a more inactive lifestyle...I just think that there are a lot of people like me that need something to start the ball rolling. [Participant 12]

Table 1. Participant information (N=12).

Characteristic	Value
Age, mean (SD)	52 (15)
Sex, n	
Male	6
Female	6
Ethnicity, n	
Black	6
White	6
Diagnosis, n	
Spinal cord injury	5
Parkinson disease	2
Arthritis	2
Multiple sclerosis	1
Stroke	1
Traumatic brain injury	1
Mobility device or limitation, n	
Manual wheelchair	4
Walker	2
Cane	1
Cane and hemiparesis	1
Hemiparesis	1
Orthotic device	1
Poor balance	1
Power wheelchair	1
GLTEQ ^a : Health contribution score, mean (SD)	34.7 (28)
GLTEQ: Sufficiently active (score ≥ 23), n	7
GLTEQ: Moderately active (score 14-23), n	2
GLTEQ: Insufficiently active (score <13), n	3
Mobile phone users, n	
Yes	10
No	2
Education, n	
Graduate degree	5
College graduate	5
Some college	2

^aGLTEQ: Godin Leisure Time Exercise Questionnaire.

Table 2. Efficiency results.

Usability tasks	Median time to completion (Interquartile range), seconds	CI, seconds
Task 1: Open the menu	3 (9.2)	2.5-10.4
Task 2: Locate and open a paper	8.9 (6.6)	7.2-15.0
Task 3: Locate a badge	21 (7.5)	16.5-23.9
Task 4: Newsfeed one-word post	37.5 (26.3)	23.4-42.6
Task 5: Add a user as a friend	12 (24.8)	9.1-31.1
Task 6: Locate and view the leaderboard	6 (2.1)	4.3-6.63

Textbox 1. Qualitative themes and subthemes.

Facilitates exercise adoption
• Circumvents exercise barriers
• Reach and Impact
• Opportunities for social support
• Innovative
Positive video experience
• Mode of delivery
• Exercise movements
Easy to learn
• Intuitive
• Short learning curve

Positive Experiences of Videos

Participants held favorable views of how the exercise videos were packaged and delivered. In addition to having control over the exercise environment (ie, the home setting), participants also experienced a sense of control over the pace of the exercise sessions, which was primarily because of the ability to start and stop videos at their convenience. One participant commented:

I felt like I was in charge, as far as, getting it, doing it, and stopping when I need to. [Participant 9]

Moreover, while performing the videos, participants felt as if they were engaged in a real-time group exercise class because of the enthusiastic and engaging mannerisms and rhetoric provided by the exercise instructor:

She [the instructor] said you could go at your own pace...Even though it was not back and forth communication, it was just the way she talked to you; she wasn't condescending. [Participant 4]

Participants also acknowledged a high level of appreciation for the exercise movements. All participants found videos that contained movements that were suitable to their functional ability and reported that the movements were potentially inclusive for a large variety of individuals with disabilities. Participants also noted favorable perceptions of the novelty, variety, and perceived health benefits of the movements, along with the comfortable pace and nonjudgmental manner to which they were guided.

Easy to Learn

Participants identified that the app was *easy to learn*. When asked how confident they felt using the app independently, participants reported high levels of confidence. This was because of the ease at which the app could be navigated and operated, as well as the similarity of the app user interface compared with other available apps in the marketplace. However, participants did mention that efficient use of the app would require a learning curve, which could be achieved independently with brief instructions before use.

Discussion

Summary

Multiple barriers must be overcome for many PWD to engage in regular exercise. For this reason, we designed an app that provides high quality exercise videos that are customized for people with a range of physical disabilities and can be accessed in the home setting through a tablet. The usability of this system was tested through separate quantitative and qualitative assessments. These findings are discussed in an integrated format to provide a holistic evaluation of usability. Overall, the findings demonstrated that the SUPER-HEALTH app was effective, valuable, and useful for people with disabilities.

Quantitative Findings

Quantitative results demonstrated that a variety of PWD could successfully operate the SUPER-HEALTH app. The high

percentage of successful users (>95%) on their first attempt achieved our a priori criteria for acceptable effectiveness. The only minor issue related to efficiency was the time taken for completion of the 3 tasks (adding another user as a friend, locating an earned badge, and creating a post on the Newsfeed). This informed the development team that improvements could still be made to certain visual aspects of the app.

Qualitative Findings

The qualitative results demonstrated overtly positive themes related to usefulness and satisfaction. Combined with inclusive exercise program versions, opportunities for social support, and an intuitive user interface, participants reported that the app was potentially valuable for themselves and the general population of people with disabilities who desire to start an exercise program. Specifically, the app was considered an innovative and convenient alternative to onsite exercise at a fitness facility because it circumvented several barriers (eg, weather, transportation, health conditions or symptoms). These barriers are consistent with those reported in the extant literature for PWD [2].

Integrated Findings

On the basis of the integrated quantitative and qualitative findings, the research team addressed 2 critical development questions: (1) Were further revisions to the app necessary? and (2) Were further usability tests necessary? Due to the positive qualitative feedback and effectiveness findings, the research team collectively agreed that no further usability tests were necessary. However, based on efficiency data and the *easy to learn* theme, the researchers informed the development team to add minor visual improvements to app version 2.5.1 (eg, increased size of buttons and fonts and alterations to wording and color) and provide future participants or users with more detailed instructions before tablet use.

Future Studies

In addition to testing the usability of the SUPER-HEALTH app, study findings provide a foundation for researchers and developers who aim to tailor exercise apps or similar Web-based programs for adults with physical disabilities. Qualitative findings suggested that PWD perceive several benefits to self-regulated Web-based exercise programs. First, individuals appreciate a sense of control over the pace of exercise sessions,

which provides ample time to learn new movements and take breaks when necessary. Second, some individuals who are hesitant about exercise in a public setting because of perceived judgment from others, might prefer app-based exercise in the home setting versus onsite exercise at a facility. Last, participants reported that an exercise app should not replace physical activity participation within the community such as exercising at a nearby facility or park. Instead, participants noted that the end goal for exercise-based apps should be to transition people from exercising in the home setting to physical activity within their community.

Limitations

This study had a few limitations. First, although a sample size of 12 may be sufficient for detecting usability issues, the generalizability of these findings is limited to individuals with similar conditions, impairments, or characteristics (eg, education level, ethnicity, and technology proficiency) as our study participants. Second, most participants were active exercisers recruited through the network of an internationally recognized fitness facility, and therefore may not represent the larger population of individuals with disabilities, including those who are inactive. However, we felt the inclusion of active individuals provided rich insight on both exercise adoption (ie, beginning participation in exercise) and long-term participation (ie, sustainability). We also did not want to exclude individuals who could potentially benefit from participation in the larger trial. Third, a few individuals showed symptoms of cognitive impairment that could have explained the variability observed in efficiency data, but cognitive impairment was not assessed by the research staff. Fourth, the study did not include an even distribution of participants among the 3 exercise video levels and only examined the usability of select videos within the program, which warrants an examination of program feasibility.

Conclusions

This study demonstrated that the SUPER-HEALTH app provides a simple platform that can be easily operated by a wide variety of users with physical disabilities. Study findings also provide insight into participants' preferences for mobile exercise apps that can inform future research and development projects. Future research should examine app feasibility in the real-world setting (ie, home) to provide further insight into the app's usability before implementation in an exercise intervention.

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Authors' Contributions

All authors contributed to the drafts of this manuscript. BL formulated the initial manuscript draft. BL managed the usability testing and communicated the findings to MT, who led the software development team. JH and BL conducted the usability testing. BL and JW analyzed the qualitative data. HJY developed the exercise videos. JR oversaw all areas of development.

Conflicts of Interest

This study involved 2 project teams: a development and research team. A total of 2 authors of this study were part of the development team: MT and JR. Although these authors contributed to the preparation of this submission, a separate research team led by BL implemented the usability testing, analyzed the data, and reported the findings here in this manuscript.

Multimedia Appendix 1

Qualitative interview script.

[[PDF File \(Adobe PDF File, 40KB - formative_v3i1e11689_app1.pdf](#)]

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Abbreviations

GLTEQ: Godin Leisure-Time Exercise Questionnaire

mHealth: mobile health

M2M: movement-to-music

PWD: people with physical disabilities

SUPER-HEALTH: Scale Up Project Evaluating Responsiveness to Home Exercise and Lifestyle Tele-Health

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Original Paper

An mHealth Assistive System “MyLung” to Empower Patients with Chronic Obstructive Pulmonary Disease: Design Science Research

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) comprises a group of progressive diseases that deteriorate lung functions. When patients cannot breathe, nothing else in their lives matter. Breathlessness has negative implications on patients' lives, which leads to physical and psychological limitations. Moreover, the lack of relevant and updated information about the causes and consequences of the disease can exacerbate the problems of health literacy, information accessibility, and medical adherence.

Objective: The objective of this study is to design an innovative mobile health (mHealth) app system called “MyLung” that provides complete solutions in order to increase self-awareness and promote better self-care management. This system, an information technology artifact, includes three novel integrative modules: education, risk reduction, and monitoring.

Methods: The utility and effectiveness of the assistive mobile-based technology were evaluated using a mixed-methods approach. The study combined quantitative and qualitative research methods to thoroughly understand how the assistive mobile-based technology can influence patients' behavioral intention to change their lifestyle. Thirty patients were categorized into two groups (intervention group and control group).

Results: The results from the quantitative analysis led to four follow-up interviews in the qualitative study. The results of the quantitative study provided significant evidence to show that the design of MyLung leads to a change in the awareness level, self-efficacy, and behavioral intention for patients with COPD. The *t* tests revealed a significant difference before and after using the mobile-based app with regard to the awareness level (mean 3.28 vs 4.56; $t_{10}=6.062$; $P<.001$), self-efficacy (mean 3.11 vs 5.56; $t_{10}=2.96$; $P=.01$), and behavioral intention (mean 2.91 vs 4.55; $t_{10}=3.212$; $P=.009$). Independent sample *t* tests revealed significant differences between the intervention group and the control group in terms of the awareness level (mean 4.56 vs 3.31; $t_{19}=4.80$; $P<.001$) and self-efficacy (mean 5.56 vs 3.66; $t_{19}=2.8$; $P<.01$). Integration of findings from quantitative and qualitative studies revealed the impact of the design in a comprehensive manner. These inferences are referred to as “meta-inferences” in this study.

Conclusions: We designed an innovative assistive mobile-based technology to empower patients with COPD, which helped increase awareness and engage patients in self-care management activities. The assistive technology aims to inform patients about the risk factors of COPD and to improve access to relevant information. Meta-inferences that emerge from the research outputs contribute to research into chronic management information systems by helping us gain a more complete understanding of the potential impacts of this proposed mobile-based design on patients with chronic disease.

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KEYWORDS

assistive technology; patient empowerment; chronic obstructive pulmonary disease; design science research

Introduction

Background

Chronic obstructive pulmonary disease (COPD) is a prevalent disease worldwide and a major cause of morbidity and mortality [1]. COPD is a group of obstructive lung diseases encompassing multiple conditions that share two common factors: airflow limitation and unusual inflammations in the lung. Patients with COPD experience symptoms such as chronic cough, sputum production dyspnea, chronic sputum, hyperinflation, and wheezing [1]. Several factors are responsible for triggering COPD symptoms and are based on two categories: lifestyle (typically, long-term smoking) and occupational or environmental factors. Patients with COPD are susceptible to the risk of frequent episodes or exacerbations. According to Celli et al [2], exacerbation is defined as “sustained worsening of the patient’s condition from the stable state and beyond normal day-to-day variations that is acute in onset.”

Because COPD conditions have a long-term effect, patients frequently suffer from complications and require constant education and awareness to promote better empowerment [3]. Education empowerment increases patients’ knowledge of matters associated with their conditions [4]. Patients with chronic diseases should receive an effective education on how to actively manage their condition on a daily basis. Equipping patients with education empowerment mechanisms about their chronic conditions, such as understanding the consequence of risks and receiving timely guidelines, has been associated with improved self-management and self-control of disease [5]. These mechanisms will help patients change their behaviors with regard to managing their disease conditions [5].

Access to health care information and educational resources becomes a challenge for patients with COPD because of the barriers that prevent easy delivery of information. These barriers result from physiological factors relevant to patients, environmental settings, and cost of educational programs [6]. Physiological barriers play a major role in the way a patient with COPD is able to perceive and process health information [7]. The consequences of COPD can be better managed with information technology, in particular, mobile health (mHealth) and telemedicine. mHealth technologies can enable a variety of technical features that facilitate better education and self-management for patients with COPD, which, in turn, persuade patients to change their behavioral intentions toward self-care. Features included in such mobile technologies can be utilized for health-related purposes. They should be useable by all types of patients, including the elderly, people with low literacy, and people with disability [8]. To give an illustrative example, a patient can use a mobile app to plan daily activities in advance and will receive notification messages or short videos to remind him/her of the activities. Additionally, patients can monitor their symptoms and vitals when related data are collected from the sensors through the use of Bluetooth.

COPD can lead to behavioral problems [5] that increase the threat of disease progression. These problems are related to daily lifestyle and medication-taking behaviors. Behavioral problems occur due to a lack of access to appropriate skills and knowledge that can help patients better manage their conditions [9]. The consequences of breathlessness are manifested as functional impairment that leads to psychological limitations. Patients with COPD always experience anxiety, which causes depression and distress [10]. When patients panic about the fear of becoming breathless, they cannot be easily motivated to engage in self-care behavioral activities. Additionally, better lifestyle behaviors can be accomplished when patients receive recommendations about outdoor pollution hazards, smoking cessation techniques, and regular exercises. Relevant knowledge and skills help develop self-efficacy, which increases patients’ confidence in their abilities to perform behavioral actions.

A behavioral change-support system (BCSS) has become an attractive tool for information system researchers to explore and understand the mechanism of empowerment education for adult learners. BCSS has been found to be an important agent of change at individual and social levels [11]. When the learning and recommendation content of interventions is designed with respect to BCSS strategies, the intervention will influence patients’ engagement and behavioral change through a real-life experience. With the use of such strategies, the self-management intervention tool for COPD can include features such as task compression and follow-up looping [11].

The objective of this research is to design and develop an innovative mobile-based technology that offers a complete solution for patients with COPD. This design would resolve the issues of lack of awareness about the risk factors of COPD, information accessibility, and management of COPD symptoms among patients with COPD. The problems are investigated through the lens of design science research [12,13], which is a research approach that aims to design and evaluate an innovative technology [12] and involves processes that consult scientific theories (ie, health belief model) [13]. Design science research sheds light on patients’ needs and creates an effective assistive technology to fulfill those needs. The innovative design introduces three modules with complete and integrated features. The design offers education, risk reduction, and monitoring modules in one artifact called “MyLung.” Therefore, the questions of this study drive the design process to create an effective information technology artifact. We aimed to address the following main research question: How can an effective integrative assistive mobile-based technology be designed to improve patients’ understanding of COPD (knowledge about the risk factors and consequences of COPD) and to increase patient behavioral intention toward self-care?

Prior Work

Telemonitoring and mHealth technologies are relatively new fields in COPD research [14]. Tabak et al [15] reported a pilot study on the use of a telehealth program for patients in the stable stage of COPD. The telehealth program consisted of different

features including Web-based exercise and self-management of COPD exacerbations. The system helped patients measure their physical activities via an accelerometer-based activity sensor. The physical activities were presented on the Web portal. In order to manage any exacerbation, patients were asked to fill in their diary on the Web portal which, in turn, fed the decision algorithm to detect the exacerbation. Although the study provided a solution to manage patient exacerbations, the design of the system lacked simplicity. Hardinge et al [16] reported the findings of a 6-month cohort study of COPD patients' use of an mHealth app adapted to run on an Android tablet. The app was designed by a multidisciplinary team that included primary care physicians, respiratory nurses, a secondary care respiratory physician, a psychiatrist, and engineers. The app allowed patients to self-report their symptoms. Neither of the abovementioned studies showed promising results on the effectiveness of app usage. The failure to detect a significant effect on adherence to daily activities may be attributed to the process of designing a solution that lacks motivation and engagement mechanisms. Additionally, both designs lacked empowerment and behavioral motivation elements.

Methods

Design

The mobile-based technology follows design science research [12,13]. Design science research is well established in information systems research that aims to design and implement innovative technologies through design cycles [12]. The research design comprises two design cycles, as illustrated in Figure 1. The first cycle in this research project is referred to as a prototype design cycle, and the second cycle is referred to as the final design cycle.

The first design cycle was the prototype design, which started by defining a specific research problem. The research problem focuses on issues related to educational empowerment and lack of information accessibility for patients with COPD. To establish problem awareness, an initial literature review was conducted, guided by the research problem, in order to introduce a set of meta-requirements. To determine the gap in the literature, four domains were considered from the problem, namely, information access, patient educational empowerment, chronic disease management, and mobile health. Guided by the problem-awareness step, we used the health belief model (HBM) theory and BCSS principles to govern both the design requirements and process. Using knowledge gained from the literature and kernel theories, preliminary design requirements were conceptualized. Subsequently, the design requirements were translated into designed features for prototype implementation. A demonstration session was then conducted with a COPD physician, in which he examined the prototype and provided more design requirements that fit patients' needs. To collect more feedback on the effectiveness and usability of the mobile-based prototype, we conducted a focus group interview with information technology and health experts. During the focus group session, each participant observed the prototype and offered feedback through an online survey. The new requirements and feedback initialized a new design cycle

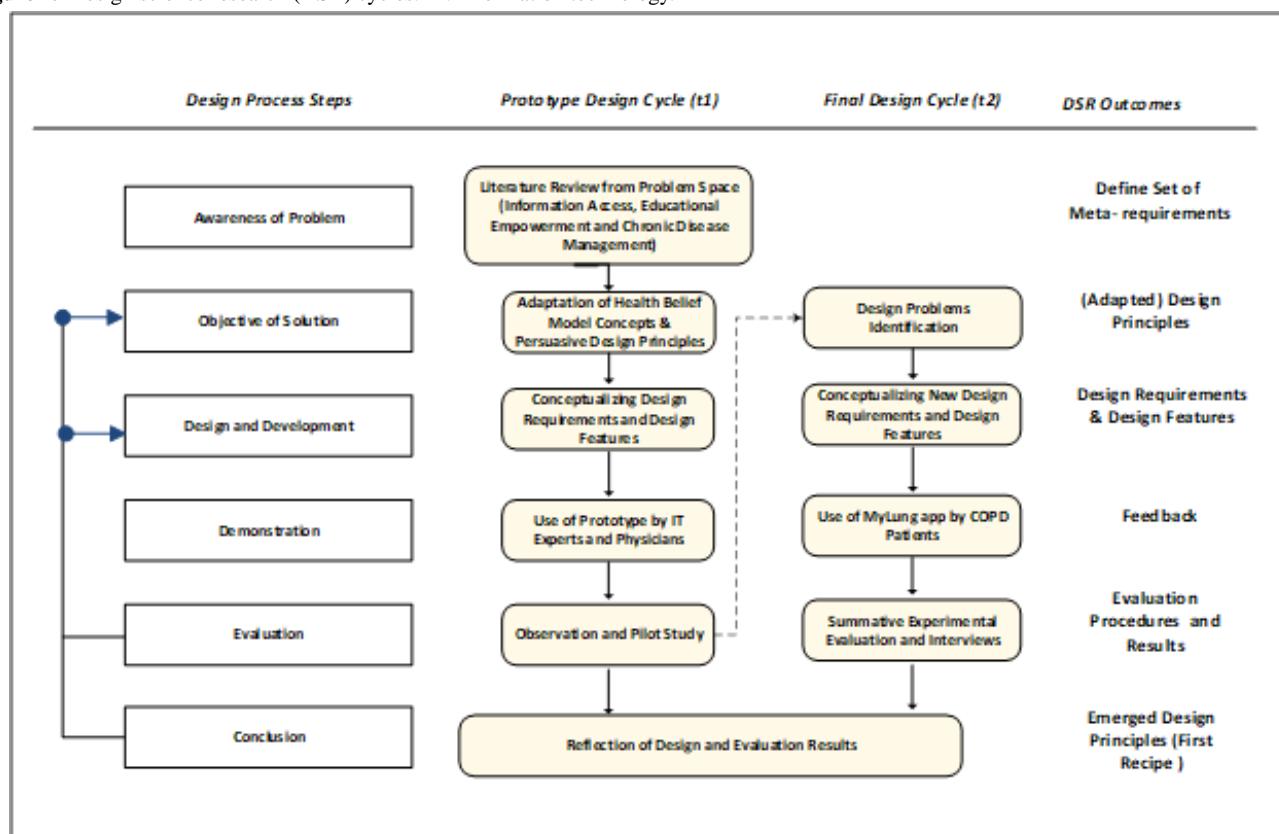
for better implementation of innovative mobile assistive technology design.

In the second design cycle, the adapted requirements were conceptualized to guide development of the final designed features. Thus, we returned to the literature and consulted the BCSS principles to address new suggested requirements. The features were designed to provide a solution within one information technology artifact, which we called "MyLung," and the design features were implemented to improve the quality of life for COPD patients. The information technology artifact included an educational module, a risk-reduction module, and a monitoring module. The educational module was designed to increase patient's level of understanding about COPD by providing reliable educational videos and information. The risk-reduction module comprised features that empower patients with knowledge about ways to avoid risk-related factors. The monitoring module included features that allow patients to self-monitor their symptoms and vitals, including peripheral capillary oxygen saturation (SpO_2). The SpO_2 value is entered through a medical device via a Bluetooth low-energy connection, while the symptoms are entered using a clinical COPD questionnaire. The monitoring module also provides a dashboard that helps caregivers and physicians intervene before exacerbations occur. Figure 2 shows screenshots of the mobile-based app that was used by real patients with COPD.

Procedure

The evaluation study started after obtaining institutional review board approval from Claremont Graduate University and used a mixed-method approach and a sequential explanatory design: Quantitative data were first collected from the questionnaires that were distributed through Qualtrics (Seattle, WA), following which qualitative data were collected in semi-structured interviews. A purposive sampling was used to select patients with COPD who visited a pulmonary medicine clinic in southern California. With purposive sampling, patients were selected based on the research criteria listed below. Subsequently, patients were assigned to one of two groups (intervention and control groups) without the researchers knowing about patients' behavioral intentions. The intervention group received the MyLung app, and the control group received booklet-based information. We randomly assigned 15 patients to each group; 9 patients dropped out of the study, leaving a final sample of 21 patients (11 patients in the intervention group and 10 patients in the control group). On an average, the patients were elderly: 9% were 33-44 years old, 6% were 45-54 years old, 33% were 55-64 years old, 19% were 65-74 years old, and 33% were older than 75 years. Of the total, 52% were female. All patients spoke English at least somewhat fluently and were fairly educated, with 10% having bachelor's degrees, 38% having associate degrees or at least some college education, 42% having a high school diploma, and 10% having less education than a high school diploma. We started the subject recruitment process and collected data in October 2017.

The inclusion criteria were as follows: receipt of a COPD diagnosis, acceptable literacy level to read and deal with a smartphone, and possession of a smartphone (Android or iPhone).

Figure 1. Design science research (DSR) cycles. IT: information technology.

Patients in the intervention group downloaded the MyLung app from Google Play or the Apple App Store, received an iHealth Pulse Oximeter (iHealth Labs Inc, CA), and participated in a training session. During the training, we made sure that patients were able to connect the app with the pulse oximeter and understand the app features. Additionally, patients who were assigned to the intervention group were given instruction guides on how to use the MyLung features, whereas patients in the control group were given a booklet comprising traditional educational material about COPD. Prior to the training session and participation in the experiment, patients in both groups had to complete a presurvey. The survey consisted of 11 questions and was administered to patients with COPD to measure their awareness level and knowledge of COPD, self-efficacy, perceived severity, and overall intention to engage in a healthy behavioral style. The postsurvey was sent to patients 1 month after the recruitment day. Each patient in both groups received an exit survey questionnaire that was similar to the presurvey. The results from the quantitative analysis led to several follow-up interviews used in the qualitative study. The qualitative analysis yielded rich insight into phenomena related to app experience and behavioral change for patients with COPD.

Measurements

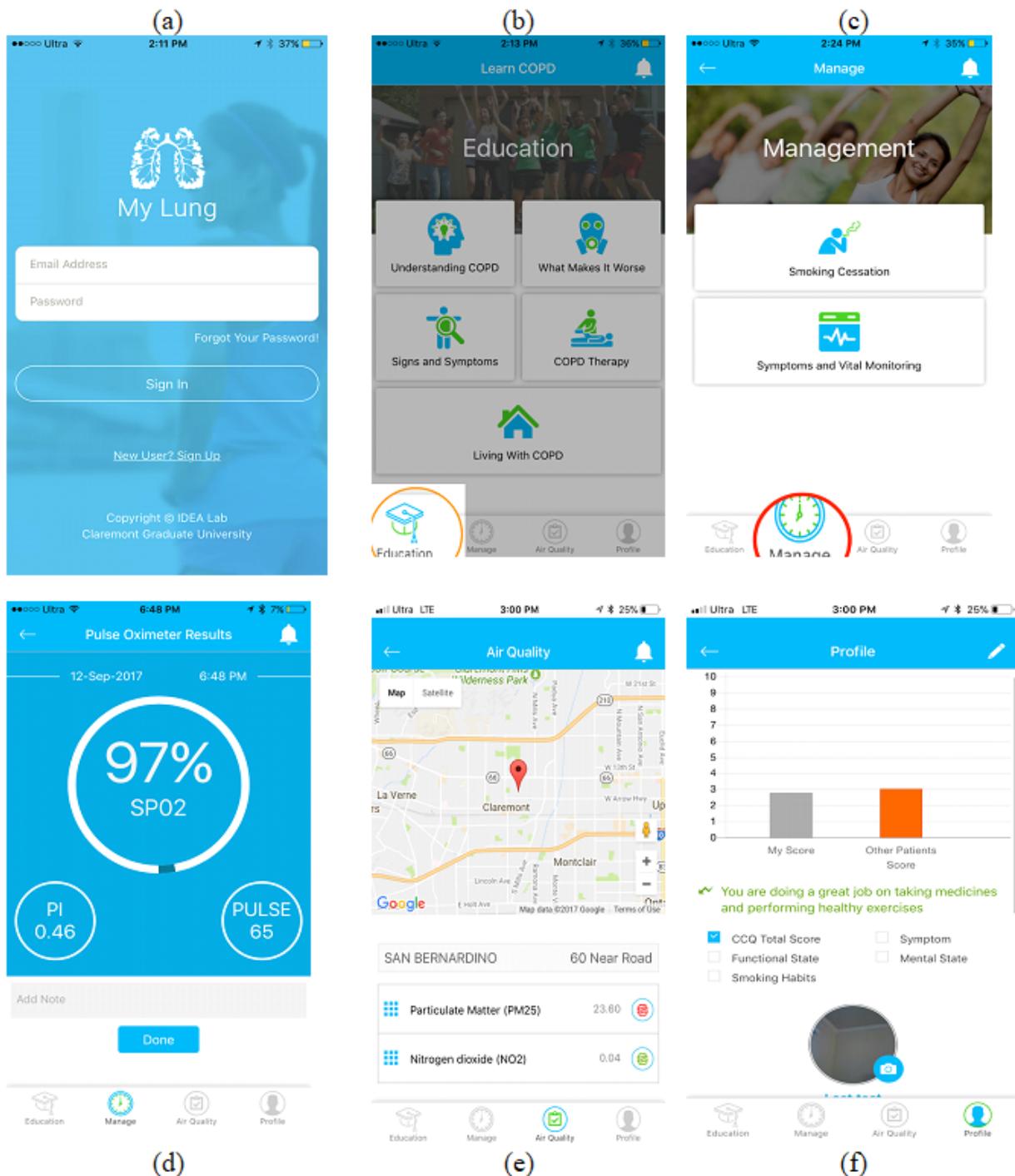
In this section, each of the measurements is explained in detail. The measurements include the level of understanding, perceived severity, self-efficacy, and behavioral intention. The scales used for those measurements are derived from validated instruments.

Perceived Awareness

To measure the change in the level of awareness about COPD, an existing, validated questionnaire was adapted. The understanding COPD questionnaire (UCOPD) assesses patients' understanding of COPD including their recognition of COPD exacerbations [17]. The instrument includes six items designed to assess patients' perceptions of COPD. The items are rated on a Likert-type 5-point scale for each response (strongly disagree=1, disagree=2, neither agree nor disagree=3, agree=4, and strongly agree=5). The mean score for the responses of those six items was computed and used for the analysis.

Self-Efficacy

“Self-efficacy” is one of the HBM determinants that explains behavioral intention. The construct reflects patients' belief in their ability to perform behavioral tasks such as physical exercises. In this study, we selected 10 measurement items from a validated and reliable COPD self-efficacy scale described by Wigal et al [18] to measure the self-efficacy level. We selected those items because they show high factor loading. In the context of COPD, the measurement of self-efficacy determines how confident patients are in managing their breathing difficulty or avoiding breathing difficulty in different situations. The items are rated with a 7-point Likert scale (from extremely uncomfortable=1 to extremely comfortable=7). The mean score for the responses of those 10 items was computed and used for the analysis.

Figure 2. Screenshots from the MyLung mobile app.

Perceived Severity

“Perceived severity” reflects how patients perceive the consequences of COPD. Perceived severity is measured using a scale adapted from the HBM instrument by Champion [19]. The instrument determines a patient’s level of perceiving the seriousness of COPD. The instrument includes eight items rated on a 5-point Likert scale (from strongly disagree=1 to strongly agree=5). The mean score for the responses of those eight items was computed and used for the analysis.

Behavioral Intention

Behavioral intention toward self-care is reflected from the patient’s engagement in performing physical exercises and his/her intention to avoid related risk factors (eg, avoiding outdoor pollution). Behavioral intention is measured using a 1-item scale: “I intended to engage in the COPD recommended behavior.” The response to this item was rated on a 5-point Likert scale (from strongly disagree=1 to strongly agree=5).

Results

The pre-exposure analysis showed that all patients with COPD in the two groups had similar perceptions about COPD, thus indicating that the sample was representative and there was no bias in sample selection (Table 1).

Quantitative Results

The differences before and after use of the MyLung app/booklet are presented in Table 2. The differences between the two groups after use of the MyLung app/booklet are presented in Table 3.

The paired-sample *t* test revealed that the difference in the UCOPD score for the awareness level before and after using the MyLung app was significant in the intervention group as compared to the control group (mean 3.28 vs 4.56; $t_{10}=6.062$; $P<.001$). Similarly, the independent sample *t* test revealed that the difference in the UCOPD score between the intervention group and the control group was significant after using the MyLung app (mean 4.56 vs 3.31; $t_{19}=4.80$; $P<.001$). A paired-sample *t* test revealed that the difference in the self-efficacy score before and after using the MyLung app was significant in the intervention group as compared to the control group (mean 3.11 vs 5.56; $t_{10}=2.96$; $P=.014$). In addition, the independent sample *t* test (Table 3) revealed that the difference in the self-efficacy score after using the MyLung app between the intervention group and the control group was significant (mean 5.56 vs 3.66; $t_{19}=2.8$; $P<.012$). Although there were marginal differences in the perceived severity score between groups before and after using the app, statistical analysis showed that the difference between the mean scores was not significant. As shown in Table 2, a paired-sample *t* test revealed that the difference in the perceived severity score before and after using the MyLung app in the intervention group was not significant

as compared to the control group (mean 3.03 vs 3.28; $t_{10}=0.540$; $P=.60$). Similarly, the independent sample *t* test (Table 3) revealed that the difference in the perceived severity score after using the MyLung app between the intervention group and the control group was not significant (mean 3.28 vs 2.96, $t_{19}=0.864$, $P=.39$). As seen in Table 2, a paired-sample *t* test revealed that the difference in the behavioral intention score before and after using the MyLung app in the intervention group was significant as compared to the control group (mean 2.91 vs 4.55; $t_{10}=3.212$; $P=.009$). However, the independent samples *t* test (Table 3) showed that the difference in behavioral intention score after using the MyLung app between the intervention group and the control group was not significant (mean 4.55 vs 3.60; $t_{19}=2.05$; $P=.054$). This result might be related to the small number of subjects included in the study. Additionally, Table 2 reveals that there was no significant difference in all measurements before and after receiving the booklet-based training (control group). This result concludes that booklets have no impact on patients' awareness and behavioral determinants.

Qualitative Results

Overview

We conducted a qualitative thematic analysis to extract key themes from the qualitative data. Braun and Clarke [20] defined thematic analysis as a process of identifying meaningful patterns from qualitative data. Each pattern relates to a theme that is built using the process of coding interview transcripts [20]. Thematic analysis is used in information systems research for different purposes. Information systems researchers adapt thematic analysis to understand interesting phenomena related to information systems [21]. Additionally, thematic analysis is used in the design science paradigm to evaluate the effectiveness of information technology artifacts [22,23].

Table 1. Pre-exposure analysis comparing patients' perceptions between the intervention group and control group.

Measure	Intervention group (n=11), mean score	Control group (n=10), mean score	Mean difference	Levene test		<i>t</i> test	
				$F_{2,19}$	<i>P</i> value	<i>t</i>	<i>P</i> value (two-tailed)
Awareness level	3.28	3.33	0.05	5.86	<.01	0.2	.84
Self-efficacy	3.11	4	0.89	3.6	.07	1.57	.13
Perceived severity	3.03	2.52	0.49	2.72	.11	1.82	.08
Behavioral intention	2.91	3.1	0.19	1.11	.30	0.39	.70

Table 2. Pre-post comparisons within groups.

Measure	Control (n=10), mean score				Intervention (n=11), mean score			
	Before	After	Difference	<i>P</i> value	Before	After	Difference	<i>P</i> value
Awareness level	3.33	3.31	0.02	.95	3.28	4.56	1.28	.001 ^a
Self-efficacy	4	3.66	0.34	.34	3.11	5.56	2.45	.014 ^a
Perceived severity	2.52	2.95	0.43	.43	3.03	3.28	0.25	.60
Behavioral intention	3.1	3.6	0.5	.50	2.91	4.55	1.64	.009 ^a

^aThese values are significant.

Table 3. Comparison between groups on postsurvey measurements.

Measure	Intervention group (n=11), mean score	Control group (n=10), mean score	Mean difference	Levene test		t test	
				F _{2,19}	P value	t	P value (two-tailed)
Awareness level	4.56	3.31	1.25	3.77	.07	4.79	.001 ^a
Self-efficacy	5.56	3.66	1.9	1.62	.22	2.78	.01 ^a
Perceived severity	3.28	2.95	0.33	1.23	.28	0.86	.40
Behavioral intention	4.55	3.6	0.95	4.32	.051	2.05	.054

^aThese values are significant.

Four patients participated in our qualitative study. We started the first semistructured interview with Participant 13 and analyzed the transcript of this interview. The finding from the analysis led to the subsequent interview with Participant 3 who revealed more insights for the app's usability. Subsequently, we conducted two more semistructured interviews with Participants 6 and 14. We stopped conducting more interviews when the saturation point was reached. This saturation point indicated that no more insights were being generated and all emerging concepts were fully explored [24]. The process of analysis started by coding the interview transcripts using a computer-assisted qualitative data analysis system, NVivo (QSR International, Melbourne, Australia). In this study, the coding started by capturing information related to a patient's empowerment and user experience. We then related and categorized codes that emerged into subthemes to obtain a comprehensive view of the information. Finally, we related subthemes to each other and defined a theme for each subtheme category. This process ended by identifying four themes: patient empowerment, quality of life, user experience, and perceived seriousness.

Patient Empowerment

Patient empowerment refers to the process of seeking knowledge about patients' health and motivating them to take responsibility for their own health [25]. Patient empowerment can be established by increasing patients' attention to their COPD symptoms. One participant noted that his attention to COPD symptoms increased after using the MyLung app.

It [the app] helped me to pay a little more attention to the symptoms. I am the type that will just ignore them. [P14]

The MyLung app not only increases patients' attention to their COPD symptoms, but also influences caregivers' attention in order to avoid imminent COPD episodes.

Yeah, it was kind of giving me a warning to kind of pay attention. I had two days of that, and that was the first two days I put him on his antibiotic, and then it stopped giving the warnings after he started to feel a little bit better. [P14]

Because of the decline in their daily activity, patients with COPD are socially isolated. The MyLung app encourages caregivers to be more proactive and provide support to their loved ones. The results show that when caregivers interact with the MyLung dashboard, they feel closer to their patients.

I've dealt with a lot of health issues with both...both my husband and my dad...and honestly, this is the scariest one, and so it was nice to go back...When he started not feeling good, I'm looking through everything you had on there. [P14]

Patients can be empowered by their COPD physicians through education, counseling, and patient-centered care [26]. Moreover, the COPD physician can empower patients with an early health decision before a COPD exacerbation occurs. This decision can be delivered through a dashboard that presents patients' symptoms and vitals to the COPD physician. Patients with COPD feel empowered when a COPD physician receives their information daily.

[I]f my doctor was receiving that information, that kind of made me feel a little better. You know, like if he was to see something that wasn't normal, or if something was too high or too low. [P6]

Patients with COPD can evaluate their progress in comparison with other patients by tapping on the profile feature in the MyLung app. When a COPD patient is empowered by information about other patients' progress, he/she will be persuaded to change his/her lifestyle [11].

I liked the profile, overall, because it helped me to see kind of where I was at, at least in comparison to other people. [P3]

One participant described how the profile feature aided her in evaluating her progress.

I notice that...my symptoms a lot of times were a little bit worse than others, but...always...[my] mental state, overall, was always better than others. [P14]

Health-Related Quality of Life

By using the MyLung app, health-related quality of life can be improved for patients with COPD. Health-related quality of life is an outcome that can be determined by patient's behavior regarding self-management activities. According to Bourbeau [27], behavioral change is considered a major factor for improving health outcomes in patients with COPD.

One participant explained how she changed her behavior to avoid outdoor air pollution.

I try to stay inside. Well, I'm not outside a whole lot anyway, but yeah, if it's in red I just try to stay inside more than I normally would. [P6]

Another patient with COPD changed her health lifestyle after using the MyLung app. She modified her dietary habits and performed more breathing exercises.

Things you didn't know before, you learn, and you can apply them...eating healthier, number one. [And], trying to exercise more. [P3]

Health-related quality of life can also be determined by the outcome of the patient's symptoms. A patient noticed an improvement in her breathing capacity, which was enabled by avoiding risk factors and engaging in breathing exercises provided by the MyLung app.

It [the app] helps me with my breathing... [P6]

Similarly, another patient noticed that her COPD symptoms decreased after taking the medication. The notification messages sent to her indicated that her symptom state was higher than normal.

The only thing that has changed is the cough. That decreased a lot once I got the medication. That's why I changed to that one. [P13]

User Experience

User experience occurs when a patient interacts with the app. User experience is defined as the consequence of user expectation of system services within which the interaction occurs, including pleasure and enjoyment [28,29].

As noted above, most patients who use the app are elderly. Thus, an intuitive design can help patients access educational information with the least effort and complete entering their COPD symptoms quickly. Therefore, we ensured that the user experience involved tapping through as few screens as possible.

[T]he education part was the least complicated because everything was just right there. [P14]

Although Participant 14 faced some issues in connecting the pulse oximeter device to the app, his overall experience with the app's usability was positive.

I think overall, it was easy to use. The only issue [I] ever had was sometimes connecting the device on the finger to the thing. It took a while. Sometimes going in and out, to connect. But other than that, it was very easy to use. [P14]

The intuitive design led to patient satisfaction with the app content, practicality, and educational module that comprised of texts and videos.

...it's good educational-wise for people with COPD, so you learn things that you didn't know before. I just thought it was a good...I think it's a good app. [P3]

They're [app features] very helpful and I was very satisfied. [P6]

Educational information is delivered to the patients with COPD in many ways to ensure they have reusable content. The app content includes texts, images, and videos and has been organized in the way patients want or need to consume information. One participant explained how she benefited from educational tips by applying them to managing her conditions.

[In]the educational parts, you can go back and watch the educational part and it'll give you tips as to how to manage your breathing, what to do, you know, for COPD exacerbation if you're not knowledgeable, and use those tips and kind of monitor, and use the tips, and they're helpful like that. [P3]

Moreover, patients' experience with the app's usability can be evaluated by having effective notification messages that warn patients before a COPD exacerbation occurs. These messages can guide patients and their caregivers to take action.

...it [the notification message] helps me monitor my oxygen, and it just seems to be very helpful. [P3]

Well, I definitely like the warning because at least I know to keep a closer eye... [P14]

Although most patients with COPD were satisfied with the app, two patients encountered some challenges using the pulse oximeter device. These challenges related to both Bluetooth connectivity and reading precision. Occasionally, Participant 14 faced some issues connecting the pulse oximeter device to the app.

The only issue [I] ever had was sometimes connecting the device on the finger to the thing. It took a while. Sometimes going in and out, to connect. [P14]

Female patients who were wearing nail polish might have received inaccurate readings from the pulse device, as nail polish can be problematic for obtaining a reliable reading, particularly for patients with COPD who are wearing black, green, or blue nail polish [30]. Over the course of time, one patient using MyLung noticed that her SpO₂ values were not accurately reflected when she was wearing nail polish. She thought the pulse oximeter device did not work properly.

Well sometimes it doesn't work if you have fingernail polish on...Not annoying, you just have to maneuver your finger. [P3]

Perceived Seriousness

Patients perceive the seriousness of COPD when they believe that it is life threatening. The consequences of the disease can have a bearing on the quality of life and economic impacts, among other aspects. Perceived severity is a key construct of the HBM. This construct was used in the quantitative study to measure the effectiveness of the MyLung app, as it explains how patients with COPD achieve higher levels of understanding of the seriousness of risks after using the MyLung app. Although the quantitative study showed that using the MyLung had no effect on perceived severity, qualitative interviews were able to gather insight into patients' perception of disease seriousness.

Patients can respond to the seriousness of the disease by avoiding risk factors that threaten their lives. Participant 6 explained how the MyLung app increased her attention toward outdoor pollution.

Well, I mean...like, if the air is bad just to stay out of it. [P6]

Patients also perceived the seriousness of the disease from economic impacts. Patients were afraid of losing their jobs.

Patients also began to worry about the increasing cost of health insurance coverage.

I got the intentions to stop, for a couple of reasons. My health and also my insurance. If I stop smoking, then my insurance will go down. [P13]

Discussion

This research study designs and evaluates an assistive technology for patients with COPD to increase awareness levels and engage patients in self-care management activities. The assistive technology aims to inform patients about the risk factors of COPD and to improve access to relevant information. Integrating the findings from quantitative and qualitative analyses led to inferences that described the impact of the design in a comprehensive way. These inferences are referred to as “meta-inferences” [31,32]. According to Venkatesh et al [31], meta-inferences are defined as “the theoretical statements, narratives, or a study inferred from an integration of findings from quantitative and qualitative strands of mixed methods research.” In this study, the inferences that emerged are generalized statements that can be adapted by other researchers interested in assistive technology in respiratory diseases. For enhancement of meta-inferences, we developed the quantitative inferences first and the qualitative inferences second. The results show a great deal of convergence between the quantitative and qualitative inferences, but also reveal some inconsistent findings. Overall, themes that emerged from the qualitative analysis were found to be compatible with the quantitative findings. We found

that the design of the MyLung app empowered patients with tools that led to improving their quality of life and increased their intentions in health behavioral tasks. We found that the MyLung app is useable, and patients were satisfied with the app experience. Although the perceived severity of COPD was not significant in the quantitative study, the qualitative analysis revealed a contrasting result: Patients with COPD perceived the severity of the disease when they believed that the consequences of COPD would threaten their life. In addition, the qualitative results provided evidence to show that patients are concerned about the financial burden caused by disease treatment. Considering the integrated findings or inferences from both analyses, we arrived at the following meta-inferences: (1) The design of assistive technology for patients with COPD will empower patients with a mechanism that improves patients’ quality of life and increase patients’ intention toward health behavioral tasks. (2) The design of assistive technology for patients with COPD is technically usable.

Our findings and meta-inferences have implications for assistive technology design, research on chronic condition management, and health care. The results of this study can inform research on health information design. Meta-inferences act as propositions that give researchers a useful starting point and direction for future research to understand and investigate phenomena related to research in chronic disease management information systems. Researchers should investigate the role of design in integrative mobile-based technology for patient empowerment and health outcomes.

Conflicts of Interest

None declared.

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Abbreviations

BCSS: behavioral change-support system

COPD: chronic obstructive pulmonary disease

HBM: health belief model

mHealth: mobile health

SpO₂: peripheral capillary oxygen saturation

UCOPD: understanding chronic obstructive pulmonary disease

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Original Paper

Development of PositiveLinks: A Mobile Phone App to Promote Linkage and Retention in Care for People With HIV

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Abstract

Background: Linkage to and retention in HIV care are challenging, especially in the Southeastern United States. The rise in mobile phone app use and the potential for an app to deliver *just in time* messaging provides a new opportunity to improve linkage and retention among people living with HIV (PLWH).

Objective: This study aimed to develop an app to engage, link, and retain people in care. We evaluated the acceptability, feasibility, and impact of the app among users.

Methods: App development was informed by principles of chronic disease self-management and formative interviews with PLWH. Once developed, the app was distributed among participants, and usability feedback was incorporated in subsequent iterations. We interviewed app users after 3 weeks to identify usability issues, need for training on the phone or app, and to assess acceptability. We tracked and analyzed usage of app features for the cohort over 2 years.

Results: A total of 77 participants used the app during the pilot study. The query response rate for the first 2 years was 47.7%. Query response declined at a rate of 0.67% per month. The community message board was the most popular feature, and 77.9% (60/77) of users posted on the board at least once during the 2 years.

Conclusions: The PositiveLinks app was feasible and acceptable among nonurban PLWH. High participation on the community message board suggests that social support from peers is important for people recently diagnosed with or returning to care for HIV.

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KEYWORDS

mHealth; HIV; treatment adherence and compliance; retention in care

Introduction

Background

HIV treatment has markedly improved in the United States over the last 20 years, and morbidity and mortality have declined as a result. Although effective treatments are available, not

everyone with HIV consistently accesses care. Estimates suggest that of the 1.1 million people living with HIV (PLWH) in the United States, 85% are diagnosed, 62% are linked to medical care, and 49% maintain a nondetectable viral load [1]. These gaps in the cascade of HIV treatment are related to poorer clinical outcomes. Patients who *no-show* at visits within the first 2 years of initiating care fail to achieve virologic

suppression as quickly as those who keep all appointments [2-4]. Delayed linkage to care, missed visits, and poor retention are associated with increased morbidity and mortality for PLWH and increase the risk of new infections [5-7].

High initial contact and enhanced personal contact improve visit constancy and adherence and reduce the likelihood of a substantial gap in HIV primary care during the first 12 months of follow-up [8,9]. Frequent contact with new patients may help reduce the perceived stigma of HIV and structural barriers to health care [8-10]. Social support also plays an important role in retention in care and clinical outcomes. With perceived social support, PLWH have improved physical and mental health and are more likely to achieve viral suppression than those without social support [11,12]. However, social support can be challenging to access, especially in rural areas. In the United States, the HIV epidemic has shifted away from concentrated urban centers to nonurban areas in the southeast [13,14]. Factors prevalent in this region and disproportionately affecting HIV prevention efforts—as well as linkage and access to health care—include poor health infrastructure, lack of health insurance, unique demographic and racial characteristics, high rates of other sexually transmitted infections, poverty, and low access to affordable housing [15-17]. Mobile health (mHealth) interventions provide a platform that can efficiently deliver evidence-based practices for linkage to and retention in care to harder-to-reach populations. Mobile technology is particularly well-suited to deliver ecological momentary assessments (EMAs) and interventions, which reach people in their everyday lives and natural settings in *real time* [18]. Such interventions have been feasible, acceptable, and efficacious in a variety of chronic disease management and health promotion contexts such as diabetes care and smoking cessation [19]. Text messaging interventions can promote health behavior change, treatment adherence, appointment attendance, and better patient outcomes in many chronic diseases [20-22]. In HIV care, text messaging interventions have demonstrated improved medication adherence and improved physiologic measures of CD4 counts and viral loads [23-30].

mHealth interventions that are based on mobile phone apps have some advantages over texting, such as richer functionality and enhanced security.

Evidence Gaps

However, many health apps currently available are not rigorously evidence-based [31], including those targeting PLWH [32,33]. Recent research on mHealth interventions places emphasis on user-centered and theory-based design to tailor apps to users' motivations and preferences and to understand device usability [34,35]. Timing messages to correspond to medication dose, individual tailoring of message content or user-based personalization, and sending messages with content designed to evoke a reply from recipients (bidirectional) may lead to better outcomes due to enhanced engagement [25]. PLWH seek reliable information about HIV and other health topics, connection with other PLWH, assistance with medication and appointment reminders, and tools for self-management [36-39]. Other desirable mHealth features include attractive, private, and individualized design, goal setting, motivational

messages, wording that would not inadvertently reveal HIV status, password protection and other security measures, interaction with other participants, and the ability to customize reminders [40]. In addition, technology that can address mental health and emotional needs is particularly important to PLWH [41]. Interventions that provide access to online peer-to-peer support can improve psychological health and empowerment for PLWH and may help address issues of loneliness and stigma [42-44].

Despite the growing evidence for mHealth interventions for PLWH, many gaps remain. In particular, there is a need for (1) more evidence-based and user-centered design; (2) interventions that target hard-to-reach and vulnerable populations; (3) attention to linkage and retention in care; and (4) provision of connection to others while being private and secure [34,45-48]. To address these needs, our team has designed and piloted an mHealth intervention for PLWH called PositiveLinks. To our knowledge, PositiveLinks is unique in specifically targeting linkage and retention in care for PLWH and in reaching a nonurban population in the Southeastern United States. Our prior work showed that PositiveLinks participants demonstrated an improvement in retention in care and viral suppression with 12 months of follow-up [49]. The purpose of this study was to share the process of developing PositiveLinks and to contribute to the literature on how to design evidence-based mHealth interventions tailored for vulnerable target populations.

Methods

Expert Development Phase

The primary goal of PositiveLinks is to improve linkage and retention in HIV care. The intervention aims to accomplish this goal by encouraging self-monitoring of medication adherence, stress, and mood; by providing access to vetted medical information about HIV; and by increasing social support. The development was informed by our team's prior work on text-based mobile interventions, which demonstrated that PLWH respond to bidirectional queries and value tailored messaging to their responses [50,51]. The team also used the emerging mHealth evidence base as well as commonly identified needs among our patient population to design the first version of the app. Key features were designed to promote chronic disease self-management through self-regulation and feedback, just-in-time assistance, and social support. EMAs of medication dosing, mood, stress, and appointment reminders targeted possible behavioral and psychological barriers to care. With access to patient-reported information, PositiveLinks staff members could respond in nearly real time to threats to medication adherence and retention in care. To motivate participants to use the app regularly, we included engaging features such as weekly quiz questions and a community message board. The latter also functions to reinforce social support by peers.

Formative Phase

A total of 17 patients from the University of Virginia Ryan White Clinic provided feedback on the design, desirability, usability, usefulness, and fit in everyday life of app features for nonurban PLWH users. These formative phase participants were

recruited as a convenience sample from the clinic to include demographic characteristics similar to the clinic's patient population. Participants had a mean age of 43.7 years (SD 15.3). Moreover, 59% were male, 35% female, and 6% transgender male to female. In addition, 53% identified as African-American, 35% as white, and 6% as Hispanic. We sought the perspectives of both those recently diagnosed with HIV and those who had been living with HIV for many years to capture varying perceptions of the needs, barriers to engagement, and challenges to medication adherence. Participants also provided input on app features that might help someone newly diagnosed with HIV.

Feedback was elicited with open-ended questions first, followed by a review of preliminary app screenshots. Interviews with participants were audiotaped and transcribed. The transcriptions were summarized in notes by 3 reviewers, and key themes were identified. The reviewers discussed these themes and reached consensus on key input relevant to the design of app features to enhance fit and usability for our clinic population. Participant feedback was sorted by feature and disseminated to the app developer to integrate user input about features and content.

For example, formative participants offered feedback on the dashboard and daily queries and noted their desire to annotate query responses so that they could document triggers, aids, or explanations for entries. Other participants appreciated the opportunity to add notes to their medication reminders. Formative participants also welcomed the idea of the community message board and emphasized the importance of the anonymity as well as the accessibility of support in a phone. Others wanted the message board to discuss and interpret recent news or research about HIV.

After developing the app prototype following the analysis of patient input, we finalized the initial app to be deployed and tested. It included daily queries, a dashboard that displayed self-reported query data, a community message board, and various resources such as HIV-related information and stress management tools (Figure 1).

App Features: Queries and Dashboard

The medication query offered a simple yes-no option, whereas the mood and stress queries used sliding scales with numbers and different images to facilitate accurate, consistent reporting. Participants recorded their mood using a sliding scale from -5 to +5, with -5 representing a negative mood and +5, a positive mood. The stress query used a scale of 1 to 10, with 1 representing a low stress level and 10, a high stress level. The mood and stress queries, designed as EMAs, were sent at random times during patient-identified waking hours and asked participants to report their feelings in the moment. In contrast, participants scheduled when they wished to receive medication reminders to match their own dosing schedule. Participants received weekly quizzes structured so that some questions had correct answers, some were survey-based, and others offered participants the opportunity to reflect on their thoughts or feelings.

After responding to a query, users received an automatic response. PositiveLinks uses an algorithm to determine this

tailored message based on participants' reported stress, mood, or medication adherence. For example, if a participant logged an especially high stress level, they might receive the message, "Remember to breathe deeply." Participants could modify this message text to better suit their interests and motivations.

The dashboard section of the app synthesized participant responses to medication, mood, and stress queries in colorful bar graphs and graphics. The dashboard overview provided each user with a 2-week snapshot of their respective medication adherence, mood, and stress. Users also had the ability to view each response individually and to view data over the last 30 days, 90 days, or a year. These data were also represented in longitudinal bar graphs and a color-coded calendar for medicines (Figure 2).

Participants received weekly summary reports each Wednesday. These were developed in response to user feedback to help with interpretation of the graphs. These reports detailed participants' medication adherence, average mood, and average stress level for the previous week, their individual change from the prior week's averages, and their query response rates. Each summary invited participants to reflect on their adherence, mood, and stress and to reach out to the PositiveLinks team if they would like to discuss their health and wellness goals. Collectively, the mood and stress EMAs, medication reminder, and dashboard features sought to encourage healthy self-monitoring and care management.

App Features: Community Message Board

The community message board allowed users to share and interact with other PositiveLinks app users in a private and anonymized social network. Each participant chose a community handle to protect their anonymity. Participants could start new conversations with each other on the board or respond to older conversations in a thread. The PositiveLinks study team monitored the board for incorrect information or concerning comments. The PositiveLinks team also introduced new conversation topics on HIV or general well-being every Monday (Messaging Mondays) and posted funny videos every Friday (Funny Friday).

Pilot Phase

Enrollment for the pilot phase began in September 2013 and ended in May 2015. Participants were recruited through provider referrals at our local university-based Ryan White Clinic, from local AIDS service organizations, and through an emergency department HIV testing program at the local university hospital. Participants were either newly diagnosed with HIV (within 90 days of enrollment) or were at risk of falling out of care, as determined by their care provider. This assessment was made by providers based on their experience of patients' prior missed appointments, challenges with adherence, or psychosocial barriers that complicated care. Participation was limited to those who achieved a score of 40 or above on the Wide Range Achievement Test (WRAT-4) [52] or passed a subsequent reading test corresponding to an approximately fourth grade level. Participants from the formative phase were allowed to enroll in the pilot phase if they wished to do so.

Figure 1. Screenshots of key app features: a: app home screen; b: medication query; c: mood query; d: appointment page; e: community message board; f: FAQ section.

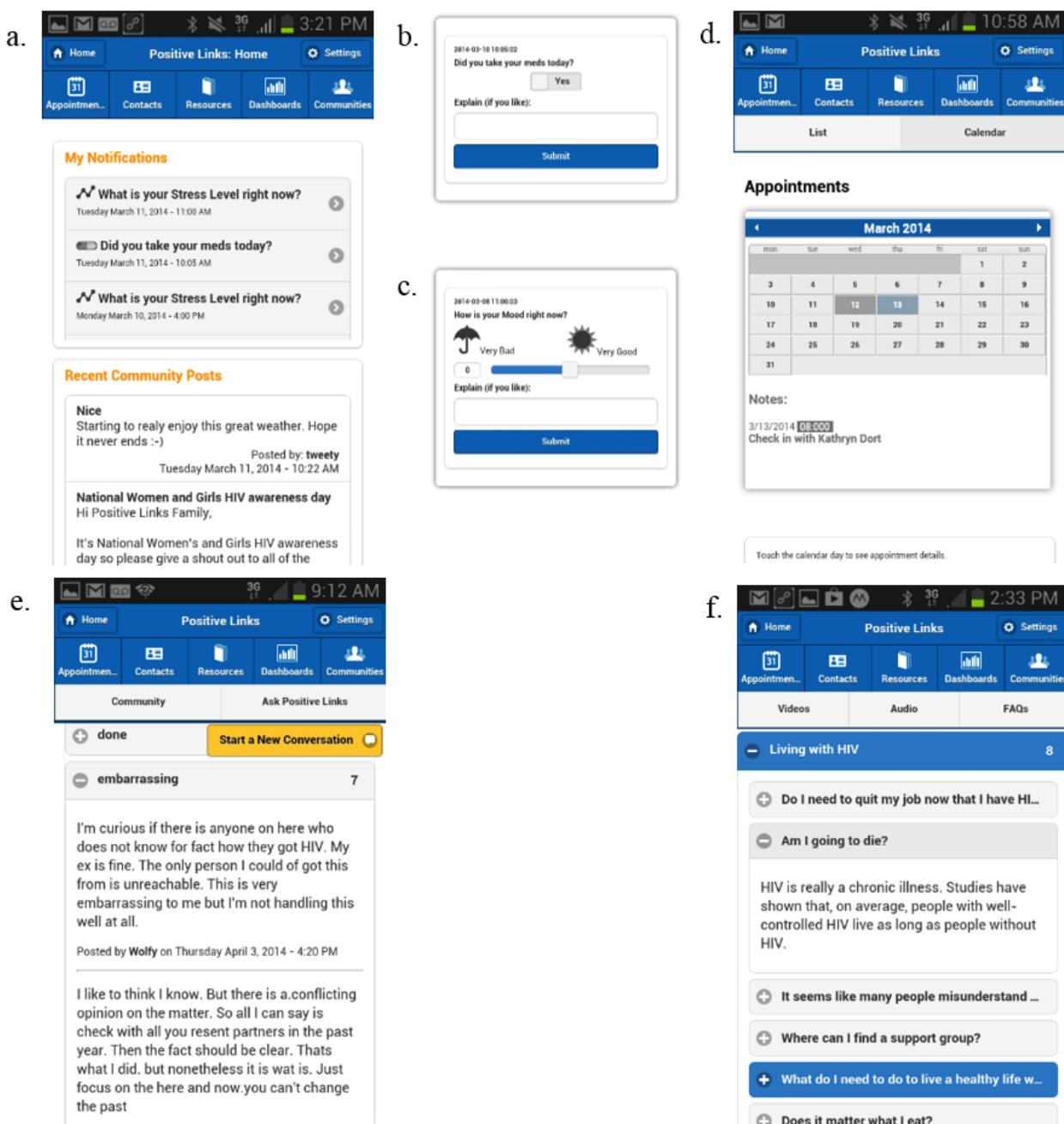


Figure 2. Screen shot of graphs showing mood, stress, and medication tracking: a: dashboard overview; b: medication calendar view; c: mood graph; d: stress graph.



During enrollment, individuals consented to participate in the study, completed the WRAT-4 literacy test, answered baseline questions, and learned how to use a phone and the PositiveLinks app. Participants received either a Samsung Galaxy 2 or Galaxy 3 phone with unlimited minutes, texts, and data for the study year. Although smartphone ownership is high in the United States, our clinic population includes many patients of lower socioeconomic status who do not have access to smartphones. In our experience, lack of reliable phone contact has been a barrier to patient follow-up. Patients were provided with phones to overcome this barrier and give all participants the opportunity to use the app. Providing phones also allowed increased security to prevent potential privacy breaches. Before distributing to participants, the PositiveLinks team encrypted and password-protected the phones and installed a remote locate-and-wipe functionality. The app was also password protected.

Participant Characteristics

At enrollment, participants completed baseline assessments of self-reported demographic information (age, sex, and race/ethnicity), socioeconomic data (employment, education, and insurance status), distance from clinic, and prior cellphone ownership. HIV-specific information included treatment with antiretroviral therapy and self-reported adherence. Mental health measures included substance use, perceived stress [53], HIV-related stigma [54], and social support [55]. The study team collected a viral load from the electronic medical records at baseline for each participant.

App Usage

App usage data included response rates and values for the 3 daily queries for medication, mood, and stress, weekly quiz response rates, and posts to the community message board. These data were calculated monthly for the whole cohort from September 29, 2013, to September 26, 2015. Community board posts were further analyzed based on the number of enrolled members during the month.

User Perceptions of the App

To capture participants' initial impressions of the phone and PositiveLinks app, study coordinators contacted participants 3 weeks after enrollment to conduct usability interviews. In these interviews, the team assessed ease, utility, and attractiveness of the app and elicited feedback on what the participant would change. Coordinators conducted these semistructured interviews on the phone and in-person. Audio files of the interviews were loaded into a database and summary notes, shared with the team. These interviews also provided coordinators with the opportunity to answer any questions that participants might have or troubleshoot technical issues early on in their participation.

Results

Pilot Phase

Participant Characteristics

A total of 77 participants enrolled in the PositiveLinks pilot study between September 25, 2013, and May 28, 2015 (Table 1). Participants' median age was 33 years (range 18 to 57). For male participants, 49% (24/49) reported having sex with men, 31% (15/49) with women, and 16% (8/49) with both. For female

participants, 88% (23/26) reported having sex with men and 4% (1/26) with men and women. Moreover, 49% (38/77) of participants identified as black and non-Hispanic, and 34% (26/77) identified as white and non-Hispanic. A majority of participants 65% (50/77), had a high school equivalent education or lower, and 30% (23/77) attended some college, community college, or more. At baseline, 44% (34/77) of participants were unemployed, and only 25% (19/77) were employed full-time. In addition, 43% (33/77) had public insurance, and 30% (23/77) had no insurance. At enrollment, 73% (56/77) owned a mobile phone, and 66% (37/56) of those currently owning mobile phones had smartphones.

Participants had been diagnosed with HIV for an average of 60 months at the time of enrollment (median 1.7 years [SD 6.3]), and 47% (36/77) were virally suppressed (<200 copies/ml). Of the 77 participants in the pilot phase, 17 were new to care, defined as being diagnosed with HIV less than 90 days before enrollment in the study. Of the 55 participants on antiretroviral medication at baseline, 16% (9/55) reported missing a dose that past weekend. Half of participants reported using noninjection drugs in the past 12 months (38/77), but very few reported injection drug use in the last 12 months (5/77, 7%). Nearly half, 47% (36/77), reported binge drinking in the past 12 months (4 drinks in a sitting for women and 5 drinks for men).

App Usage

In the first 2 years of the pilot study, participants responded to 48% (46,457/97,198) of sent daily queries (Table 2). Medication adherence, excluding nonresponses, was reported as 94% (14,837 affirmative responses/15,825 total responses) during this 2-year pilot. Nonresponses were not included in adherence

assessment because we could not reliably determine if nonresponse corresponded to a missed dose or only a missed query. Average participant mood was 1.49 (SD 2.95), and average stress was 2.95 (SD 2.36). Response rate for quizzes was 45.3% (1997/4411).

Participants used the notes feature on their medication, mood, and stress queries only 3.5% (1643/46,457) of the times they responded to questions. Notes in their medication responses included explanations such as “Almost missed it because of meetings” or encouragement, “Every morning like washing my face!” or “Always!!! They r my lifeline.” For stress query notes, participants referenced certain stressors such as rent, landlords, disclosure of status, and taking their medications. Notes included in mood responses covered a broad spectrum of emotion and depth—from short, celebratory notes (“Getting my GED”; “My hubby is coming home”) to more reflective comments. A week after learning of his HIV diagnosis, a newly-diagnosed participant wrote:

Feeling normal. At least for the meantime. Still a worried about so much but having a new phone is making the blow a little lighter.

The PositiveLinks community message board was a widely used app feature (2073 posts in 2 years), though participation varied over time and by user. Moreover, 60/77 participants (78%) posted on the board at least once, and many participants noted in usability interviews that they followed the message board even if they never posted themselves. Average community message board posts per enrolled member was 2.2 per month (SD 1.7), whereas average posts per poster was 5 per month (SD 2.7).

Table 1. Participant characteristics for the pilot phase.

Demographic characteristics	Statistics (N=77)
Age (years), mean (SD)	36 (11.7)
Gender, n (%)	
Male	49 (64)
Female	26 (34)
Transgender male-to-female	2 (3)
Race/ethnicity, n (%)	
Black, non-Hispanic	38 (49)
White, non-Hispanic	26 (34)
Hispanic	6 (8)
Other	6 (8)
Refused	1 (1)
Education completed, n (%)	
Less than high school	15 (20)
GED ^a or high school graduate	35 (46)
Trade, technical training, or community college	6 (8)
Some college	15 (20)
College graduate	6 (8)
Employment, n (%)	
Full-time	19 (25)
Part-time	10 (13)
Disabled	9 (12)
Unemployed	34 (44)
Other	5 (7)
Insurance, n (%)	
Public (Medicare or Medicaid)	33 (43)
Private	16 (21)
None	23 (30)
Other	5 (7)
Percentage of federal poverty level, n (%)	
0	34 (44)
1-100	23 (30)
101-200	16 (21)
201-300	3 (4)
Over 300	1 (1)
WRAT ^b literacy score, mean (SD)	55 (9.1)
Mobile phone exposure	
Own a mobile phone at baseline, n (%)	56 (73)
If yes, is it a smartphone? (N=56), n (%)	
If yes, is it an Android (N=37)	27 (73)
If yes, is it an iPhone (N=37)	9 (24)
HIV health, n (%)	

Demographic characteristics	Statistics (N=77)
Currently taking antiretroviral medication	55 (71)
If yes, missed doses past weekend? (N=55)	9 (16)
Viral load suppression (<200 copies/ml)	36 (47)
Substance use, n (%)	
Past 12 months–non injection drug use	38 (49)
Past 12 months–injection drug use	5 (7)
Smoke cigarettes at present	42 (55)
Last time you binge drank, n (%)	
Never	17 (22)
In the past year	36 (47)
Over a year ago	24 (31)
Mental health	
Perceived Stress Score, mean (SD), (PSS10, range 0-40)	30 (8.8)
Berger Stigma Scale, n (%)	
Low Stigma (41-80)	10 (13)
Moderate Stigma (81-120)	56 (73)
High Stigma (121-160)	11 (14)
Social support appraisal, mean (SD), (SS-A, range 23-71)	48 (29.2)

^aGED: General Education Development.

^bWRAT: Wide Range Achievement Test.

Table 2. Descriptive statistics of app usage over the first 2 years of the pilot study.

App usage by feature	Statistics
Total queries	97,198
Total query responses, n (%)	46,457 (47.8)
Medication queries	32,701
Medication responses, n (%)	15,825 (58.4)
Medication responses with notes, n (%)	503 (3.2)
Affirmative responses, n (%)	14,837 (93.8)
Negative responses, n (%)	988 (6.2)
Mood queries	32,304
Mood responses, n (%)	15,346 (47.5)
Mood responses with notes, n (%)	578 (3.8)
Stress queries	32,193
Stress responses, n (%)	15,286 (47.5)
Stress responses with notes, n (%)	562 (3.7)
Quizzes	4411
Quiz responses, n (%)	1997 (45.3)
Total community message board posts	2073
Unique posters (N=77), n (%)	60 (78)
Monthly posts per enrolled member, mean (SD)	2.2 (1.7)
Monthly posts per poster, mean (SD)	5.0 (2.7)

Participants' app engagement declined slightly over time during the first 2 years of the pilot study. Query response rates declined at an average rate of 0.71% each month. For the first 6 months of the pilot study, the cohort response rate was 56.2% (SD 14.6); however, this rate decreased to 40.7% (SD 6.6) in the last 6 months. Community message board usage peaked at 6.9 posts per enrolled member per month during month 4 of the pilot study and decreased at an average rate of 0.15 posts per enrolled member per month (Figure 3). Graphs are summarized in 4-week

Figure 3. Graphs of cohort engagement over the first 2 years of the pilot study: a. monthly query response rates; b. community board usage per enrolled member.

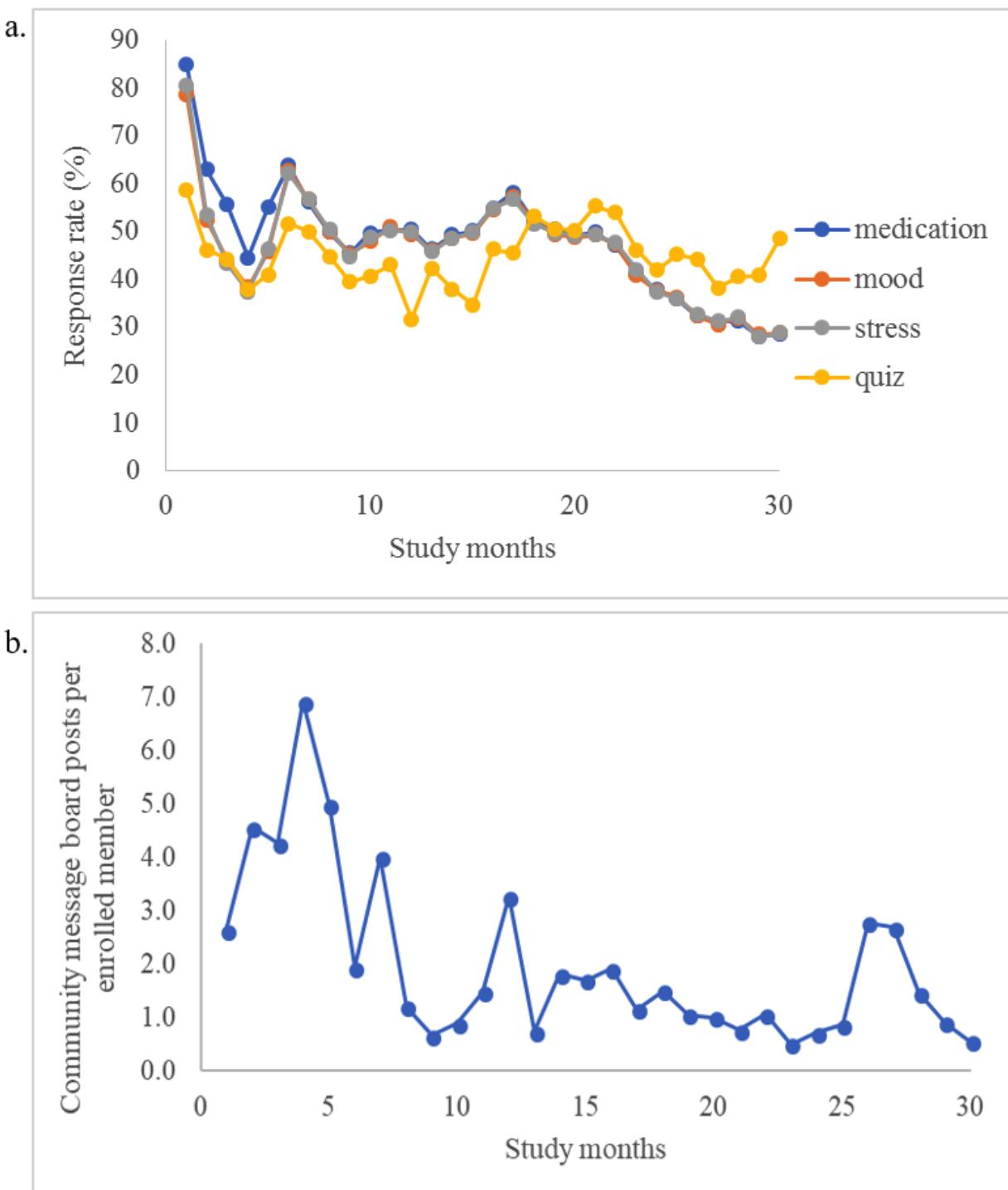
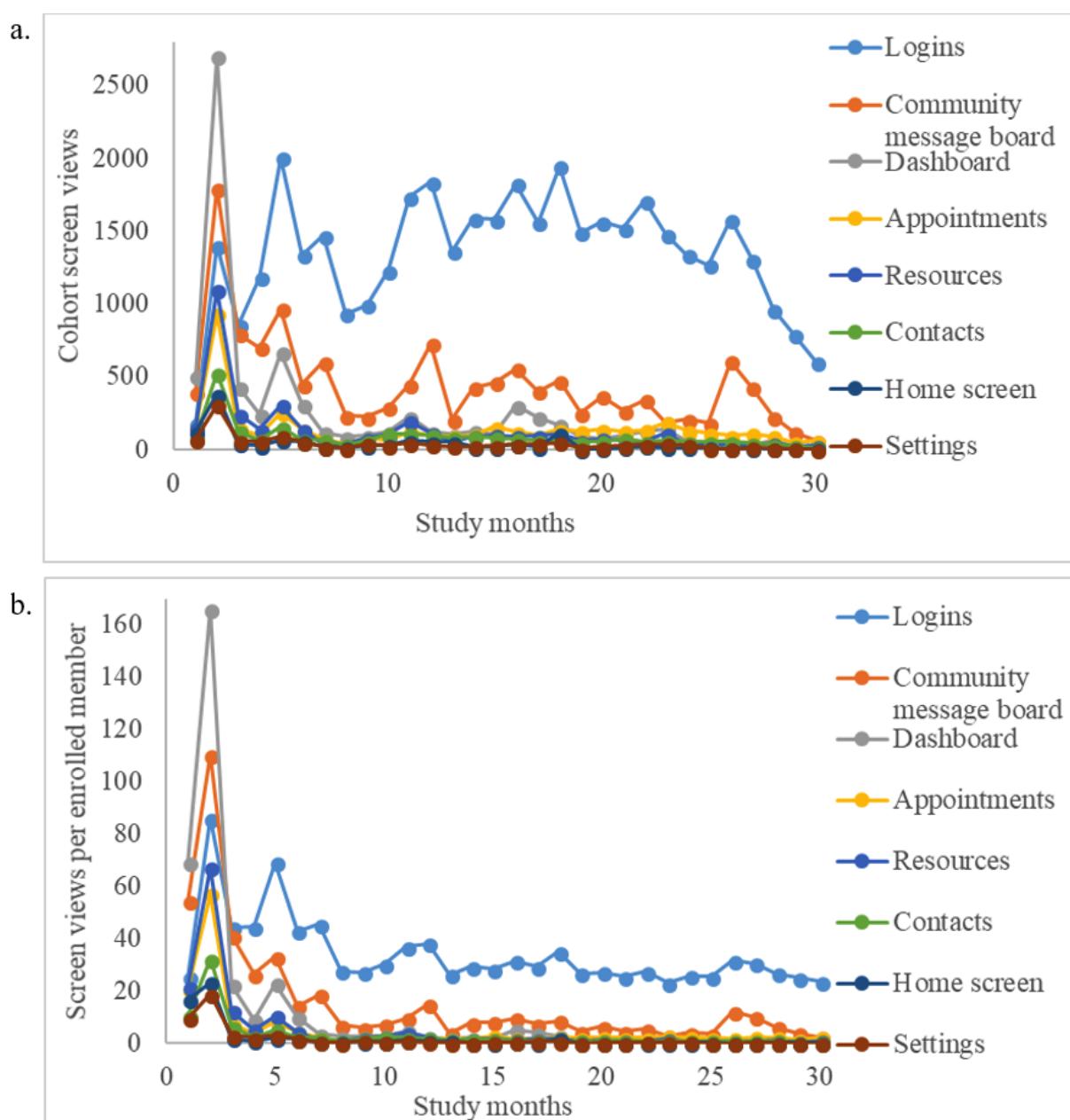


Figure 4. Cohort screen views over the first 2 years of the pilot study: a: monthly screen views for the cohort; b: monthly screen views per enrolled member.



User Perceptions of the App

Overall Usability

The majority of participants who completed the usability interviews (49/55, 91%) reported that the app was easy to use. When usability interviews identified users having difficulty navigating certain features, such as not knowing where the resources section was or not realizing they could customize their automatic reply messages, the interviewer provided additional training to those users. Other issues identified were users having trouble signing into the app when they had a weak Wi-Fi signal or having trouble with video links. Issues related to app usability, such as difficulty scrolling through notifications, were addressed by the development team. Users

could also contact the PositiveLinks team at any time about technical difficulties as they occurred, such as cracked screens or connection problems, and receive assistance.

Queries and Dashboard

In the usability interviews, participants reported that tracking mood and stress provided an opportunity to reflect on sources of variability (either positive or negative) and, potentially, to modify them. The dashboard allowed participants to visualize trends over time and consider possible explanations for these trends. As one participant observed, “when I have high stress levels I can go back and look and reflect on what I coulda done different that day and you know what was I dealing with at that moment.” Many participants used the app’s medication query as a reminder and as motivation to take medications. In addition,

one participant stated, “after a while you get tired of taking pills and stuff but it just like a nice reminder...it’s been encouraging me to or reminding me that I need to take better care of myself.”

Community Message Board

The community message board fostered lively discussions. Prior qualitative analysis showed that the majority of posts by participants (62%) contained psychosocial content, such as discussion of stressors, coping strategies, and relationships; 29% of posts contained community chat; and 10% of posts contained biomedical content, such as discussion of medications [56]. Prior analysis of social support on the community board has revealed that in 52% of posts, participants were providing social support to each other, and 64% of participants regarded connection with others living with HIV as a key benefit of the app [57].

Of the community message board messages, 11% were posted by the PositiveLinks team regarding announcements about clinic events, updates to the app, news and information about HIV, funny videos, and uplifting or inspirational messages. Moreover, 2 threads on the community message board involved a participant expressing suicidal thoughts, which were addressed by responses from other participants and the PositiveLinks team reaching out to the poster. Follow-up posts from the PositiveLinks team shared resources for dealing with stress and mental health concerns. Three threads involved issues of privacy as participants expressed the desire to meet in person or share contact information. The PositiveLinks team responded with reminders that the community remains anonymous to protect all members’ privacy and discussion of other ways to meet, such as support groups or clinic events. The PositiveLinks team also addressed misinformation on the community message board in 5 posts and answered specific questions in 4 posts.

In usability interviews, participants shared that the community message board connected them to people going through similar situations and provided a sense of not being alone. For example, “You know getting to see other people’s perspective on life, let me know that I’m not going through this by myself, there is other people out there like me, it’s good.” There was a reciprocal relationship on the community message board between giving and receiving support. For many participants, the community felt like having a family who understood them, “You get to talk to people who are going through exactly what you are going through. When you are down somebody uplifts you, when somebody else is down you can uplift them, it’s basically like one big family.”

Connection to Care

Participants reported that using the app made them feel more connected to HIV care and more motivated to be consistently in care. One stated, “I feel closer, I feel like I’m more involved.”

Those who were new to care or returning after a lapse could use the app to overcome barriers to care, such as social isolation and lack of knowledge about HIV care. For example, “It makes me more aware and...has opened my eyes that I’m not alone” and “I know more I guess...just know what to expect.” The app also provided practical assistance in setting reminders about appointments. For example, “I like going into the app, it helps me make sure that I’m doing what I need to do and keeping track of my medications and I actually used it to remind myself that I had the appointment today because I would have totally forgotten.” In addition, one participant summarized the perceived impact of multiple features of PositiveLinks:

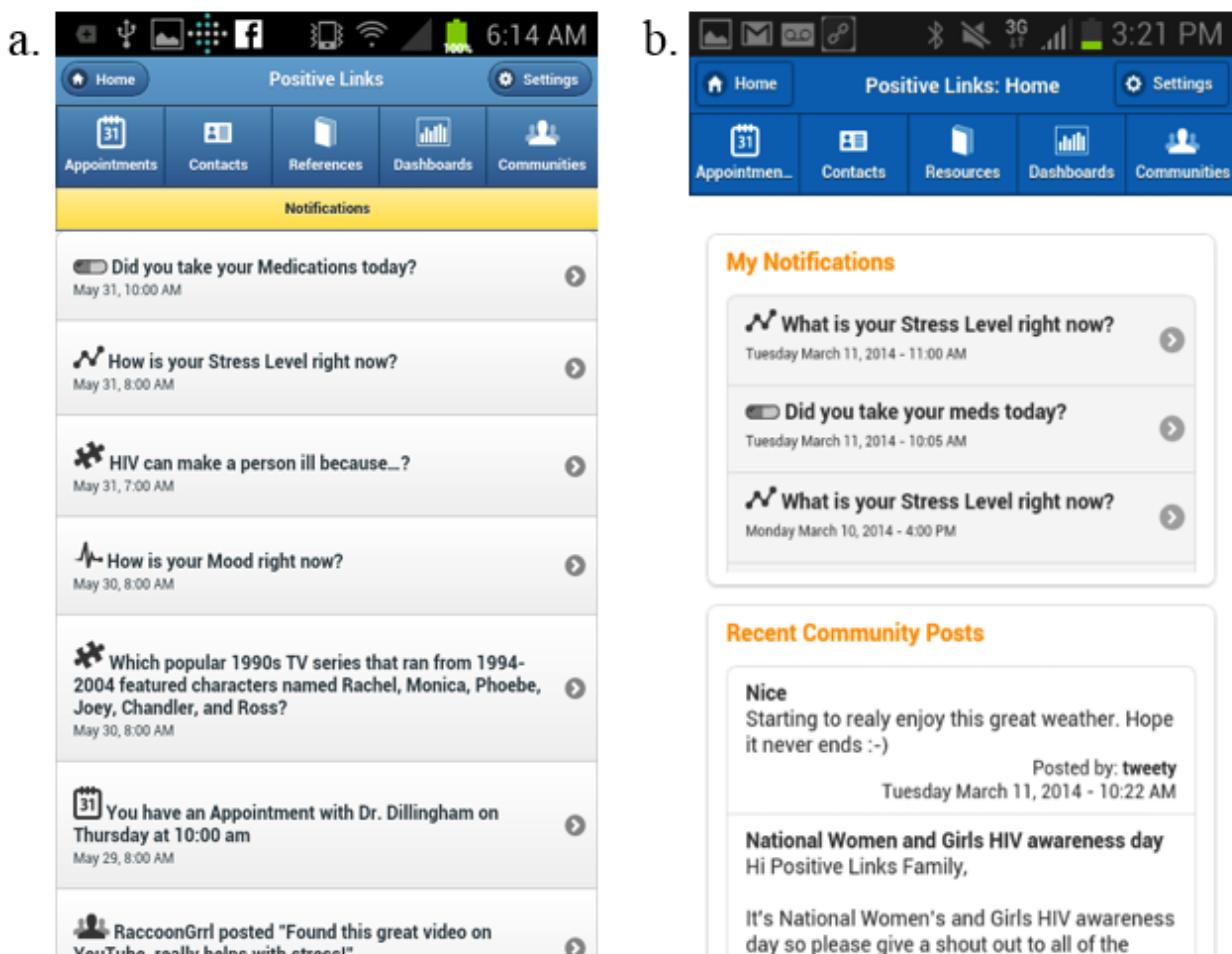
I just know that if it wasn’t for the app or the phone, I probably wouldn’t be here today. I would probably have given up. I wouldn’t be taking my meds. When I have not taken my meds in the past, I would give up. But I keep up with my appointments. I come to my appointments. I’m here today. I take my meds frequently.

User-Driven Iteration of App Development

Participant usability interviews and feedback, as well as app data, helped the research team further develop and iterate the app throughout the pilot study. The queries and dashboard remained mostly in their initial format. However, weekly summary reports and monthly response raffles were added in response to usage and feedback patterns. The weekly reports sought to prompt reflection about adherence, whereas the raffle incentivized consistent self-monitoring. The monthly raffle included participants with 100% response rates across medication, mood, and stress queries, and a randomly selected qualifying participant was awarded a US \$50 gift certificate. The winner and all participants included in the raffle were acknowledged (by their anonymous handle) on the community message board. Looking at response rate data during the 2 months before and after the raffle began, we observed an increase in response rates from 44.6% to 59.1%.

The community message board also evolved in its design and content in response to user feedback. Initially, participants received a push notification with a part of the newly posted message any time there was a new post on the community message board. Later, as more users enrolled and community message board participation increased, the notifications screen became crowded with messages and participants had to scroll down to see their own medication, mood, and stress queries. In response to this, the notifications screen was split so that queries and weekly summaries appeared at the top and community message board posts were in a separate feed at the bottom (Figure 5), and users were given the option to turn off push messages from the community message board.

Figure 5. Split notification screen: a: home screen before feedback; b: home screen after member feedback.



Additional changes made in response to user feedback were the addition of a funny video message by the staff each Friday (January 2014) and changes in the color palette. Participants were positive about the changes and felt proud when they recognized changes to the app that they suggested.

Conversations and questions on the community message board also allowed PositiveLinks team members to begin relevant discussion topics. In usability interviews, participants expressed a desire for more conversation on what was going on with HIV in the news. In responding to these needs, the team introduced conversations such as how the Affordable Care Act may change insurance for HIV care and other current events relevant to HIV. When participants expressed confusion about the biology of HIV in community message board posts and in response to quiz questions, the PositiveLinks team posted information to help address these issues. The team also addressed participants' expressed needs with general health posts such as how to deal with stress or how to respond to others with empathy. The resources feature of the app was updated throughout the study based on topics of interest to the participants.

Discussion

Principal Findings

Sustained usage of the many PositiveLinks features over 2 years and positive feedback in usability interviews indicate that this type of an app is both feasible and acceptable. Its evidence-based design was informed by self-management principles of self-regulation and feedback, just-in-time assistance, and social support. Furthermore, its development process has been iterative and enriched by the input of the users themselves to create an app customized to their preferences. Most prior studies of mHealth interventions for improved treatment adherence in HIV [25,30] and other chronic diseases [20,21] in the United States have been focused on urban populations. This app may fill an important need in a nonurban community in the Southeastern United States, where PLWH are at risk for poor clinical outcomes owing to a disproportionate burden of low health literacy, low socioeconomic status, substance abuse disorders, and social and geographic isolation, affecting their ability to attend appointments and access medications [13-17]. PositiveLinks capitalizes on mobile phones' increasing popularity and accessibility by using a mobile platform to reach our geographically dispersed population of PLWH.

PositiveLinks builds on prior work supporting the use of mHealth interventions to encourage self-monitoring and medication adherence for PLWH [58-62]. Our development process drew from formative work exploring needs and preferences for app design in other populations of PLWH [37-40], while also seeking our target users' input to customize PositiveLinks for them. Drawing on previous studies that demonstrated improved HIV medication adherence with messaging matched to dosage time [25], the PositiveLinks app allowed participants to customize their medication query timing so that it could function as a reminder to take their medications. By contrast, the mood and stress queries were EMAs sent at random times each day [18]. For each query type, users could customize the push messages that they received in response to their replies.

The community message board was a popular feature of the PositiveLinks app. The usability interviews and prior analysis of community message board content [56,57] indicated the board fulfilled a desire to receive information and social support. In contrast to publicly available online support groups [43,44], the community message board was accessible only through the private secure app and was monitored by the PositiveLinks study team. This approach may mitigate potential disadvantages of online interaction, such as misinformation.

The PositiveLinks study was unusual among mHealth interventions by following participants for an extended period of time allowing for more accurate assessment of user fatigue [20]. We noted a gradual decline in app usage over time. Nonetheless, 45% of participants responded to at least 1 daily query during the last month of the 2-year pilot. For those participants whose usage declined, possible reasons included habituation or fatigue from daily queries. Similar declines have been observed in text-based interventions [25]. It is also possible that the app serves different functions for users over time, with more frequent feedback being more helpful early on or during a time of crisis. The optimal *dosage* of mHealth interventions to achieve effective self-management remains to be established. The usability interviews were conducted early in participants' usage to catch possible problems early and did not directly address sustainability or possible reasons for change in app use over time. The monthly raffle provided some incentive for query responses. A financial reward for reporting can reinforce desired behaviors and be acceptable to PLWH [46], but too much reliance on incentives may not be feasible in scaling up mHealth interventions in the future.

In addition to encouraging self-monitoring, the queries also helped identify users having difficulty with medication adherence, mood, or stress. Previous studies have noted that patients are interested in this kind of data sharing, although they also express reservations about the security of the information and concerns about negative reactions from providers to data [40]. In formative and usability interviews conducted with our participants, individuals did not share the same concerns and, in general, appreciated the role of the EMAs as a potential safety net. The community message board also identifies users who may need just-in-time help (such as a mental health crisis), with opportunities for the team to reach out to them. Next steps in PositiveLinks app development include sharing participants'

query data with their HIV clinicians and mental health providers to facilitate care in between clinic visits.

The iterative user-driven approach to development has enhanced PositiveLinks' usability and acceptability by allowing improvements in response to users' perceptions and experiences. It is not possible to respond to all user feedback, but efforts were made by the study team to accommodate suggestions that were feasible and consistent with the goals of the PositiveLinks project. From a research standpoint, it can be challenging to analyze app usage data when the app changes along the way, with further refinement of features and functions. However, study participants reported that having a voice in the app development was empowering and helped them to identify with the app, as part of the *PositiveLinks Family*.

Limitations

This study has several limitations to consider. Owing to the study's small sample size, we are not able to perform a detailed analysis of differences in app use by subgroups. The observed differences in app use (with some participants not using the app or not using certain features) suggest that the app does not meet the needs of all participants equally. Quantitative measures of acceptability and sustainability were not performed in this analysis and could be a useful addition to future studies. Security and concern for participants' privacy required incorporation of mandatory password protection, encryption, and remote wipe capabilities for lost phones. Additional staff efforts were made to preserve anonymity on the community message board, particularly when participants expressed interest in meeting in person or sharing more personal information. For some participants, these additional security features to access the app may have created a barrier to use. Even with these measures, the risk of compromised identity and HIV status may not be entirely eliminated. Potential challenges in scaling up the app will also need to be considered. This deployment of PositiveLinks required funding to procure and maintain phones, data plans, and staff time. A determination of whether provision of mobile phones and data plans is essential to usability and acceptability is also needed. It must also be noted that this pilot was conducted at a single HIV care site and may not be generalizable to other settings, especially settings in which participants do not have access to smartphones.

Conclusions

In conclusion, this report on the development of PositiveLinks demonstrates that patient-centered iterative design and testing yielded an appealing mHealth intervention for an at-risk group of PLWH. Participants used the app, contributed to its design, and perceived it as beneficial in their coping with HIV. In the pilot phase, the PositiveLinks app features permitted self-monitoring and personalized feedback, and facilitated access to social support, all of which are important elements of chronic disease management. Further investigation is needed to delineate which features of this multicomponent mHealth intervention are most effective. The next iteration of PositiveLinks incorporates additional features desired by participants, including sharing query responses and messaging with their care providers in the clinic. Expansion to other sites and populations is also planned.

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Conflicts of Interest

RD, KI, and ALW have consulting agreements with Warm Health Technology, Inc. This company was formed in April 2018 to support dissemination of PositiveLinks to other entities caring for PLWH. The other authors have no conflicts of interest to declare.

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Abbreviations

EMAs: ecological momentary assessments

mHealth: mobile health

PLWH: people living with HIV

WRAT-4: Wide Range Achievement Test

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Original Paper

The Development of VegEze: Smartphone App to Increase Vegetable Consumption in Australian Adults

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Abstract

Background: Poor-quality dietary patterns are often characterized by inadequate consumption of fruits and vegetables. Changing dietary behavior is difficult, and although it is often clear what needs to change, how to enact change is more difficult. Smartphones have characteristics that may support the complexity of changing dietary behavior.

Objective: This paper describes the iterative process of developing a theory-based smartphone app called VegEze that aimed to increase vegetable consumption.

Methods: To upscale, reach target users, and create a user-friendly end product, a collaborative research-industry partnership was formed to build the app over a 20-week period. The Integrate, Design, Assess, and Share framework was used as a scientific basis to guide the development. The behavior change wheel was also used as a theoretical grounding in combination with other theory-based strategies, such as self-monitoring, social comparison, and gamification—which have all been shown to be successful in dietary change or digital health interventions. We conducted 1 consumer survey (N=1068), 1 usability testing session (N=11), and a pilot effectiveness and usability trial (N=283) to inform the design of the app.

Results: The target behavior for the app was defined as *having 3 different types of vegetables at dinner*. The perceived achievability of this target behavior was high; 93% of respondents (993/1068 users) felt they were *likely* or *very likely* to be able to regularly achieve the behavior. App features that users wanted included the following: recipes and meal ideas (876/1068, 82% of users), functionality to track their intake (662/1068, 62%), and information on how to prepare vegetables (545/1068, 51%). On the basis of importance of self-monitoring as a behavior change technique (BCT) and its rating by users, the vegetable tracker was a core feature of the app and was designed to be quick and simple to use. Daily feedback messages for logging intake and communicating progress were designed to be engaging and fun, using friendly, positive language and emoji icons. Daily and weekly feedback on vegetable consumption was designed to be simple, informative, and reinforce monitoring. A creative team was engaged to assist in the branding of the app to ensure it had an identity that reflected the fun and simple nature of the underlying behavior. The app included 16 BCTs, most of which were from the goals and planning subsection of the BCT taxonomy.

Conclusions: Combining a theoretical framework with an industry perspective and input resulted in an app that was developed in a timely manner while retaining its evidence-base. VegEze is an iOS app currently available in the App Store, and the overall impact of the VegEze app will be evaluated in an uncontrolled, quantitative study.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12618000481279; <http://www.anzctr.org.au/TrialSearch.aspx?searchTxt=ACTRN12618000481279> (Archived by WebCite at <http://www.webcitation.org/769oG9EaA>)

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KEYWORDS

mHealth; mobile applications; vegetables; adult

Introduction

Background

Poor diet quality is one of the most important modifiable risk factors for chronic disease [1]. Poor-quality diets are generally characterized by inadequate consumption of fruits and vegetables, and overconsumption of unhealthy, energy-dense, discretionary foods [2]. A diet that contains plenty of vegetables, including a variety of types and colors, can provide a range of beneficial nutrients that may help to reduce the risk of obesity and some chronic diseases [3]. Despite the known benefits of increasing vegetable consumption, intake remains low [4,5]. For example, in Australia, about 95% of adults do not meet the recommended intake of vegetables [5], which means that they are missing out on essential vitamins, minerals, and dietary fiber that vegetables can provide.

Population-level nutrition and obesity prevention interventions have had small to modest success in improving diet quality [6-8]—most likely because dietary behavior change is difficult and multifaceted. Although, it is often clear what needs to change, for example eat more vegetables, how to action changes is more difficult [9]. The interplay between individual-level (eg, willpower and motivation), household-level (eg, availability and finances), and community-level factors (eg, accessibility to fresh food and social norms) are all likely to affect dietary change [10].

Smartphones have characteristics which may support the complexity of changing dietary behavior. For example, smartphones are increasingly ubiquitous, have the ability to reach individuals at nearly any time or place, can be highly interactive, can deliver information in a way that is engaging and rewarding, and provide timely feedback [11]. Tailored feedback can also grow with user inputs [12], creating a personalized experience, which may encourage extended engagement and success with an intervention [13]. Therefore, smartphone-based behavior change interventions have the potential to be effective and also accepted by individuals. They may also serve as a cost-effective and scalable way to deliver behavioral nutrition interventions to a large audience. However, to have the greatest likelihood of success, these interventions also need to utilize existing scientific knowledge and theory [12,14].

An explosion of healthy eating smartphone apps has occurred in recent years (eg, MyFitnessPal, Lifesum, Lose It!, and Easy Diet Diary). However, many commercial apps are not scientifically developed, based on behavioral theory or evidence, and have yet to undergo rigorous evaluation [11,15]. Regardless

of this, high and consistent downloads suggest they have significant reach and appeal, at least in the short term [16]. Apps are also being developed and used by the research community, but unfortunately the pace of development and evaluation in research means that the temporal lag limits their potential impact [17]. Despite contrasting times from conceptualization to market, both scientific and commercial entities want to develop engaging and effective apps and working together could result in better end products.

Objectives

This paper describes the iterative development process to build a mobile app that considers both the scientific and commercial validity and that targets a complex and critically important dietary behavior—increasing vegetable consumption. The Integrate, Design, Assess, and Share (IDEAS) framework was used as a scientific basis to guide the development of the app [18]. The IDEAS framework is a flexible approach for developing digital interventions and is used here to provide a detailed description of the journey of building VegEze—an app to increase vegetable variety and consumption.

Methods

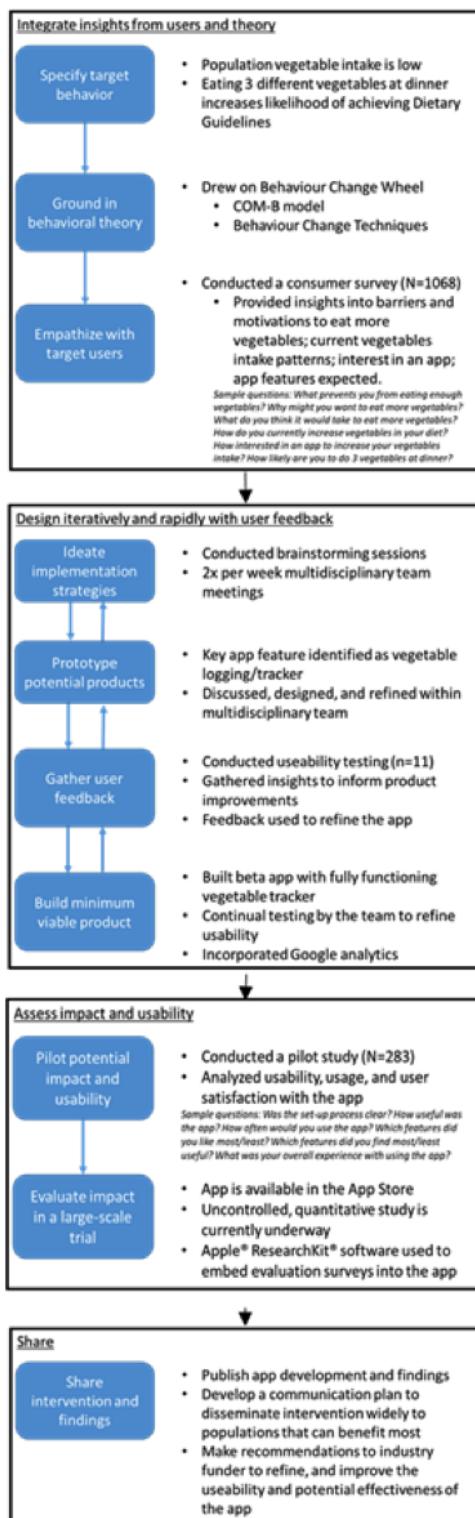
Ethics Approval

The development and evaluation of the app was approved by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) Health and Medical Human Research Ethics Committee Low Risk Review Panel (LR13/2017) and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618000481279).

Overview

The development of the VegEze app was conducted using the IDEAS framework. The IDEAS framework brings together a combination of approaches necessary for the development of effective technologies. The framework draws on behavioral theory, design thinking, user-centered design, rigorous evaluation, and dissemination—which have all been shown to be important for digital health interventions [18]. The framework outlines a step-by-step process for integrating these approaches, and although depicted as a linear process, it is intended to be iterative, and stages should be revisited as required during the development process [18]. The framework also provides theory-based behavioral science strategies to support the intervention design. **Figure 1** is an adaptation of the IDEAS framework flowchart [18], providing an overview of the processes that were used in the development of the VegEze app.

Figure 1. The application of the IDEAS (Integrate, Design, Assess, and Share) framework to the development of the VegEze smartphone app. Due to project requirements, the first 3 phases of part 1 of this study took place in a different order to original IDEAS framework. COM-B: capability, opportunity, and motivation to engage in the behavior.



Part 1: Integrating Insights From Users and Theory

Procedure

The first 3 phases of the IDEAS framework were designed to gather insights from users and behavioral theory to focus the intervention process around a specific and measurable target behavior.

Phase 1: Specify Target Behavior

Specifying the target behavior was, in the first instance, an evidence-based decision drawing on existing data and literature, which was later tested with potential users before proceeding with the app development. To determine the degree of the problem, which is inadequate consumption of vegetables in the Australian population, we examined data from the Australian

National Nutrition and Physical Activity survey. This is the latest nationally representative survey of dietary intake available in Australia [5]. The complex sampling method and design of this survey means we are able to make estimates of intake for the Australian population based on the data collected from a sample of 9341 adults [19]. These data provided estimates of the percentage of the population meeting the recommended vegetable intake targets as prescribed by the Australian Dietary Guidelines [3].

To more precisely define a specific target behavior within the context of increasing vegetable consumption, secondary data analysis of the CSIRO Healthy Diet Score survey was performed. The CSIRO Healthy Diet Score is an online short food survey that has collected data from over 198,000 Australians [2]. This survey asks about food group intake such as fruits and vegetables, as well as a range of food habits including *how often does your evening meal contain 3 or more different vegetables?* Secondary analysis explored the association between this specific behavior and individuals' total vegetable consumption and likelihood of meeting the Australian Dietary Guideline targets.

Phase 2: Ground in Behavioral Theory

The development of the app also drew on the behavior change wheel (BCW) as a theoretical grounding [20,21] in combination with other theory-based strategies, such as self-monitoring, social comparison [22-24], and gamification [25-27]—which have all shown to be successful in either dietary change or digital health interventions. The BCW is an integrative guide for understanding behavior change and is a synthesis of many previously published theoretical frameworks from this field. Central to the BCW is the capability, opportunity, motivation, and behavior (COM-B model) that recognizes that for a behavior to occur, an individual must have the capability, opportunity, and motivation to engage in the behavior (COM-B). The first step of the BCW process is to specify the target behavior (similar to phase 1 described here). Then, subsequent steps identify what needs to change to perform this target behavior. To help quantify this and prioritize features of the app, we administered the COM-B self-evaluation questionnaire in a sample of potential users [20].

The app also drew on theory-based behavior change techniques (BCTs). The final version of the app was independently coded by 2 trained research assistants for inclusion of techniques from the 93 BCTs taxonomy [23]. This coding was done at the end of the development process to reflect the techniques employed in the final version of the app.

Phase 3: Empathize With Target Users

We conducted an online consumer survey with potential users to understand how the identified target behavior (eat 3 different vegetables at dinner) was received by potential users, and to elicit perceptions about performing this behavior.

Participants

Potential users were recruited via email from a database of individuals who had previously participated or expressed an interest in participating in online nutrition and health-related surveys or programs. An email was sent to 9900 individuals on

the database and 1068 individuals completed the survey within 24 hours. These participants were majoritively female (84% female) with an average age of 56 years (range 20-90 years).

Part 2: Design Iteratively and Rapidly With User Feedback

Procedure

Phase 4: Ideate Creative Implementation Strategies

To upscale, reach target users, and create a user-friendly end product, a collaborative research-industry partnership was formed which brought a multidisciplinary team together to build the app over a 20-week build phase. The team was led by a product development manager (from industry) and nutrition scientist (researcher), and included research dietitians, behavioral scientists, product developers, and software engineers. The multidisciplinary project team met regularly throughout the development process to ensure a rapid build phase. The ideation phase also focused on translating insights from users and theory into features of the app. The process of brainstorming ideas for the app was highly iterative and incremental.

The app was built using the principles of agile software development which supports a *minimum viable product* approach. The development team had 7 2-week sprints (14 weeks total development) and aimed to release usable features at the end of each sprint for the broader project team to review and then test with users.

Phase 5: Prototype a Potential Product

The build started by prototyping different ways to track vegetable intake. On the basis of the importance of self-monitoring as a BCT and its rating by potential users in the consumer survey (a tracker for vegetable intake was the second highest rated feature that users expected and highest in terms of a functionality feature), this feature was going to be a core component of the app. In addition to communicating progress, a tracker can be used to communicate and reinforce the specific target behavior.

Phase 6: Gather User Feedback on the Prototype

Initial user testing was conducted in a small sample of people, who were not known to the project team. Members of the development team approached individuals and asked them to complete 4 tasks on the prototype provided. The individuals were observed using the prototype app as they were asked to: add cauliflower, sweet potato, and corn to dinner; add capsicum to breakfast; add salad for lunch; and add carrots for a snack.

Participants

A total of 11 people were approached within a local cafe and asked to participate in the initial user testing session. They were asked to use the app to do the 4 tasks and provide feedback on their experience. The perceived age of the participants was 25 to 45 years (demographic information was not asked to maintain anonymity).

Phase 7: Build Minimum Viable Product

The beta version of the app was developed with fully functional versions released and tested iteratively by the project team, with feedback provided to the project lead of the development team at regular intervals. To ensure the effectiveness and usability of the app could be assessed, evaluation surveys were designed and embedded into the app using Apple ResearchKit software. The length and usability of these surveys were tested as part of this phase as well. The beta version of the app focused on the onboarding process, refining the vegetable tracker and user experience, developing a framework for providing feedback, and the visual branding. In addition, a creative team was engaged to assist in the branding of the app to ensure it had an identity that reflected the fun and simple nature of the underlying behavior.

Part 3: Assess Effectiveness and Usability

Procedure

Phase 8: Pilot Potential Effectiveness and Usability

The aim of this phase was to conduct a small-scale evaluation to test the potential effectiveness of the app and to inform final refinements as required. In this phase, it was also important to understand potential of usage of the app in terms of frequency and duration of use, as well as user satisfaction with the app. Potential users were invited to use the app for 3 days, providing feedback through 3 evaluation surveys that included 1 immediately post download, 1 after 24 hours of use, and 1 after 3 days of use. On the basis of the feedback and experience of the participants, a list of suggestions for improvements was compiled. The list of suggestions was discussed among the project team and prioritized before it was implemented into the final version of the app.

Participants

A new sample of potential target users, recruited through the same database described above, was invited to download the beta version of the app. A total of 553 participants registered their interest in the pilot study. Of these, 311 downloaded the app (311/553, 56% of those interested) and 283 completed the baseline survey (283/311, 91% of those who downloaded the app). Participants used the app for about 24 hours and were asked to complete a second survey (post download survey, n=146), followed by a final survey about 3 days after download (post pilot survey, n=103). The sample that completed the baseline survey was largely female (84%), with mean age 48 years, and 46% were overweight or obese.

Results

Part 1: Integrating Insights From Users and Theory

Phase 1: Specify Target Behavior

Data from the latest Australian National Nutrition survey suggest that less than 4% of adults consume enough vegetables to meet the Australian Dietary Guidelines [5]. The Australian Dietary Guidelines and Go for 2 & 5 campaigns encouraged the population to “enjoy plenty of vegetables”, “increase consumption”, and include “different types and colours” with a prescription for total daily recommended servings [7]. However, in the context of behavior change, the advice within this literature broadly addresses the problem of inadequate vegetable consumption, without identifying a highly specific target behavior.

Data from the CSIRO Healthy Diet Score survey showed that respondents reporting “always” having 3 different types of vegetables at their evening meal had higher overall vegetable consumption relative to other frequencies. These people were also more likely to meet the recommended daily intakes [28]. Review of other literature also suggests that serving a variety of vegetables can help in selecting a healthier meal [29] and is an effective strategy to increase vegetable consumption in a single meal [30]. On the basis of the CSIRO Healthy Diet Score data and other acute studies, the target behavior for the app was defined as *having 3 different types of vegetables at dinner*. This is a novel, specific, and an actionable behavior that is associated with an increased likelihood of the desired outcome—that is increased vegetable consumption. In addition, it is measurable, easy to self-monitor, and has the potential to produce a cascade benefit, that is improving vegetable consumption at other meal times. Therefore, the initial target behavior was to *eat 3 different vegetables at dinner*.

Phase 2: Ground in Behavioral Theory

The app draws on the BCW framework, and the COM-B self-evaluation questionnaire was administered as part of the online consumer survey to elicit reasons associated with individuals' COM-B. When asked what they thought it would take to increase vegetable intake, 37% of responses from survey participants were reasons associated with their capability (eg, have better planning skills, cooking skills, and knowing how to eat more vegetables), 33% were for reasons associated with motivation (eg, developing better plans and a habit of eating more vegetables, feeling like I want to eat more vegetables), and 30% were reasons associated with opportunity (eg, having more time and triggers to prompt me to eat more vegetables). Therefore, respondents reported needing help in all areas of behavior change according to the COM-B theory (Table 1).

Table 1. Most common reasons reported for wanting to eat more vegetables from the consumer survey (N=1068). Survey question: “Why might you want to eat more vegetables?”

Response to survey question	Users, n (%)
To be healthier	822 (77)
Increase nutrient intake	726 (68)
Increase fiber intake	662 (62)
Want to lose weight	555 (52)
Feel better	491 (46)
Meet recommendations	267 (25)
Feel like I should	160 (15)
Doctor or health professional told me to	32 (3)
Friends/family eat more than I do	11 (1)

Phase 3: Empathize With Target Users

The online consumer survey aimed to understand how the target behavior (eat 3 different vegetables at dinner) was received by potential users, and to elicit perceptions about performing this behavior. Respondents were generally health conscious and health literate, with 94%-99% reporting that they felt it was “important” or “very important” to eat enough and a wide variety of vegetables each day, and 71% correctly identifying the daily recommended number of serves of vegetables. However, 66% of this sample still believed they would like to eat more vegetables, and this was largely for health-related reasons (Table 2).

In addition, 56% of respondents were “interested” or “very interested” in an app to specifically help with achieving the target behavior of eating 3 types of vegetables at dinner (Table 3). Interestingly, this was similar to those interested in the more traditional intervention target of “increasing vegetable intake” (55%). In the context of the app and perceived achievability of this target behavior, 93% of respondents felt they were “likely” or “very likely” to be able to regularly achieve the behavior,

and most (68%) thought they would be able to do it for 30 days or more (Table 3).

In addition to administering the COM-B self-evaluation questionnaire, the survey respondents indicated their preferences for features in an app and their current vegetable eating behaviors. App features that users reported to want included recipes and meal ideas (82% of users), functionality to track their intake (62%), and information on how to prepare vegetables (51%, Table 3).

Most people reported to consume vegetables at their dinner meal (98% of respondents), but many also included vegetables with lunch (85%). Consuming vegetables at breakfast (11%) or as a snack (19%) was less common. The most common ways participants indicated eating vegetables in their meals were by including vegetables in dishes such as stir fries (48%), salads (39% as a side salad and 38% as a main), and 32% reported *hidden* within a dish such as spaghetti bolognese. In addition, 66% of respondents reported that they *mix it up* and consume vegetables in a variety of ways. This information was used to guide the development of recipes and meal ideas.

Table 2. Most common reasons from the Capability, Opportunity, and Motivation to Engage in the Behavior Self-Evaluation Questionnaire about what it would take to increase vegetable intake from the consumer survey (N=1068). Survey question: “What do you think it would take to increase your vegetable intake?”

Response to survey question	Users, n (%)
Having better planning skills	150 (14)
Developing better plans for eating more vegetables	128 (12)
Developing a habit for eating more vegetables	107 (10)
Having more time	96 (9)
Having better cooking skills	85 (8)
Knowing how to eat more vegetables	75 (7)
Having more triggers to prompt me to eat vegetables	64 (6)
Developing greater will power	53 (5)
Feeling that I want to eat more vegetables	53 (5)

Table 3. Evaluation questions about the proposed app from the consumer survey (N=1068).

Survey question	Users, n (%)
How interested are you in an app to help you to eat 3 types of vegetables at dinner?	
Very interested	299 (28)
Interested	299 (28)
Neutral	224 (21)
Not interested	96 (9)
Not at all interested	117 (11)
How long do you think you could do this for?	
Less than 7 days	53 (5)
7 days	96 (9)
14 days	107 (10)
21 days	85 (8)
30 days or more	726 (68)
What features would you like to see in an app to increase vegetable intake?	
Recipes	726 (82)
Tracker	662 (62)
How to info	545 (51)
Weekly reports	459 (43)
Info on guidelines	417 (39)
Health info	342 (32)
Challenges	310 (29)
Rewards	235 (22)
Engage family	150 (14)
Photo gallery	96 (9)
Social sharing	64 (6)
Leaderboard	43 (4)

Part 2: Design Iteratively and Rapidly With User Feedback

Phase 4: Ideate Creative Implementation Strategies

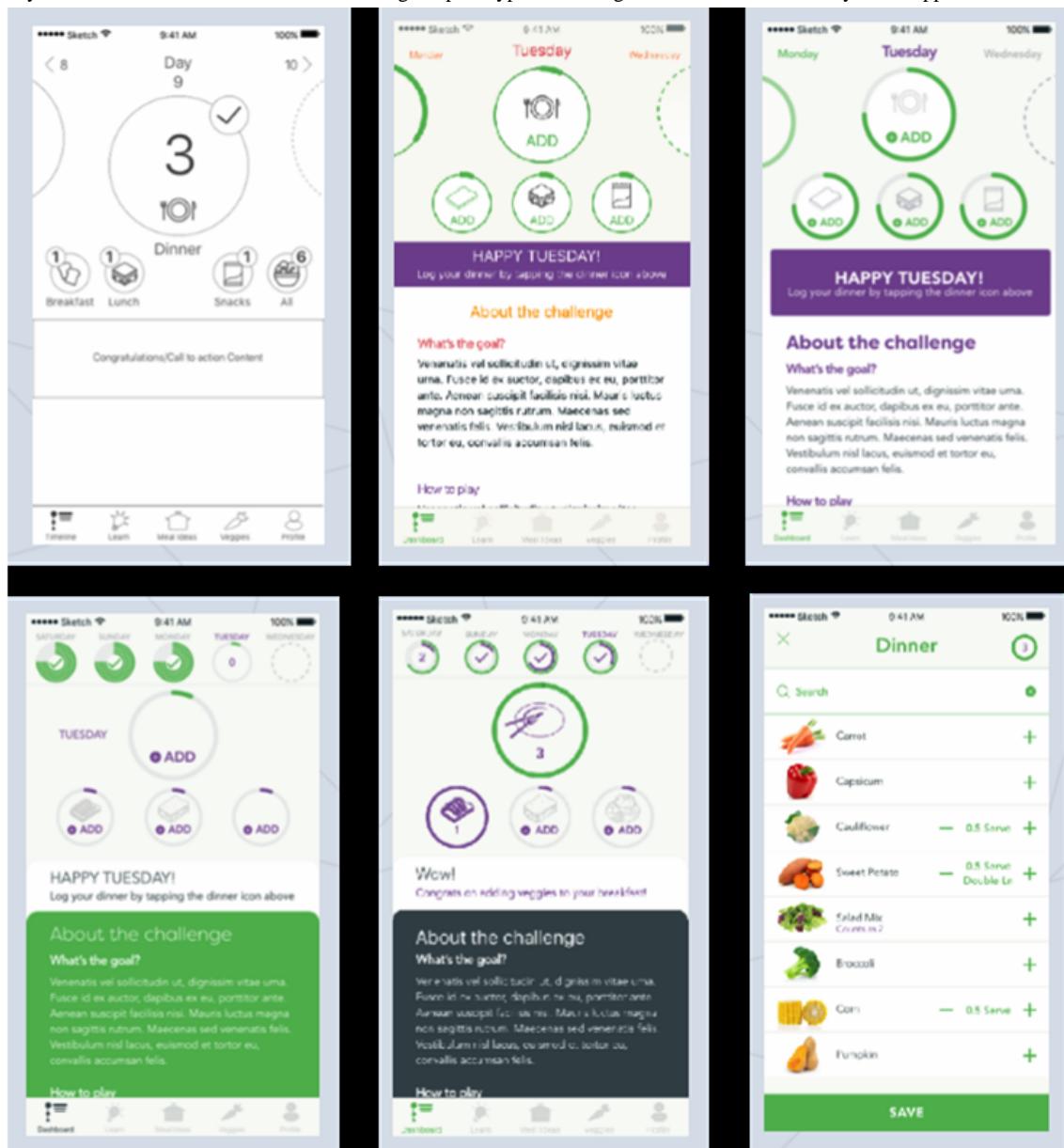
The multidisciplinary project team met twice per week throughout the 20-week development process that allowed us to generate and refine ideas and implement behavior change strategies within features that target users had reported to expect from the app. This was done collaboratively to retain the scientific evidence base while also maximizing the user experience.

At the end of each of the 7 development sprints, usable features were released, reviewed, and tested by the project team. From the fourth sprint, we started to release features to test with users. By using this approach, we were continually able to provide feedback to the development team and facilitate a rapid assembly of the app.

Phase 5: Prototype a Potential Product

Consumer feedback indicated that a large proportion of users consumed vegetables at lunch as well as dinner, so the project team decided that the tracker would allow vegetables to be tracked at all meals across the day.

To empathize with users, the vegetable tracker feature needed to be quick and simple to use, highly applicable to a range of users by including a large variety of different vegetables and accommodating of users from across the health and motivation spectrums. Unlike traditional scientific methods, emphasis was therefore placed on simplicity and intuitiveness of this dietary intake recording tool. Its core functionality was to record variety of vegetables consumed (ie, the types) as well as servings (ie, the amount). A vegetable list of 125 vegetables was created, and a prototype vegetable tracker allowed users to scroll the vegetable list and click through to record the type and amount of vegetables consumed at each meal of the day. The prototype featured only the core component to ensure the app reached the target behavior as effectively as possible (Figure 2).

Figure 2. Early low resolution wireframes used in iterating the prototype for the vegetable tracker functionality of the app.

Phase 6: Gather User Feedback on the Prototype

The initial user testing provided feedback on the prototype and assessment of the functionality of navigating the vegetable list and logging vegetables consumed in meals. The key observations were that all participants were able to complete all tasks in minimal time and the flow of entering items was reasonably easily learnt. The meal icons for breakfast, lunch, dinner, and snacks appeared to be confusing, as users were not able to easily differentiate meals. Using circles for the meal icons also appeared to be confusing as users seemed to require more context in terms of what they were aiming for and how to fill them in. The recommendations for refinement from the development team included (1) further iteration on the design of meal icons, (2) creation of onboarding screens to help the user navigate, (3) more focus on the development of *progress indication*, and (4) to continue testing and iterating the dashboard design for further testing in the pilot trial. This feedback was included into the next iterations of the app.

Phase 7: Build Minimum Viable Product

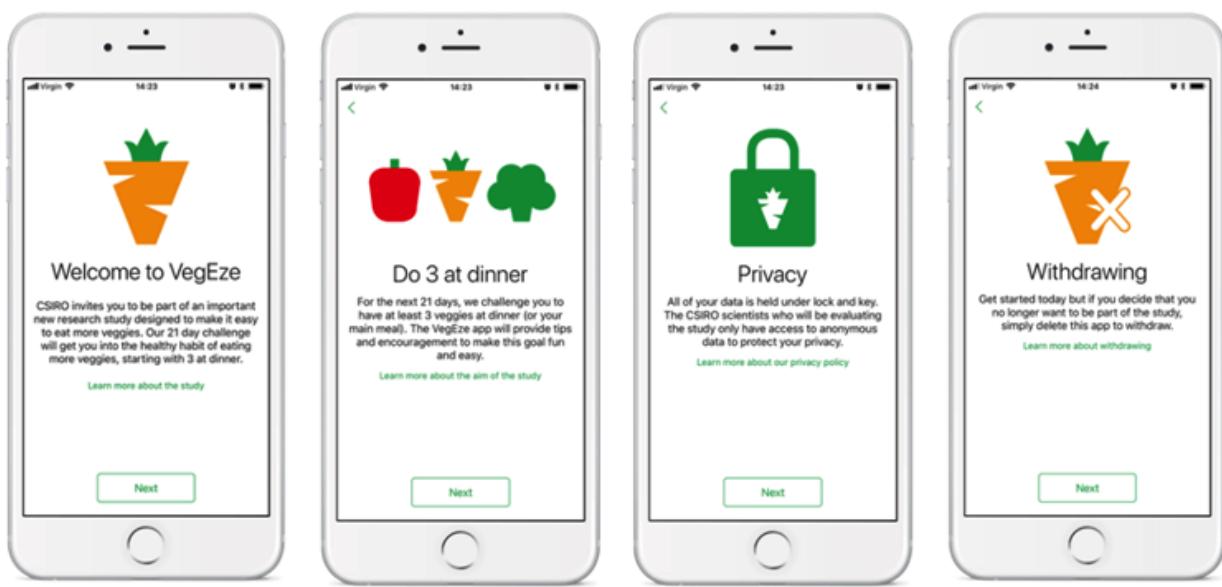
The beta version of the app was developed with fully functional versions released and tested iteratively by the project team, with feedback provided to the project lead of the development team at regular intervals. The beta version of the app focused on the onboarding process, refining the vegetable tracker and user experience, developing a framework for providing feedback, and the visual branding.

The onboarding process included ethics documentation and consent as well as the baseline evaluation survey. The consent process and evaluation surveys were embedded into the app using Apple ResearchKit software (Figure 3). The survey questions drew on previously validated questionnaires to assess amount and variety of vegetables (as the primary outcomes) [31] and psychological predictors of intake (as possible covariates of behavior change) such as attitudes, intentions, and nutrition-related self-efficacy [32-34]. The baseline evaluation survey was initially designed by researchers, and then refined

for length and readability based on feedback from developers and the broader project team. Although it extends the registration process, inclusion of the survey is considered essential to allow for detailed evaluation of the app. Google Analytics was used to collect app usage data to allow us to understand the interactions between patterns of use and successful behavior change.

The user experience for the early versions of the app was centered on perceived ease of logging intake and usability of the vegetable list. In the prototype, the vegetable list was ordered by frequency of consumption per meal based on population intake data from the Australian National Nutrition Survey [35], and then over time ordered with user's inputted data. Each vegetable item in the list had a name, image, and an information button (which allowed users to click through to details on standard serve size information). Serves could be added with a tap of the “+” and “-” icons for each vegetable in the list.

Figure 3. A sample of screenshots of the consent process which was embedded in the app using Apple ResearchKit software.



Part 3: Assess Effectiveness and Usability

Phase 8: Pilot Potential Effectiveness and Usability

The majority of the participants who registered (492/553, 89%) reported they thought they would like to use the app at least once a day, and 87% felt they would use the app for 2 to 3 min per day or more. When asked how long they thought they could maintain the challenge of eating 3 different types of vegetables at dinner, 67% of users at baseline felt they could maintain it for 21 days or more.

App Usage

During the testing period (7 days), 265 (265/283, 94%) users who completed the baseline survey logged their vegetable intake at least once. Users averaged 5 sessions in the app during this period, with an average daily engagement time of 3 min 54 seconds. There were 1419 vegetable logs recorded, an average of 5.4 logs per user. The majority of these logs were for the evening meal (1042/1419, 73%).

The framework for the frequency and content of feedback messages sent via push notifications was developed by the project team. A total of 3 types of notification messages would be sent including daily feedback for logging as well as content and recipe notifications which were sent on a random schedule 3 to 4 times per week. Daily feedback messages for logging intake and communicating progress were designed to be engaging and fun using friendly and positive language and emoji icons. Daily and weekly feedback and graphs on the variety and serves of vegetables logged were designed to be simple and informative and reinforce monitoring.

Finally, the creative team proposed various names and logos that were tested as part of the pilot study (phase 8). The name *VegEze* with the byline *Do 3 at dinner* received the most positive response from potential users and the project team agreed to use this branding for the app.

Feedback Questionnaire

After downloading the app, at least 80% of users *agreed* or *strongly agreed* that the setup process of the app, including completing the baseline evaluation survey, was clear and relatively easy to complete. After using the app for a few days, 85% of users reported to like the tracking feature to record type of vegetables, and 79% liked the tracking feature to record serves consumed. Importantly, 75% of users felt the vegetable logging feature was easy to use, and 69% found it was useful:

A powerful motivator - more than I expected. I liked the quality of the images of vegetables and the search function.

I find the information about how much a serving size is for each vegetable is really useful. I would probably just assume I'm eating enough by having a few beans, pieces of carrot and broccoli florets for dinner - but know I know exactly how much I need to eat.

I like the scroll and search option to find veges and the incremental steps to measure vege intake. REALLY liked the option to click on the vege to show what a serving actually is AND the photo of the vege - great; ease of use, thumbs up.

Immediately following download, 75% of users (104/146) felt their overall experience of using the app was positive, and after a few days of using the app, 81% of users felt their experience was positive. Immediately following download, 86% of users reported they would use the app at least once a day, and this remained high at the end of the pilot trial (78% of users). Post download and post pilot, 80% and 87% of users, respectively felt they would use the app for 2 to 3 min. About one-third of users felt they would use the app for 1 to 3 months, and another third for more than 3 months. Finally, 63% of users who completed the post pilot survey (n=103) felt the app was easier or much easier than other health apps, and 69% indicated they would give the app 4 out of 5 stars

Enjoying using the app so far and it's definitely challenged me to increase my veg intake at dinner.

Yes, I'm very impressed with how many veggies there are to choose from. Being a creature of habit it certainly opens your eyes to what you can eat.

Refinement Before Final Release

On the basis of the pilot evaluation, a few issues were identified by users in regard to the vegetable list and logging of vegetables that were addressed in the final sprint of the app. For example, the development team further refined the process for adding and deleting vegetables at different meal times to make it easier for users, the order of the vegetable list was revisited, and finally, users wanted more visual feedback of their total vegetable servings in addition to total types.

The final sprint focused on the gamification elements of the app and the content, which was not part of the beta version. The consumer survey in phase 3 suggested that gamification features such as challenges and rewards were expected by 29% and 22% of respondents, respectively. Although these were not the most highly ranked features, gamification is increasingly popular within apps [26]. Gamification has the potential to facilitate behavior change by increasing motivation and making an everyday task more fun to achieve [25]. The release version of the app invites users to participate in a 21-day challenge to have

3 different types of vegetables at dinner (Figure 4). To encourage autonomy, challenges can be reset and restarted at any time by the user. In addition to the challenge, other gamification features include rewards and a form of leaderboard (Figure 4). A rewards-based scheme was built into the challenge whereby individuals achieved different levels depending on their intake. A leaderboard displays the different awards and the percentage of individuals using the app who are striving for each award—a deidentified form of social comparison. These gamification elements in the app were developed by the behavioral scientists and then further fleshed out by the project leaders to achieve features that were fun and motivating but also realistic within the project constraints.

The consumer survey described in phase 3 suggested that 82% of respondents expected recipe and meal ideas in the app as well as information on how to prepare vegetables (51% of respondents). The content framework divided articles into 3 categories: (1) evidence-based fun facts on vegetables, (2) recipe and meal ideas all containing 3 different vegetables, and (3) tips and tricks on how to prepare and include vegetables in meals (Figure 4). The recipe and meal ideas covered stir fries, mixed dishes, and main and side salads as well as meals with *hidden* vegetables given that the consumer survey suggested respondents were eating vegetables in a variety of ways. Moreover, 2 research dietitians worked together to develop 74 short articles and 57 recipes and meal ideas for inclusion in the app.

Two-way user feedback was central to the app (Figure 4). The home screen became the place where users can review their progress of the day with carrot icons representing the number of types consumed in each meal for the current day. With a bar slider at the top of the screen, users can review previous days at a glance with a *tick* indicating that the goal was met (Figure 4) or across the challenge period in a calendar format (Figure 4). With a swipe from the home screen, users can also review their progress toward reaching the recommended number of serves per day as well as review the past progress on reaching this target with a simple visual bar chart (Figure 4).

As described in phase 2, the app drew on theory-based BCTs. The final release version of the app was independently coded by 2 trained research assistants, who identified 16 BCTs used within the app, most of which were from the goals and planning subsections of the BCT taxonomy (Table 4).

Figure 4. A sample of screenshots from the VegEze app as published in the App Store. (a) Log in and welcome screen; (b) Home screen displaying motivational feedback message, progress for current day for types of vegetables consumed, and vegetable log; (c) Vegetable list and logging functionality; (d) Example of a standard serve of vegetables; (e) Summary challenge screen and level achieved; (f) Feedback screen of serves of vegetables consumed for the day and across the challenge; (g) Leader board of achievements; (h) Example of “How to” content from the Learn section; (i) Learn screen; (j) Example of a recipe from the Meal ideas section.

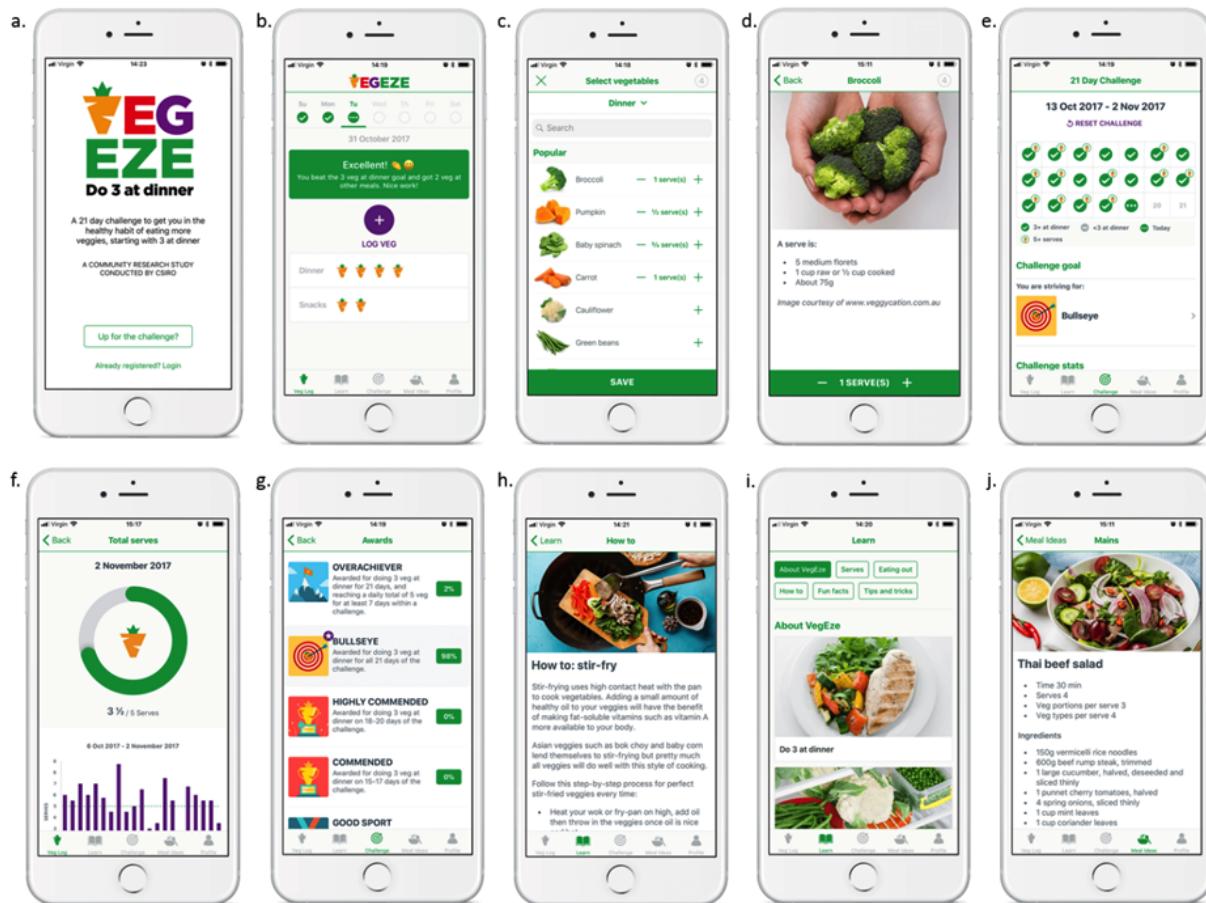


Table 4. The VegEze app was coded for the inclusion of 16 behavior change techniques (BCTs) from the BCT taxonomy.

BCT category	BCT description	Example of intervention component in the app
Goals and planning		
1.1 Goal setting (behavior)	Set or agree a goal defined in terms of the behavior to be achieved	Sets a goal to eat 3 types of vegetables at dinner each day for 21 days
1.4 Action planning	Prompt detailed planning of performance of the behavior	Encourages planning and preparation to eat a variety of vegetables at dinner
1.5 Review behavior goals	Review behavior goals in light of achievement	Daily feedback messages and visual displays provided on types of vegetables consumed
1.6 Discrepancy between current behavior and goal	Draw attention to discrepancies between current behavior and the goal	Home screen and daily feedback messages point out differences between the number of types of vegetables consumed and target; and feedback screen provides feedback about consumption of serves of vegetables relative to Dietary Guidelines
1.7 Review outcome goals	Review the outcome goal in light of achievement	At the end of the challenge, feedback on achievement is provided and a new goal can be set
Feedback and monitoring		
2.2 Feedback on behavior	Monitor and provide informative or evaluative feedback on behavior	Daily feedback messages and visual displays provided on types of vegetables consumed
2.3 Self-monitoring of behavior	Establish a method for the person to monitor and record their behavior	Vegetable log asks participants to record consumption daily
Natural consequences		
5.1 Information about health consequences	Provide information about health consequences of behavior	Learn section provides information on the health benefits of consuming vegetables
5.3 Information about social and environmental consequences	Provide information about social and environmental consequences of behavior	Learn section provides information about the benefits to their family and environmental benefits to consume and not waste vegetables
5.6 Information about emotional consequences	Provide information about emotional consequences of behavior	Learn section provides information that eating vegetables increases energy and sense of well-being
Comparison of behavior		
6.2 Social comparison	Draw attention to other people's performance to allow comparison with own performance	A leaderboard displays the different awards and the percentage of individuals using the app who are striving for each award
Repetition and substitution		
8.1 Behavioral practice or rehearsal	Prompt practice of the behavior to increase habit	Daily push notifications to prompt behavior
8.3 Habit formation	Prompt rehearsal and repetition of the behavior in the same context repeatedly	Push notification to prompt consumption of 3 types at dinner each day
Reward and threat		
10.3 Nonspecified reward	Arrange delivery of a reward if there have been effort and progress in behavior	Virtual rewards received for logging and achieving progress toward 3 vegetables at dinner
10.6 Nonspecific incentive	Inform that a reward will be delivered if effort and progress in behavior are made	Information section informs of virtual rewards for logging and achieving progress toward 3 vegetables at dinner
Scheduled consequences		
14.5 Rewarding completion	Build up behavior by arranging reward following final component of the behavior	Participants receive virtual rewards for eating 3 vegetables, which is contingent on them buying, cooking, and eating vegetables

Phase 9: Evaluate With a Trial of the Product

It is planned that the overall impact of the VegEze app will be evaluated using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [36,37] in an uncontrolled, quantitative study designed to measure its

effectiveness in increasing daily vegetable consumption after 21 and 90 days as well as to determine the associations between user characteristics and outcome measures. The RE-AIM framework focuses the evaluation on 5 program components that are considered together to determine the public health impact of the initiative. These components include reach,

effectiveness, adoption, implementation, and maintenance. The RE-AIM evaluation framework is commonly used to translate research and understand impact within *real-world* settings [36,37]. Changes in vegetable intake will be measured via self-report in the surveys embedded in the app and will be administered at baseline, day 21, and day 90. User characteristics, which will be explored in the evaluation trial for their association with app usage patterns or dietary intake, include, for example, demographic characteristics such as age and gender, health indicators such as weight status, and baseline vegetable intake.

VegEze is currently available in the App store as a standalone research app, and participants have been recruited to take part in the evaluation study through television, radio, and social media. The results of this evaluation will be published and the execution of a communication plan will ensure the results are shared widely at the completion of the trial (phase 10 of the IDEAS framework but not discussed here).

Discussion

Overview

This paper has described the theoretically and commercially derived development of the VegEze app and its features and functionality. Combining a theoretical framework with an industry perspective and input has resulted in an app that was developed in a timely manner while retaining its evidence-base. It has been suggested that the pace of the development, evaluation, and dissemination cycle is too structured and slow in academia, inhibiting the progress in meaningful and engaging smartphone interventions [12,17]. However, few have worked closely with industry partners to remedy this. The quick build phase of VegEze is evidence that academic-industry partnerships can work efficiently and effectively to develop products that target important population health issues.

There are advantages and disadvantages of a rapid build phase that should be acknowledged. The sequential sprints and the staged release of new app features at the completion of each sprint allowed the project team to provide timely feedback to the development team in a highly iterative and continuous refinement process. The rapid development phase also ensured the project team focused on the essential functionality and core features expected by the target users and spent relatively less time on the *nice to have* features that were of limited appeal and utility to our audience. However, with more time we may have been able to benchmark normal usage and develop strategies to maximize user engagement for all features of the app. Regardless, this project demonstrates that a high-quality app that meets users' expectations can be built in a short time frame, with industry support, a commercial development partner, and a motivated multidisciplinary project team.

Internet and mobile phone technology are commonly used as a delivery medium to promote health behavior, both in research and within the health and wellness industry. It has been estimated that half of all mobile phone users have downloaded a health-related app, with fitness and nutrition apps being most commonly downloaded and used at least once daily [38].

However, the effectiveness of these products is not always evaluated, and more specifically, the features of digital products that are associated with effective behavior change is not well understood [14,15]. Only a small proportion of commercially available apps have a theoretical grounding [15], yet reviews of digital interventions published in the scientific literature support the use of theoretical frameworks and theoretically based BCTs [14,15]. A recent review suggested interventions that used theory more extensively and included a greater number of BCTs were more effective than those without a strong theoretical foundation or which used fewer techniques [14]. VegEze is available in the App store; however, it differs from other commercially available apps—its development was strongly guided by an evidence-based framework, behavioral theory, and drew on 16 BCTs. The planned trial will evaluate the impact of VegEze and explore the use of app features and their association with increased vegetable intake.

Review of literature suggest interventions in the general adult population can increase consumption of fruits and vegetables by 0.2 to 0.6 serves per day or up to 1.4 in more controlled environments [39], but this increase is likely because of changes in fruit intake and to a lesser extent, vegetable intake [40]. A more recent review of electronic and mobile health interventions for young adults found from the studies that reported vegetable intake independent of fruit, 4 out of 5 studies increased intake, with reported increases between 0.1 and 0.4 serves per day [41]. Through media coverage and the use of social media, we are expecting that the VegEze app will reach over 5000 people and achieve an average increase of between a quarter to half a serve, and possibly higher in those who have low vegetable intakes.

Strengths

Self-monitoring is one of the most commonly used BCT within smartphone interventions [15]. The VegEze app has at its core the fundamental behavioral techniques of self-monitoring and goal setting. These techniques have been applied in interventions targeting a multitude of behaviors and are consistently identified in various theories as fundamental for the process of behavior change [42]. However, how these are operationalized is critical to the target behavior. We have been careful in how these techniques have been applied in a way tailored specifically to the behavior of interest. We have also been careful in balancing the scientific evidence-base, with the fun, engaging, and usability elements expected from commercial grade apps—largely the result of an ongoing exchange of ideas between the members of the multidisciplinary project team. Finally, the IDEAS framework helped to focus the priorities of the app development and retain scientific method. The use of Apple ResearchKit software means that evaluation surveys are embedded into the app and will allow for a robust evaluation phase. Using the ResearchKit software also saved on development time; however, restricting the initial build to Apple products could also be seen as a limitation. The results and feedback from the planned evaluation study will inform further development of the iOS app as well as expansion to Android products.

Limitations

Although the development of the app was informed by large groups of potential users, they were individuals who had previously registered or participated in health-related initiatives and are likely to have a higher vegetable intake overall than the general population. The barriers to consumption and strategies to increase intake may differ in those who are already consuming vegetables compared with those with low consumption or compared with those who intend to increase consumption. The appeal and impact of the app to a broader range of users will be part of the evaluation. In addition, the majority of the consumer sample were women, aged in their late 40s or early 50s, health motivated, and all volunteered to help in the development of an app targeting vegetable consumption. It is possible that the particular nature of this sample may have informed the development of app features that do not appeal as much to other groups of the population. We expect using mass and social media to recruit for the evaluation trial will result in a more diverse group of users so that as part of the evaluation we can better understand the variation in uptake and usage of the app by different user characteristics. Participants of the pilot

trial used the app for 5 out of a possible 7 days, with an average daily engagement time of almost 4 min. Another literature suggests that, among mobile phone users in the United States, 65% opened their health apps once per day, and 44% used their app for between 1 and 10 min [38]. Achieving sufficient engagement and maintaining user retention rates is difficult, and although the usage of participants in the pilot trial was similar to other research, we will explore usage patterns in greater detail as part of the planned evaluation trial.

Conclusions

The development of VegEze was the result of a research-industry partnership that brought together scientific evidence and commercial *know how* to develop an app targeting inadequate vegetable consumption among Australian adults. The IDEAS framework involved a number of iterative steps and helped to retain a theoretical foundation without compromising the pace of the pathway to market. The effectiveness of the app is currently being evaluated in a large-scale, *real-world* trial, and the results will be reported using the RE-AIM framework.

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Conflicts of Interest

None declared.

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Abbreviations

BCT: behavior change techniques

BCW: behavior change wheel

COM-B: capability, opportunity, and motivation to engage in the behavior

CSIRO: Commonwealth Scientific and Industrial Research Organisation

IDEAS: integrate, design, assess, and share

RE-AIM: reach, effectiveness, adoption, implementation, and maintenance

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Original Paper

Pregnant Users' Perceptions of the Birth Plan Interface in the "My Prenatal Care" App: Observational Validation Study

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Abstract

Background: Birth plans are meant to be a declaration of the expectations and preferences of pregnant woman regarding childbirth. The My Prenatal Care app engages pregnant women in an educational intervention for a healthy pregnancy. We hypothesized that users' positive perception of an in-app birth plan is a relevant step for establishing direct communication between pregnant women and the health care team, based on an online report available on the app.

Objective: This study aimed to evaluate pregnant women's perception about the communicability of birth-plan preparation using a mobile app.

Methods: This was an observational, exploratory, descriptive study. The methodology was user centered, and both qualitative and quantitative approaches were employed. The tools of the communicability evaluation method were applied. Overall, 11 pregnant women evaluated their experience of using a birth-plan prototype interface. The evaluation was performed in a controlled environment, with authorized video recording. There were 8 task-oriented interactions proposed to evaluate interface communicability with users when using the Birth Plan menu. For evaluating perceptions and experiences, a survey with structured and open-ended questions in addition to the free expression of participants was conducted. The primary outcomes assessed were interface communicability and user's perception of the Birth Plan prototype interface in the My Prenatal Care mobile app. Secondarily, we involved users in the prototyping phase of the interface to identify bottlenecks for making improvements in the app.

Results: Regarding users' performance in accomplishing previously prepared tasks, we found that 10 of 11 (91%) women were capable of completing at least 6 of 8 (75%) tasks. A positive relationship was found between the number of communicability problems and the success of completing the tasks. An analysis of the records revealed three communicability breakdowns related to the data entry, save, and scrollbar functions. The participants freely expressed suggestions for improvements such as for the save function and the process of sharing the birth-plan form upon completion.

Conclusions: Users had a positive perception of the Birth Plan menu of the My Prenatal Care app. This user-centered validation enabled the identification of solutions for problems, resulting in improvements in the app.

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KEYWORDS

birth plan; perinatal care; usability, mobile health; mobile app; pregnancy; prenatal care; mobile phone

Introduction

A birth plan is a description of a pregnant woman's expectations and preferences regarding childbirth [1,2]. Planning the birth during the antenatal period promotes health education and fosters communication between women and health professionals [3]. The World Health Organization recommends birth plans as a part of prenatal care [4]. The wide use of such planning can mitigate excessive medicalization during childbirth and empower women to be the protagonist during childbirth [5]. Pregnant women should receive comprehensive health care that is continuous and customized from the prenatal period until delivery [6]. Hence, relevant clinical information needs to be available at the time of the delivery, including a birth plan.

Mobile apps related to pregnancy, birth, and childcare are important information sources for users, as they combine education and functionalities of communication to support the self-management of health [7]. App adherence can influence pregnant women's behavior such as keeping prenatal care schedules, improve health care, and promote self-care [8].

The My Prenatal Care app (Figure 1) was created in 2016 to engage pregnant women in an educational intervention for a healthy pregnancy, delivery, and puerperium [9]. This app is part of a project that aims to highlight the importance of gestational dating at birth to recognize premature newborns. Developed by an academic and multidisciplinary team of researchers, this app is organized into the following three sections: My Pregnancy, The Delivery, and My Baby Is Born. Domain specialists have validated the scientific content in the app, which is offered in Portuguese, English, and Spanish [9]. The app is available for free in app stores, with 100,930 downloads reported until November 4, 2018, of which 90,290 downloads are from Android devices and 10,640 are from iOS devices. Before introducing the birth plan in this app, an

exploratory study analyzed a planning proposal to support obstetric care and the development of an interoperable open electronic health record (EHR) [10] standard for entries of clinical information in electronic system interfacing [11]. The proposed Birth Plan menu contains expectations for the birth moment and parts of individual medical history, which can be declared by the users at any point in time. The interface menu was prepared with the following eight sections: Identification, My History, My Pregnancy, Preparations, My Childbirth, Delivery, Other desires and expectations, and Share (Figure 2) [11].

The human-centered design and development of systems require that apps be made usable and useful by focusing on the users [12]. Usable systems are beneficial for supporting an appropriate human-system interaction and fostering patient adherence [13,14]. In this context, communicability is an attribute of software that effectively conveys to users the underlying design intent and interactive principles [15]. The communicability evaluation method is an approach to evaluate the quality of the designer's communication with the user through the interface. Proposed by de Souza (2005), this evaluation allows the identification of communication breakdown with the computational artifact during user interaction [16]. We hypothesized that a positive perception of users on the in-app birth plan template is an essential step for establishing direct communication between pregnant women and the health care team at birth, based on an online report available on the app. With the early involvement of users in the prototyping phase of the interface, resolving communicability barriers would result in improvements that promote adherence to and foster the utility of this app. The present study aimed to validate an interface for birth-plan preparation in the My Prenatal Care app by examining interface communicability and the perceptions and experiences of a sample of the target population.

Figure 1. The My Prenatal Care app.



Figure 2. The Birth Plan menu within the main menu of the app.

Methods

Study Design

This observational, exploratory, descriptive study employed an interdisciplinary approach combining health and information sciences. The methodology was user centered and employed qualitative and quantitative approaches to assess pregnant women's experience of using the Birth Plan menu of the My Prenatal Care mobile app. Pregnant woman who agreed to participate in the study individually answered a semistructured questionnaire (Multimedia Appendix 1). Their responses were analyzed to identify their sociodemographic and obstetric profiles and assess their previous experience with mobile technology.

To identify the points of communication breakdown, task-oriented interactions were analyzed by two of the three steps in the communicability evaluation method—tagging and interpretation. Communication breakdowns were defined as disruptions occurring during user interaction based on the computational artifact acquired from video analysis, according to a prespecified set of utterances [15]. Tagging involves selecting words from utterances regarding a user's reaction during interaction [16]. Communication was assessed based on the ruptures identified in the communicability evaluation method [15,16]. Finally, users' experiences were examined by conducting an individual survey. The study was conducted in Portuguese. In this report, we intended to achieve comprehensiveness and quality with respect to the effectiveness of digital programs proposed in the mHealth Evidence Reporting and Assessment checklist published by the World Health Organization [17].

Recruitment and Settings

The research protocol was approved by the Ethics Committee of the Universidade Federal de Minas Gerais, with the national register number CAAE-68076617.2.0000.514 in Plataforma Brasil. All participants were informed that participation was

voluntary and were provided the details of the study. To ensure voluntary participation, they were allowed to withdraw their consent at any time, without any consequences. Written informed consent was obtained from each participant. To avoid influencing the users' perceptions positively, they were not provided any direct or indirect gratification. Additionally, there was no burden on the participants, except their time.

The participants were recruited from the university's prenatal care center. High-risk pregnancies are often referred to this public and teaching health care institution. Data were collected from December 2017 to January 2018. The participants attended institutional focus groups led by obstetric nurses before enrollment in the research. During these group sessions, the importance and objectives of elaborating a birth plan and preparation for birth were discussed. This educational approach is routine in this unit and is not part of the methodology.

User Sampling

Considering the significant variance in the computer skills of our population, this study used a convenience sample of 11 participants to evaluate users' perceptions of the birth-plan interface tested in this study. Based on a previous report, the detection of usability problems requires at least five users, because the function of the number of users tested or the number of heuristic evaluators is modeled as a Poisson distribution [18]. According to a study by Nielsen in 2000, 85% of usability problems can be revealed by involving five users during iterative design evaluation [19]. However, for a comprehensive analysis of problems, the number of required users is almost doubled [20].

A total of 15 women expressed interest in participating in this study during their prenatal care visit. Three women dropped out of the study citing fatigue during the ethics information sessions before communicability testing. One pregnant woman was excluded during the tests because of visual impairment. The final sample comprised 11 participants.

Study Procedures

Pilot Evaluation

We conducted a pilot evaluation to prepare a controlled video-shooting environment. Four women (of whom two were not pregnant) who were not part of the main sample were invited to validate the setting, equipment, and instruments prepared for the monitored interaction between the participants and the interface. First, the equipment and mobile devices were tested and adjusted for effective recording of the interactions in two nonpregnant women. Second, data-collection instruments to be used for the participants and for evaluation of communicability were tested in two pregnant women. Poor image quality revealed the need to replace one video camera, while the data-collection instruments were considered adequate. We captured images during the test from four different angles using one tablet (a 7-inch Samsung tablet) and two Sony high-definition digital cameras supported by tripods and software. During the execution of the predefined tasks, one angle captured the manipulation of the mobile device, one recorded the face, the third recorded and entire body. The AZ-Screen-Recorder software (Hecorat Global Technology, Hanoi, Vietnam) continuously captured images of the mobile interface during the experiments. Further, observational notes were taken during filming.

Communicability Evaluation Method

In order to identify and adjust human-computer interaction problems, we used the communicability evaluation method. The focus was on the quality of the user interaction while using the Birth Plan prototype interface. The researcher verbally and in writing advised the participants about the task to be executed in the app. The participants were free to talk during the test and received a fictitious case report ([Multimedia Appendix 2](#)) based on a real situation, in which a pregnant woman named Ana, who had already created a birth plan using the My Prenatal Care app, wanted to change some aspects of the birth plan. The participants were asked to perform eight modifications in the birth plan using a smartphone. The same smartphone with the same internet speed was used by the users in all tests—a Samsung Galaxy J5 smartphone with an Android-based operating system connected with 3G broadband internet. Each task purposefully included one of the menus of the Birth Plan prototype interface for exploring all the menus ([Figure 2](#)).

The experimental scenario was exclusively used for testing in order to avoid interruptions and displacement. No help was provided by the researchers or third parties. Identical task-oriented interactions were used for each participant individually. The evaluation started with a fictitious case in which the strategy for the communicability test was implemented by minimizing personal involvement or deep reflections. This procedure allowed the users to work impartially only on the tasks without personal opinions.

Video record analysis, tagging, and interpretation were performed for identifying breakdowns in communicability and problems in human-computer interaction by detailing the moments and interfaces in which they occurred [[15,16](#)]. We created a tag for each difficulty expressed by the user based on the following expressions from the metacommunication message

approach recommended by de Souza [[16](#)]: “What’s this?” “Why doesn’t it?” “Help!” “Where is it?” “What now?” “What happened?” “Oops!” “Where am I?” “I can’t do it this way,” “Thanks, but no, thanks,” “I can do otherwise,” “Looks fine to me,” and “I give up.”

The video recordings and observation notes were reviewed repeatedly for analysis and tagging using the Filmora software (Wondershare Technology, Shenzhen, China). Communication breakdowns were analyzed to measure interface communicability for the users. Two authors (JC and IO) judged the participants’ interaction with the interface. All video material and notes were first analyzed individually and then combined based on consensus between judges, following the communicability evaluation method [[16](#)]. Communicability was measured by the frequency of breakdowns in each task and by each tag. The outcomes were classified as follows: tasks completed without interaction breakdown, tasks completed with interaction breakdown, and unfinished or unrealized tasks. The frequency of instances of communicability breakdown in each category was used for subsequent analyses.

User Experience

An individual in-person evaluation assessed users’ experience regarding the interaction with the system. We conducted a semistructured survey with one question on the difficulties experienced in completing the test and two open-ended questions allowing for free expression to provide suggestions and record experiences/opinions ([Multimedia Appendix 3](#)). Adjectives or expressions associated with the individual experience during the test were captured. This evaluation aimed to identify the difficulties and user perception in using the in-app birth-plan interface.

Data Analysis

All data were stored in an Excel database and analyzed in IBM SPSS 22.0 (IBM Corp, Armonk, NY). Descriptive statistics explored the characteristics of the participants, summarized according to the nature of the variables. The numerical variables were described using minimum and maximum values, average, and SD. The variables are presented using absolute and relative frequencies. The responses for the difficulties experienced in performing the tasks were presented in terms of absolute and relative frequencies. The qualitative evaluation described how positive the users’ experience was in interacting with the app.

Results

Participant Characteristics

The age of the 11 pregnant women enrolled in this study ranged from 18 to 39 years, with an average age of 30.7 (SD 6.5) years ([Table 1](#)). Two participants had a postgraduate level of education. However, most of them had studied only until the high school level (7/11, 64%). Marital status or stable marriage was predominant (9/11, 82%), and eight of the participants (8/11, 73%) were employed.

Regarding the obstetric profile of the participants, gestational age ranged from 17 to 39 weeks of gestation and almost half of the participants were parous (6/11, 55%). However, only half

(3/6, 50%) of the parous participants classified their previous childbirth experience as good. None of the participants had previous experience in making a birth plan.

All participants owned a smartphone, and 10 of 11 (10/11, 91%) had access to mobile internet. The same frequency was observed for experience with a device with an Android-based operating system. The duration of daily smartphone use was 3 hours or more for 6 of the 11 women (55%), while 4 of the 11 (37%) used their phones for more than 5 hours per day. WhatsApp was the most frequently used app (9/11, 82%). Seven (7/11, 63%) participants reported no experience with health and well-being apps, while three had used an app to support their present gestation.

Communicability Evaluation Method

Task 8 was the only task that was completed by all the participants (Table 2). It pertained to sharing a birth plan output file with a person from the participant's WhatsApp contacts. The participants took the longest time to complete the tasks for the "Identification" menu (Task 1), followed by the "Other desires or expectations" menu (Task 7). The lowest performance was observed for Tasks 1, 4, and 6, among which Tasks 4 and

6 pertained to accessing specific options in the menu and changing them.

The number of tags found in the analysis of the video recordings, after considering the observers' notes, is presented in Table 3. The distribution of the tags by activity and participants allowed a more in-depth analysis of users' interaction with the interface, thereby adding new insights and identifying communicability problems.

The most-frequent tag—"What happened?"—was associated with starting the "Save" action 16 times. We observed repeated attempts to use the "Save" action after finishing tasks because the provided feedback was not perceived by the user. The second most-frequent tag, with 14 instances, was "Where is it?" This tag symbolizes the difficulty of the user in finding functionalities in the interface to perform the required actions [16]. There were 10 instances of "Looks fine to me." In these situations, the user was convinced of having performed the task successfully. However, the users did not actually perform the task successfully. We interpreted this as a problem in human-computer interaction due to an incomplete message from the designer of the interface.

Table 1. Characteristics of the study participants (N=11).

Variables	Values
Demographic characteristics	
Age (years), mean (SD), (range)	30.7 (6.5), 18-39
White race, n (%)	6 (55)
High school or lower education, n (%)	7 (64)
Not single, n (%)	9 (82)
Employed, n (%)	8 (73)
Obstetric information	
Gestational age (weeks), mean (SD); range	32.5 (8.2); 17-39
Nonparous, n (%)	6 (55)
Good experience with previous birth ^a , n (%)	3 (50)
No prior experience with a birth plan, n (%)	11 (100)
Mobile technology experience, n (%)	
Smartphone ownership	11 (100)
Having access to mobile internet on the smartphone	10 (91)
Using a smartphone with an Android-based operating system	10 (91)
Most frequently used app is WhatsApp	9 (82)
Using a smartphone for ≥ 3 hours daily	6 (55)
Never used a mobile health app	7 (64)

^aN=6 for parous women.

Table 2. Outcomes for using the Birth Plan prototype interface according to each task completed (N=11).

Task number	Task	Participants who performed the task, n (%)
1	Finding the Identification menu: Enter the phone number 122334455 for the primary care contact	8 (73)
2	Finding the My History menu: Change parity to 2	10 (91)
3	Finding the My Pregnancy menu: Write “I used ferrous sulfate”	10 (91)
4	Finding the Preparations menu: Change the option to “Yes” for Photographer/Movie	8 (73)
5	Finding the Birth Position menu: Change to “squatting position”	10 (91)
6	Finding the Birth menu: Choose the “By myself” option in the baby’s first shower	8 (73)
7	Finding the Other desires and expectations menu: Write “I would like to hire a professional photographer”	10 (91)
8	Finding the Share menu: Share the Birth Plan with Ana’s friend through WhatsApp	11 (100)

Table 3. Frequency of tags analyzed with the communicability evaluation method to assess user interactions and the Birth Plan prototype interface.

Tag	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Total
Where is it?	2	1	2	2	2	1	0	4	14
Looks fine to me	2	1	1	2	1	3	0	0	10
What happened?	5	3	2	2	3	1	0	0	16
Help!	3	0	0	1	0	0	0	0	4
Oops!	3	1	0	0	0	0	0	0	4
Where am I?	0	0	0	1	0	0	0	0	1
What now?	1	0	0	0	0	0	0	4	5
I give up	1	0	0	1	0	0	0	0	2
Total	17	6	5	9	6	5	0	8	56

The analysis of the execution of Task 4 presented nine instances of tags. A higher difficulty could be attributed to the positioning of this entry in the menu options. We intentionally asked the participants to localize this entry in the bottom edge of the menu to analyze the interaction between the users and the scrollbar. We noticed a positive relationship between the number of communicability breakdowns and success in completing tasks, except for Task 8, which had eight instances of tags. A breakdown of communication occurred because the users chose the option “Share” in the Birth Plan menu; the symbol that indicated loading lacked text and was not sufficient for users to understand its function. Another point of breakdown was when the users did not immediately realize that Ana’s friend (a fictitious contact for sharing the birth plan) could be one of their contacts.

Task 7 was not assigned any tag, and 91% (10/11) of the users completed the task. Tasks 1 and 4 were associated with the highest number of tags, indicating a higher frequency of communication breakdown compared to the other tasks. These tasks had the lowest completion rate (8/11, 73%). Task 1, which received 17 tags, pertained to the first contact with the Birth Plan prototype interface. Therefore, the initial difficulty experienced by the users was expected. However, we found communication breakdowns in two other instances: One was

related to a difficulty in finding the option “Phone Number” in the Birth Plan menu, and the other was related to the feedback of the save function.

Table 4 presents the individual performance of users for each task. Most of the tasks previously prepared to be performed in the Birth Plan menu (6/8, 75%) were completed by the majority of pregnant users (10/11, 91%). Three users (3/11, 27%) completed all tasks despite interaction breakdown. Five users (5/11, 45%) completed the majority (7/8, 88%) of the tasks. The lowest performance was observed in a user with texting difficulty because of a congenital malformation on her fingers (P2).

User Experience

Nine participants (9/11, 82%) reported having no difficulties when they were preparing a birth plan using the app. Two of them reported impairments associated with their ability to handle smartphones, but the impairments pertained to their ability, in general, and not solely during the study. They expressed spontaneous phrases about their experience of and opinion about the Birth Plan prototype interface ([Multimedia Appendix 4](#)). The content of responses that included adjectives and expressions associated with the app or the experiment were identified and summarized according to opinion (**Table 5**).

Table 4. Users' individual performance on the communicability evaluation method according to breakdown.

Participant number	Tasks completed without breakdown of interaction	Tasks completed with breakdown of interaction	Unfinished or unrealized tasks
1	4, 6, 7, 8	1, 2, 5	3
2	None	1, 2, 3, 8	4, 5, 6, 7
3	2, 3, 4, 5, 7	8	1, 6
4	2, 3, 5, 6, and 7	1, 4, 8	None
5	2, 3, and 7	1, 5, 8	4, 6
6	2, 4, 6, and 7	3, 5, 8	1
7	1, 3, 5, 6, 7, 8	2	4
8	7, 8	1, 2, 3, 4, 5, 6	None
9	3, 4, 5, 6, 7	1, 8	2
10	2, 3, 4, 5, 6, 7, 8	None	1
11	4, 5, 6, 7, 8	1, 2, 3	None

Table 5. Tally of users' opinions regarding the Birth Plan prototype interface.

Users' opinions	Users
Positive perceptions	
Communication	P5 ^a , P9, P11
I liked it	P5, P6, P7, P8
Great or excellent	P1, P7
Good or very good	P2, P4, P10
Cool	P3
Interesting	P3, P6, P8, P9
Relaxed	P10
Process-related perceptions	
Learning	P2, P10
Improvement of care	P4
Practicality	P11
Speed	P11
Ease	P7
Monitoring autonomy	P1, P5, P9

^aP: participant.

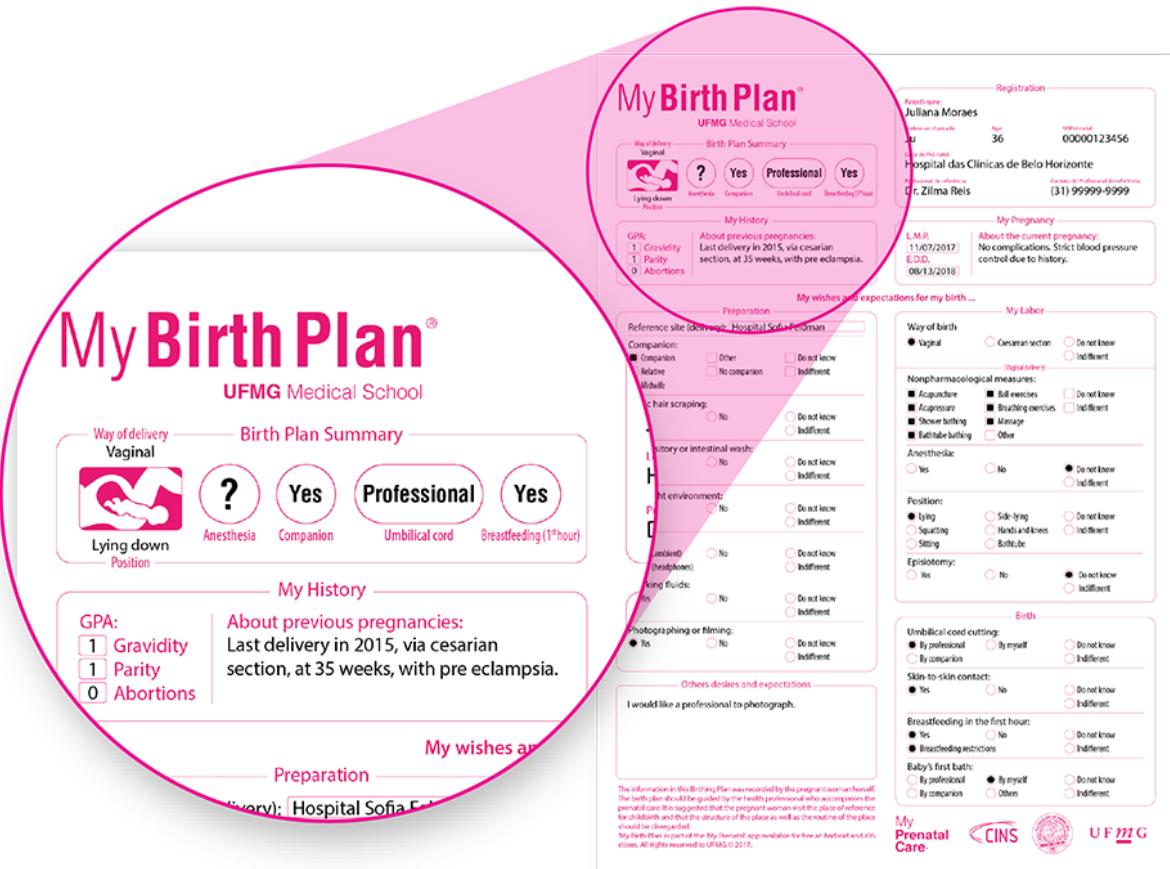
Discussion

Principal Results

In this study, we validated a birth-plan interface in terms of its communicability based on the interactions and perceptions of pregnant users for creating an in-app birth plan. Our main finding was the positive perception of users regarding birth-plan preparation in the app. An advantage of using a mobile app for creating and sharing birth plans is that it is promptly available for future retrieval anywhere the birth may take place. This document is personal to each woman once she has expressed her wishes and should be reviewed during every follow-up visit

and modified, if any complications arise [4]. Planning birth is a part of prenatal care, and the app interface supports flexibility in the user's answers and any subsequent modifications made before delivery. The offered interface contains a self-explanatory questionnaire with structured and preformatted questions and answers as well as opportunities for free description (Figure 3). Previous reports showed that the provision of skilled care during delivery and women's satisfaction can be improved with communication between pregnant women and health professionals through prior planning for birth [21]. We hope that during labor, discussing the birth plan with caregivers can be helpful by accessing it on the smartphone or transferring it from the app to local information systems.

Figure 3. A completed Birth Plan ready to be shared in the My Prenatal Care app. The amplified area shows the structured questions and free descriptions by the pregnant women.



To play an active role in identifying a pregnant woman's needs, birth plans are being introduced during prenatal care by involving women in discussions with future care providers and listening to their desires and flexibilities regarding the birth experience [22]. An editable birth plan as an in-app function should enhance interactions between users and the app when attending to interactive requirements. The lack or low number of instances of communicability breakdown, which were identified using the communicability evaluation method in this study, were related to completed task executions. This methodology, a systematic and qualitative procedure, adequately evaluated users' experience of interaction with the interface by emphasizing the aspects of communication, as was done in previous studies [15,23]. When applying the communicability evaluation method in this study, we expected that the early involvement of pregnant women users in the prototyping phase of the birth plan interface would help identify bottlenecks and improvements that need to be made in the app. We believe that successfully evaluating human factors when analyzing the human-interface interaction can promote users' adherence to the electronic birth plan.

With respect to the complete execution of tasks and based on the analysis of the communicability breakdowns identified by the communicability evaluation method, the results pointed out the areas that could be enhanced in the app. Regarding improvements in the interface for solving communication

problems, we introduced some modifications. The "Save" message now appears in a new window that opens automatically at the center of the screen, thereby signaling the saving process. Another modification was the appearance of the text message "Loading" when the "Share" command is used. For better interaction with the scrollbar, we plan to use an animation to signal the bar.

Our findings revealed favorable outcomes for the overall user experience. Most of the pregnant users did not report difficulties when performing the tasks with the Birth Plan prototype interface. The user experience survey revealed that all of them expressed good opinions, and "I liked it," "Interesting," and "Communication" were some of the positive aspects that the users associated with the app (Multimedia Appendix 4). Impairments in task executions were associated with the participants' ability to handle smartphones. Moreover, one of the participants had a congenital malformation in her fingers. A challenge for future versions of the app is offering better opportunities to users with disabilities.

Another point to highlight is the sharing of clinical data among systems. Health data include relevant information that might support medical decisions. EHRs demand essential properties such as sharing data with semantic interoperability, preserving flexibility for modifications, and fostering efficacy to promote communication among stakeholders [24]. Credible apps related to perinatal care should be developed and managed in

partnership with qualified health care professionals [7]. In this study, we first prepared a standardized model of information to transfer the birth-plan report from prenatal care to childbirth through digital channels [11]. The framework for the birth plan was based on a structured model of information and a reference template based on open EHR specifications [10]. In fact, the interoperability of the clinical data among information systems was not tested. However, because medical concepts and a data format were specified, the entries for the birth-plan questions can be correctly interpreted by a health professional or are understandable in an electronic medical record.

Limitations

This study had some limitations. Although the sample was considered adequate to validate tests of human-computer interaction, it did not allow for inferential statistical analysis. Regarding penetrability, technologies directed toward pregnancy care require flexibility in order to support different models of birth, specific circumstances, and cultural meanings of childbirth. We can assess the scope and usefulness of this tool only by monitoring the adoption of the app. In the future, we wish to conduct another study involving different centers, cultures, and languages, as the app is currently offered in only three languages. Furthermore, we would like to compare pregnant women's perceptions when birth plans are declared in a traditional manner such as orally, in writing, or through information technology.

Another limitation was the controlled experimental scenario, which may not reflect real-world situations. However, the present study avoided bias in analysis owing to differences in the speed of the internet connection and smartphone performance.

An important factor is the limitation of the use of technology in a health care setting. During pregnancy, it is advisable that prenatal care be provided by health professionals directly to pregnant women. Any impact of a birth plan in improving the

quality of care cannot be attributed only to the app, but also to best obstetric practices [25].

Comparison with Prior Work

Mobile apps have become a primary source of health guidance for people. Other reports with similar target users have revealed that internet access through websites or mobile apps is useful in helping women adopt a healthy lifestyle during pregnancy and in self-managing their prenatal care [26,27]. In fact, the introduction of an obstetric EHR has improved documentation completeness [28]. The internet may be a promising modality for communication toward the provision of comprehensive health care during pregnancy [29]. However, the quality and safety evaluation of health and well-being apps remain inadequate [30]. The user interface design, performance, and stability of the software program is a part of this validation. The interaction among conventional mobile systems is based on a modified version of a human-desktop computer interface [31]. During the development of personal health records, human-centered design allows the development team to focus on users' needs to increase the satisfaction with and acceptance of the system [12]. Our project aimed to introduce the birth plan as a personal health record, prepared by pregnant women in the community and assessed by a free and institutional app with a significant number of users.

Conclusions

The interface for birth plan-preparation tested in this study, which was provided through a mobile app, was perceived positively by pregnant study participants. Its user-centered validation enabled the identification of new solutions to solve communication problems, resulting in improvements to the app. This experience revealed real-world perspectives on the communicability for creating an in-app birth plan and on supporting information sharing among pregnant women and the health care team.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire on users' characterization.

[[PDF File \(Adobe PDF File\), 77KB - formative_v3i1e11374_app1.pdf](#)]

Multimedia Appendix 2

Fictitious case report.

[[PDF File \(Adobe PDF File\), 81KB - formative_v3i1e11374_app2.pdf](#)]

Multimedia Appendix 3

User experience test survey.

[[PDF File \(Adobe PDF File, 60KB - formative_v3i1e11374_app3.pdf](#)]

Multimedia Appendix 4

Qualitative analysis of the perceptions of users.

[[PDF File \(Adobe PDF File, 118KB - formative_v3i1e11374_app4.pdf](#)]

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Abbreviations

EHR: electronic health record

P: participant

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Original Paper

Challenges in the Development of e-Quit worRx: An iPad App for Smoking Cessation Counseling and Shared Decision Making in Primary Care

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Abstract

Background: Smoking is the leading preventable cause of morbidity and mortality in the United States, killing more than 450,000 Americans. Primary care physicians (PCPs) have a unique opportunity to discuss smoking cessation evidence in a way that enhances patient-initiated change and quit attempts. Patients today are better equipped with technology such as mobile devices than ever before.

Objective: The aim of this study was to evaluate the challenges in developing a tablet-based, evidence-based smoking cessation app to optimize interaction for shared decision making between PCPs and their patients who smoke.

Methods: A group of interprofessional experts developed content and a graphical user interface for the decision aid and reviewed these with several focus groups to determine acceptability and usability in a small population.

Results: Using a storyboard methodology and subject matter experts, a mobile app, e-Quit worRx, was developed through an iterative process. This iterative process helped finalize the content and ergonomics of the app and provided valuable feedback from both patients and provider teams. Once the app was made available, other technical and programmatic challenges arose.

Conclusions: Subject matter experts, although generally amenable to one another's disciplines, are often challenged with effective interactions, including language, scope, clinical understanding, technology awareness, and expectations. The successful development of this app and its evaluation in a clinical setting highlighted those challenges and reinforced the need for effective communications and team building.

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KEYWORDS

mobile health; smoking cessation; primary care; decision aid

Introduction

Background

Smoking is the leading preventable cause of morbidity and mortality in the United States [1]. Each year, smoking kills nearly 450,000 people in the United States and costs almost US

\$100 billion in health care costs and productivity losses. An estimated 19% of adults in the United States smoke [1]. Although numerous interventions improve the likelihood of successful smoking cessation and the resulting health benefits [2], most smokers relapse or require several interventions and attempts before staying smoke-free [3]. Primary care physicians

(PCPs) have an opportunity to discuss smoking cessation evidence in a way that enhances patient-initiated change [4] and quit attempts [5] using new approaches. Unfortunately, although current guidelines summarize the comparative effectiveness of available smoking cessation medications, counseling techniques, and other methods, including smoking cessation apps and social media tools [6-8], physicians discuss cessation with smokers infrequently and underutilize tobacco cessation medications [9,10]. A shared decision-making (SDM) tool can add value to the interchange between a PCP and patient.

Methods that allow physicians to conduct more frequent, efficient tobacco counseling are necessary to disseminate smoking cessation evidence [11-14] and could have a substantial impact, as even brief counseling by a PCP can increase the likelihood of smoking cessation [4]. Decision aids are a method that can assist clinicians and patients in finding motivating, personally effective quit strategies that can be integrated into physician offices where patient-provider discussions about smoking cessation typically occur [15].

Innovative Approaches

The use of a hand-held electronic tool can increase physicians' comfort with cessation counseling [16]. Furthermore, SDM has the potential to engage and inform patients and improve quality of care, especially when combined with decision aids and health information technology tools [17]. Integrating such tools can also enable better and timely interaction between a PCP and patient. Tudor-Sfetea et al evaluated mobile health (mHealth) apps in the context of smoking cessation [18]. As a result of using Quit Genius or Smokefree, which are 2 smoking cessation mobile apps in the United Kingdom, this study demonstrated positive preliminary changes in smoking behavior and it was demonstrated that these apps are feasible and potentially effective tools [18].

With so many options for cessation support, it is important for clinicians to personalize evidence-based interventions that are both useful and appealing to patients. During primary care office visits with competing priorities [19], applying patient-centered outcomes research (PCOR) for any given problem can be challenging but can also benefit workflow in the clinic setting by increasing efficiency.

To address these opportunities and challenges, we developed an iPad/tablet-based mHealth decision aid app (e-Quit worRx, University of Cincinnati) to assist PCPs in disseminating PCOR evidence about smoking cessation options and engage in SDM.

The primary objective of this research effort was to develop an acceptable and easy-to-use smoking cessation decision aid that incorporated PCOR evidence into an mHealth tablet-based app called e-Quit worRx. We have discussed the challenges of developing the app through an iterative process.

Methods

Project Team

An interdisciplinary team of subject matter experts was formed to complete this project. These experts included specialists in primary care, smoking cessation and social work, health information technology and mHealth, app development and computer programming, and qualitative and primary care practice-based research. Each brought a unique perspective to the overall design of the app both in functionality and utility.

Conceptual Framework

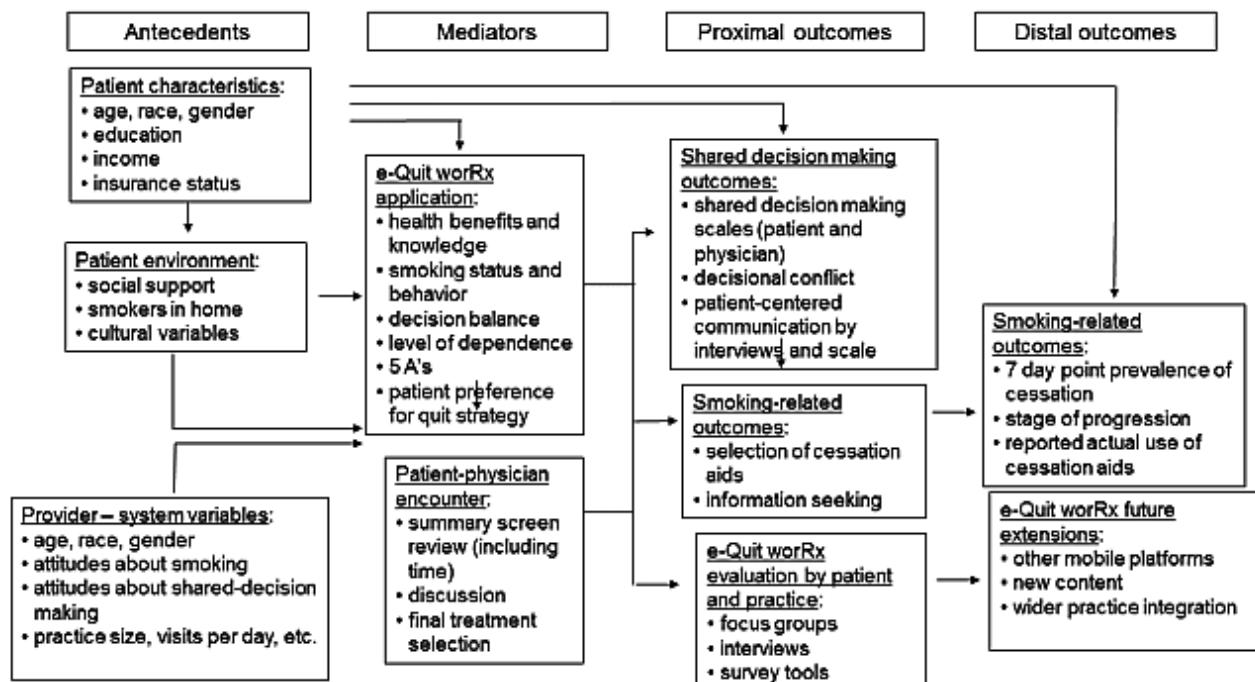
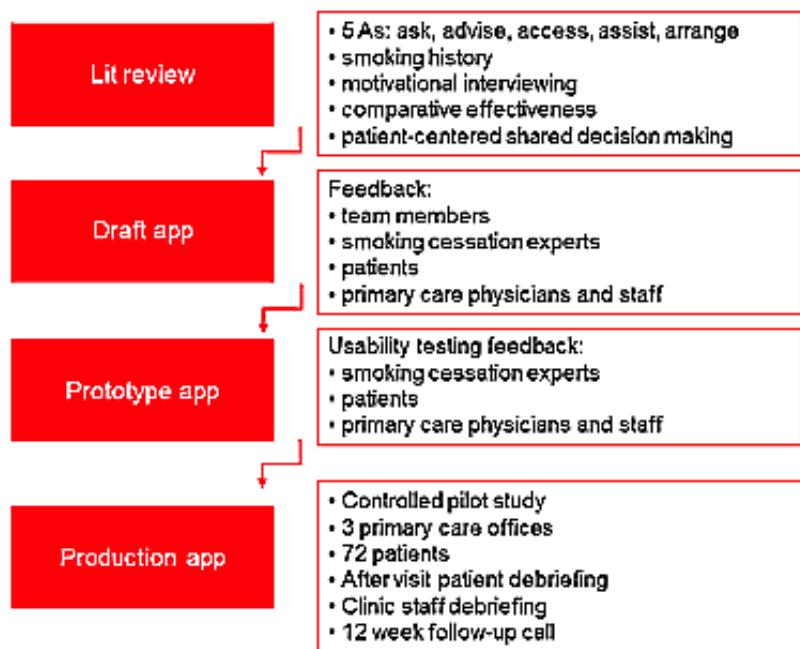
This project was guided by a conceptual framework grounded in SDM and behavioral theories of smoking cessation (eg, stages of change and the 5As—Ask, Advise, Assess, Assist, and Arrange; *Figure 1*) [20]. This framework includes key determinants, tools, and outcomes that lead to SDM and smoking cessation. We adapted frameworks developed for primary care for smoking cessation counseling [21] and for SDM such as those used in colorectal cancer screening [22] to create a conceptual framework to guide the study innovations, interventions, and outcomes. We aimed to combine theory-driven aspects of smoking cessation (eg, stages of change and self-efficacy) with iPad-based interactive, tailored delivery of PCOR evidence to smokers at the point-of-care (their PCP's office). The overall goal of the decision aid was to provide evidence-based and patient-centered smoking risk and cessation information to patients. Once developed and acceptable to patients and physicians, the decision aid would then be introduced into a routine office visit while minimizing physician and office staff training and ongoing time commitment.

Project Design

The project was completed in 3 phases using a design process depicted in *Figure 2*: (1) development of a storyboard of app content and flow and initial app version; (2) evaluation of the app at various development stages with physicians, medical staff, and patients through an iterative process and app refinement; and (3) clinical pilot testing of the app with patients in the PCPs office. This process was used in the first 2 phases. The third phase will be reported in a separate study.

Phase 1: Content Development, Initial Feedback, and Storyboarding

Development of a new task or device is often conceptualized through the use of storyboarding [23]. Some processes of app development that are Web based have recently been patented [24]. Iqbal et al have laid out some of the requirements for engineering practices of mobile app development [25]. This process, although challenging, provides an excellent tool for development teams to understand what the final process or device should look like and how it works. The entire research team laid out a storyboard for how the app should flow from a physician and patient perspective.

Figure 1. Conceptual framework for shared decision making using an app for evidence-based smoking cessation.**Figure 2.** Study flow and app design process.

One of the steps in the storyboarding process is to provide input on how the user will interact with the app. Human factors and ergonomics play a role as well. To accomplish this, separate focus groups with patients and smoking cessation experts were held as well as individual interviews with PCPs and medical support staff. The goal of these initial sessions was to understand what stakeholders wanted and needed to be included in a clinical encounter for smoking cessation. These interviews addressed, as appropriate, previous smoking attempts, previous and desired communication about smoking, use and comfort with electronic

media, and knowledge and comfort with evidence-based smoking cessation tools.

Clinical evidence-based content for app development was obtained in a large part from the Smoking Cessation Guidelines for Clinicians [6] and Cochrane reviews [2]. In addition, content from the following were also obtained: the Centers for Disease Control and Prevention's smokefree.gov website [26] and incorporation of feedback from focus group interviews as well as knowledge from the scientific literature in the following: (1) PCOR studies in the areas of primary care [4,27-29], (2)

smoking cessation medications [30], (3) mHealth tools [31-34], and (4) decision aids [35].

e-Quit worRx Coding and Design

The team used an iPad platform (iPad 2, Apple), using iOS 7, as the user interface for the decision aid. Code for the app was written in Apple's Xcode software on a MacMini using the Swift programming language (Apple). In total, 2 graduate students from the university's computer science program worked with the team to write the code. Prototype app versions were tested on 3 iPad 2 devices.

Phase 2: Iterative Usability Testing With Stakeholders and End Users

Once a prototype app (version 1.0) was complete, a second round of key informant interviews was completed with patients, clinicians, and clinical support staff. These interviews focused on usability and included a modified System Usability Scale (SUS) as well as a semistructured questionnaire [36]. Interviews touched upon participants' experiences using the app,

recommendations for modifications, and evaluations of specific app components. Initial rounds of testing used concurrent think-aloud techniques to elicit real-time feedback and emotional responses. Later rounds of testing used retrospective think-aloud techniques to assess important metrics, such as accuracy and time, needed to complete tasks on the app.

Participants

This study was approved by the Institutional Review Board of the University of Cincinnati.

For the first 2 phases described in this study, our team sought feedback from and recruited key stakeholders including patients and PCPs and primary care office staff (nurses, medical assistants, and office managers) ranging in their comfort and familiarity with technology. Table 1 summarizes the demographics and role of all participants. We also sought feedback from an interdisciplinary team of faculty and staff from the University of Cincinnati with expertise in addressing tobacco cessation.

Table 1. Basic demographics and role in Phase 1 and Phase 2. The data reported here reflects those individuals who participated in year 1 in the following: (1) interviews (clinical personnel), (2) focus groups (experts and test patients), and (3) the testing with both clinical personnel and test patients.

Stage, position	Demographics		
	Gender	Age (years)	Race
Interviews^a			
PCP ^b	F	38	Asian
PCP	F	31	White
PCP	F	31	White
PCP	F	54	White
PCP	F	49	Asian
PCP	F	62	White
Staff registered nurse	F	57	African American
Staff registered nurse	F	38	White
Staff MA ^c	F	43	White
Staff MA	F	36	African American
Staff MA	F	33	White
Expert focus group			
Assistant professor	F	42	White
PhD researcher	M	42	White
Professor, clinical pharmacist specialist	F	58	White
Nicotine expert	M	(Missing)	African American
Professor	F	47	White
Director, addiction division, Veterans Affairs	M	49	White
Tobacco treatment specialist (retired)	F	71	White
Coordinator/lung cancer screening	F	58	White
Case manager/lung cancer screening	F	43	White
Patient focus group (smoker)			
Yes	F	69	White
Yes	M	66	White
Yes	M	39	White
Yes	F	29	White
Yes	F	33	White
App testing with clinical personnel			
PCP	F	30	African American
PCP	F	54	White
PCP	M	40	White
Staff registered nurse	F	57	White
Staff registered nurse	F	38	White
App testing with patients			

Stage, position	Demographics		
	Gender	Age (years)	Race
— ^d	M	30	White
—	F	52	White
—	M	66	White
—	F	59	White
—	M	29	White
—	M	47	White
—	M	55	White

^aInterviews are from clinical personnel from 3 clinical sites.

^bPCP: primary care physician.

^cMA: medical assistant.

^d—: not applicable.

Patient participants were recruited from the target practices for the eventual pilot trial and recruitment guidelines were in line with previous similar studies [27]. Nonpatient participants were recruited using the snowball technique, beginning with physicians and experts known to the research team, who were then asked to recommend others who could speak on the topic of interest and so on.

A mixed-methods approach was incorporated for app design. The primary outcome was to determine usability. Data sources included qualitative feedback from semistructured interviews and focus groups with key stakeholders, SUS results, and feedback and discussions among our research team members. Interviews were conducted until saturation was achieved—no new ideas were being brought forward [37]. The stakeholders included 10 patients, 7 clinical support staff members (medical assistants and nurses), 8 primary care providers (physicians and advanced practice nurses), and 9 smoking cessation experts.

Results

Overview

Stakeholder feedback was obtained iteratively before the first app version and with each of the 5 app versions (Table 2). During each increment, changes were made in app content, appearance, and flow based on detailed feedback from the focus groups with changes between versions ranging from relatively minor content revisions or additions to major changes to the graphical user interface. Figure 3 illustrates representative screenshots showing how the app content and appearance changed from version to version.

Readability

Testing of version 2.2 produced feedback that the literacy level was too high for the clinical populations served. A literacy evaluation revealed that the initial text averaged a seventh-grade reading level. Between app versions 2.2 and 2.3, text edits were made screen-by-screen and each focused on improving readability to a fifth-grade reading level (Figure 4 illustrates the decrease in the reading level and an increase in ease of reading; enabling a wider audience to understand the wording and phraseology of the app).

Usability

Usability, as assessed with the SUS, increased with each version for a final of 90/100, above 65 was considered usable (Table 3). After iterative usability testing, a final app version was ready for pilot testing in the clinical setting.

Description of e-Quit worRx

The app-based decision aid *e-Quit worRx* has several key components, including collecting (1) a comprehensive smoking history, (2) personal reasons for and against smoking, (3) barriers and facilitators to quitting, (4) describing treatment options, including their level of evidence, risks, and costs, and finally (5) summarizing content to aid in SDM. The graphical user interface was unidirectional but used branching logic based on user input. The app begins with a splash screen followed by a secure login screen so that user data were encrypted on the device. Before each participant used the device, the research assistant or principal investigator logged in for the user. The system then randomly assigned a number for each participant.

The app was designed to personalize users' examination of the positive and negative effects of smoking and increase their knowledge of smoking cessation treatment options.

Treatment options included first-line medications, therapy including local cognitive behavioral therapy providers, and other treatments such as telephone quit lines and mHealth tools.

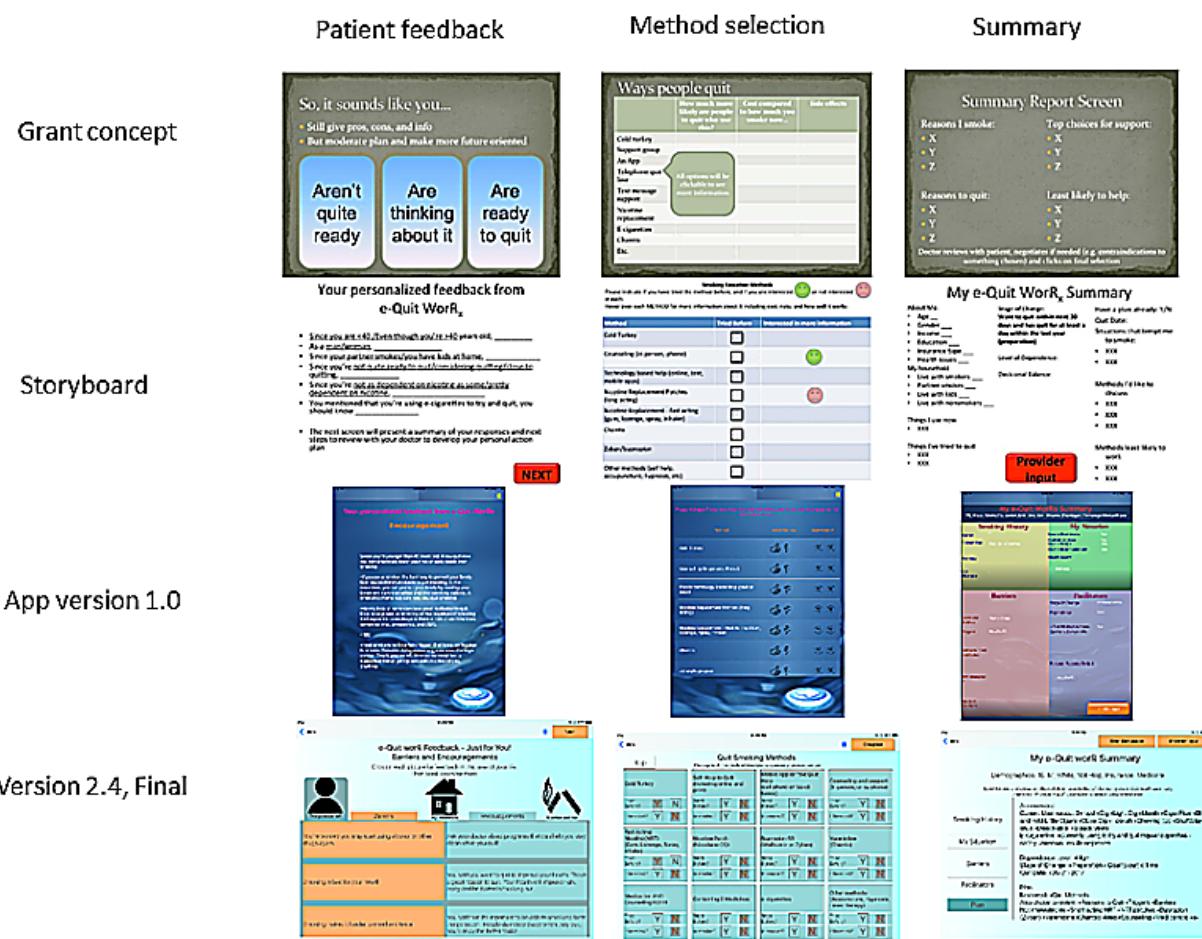
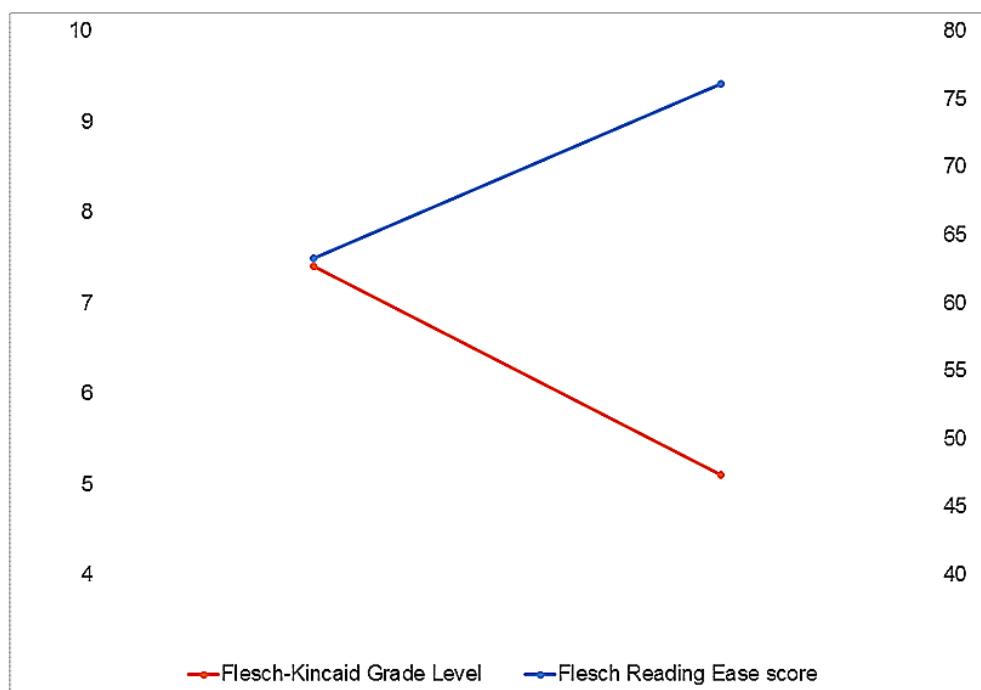
A summary screen was saved, entirely customized to an individual's input, to facilitate discussion with their PCP. The summary screen included personalized information derived from their responses. In addition to summarizing their personal considerations about the pros and cons of smoking, it summarized interest in the various cessation aids. The app included a provider input screen, where a plan was selected and an exit interview was to be completed by the research team after the clinical encounter.

The app collects basic demographics, including race, sex, income, age, frequency of smoking, and desire to quit for control groups and intervention groups.

Table 2. Themes from qualitative analysis of focus groups and usability testing.

Stage, position, theme	Representative quote
App development	
Patients	
Present treatment options in the app	“Present different treatment options, main risks of things, like with Chantix it is a plus and minus because it is actually very good at helping some people but it can have some nasty side effects.”
Present cost in the app	“There was a cigarette calculator thing that I went online and you put in how many years you have smoked and how much and with that you could have bought a luxury car with all that money. Something along those lines.”
Physicians	
Gauging their readiness	“I do not necessarily go through the formal stage criteria but after 20 years you have some idea of what phase someone is in. That helps to see if they are ready to quit-something like that.”
Time to complete the app information	“If you are delaying my visit because they are out there filling this thing out and we are calling them and they are not done with their survey, then it would be a problem. Has to be done in waiting room or exam room before I get there.”
Registered nurses and medical assistants	
What has worked in the past and what has not would be helpful	“I say the doctor has lots of materials and I ask them what they have been trying to do, what worked and what did not, it would be helpful to know that about the patient.”
App Testing	
Patients	
(V ^a 1.0) Visual and ease-of-use	“More uniform text style, better contrast, too dark of a background, visually challenging-just kind of drives me crazy, lots of mental gymnastics that make you leap back and forth.”
(V2.1) Customized feedback and knowledge	“I could tell that the feedback was customized at the end, kind of surprised, and I liked increased knowledge about cost of smoking and personal barriers to quitting.”
Physician	
(V2.3.1) Evidence based methods	“Evidence-based methods are helpful, pros and cons, cost is helpful.”
(V2.3.1) Saves time for visits about smoking or patient wants to discuss smoking	“Cuts back on me asking all the questions, gives you some tools that might be helpful, and app is a conversation starter.”
Medical assistant	
(V2.3.1) Time for filling out app	“It was not disruptive, It went well and we still stayed on schedule.”

^aV: version.

Figure 3. Development of select e-Quit worRx screenshots from Grant Concept to Storyboard, through iterative app versions.**Figure 4.** Grade level (left scale) and Reading Ease score (right scale) for app version 2.2 (left) and 2.3 (right).

User input, including audio capture from the exit interview, is temporarily stored on the device in an app-based database until

the session is complete. Data are then uploaded wirelessly to a Health Insurance Portability and Accountability Act

(HIPAA)-compliant Research Electronic Data Capture (REDCap) database.

Overcoming challenges faced in the design process, a user friendly and acceptable iPad app-based decision aid for use in primary care offices was created. Challenges enumerated in **Textbox 1** include navigating requests to our coders for repeated changes to both content and design, resolving conflicting feedback from our diverse group of stakeholders and even within our study group, realizing the time intensity of editing content and code, and integration into a clinical setting. We observed challenges between engineers and physicians that required management and interaction to remain on target.

Limitations

Our study had a few predicted and unforeseen limitations. Although we were able to upload content into the REDCap database, we were not, as we had foreseen, able to fully integrate the app into the electronic health record (EHR) so that patient

selections and chosen interventions would populate into the medical record. Our Health Information Technology Department reported that both the timeframe and budget were far too small for this.

Another limitation was that we were unable to create a generic app framework so that clinical content could be swapped out to create decision aid apps for other clinical scenarios, for example, diabetes medicine selection. This was an initial goal, but during the app design process, we made a decision to choose personalization for the patient over future generalizability.

We also discovered that not only would much more work have to go into making our iPad app compatible with iPhones or even Android devices, but we had to choose landscape or portrait display on the iPad instead of allowing the user to decide to ensure the app displayed correctly on the screen. Making the display orientation neutral would have required more programming time than allowed for our study.

Table 3. System Usability Scale across app versions.

App version	Usability
1.0	77.5
2.1	77.5
2.2	80.8
2.3	82.5
2.4	90.0

Textbox 1. Examples of challenges by area.

- Content development:
 1. Deciding what evidence to include when literature is conflicting
 2. Time consuming edits of text screen by screen that required medical knowledge
 3. Fidelity of detail on smoking cessation—physician versus patient confusion to the end user
- Feedback:
 1. The process was iterative and feedback was influenced by level of understanding
 2. Technical prowess
 3. Visual appearance and appeal of the app
 4. Too many colors and busyness of screen make is chaotic
 5. Compromising when feedback from different sources conflicted
- Coding and working with programming engineers:
 1. Challenging dialogue between medical and engineering/computer programming personnel
 2. Acceptability of multiple iterative change requests versus desire of programmers to get a full request, complete it once and be done
 3. Language barrier—style *British English* rather than *American English*
- Health Information Technology and clinical integration:
 1. In ability to fully integrate with electronic health record (Epic) at clinical sites to update patient's record
 2. Network access at clinical sites—workaround devised
 3. Printer access—had to purchase new printers

We were able to integrate into the clinic sites in several ways. We gained access to the network and internet connection, allowing real-time secure data transfer to our database. We enabled automated HIPAA-compliant email messaging to patients at the end of the session summarizing the interventions chosen, and we built new matching templates (ie, SmartPhrases and a SmartSet order set) for our EHR so that providers could quickly copy over patient selections from the study. Finally, although the existing clinic printers could not be used to print from our app, we placed AirPrint-enabled printers at each site to allow printing summaries for patients and PCPs.

Discussion

mHealth is no longer a novel approach or tool for health care. Tools have been developed and tested for smoking cessation [15,27-30] and other clinical conditions. Today, patients are more engaged in the management of their health than ever before. SDM tools are important in the management of disease, and some health care is actually moving toward the patient-centered home [37-39]. Acceptance of computer-based tools in addressing patients' needs whether in the home or exam room are more acceptable today as well [40-43].

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Conflicts of Interest

None declared.

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As demonstrated by this study, development of mHealth solutions is time-consuming and challenging. The life cycle of such devices is short-lived and must be upgradeable with changes in software versions, operating systems, and consumer needs. Nevertheless, health care will continue to integrate technologies such as e-Quit worRx into the management of a patient's health.

This research effort was focused on the development of an app for smoking cessation SDM using an iPad-based platform. A fully functional system was developed over several iterations. There were several challenges in the development phase. Insufficient funding limited the level of computer programming expertise. Although the students were adept at programming, the complexity of the software used to develop the app, concomitant with automatic Apple Operating System upgrades and the varying levels of communications, provided a significant challenge. Of the observations noted, 1 was the dichotomy in conversation between the graduate student programmers and clinicians. Multiple discussions and interaction with all of the research team provided resolution and a functional app, which was able to be used in clinical testing in year 2.

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Abbreviations

EHR: electronic health record

HIPAA: Health Insurance Portability and Accountability Act

mHealth: mobile health

PCOR: patient-centered outcomes research

PCP: primary care physician

REDCap: Research Electronic Data Capture

SDM: shared decision making

SUS: System Usability Scale

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Original Paper

Consumption of Health-Related Content on Social Media Among Adolescent Girls: Mixed-Methods Pilot Study

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Abstract

Background: Consumption of health- and fitness-related social media content is a predominant behavior among teenage girls, which puts them at risk for consuming unreliable health-related information.

Objective: This mixed-methods study (qualitative and quantitative) assessed health behavior attitudes and practices as well as social media use among adolescent girls. Additionally, similar practices and behaviors of adults who regularly interact with this population were studied.

Methods: Girls aged 12-18 years were recruited to complete a 28-item survey and participate in a 45- to 60-minute focus group. Adults who regularly interact with adolescent girls, including parents, teachers, and healthcare professionals, were recruited from the local community and given a link to provide online consent and complete a survey.

Results: A total of 27 adolescent girls participated in one of nine focus groups. Participants included 18 high school (age: mean 16.1 years; SD 1.3 years) and 9 middle school (age: mean 12.4 years; SD 0.7 years) girls. Eleven adults completed the online survey. Adolescents used social media to communicate and connect with friends, rather than as a source of health information. Although adolescents may see health-related content, most do not follow health-related pages or share such pages themselves, and fewer are actively searching for this information. Adolescents tend to trust information from familiar sources, and the participants reported that they do not follow official news accounts. Adults considered modeling and discussing healthy behaviors important and reportedly expected adolescents to see some level of health-related, especially fitness-related, content on social media.

Conclusions: Education interventions are warranted for both adolescents and adults with whom adolescent girls regularly interact, in the areas of sedentary behavior to guide them to access reliable online health-related information and be judicious consumers of online health information.

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KEYWORDS

adolescent; female; social media; health information; health behaviors

Introduction

More than one in five adolescents in the United States are obese [1], which could be attributed, at least in part, to unhealthy lifestyle behaviors such as inadequate physical activity and a poor diet. Only 17% of high school girls report levels of physical activity that meet aerobic guidelines; unfortunately, these levels are lower than those of their male counterparts [2]. Further, high school girls consume high amounts of sugar, practice fad dieting, and demonstrate weak nutritional knowledge and unhealthy eating habits [3]. The transformative period of adolescence is an ideal time for individuals to begin adopting positive health behaviors, especially with regard to eating habits and activity. Making positive health-related choices during adolescence can prepare an individual for a lifetime of health and wellness. Conversely, if poor eating habits and sedentary behavior are adopted during adolescence and practiced over decades, significant health-related consequences could occur [4].

Public health messages have increasingly targeted children and adolescents, but mass media efforts that have previously proved effective (ie, newspapers and television) may no longer be culturally relevant in today's society. Most (92%) adolescents search health-related information online [5], but far less (10%) adolescents reference more dated sources such as books, television news (9%), and newspapers (3%) [6]. In fact, one focus group study indicated that adolescents search for a wide range of health topics on the internet, including nutrition [7]. Public health and health care-related practices and research targeting adolescents must recognize that teenagers are at the forefront of the transition from traditional to electronic media, especially social media. Indeed, 71% of adolescents report using more than one social media site [8], and 45% of adolescents report using social media sites every day [9].

Adolescent girls appear to be at greater risk of consuming unreliable health-related information on social media than their male counterparts [6]. Age, gender, race, physical activity level, and overall health are significant predictors of the amount of information adolescents report receiving from social media sites [6]. People who are older, female, more active, and in better health are more likely to use social media sites for health information [6]. Further, health- and fitness-related social media content is predominantly consumed (liked or followed) by teenage girls [10].

Clearly, research investigating the role of social media in adolescent girls' health behaviors is warranted; however, the majority of studies investigating adolescent use of social media focuses on the impact on their psychological well-being. These studies have found unfavorable effects of social media on mental health including negative mood self-objectification, body dissatisfaction, social comparison, eating behaviors, decreased self-esteem, weight dissatisfaction, drive for thinness, and peer competition [11-19]. Even "fitspiration" images and posts that aim to inspire people to live healthy and fit lifestyles reinforce the overvaluation of physical appearance, eating concerns, and excessive exercise that could have serious negative implications on adolescents' psychological and emotional health [20]. Despite

these findings, the role of social media on influencing health behavior practices in adolescent girls is unclear.

Adolescents have access to a variety of health information via social media sites [8]. Most adolescents do not turn to social media sites for health-related information, but this should not be generalized for the whole population [6]. One in ten adolescents reported that they get "a lot" of health information from social media sites and 23% said they get at least "some" information from such sites. Some adolescents simply come across health information through links on social media sites (6%) [6]. In general, adolescents tend to be wary of posting health-related questions or viewing health-related information on social media, especially when their names can be associated with such information [6,21].

Many of these findings are from representative population surveys, but the relationship between the use of social media by adolescent girls and its effects on health behavior is likely complex and multifactorial. Understanding these relationships requires more qualitative formative research. Therefore, this mixed-methods pilot research study examined the use of and exposure to social media among adolescent girls with regard to health-related content, with a goal of identifying potential avenues for targeting their use of social media and its effects on health behavior. These findings will inform the creation of materials aimed at increasing safe consumer practices of social media use among this population.

Methods

Design

This pilot study assessed adolescent girls' attitudes, practices, and social media use related to health behavior as well as practices and behaviors of adults who regularly interact with them, by using qualitative and quantitative methods. This study was approved by the Institutional Review Board of West Virginia University (#1711839385) and Carnegie Mellon University (STUDY2017_00000559). Parents or guardians of the participants gave written informed consent and participants gave informed assent.

Participants

Adolescent girls aged 12-18 years from local middle schools and high schools were invited to participate in 45- to 60-minute focus groups and complete an anonymous survey. Recruitment emails were sent to local principals and school administrators and personnel asking them to invite girls aged 12-18 years to participate in the study. Principals and administrators who agreed were provided an email to be sent to students and their parents. Adolescent participants were compensated with US \$25. Independently, we recruited adults from the same schools where adolescents were recruited, who regularly interacted with adolescent girls, including parents, teachers, and health care professionals, and provided them a link to an online consent form and a 10-minute anonymous survey. Adults were not compensated for participating in the online survey. All those interested in completing the survey had the option to do so after providing consent. Adults and adolescent participants were not necessarily related. There was no bias against ethnicity or race.

Instruments

Adolescent girls completed a 28-item Qualtrics survey, which collected demographic information (eg, age, year in school, height, and weight) and other responses detailed below, and then participated in a focus group discussion. Adults completed a 13-item Qualtrics survey described below. Numerical response scores were used for quantitative analysis. The questions used for these surveys were not derived from validated surveys.

Adolescent Survey

To investigate the levels of physical activity, participants were asked whether they have physical education (PE) class (score: 1=yes and 2=no) and how much activity was done outside of the PE class (score: 1=every day to 5=never). To investigate sedentary behavior, the survey inquired if participants felt that the word “sedentary” described them (score: 1=describes me extremely well to 5=does not describe me). Participants also estimated the hours spent in sedentary activities such as sitting or not moving and were asked to attribute reasons for periods of no activity (boredom, laziness, fatigue, time limitations, physical limitations, financial limitations, activities enjoyed are sedentary, and other). Six questions assessed hours spent on social media, device used (computer, tablet, or cell phone), and timing (day and weekend). The questions used for this survey were not derived from a validated survey.

Adult Survey

The survey investigated health behaviors, efforts to model healthy behaviors and have health-related conversations with adolescents, use of social media, and perceptions of adolescents’ use of social media. Adult survey questions were independent of adolescent survey questions. The questions used for this survey were not derived from a validated survey.

Focus Groups

Trained female researchers moderated focus groups and took notes. A semistructured protocol following standard focus group guidelines [22] was administered by trained researchers [22,23]. Focus group participants were asked questions designed to explore their attitudes toward social media-related topics, identify physical activity and sedentary behaviors, and discover how they use technology and social media. A trained note taker made comprehensive notes on a laptop computer at each focus group, and the proceedings were digitally audio recorded. Within 48 hours of the end of each focus group, a second note taker transcribed the digital recording. These notes were reviewed by the focus group moderator for clarity, thoroughness, and accuracy.

Analysis

Descriptive statistics were used to summarize numerical questionnaire data with Microsoft Excel (Microsoft Corp, Redmond, WA) and were reported as mean (SD). Content analysis to identify common themes was conducted by two independent researchers (authors MPL and MES) with a tiebreaker (author MDO) when necessary. The researchers discussed independent content analysis findings, and data were constantly analyzed and compared to determine saturation of

repetitive concepts (ie, point at which no new information, trends, or themes emerge from the data) [24].

Results

Participants

A total of 27 adolescent girls participated in one of nine focus groups (4 middle school groups and 5 high school groups) consisting of 2-5 girls each, including 18 high school (age: 16.1 [SD 1.3] years) and 9 middle school (age: 12.4 [SD 0.7] years) participants. Eleven adults completed the online survey.

Adolescent Participant Survey

Responses of the adolescent participant survey are presented in Table 1. High school participants reported spending an average of 3 hours and 23 minutes daily on social media. Most (94%) accessed social media on their phone. They reported accessing social media mostly late at night during weekdays and during the day on weekends. In addition, they used Instagram (89%), SnapChat (89%), YouTube (74%), and Pinterest (61%), with most social media time related to Instagram and SnapChat. Half of them reported participating in a PE class, and almost all (94%) reported undertaking physical activity outside of PE more than twice a week. Periods of inactivity were attributed to boredom, tiredness, or laziness (56%, 78%, and 39% of respondents, respectively).

Middle school participants reported spending an average of 1 hour and 14 minutes daily on social media on both their phone and computer. They reported accessing social media mostly after school on weekdays and during the day on weekends. In addition, they used YouTube (100%), Instagram (70%), and Snap Chat (50%), with most social media time related to YouTube (32%) and Instagram (30%). One subject did not respond to physical activity-related survey questions. Of those who responded, all reported participating in a PE class and almost all reported participating in physical activity outside of the PE class at least twice a week. Periods of inactivity were attributed to tiredness, boredom, and physical limitations (50%, 20%, and 20% of respondents, respectively).

Adolescent Participant Focus Groups

Adolescent Participants’ Self-Described Use of Social Media

Snapchat and Instagram provide social connections for high school participants; one participants said, “it’s nice to see other people and what’s happening in their lives.” Each provided a different type of opportunity: “Snapchat is for funny posts, Instagram is where you try and look good - your best life.” Although most participants had Twitter accounts, they did not use it as much. Facebook was not used and considered “out of date” and “a platform for older people.” Many girls used YouTube and had a Pinterest account, but did not report using either frequently. Middle school girls also reported using similar platforms, with more time spent on YouTube because “it’s fun to waste time on.” Middle school participants also stated that Facebook is more common among older generations; one participant commented, “my grandma has Facebook.”

Table 1. Adolescent participant survey responses.

Question and response choices	High school (N=18)	Middle school (N=9)
Age (years), mean (SD)	16.1 (1.3)	12.4 (0.7)
Grade, n (%)		
6th	N/A ^a	4 (44.4)
7th	N/A	4 (44.4)
8th	N/A	1 (11.1)
9th	3 (16.7)	N/A
10th	5 (27.8)	N/A
11th	6 (33.3)	N/A
12th	4 (22.2)	N/A
Do you have PE^b class? n (%)		
Yes	9 (50)	8 (88.9)
No	9 (50)	0 (0)
Do you participate in physical activity outside of PE class? n (%)		
Everyday	8 (44.4)	2 (22.2)
4 or more times	4 (22.2)	3 (33.3)
2-3 times	5 (27.8)	2 (22.2)
Less than 2 times	1 (5.6)	1 (11.1)
Never	0 (0)	0 (0)
How well does “sedentary” describe you? n (%)		
Extremely	0 (0)	0 (0)
Very well	0 (0)	0 (0)
Moderately	6 (33.3)	0 (0)
Slightly	6 (33.3)	4 (44.4)
Does not describe me	6 (33.3)	4 (44.4)
Periods of inactivity attributed to... n (%)		
Boredom	10 (55.6)	2 (22.2)
Laziness	7 (38.9)	1 (11.1)
Too tired	14 (77.8)	5 (55.6)
No time to be active	4 (22.2)	1 (11.1)
Physical limitations	2 (11.1)	2 (22.2)
Financial limitations	0 (0)	0 (0)
Activities I enjoy are sedentary	6 (33.3)	7 (77.8)
Others (school/homework)	5 (27.8)	3 (33.3)
Time spent on social media, mean (SD)	3 h 23 min (0.11 h)	1 h 14 min (0.03 h)
How do you access social media? n (%)		
Cell phone	17 (94.4)	8 (88.9)
Computer	9 (50)	8 (88.9)
Tablet	3 (16.7)	6 (66.7)
Time spent on social media		
Weekdays	Late night	After school
Weekends	During the day	During the day

Question and response choices	High school (N=18)	Middle school (N=9)
Which apps do you use? n (%)		
Instagram	16 (88.9)	7 (77.8)
SnapChat	16 (88.9)	5 (55.6)
YouTube	14 (77.8)	9 (100)
Pinterest	11 (61.1)	6 (66.7)
Twitter	8 (44.4)	0 (0)
Google+	3 (16.7)	3 (33.3)
Buzzfeed	2 (11.1)	2 (22.2)
Tumblr	2 (11.1)	1 (11.1)
Time spent on each (%)		
SnapChat	43	20
Instagram	36	30
YouTube	24	32
Twitter	10	0
Pinterest	6	12.5
Facebook	3	0

^aN/A: not applicable.

^bPE: physical education.

For both middle and high school girls, all social media was used for communicating and connecting—"to check up on people"—primarily friends, often instead of texting. One individual explained that social media was used to "post for everyone rather than text all of my friends." Similar social media apps were used among groups of friends, with little differences between participants in the same social circles:

I feel like we use Instagram and Snapchat more because most people have those. If I got Twitter or something, I wouldn't be on it as much and it wouldn't be as interesting, because not all of my friends would be on it to interact with and see what they are doing.

Participants used social media because they felt that "if I don't get on for a few days then I will miss out on jokes" and they would "feel behind." Social media also allows participants to connect with a larger online audience, including strangers, as a way to convey updates about their lives. Specifically, adolescents reported using Instagram "just for fun" and to connect with people, while Snapchat was considered more personal; for example, one participant commented that "Snapchat is more personal than texting because you can see your friends' faces." Participants were motivated to use Snapchat by "maintaining streaks," or sending Snapchats back and forth for consecutive days without breaking the chain of communication, which creates a record that becomes important to keep. Other forms of social media were used as entertainment (eg, "Pinterest draw you in with crafts and stuff") to access what is going on in the world (eg, "Twitter is to see the bigger world") and as a source of information, but this is often in relation to what their friends or celebrities are doing. This group primarily followed friends on social media, but also followed celebrities,

athletes, and health-related pages, and they "find people on my own or hear about from friends who to follow."

Posts seen on social media by high school girls are typically life updates from friends sharing what they are doing, pop culture, or current events from well-known figures, including the President or celebrities. Snapchats are sent back and forth as a form of conversation. Posts seen on social media include memes/funny images, advertisements, and posts from celebrities. Occasionally, high school girls see information regarding current events and advertisements, while many middle school girls see posts about sports they are involved in. A few participants mentioned that social media posts are often fake news, music related, or videos. High school participants reported posting on social media to share funny posts, like memes, or a life update that shows or describes what they are doing or who they are with and may include a picture or selfie. Participants also shared about events, including sports events and life updates (eg, achievements or activities they engage in).

Many participants admitted to not following official news sources. Therefore, regarding the reliability of social media content, participants are more likely to trust information on social media if the source is a verified account, if they have seen it posted repeatedly, or if it is posted by someone they know personally:

I'd definitely trust my friends more than celebrities although I do aspire and like them

They did not trust the information if the post was paid/sponsored or if they saw contradicting information:

Maybe I saw something that was happening and later I found out from the news that it was wrong

Participants recommend researching independently, asking others, or fact-checking to validate untrusted information.

Adolescent Participants' Exposure to Health-Related Information on Social Media

Many participants reported seeing health or nutrition-related posts from friends or official accounts including recipes, pictures of food, or workout posts. Most reported that they did not follow health or nutrition accounts on social media, but that they saw advertisements related to fitness, weight loss, and supplements that they knew were unreasonable:

I usually ignore the ads. They say stuff about "take this pill and make your body look better."

"Ten foods that can kill you" I didn't believe it.

For participants who followed health-related accounts or people on social media, many of the posts were for healthy recipes or fitness-related content. Further, some participants admitted to searching for health-related content, including workouts and healthy recipes. Both groups reported infrequent posting of health- or nutrition-related information on social media. If such a post was made, it typically related to sports performance or sharing pictures of food that looks good, is homemade, or is from a cool place. Activity-related searches were performed by high school participants to find information on healthy nutrition and workouts. Some participants searched for sports-specific workouts or exercises, conditioning programs, stretches, or drills. It was briefly mentioned that sometimes foods or recipes are investigated to determine their healthiness.

Adolescent Participants' Self-Reported Lifestyle Behaviors

Participants believed that activity is important for a healthy lifestyle. Specifically, it is important for physical and mental health, as "it's not just the foods you eat, even if you eat super healthy, you have to keep your body in shape to keep your muscles strong." Physical activity was said to be important to allow optimal performance in sports and because it makes you feel good. Many engaged in physical activity through sports (eg, "sports are a fun and good way to stay active"), working out on their own, and general physical activities like walking dogs and doing chores like yard work. Younger girls report spending their leisure time "playing outside." Many related activity to maintaining a slim figure, with some stating that "sports help them lose weight"; this topic provoked some concerning reasons for staying active including guilt (eg, "sitting around makes me feel guilty, so I'll work out"). Some expressed pressure in maintaining a healthy weight for fear of being bullied. Girls recommend finding an enjoyable activity, establishing a routine, and incorporating both exercise and healthy eating. Participants reported not using phones during physical activity, especially during team practices, but when phones were involved, they typically used them for counting steps, tracking time or distance, and playing music. Some participants used apps that prescribe specific workouts or training programs, stating "I don't usually use a phone unless

I'm following a workout." Although online, some participants took screenshots of a work out or routine to reference later when they were more motivated to be active.

Sedentary behavior seemed to be an unfamiliar topic for this audience, but when defined and explained, participants cited social media (via phone or computer), school work, and television as the primary reasons for sedentary behavior, often doing many things at once; they commented, "I just lay in bed and scroll through Instagram" or "normally, I watch TV while on the phone." Fewer high school participants than middle school participants reported being sedentary while reading. Some of the younger participants also reported being sedentary while listening to music or playing an instrument. Recommendations to reduce sedentary behavior while still participating in preferred activities included activities such as multitasking (eg, playing with the dog while watching television).

Social media pages and people who emphasize healthy lifestyles and fit bodies can leave participants feeling discouraged and envious, but also sometimes encouraged, inspired, and motivated them. One individual explained, "sometimes I'm like, not really envious, but it pushes me to want that more." High school girls were aware that many advertisements and posts were photoshopped or manipulated and acknowledged that attaining the same physique is often unrealistic:

Guys with really big muscles, that's not aspirable [sic], but people that are just fit and slim and eat healthy, that's helpful.

These participants felt "it is important for girls their age to hear about body empowerment from celebrities" but also recommended using these individuals as motivation to work out or eat healthy and to "keep pictures of your goals."

Adult Survey

The majority of adult respondents were parents and teachers of adolescent girls and reported limiting their own sedentary behaviors, getting regular exercise, and attaining healthy nutrition as at least moderately important. Further, these adults felt that it is very important to model health behaviors for adolescent girls: Most modeled limiting social media, but only about half modeled healthy eating, activity, and limiting sedentary behavior. Adults believed it is important to discuss healthy behaviors with adolescents, and most did so by discussing food choices, portion sizes, daily activity, social media use, and healthy body image. Less than half the adults discussed limiting sedentary behavior. For accessing health-related information, almost all recommend talking to parents and two-thirds answered questions directly or encouraged adolescents to talk to a health care practitioner. Only one-third of adults directed adolescents to reliable online sources. Adults expected adolescents to see some level of health-related, especially fitness-related, content on social media (Table 2).

Table 2. Adult survey responses (n=11).

Question and response choice	Value
Which of the following applies to you? n (%)	
Parent/guardian of an adolescent	6 (54.5)
Parent/HCP ^a	1 (9.1)
Parent/teacher	2 (18.2)
Teacher only	2 (18.2)
How important is it to you that you lead a healthy lifestyle? (0=not important, 10=extremely important), mean (SD)	
Regular exercise	5.9 (3.4)
Healthy nutrition	7.6 (2.0)
Limit sedentary behavior	6.9 (2.8)
How many times per week do you exercise for at least 20 minutes? n (%)	
Never	6 (54.5)
1-2 times/week	1 (9.1)
3-4 times/week	2 (18.2)
Most days	2 (18.2)
How active is your job? n (%)	
Sedentary	2 (18.2)
Lightly active	5 (45.5)
Moderately active	4 (36.4)
About how much time do you think adolescent girls spend on social media each day? mean (SD)	3.4 hours (1.5-5.5)
How does social media influence? (-5=very negative, 0=no influence, 5=very positive influence), mean (SD)	
Healthy eating	0.1 (1.9)
Activity	-1.4 (2.9)
Sedentary behavior	-0.25 (3.7)
Body image	-1 (4.3)
Importance of modeling healthy behaviors (0=not important, 10=extremely important), mean (SD)	9.3 (1.1)
How do you role model healthy behavior? n (%)	
Healthy eating	5 (45.5)
Limit social media	8 (72.7)
Healthy activity	6 (54.5)
Limit sedentary behavior	5 (45.5)
Importance of discussing healthy behaviors with adolescents? (0=not important, 10=extremely important), mean (SD)	9.1 (1.1)
Which do you discuss with adolescents? n (%)	
Food choices	9 (81.8)
Portion sizes	7 (63.6)
Daily activity	8 (72.7)
Sedentary behavior	5 (45.5)
Social media	10 (90.9)
Healthy body image	11 (100)
How do you encourage adolescents to access health-related info? n (%)	
Encourage talking to parents	9 (81.8)
Answer directly	7 (63.6)
Encourage them to talk to HCPs	7 (63.6)

Question and response choice	Value
Direct to reliable online sources	4 (36.4)
How much health-related info do you think adolescents see on social? (0=none, 10=a lot), mean (SD)	
Nutrition	3.0 (2.5)
General activity	4.8 (2.4)
Fitness	6.1 (2.2)
Sedentary behavior	2.9 (2.1)

^aHCP: health care provider.

Discussion

Adolescent girls reported using social media, specifically Snapchat and Instagram, to communicate and connect with friends. These forms of social media are mostly utilized to interact with their peers instead of traditional communication methods such as texting and to share posts that are comical or sports-related or display an aspect of their daily life. Although adolescents may see health-related content, most are not following health-related pages or sharing it themselves, and fewer are actively searching for it; they tend to trust information from familiar sources and do not follow official news accounts. Overall, among both middle and high school girls, social media is used for communicating and connecting with friends, rather than as a source of health information.

Adults influence adolescents' adoption of healthy habits [25]; therefore, it is critical that adults are aware of the nature of adolescent social media use and encourage healthy use by limiting the time spent on social media. Adequate physical activity, limited sedentary behavior, and proper nutrition are critical health behaviors that, if adopted during adolescence, can contribute to lifelong health [4]. As role models and rule enforcers, parents are critical for promoting adolescents' healthy habits. Adults in this study indicated that limiting their own sedentary behaviors, getting regular exercise, and attaining healthy nutrition were at least moderately important. However, they felt it was extremely important to model healthy practices and have conversations about health behaviors with adolescent girls. These practices could lay the foundation for establishing habits necessary for a lifetime of healthy behaviors.

Research shows that exposure to social media and "fitspiration" posts lead to more body comparisons and lower self-esteem, specifically in women [11,13,20]. With the increase in the number of social media outlets and time spent on them, the reach of social media is expanding to include younger adolescent girls [10]. In the present study, all adults reported having conversations with adolescent girls about a healthy body image, and in focus groups, the adolescent girls were aware that many advertisements and posts are photoshopped or manipulated and that attaining the same physique is often unrealistic. Paired with the girls' insistence that adolescents should hear about body empowerment suggests that the conversations adults have with adolescents are effective in promoting a healthy body image.

Adults in this study ranked physical activity as moderately important, and most discuss its importance with adolescent girls. Although only one-third of adults met the physical activity

recommendations, almost all adolescents engaged in regular physical activity outside of PE classes. Adults' efforts to emphasize activity to adolescents appears to be effective in promoting healthy behaviors. However, despite rating the importance of limiting their sedentary behavior higher than that of obtaining regular exercise, more adults discussed the importance of daily activity (73%) than those who discussed limiting sedentary behavior (45%) with adolescent girls.

Although adults considered limiting sedentary behavior important for their own health, less than half of the adults reported having these conversations with adolescent girls. In adolescent surveys and focus groups, the phrase "sedentary behavior" needed to be explained, confirming that this audience is missing out on important health information. Although this population understands the importance of physical activity, interventions and public health messages to limit sedentary behavior are warranted. Obesity is a well-documented outcome of screen media exposure, and in this study, social media use accounted for approximately half of the time adolescent girls spent being sedentary outside school. Importantly, adults' estimates of adolescent social media use (~3.4 hours of use daily) are in line with adolescents' self-reported social media use; however, adults do not think social media significantly influences health behaviors. Adolescents may benefit from interventions that replace social media with less sedentary activities, while adults may benefit from information connecting social media use and sedentary behavior with adverse health outcomes, including obesity.

Use of social media gives adolescents access to content about health information of varying degrees of trustworthiness. Girls reported seeing health-, nutrition-, and fitness-related content on social media, often in paid advertisements, and recognized the potential to encounter false information. Although verification (eg, fact-checking) was recommended, adolescent girls relied on less-stringent methods for determining what to trust (eg, posts from people they knew personally). These findings indicate that adolescents are consuming and sharing related information uncritically on social media, which could misinform them about health habits. In addition, they underscore the importance of developing and disseminating materials aimed to increase safe consumer practices of social media use in this audience.

Further, few adults (36%) in this study directed adolescents to reliable online sources of health information. Viewing unverified health-related information on social media, without adult recommendations for accessing reliable online sources, could

put adolescent girls at risk for unsafe health practices. Future interventions should aim at providing adults educational materials for reliable, online health information to share with adolescent girls.

One limitation to this pilot study was that the survey used for adolescents and adults was not validated. As described previously, this mixed-methods pilot research study aimed to examine the use of and exposure to social media among adolescent girls with regard to health-related content, with the goal of informing the creation of materials, specifically validated surveys, for increasing safe consumer practices of social media use among this population. We intend to expand this pilot study by developing validated surveys to move this area of research forward. Additional limitations include the use of convenience sampling and failure to acquire ethnic and socioeconomic status data. Further, the present study includes a small sample of adolescents and adults; although the sample was informative for this pilot study and the development of a targeted research study, the generalizability of these findings are limited.

Using a mixed-methods (qualitative and quantitative) approach, this pilot study assessed health behavior attitudes and practices as well as social media use in adolescent girls. Additionally, these practices and behaviors among adults regularly interacting with this population were examined. Although the sample size

was small, the data generated are rich and informative, and the focus group data reached the saturation point prior to termination of data collection. Results from the present study offer several potential avenues for targeting the use of social media and its effects on health behavior among adolescent girls, including education interventions for both adolescents and adults with whom these girls regularly interact, in the areas of sedentary behavior to access reliable online health-related information and be judicious consumers of online health information.

The state and use of social media are ever changing, but the potential to use social media as a form of promotion for healthy behaviors, especially among adolescents, will continue to offer promise. Social media campaigns that target this population could provide evidence-based, peer-reviewed information in a culturally relevant and age-appropriate format that could favorably impact adolescents at a transformative time. However, the success of any social media-based intervention will depend on a thorough, comprehensive understanding of the current state of social media use and behavior. Otherwise, any potential benefits of direct social media campaigns are likely to be missed. Therefore, the findings of this pilot study set a broad, informed, and meaningful foundation for any future research aimed at changing or influencing social media and its effects on health behavior.

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Conflicts of Interest

None declared.

Authors' Contributions

Research design was developed by JSD, PJM, MDO, and MPL. Data collection was conducted by MPL, ENC, MES, and MDO. Thematic analyses were performed by MPL and MES and reviewed by MDO. Writing of the manuscript was done by MPL. All authors have read and approved the final manuscript.

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Abbreviations

HCP: health care provider
PE: physical education

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