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Original Paper

# A Mobile Gaming Intervention to Increase Adherence to Antiretroviral Treatment for Youth Living With HIV: Development Guided by the Information, Motivation, and Behavioral Skills Model

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## Abstract

**Background:** Highly active combination antiretroviral treatment has been shown to markedly improve the health of HIV-infected adolescents and young adults. Adherence to antiretroviral treatment leads to decreased morbidity and mortality and decreases the number of hospitalizations. However, these clinical achievements can only occur when young persons with HIV are adherent to care. Unfortunately, adolescents and young adults have poorer rates of adherence to antiretroviral medications and poorer rates of retention in care than older adults. Novel and engaging digital approaches are needed to help adolescents and young adults living with HIV be adherent to treatment.

**Objective:** The aim of this study was to develop an immersive, action-oriented iPhone gaming intervention to improve adherence to antiretroviral medication and treatment.

**Methods:** Game development was guided by social learning theory, taking into consideration the perspectives of adolescents and young adults living with HIV. A total of 20 adolescents and young adults were recruited from an HIV care clinic in Rhode Island, and they participated in qualitative interviews guided by the information-motivation-behavioral skills model of behavior change. The mean age of participants was 22 years, 60% (12/20) of the participants identified as male, and 60% (12/20) of the sample reported missing a dose of antiretroviral medication in the previous week. Acceptability of the game was assessed with client service questionnaire and session evaluation form.

**Results:** A number of themes emerged that informed game development. Adolescents and young adults living with HIV desired informational game content that included new and comprehensive details about HIV, details about HIV as it relates to doctors' visits, and general health information. Motivational themes that emerged were the desire for enhancement of future orientation; reinforcement of positive influences from partners, parents, and friends; collaboration with health care providers; decreasing stigma; and increasing personal relevance of HIV care. Behavioral skills themes centered on self-efficacy and strategies for medical adherence and self-care. On the client service questionnaire, 10 out of the 11 participants indicated they were "satisfied with the game activities," and 9 out of 11 "would recommend it to a friend." On the session evaluation form, 9 out of 11 agreed that they "learned a lot from the game."

**Conclusions:** We utilized youth feedback, social learning theory (information-motivation-behavioral skills), and agile software development to create a multilevel, immersive, action-oriented iPhone gaming intervention to measure and improve treatment

adherence for adolescents and young adults living with HIV. There is a dearth of gaming interventions for this population, and this study is a significant step in working toward the development and testing of an iPhone gaming app intervention to promote adherence to antiretroviral treatment.

**Trial Registration:** ClinicalTrials.gov NCT01887210; <http://clinicaltrials.gov/ct2/show/NCT01887210> (Archived by WebCite at <http://www.webcitation.org/6xHMW0N11>)

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## KEYWORDS

mobile phones; adolescents; young adults; patient compliance

## Introduction

### Background

According to the Centers for Disease Control and Prevention, young persons aged 13-29 years accounted for 41% of the new HIV infections in the United States in 2015 [1], and an estimated 99,463 adolescents and young adults in the United States are living with HIV/AIDS (acquired immunodeficiency syndrome) [1]. Advances in treatments for HIV can allow those infected to manage their HIV infection as a chronic, rather than imminently life-threatening, disease [2]. However, these achievements can only be made when persons living with HIV take their medications as prescribed and maintain consistent medical care [3-6]. Unfortunately, adolescents and young adults with HIV are the least likely out of any age group to be adherent to care and have a suppressed viral load [3,7].

The percentage of prescribed doses of antiretroviral medications taken by adolescents and young adults ranges from 50% to 75% in the United States [7-9], and studies, with adults, adolescents, and children, show that achieving and maintaining an extremely high level of medication adherence (approximately 90%) is needed to obtain the full benefits of antiretroviral treatment (ART) [3,10,11]. Many of the barriers to ART adherence are similar for adults and youth; however, there are additional barriers for adolescents and young adults living with HIV [12]. Developmentally, late adolescence and young adulthood is an age-related period characterized by less inhibition, increased risk-taking, decreased motivation for planning, and less parental monitoring [13,14]. Adolescents and young adults can feel invulnerable to consequences, and this can explain the risk-taking and limit-testing behaviors seen during adolescence. Often, adolescents and young adults do not have fully developed risk assessment skills, impulse control, or organizational abilities. These characteristics are believed to contribute to lower rates of adherence to care among this age group [13-15].

### The Efficacy of Digital Interventions

Digital interventions to improve adherence to ART for adolescents and young adults hold particular promise [16]. Adolescents and young adults aged 18-29 years have high rates of mobile phone use with 98% owning a mobile phone or a smartphone [17]. Technologies, such as the mobile phone, play an increasingly significant role in adolescents' and young adults' interpersonal and environmental life, as they communicate information, reinforce cultural norms, and influence personal identity and behaviors [18]. Furthermore, gaming is popular among youth. In the United States, 99% of teenage males and

94% of teenage females play video games, and 46% of all video gaming occurs on mobile phones or portable devices [19]. The widespread appeal of digital game playing among all adolescents and young adults creates a unique opportunity to deliver health education during leisure time, outside of the clinic, and in a manner that is cost-effective and easily scalable [20]. Games can attract and maintain attention, which is a key component for effective behavior change [21]. Compelling interactive games can expose players to essential health-related content repeatedly and also give players unlimited opportunities to rehearse new skills and receive personalized feedback on health choices made within the game [21,22]. Finally, gaming has been shown to improve motivation for healthy behaviors. Motivation, defined as the process that initiates, guides, and maintains goal-oriented actions, is key to maintaining ART adherence [20,21,23].

There is a paucity of data on gaming interventions to improve adherence to ART. However, before the widespread availability of the internet and cell phones, offline games were found (in randomized controlled trials, RCTs) to impact other health behaviors among youth living with asthma, diabetes, and cancer. A diabetes game for children, called Packy and Marlon, indicated that a well-designed, educational video game can be effective in terms of improving diabetes-related self-efficacy ( $P=.07$ ), communication with parents about diabetes ( $P=.03$ ), and self-care behaviors ( $P=.003$ ). These changes occurred after diabetic youth played the game at home for 6 months, compared to a control group of diabetic youth who took home an entertainment video game that had no health content [24]. In a game called Bronkie the Bronchiasaurus, youth engage in play with a dinosaur character with asthma and help him save his homeland while trying to avoid asthma triggers (pollen, cold viruses, dust) and keep his asthma under control. An empirical study showed that playing the game for less than an hour resulted in significant improvements in a player's asthma knowledge, self-efficacy for asthma self-management, and self-efficacy for talking with friends about asthma [25,26]. Another video game, named Re-Mission, designed for a wide age range of adolescents and young adults (13-29 years) with acute leukemia, lymphoma, and soft-tissue sarcoma showed promising effects as well. Re-Mission was designed as an action-adventure game with the main character or protagonist shooting cancer-causing agents in the bloodstream. Players gain points and strength by adhering to medications in the game fantasy world. In a randomized control study with a 3-month follow-up, 375 male and female participants who played Re-Mission had significantly improved adherence to

trimethoprim-sulfamethoxazole ( $P=.01$ ) and 6-mercaptopurine ( $P=.002$ ) compared with controls after an average of only 10.7 hours of play. Adherence to trimethoprim-sulfamethoxazole was tracked by electronic pill monitoring devices ( $n=200$ ), and the proportion of doses taken correctly by those playing Re-Mission was 19% greater than those in the control group. Self-efficacy ( $P=.01$ ) and knowledge ( $P=.04$ ) also increased in the Re-Mission game intervention group compared with the control group [27,28]. The successful games reviewed above provided interactive environments where players could improve motivation and engage in behavioral rehearsal [20-22,24-28].

### Gaps in Literature

Despite the promise of digital games, reviews describe that there is a paucity of published or presented abstracts related to gaming for adolescents and young adults living with HIV [16]. Hightow-Weidman et al identified 5 digital games in development to improve ART adherence (from National Institutes of Health's RePORTER, including our intervention described here). Published outcomes or descriptions of these interventions are sparse [16]. LeGrand et al has published a description of the development phase of a game entitled Epic Allies. The game is designed to improve ART uptake, engagement in care, and adherence among young men who have sex with men (YMSM) and transgender women who have sex with men. During game play, users can earn medals and tokens for taking medications and reading health-related studies. These tokens can then be used to earn access to fun, non-HIV-related games in the app. Users can interact with one another in the app and send each other positive messages [29]. We could not find other manuscripts or published descriptions of an iPhone gaming app to improve adherence to ART for adolescents and young adults.

There are published descriptions of gaming interventions targeted to HIV negative youth, who are at risk for acquiring HIV. An evidence-based gaming intervention called PlayForward aims to reduce risk for HIV among at-risk, ethnic, and racial minority adolescents aged 11-14 years. This tablet-based game provides an interactive world using an avatar where players face challenges such as peer pressure to drink alcohol or engage in other risky sexual behaviors. Players can experience how their choices affect their health and are able to go back in time to change their choices to create different, healthier outcomes [30]. The smartphone game SwaziYolo is an interactive game for HIV-negative young adults (18-29 years) living in Swaziland, Africa. In this app, players can practice relationship and health choices while looking for love [31]. A mobile phone-optimized intervention entitled healthMpowerment is designed to reduce sexual risk behaviors among YMSM. In this intervention, YMSM can acquire *reputation points* through reading information about HIV, playing sexually transmitted infection-related games, and positive interactions with other users. These points can be used to purchase T-shirts and iPod shuffles [32].

There are no gaming interventions for older adults living with HIV. However, interventions to improve adherence to ART among older adults have tested the usefulness of less-complex technologies such as electronic reminders and/or pill bottle

opening measurements. Reviews show that the most successful interventions couple these less-complex technologies with in-person interventions to improve motivation for treatment [33-35]. Measuring adherence alone (through an electronic method such as a micro-electro-mechanical systems cap) or merely reminding patients about pill taking (with an alarm) does not significantly improve adherence in the long term [35,36].

Among older adults living with HIV, there are also promising studies that have examined interactive text messaging to improve ART [37]. A meta-analysis of 8 studies, reporting 9 interventions, shows that text messaging interventions yielded significantly higher adherence than control conditions (odds ratio [OR] 1.39, 95% CI 1.18-1.64). The mean age of participants in the studies was 40 years (range 36-42 years). Sensitivity analyses of intervention characteristics suggested that studies had larger effects when intervention texts were sent less frequently than daily and included personalized communication. Text message interventions among adults were associated with improved viral load and/or CD4+ count ( $k=3$ ; OR 1.56, 95% CI 1.11-2.20) [38]. Less data are available on text messaging interventions for younger populations living with HIV. Dowshen et al did report that personalized, interactive, daily short message service reminders were feasible and acceptable among youth living with HIV who were between the ages of 14 and 29 years (mean age 23 years). Participants in that study ( $N=25$ ) had significantly increased self-report of adherence at 12 and 24 weeks in comparison with baseline (week 0: 74.7; week 12: 93.3,  $P<.001$ ; week 24: 93.1,  $P<.001$ ) [39].

Building on this knowledge, we developed a multilevel gaming intervention to improve adherence to ART for adolescents and young adults aged 18-26 years. This intervention integrates a smart pill bottle cap (that measures adherence) with an immersive iPhone game and personalized text messaging (see [Multimedia Appendix 1](#)). The gaming intervention was informed by the information-motivation-behavioral skills (IMB) theory of learning [40-42]. The iPhone gaming app was designed for participants to experience absorbing action-oriented adventures that increase information about their health (eg, knowledge about HIV treatment, transmission, adherence), improve motivation (eg, action figures experience health benefits of adherence), and build skills (interact with clinicians at appointments, take medications as prescribed). Adherence (measured by the smart pill bottle cap) and game-related text messages are integrated into the gaming intervention. This multilevel approach integrates sound theoretical principles with novel, but intuitive, technology. The aim of this paper is to describe the development of this multilevel iPhone gaming app entitled Battle Viro.

## Methods

### Gaming App Development

Development of Battle Viro was accomplished using iterative and collaborative procedures to fully integrate the clinical experiences of adolescents and young adults living with HIV, academic researchers, and technology partners. Game development was guided by qualitative interviews with a diverse

group of adolescents and young adults living with HIV between the ages of 18 and 26 years. Guided by the principles of agile software development [43], the qualitative interviews and the game/app programming were synergistic. Agile software development aims for continuous design testing and adaptation based on continuous feedback [43].

As discussed in the Introduction, the adherence gaming app, Battle Viro, was designed to be consistent with the IMB model of health [44]. The IMB model is a well-established conceptualization for improving adherence to antiretroviral medication and engagement in treatment. Nongaming interventions based on IMB have demonstrated efficacy [40,41,45]. Reviews have suggested that interventions guided by accepted theories of change are more efficacious than those not driven by theory [46]. According to the IMB model, health information, motivation, and behavioral skills are the fundamental determinants of health behavior. Information that is directly relevant to adherence and HIV transmission and easily applied to an individual's cultural and social setting is a prerequisite for success. Motivation to engage in HIV preventive behavior, including personal motivation (favorable attitudes toward adherence) and social motivation (perceived social and cultural support for performing these acts), is also essential for healthy behavior. Finally, skills for performing adherence behaviors and a sense of self-efficacy are critical components. The IMB model, consistent with social learning theory, is broadly applicable and can be used to guide game development and create theoretically consistent gaming content [46,47]. Multiple reviews have demonstrated that behavioral interventions shown to be most efficacious are those tailored for the target population and preceded by formative research to inform intervention development [48-50].

### Sample and Recruitment

Males and females, 14 to 26 years old, were eligible for enrollment in the study according to the following criteria: (1) English-speaking, (2) in medical care for HIV and receiving ART, (3) aware of their HIV status as per clinician and clinical record, (4) able to give consent/assent and not impaired by cognitive or medical limitations as per clinical assessment, and (5) adolescent assent and consent of a parent/legal guardian if under 18 years of age or consent of youth if 18 years of age or older. Those who did not meet the above-mentioned inclusion criteria were excluded.

We recruited 20 adolescents and young adults living with HIV for qualitative interviews to guide game development after institutional review board's approval. Subjects were recruited from a convenience sample in the HIV care clinic in Rhode Island. Subjects were approached by research staff with an institutional review board-approved flyer, and written consent was obtained upon meeting with study staff for the qualitative interview. Overall, 20 subjects were approached over the course of the interviews, and all of them consented and completed the interview. Subjects were recruited until data saturation was achieved and a relative balance in the sample was achieved based on gender, age (<22 vs ≥22), race, and sexual orientation. We were not able to recruit participants younger than 18 years (as originally planned), as the vast majority of patients in our

state who are diagnosed and living with HIV are older adolescents and young adults. The mean age of participants was 22 years (range 18-26 years; 8 out of the 20 were older than 22 years). Of the total participants, 60% (6/12) identified as male, and 60% (12/20) completed 12th grade. Of the participants who identified as African American (10/20, 50%), 10% (2/20) identified as Hispanic and 30% (6/20) identified as white. In total, 40% (8/20) identified as heterosexual, 40% (8/20) identified as homosexual, and 20% (4/20) identified as bisexual. Out of these 20 participants, 12 (60%) reported missing a dose of antiretroviral medication in the previous week.

### Adaptation of the Information-Motivation-Behavioral Skills Adherence Gaming Intervention

A preliminary storyboard for the IMB gaming app proposed, entitled Battle Viro, was drafted based on the popular Mission Critical Studios game entitled Dr. Nano X: Incredible Voyage Inside the Body [51]. Dr. Nano X is a 5-star-rated mobile game (the highest rating possible) in the iTunes app store and is available on both Android and iPhone. We worked directly with the development team at Mission Critical Studios to develop Battle Viro using Dr. Nano X as a framework. Adapting our game to promote ART adherence from an already existing game greatly decreased the cost of the project. Characters, actions, and IMB messaging were built specifically for Battle Viro; however, we were able to reuse backgrounds, mechanisms of game play/controls, and many sound effects from Dr. Nano X. The adapted gaming app for this project, Battle Viro, takes place inside the human body similar to Dr. Nano.

An initial storyboard was developed for Battle Viro. The storyboard starts with a short narrative movie that explains that the player is becoming miniaturized in order to enter his or her body and destroy attacking viruses and infections (see [Multimedia Appendix 2](#)). Weapons and tools that help the player destroy virus and infections in the body can be earned by taking medications and building an alliance with medical staff. The first level begins on the surface of the skin. If players successfully battle virus, engage with providers, take medication, and make healthy decisions, they move to the next exciting level. As players become expert nanobots, they move onward through the arterial system, the lungs, kidneys, brain, and other new, vibrant, and distinctive organ systems (see [Multimedia Appendices 3-5](#)). Throughout Battle Viro, multiple messages from doctors, clinicians, and friends are integrated into play as the nanobot/protagonist successfully destroys virus and other opponents (ie, opportunistic infections) (see [Multimedia Appendix 6](#)). At the end of each level or each mission, the player's score (health status and pill count) is shown (see [Multimedia Appendix 7](#)). Each level provides new challenges in colorful body organs; however, the mission stays the same: kill the virus and build strength through taking medicine, learning information, improving motivation, and engaging with healthy characters to build skills.

### Interview Topics

The interview guide consisted of focused, but open-ended, questions aimed at maximizing participant responses (see [Textbox 1](#)). Participants were asked about information relevant to medical adherence, motivating factors to adherence, and



behavioral skills needed for adherence. The IMB model guided interview content, and participants were also queried about their general gaming experience and their reactions to the storyboard and gaming content. The qualitative interviews and app programming were synergistic [43]. Therefore, 11 participants were shown storyboards of the game and feedback was elicited, and additional 9 participants were shown an interactive iPhone version of the game as it became available, and feedback was elicited to inform further game design and development.

### Information Needed for Adherence

Participants were asked about knowledge and information that have influenced their adherence to medication and engagement in medical appointments. Questions included “What type of information from doctors or friends makes it easier to take medications for HIV?” and “What information makes it easier to come to appointments?” This part of the interview aimed to understand the specific knowledge about HIV and ART that promotes adherence behaviors. For example, probes focused on how appropriate administration, expected side effects, and drug interactions can influence adherence to medication and care (for more examples, see [Textbox 1](#)).

**Textbox 1.** Qualitative interview guide based on the information-motivation-behavioral skills model.

<p>Questions and probes</p> <p>Information</p> <ul style="list-style-type: none"> <li>• Was there knowledge or information that helped you at different times or at different ages (older vs younger)?</li> <li>• Does different knowledge or information about HIV and medication help boys vs girls?</li> <li>• What knowledge about antiretroviral treatment promotes adherence to meds?</li> <li>• Does knowing about side effects and drug interactions change decision making to take medications?</li> </ul> <p>Motivation</p> <ul style="list-style-type: none"> <li>• What are the main issues in medical care for HIV?</li> <li>• What are the things that make it hard to take HIV medications?</li> <li>• What are the attitudes or feelings that teens like you have that make it harder to take meds? Or easier to take meds?</li> <li>• How do partners, your family, and your community play a role in adherence to care?</li> </ul> <p>Behavioral skills</p> <ul style="list-style-type: none"> <li>• Do you use alarms, your phone, or reminders?</li> <li>• What do you do if you miss a dose of medication?</li> <li>• What are the strategies for adherence over time and across different situations?</li> <li>• Are there things that you do such as eating, or avoiding certain substances, that make taking medication easier?</li> </ul> <p>General gaming attitudes</p> <ul style="list-style-type: none"> <li>• What is your reaction to getting some HIV information and skills in a game?</li> <li>• Do you ever play games that teach you facts or in which you learn something?</li> <li>• Do you go online or use your phone to learn information about your health?</li> <li>• Have you ever played a health-related game before on your phone or at a computer?</li> </ul> <p>Reactions to Battle Viro</p> <ul style="list-style-type: none"> <li>• What did you like and not like about it?</li> <li>• What do you think this activity is trying to teach you?</li> <li>• How much did the material look like the other games that you play?</li> <li>• How could this activity or content be improved for teens your age?</li> <li>• Now that you have seen this game, would you want to play it?</li> <li>• Before you came here today, did you ever find anything like this in a game on a phone or on a computer?</li> <li>• Would you be worried about playing the games when others could see it?</li> <li>• What would you say if someone asked you about the game?</li> </ul>
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## Motivation for Adherence

Participants were queried about motivational issues related to adherence with probes such as “I would like to hear about what you think the serious issues are surrounding taking HIV medications and coming to medical appointments” and “What are the things that make it hard to take HIV medications?” This part of the interview was dedicated to understanding both personal and social motivations for adherence. Queries were focused on the positive and negative attitudes toward taking antiretroviral medications, perceived negative effects of nonadherence, and the individual’s perceptions of social support from significant others, family, friends, and medical care providers (for more examples, see [Textbox 1](#)).

## Behavioral Skills for Adherence

Participants were asked about the behavioral skills needed for adherence. Participants were also asked about their ability to perform necessary adherence-related tasks and his/her perceived self-efficacy for these tasks. Questions included “What are the ways that you remember to take medications and remember your appointments?” and “What events in your life make it harder to remember to take medication? Or remember your appointments?” We also asked participants about strategies for self-reinforcement for adherence over time and across different situations. We asked questions such as “Do you consciously think about your medication schedule on a long-term basis?” and “What strategies have you used or developed to remember medication or appointments based on your activities?” This part of the interview aimed to assess perceived abilities and strategies to store, obtain, and self-cue the use of medications despite challenges and across situations (for more examples, see [Textbox 1](#)).

## General Gaming Attitudes

Participants were also asked about their general attitudes and experiences with games. Participants were asked questions such as “What games do you, or people you know, play on the cellphone?”; “What types of graphics, avatars, and rewards do you like? And what do you not like?”; and “How are games useful? Do you develop any skills when you play games?” These queries elicited descriptions of popular game activities and attitudes about gaming. The responses were used to make the format and game mechanics of *Battle Viro* engaging and immersive (for more examples, see [Textbox 1](#)).

## Battle Viro Storyboard and iPhone Game

Participants were asked for feedback about the storyboard or the iPhone game (once the mobile game was ready) with the probes such as “What was the main point of this activity?,” “What could you learn from this activity?,” “Would you recommend this type of game to your friends?,” and “What is your reaction to having some HIV information and skills in an iPhone game?” After the first version of the game was developed on the iPhone, participants were asked additional and modified probes such as “Is the game easy to navigate and easy to understand?,” “Did any part of the game not work?,” and “Are there other topics that the game should cover that it does not?” Answers to these questions guided the iterative development

of the game levels, actions, characters, and graphics (for more examples, see [Textbox 1](#)).

## Medication Adherence Monitoring Tracking and Game-Related Text Messages

Participants were also asked about the electronic pill monitoring organizers and game-related text messages. We queried participants about a 7-day per week electronic device and a smart pill bottle cap. Both the smart pill bottle cap and the 7-day organizer can electronically monitor, measure, and securely relay adherence pill bottle openings to our research team. Each time a participant opens his or her smart cap organizer, this information can be wirelessly relayed to a secure network. Our gaming intervention is designed so that, if a participant misses a dose, a message is sent from the pill dispenser to study the investigator’s database on a secure server. Study investigators can then send a game graphic with an adherence-related text message to the participant. Messages were designed to encourage players if a dose was missed with phrases such as “Missing you” and “Get in the game.” If doses were taken on time, participants would receive texts with game messages that were congratulatory such as “Great job in battle” and “You are fighting well!!” Low-cost programs exist that allow text messages to be sent automatically, without research staff involvement, based on wireless adherence readings from smart pill caps or 7-day organizers. However, at this time, integrating the game-related graphic into the adherence-based text message is costlier than research staff effort to send the messages individually. Therefore, for this stage of research (game development and an upcoming small exploratory RCT), research staff will be texting participants. For a larger RCT, the cost of programming automated text messages with game graphics would be reassessed, as the technology would become scalable.

## Quantitative Feasibility and Acceptability Data

After the development of the first version of *Battle Viro*, 9 of the 20 participants played the game on an iPhone and provided both qualitative and written/quantitative feedback. Quantitative feedback was collected using adapted versions of the client service questionnaire (CSQ) and the session evaluation form (SEF). The SEF contains 13 items that assess the feasibility and perceived utility of the game. For example, the SEF states “I will be able to apply what I learned from this game in my life” (for which the response options are 1=“Strongly agree”; 2=“Agree”; 3=“Disagree”; and 4=“Strongly disagree”). The CSQ consists of 8 items that assess general satisfaction with the game. An example query from the CSQ is “In an overall, general sense, how satisfied are you with the amount of activities in the game?” (for which the response options are 4=“Very satisfied”; 3=“Mostly satisfied”; 2=“Indifferent or mildly dissatisfied”; and 1=“Quite dissatisfied”).

## Procedures

Participant consent and interviews were conducted in a private room located in the HIV clinic. Interviews were conducted by either an MD (psychiatrist) or a PhD (psychologist) with support from a trained research assistant. The research staff who conducted interviews did not provide medical or clinical services in the HIV clinic. Interviews lasted between 45 and 60 min and

were digitally recorded. Because we adapted our gaming intervention from a game that was already developed (Dr. Nano X), the system and the framework (eg, code, database, design) were already in place at the beginning of the project. Adaptations to the game occurred as themes emerged from the interviews. The qualitative interviews and game development happened concurrently [43]. This process allowed for continuous game design changes and improvements based on participant feedback and emerging themes. As part of the iterative process, biweekly meetings were held with the programmers to discuss all adaptations, including changes to content, game graphics framework, and game messaging.

## Data Analysis

### Qualitative Data

Trained research assistants transcribed verbatim the digital audio recordings of each interview. Then the MD- or PhD-level research team member reviewed the transcripts with the digital recording for accuracy. Qualitative data analysis followed the tenets of thematic analysis, which consisted of sequential steps [52,53], and interviews continued until data saturation was achieved. The research team familiarized themselves with the data, reviewing each transcription. Next, the research team met weekly and generated a list of codes as they emerged. The team generated a thematic table of the analyses and checked the extent to which the emerging themes reflected the coded data [52,54]. The team grouped the themes under the general categories of the interview guide (ART information, ART motivation, ART behavioral skills, general game attitudes, and reactions to Battle Viro). Themes were examined in their relationship to perceived utility of the game and for factors that would improve or detract from the game's impact. Team discussion and interviews continued until discrepancies were resolved.

### Quantitative Data

Participant responses on the CSQ and SEF were entered into an Excel file, and responses were verified with a second entry. Categorical response frequencies were calculated for each item of both scales. General acceptability of the intervention is illustrated using individual items from the scales. CSQ items are reported using the proportion of participants endorsing "satisfaction" with the intervention (response options "Very satisfied" and "Mostly satisfied" were combined). SEF items are reported using the proportion endorsing "agreement" with feasibility and utility of the game (response options "Strongly agree" and "Agree" were combined).

## Results

### Reactions to Battle Viro Storyboard and iPhone

A total of 20 qualitative interviews were completed. Of the 20 participants, 11 were shown the storyboard of the gaming intervention during qualitative interviews. After feedback on the storyboard from these 11 participants, the preliminary iPhone game was developed directly from the storyboard. Then, the other 9 participants were interviewed after seeing and playing

the game on the iPhone. Interviews were conducted until data saturation was achieved. Interviews from both the storyboard and iPhone game revealed a number of themes that guided game development. Participants desired informational game content that included new and comprehensive details about HIV, details about HIV as it relates to doctors' visits, and general health information. Motivational themes that emerged were the desire for enhancement of future orientation; reinforcement of positive influences from peers, partners, and friends; collaboration with health care providers; decreasing stigma; and increasing personal relevance of HIV care. Behavioral skills themes centered on self-efficacy and strategies for medical adherence and self-care (see Table 1).

Table 1 highlights the barriers and facilitators to adherence expressed by our participants and the corresponding gaming action or message that was adapted or used to enhance facilitators or challenge barriers. Table 1 also includes general gaming attitudes that influenced the development of Battle Viro and specific reactions to the Battle Viro storyboard and iPhone game. In addition to the themes in Table 1, participants who played the game on the phone said that important gaming characteristics included directly destroying HIV in game play, improving health by taking pills, a prologue/introduction with a dramatic voice-over, and images that were HIV-relevant. Participants wanted levels that become increasingly difficult (for a sense of accomplishment). Participants did not want HIV in the title of the game due to concerns about privacy and stigma but wanted to fight HIV in the game action. Participants also commented that their older friends (at least to age 26) frequently played iPhone games and those who also had HIV would like and benefit from this product. For example, a 24-year-old black male participant said, "I like the progression through organ systems." A 19-year-old white male participant said, "It was cool fighting what's inside the body and shooting and killing the HIV viruses." An 18-year-old black female stated, "I liked taking pills and fighting HIV; it mimicked real-life experience." A 25-year-old Hispanic male stated, "It was cool that I am playing a game about HIV, that it was like tailored to me," "I think my other friends who are positive would like this game," and "The sound effects and music were cool" (see Table 1).

The game was iteratively changed as comments were received that indicated a need for alteration. For example, facts about HIV and adherence were made more sophisticated when multiple participants gave feedback such that they knew most of the information given in the game, and they wanted more detailed information about side effects in the game. Many participants also asked for information about general health and substance use. A representative comment was from a 19-year-old white male who said, "I think there should be facts in the game about other health stuff, about smoking, exercise, and diet." Many participants also wanted more guidance through the levels. For example, a 25-year-old Hispanic female participant stated, "I would like better orientation to the levels," and an 18-year-old black male said, "There needs to be instructions or hints when it gets hard" (see Table 1).

**Table 1.** Qualitative interview themes and resulting game adaptations based on the information-motivation-behavioral skills (IMB) model.

IMB construct and themes	Resulting game adaptations or actions
<b>Information</b>	
New and comprehensive details of HIV	Game includes complex and realistic information about opportunistic infections and HIV. Participants fight off infections in each organ. Opportunistic infections are graphically represented. Facts about HIV, CD4 counts, immunity, and viral loads are imparted at every level. HIV is pictured.
HIV as it relates to doctors' visits	Terms and verbiage often used at doctors' visits are used and defined in the game frequently.
General health information	Participants in game receive messages about how exercise and healthy eating also effects health. Participants also receive messages about avoiding cigarettes and illicit substances throughout each level.
<b>Motivation</b>	
Enhancement of future orientation	Messages about staying alive for family, friends, and children scroll through game. As gaming participant takes more pills, and builds more health, they are able to move through levels, receive more artillery, and have more success.
Personal relevance of HIV care	Participants are shrunk down to enter into their own body in order to fight HIV. Gaming participants see how HIV affects their organs during play.
Collaborating with health care providers	Throughout the game, the participant has to partner with doctors to advance to the next level, build strength, and collect artillery.
Reinforcement of influences from peers, partners, and friends	Scrolling messages remind gamers that staying alive for partners, friends, and family is meaningful for themselves and loved ones in their lives.
Decreasing stigma	Participant is empowered to kill HIV and feel stronger with each healthy decision. Adherence to care is valued as healthy, not as a consequence of being sick.
<b>Behavioral skills</b>	
Self-Efficacy for medical adherence and self-care	Solving problems and collecting pills or swallowing pills, in the game leads to higher "Immune Status," more health, and more artillery. This leads to more game play. Perseverance throughout levels leads to success in game.
Strategies for medical adherence and self-care	Scrolling messages encourage participants to use 7 day pill organizers, schedule routine doctors' appointments, and ask providers/doctors questions about topics relevant to them.
<b>General gaming attitudes</b>	
Desire for games with levels, sound effects, colorful graphics. Ability to earn points in game, and choose avatars	Levels/ organ systems become increasingly difficult (for a sense of accomplishment). Background music, sound effects, and dramatic voice-overs included. Colorful graphics are included and change often. Choice of avatars is available. Participants earn points in game by swallowing pills.
<b>Reactions to Battle Viro</b>	
Desire for game action that is realistic with relevant info about HIV.	Participants can directly destroy HIV in game play, and graphics look like HIV. Participants improve health, and gain points in game by taking virtual pills. Participants liked progression through organ systems, with info about HIV that is pertinent to that organ system. Participants learn health facts about HIV that are complex (ie, information about opportunistic infections) during play.
Concerns about stigma.	

## Monitoring Pill Bottle Opening and Game-Related Text Messages

We asked participants about the text messages with gaming graphics and the use of a smart pill cap that measured adherence. During the interviews, we demonstrated how openings of the pill bottle were measured wirelessly, and we showed participants sample adherence-informed text messages. When looking at the smart pill cap, an 18-year-old black male participant stated, "It's cool how it links with game," and "It's awesome that there is a bottle that knows what you are doing." A 19-year-old Hispanic female participant stated, "I hate this pill bottle cap, it's clunky." A 26-year-old white male described, "It was annoying because I can't just carry it; it's too big." Multiple participants stated they would rather use their 7-day organizer. For example, a 21-year-old black female stated, "If you gave this to me, I would never use it; I would just open it every time I took a pill out of my normal 7-day organizer." A 22-year-old

black male said, "I would not use this because I would have to empty all my different pills into the same bottle, I like a daily organizer better." Participants were shown text messages that corresponded to adherence data from the smart pill cap. Participants liked the proposed text messages and an 18-year-old black female described, "These messages will remind me to take my medications." A 22-year-old Hispanic male stated, "I like the pictures" and "the texts seemed upbeat and cheerful." A 25-year-old black male participant described, "These texts are good and they make me kinda want to play the game again," and "I am glad they did not say HIV in them." Of the participants, 3 described that texts "that always say the same thing are boring" (25-year-old black male, 23-year-old black female, and a 19-year-old black male), and an 18-year-old African American male stated, "I would like more messages to have more about the game."

## Acceptability and Feasibility

CSQ and SEF scores were available from participants who played the game on the iPhone for 45-50 min. In addition, 90% (10/11) of the participants were satisfied with the activities in the game; 82% (9/11) learned a lot from this game; 73% (8/11) thought the game was well organized; 82% (9/11) felt game topics were interesting; 82% (9/11) felt they would recommend the game to a friend; 64% (7/11) felt game topics stimulated their interest in the material; 55% (6/11) felt that game topics were relevant to their lives; and 55% (6/11) felt they were able to do the activities in the game.

The gaming intervention was improved based on the above acceptability and feasibility feedback from the CSQ and SEF and also on the feedback from the iterative, qualitative interviews (see [Table 1](#)). Specifically, game play was made easier with written messages and hints throughout each level on how to move forward. We also improved narrated instructions at the beginning of each level to assist players. General health facts about smoking, eating healthy, and avoiding substances such as drugs and alcohol were incorporated into the game. To improve text messages, we included emojis and designed 10 different text messages utilizing phrases based on participant feedback. To improve on the electronic device used for measurement of medication adherence, we moved from a smart bottle pill cap to an electronic 7-day organizer made by Wisepill.

## Discussion

### Principal Findings

In this project, we utilized qualitative interviewing, focused by social learning theory (IMB), to create an iPhone gaming intervention to measure and improve treatment adherence for HIV-infected adolescents and young adults [40-43,45]. A number of themes emerged through qualitative interviews with youth that informed game development. We found that youth desired informational game content that included comprehensive details about HIV, doctors' visits, and general health information. Motivational themes or findings that emerged were the desire for enhancement of future orientation; the need for reinforcement of positive influences from peers, partners, and friends; and the promotion of collaboration with health care providers. Motivational themes also included decreasing stigma and increasing personal relevance of HIV care. Behavioral skills themes or findings centered around self-efficacy and strategies for medical adherence and self-care.

Using the IMB theory in the development of this game ensured that the intervention was informed by decades of prevention research. This study demonstrates that qualitative assessment, social learning theory, and agile software development can complement each other and are important components to the development of a culturally tailored and clinically relevant app. Participant data were used throughout the development of the game and informed the informational, motivational, and behavioral skill-building components of the game. Using a storyboard provided the research team with opportunities to share concept models with participants early on in the design process, and gather feedback with respect to necessary

modifications. Sharing the iPhone game with participants as it was developed also allowed for necessary, incremental improvements. Adolescents and young adults living with HIV provided key qualitative insights with respect to the content and design and process of the game. Culturally tailored games that are informed by those who will use them have more potential for effective integration and uptake in clinical settings.

Although iPhone games are pervasive in popular culture, few gaming apps have been developed to improve health outcomes for persons living with chronic illnesses. Findings of this study highlight several important barriers and facilitators to adherence to medication and treatment for young adults and adolescents living with HIV. Mobile interventions have the potential to reinforce skills learned in the clinic and require fewer resources to deliver patient-centered, evidence-based interventions [55]. Furthermore, apps and mobile phone games have the potential to engage adolescents in interventions who otherwise may not be willing or able to participate in prevention programs.

Gaming and mobile apps also have the potential to advance the delivery of information and promote healthy decision making in disproportionately affected populations, including disadvantaged urban and minority youth who often have less access to medical care and support [53]. National data from Pew Research Center indicate that younger, ethnic and racial minority populations use smartphones frequently, and some data show that African American youth are more likely to be mobile phone users than their white peers [56]. The adolescents and young adults in this study repeatedly expressed having access to, and familiarity with, iPhones. This widespread use of iPhones facilitates the uptake of gaming apps in clinical populations. Therefore, mobile technologies, such as smartphone games and apps, have a great potential to enhance medical care for populations who are disproportionately affected by HIV and other sexually transmitted infections.

### Limitations

Findings should be interpreted in light of study limitations. First, our participants were recruited from a single HIV clinic in New England. This clinic may not be representative of all HIV clinics in the United States or internationally. Therefore, the generalizability of the data collected to inform the development of the app is unknown and may be limited. Second, this study focused on adolescent and young adult patient perspectives. It may be equally important to integrate clinician and caregiver perspectives into the game. In the future, including friends and social networks into the app/gaming prevention programs could be novel and effective. Perspectives of family, friends, and clinicians could also lead to a more robust understanding of barriers and facilitators to adherence to medication and treatment for those living with HIV. Therefore, future research could examine the utility of integrating feedback from clinicians, caregivers, and friends into the gaming app. Finally, this app was developed for the iPhone. Development of the app for Android devices could allow for greater availability of the game and could be a forthcoming step in the future phases of research.

## Conclusions

This study is a significant step in working toward the development and testing of an iPhone gaming app intervention to promote adherence to ART. The long-term goal of this research program is to test our mobile game, Battle Viro, in a randomized trial and, if effective, disseminate the intervention to other clinical sites. There are many advantages to using newer interactive technology to improve adherence, rather than traditional face-to-face counseling, including scalability, efficiency, and cost-effectiveness. As electronic games are highly appealing to adolescents and young adults [57], they are a natural opportunity to deliver health education during leisure time and outside of the clinic [49,50,57-59]. Games can attract

and maintain attention, which is a key component for effective behavior change. Compelling interactive games can expose players to essential health-related content thousands of times and also give players unlimited opportunities to rehearse new skills and receive personalized feedback on health choices made within the game [27,60]. We are not aware of other adherence interventions that integrate medication adherence monitoring technology, text messaging, and a theoretically informed game to improve information, motivation, and behavioral skills for ART adherence. An intervention with these components may empower and engage HIV-infected adolescents and young adults, aid overburdened clinics, and result in improvements in health for youth.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

The iPhone gaming intervention.

[[PNG File, 82KB - mhealth\\_v6i4e96\\_app1.png](#) ]

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## Multimedia Appendix 2

Short narrative movie at the beginning of game.

[[PDF File \(Adobe PDF File\), 57KB - mhealth\\_v6i4e96\\_app2.pdf](#) ]

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## Multimedia Appendix 3

Players can design and individualize their game character.

[[PDF File \(Adobe PDF File\), 139KB - mhealth\\_v6i4e96\\_app3.pdf](#) ]

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## Multimedia Appendix 4

Players can improve their immune status by picking up pills in the arteries and other organs.

[[PDF File \(Adobe PDF File\), 45KB - mhealth\\_v6i4e96\\_app4.pdf](#) ]

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## Multimedia Appendix 5

Examples of gaming environments: the kidney, liver, and brain levels.

[[PDF File \(Adobe PDF File\), 199KB - mhealth\\_v6i4e96\\_app5.pdf](#) ]

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## Multimedia Appendix 6

Answering questions with allied doctors, and building knowledge, helps each player successfully move to the next level or area of the body.

[[PDF File \(Adobe PDF File\), 79KB - mhealth\\_v6i4e96\\_app6.pdf](#) ]

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## Multimedia Appendix 7

Summary of points earned at the end of each level.

[[PDF File \(Adobe PDF File\), 73KB - mhealth\\_v6i4e96\\_app7.pdf](#)]

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## Abbreviations

- ART:** antiretroviral treatment  
**CSQ:** client service questionnaire  
**IMB:** information-motivation-behavioral skills  
**RCT:** randomized control trial  
**SEF:** session evaluation form  
**YMSM:** young men who have sex with men

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Viewpoint

# Recommendations for Assessment of the Reliability, Sensitivity, and Validity of Data Provided by Wearable Sensors Designed for Monitoring Physical Activity

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## Abstract

Although it is becoming increasingly popular to monitor parameters related to training, recovery, and health with wearable sensor technology (wearables), scientific evaluation of the reliability, sensitivity, and validity of such data is limited and, where available, has involved a wide variety of approaches. To improve the trustworthiness of data collected by wearables and facilitate comparisons, we have outlined recommendations for standardized evaluation. We discuss the wearable devices themselves, as well as experimental and statistical considerations. Adherence to these recommendations should be beneficial not only for the individual, but also for regulatory organizations and insurance companies.

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activity tracker; data mining; Internet of Things; load management; physical activity; smartwatch

## Introduction

Wearable sensors (so-called “wearables”) are currently the world’s leading trend in fitness [1,2] and are being employed widely by various groups to monitor variables related to health, physical activity, training load, and recovery [3,4], often with the goal of individualizing physical activity and improving performance. Several insurance companies promote such monitoring [5] and an increasing number of organizations that regulate sports (eg, the International Football Association Board [6]), allow wearables to be worn during competitions (albeit with certain limitations).

If wearables are to be of value in enhancing health and performance [4], it is becoming more and more imperative that the data they supply are proven to be trustworthy by employing scientific approaches [7]. Unfortunately, wearables are often marketed with aggressive and exaggerated claims that lack a sound scientific basis [7], and the unreliable data they provide (and/or interpretation thereof) has resulted in costly class-action lawsuits [8] and provides little or no value to the customer.

Recent scientific evaluation of wearable data has involved widely heterogeneous study designs (including the nature and size of the study population), methodologies, criteria for comparisons, terminologies, and statistical analyses, as well as varying intensities/modalities of exercise. Assessment of novel

technology may be influenced by the particular test conditions employed [9]. For example, laboratory data may not be transferable to real-life situations and data trustworthy in a resting condition or during low-intensity exercise may become less valid at higher intensity (eg, due to motion artifacts). Thus, variations in methodology complicate the comparison of scientific evaluations of wearable data.

From our perspective, athletes, manufacturers of wearables, and organizations concerned with health, sports, and insurance could all benefit from basic recommendations for assessment of the reliability, sensitivity, and validity of data provided by wearable sensors. The aim of this paper is to formulate such recommendations.

## *Factors Inherent to the Wearables Themselves*

### **Sensor Characteristics**

Wearables contain a wide variety of sensors (eg, electrochemical, optical, acoustic, and/or pressure-sensitive), as well as inertial measurement units and global navigation satellite systems (including global positioning systems [GPS]). More than one of these are often present within the same device. These sensors, produced by various manufacturers, are designed to monitor a variety of internal (eg, heart rate, tissue oxygenation, distribution of plantar pressure) and/or external (eg, acceleration of body segments, speed while exercising) parameters, mostly noninvasively [3]. With multi-sensor devices, the quality of data and parameters derived depends on the interplay between the sensors, each of which must therefore be scrutinized both independently and in combination with the others. Consideration of individual sensors is beyond the scope of the present recommendations and we refer the reader to other relevant work for such information [3,10,11].

### **Software**

The nature of the software in the wearable itself, as well as of the software in any accompanying device (ie, laptop, smartphone application) exerts a considerable influence on data quality. For example, the software in GPS receivers or analytical software on an accompanying device may actually alter data [12-14]. We therefore urge researchers to describe the software utilized by the wearable and accompanying devices and/or the involvement of “cloud” technology in detail.

### **Acquisition of Raw Data: Sampling Frequency and Filtering**

Although of less concern to the private consumer, to improve the reliability, sensitivity, and validity of data used for research purposes we recommend that manufacturers provide access to raw data. This issue is of particular interest in the case of multi-sensor devices, which often calculate a single value by combining data from several sensors (a common example being calculation of energy expenditure by merging heart rate with several GPS parameters), yet the contribution by each individual sensor is often unclear. Describing these contributions could enhance scientific trustworthiness (eg, by improving the algorithms employed).

A high sampling frequency, which normally enhances data quality, may be achieved artificially by filtering techniques (eg, interpolation) that produce no actual improvement in this quality [15]. Consequently, both the sampling frequency and any filtering techniques applied should be described in detail.

### **Durability**

Sensors can deteriorate or even wear out with extended use and it is clearly important to describe the durability of the wearable and its sensor technology, at least as indicated by the manufacturer. Unlike laboratory equipment, most wearables are not checked routinely, making such description essential. Wearable devices are typically brand-new when evaluated and the quality and trustworthiness of the data they provide may change with use.

### **Precise Reporting of Anatomical Positioning**

Wearables and their algorithms are often designed for use at a specific position or region of the body, which, consequently, must be indicated clearly. In certain cases, imprecise positioning may attenuate data quality [3]. For example, sensors for surface electromyography incorporated into clothing must be positioned precisely on the muscle, preferably along the midline, halfway between the entrance of the nerve and myotendinous junction [16]. On a daily basis, such accurate positioning may prove difficult, especially since this is often performed by nonprofessionals. Moreover, signal reproducibility may be affected by repeated donning and removal of garments. Consequently, we encourage researchers to describe in detail the positioning of wearables, as well as reproducibility of data. Researchers often evaluate several wearables simultaneously and such devices in close proximity can interfere with one another [15]. We recommend strongly that any potential interference be controlled for.

## *Experimental Considerations*

### **Study Population**

Selection of the study population (eg, cyclists, runners or team members, elite or recreational athletes, youth or adults, men or women) should accurately reflect the intended use of the wearable. Each population behaves differently (eg, with respect to lifestyle) and algorithms should be transferred from one specific population to another only with great care. The inclusion and exclusion criteria for participants must be described clearly. If anyone opts out of the experimental procedure or data analysis, a reason should be given.

### **Exercise Protocol**

The intended purpose and conditions for use of the wearable should be clarified. If designed for monitoring general activity, data should be collected in connection with various forms of exercise (eg, running, cycling, rowing, intermittent activities, activities of daily living) of varying intensity (eg, resting, submaximal, high), in different positions (lying, sitting, or standing), and/or while moving freely. If a wearable is intended to be used in connection with team sports such as soccer, a protocol mimicking the demands of this sport—including low-speed running, straight sprints, change-of-direction, and

tackling—is much more preferable than running constantly at low speed only.

### Potential Confounders

Factors that could influence the outcome, such as temperature and humidity, the warm-up procedure, nutritional status, and any form of encouragement, should resemble the real-life situation as closely as possible [17,18] and be described in detail.

Other potential confounders may also need to be taken into consideration. For example, sensors that monitor electrical signals (eg, for electromyography or electrocardiography) may be influenced by other devices, such as a participant's pacemaker. Optical sensors (eg, for photoplethysmography) can be affected by the photosensitivity of the skin or by vasoconstriction [19,20]. In the case of GPS receivers, the horizontal dilution of precision, as well as the number of satellites to which the wearable is connected, should be reported [15]. Although there are no clear rules, two wearables should not be tested at the same time (eg, one on top of the other) or, if they are, potential interference and crosstalk should be examined for by switching the positions of the devices [21]. Adequate controlling for numerous confounding factors requires a good understanding of both the sensor technology and associated physiological and/or biomechanical processes.

### Special Considerations Concerning Reliability

Intradvice reliability concerns reproducibility within the same device [22,23], while interdevice reliability (reproducibility with different devices) is to be tested if the devices in question are intended for interchangeable use [12]. Both types of reliability should be confirmed routinely. Recently, it has been recommended that at least 50 participants and three trials should be involved in order to obtain precise estimates of reliability [23]. When multiple trials are performed at different times, potential confounders must vary as little as possible.

### Special Considerations Concerning Validity

Several different types of validity (eg, logical, convergent, and construct validity [24,25]) are probably equally important in this context, but discussion of these in detail is beyond the present scope and we refer the interested reader to other relevant articles [24,25]. Here, we focus on concurrent criterion validity, since this is probably easiest to access with respect to wearables. Concurrent criterion validity evaluates the association between data provided by the new device and another device considered to be more valid (sometimes referred to as a criterion measure or “gold-standard”) [23,25].

For certain parameters, there are generally-accepted criterion measures (eg, polysomnographic parameters of sleep [26] and an ingestible telemetric sensor for core body temperature [27]). However, for others (eg, energy expenditure at several timepoints while moving freely and in-shoe plantar pressure) no such measures are currently available. We encourage researchers to describe the trustworthiness of their criterion measures and strongly discourage the use of measures not considered to be “gold-standard” for validation of the quality of wearable data.

## Statistical Analyses

### Overview

The various statistical approaches for evaluating the reliability or validity of wearables all have limitations [28,29]. Without discouraging the usage of other robust approaches (eg, the Standard Error of Measurement for reliability studies [28] or Bland-Altman plots for validity studies [30,31]), we propose one possible approach to statistical assessment of wearable data concerning reliability, sensitivity, and validity in the following sections.

### Reliability

Reliability should be documented in terms of intrasubject variability (eg, measured as standard deviation, “...the random variation in a measure when one individual is tested many times”), which is possibly the most important indicator of the reliability of measures of performance and sometimes referred to as typical error (TE) [23]. The TE can also be expressed as the coefficient of variation (%CV) [23] and we encourage the reporting of both.

Another measure of reliability (eg, “...the change in mean value between 2 trials...”) assesses systematic bias in combination with random variations [23]. The random variation is simply a sampling error, which tends to be smaller with larger samples. Systematic bias can be due to learning by (and training of) subjects or effects related to fatigue, and consequently can often be minimized by familiarization trials or adequate rest between trials, respectively [23].

In addition, researchers should assess test-retest reliability with the intraclass correlation coefficient [32], which “represents how closely the values of one trial track the values of another as we move our attention from individual to individual” [23] or, in other words, the reliability “of the position or rank of individuals in the group relative to others” [28]. Moreover, to determine whether data provided by different wearables can be used interchangeably, it may be of interest to evaluate interdevice reliability, previously accomplished by calculating the %CV between the devices when worn simultaneously [12].

### Sensitivity

Wearables designed to track changes in performance and/or parameters over time must, of course, be sensitive to such changes [33]. Even with a reliable test, the noise can be high enough to mask changes in parameters [33]. In the case of individual elite athletes, for whom certain fitness parameters are directly correlated with performance (eg, energy expenditure at a given running intensity; the lower, the less intense), the smallest worthwhile change (SWC) is 30% of the individual's typical variation in performance [34]. Where there is no clear relationship between parameters of fitness and performance (eg, strength and team sport performance), it has been proposed that the SWC be calculated (0.2 times the between-subject standard deviation, based on Cohen's effect size principle) and compared with the noise of the measuring device or test [33,34]. This noise can be expressed as the TE, which can be obtained from reliability studies, as described above. A TE less than, similar to, or higher than the SWC can be rated as “good,” “OK,” or

“marginal,” respectively [33]. When assessing sensitivity, similar and reliable experimental approaches are required.

### Validity

Linear regression analysis can be employed to identify bias and provide an estimate of the TE in wearable data [29,35,36]. Furthermore, Pearson’s product-moment correlation coefficient should be calculated [36] to compare the degree of association [33,37] between data obtained with the criterion measure and the wearable. However, a significant correlation does not definitively mean that these data do not differ and is not, therefore, on its own a sufficient indicator of validity [30].

### Conclusions

Here, we have outlined general recommendations (summarized in Table 1) for the evaluation of the trustworthiness of

monitoring training load, recovery, and health by wearables. We are well aware that with certain technologies, other methodological considerations may be of particular importance and that new approaches are emerging constantly. Although evaluation may not be possible or even desirable in every individual context, findings in one situation should be transferred to another only with great care and appropriate justification.

The market for wearables is growing exponentially and their scientific evaluation in a trustworthy manner needs to keep pace. The success of a wearable device depends on gaining the trust of the consumer, stakeholders, and policymakers alike (eg, by transparent reporting of standardized validation, ideally carried out by an independent research institution). We are convinced that these recommendations can aid manufacturers of wearables, athletes, coaches, team managers, insurance companies, and other stakeholders and policymakers alike in evaluating wearable sensor technologies and/or selecting appropriate devices.

**Table 1.** Checklist of important considerations associated with the evaluation of data provided by wearables.

Factor	Action/recommendation
Sensor characteristics	<ul style="list-style-type: none"> <li>• Scrutiny of each sensor</li> </ul>
Software	<ul style="list-style-type: none"> <li>• Specify calculations/algorithms</li> <li>• Report the version of software and firmware involved</li> </ul>
Raw data	<ul style="list-style-type: none"> <li>• Report sampling frequency</li> <li>• Report filtering techniques and aggregation</li> </ul>
Durability	<ul style="list-style-type: none"> <li>• Report the durability and age of the device</li> </ul>
Anatomical positioning	<ul style="list-style-type: none"> <li>• Report the precise anatomical positioning of sensors</li> <li>• Report signal reproducibility upon repeated putting on and taking off</li> <li>• Report considerations concerning positioning</li> <li>• Control for and describe potential interference</li> </ul>
Study population	<ul style="list-style-type: none"> <li>• Describe the target population</li> <li>• Specify inclusion and exclusion criteria</li> <li>• Generalize to other populations only with great care</li> </ul>
Exercise protocol	<ul style="list-style-type: none"> <li>• Describe conditions (eg, ambient temperature, altitude) in as much detail as possible</li> <li>• Investigate different forms of exercise (running, cycling, walking, moving freely)</li> <li>• Apply different intensities (lying, sitting, low and high intensity)</li> </ul>
Confounders	<ul style="list-style-type: none"> <li>• Report any potential confounding factors</li> <li>• Perform assessment in both controlled and real-life scenarios</li> <li>• Check for potential crosstalk between devices</li> </ul>
Assessment of reliability	<ul style="list-style-type: none"> <li>• Determine intradevice and interdevice reliability</li> <li>• Document intrasubject standard deviation</li> <li>• Report the coefficient of variation</li> <li>• Calculate the intraclass correlation coefficient</li> <li>• Recruit at least 50 participants</li> <li>• Report systematic bias</li> </ul>
Assessment of sensitivity	<ul style="list-style-type: none"> <li>• Calculate the smallest worthwhile change</li> </ul>
Assessment of validity	<ul style="list-style-type: none"> <li>• Choose an appropriate criterion measure and assess the reliability of this measure as well</li> <li>• Perform linear regression analysis</li> <li>• Calculate Pearson’s product-moment correlation</li> </ul>

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## Conflicts of Interest

None declared.

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## Abbreviations

- %CV:** coefficient of variation
- GPS:** global positioning system
- SWC:** smallest worthwhile change
- TE:** typical error

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Original Paper

# Managing Patient-Generated Health Data Through Mobile Personal Health Records: Analysis of Usage Data

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## Abstract

**Background:** Personal health records (PHRs) and mHealth apps are considered essential tools for patient engagement. Mobile PHRs (mPHRs) can be a platform to integrate patient-generated health data (PGHD) and patients' medical information. However, in previous studies, actual usage data and PGHD from mPHRs have not been able to adequately represent patient engagement.

**Objective:** By analyzing 5 years' PGHD from an mPHR system developed by a tertiary hospital in South Korea, we aimed to evaluate how PGHD were managed and identify issues in PGHD management based on actual usage data. Additionally, we analyzed how to improve patient engagement with mPHRs by analyzing the actively used services and long-term usage patterns.

**Methods:** We gathered 5 years (December 2010 to December 2015) of log data from both hospital patients and general users of the app. We gathered data from users who entered PGHD on body weight, blood pressure (BP), blood glucose levels, 10-year cardiovascular disease (CVD) risk, metabolic syndrome risk, medication schedule, insulin, and allergy. We classified users according to whether they were patients or general users based on factors related to continuous use ( $\geq 28$  days for weight, BP, and blood glucose, and  $\geq 180$  days for CVD and metabolic syndrome), and analyzed the patients' characteristics. We compared PGHD entry counts and the proportion of continuous users for each PGHD by user type.

**Results:** The total number of mPHR users was 18,265 (patients:  $n=16,729$ , 91.59%) with 3620 users having entered weight, followed by BP ( $n=1625$ ), blood glucose ( $n=1374$ ), CVD ( $n=764$ ), metabolic syndrome ( $n=685$ ), medication ( $n=252$ ), insulin ( $n=72$ ), and allergy ( $n=61$ ). Of those 18,256 users, 3812 users had at least one PGHD measurement, of whom 175 used the PGHD functions continuously (patients:  $n=142$ , 81.14%); less than 1% of the users had used it for more than 4 years. Except for weight, BP, blood glucose, CVD, and metabolic syndrome, the number of PGHD records declined. General users' continuous use of PGHD was significantly higher than that of patients in the blood glucose ( $P<.001$ ) and BP ( $P=.03$ ) functions. Continuous use of

PGHD in health management (BP, blood glucose, and weight) was significantly greater among older users ( $P<.001$ ) and men ( $P<.001$ ). In health management (BP, weight, and blood glucose), overall chronic disease and continuous use of PGHD were not statistically related ( $P=.08$ ), but diabetes ( $P<.001$ ) and cerebrovascular diseases ( $P=.03$ ) were significant.

**Conclusions:** Although a small portion of users managed PGHD continuously, PGHD has the potential to be useful in monitoring patient health. To realize the potential, specific groups of continuous users must be identified, and the PGHD service must target them. Further evaluations for the clinical application of PGHD, feedback regarding user interfaces, and connections with wearable devices are needed.

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## KEYWORDS

personal health record; mobile health; patient engagement; patient-generated health data; health records, personal; telemedicine; patient participation

## Introduction

Patient centeredness and patient engagement are essential characteristics of health care services and provide the greatest benefits to patients [1]. In precision medicine, patient engagement and patient-generated health data (PGHD) are regarded to be as important as clinical and genomic data [2-5]. As wired, widespread tools for data collection, mobile phones and apps can generate engagement and gather data [2,3,5,6]. Mobile patient health records (mPHRs) can integrate and manage such kinds of data and can be connected with other mobile services. Moreover, for personalized care and customized treatment, sufficient patient data are required [6,7]; intermittent information collected at the hospital may not provide sufficient patient data [8]. Therefore, the establishment of a health platform for patients and patient participation is needed, and patient health records (PHRs) are an appropriate tool for this purpose [6].

Patient information accumulated through mPHRs and wearable devices can help build a personalized baseline [2]. PGHD have the potential to change the paradigm for existing normal ranges [2]. Information gathering through patient health platforms is expected to benefit medical care and patient health outcomes [9-14]. Meanwhile, there are concerns about the construction of such patient health platforms [10,15,16]. In particular, mHealth apps, which are easily accessible to patients and health personnel, are frequently discontinued and discarded [17]. It is necessary to encourage long-term use to maximize the effects of the health outcomes of the health platform and fully utilize the collected information. To this end, it is necessary to analyze factors that affect the long-term use of health platforms. Several studies have been conducted regarding this topic.

Previous studies have noted the lack of usage data research that analyzes the use of mPHRs from the perspective of PGHD [6,10]. In particular, there is a lack of research on modifiable factors (eg, service menu) and the persistence of health platforms based on data. In addition to user-specific characteristics (eg, age, sex, diagnosis), studies should be conducted on the modifiable factors that affect use duration, to facilitate activities that promote continued use.

We conducted this study using data on the 5-year use of an mPHR system distributed by a tertiary hospital in South Korea. The mPHR system, which has been used since 2010, provides several functions through which users can log their health data. Based on actual usage data, we investigated the usage pattern and characteristics of the users of PGHD services. To the best of our knowledge, this is the first study on the long-term use and input of PGHD through mPHRs.

## Methods

### Data and Mobile Patient Health Record Description

We collected the log data of an Android-based mPHR app called My Chart in My Hand (MCMH) at Asan Medical Center (AMC), which is the largest general hospital in South Korea. AMC established the Ubiquitous Health Center in 2009, and the MCMH was implemented on December 27, 2010, after collaboration with a Korean telecommunication company (SK Telecom Co Ltd, Seoul, Republic of Korea) [18]. The Ubiquitous Health Center is responsible for the development, operation, and management of telehealth services and various apps related to mHealth in AMC. Released in January 2011, MCMH is the first mPHR in South Korea; it enables patients to view and manage their own health records [19,20]. MCMH 2.0 has been operational since 2016; it offers more diverse functions for patient engagement (disease diaries and assessment tools [patient survey] for symptoms, lifestyle, quality of life, and stress, which can be used in clinics for cancer, inflammatory bowel disease, diabetes, and pediatric asthma and atopy) and medication consultations with a clinical pharmacist. This study is a user pattern analysis for MCMH 1.0, which was operational from the end of 2010 until 2015. MCMH 1.0 provides the following 4 menus: My chart, Health management, Medication management, and Outpatient support service [21]. Among these 4 functions, PGHD belong to the Health management, Medication management, and My chart menus. MCMH is not restricted to AMC patients. General users can download the app and use the functions related to the above PGHD, although the functions connected to the AMC hospital information system are limited to its patients.

**Figure 1.** Patient-generated health data (PGHD) screens in the My Chart in My Hand app for the Health management, Medication management, and My chart menus. The functions corresponding to PGHD in the 3 screens are indicated by dashed boxes. The original app showed menu names in Korean, which have been translated into English. AMC: Asan Medical Center; BMI: body mass index; BP: blood pressure; BST: blood glucose level; CVD: cardiovascular disease; HT: height; EMR: electronic medical record; WT: weight.



The items in dashed boxes in [Figure 1](#) show the detailed PGHD items that the user stores in MCMH. The health management function provides features for tracking and updating PHRs, such as blood glucose levels, blood pressure (BP), and weight. Based on the information entered by patients, body mass index, 10-year cardiovascular disease (CVD) risk, and metabolic syndrome risk can be calculated. The medication management function provides medication schedulers and reminders of when to take medicines. Users can manage their medication schedules (Medication) and insulin injections (Insulin) themselves through this function. Users are required to input data manually on these PGHD functions, as there is no functionality for accepting data streams from personal tracking devices.

### Study Design

To identify the usage pattern of the PGHD functions according to the type of PGHD, user type (patient or general user), and continuous use of the function, we analyzed the logs of all users who signed up and logged in more than once between December 2010 and December 2015. MCMH 1.0 was launched on December 20, 2010, for test users and on December 27, 2010 for all users. It was replaced with MCMH 2.0 on December 31, 2015.

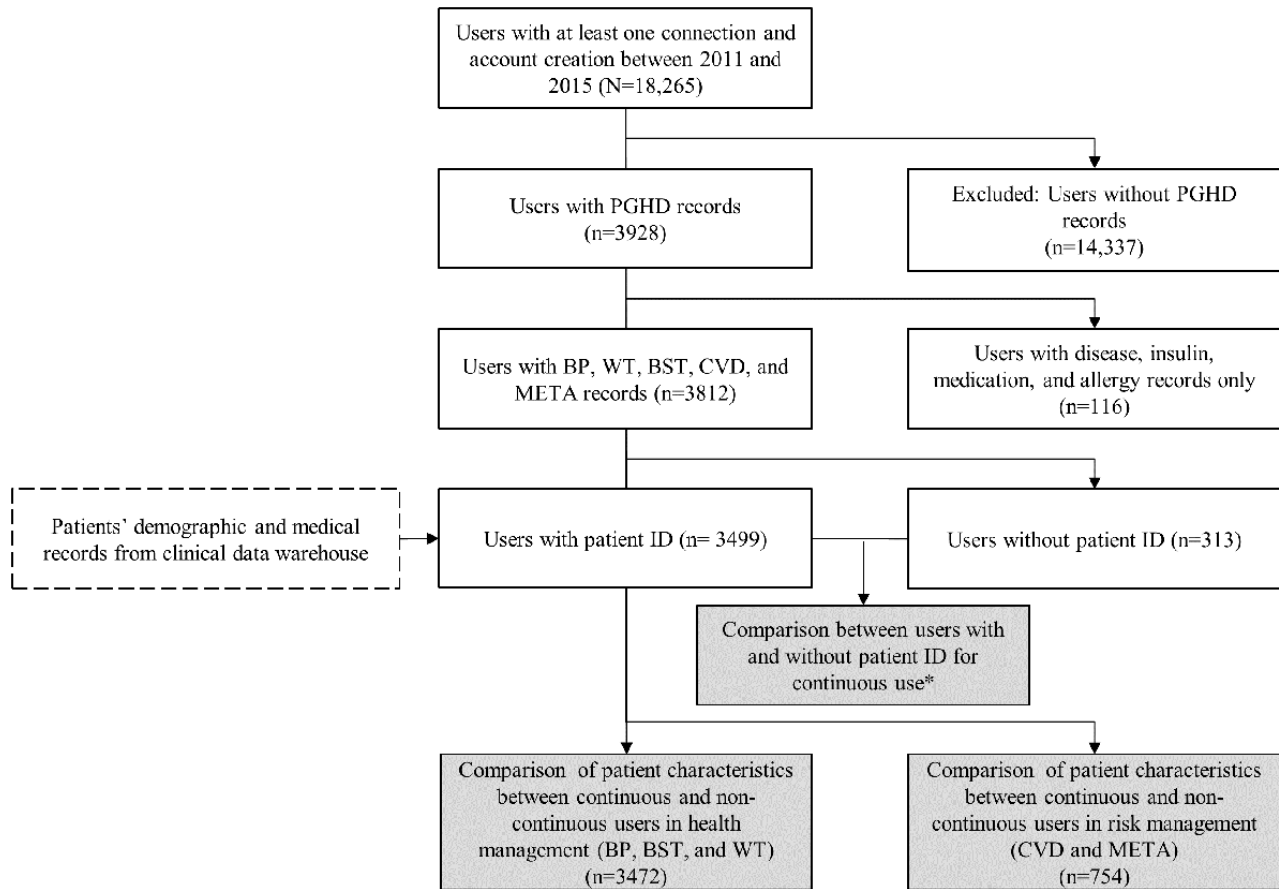
As there are no existing criteria for continuous use of PGHD services, this study defined the criteria for each PGHD function. We defined continuous use as follows: weight, BP, and blood glucose entered at least once per week and used for at least 4 weeks (28 days); 10-year CVD risk and metabolic syndrome risk entered at least twice and used for at least 180 days. Because weight, BP, and blood glucose are continuous values that

indicate users' daily health status, 10-year CVD risk or metabolic syndrome risk is a risk-evaluation function that has no definite consensus regarding the evaluation period; we derived these criteria differently through discussion.

The user logs contained time stamps for each PGHD function, recorded whenever an individual used these functions. We also gathered demographics and medical records for patients, such as age, sex, residence, and health information, including hospital visits and presence of chronic diseases, using our clinical research data warehouse [22]. We conducted demographic and medical record comparison analysis of patients between continuous use and noncontinuous use by classifying the PGHD variables into health (BP, weight, and blood glucose) and risk (10-year CVD risk and metabolic syndrome risk) management. Distance from AMC to the patient's residence was designated as short distance if the patient lived in the capital region with AMC and as long distance if the patient lived outside the capital [18]. The presence of chronic disease was classified by the definitions of the Korea Center for Disease Control and Prevention: cancer (C00-C97), diabetes (E10-E14), CVD (I20-I51), cerebrovascular disease (I60-I69), chronic lower respiratory disease (J40-J47), and liver disease (K70-K76) [23,24]. We classified all diseases according to the *International Classification of Diseases, 10th Revision*.

This study was approved by the AMC's institutional review board (no. 2017-1128). The ethics committee waived the need for informed consent, as this study used routinely collected log data that were anonymously managed at all stages, including during data cleaning and statistical analyses.

**Figure 2.** Patient inclusion and exclusion criteria (white boxes) and flow through the study. The gray boxes show user log analyses. The dashed boxes indicate additional patient clinical data obtained from the users. \*Criteria for continuous use: weight (WT), blood pressure (BP), and blood glucose level (BST) entered at least once per week and used for at least 28 days; 10-year cardiovascular disease (CVD) risk and metabolic syndrome (META) risk entered at least twice and used for at least 180 days. ID: identifier; PGHD: patient-generated health data.



## Data Analysis

Figure 2 shows the patient selection flow for the study. Among a total of 162,661 users who downloaded and created an MCMH account, we excluded 144,396 users who had never accessed MCMH services. Therefore, we considered a total of 18,265 actual MCMH users for inclusion in the study. We first excluded 14,337 users without PGHD records. The number of those with PGHD records who used only the disease, insulin, medication, and allergy functions was relatively small, with 116 users, so we focused on 3812 users with records for BP, weight, blood glucose, 10-year CVD risk, and metabolic syndrome.

We performed a comparative analysis of the continuous use of PGHD services between AMC patients ( $n=3499$ ) and general app users ( $n=313$ ). To analyze the demographic and clinical characteristics, we extracted related variables from the clinical data warehouse only for patients. We then analyzed patients' characteristics according to their continuous use of health management (BP, weight, and blood glucose) and risk management (10-year CVD risk and metabolic syndrome risk) functions.

We compared means and of frequencies with the Student *t* test and chi-square test, respectively. If the observed value was less than 5, we performed Fisher exact test. All reported *P* values

were 2-sided, and *P* values less than .05 were considered significant. Also, we performed a multiple logistic regression analysis with adjusted age and sex. Data analyses were conducted with the R software, version 3.3.1 (R Foundation).

## Results

### Overall Use Characteristics

Within 5 years of MCMH operation, a total of 18,265 users downloaded the app and logged in more than once. Among these users, 16,729, or 91.59% of the total, were AMC patients. Patients had a statistically significant (1.8 times) longer use of the system (average period of use: 251.86 vs 467.84 days) and a pattern of accessing the app more than 6 times compared with general users (average number of accesses: 8.26 vs 50.96).

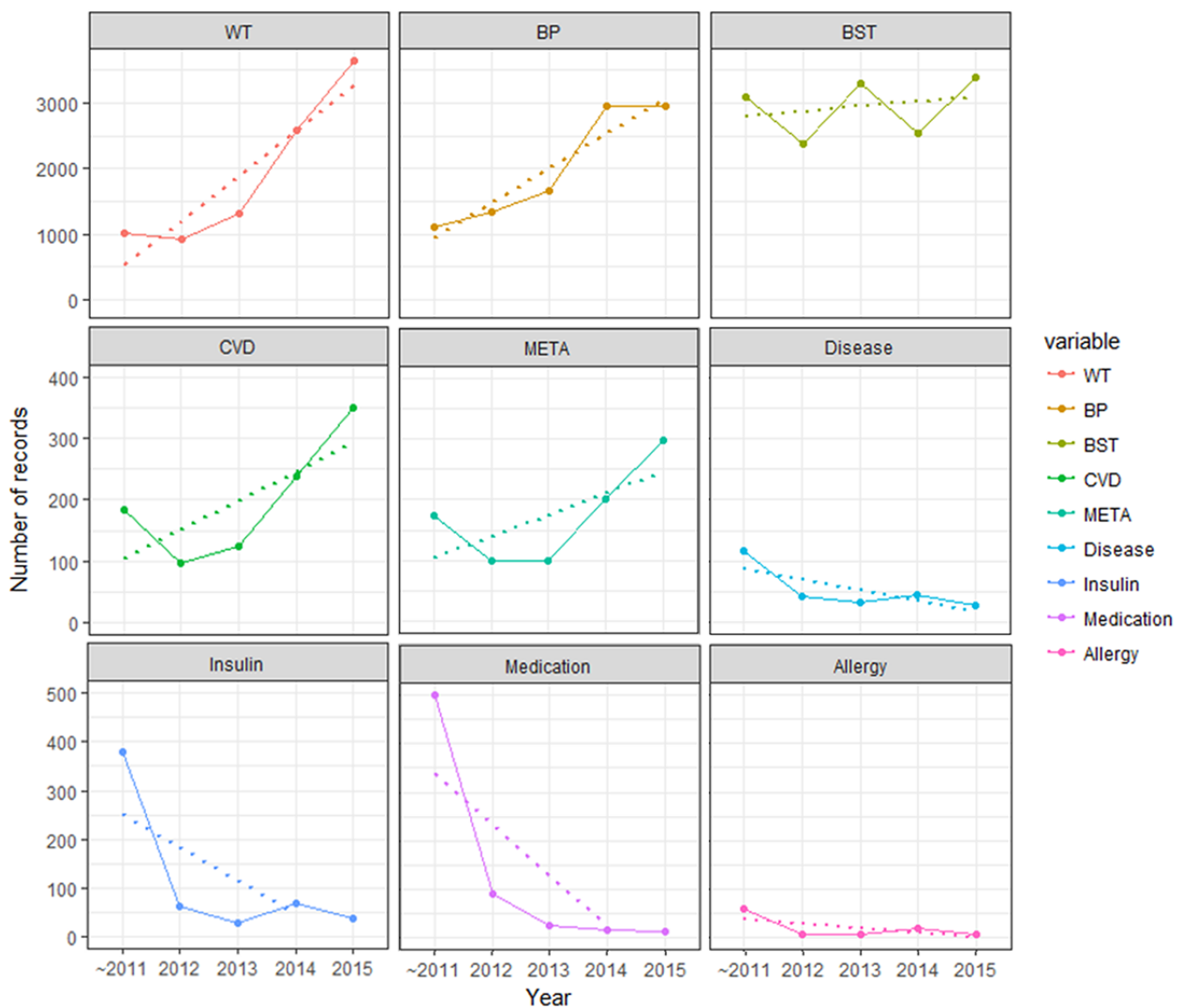
Among all users, 21.50% (3928) had at least one PGHD record (Table 1). In the PGHD, data input was significantly higher in the group of general users: blood glucose ( $P=.003$ ), weight ( $P<.001$ ), and allergy ( $P=.04$ ). The average number of records per user was also significantly higher in general users: 6.89 (SD 24.79) vs 4.41 (SD 31.46) ( $P=.009$ ). The median values of 1 for all categories except insulin indicate that more than half of the users made only 1 entry in each category. There was no significant difference in the remaining PGHD items.

**Table 1.** Numbers of users who entered patient-generated health data in the app by user type (hospital patients and general app users).

Variables	General users (n=329)			Patients (n=3599)			Total (n=3928)			P value <sup>a</sup>
	No.	Median	Mean (SD)	No.	Median	Mean (SD)	No.	Median	Mean (SD)	
Blood pressure	143	1	9.13 (27.31)	1482	1	5.87 (43.56)	1625	1	6.16 (42.39)	.10
Weight	275	1	1.44 (2.17)	3345	1	2.71 (15.89)	3620	1	2.61 (15.29)	<.001
Blood glucose level	154	1	20.39 (45.03)	1220	1	9.45 (51.92)	1374	1	10.70 (51.31)	.003
10-year cardiovascular disease risk	81	1	1.29 (1.04)	683	1	1.30 (1.24)	764	1	1.29 (1.22)	.49
Metabolic syndrome risk	75	1	1.32 (1.19)	610	1	1.26 (1.05)	685	1	1.27 (1.07)	.36
Medication	44	1	2.25 (2.79)	208	1	2.50 (3.82)	252	1	2.46 (3.66)	.303
Disease	60	1	1.58 (1.40)	115	1	1.45 (0.85)	175	1	1.49 (1.07)	.26
Insulin	16	1	15 (31.94)	56	2	6 (10.11)	72	2	8.02 (17.90)	.15
Allergy	16	1	1.18 (0.52)	45	1	1.88 (2.52)	61	1	1.70 (2.20)	.04

<sup>a</sup>Student *t* test.

**Figure 3.** Analysis of the tendency of patient-generated health data (PGHD) to increase or decrease by year. The mobile patient health record log of input by type of PGHD was analyzed by year. The solid line represents the actual number of records, and the dashed line represents the trend for the record. BP: blood pressure; BST: blood glucose level; CVD: 10-year cardiovascular disease risk; META: metabolic disease risk; WT: weight.



### Patient-Generated Health Data Entry Distribution

The distribution of total PGHD items was divided into 2 patterns: increasing and decreasing (Figure 3). Items with an increasing pattern were Health management menu items: weight, HT, BP, blood glucose, 10-year CVD risk, and metabolic syndrome risk. Items that showed a decreasing pattern were diseases, insulin, medication, and allergy, belonging to the Medication management and My Chart menus. Among the increasing patterns, the weight value increased the fastest (slope=685.8,  $R^2=.857$ ), followed by BP (slope=526.1,  $R^2=.884$ ), and 10-year CVD risk (slope=47.2,  $R^2=.552$ ). In the decreasing pattern, medication showed the steepest decrease (slope=-104.6,  $R^2=.623$ ).

We performed a periodic usage analysis of the 3 most recorded PGHD items (BP, weight, and blood glucose) among the 9 PGHD items (Figure 4). To determine how long users took to enter their PGHD, we first divided the users into 7 groups based on the duration of use (Figure 4). According to the analysis, approximately 70% of users generated PGHD only once; 11% to 14% of them used MCMH for more than 4 weeks but less than 1 year, and only 6% to 9% used it for more than 1 year and less than 4 years. Only less than 1% of users used it for more than 4 years. In the graph between the actual value of usage duration and PGHD records (Figure 4), some users have PGHD records for more than 5 years (over 1825 days), which is the result of transferring users' preexisting records before the MCMH service started.

### Comparison Between Patients and General Users in Continuous Use of Patient-Generated Health Data Functions

To characterize continuous users of the PGHD functions, we defined the criteria for continuous use of health (at least 28 days for BP, weight, and blood glucose) and risk (at least 180 days for 10-year CVD risk and metabolic syndrome risk) management, and then analyzed the differences between AMC patients and general app users. A total of 175 mPHR users

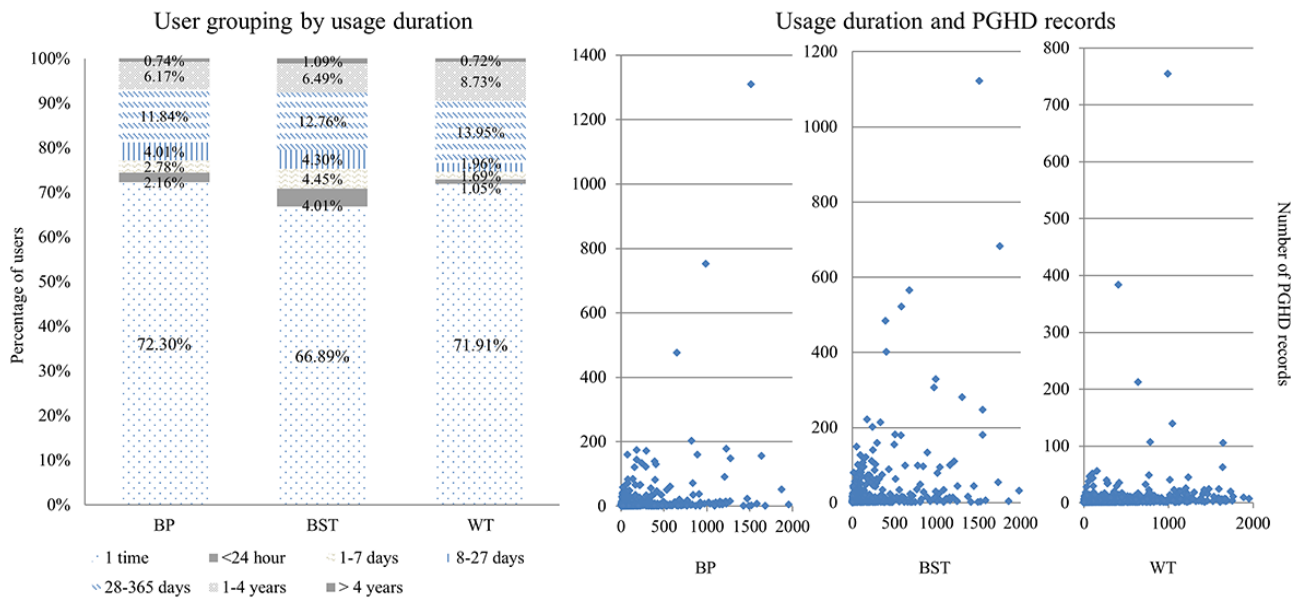
continued to use the PGHD functions. General users were significantly higher than patients in continuous use of PGHD for blood glucose ( $P<.001$ ) and BP ( $P=.03$ ). For other PGHD items, there was no statistically significant difference in continuous use between the 2 user types (Table 2).

### Characteristics of Patients Who Continuously Used Patient-Generated Health Data Functions

To identify the characteristics of users who continuously used PGHD functions, we conducted a comparative analysis of the related data on demographics, diagnoses, and hospital visits in the health and risk management menus of MCMH (Table 3). This analysis was limited to patients, for whom demographic, diagnostic, and hospital visit records could be identified. A total of 142 patients used PGHD continuously. The continuous use of PGHD services in the health management sector was statistically significant for older individuals and men (both  $P<.001$ ). For continuous use of PGHD services, there was no statistically significant difference in overall chronic disease ( $P=.08$ ), but diabetes ( $P<.001$ ) and cerebrovascular diseases ( $P=.03$ ) differed significantly. These characteristics were also significant in age- and sex-adjusted multivariate regression analyses (diabetes:  $P<.001$ ; cerebrovascular disease:  $P=.03$ ). In those with diabetes, continuous users were younger than noncontinuous users (average age 42.75 vs 49.50 years,  $P=.04$ ). This is young relative to the average age of continuous users of the entire PGHD group (average age 42.75 vs 51.81 years, respectively). In those with cerebrovascular disease, continuous users were older than noncontinuous users, which was not statistically significant (average age 61 vs 48.2 years,  $P=.33$ ). In each disease group, there was no significant difference between the 2 groups (continuous vs noncontinuous) in sex, distance from the hospital, and type of visit.

Hospital visit experience was not statistically related to continuous use; all continuous users made emergency room and outpatient visits. In risk management, there were no significant differences between continuous and noncontinuous users.

**Figure 4.** Analysis of patient-generated health data (PGHD) by duration of app use. Left: Duration of use divided into 7 categories, from once to more than 4 years of use. Right: Actual duration of use (x-axis) and number of PGHD records generated by each user (y-axis); 1 point represents 1 user. BP: blood pressure; BST: blood glucose level; WT: weight.



**Table 2.** Comparison between general app users and Asan Medical Center patients for continuous use of patient-generated health data functions.

Categories/Variables/Continuous use	Users, n (%)			P value <sup>a</sup>
	General users (n=313)	Patients (n=3499)	Total (n=3812)	
<b>Health management</b>				
<b>Blood pressure (n=1621)</b>				.03
No	130 (8.30)	1437 (91.70)	1567	
Yes	9 (16.67)	45 (83.33)	54	
<b>Weight (n=3620)</b>				.70
No	275 (7.64)	3323 (92.36)	3598	
Yes	0 (0.0)	22 (100.00)	22	
<b>Blood glucose level (n=1371)</b>				<.001
No	128 (9.98)	1154 (90.02)	1282	
Yes	23 (25.84)	66 (74.16)	89	
<b>Risk management</b>				
<b>10-year cardiovascular disease risk (n=764)</b>				.97
No	76 (10.61)	640 (89.39)	716	
Yes	5 (10.42)	43 (89.58)	48	
<b>Metabolic syndrome risk (n=685)</b>				.72
No	71 (11.06)	571 (88.94)	642	
Yes	4 (9.30)	39 (90.70)	43	

<sup>a</sup>Chi-square test.

**Table 3.** Characteristics of patients who used patient-generated health data functions in health and risk management continuously (“Yes”) versus those who did not (“No”).

Variables/Categories	Health management <sup>a</sup> (n=3472)				Risk management <sup>b</sup> (n=754)			
	Yes (n=94)	No (n=3378)	<i>P</i> value <sup>c</sup>	<i>P</i> value <sup>d</sup>	Yes (n=50)	No (n=704)	<i>P</i> value <sup>c</sup>	<i>P</i> value <sup>d</sup>
Age (years), mean (SD)	51.81 (12.07)	43.79 (15.37)	<.001	N/A <sup>e</sup>	46.98 (11.67)	47.92 (11.24)	.58	N/A
<b>Sex, n (%)</b>			<.001	N/A			.75	N/A
Male	76 (81)	2101 (62.20)			35 (70)	470 (66.8)		
Female	18 (19)	1277 (37.80)			15 (30)	234 (33.2)		
<b>Distance to the hospital, n (%)</b>			.41	N/A			.26	N/A
Short	35 (37)	1103 (32.65)			12 (24)	231 (32.8)		
Long	59 (63)	2275 (67.34)			38 (76)	473 (67.2)		
<b>Disease classification<sup>f</sup>, n (%)</b>								
Cancer (C00-C97)	11 (12)	606 (17.94)	.14	.08	8 (16)	99 (14.1)	.87	.63
Diabetes (E10-E14)	12 (13)	122 (3.61)	<.001	<.001	2 (4)	29 (4.1)	>.99	.96
Cardiovascular disease (I20-I51)	4 (4)	90 (2.66)	.33	.55	2 (4)	19 (2.7)	.64	.57
Cerebrovascular disease (I60-I69)	4 (4)	38 (1.12)	.03	.03	0 (0)	14 (2.0)	.62	.98
Chronic lower respiratory disease (J40-J47)	1 (1)	15 (0.44)	.36	.35	0 (0)	2 (0.3)	>.99	.98
Liver disease (K70-K76)	14 (15)	299 (8.85)	.08	.42	4 (8)	72 (10.2)	.79	.59
Chronic disease	39 (42)	1070 (31.68)	.08	.27	15 (30)	218 (31.0)	>.99	.92
<b>Type of hospital visit, n (%)</b>								
Emergency room	59 (62)	1811 (53.36)	.15	N/A	30 (59)	371 (52.1)	.43	N/A
Outpatient department	94 (98)	3,334 (98.70)	.68	N/A	49 (96)	699 (98.2)	.264	N/A
Hospitalization	76 (79)	2,689 (79.60)	>.99	N/A	42 (82)	544 (76.4)	.423	N/A

<sup>a</sup>Blood pressure, weight, and blood glucose.

<sup>b</sup>Metabolic syndrome and 10-year risk of cardiovascular disease.

<sup>c</sup>*t* test (for continuous), chi-square test, or Fisher exact (for categorical) test.

<sup>d</sup>Multiple logistic regression test adjusted for age and sex.

<sup>e</sup>N/A: not applicable.

<sup>f</sup>Korea Center for Disease Control and Prevention classifications.

## Discussion

### Principal Findings

The mPHR used in this study was a feasible platform for managing PGHD, for the following reasons. First, it was available not only to patients but also to general users; it was used as a platform to store and refer to general users' health information. Although the number of users was small, the fact that there were long-term users entering their health information means that this app was used as a suitable tool for storing and referring to health information. Second, there were enough long-term users to show significant differences in usage patterns. Third, the upgraded version, which reflects usage patterns and user needs, of the existing mPHR is expected to improve user satisfaction and to contribute additional data for further research.

This study is unique compared with previous studies based on the following characteristics. First, we used actual usage data

to investigate long-term use. Meanwhile, research on telecare for chronic disease management lacks enough studies for a sufficient period of time. Second, our analysis was based on users rather than just on patients of AMC. We also compared usage by those who had been in hospital (patients) and those who had not (general users). Third, the mPHR we examined is the first one to provide patient information to patients in Korea, and our study included analysis and consideration of the modifiable factors for long-term use promotion.

### Overall Usage Pattern and User Characteristics

Most of the mPHR users were patients (91.59%), and we found them to have significantly longer and more frequent use. However, general users used more of the overall PGHD functions ( $P=.009$ ). There was a significant difference in blood glucose ( $P<.001$ ). General users submitted more BP and insulin records, although the differences were not significant. MCMH is not a type of mPHR that mainly aims at chronic disease



management; it is a comprehensive platform that includes such services as providing patient information and setting appointments. Therefore, the more frequent use by patients is attributed to the greater number of services available through the mPHR relevant to them than to general users. Nonetheless, general users used it more actively for storing and referring to health information. This result confirms the potency for managing patient health information through an mPHR.

### Patient-Generated Health Data Entry Distribution

According to a 2011 survey by the Consumer Health Information Corporation, 26% of health apps were abandoned after one use, whereas 79% were used up to 10 times before being abandoned [25]. Approximately 70% of the users of the mPHR entered PGHD only once, but this should be considered in the context that PGHD is one of the functions of the mPHR. In addition, about 10% of PGHD users (weight: 9.45%; blood glucose: 7.49%; BP: 6.91%) entered health records for more than 1 year. Thus, the PGHD functions have the potential for long-term health monitoring.

The total use of weight, BP, blood glucose, CVD, and metabolic syndrome menus tended to increase, whereas the use of diseases, insulin, medication, and allergy menus tended to decline. The data to be input into the diseases, insulin, medication, and allergy menus (eg, entering the whole name and dose of the medication and selecting the insulin injection site) are more complicated than in other functions. On the other hand, BP, weight, and blood glucose menus required users to input only a few numerical values, and CVD and metabolic syndrome required users to check several boxes for risk evaluation. The user interface problem at the time of data input can be considered to have caused these differences. In addition, while biosignals such as weight, BP, and blood glucose were entered for the purpose of managing health data by the users themselves, the functions that are out of the scope of the users' management might provide less motivation for continuous use, without rewards such as the feedback of clinicians. Also, the increase in the use of biosignal input functions suggests that automatic input of data through wearable devices, body scales, or blood glucose meters may be helpful for encouraging continuous use. Linking PHR data would reduce the inconvenience to users of inputting data for diseases, insulin, medication, and allergy.

### Comparison Between Patients and General Users

General users' tendency to use the blood glucose and insulin functions longer showed the need for a reliable app service for diabetes management. The mPHR was developed for general care, not only for chronic disease management. Therefore, services for patients with chronic diseases were limited. However, despite the small proportion, there were long-term users for chronic diseases management, especially for diabetes.

One of the main reasons for the abandonment of health apps is the mistrust of app developers [17]. Although many studies have indicated the effectiveness of diabetes management through patient health platforms, the use of mobile apps for diabetes management was not universal in Korea at the time of the MCMH mPHR launch. Recently, PHRs focused on chronic diseases have emerged [26]. Therefore, users looking for a

reliable app for diabetes management, even though they were not patients of AMC, used the MCMH mPHR.

### Patients' User Characteristics

Significantly, male users, elderly users (mean age 51.81 vs 43.81 years), and users with a diagnosis of diabetes tended to use the health management functions continuously. In the case of cancer, which accounted for more than half of all chronic diseases, the incidence in Korea increased by age beginning with users in their 80s, and the incidence among men was higher than that among women (445.2/100,000 vs 397.6/100,000 [27]). In addition, according to a 2015 report in Korea, the average age at first diagnosis of diabetes mellitus was 57.11 (SD 13.9) years for men and 60.57 (SD 14.9) years for women. According to a survey in 2016, in South Korea, the percentage of males who own a smartphone is higher than that of females, and the percentage decreases after the age of 30 years [28]. Nonetheless, the high proportion of long-term use of PGHD services by elderly patients reflects the age characteristics of patients living with chronic diseases. However, in a subanalysis of users with a diagnosis of diabetes, the younger users (average age: 42.75 vs 49.50 years) tended to use PGHD services continuously, and there was no significant difference in the sex of users. Hence, the number of continuous users with diabetes was small (n=12), and more in-depth research such as user surveys or interviews is required to understand the detailed usage patterns.

### Limitations of This Research

The main limitation of this study was the lack of a clinical practice application of the PGHD collected in the mPHR; the PGHD in MCMH version 1.0 were used for simple reference without any feedback from a health provider. This aspect is improved in MCMH 2.0, and the PGHD in the mPHR are used clinically in centers for diabetes, cancer, inflammatory bowel diseases, and pediatric and atopic asthma.

Another limitation was the definition of continuous use of PGHD services. In this study, we defined our own criteria through discussions among the researchers. Various criteria may be applied when considering the nature of patients' diseases and hospital visit intervals. The low percentage of those who used the service continuously was also a major drawback of this analysis.

Ease of data entry can also affect PGHD service usage. Since wearable devices were not connected to our mPHR, we expected that data input convenience would be poor. Therefore, if wearable devices could be linked to the mPHR, the low compliance may be improved. However, appropriate devices and scenarios need to be considered to collect PGHD effectively. Previously, encouraging results have been reported in cancer and diabetes management. A recent study focused on short-term patient management through wearable devices [29]. Further research on collecting PGHD through wearable devices and long-term mPHR operation in clinical applications should be conducted. In this study, we found a relatively small number of users who continuously used the mPHR's PGHD functions. There are many possible causes for this (eg, user interface inconvenience, low motivation, input error), but further research

such as conducting questionnaire surveys is also necessary for clearer understanding.

### Conclusion

Although a small proportion of users managed their PGHD input continuously through the mPHR, we found the mPHR to be a tool for integrating PGHD and patient medical information.

Studies examining the factors promoting the continuous use of PGHD functions in mPHRs and the consensus of the continuous use of various PGHD types are needed. Further evaluation for the clinical application of PGHD, feedback regarding user interfaces, and connections with wearable devices are needed as well.

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### Authors' Contributions

YRP, YL, and JHL initiated the study, designed data collection and analysis methods, and drafted the manuscript. YRP, JYK, JK, and JHL acquired the data. YRP and JHL preprocessed the data. YRP, YL, HRK, and JHL conducted statistical analysis and interpretation. JHL and YHK reviewed and discussed the results. YHK and WSK supervised the study. All authors reviewed and revised the draft paper.

### Conflicts of Interest

None declared.

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## Abbreviations

- AMC:** Asan Medical Center
- BP:** blood pressure
- CVD:** cardiovascular disease
- MCMH:** My Chart in My Hand
- mPHR:** mobile personal health record
- PGHD:** patient-generated health data
- PHR:** personal health record

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Original Paper

# Perceptions of Adolescents With Cancer Related to a Pain Management App and Its Evaluation: Qualitative Study Nested Within a Multicenter Pilot Feasibility Study

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## Abstract

**Background:** Pain in adolescents with cancer is common and negatively impacts health-related quality of life. The Pain Squad+ smartphone app, capable of providing adolescents with real-time pain management support, was developed to enhance pain management using a phased approach (ie, systematic review, consensus conference and vetting, iterative usability testing cycles). A 28-day Pain Squad+ pilot was conducted with 40 adolescents with cancer to evaluate the feasibility of implementing the app in a future clinical trial and to obtain estimates of treatment effect.

**Objective:** The objective of our nested qualitative study was to elucidate the perceptions of adolescents with cancer to determine the acceptability and perceived helpfulness of Pain Squad+, suggestions for app improvement, and satisfaction with the pilot study protocol.

**Methods:** Post pilot study participation, telephone-based, semistructured, and audio-recorded exit interviews were conducted with 20 adolescents with cancer (12-18 years). All interviews were transcribed and independently coded by 2 study team members. Content analysis was conducted to identify data categories and overarching themes.

**Results:** Five major themes comprising multiple categories and codes emerged. These themes focused on the acceptability of the intervention, acceptability of the study, the perceived active ingredients of the intervention, the suitability of the intervention to adolescents' lives, and recommendations for intervention improvement.

**Conclusions:** Overall, Pain Squad+ and the pilot study protocol were acceptable to adolescents with cancer. Suggestions for intervention and study improvements will be incorporated into the design of a future randomized clinical trial (RCT) aimed at assessing the effectiveness of Pain Squad+ on adolescents with cancer health outcomes.

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## KEYWORDS

pain; adolescent; cancer; supportive care; mHealth; qualitative

## Introduction

### Background

Up to 96% of adolescents with cancer experience pain related to the disease or associated invasive procedures and treatment [1]. Pain negatively impacts adolescent health-related quality of life (HRQoL) [2], impedes cancer recovery [3], interferes with activities of daily living [4], and results in long-term morbidity [5,6]. Pain may also represent a significant cost burden to the health care system and families [7], with pain being the most common reason for adults with cancer to utilize emergency health services [8-11]. Treatment advancements and health care system transformations have resulted in adolescents with cancer receiving much of their care on an outpatient basis [12]. This change may mean that a significant proportion of adolescent cancer symptoms (including pain) are experienced in an environment where management options may be suboptimally applied (eg, at home). In addition, adolescents with cancer have emerged as a childhood cancer subgroup with unique developmental characteristics and a unique cancer epidemiology [13-15]. These characteristics suggest that the cancer pain experience and appropriate management techniques may be different for adolescents when compared with younger children and adults [15-17].

In response to these issues, our team has developed a smartphone-based app, called Pain Squad+, that is capable of providing adolescents with real-time pain management support (Multimedia Appendix 1) [18,19]. The app integrates automated valid and reliable pain assessments [1] and personalized pain self-management advice with centralized decision support via a pediatric oncology-trained registered nurse to enable adolescents to better manage their pain in real time, regardless of their location (eg, hospital, home, school).

The development of Pain Squad+ has followed the phased approach to designing and evaluating complex interventions outlined by the UK Medical Research Council (MRC) [20]. In particular, we established a pain management evidence base for the intervention using a systematic review and expert consensus conference [21,22]. We then developed a Pain Squad+ software prototype and adapted the software to the needs of adolescents with cancer using iterative cycles of usability testing [18]. Next, the feasibility of implementing Pain Squad+ for a future randomized controlled trial (RCT) and preliminary intervention effect estimates were determined using a multicenter pre-post test pilot study [19]. The pilot study demonstrated a 77% (40/52) accrual rate, a 5% (2/40) withdrawal rate, technical issues to be experienced by 15% (6/40) of participants,  $69 \pm 38\%$  adherence to pain reporting, and that Pain Squad+ was highly acceptable to adolescents with cancer, based on the quantitative

Acceptability E-Scale (AES) [23]. Small to moderate effect sizes showed the potential impact of Pain Squad+ on key clinical outcomes, including pain intensity, HRQoL, and pain interference.

### Objective

The pilot study used a nested design with a qualitative exit interview conducted with adolescent participants once they completed or withdrew from the study [24]. The nesting of these qualitative interviews within the pilot was informed by the UK MRC framework and was intended as an in-depth process evaluation assessing our capacity to implement the intervention and clarifying mechanisms by which the intervention may work [20]. Our specific study aim was to elucidate the perceptions of adolescents with cancer who participated in these exit interviews as they related to Pain Squad+ acceptability, perceived helpfulness of Pain Squad+, and suggestions for app improvement, as well as satisfaction with the pilot study protocol. The ultimate goal of this research was to use these perceptions to inform changes to the Pain Squad+ app and study protocol before conducting an adequately powered RCT.

## Methods

Reporting in this paper is in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) tool [25] (Multimedia Appendix 2).

### Study Design

Guided by phenomenological inquiry [26], this semistructured interview-based qualitative study was nested within a pilot study. The pilot used a one-group pre-post study design examining the feasibility and preliminarily effectiveness of Pain Squad+ (ClinicalTrials.gov NCT02901834). The methods and results of the pilot study have been previously published [19].

### Setting and Participants

Forty participants were recruited for the pilot from two hematology/oncology divisions at Canadian pediatric tertiary care centers. Adolescents who met the following inclusion criteria were eligible: 12-18 years old, English-speaking and reading, undergoing cancer treatment, at least 2 months from diagnosis, and having self-reported pain of  $>3/10$  at least once in the week before recruitment. Exclusion criteria were as follows: major comorbid conditions or receiving end-of-life care. Adolescents were primarily being treated on an outpatient basis, although some participants were hospitalized for periods during the study for disease, treatment, or complication-related reasons. We did not record the amount of hospitalized time. Enrollment in the pilot study was the only eligibility criterion for participation in qualitative interviews. To include the

perspectives of adolescents who could have potentially varied in terms of their satisfaction with and commitment to the study, adolescents who withdrew from the pilot were eligible for participation in this study. A purposive maximum variation sampling strategy was used to recruit adolescents for the interviews. Specifically, adolescents who varied in terms of age, sex, diagnosis, and pilot-related outcomes (ie, quantitatively rated app acceptability, adherence, and pre- to poststudy change scores on health-related study outcome measures) were selected to participate. The number of adolescents interviewed was determined by the number of interviews needed to reach data saturation [27].

## Intervention

The Pain Squad+ app is an mHealth technology aimed at supporting the management of pain by adolescents with cancer and clinicians. The study team loaned adolescents participating in the pilot an Apple iPhone 6 loaded with the app. Using the app, adolescents completed a 22-item valid and reliable pain assessment [1] twice daily in the morning and evening for 28 days at times they specified. Three audible notifications occurring within a 30-min window signaled adolescents to complete each assessment and if a pain assessment was not completed within this time frame, it was considered missed. Adolescents were also able to complete an 8-item short-form pain assessment anytime between the morning and evening reports if pain was experienced. If an adolescent reported pain on any assessment, they received real-time pain self-management advice from the app according to an evidence-based investigator-developed algorithm. Recommendations could be pharmacological (eg, reminders to adhere to prescribed medications), psychological (eg, distraction techniques), or physical (eg, yoga instruction). In all cases, if pain advice was given, adolescents received a notification to complete another pain assessment in 1 hour and were provided with additional advice as appropriate. In addition to self-management advice from the app, email alerts related to clinically significant pain [28] (ie, 3 consecutive pain reports of  $\geq 3/10$ ) were sent to a study pediatric oncology-trained registered nurse. The nurse then contacted the adolescent and their medical team to discuss the case and initiate provider-driven intervention such as medication changes. To encourage adherence to pain assessment reporting and to using management advice, the Pain Squad+ app was gamified with adolescents playing the role of law-enforcement officers who receiving rewards for engagement with the app.

## Procedure

Ethics approval was obtained from the Research Ethics Boards at both study sites. Consent was obtained from interested and eligible adolescents. Parental consent for research involvement is not required in our jurisdiction. At enrollment, adolescents completed questionnaires on demographic information and comfort with smartphone devices. Disease-related data were collected from the adolescent's health record. Adolescents also completed prestudy measures for the following preliminary effectiveness outcomes: (1) pain intensity (2) HRQoL, (3) pain interference, and (4) pain management self-efficacy. Pain intensity was assessed using the Brief Pain Inventory, which

assesses current pain and worst, least, and average pain in the preceding week on a 0 to 10 numerical rating scale [29,30]. Health-related quality of life was assessed using the Pediatric Quality of Life Inventory (PedsQL) 4.0, which is a valid and reliable 23-item instrument assessing general physical, emotional, social, and school function [31]. Higher scores represent better HRQoL. Pain interference was assessed using the Patient-Reported Outcomes Measurement Information System Pediatric Pain Interference Short-Form scale (PROMIS PPI-SF), which is a valid 8-item scale assessing the impact of pain on function. Participants scores are standardized and interpreted such that 60 represents high pain interference, 70 represents very high pain interference, 40 represents low pain interference, and 30 represents very low pain interference [4,32]. Pain management self-efficacy was assessed using an investigator-developed question as there were no appropriate psychometrically sound scales to assess this construct at the time of the study.

Adolescents were then asked to use the Pain Squad+ app for the 28-day period. Adherence to Pain Squad+ was defined as 100% when 56 reports (2 reports per day for 28 days) were completed. On day 29, each adolescent who did not formally withdraw participation was asked to complete poststudy outcome measures and the AES. The AES collected data on the degree to which Pain Squad+ was satisfactory to participants in terms of how difficult, helpful, enjoyable, and understandable it was to use, and how tolerable the amount of time required to complete it was. The possible total score range for the AES is 6 to 30, and greater scores indicate higher acceptability.

A semistructured, telephone-based, and audio-recorded interview was conducted with a sample of pilot study adolescents. These adolescents had completed the pilot between 1 day to 2 weeks before the interview. This time frame was selected to help ensure that adolescents could accurately recall the use of the app and participation in the study, while also being flexible to adolescents' individual schedules. An interview guide based on a version that was previously and successfully used with adolescents with cancer [33] guided interviews, and field notes were taken. All interviews were conducted by one investigator (LJ) who is a pediatric oncology nurse and was familiar with many of the interviewed adolescents before the study. The interviewer was not blinded to participant characteristics or Pain Squad+ outcomes but used a bracketing procedure during interviews and analyses to minimize the impact of subjectivity on findings [34]. No other individuals besides the interviewer and adolescent were present for interviews. Interview topics included app acceptability, app ease of use and understanding, recommendations for app changes, the perceived clinical value of the app, and the acceptability of study involvement. All interviews were audio-recorded.

## Data Analysis

A trained transcriptionist transcribed interview audio-recordings verbatim. Data analyses began once the first interview was transcribed, allowing issues identified in early interviews to inform later interviews using constant comparative analyses [35]. The transcribed data were managed using NVivo 10.0 software (QRS International, Australia). Field notes were also

included in the analysis. All data were read several times by 2 authors (LJ and VH) to obtain an overall understanding and identify data codes. The authors then independently coded the data using a line-by-line technique based on the study objectives. Using content analysis, codes were grouped into categories based on between-code relationships. Categories were generated until all data were classified under the existing categories [26,36,37]. Categories were then grouped into themes. Quantitative data were integrated into the analysis process to illustrate or clarify qualitative results using a mixed methods matrix approach [38]. It was intended that discrepancies in opinion regarding categories and themes would be resolved using group discussion with a third party; however, no discrepancies occurred. An audit trail consisting of analytical decisions was kept as a means to enhance validity [34].

## Results

### Participants and Interview Process

All 20 adolescents who were approached to participate in poststudy interviews agreed to do so. Nineteen out of 20 (95%) of these interviewed adolescents had completed the entire pilot study, and 1 out of 20 adolescents (5%) withdrew from participation after completing 5 days of the intervention due to worry about damaging the loaned phone. [Multimedia Appendix 3](#) presents adolescent characteristics, Pain Squad+ adherence, AES scores, and health outcome change scores (from pre- to poststudy). Interview length ranged from 7 to 20 min, and no adolescents had any issues recalling the use of the app or study participation. Interview data were categorized into 5 main themes: acceptability of the intervention, potential active ingredients of the intervention, suitability of the intervention, recommendations for improvement, and acceptability of the study. Each theme comprised several categories and codes as shown in [Table 1](#).

### Acceptability of the Intervention

#### General Impressions

All adolescents enjoyed using Pain Squad+. Adolescents stated the app was “fun” (female, 12 years), “really neat” (female, 15 years), and engaging.

One of the adolescents stated:

*It's really appealing to the eye. The color, the theme is good. The font. And it's not really that hard to understand. The vocabulary is really straightforward and all of the things on it, like you know, the multiple-choice questions and the [visual analogue scale] sliders are really easy to use. And for cons? Don't really think I can really think of any.* [Male, 16 years]

#### Usability

Every adolescent endorsed the ease of use of Pain Squad+:

*It was really easy. It was very straightforward. It wasn't really complicated. It was just like simplified so it was easy to use for little kids.* [Male, 16 years]

One adolescent specifically reported that because of her familiarity with smartphone apps, use of Pain Squad+ was not problematic:

*I'm used to that stuff so it made it easy.* [Female, 16 years]

Thirteen participants discussed ease of understanding related to the pain assessment questions and pain management advice. For instance, one adolescent stated:

*It was really straightforward. I think all the questions were worded well so you could like understand what they were getting at.* [Female, 16 years]

Two participants endorsed the app as efficient to complete:

*It was good because it was really fast and easy.* [Male, 14 years]

### Specifically Endorsed App Elements

Specific elements of Pain Squad+ that were well-liked or helpful to adolescents were the pain management advice, the design and gamification mechanics (endorsed by all participants), and the ability to use the app in real time and in any environment, especially when at home. Speaking about the pain self-management advice, one participant stated:

*I thought the pain help ideas were really awesome. When they suggested like different things that you could do? Those were really helpful. And they had some [pieces of pain management advice] where they would suggest like relaxation and breathing, and how do I do that. And then you click on it and there is someone talking to you, walking you through it. Like how to relax. So that's helpful because someone can tell you to relax, but you can just be sitting there like, "I don't know how."* [Female, 16 years]

Referring to the ability of the app to provide pain management advice at any time and in any environment, adolescents said:

*I think overall it was good. Probably one of my favorite parts of it was that you could do the 8 questions in the middle (short-form pain assessment). That helps a lot.* [Female, 12 years]

*There was stuff you could try at home and like do yourself. So I liked that.* [Female, 15 years]

### Challenges

Sixteen adolescents discussed challenges they experienced with the app. Twelve participants stated that the 22-item morning and evening pain assessments included too many questions

*It was okay and too much. Because sometimes people don't want to like keep...um...doing the same thing over again...22 questions every time.* [Male, 16 years]



**Table 1.** Post-pilot study interview themes, categories, and codes.

Theme and category	Codes
<b>Acceptability of the intervention</b>	
General impressions	<ul style="list-style-type: none"> <li>• Enjoyed use</li> </ul>
Usability	<ul style="list-style-type: none"> <li>• Easy to use</li> <li>• Easy to understand</li> <li>• Quick to complete</li> </ul>
Specifically endorsed app elements	<ul style="list-style-type: none"> <li>• Pain management advice</li> <li>• Design and gamification mechanics</li> <li>• Real-time any-environment reporting</li> </ul>
Challenges	<ul style="list-style-type: none"> <li>• Number of assessment questions</li> <li>• Notifications</li> <li>• Other technical problems</li> </ul>
<b>Potential active ingredients of the intervention</b>	
Self-management support	<ul style="list-style-type: none"> <li>• Engagement in self-management</li> <li>• Self-monitoring of pain</li> <li>• Patient-provider communication</li> </ul>
Study nurse support	<ul style="list-style-type: none"> <li>• Value of nurse</li> <li>• Timing of nurse support</li> </ul>
<b>Suitability of the intervention</b>	
Impact on daily activities	<ul style="list-style-type: none"> <li>• Perceived burden</li> </ul>
Recommended usage	<ul style="list-style-type: none"> <li>• Appropriateness when ill</li> <li>• Appropriateness when symptom-free</li> <li>• Recommended usage</li> </ul>
Recommended improvements	<ul style="list-style-type: none"> <li>• Additional self-management advice</li> <li>• Additional gamified mechanics</li> <li>• Tutorials on use</li> <li>• Audio-visual assets</li> <li>• Review data</li> </ul>
<b>Acceptability of the study</b>	
General impressions and specific likes	<ul style="list-style-type: none"> <li>• General impression</li> <li>• Specific likes</li> </ul>
Motivation for participation	<ul style="list-style-type: none"> <li>• Altruism</li> <li>• Novel experience</li> <li>• Gamification</li> </ul>
Challenge	<ul style="list-style-type: none"> <li>• Study phone</li> </ul>

Nine adolescents described challenges related to the frequency of pain assessment notifications. The notification issue appeared to be related to a technical problem with the app software server, where repeated notifications to complete the same pain assessment questionnaire were sent to some study phones, which was “annoying” (Female, 17 years) for adolescents:

*Even if I did do my case (pain assessment), it would still just keep on giving notifications. And I know that after you say, “yes” to the case, (the app will) follow-up (on the severity of pain one hour later). But even if I would do the follow-ups, it would just keep*

*on giving more and more (notifications).* [Female, 15 years]

Technical problems were the final app-related challenge cited. One adolescent described an issue likely related to the app being unable to connect to the internet:

*Sometimes it was hard for me to do it. Like 2 or 3 times I couldn’t (use the app), because like as soon as I clicked on the app, the screen would just go white.* [Male, 14 years]

Two adolescents reported an issue related to not receiving scheduled reminders to complete pain assessments:

*I think it was a problem with my version [of the app] but I wasn't getting any reminders (to complete pain assessments)...So I set up just a regular alarm on the clock the phone has itself. [Male, 17 years]*

## Potential Active Ingredients of the Intervention

### Self-Management Support

All participants reported that the ability of Pain Squad+ to support pain self-management was of therapeutic benefit. For example, one participant stated:

*Yeah because being like an out-patient, you're not at the hospital all the time. And you don't want to call the doctor every time you have something as simple as a stomach ache when you know you got tips from the app to help. [Female, 14 years]*

The ability for adolescents to self-monitor their pain through routine assessments was also considered a valuable self-management feature of the app:

*Yeah especially because it really helps me to track my pain and remember everything. [Male, 14 years]*

Improved awareness of pain was also a perceived benefit of the app:

*Some of the questions were things that I didn't really consider when I was thinking about my pain. So (Pain Squad+) helped with (recognizing how pain) affected me and all that. [Female, 16 years]*

Pain Squad+ helped to facilitate adolescents' communication about pain and pain treatments with their medical team. Highlighting this finding, one adolescent said:

*I think when I had a problem at home, like experiencing some kind of pain, after inputting it into the app and coming back to the hospital, talking to my doctor was easier. [Male, 17 years]*

### Study Nurse Support

Ten participants discussed interaction with the Pain Squad+ study nurse as being of therapeutic benefit. Most adolescents appreciated knowing that the nurse was a component of the intervention even if they did not require pain management support from the nurse during the study. In particular, these adolescents viewed nurse involvement in Pain Squad+ as an extra layer of pain treatment support in the event that self-management strategies were ineffective:

*I liked that when you answer questions if you go higher (in pain intensity rating), a nurse actually calls you and like asks about your pain. It's actually a good thing because like if you actually have pain and you don't know what to do, she can help you. [Male, 15 years]*

Three adolescents, however, reported not believing the nurse was essential to the Pain Squad+ intervention and that the recommended self-management strategies were sufficient to support pain treatment:

*I had it pretty controlled on my own. [Female, 16 years]*

One adolescent commented that he experienced some difficulty in connecting with the nurse when she attempted to contact him:

*The part where you get the advice from the nurse was good but then sometimes I would just miss her if I was out or my phone was on silent. So, it might be better if she left you a (text) message so that you could check what she was telling you to do. [Male, 14 years]*

## Suitability of the Intervention

### Impact on Daily Activities

Seven participants commented that use of the app fits well with their usual daily activities, for example:

*Oh it was good, it was good. It didn't really take that much time and effort. [Female, 17 years]*

### Recommended Usage

Nine participants stated that completing morning and evening pain assessments when not experiencing pain was not appropriate. In particular, one adolescent said:

*Yeah, I didn't really have pain all of the time. So, I think [the number of notifications] just wasn't for me, but I'm sure for someone who's going through the pain it's going to be really helpful. [Male, 16 years]*

When asked about his lack of interaction with Pain Squad+, another adolescent said:

*Like it got a little tiring sometimes. Because especially there are days I didn't feel any problems, like have any problems, and I felt less inclined to actually finish the surveys. [Male, 17 years]*

## Recommendations for Improvement

Six adolescents suggested that the app include additional pieces of self-management advice. For example:

*I think if there were more ways to help you manage your pain added on, then it would be more helpful. [Male, 14 years]*

These adolescents did not, however, have specific recommendations regarding which pieces of management advice should be added. Four participants recommended enhancements to the gamification mechanics of the app. One adolescent stated:

*Um, maybe like something a little more than just like how you "level up" (by completing pain assessments and management advice). Just...more to do with that. A little more interactive kind of thing...like even more, fun. [Female, 14 years]*

Three participants recommended adding tutorials to Pain Squad+ on how to use the app. Another two adolescents recommended converting text-based content into an audio- or video-recorded format. For example:

*Umm I think probably like uh a few videos from actual professionals, healthcare professionals, like doctors. Or like maybe like, err therapists, like massage therapists. If there was like maybe, for example like a massage therapist showing someone how to relieve pain in a certain area. [Male, 14 years]*

Finally, three adolescents suggested incorporating a capacity to visually review previously logged pain reports in order to track pain treatment progress.

## Acceptability of the Study

### General Impressions and Specific Likes

Overall, adolescents enjoyed participating in the pilot, stating that the study was “really good” (Male, 15 years) and they “didn’t mind” (Female, 14 years) participating. Specifically, adolescents endorsed the ease of study participation and the ability to use the intervention for a time:

*And I don’t know, I really liked...I just liked the app. I liked being able to record my pain, like without just writing it down in like a journal or something you know? I really liked how they gave me suggestions for like what I could do. I just liked it all, overall.* [Female, 16 years]

Two adolescents specifically cited completion of the outcome measures as a well-liked study component, with one participant stating:

*I liked the questionnaires at the beginning and the end. Just to like compare sort of how you’re doing before and after.* [Female, 15 years]

### Motivation for Participation

Two participants discussed the chance to potentially help other adolescents with cancer as their rationale for study involvement. For example:

*I just liked, you know, contributing to the development of this app. It will be a huge help to other little kids going through cancer.* [Female, 16 years]

Another adolescent mentioned the novel experience of being a research participant as her motivation for participation. Finally, 6 participants stated that they were motivated to continue participation because of the gamification mechanics, for instance:

*Yeah but it was pretty cool. It made you sort of want to do it more. “Okay I’ve got to do this because I want to get the next level.”* [Female, 16 years]

### Challenge

The use of the study phone loaned to participants was a challenge for 5 adolescents. These participants already owned a smartphone and considered care and use of a second phone to be a burden:

*Half the time, I wouldn’t even hear it because it would be in a different room or something and I just totally forget about it. If (Pain Squad+) was on my actual cell phone I probably would have done it more. But it wasn’t on my actual phone that I have on me all the time.* [Female, 14 years]

## Discussion

### Principal Findings

Pain is a problematic issue for adolescents with cancer [1,2] that may be mitigated with the rapid self-management support made possible by mHealth interventions [19]. Adolescents with cancer who participated in a pilot of the Pain Squad+ smartphone-based real-time pain self-management app reported that they generally liked the app and considered it helpful. In particular, adolescents reported that the app was easy to use and understand, supported the self-care of pain, and simplified patient-provider communication. The suitability of the app to adolescents’ lives and the acceptability of participating in the pilot were also shown. Finally, challenges related to app use and pilot participation that will inform intervention and study protocol changes were described.

Adolescents with cancer considered the intervention satisfactory, despite variations in age, sex, diagnosis, level of interaction with the app, and change scores on study outcome measures. As indicated by high levels of engagement with the app [19], adolescents liked the capacity of the app to support pain treatment *via* the advice provided (especially when they were outside the hospital), pain self-monitoring, and facilitation of communication with health care providers. These findings suggest that mHealth-based self-management of cancer symptoms in real time is amenable to young patients, echoing results from other mHealth-based disease self-management research conducted with youth [39-43]. Additionally, in accordance with previous research [33,44], all interviewed adolescents found the design and gamification mechanics attractive and acceptable. Gamification mechanics are a relatively novel addition to mHealth interventions, and there is still limited literature on benefits with respect to patient behavior change. However, the role these mechanics may play in incentivizing self-management behaviors in chronic conditions [45-47], combined with their acceptability to patients, makes the evaluation of their application to mHealth interventions an area for future exploration.

Challenges adolescents experienced with Pain Squad+ suggested that real-time symptom assessments questionnaires should be brief and notifications directing patients to interact with apps should be minimized. These findings are in contrast with previous studies conducted by our group that showed adolescents to report high acceptability with a 22-item pain questionnaire and the same notification schedule employed presently [1,33]. However, adolescents in the previous studies completed pain assessments only twice-daily for 14 days rather than for 28 days. Acceptability may have been adversely impacted by the increased length of pain reporting used in this study, as well as the technical issues we experienced related to the server sending some adolescents numerous notifications. Additionally, a number of adolescents suggested that it would be preferable to interact with the app only when symptomatic and that the scheduled morning and evening pain reports were not necessary. Creating an optimal balance between improving user engagement with symptom reporting and limiting alert fatigue [48] should be considered in developing real-time

mHealth interventions. The technical problems experienced by adolescents also represented a challenge to intervention use. mHealth technical malfunctioning limits intervention usability [49] and also may represent a safety issue for users if the device does not collect, interpret, and deliver medical information to patients and health care providers as intended [50]. Pain Squad+ software modifications to ensure sound functioning and improve the user experience will be made before a subsequent Pain Squad+ RCT research is conducted.

Generally, adolescents suggested that both pain self-management advice and study nurse involvement contributed to the therapeutic benefit of the app. Previous qualitative research with adult cancer patients engaged in studies of similar real-time symptom management interventions also showed positive feedback related to the role of a health care provider in remotely monitoring symptoms [51,52]. Acceptability of the nurse suggests the role may be a valuable component of real-time symptom management interventions for cancer patients. During the pilot trial, however, only 38% (15/40) of participants actually interacted with the nurse [19], who represents a cost addition to the intervention. A planned Pain Squad+ RCT will, therefore, use a 3-arm design (ie, Pain Squad+ with nurse interaction, Pain Squad+ without nurse interaction, and control) to elucidate the therapeutic benefit and cost implications of clinician involvement.

On the basis of thematic analyses of interview data, satisfaction with the pilot study protocol in general, was high. Engagement in the study was considered easy and the chance to use the intervention was liked. Participant reports of altruism as the motivation for study participation agree with previous studies of adolescents with cancer engaged in research [53,54]. Other motivations for participation included the novelty of being involved in research and the gamification of the app. The cited challenge associated with study participation related to the loaned study phone. Fear of damaging the phone was the reason for the single episode of study attrition, and using the study phone if an adolescent owned their own phone was considered a burden. Given that 80% to 87% of Western adolescents currently own a smartphone [55,56], our future RCT will involve installing Pain Squad+ on adolescent's personal devices and loaning phones only as necessary.

### Limitations

A potential limitation of this study involved the introduction of potential cognitive biases into study findings. In particular,

experimenter bias may have been introduced as the study member who conducted the interviews and data analyses was a PhD student whose dissertation focused on the development of Pain Squad+. To minimize the effect of a bias whereby the student could be overly positive when interpreting participants' remarks about the app and study, an additional study member independently conducted coding and analysis, and an audit trail detailing analyses decisions was kept. Bracketing or mentally suspending biases also minimized the impact of researcher subjectivity during data collection and analysis [34]. A second limitation relates to social desirability response bias whereby to provide a socially desirable response to the interviewer, adolescents could have denied negative thoughts and feelings about the app [57]. To minimize this effect, at the onset of interviews, adolescents were told that both positive and negative feedback was equally important. A final limitation relates to the pilot study design. Because we used a pre-post study pilot, we could not explore the experience of adolescents being randomized to treatment arms or the acceptability of participating in the control condition.

### Conclusions

This study has demonstrated the acceptability and perceived helpfulness of the Pain Squad+ intervention and pilot study protocol to adolescents with cancer, albeit with a few caveats and suggestions for improvement. This study also shows that both self-management and clinician support are generally considered as helpful ingredients in mHealth real-time symptom management interventions for adolescents. However, because not all adolescents agreed that the nurse involvement in the intervention was necessary, future research will elucidate the value of clinician support in improving pain-related outcomes for adolescents. Using the UK MRC framework, this qualitative research provides evidence that will be used to refine the Pain Squad+ intervention and study protocol to design a successful RCT. Specifically, we will modify the Pain Squad+ software by truncating the pain assessments, minimizing the number of notifications received by adolescents, and addressing technical problems related to accessing the app through the internet. Satisfaction with the protocol was generally demonstrated, but modifications to improve acceptability by including the capacity to install adolescents' personal phones will be added before an RCT. Study findings have applicability to other researchers engaged in the design and development of mHealth- and internet-based interventions for youth with chronic and life-limiting health conditions.

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### Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Pain Squad+ pain management app screenshots. Top to bottom, left to right: (a) pain management screen; (b) sample of pain self-management recommendations; (c) detailed view of "Mental Games" pain management recommendation; (d) sample of "gamification" reward for adherence (ie, advancement through law-enforcement ranks); and (e) view of user placement within law-enforcement ranks to encourage adherence.

[[PDF File \(Adobe PDF File\), 243KB - mhealth\\_v6i4e80\\_app1.pdf](#)]

## Multimedia Appendix 2

Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist.

[[PDF File \(Adobe PDF File\), 44KB - mhealth\\_v6i4e80\\_app2.pdf](#)]

## Multimedia Appendix 3

Characteristics of interviewed Pain Squad and participants.

[[PDF File \(Adobe PDF File\), 52KB - mhealth\\_v6i4e80\\_app3.pdf](#)]

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## Abbreviations

**AES:** Acceptability E-Scale

**HRQoL:** health-related quality of life

**UK MRC:** United Kingdom Medical Research Council

**RCT:** randomized controlled trial

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Original Paper

# Mobile Breast Cancer e-Support Program for Chinese Women With Breast Cancer Undergoing Chemotherapy (Part 1): Qualitative Study of Women's Perceptions

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## Abstract

**Background:** Women with breast cancer undergoing chemotherapy experience difficulty in accessing adequate cancer care in China. Mobile apps have the potential to provide easily accessible support for these women. However, there remains a paucity of randomized controlled trials to evaluate the effectiveness of app-based programs targeting specifically women with breast cancer undergoing chemotherapy. Moreover, women's perceptions and experiences related to using and interacting within the app-based program have rarely been reported. Therefore, an app-based Breast Cancer e-Support program was developed and evaluated using a randomized controlled trial. Based on the incorporation of Bandura's self-efficacy and social exchange theory, Breast Cancer e-Support program lasted for 12 weeks covering 4 cycles of chemotherapy and had 4 components: (1) a Learning forum, (2) a Discussion forum, (3) an Ask-the-Expert forum, and (4) a Personal Stories forum.

**Objective:** As a part of the randomized controlled trial, the aim of this study was to explore the participants' perception of Breast Cancer e-Support program, its strengths and weaknesses, and suggestions to improve the program.

**Methods:** A descriptive qualitative study was employed. Thirteen women with breast cancer from 2 university-affiliated hospitals in China, who were randomly allocated to the Breast Cancer e-Support program in the randomized controlled trial, were interviewed from November 2016 to February 2017. Purposive sampling was used based on women's scores of self-efficacy after the completion of the intervention. Inductive content analysis was used to analyze the transcripts, allowing the categories and subcategories to flow from the data.

**Results:** The qualitative interviews revealed that participants perceived the Breast Cancer e-Support program to be helpful in enhancing knowledge, improving confidence level, and promoting emotional well-being. Women also identified access to tailored advice from experts and convenience as the benefits of this program. Physical or psychological health status, stigma related with breast cancer, and app instability were mentioned as the challenges to engagement. Suggestions for improvement included adding message reminders to prompt instant communication and search engine to locate information quickly, supplementing more interesting and practical knowledge, updating the information more often, and quickening the responses to women's questions. The participants recommended the Breast Cancer e-Support program to be incorporated as routine care to support women during chemotherapy.

**Conclusions:** This study demonstrates the potential of the Breast Cancer e-Support program to support women during chemotherapy. Future app-based programs should apply a family-centered approach and provide more support on stigma associated

with the disease to encourage engagement with the app. Suggestions of improvement regarding the design, content, and operation of the app-based intervention should be addressed in future studies. It is promising to incorporate the Breast Cancer e-Support program into routine care to generalize the benefits.

**Trial Registration:** Australian New Zealand Clinical Trials Registry ACTRN12616000639426; <http://www.ANZCTR.org.au/ACTRN12616000639426.aspx> (Archived by WebCite at <http://www.webcitation.org/6v1n9hGZq>)

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## KEYWORDS

mobile app; breast cancer; chemotherapy

## Introduction

Breast cancer is the most commonly diagnosed cancer for Chinese women [1], and chemotherapy is widely used to treat breast cancer [2]. Women with breast cancer receiving chemotherapy experience difficulty accessing adequate cancer care in China because of the shortage of oncology-trained health care professionals (HCPs) [3,4], and the increasing incidence of breast cancer [5]. In recent years, China's Ministry of Health has developed a national plan aiming to provide easily accessible and affordable health service to prevent and control cancer [6]. Mobile apps offer one means in this endeavor to support patients [7].

It is widely recognized that the use of chemotherapy causes a variety of side effects such as nausea, insomnia, and pain, which adversely affect women's psychological well-being and quality of life (QoL) [8,9]. Effective symptom management is thus crucial, and a sense of self-efficacy and social support are needed for women to initiate and maintain appropriate symptom management strategies [10]. Furthermore, the majority of women receiving chemotherapy for breast cancer are treated in the out-patient setting and have to manage most symptoms at home without direct support from HCPs [11]. Apps could provide an innovative platform to overcome the accessibility barrier, where women can acquire knowledge and communicate with peers and HCPs when and where needed [7].

In 2017, 89% of the Chinese population owned a mobile phone [12], and approximately 653 million Chinese people accessed the internet via their mobile phone [13]. Taking advantage of their easily accessibility, apps have the potential to demonstrate their value on health promotion with a robust program. However, our recent integrative review found that there remains a paucity of randomized controlled trials (RCTs) to evaluate the app effectiveness specifically targeting at women with breast cancer undergoing chemotherapy [14]. Furthermore, women's perceptions and experiences related to using and interacting within the app-based programs during chemotherapy have rarely been reported [14].

Therefore, an app-based Breast Cancer e-Support program was developed [15] and evaluated using a single-blinded, multicentered RCT (ACTRN: ACTRN12616000639426) [16]. The components of this program were guided by four factors (direct mastery experiences, vicarious experiences, verbal persuasion, and arousal state) from Bandura's self-efficacy theory [17] and structural support and functional support from

the social exchange theory [18]. This program supported women for 12 weeks covering four cycles of chemotherapy and had been shown to significantly improve the self-efficacy, QoL, and symptom interference on daily life for women at 3 months of follow-up, as reported in Part 2 of this study (forthcoming) [19].

Process evaluation is an important part of an RCT to understand the program effectiveness [20]. Identifying how women appraise different components, especially for a multicomponent app-based program, can give insights as to why and how the program achieves or fails in the desired outcomes, further improving the design of a future trial [21]. Thus, this qualitative process evaluation aimed to explore the participants' perception of Breast Cancer e-Support program, the strengths and weaknesses of this program, as well as their improvement suggestions.

## Methods

### Study Design and Participants

A descriptive qualitative study was employed. The first author recruited women from the intervention group in an RCT examining the effectiveness of the Breast Cancer e-Support program. Women were eligible for the main study if they had commenced chemotherapy at the study sites after diagnosis of breast cancer, were able to access the internet via a mobile phone, and were able to read and write Mandarin. The study was approved by the institutional review board of Xiamen University affiliated Zhong Shan Hospital (zhu20151023), Central South University affiliated Hunan Cancer Hospital (zhu20151026) in China, and the University of Newcastle in Australia (H-2015-0448). Written consent forms were obtained from all participants.

### Breast Cancer e-Support Program

A website was developed, with the introduction of the Breast Cancer e-Support program and the two-dimensional code for women to scan (Figure 1) [22]. Once women downloaded the app, the home page displayed a button for the user to submit an application that the first author (JZ) either approved or declined through the app background thread to ensure only the intervention group had access to the Breast Cancer e-Support program with a unique username and self-set password. This application process prevented contamination between the two groups and protected the privacy of participants in the Breast Cancer e-Support program.

**Figure 1.** Screenshot of the Breast Cancer e-Support program Website.

The development process of the Breast Cancer e-Support program applied user-centric design and assessed the perceived ease of using the app [15]. This program supported women for 12 weeks covering four cycles of chemotherapy (1st-4th cycle of chemotherapy), with each cycle lasting 3 weeks. The Breast Cancer e-Support program had four components: Learning forum, Discussion forum, Ask-the-Expert forum, and Personal Story Forum [16]. The Learning forum provided knowledge and symptom management strategies related to breast cancer and chemotherapy. The Discussion forum offered an online platform for women to chat with one another. The Ask-the-Expert forum served as a communication channel for women to ask questions and receive advice directly from experts within 24 hours. The Personal Story forum presented five encouraging stories of other women who had successfully overcome obstacles during chemotherapy. On the basis of women's topics and questions, the information in the learning forum was updated every 2 weeks to address women's concerns. The Discussion forum and Ask-the Expert forum were moderated by the first author (JZ) who is an HCP. The moderator facilitated the online discussions and sent a reminder message to the doctors with incoming questions. Eight doctors from the study sites joined this program and responded to the questions in the Ask-the Expert forum. Technical assistance was available for the workday. The details of the Breast Cancer e-Support program can be found in the study protocol published in *BMC Cancer* [16].

### Recruitment

For the process evaluation, we applied purposive sampling based on scores in the primary outcome of self-efficacy at 3 months. The Stanford Inventory of Cancer Patient Adjustment was used to assess women's self-efficacy to manage cancer-related

problems [23]. The Stanford Inventory of Cancer Patient Adjustment contained 38 items rated from 0 (not at all confident) to 10 (absolutely confident). Higher total scores represent higher self-efficacy. We selectively approached women with higher and lower (ratio 1:1) scores than the mean score of self-efficacy. We achieved data saturation at the 10th participant. No additional data were yielded with three additional interviews, giving a total sample of 13 women [24]. Of the 13 interviewed women, 7 participants were higher and 6 participants lower than the mean score of self-efficacy.

Interviews were conducted from November 2016 to February 2017. As these two participating hospitals are in two different provinces in China, we undertook face-to-face interviews for women in Zhong Shan Hospital and telephone interviews for women in Hunan Cancer Hospital to achieve a sufficient sample size. The first author (JZ), who was a female PhD student in nursing and who had established a good relationship with women during moderating the online discussion, invited women by telephone to participate, giving a clear explanation of the aims of the interview. Women were informed that the interview would take 10 to 20 min and that the interview would be audiorecorded. A total of 18 women were approached. Five women declined to be audiorecorded and thus excluded. A total of 5 women from Zhong Shan Hospital were interviewed one-to-one in a meeting room in the hospital. Field notes were taken during the interviews. A total of 8 women from Hunan Cancer Hospital were interviewed by telephone. The duration of the interviews ranged from 7 to 27 min.

A semistructured interview guide (Table 1) with five questions was prepared for the interview. Two academic experts in psychoeducation and cancer care provided comments on clarity and content of the interview guide.

**Table 1.** Semistructured interview guideline for process evaluation.

No.	Probing questions
1	What was your experience of using this program? Probe: How did you feel participating in this program?
2	What were the main strengths or benefits of this program for you? Probe: Which aspect of this program was most beneficial for you? Why?
3	What were the main weakness of this program for you? Probe: Which aspect of the program was least beneficial for you? Why?
4	What suggestion will you give to improve this program? Probe: How can this program be improved further?
5	Do you think this program should be continued?

## Analysis

Inductive content analysis was used to analyze the transcripts, allowing the categories to flow from the data [25]. Qualitative content analysis was conducted in the original language, following Graneheim and Lundman's [26] steps for analysis procedures to achieve trustworthiness. Audiotapes were transcribed verbatim into written Chinese by the first author immediately after the interview. The first (JZ) and third authors (DG) performed the initial coding independently. Transcripts and field notes were repeatedly read through to obtain a broad picture of the whole. Transcribed data were coded and analyzed. The various codes were compared regarding the differences and similarities, and interpretations of the codes were sorted into subcategories. Finally the underlying meanings of the subcategories were grouped into categories. The research team had regular meetings to examine and revise the tentative subcategories and categories. Any coding discrepancies were discussed to ensure consensus. Two experts in qualitative research reviewed the process of data collection and analysis. Participant's quotes were translated into English. English translation of the results and direct quotes were checked by the last author who is bilingual (English and Chinese).

## Results

### Sample Characteristics

For all 114 participants in the RCT, the mean of self-efficacy score at 3 months was 212.1 (SD 58.1; range 74-368). The mean age was 47.2 years. The majority of women were married (96.5%, 110/114), had received elementary or middle school (57%, 65/114) education, and were currently unemployed (74.6%, 85/114). Only 14 women (12.3%, 14/114) lived in a household with above average level of monthly family income ( $\geq$ US \$739) [27]. The majority of women were diagnosed with breast cancer stage II (43.0%, 49/114), followed by stage III (36.7%, 42/114). A total of 97 women (85.1%, 97/114) had undergone a mastectomy, and 5 (4.4%, 5/114) had chosen breast conserving surgery. The majority of women received eight cycles (51.8%, 59/114) and six cycles (21.1%, 24/114) of chemotherapy.

In total, 13 women in the intervention group participated in the interview, with mean score of self-efficacy at 3 months as

218.58 (SD 68.1; range 108-349). These 13 women had comparable demographic or clinical characteristics as all participants in the RCT, except for education level ( $\chi^2_{0.05,4}=10.8$ ,  $P=.01$ ). The interviewed women had significantly higher education level than all participants in the RCT. The demographic or clinical variables of the 13 participants are summarized in Table 2.

### Overview

From the content analysis, four categories emerged: (1) benefits of participation, (2) challenges to engagement, (3) suggested improvement, and (4) future direction. All the categories and subcategories are summarized in Textbox 1.

### Category 1: Benefits of Breast Cancer e-Support Program

A total of 9 women found that the Learning forum was most beneficial, and 3 believed that the Discussion forum was most beneficial. A total of 5 women found the Personal Story forum as being least beneficial. Six women did not identify any forum to be least beneficial. Participants reported many benefits from the different forums, including enhanced knowledge, improved confidence levels, promoted emotional well-being, access to tailored advice from experts, as well as being easy to use, convenient, and easily accessible.

#### Subcategory 1: Enhancing Knowledge on Symptom Management, Breast Cancer, and Chemotherapy

Most of the women mentioned that they gained a better understanding of breast cancer, chemotherapy, and how to manage a variety of symptoms after participating in the Breast Cancer e-Support program:

*I was very interested in reading the content in the Learning forum. In the past, I never thought about breast cancer. Before the diagnosis, I had no knowledge on anything about breast cancer...But now it happened to me. I read the knowledge in the Learning forum and I really have learnt a lot. I felt good when reading the content. [Informant 7]*

*I like to read information on symptom self-management. In the past, I searched the web for it, but was not sure whether the information was useful. I trust the information on the app to be*

*accurate...You know, when I was having chemotherapy after surgery, I was a bit scared. I did not know what symptoms I would experience, how to self-manage symptoms, how to choose food, and how to prevent oedema. The Learning forum has everything...the related information. I learnt a lot. I obtained knowledge which I did not know before.*  
[Informant 5]

### Subcategory 2: Improved Confidence Level

Two women said they felt more confident as they watched the encouraging videos in the “Personal Story forum,” and 3 women mentioned that their confidence levels were increased when reading other participant’s experiences shared in the “Discussion

forum.” Others’ stories served as the role models to build confidence for these women. When women saw someone succeed in a similar situation, they felt empowered and more positive:

*My favourite is “Personal Story forum”. They are real stories. I like to watch others’ stories. For example, Miss XX, who is 60 years old, wear a wig, put on make-up, and travel a lot after chemotherapy. I think attitude is very important. Miss XX is older than me and had more advanced breast cancer. When I saw she could survive the chemotherapy and had a good life, I felt more confident that I can do it.*  
[Informant 3]

**Table 2.** Demographic or clinical data of participants in the process evaluation.

Items	Value
Age in years, mean (SD; range)	49.5 (9.5; 30-65)
<b>Married status, n (%)</b>	
Married	13 (100)
<b>Education level, n (%)</b>	
University level or above	4 (31)
High school	6 (46)
Middle school	2 (15)
Primary school	1 (8)
<b>Current employment, n (%)</b>	
Employed	3 (23)
Unemployed	10 (77)
<b>Monthly family income (USD), n (%)</b>	
≥\$739 <sup>a</sup>	3 (23)
\$443-\$738	5 (39)
\$149-\$442	3 (23)
≤\$148	2 (15)
Body mass index, mean (SD; range)	23.3 (2.3; 19.5-27)
<b>Cancer stage, n (%)</b>	
Stage III	6 (46)
Stage II	4 (30)
Stage I	3 (23)
<b>Surgery, n (%)</b>	
Mastectomy	12 (92)
Breast conserving surgery	1 (8)
<b>Cycles of chemotherapy, n (%)</b>	
Eight cycles	6 (46)
Six cycles	4 (31)
Four cycles	3 (23)

<sup>a</sup>≥US \$739 above average level of monthly family income in China [27].

**Textbox 1.** Categories and subcategories from the process evaluation.

<p>Benefits of Breast Cancer e-Support program</p> <ul style="list-style-type: none"> <li>• Enhanced knowledge</li> <li>• Improved confidence level</li> <li>• Improved emotional well-being</li> <li>• Received advices from experts</li> <li>• Easy to use, easily accessible, and convenient</li> </ul> <p>Challenges to engagement of Breast Cancer e-Support program</p> <ul style="list-style-type: none"> <li>• Physical or psychological health status</li> <li>• Stigma with breast cancer</li> <li>• Instability of the app</li> </ul> <p>Suggested improvement</p> <ul style="list-style-type: none"> <li>• Design improvement</li> <li>• Interesting, plain, and practical content</li> <li>• The information being updated more often</li> <li>• Quicker responses to women's questions</li> </ul> <p>Future direction</p> <ul style="list-style-type: none"> <li>• Breast Cancer e-Support program as routine care</li> <li>• Breast Cancer e-Support program open to caregivers</li> <li>• Breast Cancer e-Support program applied to other cancer patients</li> </ul>
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### Subcategory 3: Improved Emotional Well-Being

Most women mentioned that they felt much better when they read the information in the Learning forum and interacted with peers and HCPs through the program. They were less distressed as their perception about breast cancer altered and their queries answered. They felt reassured knowing that they were not alone in the struggle with breast cancer, and they had peer and professional support available. This is revealed from the following statements by 2 women:

*I feel better to talk to someone who are in similar situation. Cancer is not a good thing. If I always think about breast cancer alone at home, it is so easy for me to feel bad. I didn't feel alone when I talked with peers through your program. They might have worse or better conditions than me, but they understand what I meant (Laugh...). This may be the source of comfort and help. [Informant 13]*

*Before I joined your program, I searched online and I was overwhelmed by the horrible information on breast cancer. I got more and more anxious during surfing the internet. But your program was different. There was credible information and expert advice. The more I used the app, the better I felt. [Informant 2]*

### Subcategory 4: Received Advice From Experts

Some women appreciated the Ask-the-Expert forum as the advice was tailored to their own needs, which was "direct and

targeted help." They felt supported as they had experts to answer their queries and received timely responses. The advice from an expert acknowledged their symptoms, validated their concerns, interpreted the lab results, and gave some useful suggestions. One woman stated:

*When I faced with something I didn't know, I was so anxious. But my doctor was very busy and he had no time to communicate with me. After I jointed your program, I could ask questions through the app regarding my medical condition. I could upload the lab results through your program. Then I received corresponding advice from experts. I felt followed up. When I knew more about my medical condition, I felt more likely to gain control of my life. [Informant 4]*

### Subcategory 5: Easy to Use, Easily Accessible, and Convenient

Ten women expressed that one of the biggest benefits of the Breast Cancer e-Support program was that it was easy to use and convenient. Tapping into the app enabled them access to the knowledge and easy communication with peers and HCPs. This was especially helpful for women who lived long distances from the hospital. One woman stated:

*I have no difficulty in using the app. I live far away from the hospital and I have no doctor close to me. When I had questions about my medical condition, I could not find the answer in the internet. Then I asked questions through the app. Aha, the professor or*

expert responded. Sometimes they gave me quick feedback. Sometimes, they answered my questions the next day. Yes, we can also make our judgement, but we are not sure at that time. The response from the expert provided me the direction. I believe this is the strength of the app. [Informant 8]

### **Category 2: Challenges to Engagement of Breast Cancer e-Support Program**

Participating women highlighted several challenges to engagement in the Breast Cancer e-Support program. Challenges were associated with physical or psychological health status, stigma with breast cancer, and instability of the app.

#### **Subcategory 1: Physical or Psychological Health Status**

Some women mentioned that the severe physical symptoms such as nausea and fatigue hindered their engagement of the program. Psychosocial symptoms related to fear of recurrence and death added to their distress, further hampering women's engagement of Breast Cancer e-Support program. This is echoed by the following statements:

*During the three days hospitalization for chemotherapy, I felt like dying and I couldn't even think about opening the app. When I came back home and I recovered a little bit, still my health was quite fragile. I couldn't spend long time reading the app or have enough energy to read in depth. [Informant 1]*

*During chemotherapy, I guess, all people felt very down. We had lots of negative thoughts (Pause for a while). For me, I would reduce the usage of the app. When I recovered a little bit, I might resume using the program. [Informant 2]*

#### **Subcategory 2: Stigma With Breast Cancer**

Some women experienced stigma with breast cancer. They perceived themselves as having a "disability" and felt that they would be rejected by family and friends if they made their condition known. Women felt ashamed to have breast cancer, and using this program reminded them of their illness. Women who felt this way reduced the usage of the Breast Cancer e-Support program because they did not want to be reminded that they had breast cancer or they were different:

*If I told my friends that I had breast cancer, they would reject me. I had such experience...They perceived me as a different person. How can I have the courage to tell people about my disease? I do not want to touch the topic of "breast cancer". I've tried to put it behind me...Using this program, reading and chatting, it constantly reminds me of my illness. I need to be done with it. [Informant 7]*

#### **Subcategory 3: Instability of the App**

One woman complained that the app was not stable. She gave up using the program when experiencing difficulties in logging in. She stated:

*The app sometimes was unstable. It didn't work when I tried to open it. I contacted with someone in the*

*hospital and reinstalled the app. Then I could log in. However, after a periods of time, I couldn't open the app again. Finally I gave up using your program. I haven't log in for the recent month. [Informant 5]*

### **Category 3: Suggested Improvement**

Many women gave suggestions on how to improve this program, including design improvement; interesting, plain, and practical content; updating the information more often; and quickening response to women's questions.

#### **Subcategory 1: Design Improvement**

Some women suggested a design or technical improvement such as adding the message reminder and search engine to facilitate instant communication in the Discussion forum and help women to locate the information they needed in the Learning forum. Two women were of the following opinion:

*The app may be improved by adding the message reminder, like that in chat tools such as QQ or Webchat. Once someone writes a message, the app will have message reminder to notify others. Then others will read and join the discussion..., like conversation with each other. If you write a message and nobody responds, then you lose the interest to continue writing. Sometimes we just need to talk to others. But if we always need wait for a while, we may lost interest. [Informant 2]*

*There are too many content in the Learning forum. I was overwhelmed by the information each time I opened it. I do not have patience to read all of them...But the screen of the mobile phone is so small and it takes long time to find the knowledge you want. The program can be improved by adding search engine in the Learning forum. If I search for "nausea", then all the knowledge related to nausea will come out. Search engine will help save my time. [Informant 3]*

#### **Subcategory 2: Short, Interesting, Plain, and Practical Content**

Some women mentioned that the information in the Learning forum should be short, interesting, and practical. Also plain language should be used to convey the knowledge. Adding more content on food choice was requested by 6 women. Five women said they didn't tap into the "Personal Story forum" very often and hadn't benefitted from the video much. Videos being too long was identified as the main reason, and the majority of women suggested that the video should be short and focused:

*Please add more information on the food choice. We need to eat every day, however, there is conflicting advice on food choices on the internet, such as whether we should eat honey, chicken, leek, etc. We are in a dilemma on what we should eat. The apps can provide detailed information on food choice, the time of food intake, the cooking methods, etc...Such practical information would be very helpful. [Informant 11]*

*The videos are always long. I opened the first video and it showed that the video would take 25 minutes. I thought I would watch it when I had enough time. Then I never found time to open it again. I forgot it (Laugh...). Actually, when I was quite physically fragile, I prefer to short and fast information...sometimes, fragmental information. I like to use the Ask-the-Expert forum and Learning forum to search for answers to my own questions. It was quick. I couldn't settle myself down to watch the whole video. The video should be short and focused. Three to five minutes would be enough for one story.*

### **Subcategory 3: Update the Information More Often**

Some women mentioned that the information should be updated more often because they required different information and faced new problems as their chemotherapy progressed. One woman stated:

*We have so many people in the discussion forum. En...During chemotherapy, always there are new problems occurred for different people. Reading the same materials seems inadequate. We hope there are more updated information. For me, I have no illness experience before and I have no medical knowledge. Every day I like to open the Learning forum for reading. It will be great if you could update more often your information such as food choice, or medical follow-up. [Informant 7]*

### **Subcategory 4: Quicken the Responses to Women's Questions**

Some women said they preferred receiving an answer immediately from the HCPs, but there were often delays in responses to their questions:

*I like the Ask-the-Expert forum. But, if we have some questions in my mind, we are quite anxious. I want a response right away. But, it seems...maybe the doctor were at rest, or at work. It always took some time for the doctors to answer our questions. [Informant 11]*

### **Category 4: Future Direction**

Most women were satisfied with this program and advocated it as routine care. Some women also suggested opening this program to caregivers. One woman recommended applying this program to other cancer groups.

### **Subcategory 1: Breast Cancer e-Support as Routine Care**

Most of the women said that as this program was very beneficial for them, this program should be available to more women with breast cancer as routine care:

*It is great if all women with breast cancer could receive this program, which might help them go through the chemotherapy. Thank you very much...From my own experience in this program, I knew more about breast cancer and chemotherapy, and I felt more confident to cope with the disease. The programs must be helpful for them you know. [Informant 1]*

### **Subcategory 2: Breast Cancer e-Support Open to Other Family Members**

Some women suggested that the Breast Cancer e-Support program should be open to other family members, especially for women who are illiterate and who are very old:

*Many women with breast cancer come from the countryside. They are illiterate, or they cannot read and speak Mandarin. However, they also suffered a lot from the chemotherapy. If you can open the program to other family members who can read and convey the knowledge to the women, they would also benefit from your program. [Informant 2]*

*Some people, like me, 40 or 50 years old. Well, this group believe the apps is a little bit troublesome. They feel challenged to use the new technology. This is a problem. Although they are not willing to participate, they often consulted me on some questions and they were quite interested in the knowledge. If this program can be available for their family members, such as their son or daughter, it would be helpful. [Informant 11]*

### **Subcategory 3: Breast Cancer e-Support Applied to Other Cancer Patients**

One woman, who actively participated in the Discussion forum and Ask-the-Expert forum, mentioned that this program should be applied to all cancer patients because of common issues such as health, food choice, and exercise. She stated:

*If the app can be used by all types of cancer patients, not only breast cancer, which will be good. We have lots of common topics to discuss, such as maintaining health, choosing appropriate food, exercising on a regular basis. That will be a great platform to promote health for cancer patients. From my point of view, it is quite helpful to expand the scope of the application. Haha... [Informant 6]*

## **Discussion**

### **Principal Findings**

In this study, we evaluated participants' perception of an app-based program that they had access to during four cycles of chemotherapy. This process evaluation supported the quantitative results of the RCT that the Breast Cancer e-Support program was useful and feasible [19]. This study helped in understanding what challenges exist with the engagement of the Breast Cancer e-Support program. Despite the challenges, the participants provided constructive suggestions for improvement related to the design, content, and operation of this program. The participants recommended the Breast Cancer e-Support program be incorporated as routine care to support women during chemotherapy.

Women in this study reported that the Breast Cancer e-Support program was helpful in enhancing knowledge, improving confidence level, and promoting emotional well-being. They valued the tailored advice from experts. These findings could be explained by the theoretical framework of this program:



Bandura's self-efficacy theory [17] and the social exchange theory [18]. Self-efficacy, an individual's perceived ability to perform a particular task in a given situation, is an important concept that influences women's ability to manage their disease and chemotherapy [17]. Four factors such as direct mastery experiences, vicarious experiences, verbal persuasion, and perception of their physiological state from Bandura's self-efficacy theory [17] were addressed in the Breast Cancer e-Support program by offering knowledge and skills, providing hopeful stories, and encouragement from peers and HCPs. In addition, supported by social exchange theory, the Breast Cancer e-Support program provided a channel to connect women with structural support and a variety of functional support, which are identified as the essential components of social support [18].

Many women stated that the Breast Cancer e-Support program was easy to use and convenient. Compared with traditional face-to-face interventions, connecting with the Breast Cancer e-Support program meant that women were able to access information and social support at anytime and anywhere [28]. Taking advantage of the app's technical capabilities, this program provided women the opportunity to learn tailored information, watch encouraging stories, and chat with peers and HCPs [16]. Even though the majority of women enjoyed the convenience and multifunctional ability of the Breast Cancer e-Support program, one woman identified the app instability as a challenge to the engagement of this program. It is hard to determine whether the app instability was because of the internet connection or the app itself. But still, there is a need to improve the app reliability and to offer sufficient technical support service to participants [29].

This study revealed that some participants felt too sick or in a low mood to use the Breast Cancer e-Support program during chemotherapy. Consistent with our study, the association between poor health status and infrequent computer use was reported [29,30]. Furthermore, Chinese women might fail to disclose their negative emotions when confronting a life-threatening disease [31], which may have prevented participants in this study from sharing their feelings in the Breast Cancer e-Support program. In traditional Chinese culture, family members are obliged to take care of the patients [32]. Family-centered approach should therefore be adopted in the future app-based studies, so that a family member can also use the app in need when women are experiencing severe physical and psychosocial symptoms.

In our study, stigma related to breast cancer was reported to prevent the utilization of this program. Culturally, Chinese women are not willing to talk openly about breast cancer because of the perceived social rejection and low self-esteem associated with being ill and the disfigurement of breast surgery [31]. Women's concerns on stigma may also hinder their emotional expression and support seeking behaviors in this program, thus reducing their engagement. Culturally sensitive education and peer support were reported to help reduce stigma and increased a sense of belonging for Chinese women with breast cancer [33]. Integration of culturally tailored support regarding stigma into the Breast Cancer e-Support program may alter women's perception on stigma, thus improving their engagement.

During process evaluation, women also gave constructive suggestions for improvement in design, content, and operation of the Breast Cancer e-Support program. Design improvement involved adding message reminders to prompt instant communication with peers and shorten the response time from the experts, as well as adding a search engine function to help quickly locate information. Content improvement included supplementing more interesting and practical knowledge (eg, more pictures, cartoons, and food choices), plain language used, and short and concise videos to convey information. Our study indicates the demand for health service that optimizes on instant communication and improves efficiency on information delivery [34]. Operational improvement referred to knowledge being updated more often and questions being responded to more quickly. HCPs' involvement, such as knowledge updating and timely feedback, is crucial to reinforce women's app engagement [34]. In recent years, user-centered design has gained recognition in app development [35], and user-friendliness has been incorporated in the app assessment [36,37]. Thus, these valuable comments from users' experiences identified in our study should be addressed in future app designs and operation to encourage app engagement.

In our study, half of the interviewed women emphasized the importance of diet guidelines during chemotherapy. They believed that food choice was very practical, and this program should add more diet details. Diet is imbued with Chinese culture [38], and the need for more specific diet information was considered important. Traditional Chinese medicine is evident regarding diet and food properties among Chinese women with breast cancer undergoing chemotherapy [39]. Specific food recommendations that are culturally sensitive should be addressed for future app-based programs targeting different sociocultural groups.

Many participants recommended the incorporation of this program as routine care during chemotherapy. Some suggested the Breast Cancer e-Support program should be generalized to other family members or other cancer patients. These recommendations indicated that women regarded this program useful and beneficial to other patients. With the increasing growth of mobile phone users [12], it is possible for all patients and their family caregivers to have such an app service available. Moreover, benefiting from the rapid advances in mobile technologies [7], future app-based intervention may convey information via multimedia for illiterate and old patients.

### Strengths and Limitations

This study has limitations. This study was limited to those who were able to access the internet via a mobile phone and who were willing to be interviewed. This inclusion criteria may have narrowed the participant cohort to those who were technologically comfortable with mobile phone use and who had a high level of motivation to share their experiences. Moreover, there might be bias of the findings as the interviewed women were better educated than all participants in the RCT. Our results may not be representative of the views of all women with breast cancer in general. Two women in the intervention group who never accessed the program were not interviewed (one lost contact, one refused). Therefore, we were unable to

explore further the reasons for nonuse of the app-based program. The strength of the study is that this process evaluation gathered rich qualitative data of participants' views on the benefits, challenges, improvement suggestions, and recommendation for an innovative intervention.

### Conclusions

The study provides evidence on the benefits of the Breast Cancer e-Support program and contributes to an increased understanding of some challenges of why women could not engage in this program as much as expected. This study also discussed some improvement suggestions and future direction of the app-based program from participants' view. Such knowledge is crucial, and future app-based interventions could address participants'

improvement suggestions on design and operation, apply family-centered approaches, and provide more support on stigma associated with the condition to encourage the app engagement and provide better support.

Our study also has global significance because apps are being increasingly recognized as supplementary interventions when the feasibility of traditional face-to-face interventions are challenged. This app has the potential to be used by Chinese women in Australia and also be translated to other languages to help the culturally and linguistically diverse groups to promote their health outcomes. The knowledge generated from the study can be used to develop guidelines for future health care app development.

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### Authors' Contributions

JZ contributed to the conception and design of the study, acquisition of data, analysis of data, funding acquisition, writing original draft and revision, and final approval of the submitted version. LE contributed to the conception and design of the study, writing, review and editing for important intellectual content, and final approval of the submitted version. DG contributed to the acquisition of data, analysis of data, writing and review and editing for important intellectual content, as well as final approval of the submitted version. SY and QH contributed to the acquisition of data, writing, review and editing for important intellectual content, as well as final approval of the submitted version. SWCC contributed to the conception and design of the study, project administration, writing, review and editing for important intellectual content, as well as final approval of the submitted version.

### Conflicts of Interest

None declared.

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## Abbreviations

**HCP:** health care professional

**QoL:** quality of life

**RCT:** randomized controlled trial

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Original Paper

# Women's Perceptions of Using Mobile Phones for Maternal and Child Health Support in Afghanistan: Cross-Sectional Survey

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## Abstract

**Background:** Growing rates of global mobile subscriptions pave the way for implementation of mobile health (mHealth) initiatives, especially among hard-to-reach populations.

**Objective:** This study aimed to determine the perceptions of Afghan women regarding the use of mobile phones for maternal and child health services.

**Methods:** A cross-sectional survey was conducted in both rural and urban districts of Nangarhar Province, Afghanistan. The interviewer-administered questionnaire was used to assess participants' demographic profile, mobile phone usage, and perception of respondents toward different aspects of health care delivery via mobile phones.

**Results:** Of the 240 participants, 142 (59.2%) owned mobile phones and 220 (91.7%) routinely used mobile phones. Approximately 209 (87.1%) of participants were willing to receive health messages via a mobile phone. Automated voice call was the most preferred method for sending health messages. More than 90% of the women reported that they would like to receive reminders for their children's vaccinations and antenatal care visits.

**Conclusions:** Users' perception was associated with mobile phone ownership, literacy level, and experience using mobile phones. In the study area, where the literacy rate is low, mHealth was well perceived.

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**KEYWORDS**

Afghanistan; mobile health; maternal health, child health; perception; mobile phone

## Introduction

Mobile technology has been treated as a necessity in both the developed and developing world. The high demand for this technology has resulted in exponential growth in the number of cellular subscribers worldwide. In 2014, there were more than 7 billion subscribers, with an average penetration rate of 96% [1].

Given the unprecedented growth in the use of mobile technology, much research and increasing resources have been devoted to the development of its application in various domains beyond its core functionality of telecommunication. The use of

mobile phone devices to support medical and public health practices has led to the emergence of a new field of eHealth known as mobile health (mHealth) [2]. mHealth can be used for complex applications for health; however, simple health support applications using mobile phones' core functionality have also been developed [2]. In Afghanistan, a postconflict country, there were no mobile network operators until 2003; now there are 5 mobile network operators providing services to more than 20 million subscribers with a penetration rate of 83% covering 90% of the population [3]. A lack of landline telephones in most areas, high demand, a competitive market, and decreasing costs of mobile devices and services have all

contributed to the rapid growth of mobile telephone services in the country.

Although gender inequality in Afghanistan has been improving in the past decade, accessibility to education and health care remains a great challenge among Afghan women. The national literacy rate for adult females was only 17% in 2012 [4]. Despite the limited access to education and health, a survey among Afghan women has shown that about 80% of women have access to a mobile phone [5]. This high rate of mobile phone use among Afghan women suggests that application of mHealth could be an effective method to promote maternal and child health.

Maternal and child health is a key priority area for the Ministry of Public Health of Afghanistan. The maternal mortality rate has been decreased from 1600 per 100,000 live births in 1990s to 327 per 100,000 live births in 2010 [6,7]. However, maternal mortality and child mortality rates in Afghanistan are still high compared with those in other countries. Lack of information is an important factor that contributes to poor health outcomes [8]. People in rural areas may not have access to many sources of information; for years, radio had been the only reliable medium for transferring information to the rural population.

Studies have shown that mobile phones can be used as an effective means for disseminating health-related messages to target populations. A study in India showed that mobile phones can be considered as an acceptable means of health care delivery [9]. Studies also show positive perceptions toward using mobile phone for health purposes; however, some important factors need to be considered before designing and implementing such a program, including user preference of receiving messages, tone and frequency of messages, and privacy and confidentiality [2,9-13].

This study aimed to determine the perceptions of Afghan women regarding the use of mobile phones for supporting maternal and child health, and the associated factors with those perceptions. This preintervention study could provide viable information in terms of contextualization for the development of appropriate mHealth initiatives.

## Methods

### Study Design

This cross-sectional survey was conducted in two study sites (rural and urban) in Nangarhar Province, Afghanistan, from August 2015 to September 2015. Nangarhar Province, consisting of 22 districts, is one of the largest provinces in the country. Women of child-bearing age (18-49 years) who resided in the study areas and who agreed to participate in our study were considered eligible for the survey.

A sample size of 240 (120 per study site) was calculated with expected women's perceptions toward utilization of mHealth of 80% with 5% error and 80% power. A multi-stage stratified random cluster sampling was performed to select the study sites. First, the 22 districts were classified as rural or urban areas. One district in an urban area (Jalalabad City) and 2 districts in a rural

area (Rodat and Kama) were randomly selected. Then, 1 subdistrict per district in the rural area and 2 subdistricts in the city were randomly chosen. Finally, 2 villages or sectors in each subdistrict (total of 8 villages/sectors) were randomly selected for data collection.

Systematic sampling was used to select households in each village. Finally, random sampling was used for selecting 1 interviewee in each household.

The interviewer-administered questionnaire used in this study was adopted from a similar study conducted in India [9]. The questionnaire was reviewed by 3 experts before implementation. The interviewers were trained for data collection. The questionnaire assessed participants' demographic profile, mobile phone usage, and perception of respondents toward different aspects of health care delivery via mobile phones.

### Data Analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 18 (SPSS Inc, Chicago, IL). Frequencies, means, and SD were used to describe the variables. Demographic and mobile phone usage data were compared between respondents in rural and urban areas. Chi-square and binary logistic regression models were used to identify factors associated with perceptions and willingness to use mobile phones for health. Multiple logistic regression was performed to determine adjusted odds ratio (OR) for the perceptions and willingness to use mobile phones for health; the adjusted variables included residence, ability to read, ownership of mobile phone, routine use of mobile, age group, and duration of mobile phone use.

### Ethical Statement

The study was approved by the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, Thailand, and the Institutional Review Board of the Ministry of Public Health, Afghanistan. Information about the study was provided to participants, and informed consent was obtained from each participant.

## Results

### Characteristics of Participants

A total of 240 women participated in the study (120 participants from urban areas and 120 from rural areas). The mean household size was 7.1 individuals with an SD of 3.0 (minimum 2, maximum 14). Most households (228/240, 95%) had at least 1 mobile phone. Few participants were employed, and 89.6% (215/240) were housewives. Only one fourth of the women (57/240) were able to read, and among those, 33 had attended community-based schools (Table 1). These characteristics were not significantly different between women in the rural area and those in the urban area. Approximately, 47.5% (57/120) and 70.8% (85/120) of women in rural and urban areas, respectively, owned a mobile phone. However, most of the women (220/240, 91.7%) routinely used mobile phones for making calls. The main reason for not using mobile phones was the cost.

**Table 1.** Demographic characteristics of the study population (N=240).

Characteristics	n (%)
<b>Living area</b>	
Rural	120 (50.0)
Urban	120 (50.0)
<b>Ability to read</b>	
No	183 (76.2)
Yes	57 (23.8)
<b>Education level</b>	
No education	183 (76.2)
Informal education (community-based study)	33 (13.8)
Primary and secondary	9 (3.8)
High school	15 (6.2)
<b>Occupation</b>	
Housewife	215 (89.6)
Teacher	11 (4.6)
Officer	4 (1.7)
Other	10 (4.1)
<b>Have children</b>	
No	13 (5.4)
Yes	227 (94.6)

Women in both rural and urban areas had, on average, approximately 4 years of experience in using mobile phones. Most of the respondents (154/220, 70.0%) were familiar with both the voice call and short message service (SMS) function; however, only 24.1% (53/220) of them used the SMS function. Overall, only 16.8% (37/220) of women were familiar with voice calls, SMS, and interactive voice response (IVR) functions. Mobile phones were commonly used for alarm setting (for prayers or waking up) and listening to the radio. Only 2 respondents from urban areas used the mobile phone alarm feature as a reminder for taking medication (Table 2).

### Perceptions Toward Using Mobile Phones for Health

About 72.1% (173/240) of our respondents thought that mobile phones could be used for health support. There was no significant difference regarding the perception of using a mobile phone for health purposes between women in rural and urban areas. Of these 173 respondents, 80.3% (n=139) and 75.7% (n=131) thought that mobile phones could be used for making appointments and counseling purposes, respectively, whereas 19.1% (n=33) reported that it could be used as a means for

disseminating health-related information, and 8.7% (n=15) suggested that mobile phones could be used for treatment or vaccination reminders. According to responses to open-ended questions, other mobile phone purposes were to communicate with pharmacists regarding medication, receiving updates about hospitalized relatives, and receiving lab results from the hospital (Table 3).

Perceptions toward using mobile phones to support health were significantly associated with literacy, ownership and usage of a mobile phone, and age. Women who were able to read were 20 times more likely to agree that mobile phones can be used to support health compared with illiterate women. Those who owned or routinely used a mobile phone were about twice more likely to use a mobile phone for health support; however, this association was not significant after adjusting for other variables. In addition, younger women (aged  $\leq 31$  years) were 3 times more likely to perceive the usefulness of using a mobile phone for health purposes. However, this perception was not significantly different among women in rural areas and those in urban areas (Table 4).

**Table 2.** Characteristics of mobile phone use (N=240). IVR: interactive voice response. SMS: short message service.

Characteristics	Study site		Total	P value
	Rural (n=120)	Urban (n=120)		
<b>Ownership of mobile phone, n (%)</b>				
No	63 (52.5)	35 (29.2)	98 (40.8)	
Yes	57 (47.5)	85 (70.8)	142 (59.2)	<.001
<b>Routine use of mobile phone, n (%)</b>				
No	14 (11.7)	6 (5.0)	20 (8.3)	
Yes	106 (88.3)	114 (95.0)	220 (91.7)	.06
Duration of mobile use (years), mean (SD)	4.27 (1.99)	4.41 (1.91)	4.35 (1.94)	.49
<b>Familiarity with mobile functions, n (%)</b>				
Voice call	14 (13.2)	15 (13.2)	29 (13.2)	.99
Voice call and SMS	74 (69.8)	80 (70.2)	154 (70.0)	
Voice call, SMS, and IVR	18 (17.0)	19 (16.6)	37 (16.8)	
<b>Using mobile phone for SMS, n (%)</b>				
No	82 (77.4)	85 (74.6)	167 (75.9)	
Yes	24 (22.6)	29 (25.4)	53 (24.1)	.62
<b>Using mobile phone as alarm, n (%)</b>				
No	77 (72.6)	70 (61.4)	147 (66.8)	
Yes	29 (27.4)	44 (38.6)	73 (33.2)	.07
<b>Using mobile phone alarm (n=73), n (%)</b>				
	<b>n=29</b>	<b>n=44</b>		
For prayers	15 (51.7)	20 (45.5)	35 (47.9)	
For waking up	12 (41.4)	20 (45.5)	32 (43.7)	
For taking medicine	0 (0)	2 (4.5)	2 (2.7)	
Other	12 (41.4)	17 (38.5)	29 (39.7)	
<b>Using mobile phone for other functions (n=167), n (%)</b>				
	<b>n=81</b>	<b>n=86</b>		
Radio	65 (80.2)	71 (82.6)	136 (81.4)	
Audio (MP3 and/or MP4)	18 (22.2)	16 (18.6)	34 (20.4)	
Games	19 (23.5)	21 (24.4)	40 (24.0)	
Camera	14 (17.3)	18 (20.9)	32 (19.2)	
Internet	0 (0)	9 (10.5)	9 (5.4)	
Calculator	10 (12.3)	12 (14.0)	22 (13.2)	
Torch or flash light	53 (65.4)	47 (54.7)	100 (59.9)	
<b>Reasons for not using mobile phone (n=20), n (%)</b>				
	<b>n=14</b>	<b>n=6</b>		
Lack of money	12 (86)	4 (67)	16 (80)	
Lack of permission	7 (50)	2 (33)	9 (45)	
Unable to use mobile phone	4 (29)	2 (33)	6 (30)	



**Table 3.** Perceptions toward using mobile phones for health purposes. SMS: short message service.

Perceptions	Study site		Total, n (%)	P value
	Rural (n=120), n (%)	Urban (n=120), n (%)		
<b>Do you think mobile phones can be used for supporting health?</b>				
No	39 (32.5)	28 (23.3)	67 (27.9)	.11
Yes	81 (67.5)	92 (77.7)	173 (72.1)	
<b>Ways mobile phones can be used for supporting health</b>				
As a mean for disseminating health-related information	9 (11.1)	24 (26.1)	33 (19.1)	
As treatment or vaccination reminder	8 (9.9)	7 (7.6)	15 (8.7)	
For making appointments	64 (79.0)	75 (81.5)	139 (80.3)	
For counseling	62 (76.5)	69 (75.0)	131 (75.7)	
Other	6 (7.4)	6 (6.5)	12 (6.9)	
<b>Openness to receiving health advice via a mobile phone</b>				
No	20 (16.7)	11 (9.2)	31 (12.9)	.08
Yes	100 (83.3)	109 (90.8)	209 (87.1)	
<b>Topics of interest</b>				
Nutrition	30 (25.0)	36 (30.0)	66 (27.5)	
Breast feeding	75 (62.5)	71 (59.2)	146 (60.8)	
Pregnancy	95 (79.2)	95 (79.2)	190 (79.2)	
Vaccination	105 (87.5)	82 (68.3)	187 (77.9)	
Hygiene	35 (29.2)	40 (33.3)	75 (31.3)	
Other	16 (13.3)	24 (20.0)	40 (16.7)	
<b>Preferred frequency for receiving health information</b>				
Daily	39 (32.5)	22 (18.3)	61 (25.4)	.03
Weekly	57 (47.5)	75 (62.5)	132 (55.0)	
Monthly	24 (20.0)	23 (19.2)	47 (19.6)	
<b>Preferred method for receiving health information</b>				
SMS	3 (2.5)	12 (10.0)	15 (6.3)	.009
Automated voice call	96 (80.0)	98 (81.7)	194 (80.8)	
No preference	21 (17.5)	10 (8.3)	31 (12.9)	
<b>Willingness to use a free health call center/ help - line number</b>				
No	28 (23.3)	19 (15.8)	47 (19.6)	.14
Yes	92 (76.7)	101 (84.2)	193 (80.4)	
<b>Openness to receiving reminders about National Immunization Days</b>				
No	35 (29.2)	32 (26.7)	67 (27.9)	.67
Yes	85 (70.8)	88 (73.3)	173 (72.1)	
<b>Openness to receiving reminders for children' s vaccinations</b>				
No	9 (7.5)	16 (13.3)	25 (10.4)	.14
Yes	111 (92.5)	104 (86.7)	215 (89.6)	
<b>Openness to receiving reminders for tetanus vaccination</b>				
No	7 (5.8)	9 (7.5)	16 (6.7)	.61
Yes	113 (94.2)	111 (92.5)	224 (93.3)	

Perceptions	Study site		Total, n (%)	P value
	Rural (n=120), n (%)	Urban (n=120), n (%)		
<b>Openness to receiving reminders for antenatal/ perinatal care visits</b>				
No	9 (7.5)	6 (5.0)	15 (6.3)	
Yes	111 (92.5)	114 (95.0)	225 (93.8)	.42
<b>Preferred time for receiving reminders</b>				
On the day	5 (4.4)	5 (4.5)	10 (4.4)	.34
1 day before	37 (32.5)	49 (44.1)	86 (38.2)	
2 days before	67 (58.8)	53 (47.7)	120 (53.3)	
1 week before	5 (4.4)	4 (3.6)	9 (4.0)	
<b>Preferred method for receiving reminders (n=235)</b>				
	<b>n=120</b>	<b>n=115</b>		
Voice call	96 (80.0)	92 (80.0)	188 (80.0)	.01
SMS	3 (2.5)	12 (10.4)	15 (6.4)	
No preference	21 (17.5)	11 (9.6)	32 (13.6)	

### Mobile Phone Usage for Health Promotion

The majority (209/240, 87.1%) of our respondents were open to receiving health advice via mobile phones. Only 31 women (31/240, 12.9%) refused to receive health information. Those who refused were asked for the reason in an open-ended question. Among those women, 10 cited cultural restrictions, and one stated, "I don't need it as we have health professionals in our family."

The percentages of respondents' preferred topics were as follows: pregnancy, 79.2% (190/240); vaccination, 77.9% (187/240); breast feeding, 60.8% (146/240); hygiene, 31.3% (75/240); and nutrition, 27.5% (66/240). Other suggested topics included family planning, infertility causes, and information on specific diseases, such as diarrhea, hepatitis B, malaria, and human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS). More than half of the respondents (132/240, 55.0%) preferred to receive the information on a weekly basis, whereas 25.4% (61/240) preferred to receive it on a daily basis, and 19.6% (47/240) preferred monthly. In terms of the method for receiving health information, the majority (194/240, 80.8%) of respondents preferred automated voice calls, whereas only 6.3% (15/240) preferred SMS, and the remainder had no preference (Table 3).

A total of 80.4% (193/240) of the participants were willing to use a toll-free health call center or hotline numbers for obtaining health-related information of their interest; the reported reasons

for not wanting to use these methods were related to cultural and gender issues, or reluctance/fear to talk to health professionals. Regarding the factor associated with openness to receive health information via a mobile phone, those who owned a mobile phone and those who used it routinely were more likely to be open to receiving information in comparison with those who did not own or use one routinely. However, these associations were not significant after adjusting for other variables. Other factors, including literacy, residency, and age, were also not significantly associated with respondents' willingness to receive health information via a mobile phone (Table 5).

### Usage of Mobile Phone for Medical Reminders

Approximately 72.1% (173/240) of the participants were willing to receive reminders for National Immunization Days, whereas 89.6 (215/240) wanted to receive reminders for vaccinations and antenatal care visits during pregnancy, as well as reminders about their children's vaccination schedules.

More than half (120/225, 53.3%) of the participants wanted the reminders 2 days before the scheduled date, whereas 38.2% (86/225) preferred to receive these reminders 1 day before. Only few respondents wanted to receive reminders on the day of immunization (10/225, 4.4%) or 1 week before the scheduled date (9/225, 4.0%). Voice calls were the most preferred method to receive the reminders (188/235, 80.0% of respondents; Table 3).

**Table 4.** Factors associated with perceptions about the use of mobile phones for supporting health (N=240). OR: odds ratio.

Variables	Can mobile phone be used to support health?		Crude OR (95% CI)	Adjusted OR (95% CI)
	No	Yes		
<b>Residence, n (%)</b>				
Rural	39 (32.5)	81 (67.5)	1	1
Urban	28 (23.3)	92 (76.7)	1.58 (0.90-2.80)	1.22 (0.59-2.52)
<b>Ability to read, n (%)</b>				
No	66 (36.1)	117 (63.9)	1	1
Yes	1 (1.8)	56 (98.2)	31.59 (4.27-233.48)	20.11 (2.61-155.15)
<b>Ownership of mobile phone, n (%)</b>				
No	41 (41.8)	57 (58.2)	1	1
Yes	26 (18.3)	116 (81.7)	3.21 (1.79-5.76)	2.23 (1.07-4.61)
<b>Routine use of mobile phone, n (%)</b>				
No	12 (60.0)	8 (40.0)	1	1
Yes	26 (18.3)	116 (81.7)	4.50 (1.75-11.58)	2.61 (0.87-7.86)
<b>Age group ( years ), n (%)</b>				
32 or older	43 (39.8)	65 (60.2)	1	1
31 or younger	21 (16.8)	104 (83.2)	3.28 (1.79-6.01)	3.32 (1.56-7.06)
Duration of use (years), mean (SD)	3.73 (1.758)	4.55 (1.971)	1.27 (1.07-1.51)	1.32 (1.08-1.61)

**Table 5.** Factors associated with willingness to receive health information via a mobile phone (N=240). OR: odds ratio.

Variables	Willing to receive health information via a mobile phone		Crude OR (95% CI)	Adjusted OR (95% CI)
	No	Yes		
<b>Residence, n (%)</b>				
Rural	20 (16.7)	100 (83.3)	1	1
Urban	11 (9.2)	109 (90.8)	1.98 (0.91-4.34)	1.96 (0.77-5.04)
<b>Ability to read, n (%)</b>				
No	28 (15.3)	155 (84.7)	1	1
Yes	3 (5.3)	54 (94.7)	3.25 (0.95-11.13)	2.25 (0.61-8.37)
<b>Ownership of mobile phone, n (%)</b>				
No	21 (21.4)	77 (78.6)	1	1
Yes	10 (7.0)	132 (93.0)	3.60 (1.61-8.04)	2.37 (0.95-5.93)
<b>Routine use of a mobile phone, n (%)</b>				
No	8 (40.0)	12 (60.0)	1	1
Yes	23 (10.5)	197 (89.5)	5.71 (2.12-15.42)	2.82 (0.94-8.47)
<b>Age group (years), n (%)</b>				
32 or older	16 (14.8)	92 (85.2)	1	1
31 or younger	15 (12.0)	110 (88.0)	1.28 (0.60-2.72)	1.02 (0.39-2.65)
Duration of use (years), mean (SD)	4.78 (2.430)	4.29 (1.886)	0.88 (0.71-1.10)	0.88 (0.71-1.09)

## Discussion

The recent growth in mobile phone apps and the number of mobile phone subscribers in Afghanistan provides an opportunity for applying mobile technology to support health

care in the country. Currently, mHealth initiatives have been adopted and reported to be successful in improving health worldwide [2]. Given a high penetration rate, mobile phones can be an effective medium for transmitting health information to the population, particularly among vulnerable groups,

particularly women, who may have fewer opportunities to access health information in general. However, the success of mHealth initiatives may vary across different populations. Low literacy and technical capacities are considered a barrier for mHealth adoption [2]. It is therefore critical to understand the baseline perceptions and needs of particular users before initiating an mHealth program. This study explored the potential of using mobile technology to support maternal and child health among Afghan women.

The literacy rate among the women in our study was 24%, which is higher than the national literacy rate for adult females (17%) in Afghanistan [4]. However, the national literacy rate includes older women, many of whom are illiterate; the target population in our study comprised only women of a child-bearing age. Although only half of the women in our sample owned a mobile phone, more than 90% of them had access to a mobile phone and had routinely used one for an average of 4 years. This high accessibility means there is great potential in using mobile phones as a medium for health education.

Only 20 out of 240 women in this study reported that they had never used a mobile phone. A previous study described cultural restrictions and lack of permission for women regarding the use of mobile phones in Afghanistan [5]; however, this reason was only reported by 9 respondents in this study. The main reason for not using a mobile phone was poverty, which was reported by 12 women living in rural areas and 4 in urban areas.

The characteristics of mobile usage were not significantly different between women living in rural areas and those in urban areas, except for ownership of a mobile phone. This may be attributable to the common cultural and social values shared by women in both the urban and rural areas in the province. However, the difference in mobile phone ownership reflects the socioeconomic difference between rural and urban areas.

The majority of our respondents were not familiar with IVR. The effectiveness of using IVR for health education remains uncertain according to the literature. Some studies show the effectiveness of IVR [14], whereas others describe users' technical difficulty in using it [15]. A study in Uganda showed that training a target population on how to use IVR before project implementation was possible only for small projects [15]. For larger programs, the alternative of using SMS/voice calls may be more effective.

The radio is still the most used and reliable source of news and information in Afghanistan [16], and most mobile phones can support FM radio; more than half of our respondents use mobile phones to listen to the radio. Women's perceptions of mHealth were assessed. About three quarters of the respondents responded positively. This perception was not significantly different between the urban and rural population, but was significantly different for other demographic characteristics. The literacy rate and ownership of a mobile phone were strongly associated with positive perceptions. This suggested that improving the literacy rate may have an impact on the success of mHealth implementation. Younger women were also more likely to perceive usefulness of mHealth compared with older women, consistent with a national survey conducted in Kenya [17]. This is likely because younger generations are generally

more familiar with mobile technology compared with older people.

Majority of the participants were open to receiving health-related information on their mobile phone. This openness was associated with literacy, mobile phone ownership, and routine use of mobile phones. Literate women were 3.6 times more likely to be open to receiving health-related information on mobile phones in comparison with illiterate women. This suggests that mHealth initiatives in Afghanistan could increase, as literacy rates are improving in the country, especially among women. Very few of our respondents were not open to receiving such information, and the reported reasons were mostly related to culture and gender.

Although SMS is the globally preferred method for receiving health-related messages [2], our study showed different results. Most of our respondents preferred voice calls for receiving health-related information and medical reminders. It is obvious that individuals with a low literacy level prefer voice calls in comparison with SMS and/or IVR. For the effectiveness of any mHealth initiative, it is important to consider the end users and target population's literacy level and preferred type of communication for receiving health-related information and medical reminders.

SMS is the globally preferred method and it is considered to be nonintrusive, as the receivers can read the messages at their convenience instead of answering a call [2,9]. A study conducted in Karachi, Pakistan, shows that SMS reminders were useful for tuberculosis patients in terms of treatment adherence; however, that study also suggested that a two-way reminder system might better support patients in medication adherence in low-literacy populations [18]. A study from rural areas of India also reported that voice calls were preferred in comparison with text messages for medical reminders and health promotion messages [9]. A study conducted in Kenya also observed that telephone call was a more preferable mode of communication among women living in remote areas, whereas women in nonremote areas were likely to prefer text message as their mode of communication [19]. Considering the low literacy rate among Afghan women, voice calls should be the most effective form of communication for an mHealth initiative. However, this may change if literacy rates continue to improve.

The frequency of health-related message delivery is an important issue to be considered while adopting mHealth initiatives. More frequent messages may result in intervention fatigue [13]. Our study showed that more than half of our respondents preferred to receive messages on a weekly basis, rather than daily or monthly.

Medical reminders can play a significant role in treatment/vaccination adherence. A study in rural Kenya showed that mobile phone-based strategies are useful for delivering reminders to target groups. Text message reminders can effectively increase immunization coverage [20]. In addition, a systematic review study documented that text messaging increased adherence to antiretroviral therapy and smoking cessation [21]. In this study, approximately 90% of the women were willing to receive vaccination reminders. Unlike previous studies, most of our respondents preferred to receive voice call

reminders rather than text messages. More than half of our respondents preferred to receive reminders 2 days before the appointment date. Because some respondents live far from health facilities, they would need to plan their visit after receiving the reminder. According to national statistics, only 47% of Afghan children under 1 year of age receive the third dose of the Penta III vaccine (hepatitis B and influenza type B vaccines are added to Diphtheria-Pertussis-Tetanus (DPT) vaccine, and are administered in a single-dose vial) [7]. The World Health Organization also reported that the DPT1 to DPT3 vaccination dropout rate in Afghanistan was higher than 15% [22]. Therefore, an mHealth initiative for vaccination reminders, customized for this specific target group, would be one of the effective methods to increase vaccination coverage in the country.

This study was conducted in one province of Afghanistan, which may not represent all women living in the country, especially those in very remote regions or conflict areas. In addition, our

study areas contained at least one mobile network, and most of women in this study had used mobile phones for an average of 4 years. There are still some areas in Afghanistan with no available networks that have only recently obtained a network; perceptions of using mobile phones for supporting maternal and child health may differ among women who are new to mobile phone use. Further studies are needed to assess mHealth perceptions among this group of women.

Our study explored the perceptions of women regarding the use of mobile phones for maternal and child health in Afghanistan. This preintervention assessment yielded valuable information for the design and implementation of mHealth interventions. Although the findings in this study are encouraging in terms of the potential benefits of adopting mHealth interventions in Afghanistan, all the end users' concerns should be considered and intervention designs should be contextualized according to the target population.

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## Conflicts of Interest

None declared.

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## Abbreviations

**DPT:** Diphtheria-Pertussis-Tetanus

**IVR:** interactive voice response

**OR:** odds ratio

**SMS:** short message service

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Original Paper

# Mobile Health Initiatives in Vietnam: Scoping Study

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## Abstract

**Background:** Mobile health (mHealth) offers a promising solution to the multitude of challenges the Vietnamese health system faces, but there is a scarcity of published information on mHealth in Vietnam.

**Objective:** The objectives of this scoping study were (1) to summarize the extent, range, and nature of mHealth initiatives in Vietnam and (2) to examine the opportunities and threats of mHealth utilization in the Vietnamese context.

**Methods:** This scoping study systematically identified and extracted relevant information from 20 past and current mHealth initiatives in Vietnam. The study includes multimodal information sources, including published literature, gray literature (ie, government reports and unpublished literature), conference presentations, Web-based documents, and key informant interviews.

**Results:** We extracted information from 27 records from the electronic search and conducted 14 key informant interviews, allowing us to identify 20 mHealth initiatives in Vietnam. Most of the initiatives were primarily funded by external donors (n=15), while other initiatives were government funded (n=1) or self-funded (n=4). A majority of the initiatives targeted vulnerable and hard-to-reach populations (n=11), aimed to prevent the occurrence of disease (n=12), and used text messaging (short message service, SMS) as part of their intervention (n=14). The study revealed that Vietnamese mHealth implementation has been challenged by factors including features unique to the Vietnamese language (n=4) and sociocultural factors (n=3).

**Conclusions:** The largest threats to the popularity of mHealth initiatives are the absence of government policy, lack of government interest, heavy dependence on foreign funding, and lack of technological infrastructure. Finally, while current mHealth initiatives have already demonstrated promising opportunities for alternative models of funding, such as social entrepreneurship or private business models, sustainable mHealth initiatives outside of those funded by external donors have not yet been undertaken.

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## KEYWORDS

mHealth; eHealth; mobile health; telemedicine; Vietnam; scoping review

## Introduction

### Background

Vietnam has attained remarkable economic and health achievements in recent decades [1], but the health system still faces significant challenges. Vietnam has a high prevalence of communicable diseases coupled with an increase in the prevalence of noncommunicable diseases [2] and a high out-of-pocket payment rate (47% as of 2015 [3]), making up

over one-third of all health care costs in Vietnam [4]. There are severe shortages in health resources, especially in remote regions, with only 7.9 physicians per 10,000 individuals overall in 2014 [5] and as few as 1 per 10,000 physicians in hard-to-reach areas [6]. These systemic challenges have encouraged the use of technology-based innovations in health care, particularly mHealth or “the use of mobile and wireless technologies to support the achievement of health objectives” [7].

mHealth initiatives remain unproven and many remain in early or pilot phases [8], despite the growing attention from researchers and policy makers as a means to confront health challenges in low-resource settings. A 2013 review of mHealth interventions in low- and middle-income countries found that few mHealth initiatives were operating at scale, and there was little evidence of formal evaluations of these initiatives [9]. Another mHealth review corroborated these findings and found a lack of significant investment in mHealth policy in low-resource environments due to a lacking evidence base. In the review, only, 15 out of 53 studies attempted to provide evidence of health care metrics such as improvements in health care processes or public health indicators [10]. The most common use of mHealth in low- and middle-income countries was phone reminders and one-way text message for follow-up appointments, data gathering, and encouragement of healthy behavior [9].

In Vietnam, the 2016 rate of mobile-cellular subscriptions as a percent of the population is 131.8, equating to more than 1 cell phone per person [11]. As of May 2017, Vietnam had about 58.9 million Internet users, which is more than half of the population [12]. SMS text messaging (SMS, short message service) is inexpensive and mobile phone service coverage is wide (eg, [13,14]).

## Objectives

While there are available research papers reviewing the state of mHealth in other low and middle-income countries [15,16], at the time of writing of this review, there were no studies summarizing the extent of mHealth research and interventions in Vietnam. mHealth is an emerging field in Vietnam, and many of the projects are still in pilot phases or are ongoing. As more initiatives start in Vietnam, it is necessary to standardize, share information, and develop a set of best practices for the country. In addition, as Vietnam is in the process of revising and rewriting its young eHealth policies, it is important to understand barriers and enablers to mHealth implementation. Aiming to advance policy and practices for mHealth in Vietnam, the goal of this scoping study is twofold: (1) to summarize the extent, range, nature, and location of mHealth initiatives in Vietnam and (2) to examine the opportunities and threats of mHealth utilization in the Vietnamese context.

## Methods

In this scoping study, we used Arksey and O'Malley's (2005) [17] 5-step framework for scoping studies to retain methodological rigor and to allow the use of multimodal information sources, including published literature, gray literature (ie, government reports and unpublished literature from internal reports), conference presentations, Web-based documents, and key informant interviews. After identifying the study objectives (listed above), we identified relevant mHealth initiatives through electronic search and discussions with key stakeholders.

## Data Collection

### *Electronic Search*

Electronic searches were performed to discover initiatives with internationally and publicly available information and publications. We conducted our literature search using the following databases and websites: PubMed MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CINAHL) PsycINFO; Medline, Academic Search Premier, Global Health, Web of Science, ClinicalTrials.gov, World Health Organization clinical trials, and Google Scholar. The first strategy searched for the combined free-text words "mHealth" AND "Vietnam OR Viet Nam" in the title, abstract, and keywords. The second strategy searched for the combined free-text words "mobile phone\$ OR cellphone\$" AND "health" AND "Vietnam OR Viet Nam" in the title, abstract, and keywords. Search terms were limited to English words. The searches were initially completed by 2 authors (JL and LD) in January 2017 and were repeated in January 2018 upon revision of the manuscript. Duplicate records were removed, and 2 authors independently screened remaining records' abstracts before proceeding to the full texts to decide for inclusion, classification, and further investigation. The criteria for a record study inclusion were if the record described an initiative that (1) utilized mobile technology in a health-related capacity and (2) was based in Vietnam.

### *Key Informant Interviews*

To minimize publication bias, key informant interviews were performed after the electronic search to collect data from unpublished work or initiatives with information not publicly available [18]. After the electronic search was completed and relevant mHealth initiatives identified, we requested to speak to representatives from each of the initiatives, aiming to obtain initiative-specific information that was not publicly available. Additional interviews were also conducted with other key stakeholders in relevant government organizations such as the Vietnam Ministry of Health, nongovernmental organizations, private organizations, and key actors and researchers at leading health science institutions such as the Hanoi University of Public Health and Hanoi Medical University. The goal of these additional interviews was to discover and collect information from other unpublished initiatives. All interviews were conducted using a semistructured format in either English or Vietnamese, with the questions left intentionally open-ended as to not limit the emergence of any mHealth themes. All interviewees were asked if they knew of other mHealth initiatives in Vietnam, lessening the chance of undiscovered initiatives. All interviewees verbally consented to being interviewed, and all interviews were recorded.

### *Initiative Data Analysis and Extraction*

Data were charted concurrently as the electronic search and the initiative-specific interviews. As we received information from the initiatives, we used an integrative process to create a list of variables, which were continuously updated based on incoming information. The definitions of the extracted variables were agreed on by 2 authors (JL, CN). In all, 3 authors (JL, NP, and HT) independently extracted all relevant information from all



available sources, including electronic search articles and initiative leader interviews recordings.

The final data collection form, consisting of data from both the electronic search and key informant interviews, included project description, type of data sources, intervention period, stage of project, continuity status of project, mHealth domain, disease area, targeted population group, type of the primary funding source, and project implementation location, as summarized in the [Multimedia Appendix 1](#). Stage of the initiative was classified as either ongoing or completed, defined by the project being finished within their intended primary data collection period. Initiatives classified as completed initiatives were then categorized into continuing or noncontinuing initiatives, defined as still actively using the technology and infrastructure built during the initiative to recruit more participants. The mHealth domain was classified based on the 2015 International Telecommunication Union M-Powering Development Initiative document [19]. The broad groups included solutions across the patient pathway (prevention, diagnosis, treatment, monitoring) and health care systems strengthening (emergency response, health care practitioner support, health care surveillance, and health care administration). The provisioning technologies used were classified into the following groups: SMS, voice-based technology, app, Web-app, video-telephony, and other functionalities. Disease areas (ie, heart disease, HIV/AIDS) and population groups (ie, health care providers, migrant women) were broadly categorized into the specific disease and population group the initiative targeted. Finally, primary funding source was classified by initiatives' main source of funding.

### Thematic Data Analysis for Key Informant Interviews

The thematic data analysis in this study involved a multistage process to develop and refine a codebook using information from the semistructured interviews with all key informants, including the initiative-specific leaders and other stakeholders. We used Young et al's (2014) study on the development and refinement of a codebook to guide the analysis [20]. The first stage focused on familiarization with the data by listening and independently taking notes from the recordings. Thereafter, 2 authors (JL and CN) created an initial list of possible codes and definitions for these codes.

In the second stage, 3 authors (JL, NP, and HT) independently extracted comments from the semistructured interviews and classified all meaningful segments into these codes. We aimed to limit interpretation at this stage. Extractors were encouraged to refine the codebook, and inconsistencies in extraction were discussed with all extractors at the completion of this stage. We did not consider data saturation, as we aimed to capture as much data as possible by interviewing all relevant stakeholders we were able to find in Vietnam.

In all, 2 authors (JL and CN) collated the information and used thematic analysis techniques [21] to iteratively create the final codebook, which included themes relating to Vietnamese sociocultural factors, technological factors, and collaboration factors. Finally, initiative leaders who were interviewed were sent a draft of the paper in May 2017, with the opportunity to review and suggest edits.

## Results

### Data Sources Overview

The initial electronic database search retrieved 128 records. After duplication removal and screening, 27 records met inclusion criteria, which were sorted into 10 initiatives (Initiative #1, 4, 6, 7, 10, 11, 13, 16, 17, and 20). Of these 27 records, there were 12 research papers [13,14,22-31], 8 conference presentations [32-39], 2 Vietnamese governmental documents [40,41], 2 graduate dissertations [42,43], 2 case studies [44,45], and 1 project technical report [46].

A total of 14 interviews were conducted, in which 12 interviews were related to one or more of the initiatives and contributed to 10 more initiatives (Initiative #2, 3, 5, 8, 9, 12, 14, 15, 18, and 19). The other 2 interviews were conducted with relevant stakeholders providing an overview of mHealth in Vietnam. A total of 6 conference abstracts, which were not available publicly, were additionally provided by the mHealth initiative leaders [47-52].

### Stage, Continuity, and Funding

Five (Initiative #3, 5, 10, 12, and 19) out of the 20 initiatives were ongoing at the time of data collection, although one of these ongoing initiatives had already analyzed preliminary results (Initiative n#10). A total of 15 initiatives (Initiative #1, 2, 4, 6, 7, 8, 9, 11, 13, 14, 15, 16, 17, 18, and 20) were already completed.

Out of these 15 initiatives completed with their intended primary research and data collection period, 4 (Initiative #1, 9, 11, and 13) were continuing to use the materials, infrastructure, and technology created during their initiatives to engage with their end users at the time of our data collection. Two initiatives (Initiative #2 and 16) were not considered for continuity, as the goal was to examine feasibility and not to create sustainable initiatives. No information could be collected about the sustainability of 2 initiatives (Initiative #17 and 20), and the remaining 7 initiatives (Initiative #4, 6, 7, 8, 14, 15, and 18) were considered not continuing.

Two initiatives directly cited budgeting constraints and difficulties seeking out funding as a primary challenge (Initiative #9 and 18). A total of 4 initiatives stated failure to find funding as one of the primary causes for the initiative's discontinuation (Initiative #6, 14, 16, and 17).

A vast majority of initiatives (n=15) were funded by external donors (Initiative #2, 3, 4, 5, 7, 8, 9, 11, 12, 13, 16, 17, 18, 19, and 20). In all, 4 initiatives were self-funded (Initiative #6, 10, 14, 15), and one was government funded (Initiative #1).

### mHealth Services in Vietnam

On the basis of the 2015 International Telecommunication Union (ITU) categorizations of mHealth, a majority of the initiatives (n=12) had some component of prevention or raising awareness and encouraging participants to adopt healthier behaviors (Initiative #3, 4, 5, 6, 7, 8, 9, 11, 13, 15, 17, and 18). For example, one of the first initiatives carried out in Vietnam in 2010 piloted the use of SMS in order to increase general health education for ethnic minority populations. This initiative

reported an increase in self-reported positive health behaviors for the participants after the initiative, including adoption of safer sexual practices and quitting smoking (Initiative #7). Another initiative, carried out by the Hanoi University of Public Health, provided sexual and reproductive health services for female migrant workers via SMS and a free counseling hotline, which were demonstrated to increase women's health knowledge (Initiative #17). Similar to these 2 initiatives, other initiatives classified in the prevention domain attempted to prevent disease by using various mHealth technologies to facilitate the dissemination of health information.

Health practitioner support or intelligent decision support systems for diagnosis, treatment, information lookup, or information dissemination, was a component of 8 initiatives (Initiative #1, 2, 3, 5, 6, 11, 13, and 16). For example, 2 initiatives sent SMS with the aim of improving the health knowledge of health practitioners (Initiative #2 and 16); however, the one completed initiative did not show increases in health knowledge post intervention (Initiative #16). The Government of Vietnam (GVN) started an initiative to build capacity for provincial satellite hospitals across the country utilizing telemedicine technology (Initiative #1). Other initiatives facilitated case management for health practitioners by allowing them easier access to information such as immunization records via a Web application in real time (Initiative #11) and case management support via SMS notifications (Initiative #13).

To address challenges in maintaining continual and consistent care to patients, 4 initiatives assisted with treatment aiming to improve medical adherence (Initiative #3, 14, 19, and 20). These 4 initiatives targeted tuberculosis (TB) medication adherence (Initiative #3), general medical adherence (Initiative #14), and antiretroviral therapy adherence (Initiative #19 and 20).

In all, 2 initiatives assisted with monitoring, which includes identifying illnesses and tracking vital changes in health parameters (Initiative #9 and 10). One initiative piloted the use of a mobile electrocardiogram (ECG) to allow heart disease patients a method to monitor their heart's activity in real time outside of the hospital setting (Initiative #10). Another initiative conducted by the Center for Creative Initiatives in Health and Population developed a Web application for individuals with autism spectrum disorder (ASD), which has allowed parents to screen for ASD at an earlier phase and has used questionnaires for the parents to monitor the child's progress (Initiative #9).

Finally, 2 initiatives displayed components of health surveillance, or the timely collection or transmission of health-data to bridge gaps between the commune, district, provincial, and national levels (Initiative #4 and 11). For example, a disease surveillance mHealth initiative aimed to upgrade an antiquated paper-based tracking system to help provide the GVN timely infectious disease statistics (Initiative #4). An immunization registration system also allowed health managers at higher health care levels to generate reports and plan immunization campaigns, reporting to save the Vietnamese government money by improving the old paper-based system (Initiative #11).

## Disease Areas and Populations Targeted

A majority of the initiatives (n=11) targeted disease areas associated with vulnerable and hard-to-reach populations. Maternal and reproductive health was the primary target of 4 of the initiatives. The end users for 2 of these initiatives were female migrants (Initiative #6 and 17), and the other 2 were ethnic minority women (Initiative #12 and 13). While 2 more initiatives addressed women and their children, 1 focused on infectious disease (Initiative #11), and the other targeted early ASD screening and tracking (Initiative #9). A total of 4 initiatives aimed to support treatment and care of persons living with HIV, with one of the initiatives focusing on adolescents living with HIV (Initiative #19) and one targeting people living with HIV (Initiative #20), and the remaining 2 initiatives targeting key affected populations (Initiative #8 and 18). Finally, one initiative targeted a nonspecific disease area, but the target population was ethnic minorities (Initiative #7).

There were 6 initiatives that did not specifically target a particular disease area. As mentioned above, one initiative targeted ethnic minorities (Initiative #7), 2 targeted nonspecific populations (Initiative #14 and 15), while the remaining 3 initiatives targeted health care providers (Initiative #1, 2, and 16), which aimed to build the overall capacity of the health care system. Additionally, there were 2 initiatives that addressed heart disease, both aiming to target those with high heart disease risk (Initiative #5 and 10). The last 2 initiatives were related to TB, with the end users being TB patients (Initiative #3) and infectious disease, with the end users being health care practitioners (Initiative #4). Overall, the end users of the mHealth initiative for 4 initiatives were health care practitioners, while the primary end users for the other 16 initiatives were aiming to create solutions across the patient pathway.

## Provisioning Technology

A few mHealth initiatives integrated multiple components of technology into their initiative, with 5 initiatives using more than one type of provisioning technology (Initiative #7, 8, 14, 17, and 19). The most popular provisioning technology in Vietnam was SMS, with 14 initiatives using SMS in some form (Initiative #2, 3, 4, 5, 6, 7, 8, 11, 13, 14, 16, 17, 18, and 19). In all, 6 initiatives used a Web application (Initiative #2, 3, 5, 9, 11, and 18), and 5 initiatives integrated voice calling into their projects (Initiative #7, 8, 14, 17, and 19). Video telephony (Initiative #1), mobile projectors (Initiative #15), mobile ECG device (Initiative #10), flashing light and sound reminders from pill bottle (Initiative #19), mobile phone app (Initiative #20), and tablet app (Initiative #12) were each used in one of the initiatives.

## Vietnamese and Sociocultural Factors

Key informants from 6 initiatives cited high mobile phone penetration (Initiative #4, 5, 13, 14, 17, and 18) as a strength of mHealth utilization in the Vietnamese context, while 7 key informants indicated strong potential to reach vulnerable participants as a strength (Initiative #2, 3, 6, 9, 14, 16, and 17). For example, the Hanoi University of Public Health conducted an mHealth initiative capable of reaching vulnerable migrant workers outside of normal working hours (Initiative #17).

Multiple sociocultural factors challenged the initiatives. Key informants from 2 initiatives indicated that Vietnamese family structure and cell phone sharing practices prevented SMS from reaching the targeted individuals (Initiatives #13 and 16). One key informant noted participants are more willing to use mobile technology than face-to-face meetings for taboo topics (Initiative #17). However, another key informant noted the use of mobile technology made participants more worried of the disclosure of confidential information (Initiative #14).

Another challenge to mHealth in Vietnam pertains to the numerous languages and dialects. Interviewees stated many of the individuals with the worst health outcomes do not speak Vietnamese, causing challenges for the initiatives targeting these non-Vietnamese speaking populations. Two initiatives translated their initiative material to ethnic minority languages (Initiative #7 and 12). Key informants from 2 initiatives stated diacritic marks used in the Vietnamese language presented a challenge for initiatives utilizing SMS, as many phones cannot correctly format these diacritic marks (Initiative #13 and 16). Consequently, initiatives commonly neglected the diacritic marks, which one initiative stated caused challenges for some participants who had trouble reading the SMS (Initiative #13).

### Technological Factors

Interviewees noted the strengths of mHealth technology across multiple domains within the health care system. From a research perspective, 3 interviewees stated technological systems facilitated researchers in managing systems by capturing more and higher quality data (Initiative #6, 9, and 11). Interviewees stated they thought mHealth led to improved management of patients and customizability of treatment (Initiative #13 and 19). For example, a project sending informational SMSs to mothers provided customized information to their participants based on the mothers' current stage of motherhood (Initiative #13).

From a provider perspective, 3 initiatives noted that mHealth facilitated the tracking and management of patients, thereby saving man-hours in a human resource-deficient setting (Initiative #3, 15, and 18). However, one initiative pointed out mHealth may subsequently shift the burden of work from one human health resource to another. For example, an initiative aiming to distribute medical education texts to physician's assistants noted the educational texts had to be generated by 6 health students in the United States and later reviewed by the principal investigator, requiring a significant amount of time from highly educated staff (Initiative #16).

Lack of technological infrastructure and technological glitches challenged mHealth initiatives. One initiative encountered technical difficulties with their toll-free number as a result of lack of connectivity between different service providers (Initiative #11). Another initiative reported participants were not familiar using toll-free numbers, as users were worried they would be charged for the calls (Initiative #7). One mHealth initiative struggled to retain and follow participants through the mHealth intervention period due to the tendency of Vietnamese users to use multiple numbers to call and text as a result of the cheap promotional SIM cards available in Vietnam (Initiative

#17). Technological glitches were mentioned as a challenge for 3 initiatives (Initiative #2, 9, and 16).

### Collaboration Factors

Initiatives had difficulty finding the appropriate technological collaborators. One initiative mentioned difficulty finding a technological consultant appropriately meeting their requirements. As a result, this initiative had to work remotely with a technological team, which created communication challenges (Initiative #14). One initiative hired an out-of-house technological team, which led to delays, misunderstandings, and even errors due to language differences (Initiative #9).

In all, 4 initiatives cited governmental procedures and bureaucracy as a barrier to mHealth utilization (Initiative #2, 14, 15, and 19). Instead of directly approaching the national government, previous initiatives have primarily partnered with the local government in order to bypass the lengthier process required to work with the GVN (Initiative #13). In addition, 4 initiatives noted that it was crucial for project managers to build strong relationships with the GVN and advocate for their mHealth initiatives in order to increase the chances of sustainability (Initiative #4, 5, 11, and 13).

## Discussion

### Challenges to Future Implementation

Vietnam is becoming an increasingly technologically driven and connected society with approximately 1.3 mobile subscriptions per person. Even though many initiatives touted mobile phone penetration as an advantage of mHealth use in Vietnam, mobile penetration is only 65%, meaning a majority of the population owns multiple phone numbers, while 35% of the population does not own a cell phone [53]. While stakeholders believe mHealth may have the potential to reduce disparity in the Vietnamese health care system, there are still populations out of the reach of mHealth. While some initiatives cited high or low acceptability, few initiatives formally evaluated the end user acceptability.

Funding and sustainability are major barriers to future mHealth initiatives. Many of the interviewees reported financial challenges, and only 4 out of 15 completed initiatives were considered *continuing initiatives*. The high percentage of external funding will challenge future initiatives, as after external funds are utilized the technological systems built still need to be continually monitored and upgraded in accordance with the changing needs of the end users. Initiatives in Vietnam are dependent on monetary constraints. Finally, there is a lack of evidence on the sustainability of these initiatives outside of the intervention context, as many of the initiatives incentivize their participants to use the mobile technology.

Technologically, mHealth in Vietnam had similar strengths and weaknesses identified in reviews of mHealth utilization in other developing countries [16]. Technological infrastructure was a barrier for previous initiatives and will likely challenge future initiatives until sufficient infrastructure is constructed. Technological infrastructure is dependent on the initiative location. Many health clinics, particularly at the commune level, still do not have Internet connections or computers, which limits

the expansion of successful projects to locations with the capacity to support these initiatives. The Vietnamese system has yet to standardize data information, making it difficult for mHealth initiatives to integrate its data with the existing system. Therefore, previous initiatives have had to build their technological systems from the ground up. Another technological barrier not mentioned by interviewees was patient privacy and protection. While more mHealth initiatives in the world are moving toward SMS encryption for increased patient protection [54,55], Vietnamese initiatives did not mention cell phone and SMS encryption, which likely are still at their early stages of development in Vietnam.

Multiple initiatives indicated governmental procedures and bureaucracy were barriers to mHealth utilization. To date, the GVN has shown little intention to foster a legislative environment conducive to mHealth initiatives. In 2010, the prime minister approved an information technology Master Plan aiming to “transform Vietnam into an advanced ICT country by 2020” [56]. The GVN aims to improve infrastructure, human resources, and access related to information communication technology; the GVN has current plans to build a national eHealth architecture and data standards [42].

Despite these ambitions, there is currently still no information technology framework or electronic medical record standardization in Vietnam, which creates discontinuous care and difficulty for mHealth initiatives to connect to existing health data within the existing infrastructure. While this Master Plan gave a general framework for the advancement of eHealth in Vietnam, there is no current legislation relating to mHealth or data security, with the only related policy document having general statements about technical standards for government agencies and one line defining Web-based health activity [57-59].

Thus far, the GVN has focused their efforts on eHealth, or the use of information and communication technologies for health [60], on telemedicine, or the delivery of health care services using communication technology [61]. In 2013, the Ministry of Health passed a decision creating telemedicine networks aiming to train providers in more rural hospitals. As of 2017, the 3 largest telemedicine systems built in Vietnam are the Viet Duc Hospital with 6 satellites, Bach Mai Hospital with 9 satellites, and 108 Military Central Hospital with 8 satellites [62]. Other than this telemedicine initiative, the GVN has shown little support for mHealth initiatives through implementation of their own mHealth projects or through the funding of other projects.

The lack of support from the GVN can be understood, as there are competing health care priorities and lack of a strong mHealth evidence base. First, the GVN is challenged by an overburdened health care system, creating many competing health care priorities, which is the largest barrier to mHealth implementation worldwide [7]. An interview with an employee from the Department of Information Technology of the Ministry of Health stated the current focus for the near future is to write, regulate, and standardize medical records; GVN currently has a pilot project to standardize electronic clinical documents but no imminent plans to support mHealth. Second, the GVN likely

does not see any concrete evidence about the effectiveness of mHealth initiatives in Vietnam. Thus far, there is a lack of successful mHealth initiatives in Vietnam, with even the largest of projects failing to reach a scale-up phase due to lack of funding and support.

A lack in mHealth investment is likely part of the GVN's informal strategy of risk reduction, as they would prefer more rigorous evidence before investing time and money into the field. While some initiatives have attempted to publish results and engage with the GVN, most initiatives have not prioritized information dissemination, as evidenced by the lack of published mHealth results in Vietnam. To date, mHealth initiatives in Vietnam are sporadic and disjointed. There are no current mHealth networks, workshops, or conferences where mHealth stakeholders may share best practices. To the best of our knowledge, the only educational institution working on training individuals for the future of eHealth and mHealth in Vietnam is the Hanoi University of Public Health, which offers an option for students to receive a bachelor's degree in public health with a specialization in Health Informatics.

### Future Opportunities

While the government has not actively promoted the use of mHealth initiatives, the GVN is not inherently opposed to mHealth utilization. The government seems to be willing to engage with mHealth initiatives, evidenced by the GVN's previous participation in advisory committees, result dissemination conferences, and examination of previous initiative results. In order to encourage governmental involvement, initiatives must share their results with each other and the GVN, which may encourage the GVN to fund the scale-up of current initiatives.

As technological infrastructure builds, the Vietnamese health care system improves, and prices for these technologies continue to decrease, the GVN might turn more of its attention to mHealth initiatives. In addition, the GVN has consistently supported telemedicine projects. In the future, to ensure the sustainability of mHealth initiatives in Vietnam, more projects must be catalyzed from within the government and from local organizations, as opposed to foreign donors.

Collaboration was an important aspect of mHealth initiatives. Some initiatives were able to bring together expertise from diverse fields. A byproduct of having diverse actors with expertise in different fields was the potential for capacity improvement, especially for the locations that the initiatives piloted their projects. Even if the initiative was not sustained for a long period of time, the intervention period often introduced new resources to the local community. In future, it will be important to maintain collaboration between diverse actors.

Finally, there has already been evidence of mHealth initiatives in Vietnam adopting alternative financing models. For example, one study examined the feasibility and willingness-to-pay for an mHealth-based antiretroviral adherence support system, finding patients who would be willing to pay for these services [63]. Other previous initiatives have attempted to make businesses out of their mobile technology, hoping to raise capital

in order to create a sustainable initiative. While current mHealth initiatives have already demonstrated promising opportunities for alternative models of funding, such as social entrepreneurship or private business models, there have yet to be sustainable mHealth initiatives outside of those funded by external donors. As technology improves and evidence increases, there will be many more opportunities for smaller organizations to thrive in the rapidly growing Vietnamese health care system.

### Limitations

Our study has several limitations. Information analyzed in this study was limited to the information available to the authors. There were initiatives that we were unable to obtain information about, and there were likely smaller initiatives that were not discovered by our search methodology. As we were in the process of writing and revising the paper, new initiatives started, and more results were likely published after our primary data collection period. The openness and accessibility of key informants differed, and the qualitative results were based on opinions of key informants. Finally, the methodology used cannot provide results about mHealth's acceptability or ability to provision higher quality care in Vietnam.

### Conclusions

These results provide important insights that are unique to Vietnam but have broad implications for mHealth worldwide. Our findings suggest the largest advantage of mHealth in Vietnam is its ability to reach hard-to-reach populations and vulnerable groups. On the other hand, mHealth implementation in Vietnam has been challenged by factors including diacritic marks in the Vietnamese language, a significant portion (35%) of the total population lacking cell phone ownership, sociocultural factors relating to privacy, and lack of technological infrastructure. Looking toward the future, the biggest threats to mHealth in Vietnam are related to the absence of government policy, uncertainty of government support, and heavy dependence on foreign funding. In conclusion, while current mHealth initiatives have already demonstrated promising opportunities for alternative models of funding, such as social entrepreneurship or private business models, sustainable mHealth initiatives outside of those funded by external donors are yet to be undertaken. mHealth is an emerging field in Vietnam and should be more rigorously studied in order to examine its effectiveness and guide future mHealth initiatives.

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### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Initiative summaries.

[[XLSX File \(Microsoft Excel File\), 55KB - mhealth\\_v6i4e106\\_app1.xlsx](#)]

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## Abbreviations

**ASD:** autism spectrum disorder

**ECG:** electrocardiogram

**GVN:** Government of Vietnam

**SMS:** short message service

**TB:** tuberculosis

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Original Paper

# Development of Whole Slide Imaging on Smartphones and Evaluation With ThinPrep Cytology Test Samples: Follow-Up Study

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## Abstract

**Background:** The smartphone-based whole slide imaging (WSI) system represents a low-cost and effective alternative to automatic scanners for telepathology. In a previous study, the development of one such solution, named scalable whole slide imaging (sWSI), was presented and analyzed. A clinical evaluation of its iOS version with 100 frozen section samples verified the diagnosis-readiness of the produced virtual slides.

**Objective:** The first aim of this study was to delve into the quantifying issues encountered in the development of an Android version. It should also provide insights into future high-resolution real-time feedback medical imaging apps on Android and invoke the awareness of smartphone manufacturers for collaboration. The second aim of this study was to further verify the clinical value of sWSI with cytology samples. This type is different from the frozen section samples in that they require finer detail on the cellular level.

**Methods:** During sWSI development on Android, it was discovered that many models do not support uncompressed camera pixel data with sufficient resolution and full field of view. The proportion of models supporting the optimal format was estimated in a test on 200 mainstream Android models. Other factors, including slower processing speed and camera preview freezing, also led to inferior performance of sWSI on Android compared with the iOS version. The processing speed was mostly determined by the central processing unit frequency in theory, and the relationship was investigated in the 200-model simulation experiment with physical devices. The camera preview freezing was caused by the lag between triggering photo capture and resuming preview. In the clinical evaluation, 100 ThinPrep cytology test samples covering 6 diseases were scanned with sWSI and compared against the ground truth of optical microscopy.

**Results:** Among the tested Android models, only 3.0% (6/200) provided an optimal data format, meeting all criteria of quality and efficiency. The image-processing speed demonstrated a positive relationship with the central processing unit frequency but to a smaller degree than expected and was highly model-dependent. The virtual slides produced by sWSI on Android and iOS of ThinPrep cytology test samples achieved similar high quality. Using optical microscopy as the ground truth, pathologists made a correct diagnosis on 87.5% (175/200) of the cases with sWSI virtual slides. Depending on the sWSI version and the pathologist in charge, the kappa value varied between .70 and .82. All participating pathologists considered the quality of the sWSI virtual slides in the experiment to be adequate for routine usage.

**Conclusions:** Limited by hardware and operating system support, the performance of sWSI on mainstream Android smartphones did not fully match the iOS version. However, in practice, this difference was not significant, and both were adequate for digitizing most of the sample types for telepathology consultation.

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## KEYWORDS

mobile health; image processing; cloud computing; whole slide imaging

## Introduction

With the data quality and speed improvements of automated microscopes and whole slide scanners [1,2], telepathology has become a major component in pathology labs [3,4]. Providing remote interpretation of digitized microscopic images and virtual whole slides, it allows diagnosis without physical transportation of samples but just data transfer over the internet. Telepathology not only greatly reduces the financial and time cost but also improves the availability and accessibility of priceless expert resources [5,6].

The reliability and practical value of virtual slides compared with the traditional glass version have been extensively assessed and recognized [7-9]. However, the high financial cost of whole slide imaging (WSI) solutions, and especially the up-front portion, has not seen a significant reduction after years of maturity, limiting its penetration into developing countries and regions or remote hospitals in the developed world [10-12]. As supplements for these situations, where limited manual operating is preferred over expensive automation, manual and low-cost alternatives of automated WSI have been studied and developed [13,14].

Ideally, utilizing tools that have been previously available to pathologists would reduce the cost of accessing WSI to its lowest and not require much operational training. Previously, we reported the development and clinical evaluation with frozen section samples of one such solution named scalable whole slide imaging (sWSI), a WSI system on smartphones [15]. With a mainstream smartphone mounted on the eyepiece of any optical microscope, a pathologist can scan the whole slide into a virtual copy by simply operating the microscope following this normal examination procedure. The image quality, based on the clinical evaluation results, is considered on par with high-end whole slide scanners for most tissue types, as assessed by senior pathologists, and its speed has been proven to be adequate for general applications.

However, the potential and assessment of smartphone-powered WSI has not yet been fully explored. On the one hand, the previous clinical evaluation was limited to working with the cryosection. Little evidence and discussion exists on the challenge of manually scanning frozen section samples compared with other types, although they have been considered among the most difficult for automatic scanners due to the unevenness and folding. On the other hand, during approximately 10 months of a public beta test in China, less than 10% of the approximately 2000 sWSI users selected the previously reported iOS version, reflecting Android's dominance in developing markets and the practical value of sWSI on

Android. This version, which possessed very different hardware and software configurations compared with the iOS one, is worth its own discussion and evaluation.

Cytology, the branch of pathology that studies and diagnoses diseases on the cellular level [16], introduces different types of challenges in the digitization revolution compared with its sister area of histopathology, which studies tissues and commonly employs cryosections for sample preparation [17-19]. Because cells are obviously smaller than the tissues that they compose, higher magnification power is required for their examination [20-23]. Consequently, the obstacles in scanning cytology samples through microscopes with smartphones include a stricter requirement of image quality, more frequent adjustment of the z-axis for focus, and varied image patterns. These characteristics make cytology samples a good test bench for a follow-up study of the clinical performance of sWSI.

In this paper, the development of sWSI on Android is reported, following up on the previous research and development of its simpler iOS version. The discussion and tests focused on camera data format optimization and factors limiting processing speed and user experience, particularly the effect of theoretical central processing unit (CPU) performance on processing speed. Emerging from model-specific hardware and firmware characteristics, and varying greatly among the hundreds of main-stream Android models, these issues can be common in developing medical imaging apps on Android with high image resolution, heavy computation, and real-time feedback. They are likely on an unavoidable path to the future of mobile health care, which is extending into image-based and artificial intelligence-powered apps. These results and discussion may provide future developers with precaution and guidance and draw the attention of hardware manufactures. On the clinical side, a follow-up clinical evaluation of sWSI scanning the ThinPrep Papanicolaou test samples was conducted and reported.

## Methods

### Review of the System Architecture, Core Algorithms, and Evaluation Results of Scalable Whole Slide Imaging on iOS

The sWSI solution is designed to provide affordable whole slide scanning service by leveraging existing optical microscopes with computer vision algorithms and universal availability of smartphones. The physical setup involves installing smartphones onto microscopes and aligning the cameras with the eyepieces, such as the one with a 3D-printed adaptor (demonstrated in [Figure 1](#)). During a scan, the user manually operates the microscope, whereas the sWSI app utilizes the image capturing

functionality and just-enough computing power of smartphones to capture high-resolution images, process with approximation, and give smooth real-time feedback. Most of the computation burden is transferred to high-performance remote servers asynchronously, and the gigapixel virtual slides can be viewed with internet browsers, similar to digital maps. The simplified sWSI solution structure is illustrated in Figure 2.

There are 3 major algorithms that are designed to implement this 2-stage distributed computation model. First, an algorithm based on Speeded Up Robust Features key point detection and matching [24] tracks the location of the current field of view by stitching it with the last one to obtain and accumulate the relative movement. This is performed with down-sampled images to trade spatial accuracy for temporal efficiency. Second, the high-resolution field of views are transferred to cloud servers and restitched at full resolution for maximal accuracy. The stitching parameters of the down-sampled copies are then used

to ensure restitching success. Finally, the highly nonlinear distortions introduced by smartphone camera lenses are corrected on-the-fly by solving a high-order polynomial model and projecting the images reversely. The model parameters are estimated from the matched key point pairs.

In the previous clinical evaluation, 100 frozen section slides were scanned with 20× objectives into virtual slides with sWSI on iOS, and examined by pathologists of the Pathology Center, Shanghai General Hospital/Faculty of Basic Medicine at the School of Medicine of Shanghai Jiao Tong University (SJTU-SMPC). The respective sample-wise diagnostic accuracies, using optical microscopy diagnosis by senior pathologists as the ground truth, were .78, .88, .68, and .50 for breast, uterine corpus, thyroid, and lung samples, respectively. The overall image quality is regarded by participating pathologists as generally on par with high-end scanners and not affecting diagnosis in most cases.

Figure 1. Typical hardware setup (left) and user interface (right).

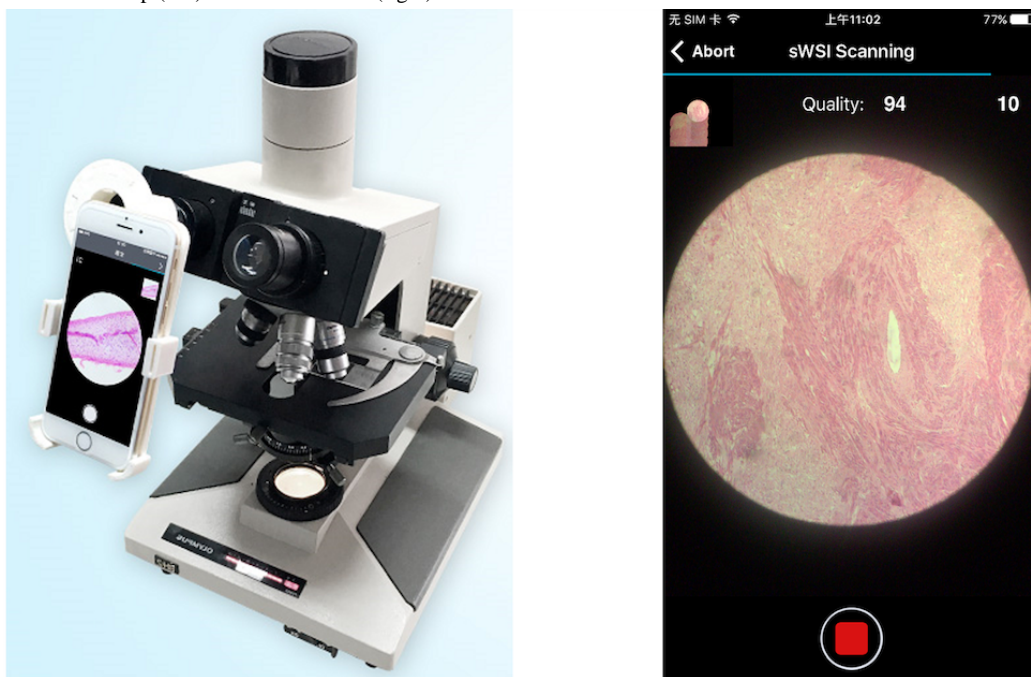
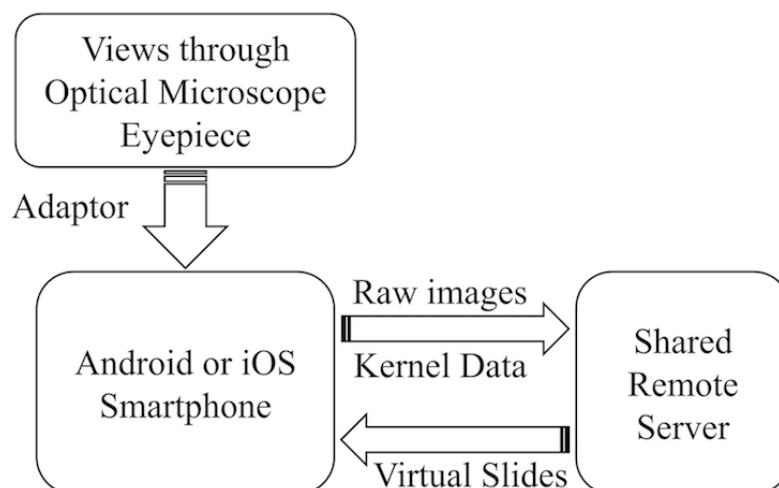
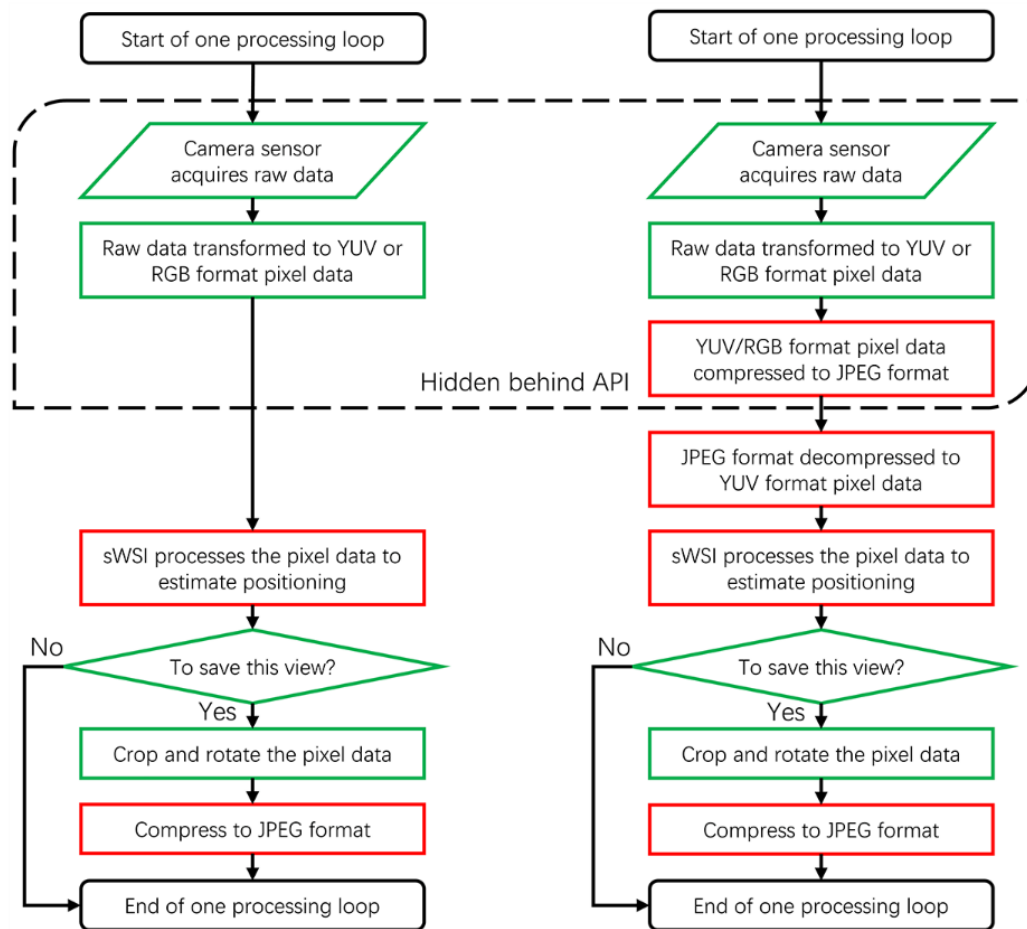


Figure 2. Simplified scalable whole slide imaging solution structure.



**Figure 3.** Image capturing and processing workflow on iOS (left) and Android (right). Computation-heavy steps are marked in red and lighter steps are marked in green.



### Optimizing Camera Data Format for High-Resolution Imaging on Android

In contrast to the proprietary iOS system on iPhones, Android is an open-source operating system that can not only be modified to a great extent but also operate on a wide variety of hardware beyond smartphones. On the positive side, this leads to a far greater number of smartphone models running Android differing in hardware specifications. Some models have retail prices of less than US \$100, yet they are theoretically capable of running the same software apps on the flagship gadgets. This diversity greatly extends the user base of smartphones, specifically in developing countries, paving the way for the worldwide delivery of eHealth services.

On the negative side, the diversity posts significant design and engineering challenges, leading to higher development costs and occasionally limiting functionality. On the Android platform, the software apps need to adapt to the operating system environment and functionality at runtime. The large Android operating system family follows baseline specifications as defined by each version of Android software development kit, and they can have very different implementations and characteristics. In addition, manufacturers may keep the most efficient but private application programming interfaces to be only accessible to software that are bundled with operating systems to lock customers into their service ecosystem.

As a hardware- and firmware-dependent component, camera drivers in Android are implemented in native code and are only indirectly accessible dynamically via public application programming interfaces. As opposed to the iOS system, where all predefined data formats are usable, Android requires a determination of their availability at runtime. As of Android software development kit version 25, the only mandated implementation of data format for photo capturing is JPEG, a compressed and not directly processable format. Because sWSI requires real-time processing of each captured view to track the positioning and provides instant feedback to users, being forced to process such a compressed data format leads to additional computationally expensive compression-decompression steps in the workflow and dramatically increases overhead, as demonstrated in Figure 3.

One intuitive alternative is to confirm whether the operating system offers pixel data in YUV or red-green-blue (RGB) format, which can be directly processed, in order to select a shorter workflow similar to iOS. Unfortunately, among the 200 popular Android models tested during the development, few models support this approach, and the issue falls into one of the following 3 categories. In the first group, alternative formats are denied outright on some models. Among the second group, direct pixel data formats are provided but only with inadequate resolution [24]. Finally, where sufficiently high resolution is available, the images are often trimmed down horizontally to

an aspect ratio of 16:9 compared with the standard 16:12 ratio, most likely intended for recording high-definition video only. For capturing photos, this would significantly restrict the field of view by up to 25% (see [Multimedia Appendix 1](#))

Even among the remaining few that are usable, data structures often lack standardization. Specifically, the byte array of pixel data often has padding structures whose specification is not accessible in a standard application programming interface. For example, assume a small image with a resolution of 4 pixels in width by 4 pixels in height. Representing this image in YUV 4:2:0 format with an 8-bit quantization would yield the byte-array structure as demonstrated in [Figure 2](#), where  $Y_{ij}$  is the Y component of pixel  $(i,j)$ ,  $U_{ij}$  and  $V_{ij}$  are respectively the U and V components shared by pixel  $(i,j)$ ,  $(i+1,j)$ ,  $(i,j+1)$ ,  $(i+1,j+1)$ . There is one Y component byte for each pixel and a pair of U and V components for each set of 4 adjacent pixels; thus, there are  $4 \times 4$ , that is, 16 bytes for the Y-plane followed by  $4 \times 4 / 4$ , that is, 4 bytes for the UV-plane. However, on some phone models, several bytes are padded to the end of each row, column, or plane of pixels, mostly likely for a better efficiency of image compression, such as making the padded width and height multiples of 16 in JPEG. However, whether the byte array structure is padded into this multiple of 16 or not can be determined by calculation and validated by the fact that all padded bytes are 0s. This approach is guaranteed by any official documents. Considering that only 1 out of the 20 Android models used during development fits this category, the released sWSI app for Android supports the universal, but inefficient, JPEG format for image capturing.

### Considerations on Developing Medical Imaging Apps on Android With Heavy Computation

The diagnostic utility of real-time medical imaging apps such as sWSI is dependent primarily on image quality, which has been widely proven across apps in different medical branches and smartphone models [25-27]. From a practical perspective, user experience, and particularly user-perceived rate of data throughput is rarely emphasized. This is a trivial issue in static imaging or video recording, such as for teledermoscopy or ophthalmoscopy, but has emerged with great significance in sWSI and likely in future apps with heavy real-time computation.

On the basis of the feedback from clinical users of sWSI on Android, we found that there are 2 ways in which the user-perceived smoothness is impaired. On the one hand, there can be frequent freezing of the user interface or a constantly low refresh rate of the camera preview. On the other hand, some phone models suffer from a low update rate of the mini-map of scanned areas and an inability to keep up with faster movement of view. Apart from the image format-related driver issue discussed above, there are other factors that may have contributed to the great variance in operating smoothness, namely, the nondata characteristics of the camera driver and the processing unit.

Depending on hardware design and firmware implementation beyond the scope of this paper, camera drivers on Android smartphones significantly differ from each other in photo

capturing overhead and lag. Here, we define the overhead as the time lapse between programmatically triggering the capture and receiving the image data. This adds delay to the whole processing loop, thereby reducing the throughput and update rate. The lag is defined as the lapse between the same trigger and when the camera preview unfreezes, as determined through a high-speed camera, with the overhead subtracted. It is out of the processing loop, but freezes the camera preview, causing no difference in speed but negatively affects the user experience. In extreme cases where processing time is as short as the lag, the preview would be permanently frozen.

The processing unit, particularly the main powerhouse of the CPU, intuitively has a strong effect on computation-hungry apps, such as sWSI. In practice, the case is very different from that for desktop computers due to the restriction on power supply and heat dissipation for mobile computing. Although the number of CPU cores ranges from 2 to 8 or more and the max CPU frequency from approximately 1.3 GHz to over 2.4 GHz, the sustainable performance for heavy computing varies far less dramatically. The increase in the number of cores is mostly intended to match computing power with dynamic workload by supporting high-frequency, power-draining cores with low-frequency, energy-saving ones. For the same reason, the boosted clock rate is similarly intended for short intervals only. Simultaneous activation of multiple cores at a high clock rate, although feasible, not only swiftly drains the battery life but also quickly leads to overheating, which forces the cores to slow down or even go offline in minutes. Ideally, spreading calculation into multiple cores at a lower frequency can be more efficient but requires system-level management, which is beyond the reach of third-party apps. As a result, sWSI on Android is optimized on single-threaded computation, and its evaluation includes the impact of max CPU single-core frequency on throughput.

### Technical Evaluation Setup

To verify the pervasiveness of the camera data format issue and CPU frequency's impact on the processing speed of sWSI, tests were performed on 200 Android smartphones of popular models marketed after 2014. These physical devices were rented through Web-based testing platforms, such as TencentUTest (Dalian SJKP Technology Co. Ltd.), Testin.cn (Testin Information Technology Co. Ltd.), and Baidu MTC (Baidu Inc.), with 10% duplicates between platforms to check for consistency. A specific version of sWSI for Android with images for simulation is uploaded onto the devices, with logs recorded for measurement. Each test run starts with collecting available image formats and the size of the captured photo, if the raw pixel data format is supported. Next, it is kept running undisrupted for 10 min using the normal processing procedure, except that the captured photo data is replaced with looping simulation dataset. In the last minute, the average processing time of each view, excluding capture overhead, is recorded for comparison. This workflow is illustrated (see figures in [Multimedia Appendix 1](#)). The test process is repeated 3 times for each model, and the average is recorded.

## Clinical Evaluation Setup

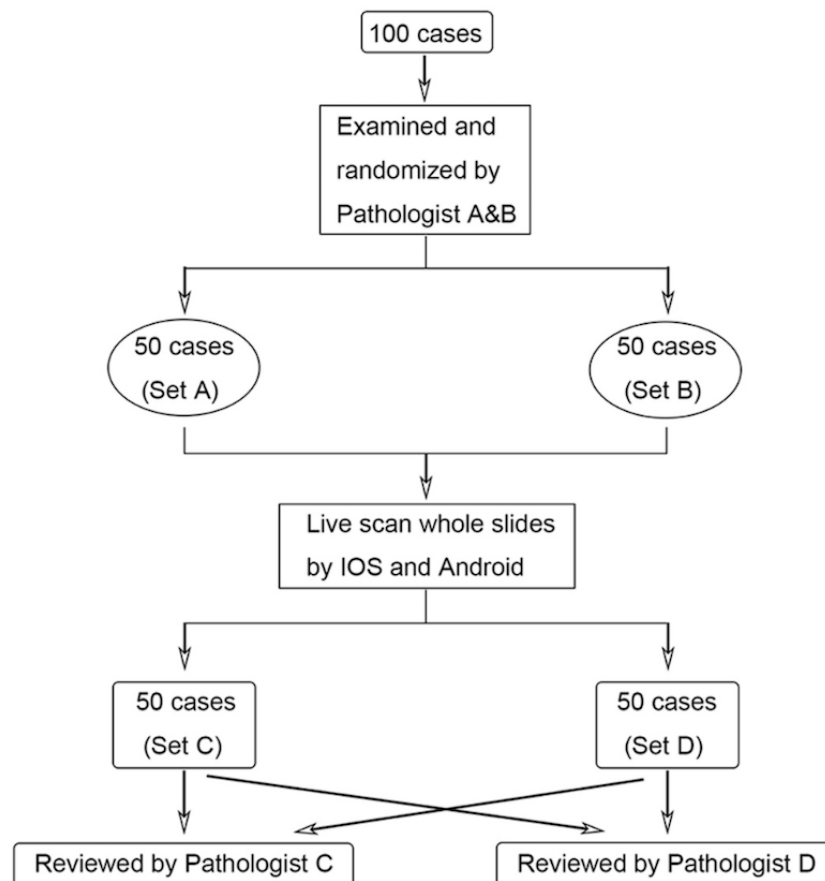
To assess the diagnosis-readiness of virtual slides produced by both sWSI on iOS and Android in challenging cases, a clinical evaluation experiment was performed in the SJTU-SMPC from August 10 to September 3, 2017. A total of 100 TCT slides collected from SJTU-SMPC between January 1 and April 1, 2017 covering one of the 6 disease categories or the normal category, were randomly selected, as listed with proportions as shown in figures in [Multimedia Appendix 1](#). These slides were prepared routinely by technicians in the department and may have issues such as unevenness and folding that are common for TCT. Examination with optical microscopy was used as the ground truth, and the sample set was split evenly into 2 groups and scanned with sWSI on Android and iOS, as summarized in [Figure 4](#). The 2 iOS devices (iPhone 6 and iPhone 7) and the 2 Android handsets (HUAWEI mate8 and XIAOMI 5s) deployed in the experiment were purchased from the second-hand market with prices varying between US \$120 and US \$200. Three low-end bio-microscopes—an Olympus BH2-BHS, an Olympus CX21, and a Phoenix PH50-1B43L-PL—were employed for sWSI scanning, whereas a high-end Olympus BX51 was used for optical microscopy. Pathologists A, B, and D were all senior faculties from SJTU-SMPC, and pathologist C was a grade II

trainee. The sWSI virtual slides were examined with a webpage-based pan-and-zoom tool on regular computer monitors without special color calibration.

The statistical metrics used in the study included accuracy, sensitivity, specificity, and Cohen's kappa coefficient (kappa). [28,29]. Accuracy was defined as the percentage of correctly classified patients. Sensitivity and specificity were defined as the proportion of people who truly have a designated disease or were truly free of a designated disease and were thus identified by the test, respectively. Cohen's kappa statistic quantifies the intermodality agreement into a single metric between 0.00 of no correlation and 1.00 of perfect match. In this study, the degree of agreement between diagnosis using conventional light microscopy and sWSI virtual slides was measured. All 4 measurements can be calculated using sample counts obtained by comparing the diagnosis to a gold standard, as with a  $2 \times 2$  contingency table demonstrated in [Table 1](#) and the formula in figures in [Multimedia Appendix 1](#).

As a sideline study, 15 of the samples were scanned with Aperio AT2, a high-end scanner from Leica, to offer a direct comparison of image quality with sWSI. These virtual slides were not examined for accuracy.

**Figure 4.** Clinical Evaluation Procedure of scalable whole slide imaging with ThinPrep cytology test samples.



**Table 1.** Assessment of diagnostic tests using 2 × 2 contingency table. sWSI: scalable whole slide imaging.

Gold standard	Positive (microscopes)	Negative (microscopes)	Total
Positive (sWSI)	True positive count: a	False positive count: b	a+b
Negative (sWSI)	False negative count: c	True negative count: d	c+d
Total	a+c	b+d	a+b+c+d

## Results

### Pixel Data Format Support on Android

The distribution of the tested Android model belonging to each camera data format issue category discussed is illustrated in figures in [Multimedia Appendix 1](#). Statistically, only 3.0% (6/200) of the models met the standard of efficient high-resolution image capturing as supporting pixel data format.

- With resolution at least 1500 × 2000 pixels.
- Without trimming on the sides.
- Without padding or mismatch in the data sizes between the captured photos and that indicated by general definition.

Thus, 97.0% (194/200) of Android models would require approximately additional 100 ms time to process each high-resolution, full field of view photo captured due to unnecessary encoding or decoding caused by photo data format capability issue compared with iOS handsets. For cases requiring real-time reaction based on the processing feedback, this may introduce a significant lag as complained by many users of sWSI on Android.

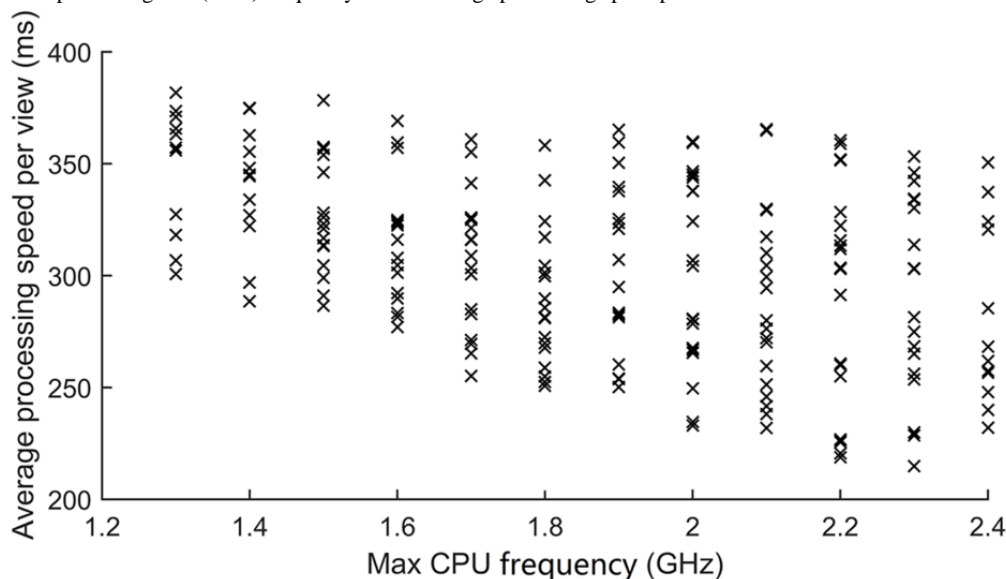
### Max Central Processing Unit Frequency Versus Scalable Whole Slide Imaging Processing Time

[Figure 5](#) illustrates the average processing time per view on different phone models grouped into their theoretical max CPU frequency. As expected, a higher CPU frequency led to a faster processing speed, but the actual gain was more likely model-dependent, and cases where devices with a lower clock rate outperformed their theoretically faster counterpart were not rare. This is likely caused directly by the decrease in core frequency due to overheating after prolonged heavy computation, as observed in the limited number of models used in development. Fundamentally, the semiconductor device fabrication nodes determining heat production, the physical size of the device, and the industrial design of the internal structure may all contribute to this result, but they are purely matters of hardware, and deeper analysis is beyond the scope of this study.

### Diagnostic Concordance

Comparing telepathological diagnosis with the sWSI virtual slides and with optical microscopy, .70 and .82 kappa was respectively achieved by pathologists C and D. The scanning time per case averaged less than 20 min. The Acc, Sen, and Spe of each pathologist are illustrated in figures in [Multimedia Appendix 1](#), and the overall results are summarized in [Table 2](#). Importantly, significant variation in lesion recognition is commonly expected between different reviewers.

**Figure 5.** Max central processing unit (CPU) frequency versus average processing speed per view.



**Table 2.** Diagnosis concordance between those based on scalable whole slide imaging virtual slides and optical microscopy.

Disease	Observer							
	Pathologist C				Pathologist D			
	Accuracy	Sensitivity	Specificity	kappa <sup>a</sup>	Accuracy	Sensitivity	Specificity	kappa
High-grade squamous intraepithelial lesion	.83	.62	.80	.66	.91	.77	.91	.72
Low grade squamous intraepithelial lesion	.80	.54	.82	.56	.85	.69	.86	.70
Human papillomavirus	.89	.71	.92	.76	.95	.88	.94	.89
Atypical squamous cells of undetermined significance	.76	.63	.50	.51	.84	.75	.94	.67
Mycete	.82	.67	.67	.64	.96	.83	1.00	.90
Malignant melanoma	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Normal	.82	.82	.66	.76	.94	.92	.90	.87
Average	.85	.71	.77	.70	.92	.83	.93	.82

<sup>a</sup>Cohen's kappa quantifies the intermodality agreement into a single metric between 0.00 (no correlation) and 1.00 (perfect match).

From a retrospective examination by the diagnosticians, the discrepancies in measurements should be primarily attributed to undercalled diagnoses with digital images. The most common mismatches noted in all data were between atypical squamous cells of undetermined significance or high-grade squamous intraepithelial lesions and low-grade squamous intraepithelial lesion, which may indicate poor reproducibility of the recognition of koilocytosis or koilocytotic atypia, followed by the discrepancy between low-grade squamous intraepithelial lesions and high-grade squamous intraepithelial lesions, suggesting a difficulty in the recognition of varying levels of cellular atypia. For example, in case 8, pathologist C and D examining sWSI virtual slides of atypical squamous cells were unable to exclude high-grade squamous intraepithelial lesion, whereas the glass-slide-based diagnosis was performed on a high-grade squamous intraepithelial lesion. Similarly, in case 2, the conventional glass-slide diagnosis was a high-grade squamous intraepithelial lesion, whereas one of the pathologists' interpretation was atypical squamous cells from which high-grade squamous intraepithelial lesion cannot be excluded on either digital virtual slides, and another pathologist's diagnosis with the Aperio system was low-grade squamous intraepithelial lesion.

The diagnosis statistics with Android and iOS smartphones are summarized in [Table 3](#) (see figures in [Multimedia Appendix 1](#)). The respective accuracies are both 0.84 for pathologist C and between 0.89 and 0.92 for pathologist D. The average kappa is .7 for Android and .72 for iOS version of sWSI. These results indicated that the reliability of diagnosis made with virtual slides scanned by Android and iOS devices were both satisfying and not significantly distinguishable.

### Scalable Whole Slide Imaging Versus Aperio AT2

Among the 15 cases scanned by both sWSI and Aperio AT2, 2 were recognized as improperly prepared, with one blurred and the other incomplete. With the scanner, case #38 was deemed not scannable, and case #66 was seriously blurred. By checking the glass slide, it was found that 2 coverslips were placed on top of case #66, and likely confused the scanner's autofocus. The same problem was avoided by manual sWSI scan (see figures in [Multimedia Appendix 1](#)). Although scanning with sWSI at lower magnification yields a lower resolution ([Figure 6](#)), compared with the scanner, the high magnification static field of views produced subjectively similar or better quality. [Figures 7](#) and [8](#) show one such comparison with 40× magnification.

**Table 3.** Diagnosis concordance between scalable whole slide imaging (sWSI) based on Android or iOS and optical microscopy.

Observer	Android				iOS			
	Accuracy	Sensitivity	Specificity	kappa <sup>a</sup>	Accuracy	Sensitivity	Specificity	kappa
Pathologist C	.84	.67	.76	.55	.84	.71	.74	.66
Pathologist D	.92	.86	.89	.84	.89	.78	.84	.78
Average	.88	.77	.83	.70	.87	.75	.79	.72

<sup>a</sup>Cohen's kappa quantifies the intermodality agreement into a single metric between 0.00 (no correlation) and 1.00 (perfect match).



Figure 6. Cases no. 57 (left), no. 76 (center), and no. 98 (right).

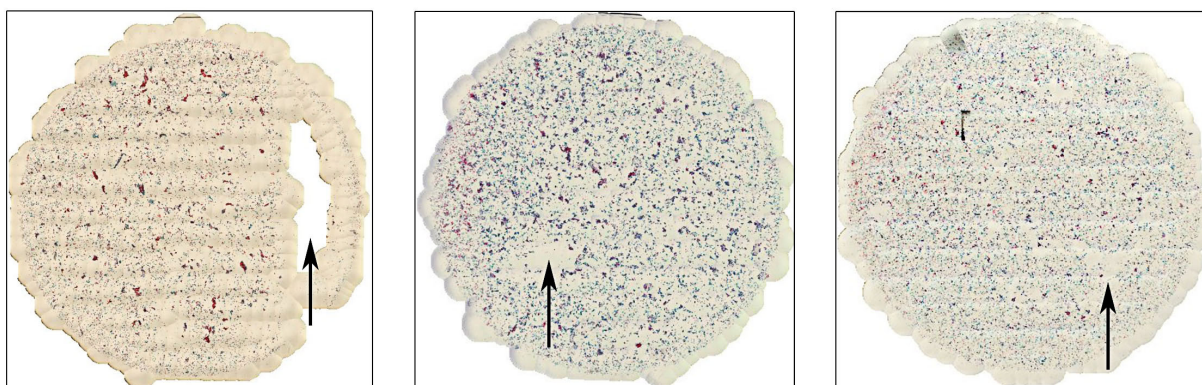
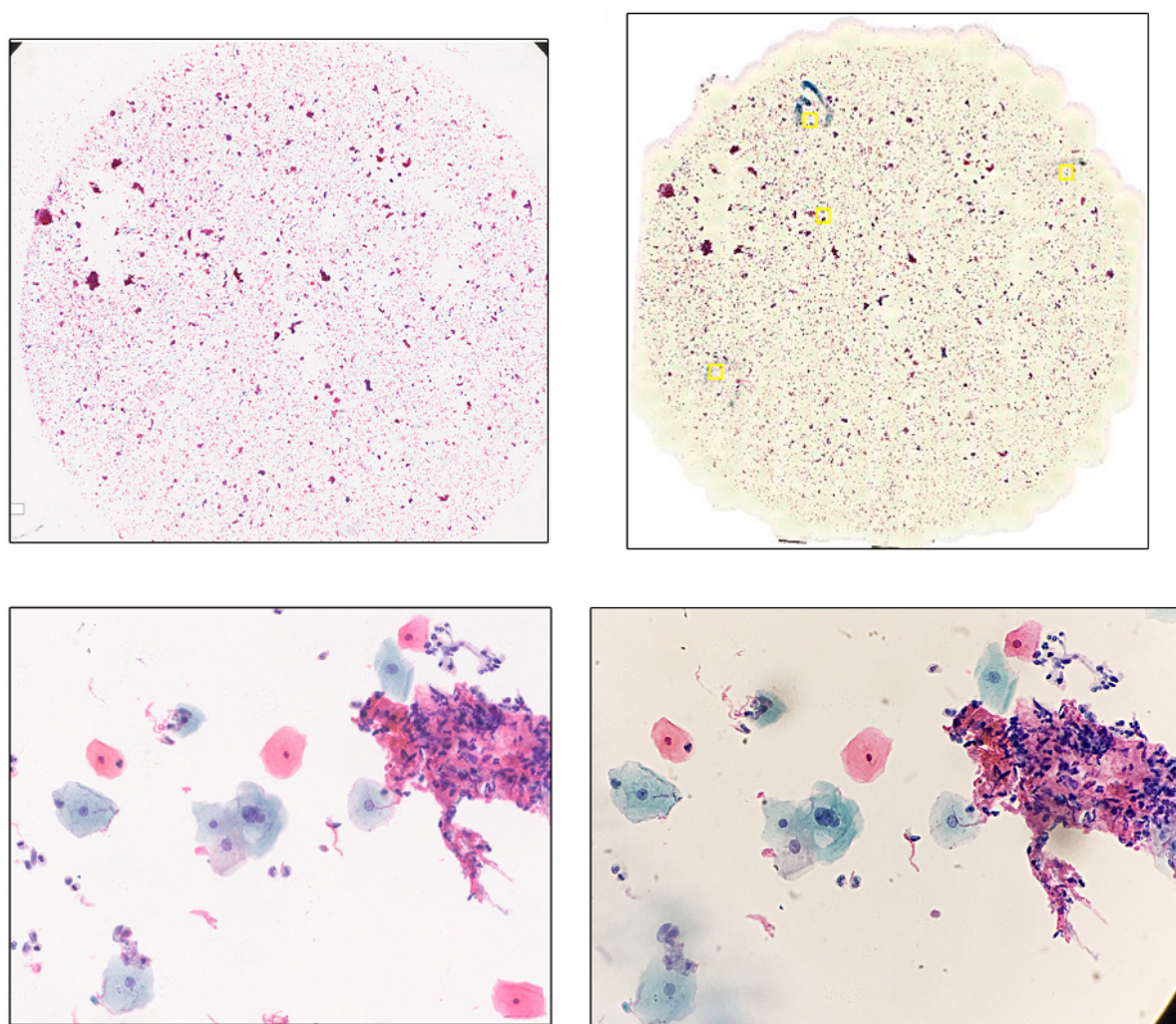
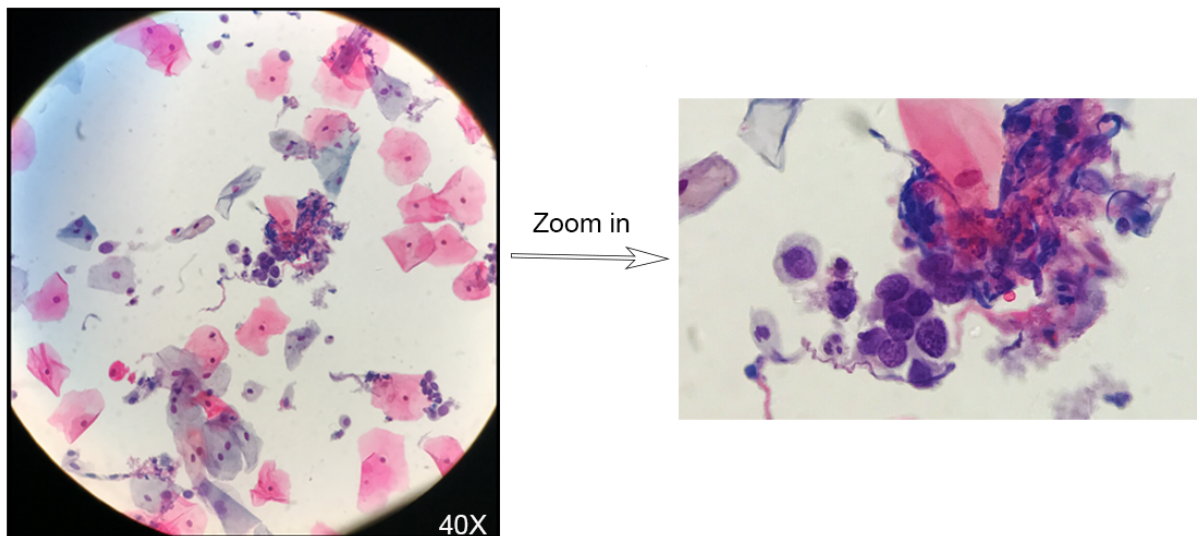


Figure 7. Case no. 35, the virtual slides (two on the top) and zoom-in regions (two on the bottom) from scalable whole slide imaging (sWSI) (two on the right) with good quality, compared with those from the Leica scanner (two on the left).



**Figure 8.** Typical views captured by a high-end whole slide scanner (right) versus a static view captured by scalable whole slide imaging (left), 40× magnification.



## Discussion

### Current Limitations

Although the sWSI solution is clinically recognized by pathologists and achieves its goal of trading full automation for saving financial cost by multiple orders, it suffers from a few technical weaknesses. Many weaknesses are caused by the inherent data model of the image stitching and distortion correction algorithm and thus may not be resolved with further development without switching to a different kernel. Others may be addressed in studies in the near future.

First, an underqualified sample preparation may limit the sWSI's spatial coverage of samples. Specifically, uneven cell distributions and densities might cause TCT slides to be partially unscannable, such as the blank region of case #57 to the right of the image as shown in Figure 6. This may be caused by having too few cells located nearby, whereas a typical distribution would approximate those in Figure 6. In these cases, the image stitching algorithm determines that few reliable key points can be used for tracking, thus denying the views. This may lead to a loss of information in these cells and, consequently, inaccurate data analysis or diagnosis.

Second, the diagnosis error introduced by reviewer bias may have underrated the quality of the sWSI virtual slides. On the one hand, both reviewers of sWSI virtual slides rarely examined digital virtual slides in routine work and complained about the different perspectives between optical and virtual microscopy. On the other hand, it is widely known that the thresholds of judging ambiguous cases vary among pathologists. In retrospect, pathologists participating in the experiment indicated multiple cases with such ambiguity. However, standardization of diagnosis criteria can be difficult to establish, as decisions are currently rarely based on quantitative measurements.

Finally, although a majority of sWSI virtual slides show no significant difference in comparison with those produced by a high-end scanner (Figure 7), there are a few in which the sWSI

virtual slides contained obvious misalignment of separate views and uneven brightness (Figure 6,) that are likely caused by an accumulation of tracking error and uncalibrated evenness of light source. These should be fixable with an improved distortion model.

### Future Work

On the basis of the reviews by senior pathologists from SJTU-SMPC of the results of a previous study and this study, sWSI has been clinically proven to be a legitimate alternative to automatic whole slide scanners. Its cost-effectiveness makes it a solid intermediate between localized optical microscopy and fully automatic but expensive scanners. However, there is room for improvement on the sWSI solution.

First, processing speed may be further enhanced. Putting hardware issues aside, there should be a number of methods to improve the image processing speed of sWSI, such as multithread optimization on more energy-efficient models and reworking the general purpose graphics processing unit. The former technique is widely used on desktop computer programs but may not be practical on mobile devices for a sustained boost due to the power constraints discussed in the previous sections. However, it may be worth further investigation on newer models, whose energy efficiency has been increasing steadily due to advanced semiconductor technology. The latter has been tested on iOS with substantial gain but shown to be unstable on some versions of the operating system, as previously reported. Considering the advantage of the general purpose graphics processing unit in energy-efficient float-point computing, further study and development of its utilization on Android may also help with reducing overheating, thus yielding considerable gain in data throughput.

Second, the low-magnification-scan-and-high-magnification-static-view method can be further explored for productivity. In this version, the microscope operator is responsible for deciding where the static views are located and thus must have diagnostic knowledge at least on the level of a junior pathologist. This requirement may be lifted if a viewer of the virtual slides, most

likely the senior professional from whom advice is sought, may interact with the operator, and mark the region instead.

Third, further testing is needed. Unlike the iOS version, sWSI on Android experiences a relatively high crash rate on specific devices after scanning approximately 500 views without detectable memory leakage or overflow. If this is related to factors other than the app's functionality, then it may indicate some other engineering obstacles for other high-performance imaging apps on Android in general.

Finally, low-cost automation of microscopes may significantly improve productivity of the sWSI solution at an affordable cost. Although automated microscope stages based on step motors are mature and widely available, high positioning accuracy leads to high prices even for recent low-cost solutions [30,31]. Since sWSI tracks the field of view through software and computation instead of physical measurement, such constraints on accuracy may be greatly relaxed from the micron level to 100-micron level, thereby reducing the cost dramatically.

## Conclusions

In this paper, the follow-up development on the Android platform and clinical evaluation of sWSI, a WSI solution on a smartphone, is reported. Due to the diversity of handsets and operating system characteristics, several factors impair the theoretical performance and user experience of the Android version compared with the previously reported iOS model. However, in a clinical evaluation of challenging TCT samples, an insignificant difference was discovered between the diagnosis accuracy based on the virtual slides produced by either version. sWSI on both mobile platforms is recognized as a reliable tool for telepathology consultation and a competitive alternative to WSI scanners.

A major problem causing a slower processing speed of sWSI on Android is the rare support of high-resolution and reliable pixel data format of cameras. In tests on mainstream Android models, only 3.0% (6/200) provided pixel data format that can be used directly for processing with at least 3-megapixel resolution, full field of view, and no padding. On other handsets, the JPEG format, which is compressed and must be decompressed for processing, is the only reliable option. This encoding-decoding process is unnecessary and computationally expensive.

In addition, it was verified that although theoretical CPU performance as measured by max frequency varied greatly, the sustainable processing speed of the computation-heavy sWSI kernel was largely model-dependent. Although more sophisticated testing is required to determine the cause, an intuitive answer is CPU thermal throttle leading to a decrease in frequency. Another observed factor leading to user-experience degradation is screen freezing caused by a lag of resuming camera preview after capturing a photo, but its quantitative effect also requires further investigation beyond the plan of this study.

In the clinical evaluation conducted in SJTU-SMPC, a diagnosis based on sWSI virtual slides reached 87.5% (175/200) accuracy and a kappa value of .76 on average, with gold-standard optical microscopy used as the ground truth. The selected slides are TCT samples covering 6 diseases as well as normal samples that are intended to complement the frozen section samples used in the previous study, as they require finer details and are difficult to scan manually due to the varying intercell distance. After retrospectively examining the data, all senior pathologists from SJTU-SMPC considered sWSI's performance on par with high-end scanners and highly suitable for smaller or remote hospitals with less frequent need for teleconsulting.

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## Conflicts of Interest

SM is a cofounder of TerryDr Info Technology Co, Ltd, the company that developed and is marketing sWSI as a commercial service.

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## Multimedia Appendix 1

Supplementary figures.

[[PDF File \(Adobe PDF File\), 340KB - mhealth\\_v6i4e82\\_app1.pdf](#)]

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## Abbreviations

**CPU:** central processing unit

**SJTU-SMPC:** Pathology Center, Shanghai General Hospital/Faculty of Basic Medicine at the School of Medicine of Shanghai Jiao Tong University

**sWSI:** scalable whole slide imaging

**TCT:** ThinPrep cytology test

**WSI:** whole slide imaging

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Original Paper

# Development of a Mobile Clinical Prediction Tool to Estimate Future Depression Severity and Guide Treatment in Primary Care: User-Centered Design

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## Abstract

**Background:** Around the world, depression is both under- and overtreated. The *diamond* clinical prediction tool was developed to assist with appropriate treatment allocation by estimating the 3-month prognosis among people with current depressive symptoms. Delivering clinical prediction tools in a way that will enhance their uptake in routine clinical practice remains challenging; however, mobile apps show promise in this respect. To increase the likelihood that an app-delivered clinical prediction tool can be successfully incorporated into clinical practice, it is important to involve end users in the app design process.

**Objective:** The aim of the study was to maximize patient engagement in an app designed to improve treatment allocation for depression.

**Methods:** An iterative, user-centered design process was employed. Qualitative data were collected via 2 focus groups with a community sample (n=17) and 7 semistructured interviews with people with depressive symptoms. The results of the focus groups and interviews were used by the computer engineering team to modify subsequent prototypes of the app.

**Results:** Iterative development resulted in 3 prototypes and a final app. The areas requiring the most substantial changes following end-user input were related to the iconography used and the way that feedback was provided. In particular, communicating risk of future depressive symptoms proved difficult; these messages were consistently misinterpreted and negatively viewed and were ultimately removed. All participants felt positively about seeing their results summarized after completion of the clinical prediction tool, but there was a need for a personalized treatment recommendation made in conjunction with a consultation with a health professional.

**Conclusions:** User-centered design led to valuable improvements in the content and design of an app designed to improve allocation of and engagement in depression treatment. Iterative design allowed us to develop a tool that allows users to feel hope, engage in self-reflection, and motivate them to treatment. The tool is currently being evaluated in a randomized controlled trial.

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**KEYWORDS**

user-centered design; depression; ehealth; primary health care; decision support techniques; risk; mental health

## Introduction

### Background

Depression affects at least 350 million people worldwide [1]. Primary care doctors are responsible for most of the identification, treatment, and management of depression [2], with between 24% and 55% of primary care attendees reporting depressive symptoms [3]. Research shows that with appropriate treatment, recovery from depression is possible [4]. However, there is frequently a mismatch between patient needs and the treatment they receive. Patients with subthreshold or mild depression who are likely to recover spontaneously are often overtreated [5], whereas patients with severe symptoms frequently do not receive minimally adequate treatment [4,6,7]. Treatment mismatch is associated with poor patient outcomes and represents an inefficient distribution of scarce resources [8,9]. Currently, there is no systematic way of matching patients with depressive symptoms with the most appropriate level of treatment in primary care.

To improve treatment allocation for depression, we developed the *diamond* clinical prediction tool that is designed to assess an individual's future depressive symptom severity and provide them with an evidence-based treatment recommendation matched to their prognosis. Details of the clinical prediction tool's development are available elsewhere [10]; briefly, it was developed after an extensive search of the literature identified no existing tools that predicted future symptom severity and could be delivered at scale in the primary care setting. Despite their potential to improve health care [11], relatively few clinical prediction tools have been successfully incorporated into routine clinical practice [12]. Doctors report that time constraints and difficulty of use and interpretation are key barriers to the implementation of clinical prediction tools [13]. Delivering a clinical prediction tool directly to patients via a digital app has the potential to overcome these barriers and increase the use of clinical prediction tools in clinical practice. Moreover, studies suggest that patient-completed tools can increase patient participation in their own health care and increase the efficiency of health care encounters [14-16].

### eHealth and User-Centered Design

Despite the wide availability of apps, they have yet to revolutionize health care, due in part to lack of uptake. User attrition from or nonadherence to electronic health (eHealth) technologies is well documented, both for patients and clinicians [17,18]. The few existing implementation studies of specific eHealth decision support technologies have identified several barriers, including low user acceptance, poor face validity, and low user-friendliness [19,20]. To successfully change health care practices, eHealth technologies must be engaging to end users, deliver easily understood information, and promote engagement with any treatment recommendation they may provide.

Explicit user-centered design, a process in which end users influence how a design takes shape [21], may improve the chances of successful implementation of technology in practice. Apps developed using this process have reported improved user acceptance, face validity, user-friendliness, and uptake [22-25].

User-centered design is based on the principles of participatory design and involves all potential stakeholders. It uses iterative formative evaluation during the entire development process and accounts for the conditions of implementation from the beginning [15,23]. In health care, the end user of a technology may be the patient, but ideally, user-based technology development should identify and take into account all potential stakeholders including clinicians, researchers responsible for the content of the technology, and representatives of the health care system [16].

### This Study

In this study, we describe the user-centered design process of an app to assess individual risk of persistent depressive symptoms and recommend individually tailored treatment based on current knowledge about best-evidence treatment for depression. Our aim was to focus on users' emotional and cognitive experience to design an acceptable tool for clinical decision support. Users were involved to determine

1. How the tool should look (to ensure it was credible, easy to use, and visually attractive)
2. What feedback was most likely to promote engagement with treatment recommendations
3. How the feedback should be presented.

## Methods

### User-Centered Design

User-centered design is an umbrella term that encompasses a range of models and approaches that software developers can employ to produce a highly usable and accessible product [26]. The term was coined in the late 1990s by Donald Norman who posited that three levels of cognitive processing should be considered in designing useable products: (1) *visceral processing*, which refers to the look and feel of a product; (2) *behavioral processing*, which relates to the experience of product characteristics such as performance and usability; and (3) *reflective processing*, which refers to characteristics such as the meaning of a product, its impact on self-image, and satisfaction [27]. Reflective processing has been shown to be most important for adoption and use of a product [21]; the successful implementation of software depends on its ability to address peoples' values, satisfy their emotional needs and expectations, and to encourage participation, acceptance, and trust [22-24]. For eHealth technologies that have the specific aim of changing clinician and patient attitudes and behaviors [21,28], reflective processing is particularly critical. Therefore, we approached our user-centered design process with Norman's framework and the importance of reflective processing in mind.

### Stage 1: Identify End Users and Context

To increase the likelihood that the *diamond* clinical prediction tool would be implemented into routine clinical practice, we identified end users and reviewed the environmental characteristics of the context in which it would be used. Environmental characteristics were collated through telephone interviews with primary care attendees experiencing depressive symptoms and discussions with clinicians and primary care researchers and through a literature review of clinical prediction

tools in practice. A narrative description of end users and their context was developed.

### **Stage 2: Concept Development**

Emotion-driven goal modeling was used to identify requirements based on patient, clinician, and research team goals regarding the app. Emotion-driven goal modeling is based on the theory of agent-oriented modeling [29] and is a method used to identify and interrelate the personal values, motivations, and emotions stakeholders have around software to specify requirements for development. It uses a modified grounded theory approach for analysis of individual interviews, group discussions, and other datasets. For this study, the data for the modeling came from two initial development meetings and five interviews with individuals who had either prior or current experience of depressive symptoms. We also identified the research team's requirements for the evidence-based content and recommendations. A literature scoping review was conducted

to identify the evidence on how to best communicate risk for persistent depression.

### **Stage 3: App Development**

Two focus groups, each lasting approximately 2 hours, were conducted by CW and AC. The 10 participants in focus group 1 (1) were presented with icons from the app without any associated text and were requested to write down and verbally present the thoughts and feelings they associated with the image; (2) formed groups of two and took turns using the app prototype on an iPad provided by the research team, followed by general discussion based on semistructured questions; and (3) were presented with the options for risk communication, followed by semistructured interview questions (Textboxes 1 and 2). On the basis of the results from the first focus group, modifications were made to the prototype. Prototype 2 was presented to participants in the second focus group, and the procedure used in the first focus group was repeated. Further modifications to the app were made based on results of focus group 2.

#### **Textbox 1.** Topic guide for focus groups 1 and 2.

1. First impressions
  - What are your first or general impressions of the app?
  - What were the best things about the app?
  - What was the biggest problem you had with the app?
2. Results or feedback
  - How did you feel about the results page?
  - Imagine you're in your general practitioner (GP) clinic and you complete the app, how would you feel?
3. Risk communication
  - What are your first impressions of (the risk communication)?
  - How do you feel about the faces?
  - How do you feel about the stick figures and numbers?
  - How would you feel if both the stick figures and the faces were presented?
4. Iconography
  - In front of you is a workbook with a picture on each page. For each picture write down what you think each picture represents. We will then discuss as a group.

#### **Textbox 2.** Topic guide for individual interviews.

1. First impressions
  - What were your first impressions of the app?
  - What did you like or dislike?
  - How did the app make you feel?
  - Did the app make you think of any questions or other thoughts when completing it?
2. Results or feedback
  - How did you feel about the message at the end (treatment recommendation)?
  - Was the information clear?



The third prototype of the app was tested in individual interviews. Seven face-to-face semistructured interviews were conducted by CW and observed by AC. Participants were given prototype 3 on an iPad while the observer took notes. After completing the app, they were interviewed using a broad topic guide ([Textboxes 1 and 2](#)) covering first impressions of the app and reactions to the feedback and treatment recommendations.

### Data Analysis

The focus groups were audiorecorded. All audio recordings and text produced by participants, moderator, and observers were included in the analysis. AC collated the written and spoken words associated with part 1 of the focus group. CW transcribed the audio recordings. We conducted thematic analysis of the data by iteratively coding individual words, concepts, and phrases and then organizing these codes into a structure of themes and subthemes using the constant comparison method [30]. CW and AC conducted independent coding and then discussed themes and relationships between themes. Because the purpose of this analysis was iterative development of the app, when possible, themes were grouped into features that were requirements of the app. These discussions were relayed back to the research team for discussion of relevance and planning further action.

### Participants

All community-dwelling adults in Melbourne, Australia, who were in the age range of 18 to 65 years and able to respond to recruitment materials in English were eligible for the study. The only exclusion criteria were being outside this age range, and, for participation in an individual interview, the absence of any depressive symptoms (as assessed by the Patient Health Questionnaire-9, PHQ-9 [31]). Participants were recruited through flyers on community noticeboards at The University

of Melbourne (Parkville campus) and via advertisements in a weekly university staff e-newsletter, Facebook, and on an online noticeboard website (Gumtree). Participants were sought from the general community, as 87% of the population visits a general practitioner (GP) at least once a year [32]. Focus group recruitment occurred in September (focus group 1) and October (focus group 2) 2014 and individual interview recruitment in February 2015. Interested individuals in the age range of 18 to 65 years were instructed to contact the study coordinator (AC) via phone or email. Upon expression of interest, demographic information was collected for all potential participants. Individuals expressing interest in an individual interview were additionally asked to complete the PHQ-9 at this point, and those with a score of <2 were considered ineligible and not included in the study sample. Participants were given a written plain language statement before participation, and consent was obtained at the time of focus group or interview attendance. Participants received an \$50 AUD gift voucher for their time.

### Ethical Approval

This study was approved by the University of Melbourne Human Research Ethics Committee (1442318, 1442584).

## Results

### Participant Characteristics

In total, 17 individuals participated in two focus groups (10 in focus group 1 and 7 in focus group 2), and 7 participated in individual interviews. The demographic characteristics of each group of participants are presented in [Table 1](#). A total of 13 participants were members of the general community, whereas 4 were university staff recruited through campus noticeboards and the staff e-newsletter.

**Table 1.** Characteristics of focus group and interview participants.

Characteristics	Focus group 1 (n=10)	Focus group 2 (n=7)	Interviews (n=7)
<b>Gender, n</b>			
Male	6	4	3
Female	4	3	4
<b>Age in years</b>			
Range	26-60	25-57	25-45
Mean (SD)	39.33 (13.36)	39.14 (13.54)	33.14 (7.64)
<b>Ethnic background, n</b>			
White	5	6	6
Asian	3	0	0
Hispanic	0	1	0
Other	2	0	1
<b>Education, n</b>			
Technical and further education	10	2	3
Bachelor	40	3	2
Postgraduate	50	2	2

## Stage 1: Identify End Users and Context

End users of the tool were identified as primary care patients and primary care doctors. All primary care patients could use the tool; however, only those whose initial responses to two questions on depressive symptoms indicated that they had depressive symptoms would be taken through to the full assessment and treatment recommendation phases. Our review of the context in which the tool would be used indicated that it should be used by the patient in the waiting room before a consultation with a GP or during the consultation itself. It was believed that this approach was most likely to promote use of the tool, motivate patients to engage in decisions around their health care, and increase the efficiency of the mental health care consultation.

## Stage 2: Concept Development

Emotion goal modeling identified that patients wanted the app to make them feel emotionally supported, and they wanted to feel confident that the information presented to them was relevant and important. Most importantly, users wanted to see the results of their assessment (ie, the risk of having depressive symptoms in 3 months' time) in a way that was meaningful to them.

Our review of the clinical prediction tool literature identified that a risk communication component, using numerical, verbal, or graphical depictions of risk, is built into most clinical prediction tools. We also identified several challenges in

communicating risk to patients: low numerical literacy even in educated populations and the attendant problem of interpretation, considerable margin of error in risk probability, the fact that risk identified by a clinical prediction tool represents a population probability rather than an individualized risk, and ethical issues surrounding the use of risk communication tools as a persuasive mechanism. Adding to these challenges was that, unlike some health problems, the risk probability around persistent depression is very wide, thus increasing the margin of error and the validity of the result. No one type of risk communication emerged as superior to another in communicating risk for persistent depression.

Clinicians wanted to have confidence that the app provided scientifically accurate information, that it looked professional, and that it was useful for improving depression care. Therefore, it was essential that the tool retain, without alteration, all the data items that make up the prognostic algorithm in the *diamond* clinical prediction tool. These questions provided the information necessary to apply the statistical algorithm to predict individual risk for persistent depressive symptoms at 3 months. The required 17 questions for the *diamond* clinical prediction tool include depressive symptom severity as measured by the Patient Health Questionnaire-9 (PHQ-9) [31]; sex; current anxiety; history of depression; presence of chronic illness affecting daily functioning; self-rated health; living alone; and perceived ability to manage on available income (see Table 2). [Table 2](#).

**Table 2.** Items forming the *diamond* clinical prediction tool.

Item number	Text
1	Do you identify more strongly as male or female?
2	In general, would you say your health is
3	Do you have any long-term illnesses, health problem, which limits your daily activities or the work you can do (including problems that are due to old age)?
4	Do you live alone?
5	How do you manage on your available income? Over the last 2 weeks, how often have you been bothered by...
6	...Little interest or pleasure in doing things?
7	...Feeling down, depressed or hopeless?
8	...Trouble falling or staying asleep, or sleeping too much?
9	...Feeling tired or having little energy?
10	...Poor appetite or overeating?
11	...Feeling bad about yourself, or that you are a failure, or have let yourself or your family down?
12	...Trouble concentrating on things such as reading the newspaper or watching television?
13	...Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual?
14	...Thoughts that you would be better off dead, or of hurting yourself in some way?
15	Have you ever been bothered by feeling down, depressed, or hopeless for longer than 2 weeks?
16	Have you ever been bothered by little interest or pleasure in doing things for longer than 2 weeks?
17	Over the last 4 weeks, how often have you been bothered by feeling nervous, anxious, on edge or worrying a lot about different things?

## Stage 3: App Development

### Initial Prototype

The initial prototype of the tool consisted of three content areas:

1. *Clinical prediction tool items*: see [Table 2](#) for items. Each item was presented on a separate screen, and visual icons intended to represent the item were presented next to the text. Research shows that a mixed format of text and icons enhances comprehension [32] and accuracy of participant responses to questions [33].
2. *A summary of users' responses*: answers to the clinical prediction tool were reflected back with the text "Things seem to be difficult for you in these areas right now" using the icons described above.
3. *Risk communication*: the patient's estimated risk of having either mild, moderate, or severe depression in 3 months' time was presented. To enhance comprehension, risk communication was presented as a comparison between likely mental health outcome in 3 months' time if the patient did or did not receive treatment. Two alternative ways of presenting risk were presented in the first focus group (see [Figure 1](#)).

### First Impressions

First impressions of the app were positive, with participants reporting it was easy to use, as illustrated in the following quote:

*I think the app in general looks quite clean and clinical, for some people a good thing, if they feel they have a problem they want to be handled in a professional way. [Male, 28]*

The purpose of the app was seen to be to raise awareness of existing mental health problems for the individual, to give hope for improvement, and to motivate the individual to pursue the next step in getting help, as illustrated in the following quotes:

*It's about education, awareness, by answering these questions your becoming aware of some problems you may have, presenting hope, there are things people can do, that you can get better. [Male, 30]*

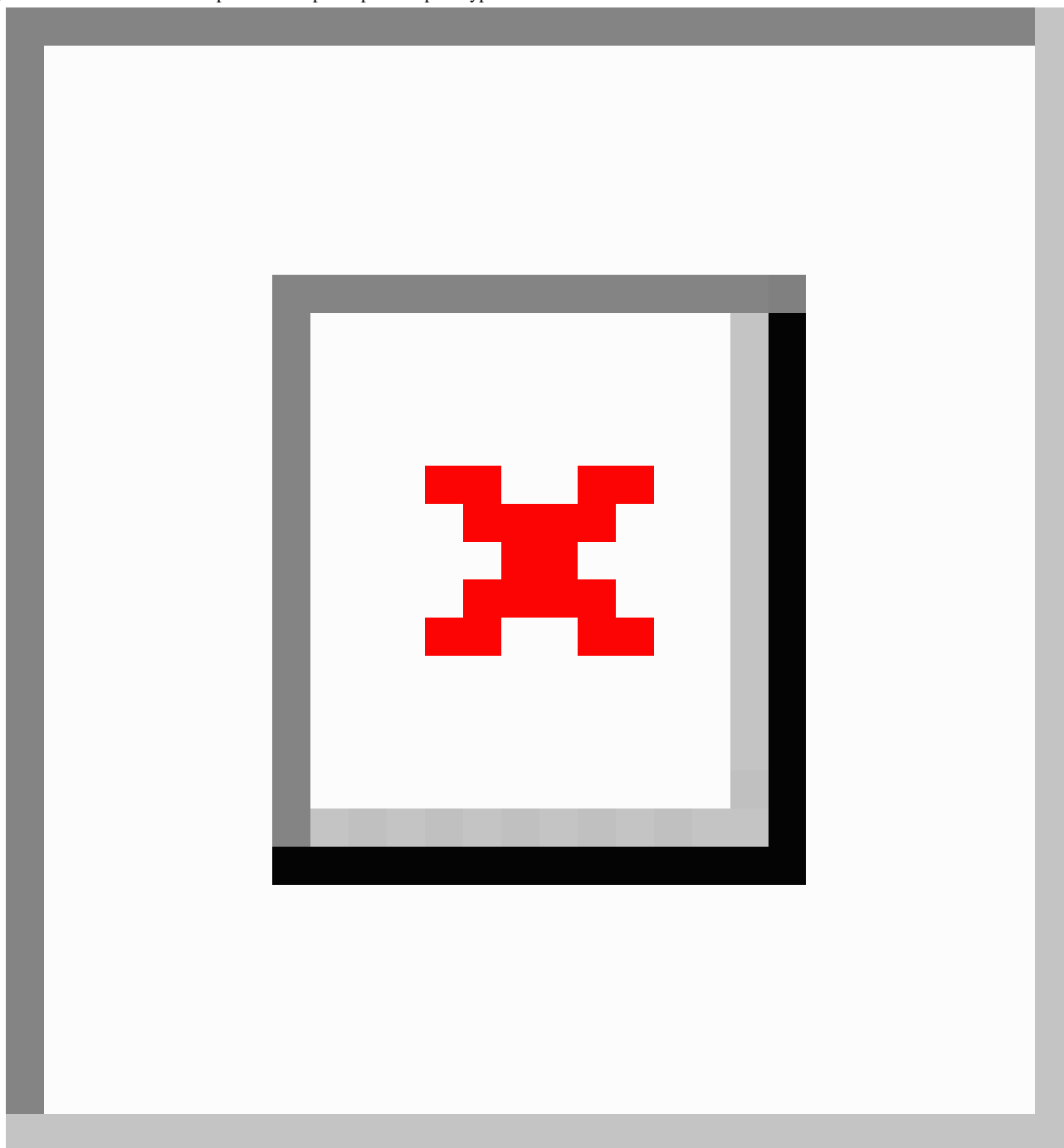
*If you are this person, then you get this educational fact—these are the areas [you need help with], [this is] how it is impacting you, [it's] a nudge to get to the next step. [Female, 26]*

Several participants noted that the "next" button, presented under each question, should be removed to streamline the app, which was agreed upon by the rest of the group.

### Iconography

There was a clear mismatch for participants between nine of the 12 the visual icons and their intended meaning. For example, participants interpreted an icon depicting a pair of hands as a representation of "charity" or "religion," when the intended concept was "health."

**Figure 1.** Risk communication presented to participants in prototype 1.



### **Summary of User's Responses**

Participants liked having a summary of their results reflected to them. However, they felt that only reflecting the “difficult” areas might have negative consequences, as illustrated in the following quotes:

*That's validation, yeah I feel that way.* [Female, 52]

*You see your problem areas, when you are depressed you just feel bad but this makes it clear.* [Female, 30]

*It could be a negative thing, like look at everything that's wrong with me...If it were only one or two, that could be identification, but getting a lot back, that*

*could be quite detrimental to some people...It would help to see what was working well.* [Male, 26]

Participants wanted more meaningful feedback about their results. They wanted an explanation of the severity of the problem, advice on prioritizing areas for attention, and a personalized treatment recommendation based on their results, as illustrated in the following quotes:

*Maybe if there is the option to emphasize some problems here it would be better, for example, I'd like to be able to emphasize my sleep problems.* [Male, 33]

*I think there needs to be an answer, to show you have a problem, to contact this GP or call this number, someone to discuss the results. [Male, 26]*

**Risk Communication**

The risk communication component was identified as the most problematic aspect of the tool. Participants were concerned that presenting risk might make already depressed people feel worse, as illustrated in the following quotes:

*If I get help I still have a one in three chance of still feeling bad? [Male, 60]*

*If it has gone 2 months and you are still sick, it's like there's only one month left [Male, 26]*

Participants were confused that the app reported risk at a population level rather than their own personal risk of suffering depression in the future, as illustrated in the following quote:

*Impersonal, I'm going to be pigeonholed. [Male, 60]*

Some participants misinterpreted the message that “with help, you will feel better in three months’ time,” as illustrated in the following quote:

*It could be shorter intervals...I mean, if you're suicidal and you have to wait three months. [Male, 60]*

All participants misunderstood the risk communication in the form of stick figures, and they felt that it had a negative message, as illustrated in the following quote:

*If you are depressed maybe you identify with the sad figure, feels hopeless, not sure this works [Female, 52]*

Most participants expressed their dislike of the portrayal of risk using emotional faces, as illustrated in the following quotes:









*Pretty scary, this looks like a Halloween pumpkin! It's a bit impersonal. [Male, 60]*

*I feel condescended to [by the animated face]. [Female, 53]*

**Prototype 2**

On the basis of the results of focus group 1, a second prototype was developed. The nine most problematic icons were removed and replaced with new icons (see Figure 2 for examples).

**Figure 2.** Example of icons replaced and more easily interpreted in prototype 2.

Intended concept	Icon	Themes from focus group 1	Revised icon	Themes from focus group 2
Energy		Purposeful, walking, active, rushing		Exercise, skipping, active
Concentration		Eye, mood, night		Thinking
Health		Charity, religious, care		Hospital, medical, medicine
Impact of age or illness on daily activities		Trapped, exit, darkness		Disabled, elderly

The “next” button was removed allowing screens to automatically transition from question to question once a response had been entered. The summary screen was redesigned to reflect areas that “seem to be ok for you right now” in addition to the “difficult” areas presented in prototype 1. Although risk communication was identified as problematic in the first focus group, it was included in the second focus group so that user preferences regarding this component could be explored further. An additional component, treatment recommendation, was added to the end of the tool. This screen informed participants that they could access an online portal with information about mental health treatment options and that a named health care professional was available to talk them through this portal.

**First Impressions**

Similar to focus group 1, participants felt that the second prototype was simple and easy to use. It was seen to be a tool that could guide a conversation with a health provider. Additionally, the app gave an opportunity for the individual to reflect on his or her symptoms, give hope for improvement, and motivate help-seeking. Two participants stated the following:

*It would be useful in telling you things you didn't know, you didn't think about, and then you'd go into the GP and say, this is right, I'm not sleeping well, it would be a prompt. [Female, 54]*

*This would be a starting point for talking to the GP, for sure, you could focus on what the problems actually are.* [Female, 34]

### Iconography

In the second prototype, participants reported that nine of the 12 icons were congruent with the intended concepts for each icon, with the remaining three approaching congruency. Participants indicated that the icons were helpful when interpreting the question and that they should be more prominent.

### Summary of User's Responses

Although participants generally felt positively toward the summary screen, they also expressed concern that if the summary did not accord with the user's experience, there was potential for a loss of trust in the tool, as illustrated in the following quotes:

*I find it interesting just to look at the two sides, what seems to be shaping up ok, and where the struggle points are. So I think there is a bit of personal reflection that can go on the results page with these emblematic little icons, I find that quite interesting.* [Male, 57]

*This is the make or break point, I mean if there are things here that people don't see in their own lives, if it's not an accurate reflection of what they answered, they'll lose trust.* [Male, 25]

*I was expecting more personalized results at the end, not just what I'm doing well in, something more detailed.* [Female, 34]

### Risk Communication

Like their counterparts in focus group 1, many participants interpreted the information as a negative prognosis, and there was a sense that the message was impersonal and untrustworthy, as illustrated in the following quotes:

*If I'm depressed, I can always find the figure down at the bottom that doesn't get better, if I were to look at that through a dark cloud, I would see myself.* [Male, 57]

*I mean, if somebody is depressed, you don't want to tell them "you're depressed, you're a sad face."* [Male, 26]

*It was a bit like it wasn't even paying attention to the answers I gave, just saying ok you'll be ok in 3 months.* [Female, 30]

### Treatment Recommendation

Participants responded positively to the treatment recommendation screens but expressed a desire for more information from the treatment recommendation regarding what they could do get better, as illustrated in the following quotes:

*Yeah its very positive, isn't it, that you can get help, that's great.* [Female, 54]

*So on the results page, maybe more like you should do this, take action. I mean I already know my sleep is not good but what should I do, how should I get better.* [Female, 34]

### Prototype 3

Given that participants in both focus groups expressed problems with the risk communication, and in the absence of a compelling alternative, we removed this element of the app entirely. Information on the treatment recommendation screen was rewritten to direct participants to specific evidence-based treatment options depending on their predicted depressive symptom severity. Treatment recommendations were based on the principles of stepped care, where the intensity of treatments increased in line with symptom severity. So, for example, patients predicted to have mild symptoms were recommended to access Internet-based self-help and psychoeducation via the myCompass program [33] and were provided with the website link.

### First Impressions

Participants did not report any negative aspects of using the app, and all participants explicitly said it was professional and easy to use.

Consistent with focus group results, interview participants indicated that the app could raise awareness of their problems, give hope, and potentially motivate them to treatment, as illustrated in the following quotes:

*It made me reflect on how my feeling have been over the past weeks and months, which did make me think, it is a bit more frequent than I thought or hoped it was.* [Female, 27]

**Table 3.** Summary of iterative development process (N/A: not applicable).

Themes and feedback from focus group 1	Revisions	Feedback from focus group 2	Revisions	Feedback from interviews	Revisions
<b>First impressions</b>					
Dislike having to press “next” to navigate to next page	Remove next button	N/A	N/A	N/A	Removed a non-functional “tap here” button
<b>Iconography</b>					
Mismatch in interpretation for 9/12 icons	Revise nine icons	Correct interpretation for 9/12 icons, with the remaining three approaching congruency	N/A	Icons viewed as helpful for people with English as a second language	N/A
<b>Summary of responses</b>					
Seeing only where things are difficult could be detrimental	Include feedback on both “difficult” areas and areas that “seem to be ok for you right now”	Desire for more personalized results	None; app should be administered in a health care setting where responses can be discussed	Seeing “difficult” and “OK” areas useful for patients with depression—counteracts overgeneralization that everything is difficult	N/A
<b>Risk communication</b>					
Focus on negative message	None; reassess in focus group 2	Focus on negative message	Removed entirely from app	N/A	N/A
<b>Treatment recommendation</b>					
Need action-oriented message	Add recommendation to review available resources through online portal	Need more tailored recommendation	Revise recommendation to direct to specific evidence-based treatment, matched to predicted depressive symptom severity	Like being provided treatment option	Minor changes to phrasing

*It made me think about how could I get more help.*  
[Female, 36]

*It would be a motivation, or maybe an opportunity.*  
[Male, 35]

### Iconography

The iconography was seen to be a seamless part of the app that could enhance understanding of the clinical prediction tool items. No participant commented on a mismatch between icon and question concept, as illustrated in the following quotes:

*Yes the pictures make sense.* [Female, 36]

*Seems pretty clear, and for people with English as a second language the infographics would help if they can't understand the more complex words.* [Male, 35]

### Summary of User's Responses

Refinements to the feedback and treatment recommendation and removal of risk communication in response to the focus groups appeared to improve the match between the app and participant needs. Although focus group participants felt the combination of the clinical prediction tool results and risk communication left them focused on the negatives, interview participants felt positively about the feedback and

recommendation, as they felt it provided solutions and a way of moving forward, as illustrated in the following quotes:

*This would feel pretty good...the fact that it offers options.* [Female, 34]

*I'd be looking forward to the [treatment recommendation], to see what options were available, of more information.* [Male, 35]

### The Fourth and Final App

The individual interviews identified only minimal changes in phrasing of the treatment recommendations and in one technical aspect of the app (a nonfunctional tap here button). These corrections were made in the final app. Table 3 provides a summary of participant feedback and subsequent revisions that resulted in the final app.

## Discussion

### Principal Findings

In this paper, we describe the process of user involvement in the iterative development of an app designed to estimate prognosis and guide treatment choice for patients with current depressive symptoms (using the *diamond* clinical prediction tool). We tested three prototypes with potential end users, with the feedback on each prototype used to develop the next, and

ultimately, the final app. Our process of iterative development with potential end users allowed us to make improvements to the content and design of the app. We addressed initial mismatches between clinical prediction tool item content and iconography so that the icons enhanced, rather than detracted, from understanding the clinical prediction tool items. Participants indicated that the app could encourage self-reflection, provide hope, and motivate them to engage with treatment. Risk communication was identified as a significant problem and therefore removed entirely from the final app. Finally, through this process, we identified user need for personalized treatment recommendations and developed this component for the final version of the app.

### Relationship With Other Literature

This study is the first to our knowledge to use explicit user-centered design principles in development of an app-based clinical prediction tool for mental health in primary care. The long-standing problem of engaging patients in mental health treatment has not to date been solved by the advancement of health technologies such as apps, due in part to limited engagement with the technologies themselves. User-centered development has been posited to address this issue by leading to more acceptable, usable, and effective mental health technologies. For example, a lifestyle and mental health screening tool developed using a user-centered approach was deemed acceptable and usable by end users [34]. In severe mental illness, user involvement in the design of a mobile app for supporting mental health was seen to be critical in generating a product that could provide a positive user experience [35]. User-centered design has been used in development of an effective online depression prevention intervention [23] and two effective chronic pain treatment interventions [36,37].

As discussed above, Norman's formative theory of user-centered design suggests that an individual's interaction with a product can be conceived of as three levels of processing: visceral, behavioral, and reflective [27]. Our results show that visceral and behavioral processing did not detract from the user experience of the app, which appeared seamless. However, although ease of use has been shown to improve implementation of software [38], it is reflective processing that is most critical for adoption and use of a product. If users are to adopt and integrate technology in meaningful ways into their lives, fulfilling their emotional expectations is critical [27]. Factors related to emotions and motivations are often neglected, however, with software developers focusing predominantly on the work processes that are required and how they will take place [39]. As we increasingly seek to identify, assess, and treat mental health problems using apps and other technologies, it is critical that ease of use is not the only consideration. The results of this study suggest that involving end users in the development process can result in an app that supports meaningful reflective processing, including prompting further consideration of the symptoms and treatment in question.

### Risk Communication

Although the majority of participants in this study did not suffer from depression, they consistently interpreted the communication of their risk for persistent depression through

a negative lens. As far as we are aware, this is the first study to have examined how best to communicate risk for depression. Given the negative biases inherent in many psychiatric illnesses, it is possible that the requirements for effectively communicating risk for these conditions may be very different to those for chronic physical conditions (including, eg, genetic disorders and cancer), which have to date received most attention in the risk communication field.

High-quality communication is considered an important component of shared decision making [40]. However, the challenges in communicating risk effectively are widely recognized; in their systematic review, Zipkin et al [41] acknowledge that there is likely no single best approach but put forward several recommendations on how to present risk messages. Although many of these recommendations were followed in this study (eg, using visual aids and positive framing and avoiding use of qualitative risk descriptors alone), others were not (eg, using a denominator of 1000 participants), leaving open the possibility that there may be alternative, more acceptable ways of presenting risk for persistent depression.

Given that risk communication has been shown to be highly influential on patient decision making [42], further examination of how, if at all, risk for depression and other mental health conditions can be communicated may assist in improving treatment uptake and adherence.

### Personalized Treatment Recommendation

During our development process, it became apparent that participants were more interested in the app as an action-oriented rather than informational tool. They desired a tailored treatment recommendation based on their individual symptoms, rather than information on their risk of persistent depression, even when this provided generic advice on the benefits of help-seeking (ie, "7 out of 10 people with extra help from a GP or health professional feel better"). This finding is consistent with research showing that patients with mental illness desire personalized information about available treatment [43]. Furthermore, tailored treatment recommendations have been shown to enhance patient engagement in their own care and improve adherence to treatment [44].

Importantly, participants in this trial were free to respond to the app however they chose, and the treatment recommendation we presented in prototype 3 was designed to identify the acceptability of this action-oriented message relative to the more passive information presented in prototypes 1 and 2 and not to provide specific treatment advice. Although our findings suggest this solution-focused approach was preferred, we did not set out to test how best to personalize treatment recommendations for depression. This is likely to be an important area of future investigation; although several models of personalized care have been proposed, particularly in the fields of cancer [45] and diabetes [46], there is currently a dearth of evidence suggesting how mental health treatment may best be tailored.

### Strengths and Limitations

We employed an iterative development process that allowed us to improve the app on a step-by-step basis. This allowed us to track shortcomings at each stage and avoid any flow on effects



by making appropriate changes to the app as we became aware of them. We were also able to add new functions to the app as suggested by participants in the focus groups.

Our use of qualitative methodologies is also a strength of this study. Focus groups are a valuable way to generate information about what a group of people think is important and how they understand a problem [47]. Thematic analysis of interview and focus group data is an appropriate method for generating explanations of phenomena that are directly relevant for the group at study [48]. Our use of audio recordings and verbatim transcription and our use of multiple coding that engaged independent researchers in cross-checking of coding and interpretation strengthens the reliability of our results [49].

There is a risk for a biased sample in both our focus groups and our interviews. Participants responded to recruitment advertising in the community that made clear the focus on mental health and mobile apps, so it is likely we recruited primarily individuals

with interest in or experience of one or both of these topics. Additionally, we recruited in an area with a highly-educated, urban population, and therefore, our recruited population may not reflect the demographics of all end users of the app.

### Future Research

The app developed in this study is being used in a randomized controlled trial to identify whether delivering the *diamond* clinical prediction tool and providing feedback and treatment recommendations in this way can improve depressive symptom severity in primary care patients, relative to usual care [50].

### Conclusions

In this study, we described how an iterative, user-centered design process led to an easy to use, engaging, and motivating app that assists in assessing prognosis and guiding treatment choice for patients with depressive symptoms. Future initiatives aimed at improving engagement with mental health assessment or treatment may consider digital apps as a platform of delivery.

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### Conflicts of Interest

None declared.

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## Abbreviations

**eHealth:** electronic health

**GP:** general practitioner

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Original Paper

# Mobile Breast Cancer e-Support Program for Chinese Women With Breast Cancer Undergoing Chemotherapy (Part 2): Multicenter Randomized Controlled Trial

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## Abstract

**Background:** Women undergoing chemotherapy for the treatment of breast cancer have frequently reported unmet supportive care needs. Moreover, easily accessible and innovative support is lacking.

**Objective:** The purpose of this trial was to determine the effectiveness of an app-based breast cancer e-support program to address women's self-efficacy (primary outcome), social support, symptom distress, quality of life, anxiety, and depression. Secondary objectives included exploring the association between women's health outcomes and the breast cancer e-support usage data.

**Methods:** A multicenter, single-blinded, randomized controlled trial was conducted. A total of 114 women with breast cancer, who were commencing chemotherapy and were able to access internet through a mobile phone, were recruited in the clinics from 2 university-affiliated hospitals in China. Women were randomized either to the intervention group (n=57) receiving breast cancer e-support plus care as usual or the control group (n=57) receiving care as usual alone. The health care team and research assistants collecting data were blinded to the women's group allocation. Bandura's self-efficacy theory and the social exchange theory guided the development of the breast cancer e-support program, which has 4 components: (1) a Learning forum, (2) a Discussion forum, (3) an Ask-the-Expert forum, and (4) a Personal Stories forum. Moderated by an experienced health care professional, the breast cancer e-support program supported women for 12 weeks covering 4 cycles of chemotherapy. Health outcomes were self-assessed through paper questionnaires in clinics at baseline before randomization (T0), after 3 (T1), and 6 months (T2) of follow-ups.

**Results:** Fifty-five participants in the intervention group and 49 in the control group completed the follow-up assessments (response rate: 91.2%). During the 12-week intervention, the log-in frequency ranged from 0 to 774 times (mean 54.7; SD 131.4; median 11; interquartile range, IQR 5-27), and the total usage duration ranged from 0 to 9371 min (mean 1072.3; SD 2359.5; median 100; IQR 27-279). Repeated measures multivariate analysis of covariance (intention-to-treat) found that breast cancer e-support + care as usual participants had significant better health outcomes at 3 months regarding self-efficacy (21.05; 95% CI 1.87-40.22;  $P=.03$ ;  $d=0.53$ ), symptom interference (-0.73; 95% CI -1.35 to -.11;  $P=.02$ ;  $d=-0.51$ ), and quality of life (6.64; 95% CI 0.77-12.50;  $P=.03$ ,  $d=0.46$ ) but not regarding social support, symptom severity, anxiety, and depression compared with care as usual participants. These beneficial effects were not sustained at 6 months. Spearman rank-order correlation showed that the

breast cancer e-support usage duration was positively correlated with self-efficacy ( $r=.290$ ,  $P=.03$ ), social support ( $r=.320$ ,  $P=.02$ ), and quality of life ( $r=.273$ ,  $P=.04$ ) at 3 months.

**Conclusions:** The breast cancer e-support program demonstrated its potential as an effective and easily accessible intervention to promote women's self-efficacy, symptom interference, and quality of life during chemotherapy.

**Trial Registration:** Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12616000639426; [www.ANZCTR.org.au/ACTRN12616000639426.aspx](http://www.ANZCTR.org.au/ACTRN12616000639426.aspx) (Archived by Webcite at <http://www.webcitation.org/6v1n9hGZq>)

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## KEYWORDS

breast cancer; chemotherapy; mobile app; self-efficacy; social support

## Introduction

Breast cancer is a major public health problem worldwide. In China, breast cancer is the most frequently diagnosed cancer for women, and approximately 81.4% of women with invasive breast cancer receive chemotherapy [1]. However, chemotherapy results in side effects such as pain, fatigue, and sleep disturbance, which adversely affect women's quality of life (QoL) and psychological well-being [2]. These women frequently report unmet supportive care needs [3]. To better support women with breast cancer undergoing chemotherapy, health promotion efforts must provide appropriate symptom management strategies, as well as build a sense of self-efficacy and social support to initiate and maintain such desired strategies [4]. With advanced technology, mobile apps provide a promising platform in ways that allow women with breast cancer to acquire knowledge and interact with peers or health care professionals when and where needed [5].

In 2017, there were approximately 1.35 billion mobile phone users in China, accounting for 89% of the Chinese population [6]. It should be possible to use apps to promote quality health care through a robust and easily accessible program. However, there remains a paucity of randomized controlled trials (RCTs) to evaluate the effectiveness of app-based programs targeting women with breast cancer undergoing chemotherapy [7]. To date, most app-based programs including women with breast cancer have not been chemotherapy specific [8], or breast cancer specific [9]. Furthermore, women's usage of eHealth interventions and their relationship with effectiveness has rarely been reported in trials [10].

We developed the app-based, interactive breast cancer e-support (BCS) program (ACTRN12616000639426) [11] under the guidance of the incorporation of Bandura's self-efficacy theory [12] and social exchange theory [13]. The BCS theoretical framework has been demonstrated to be useful in the design of a psychoeducational program to optimize patients' health outcomes [14]. The purpose of this trial was to determine the effectiveness of BCS regarding women's health outcomes. Secondary objectives included exploring the association between women's health outcomes and the BCS usage data. A descriptive qualitative study was employed in Part 1 of this study to explore participant perceptions of the BCS for those in the intervention arm [15]. We hypothesized that BCS+CAU participants would show significant better health outcomes in self-efficacy, social support, symptom management, QoL, anxiety, and depression

across time compared with CAU participants. We also hypothesized that, as more women used the BCS program, better health outcomes would be achieved. To the best of our knowledge, this is the first study of its kind in China to evaluate app effectiveness for women with breast cancer undergoing chemotherapy.

## Methods

### Study Design and Participants

The BCS study protocol was published in *BMC Cancer* [11]. A multicenter, single-blinded, parallel RCT was used to evaluate the effectiveness of BCS. Women were eligible to participate if they were diagnosed with any stage of breast cancer within the prior 3 to 8 weeks, were able to access the internet through the mobile phone, were able to read and write Mandarin, and were commencing chemotherapy. Women were excluded if they had concurrent major physical illnesses or chronic mental health conditions.

The study was conducted between May 2016 and February 2017 at two university-affiliated hospitals in China. Ethics approvals were granted from the Institutional Review Board of Xiamen University affiliated Zhong Shan Hospital (ZSH) and Central South University affiliated Hunan Cancer Hospital (HCH) in China and the University of Newcastle in Australia. The clinicians introduced the BCS program to eligible women in the oncology clinics, and the researchers (JZ and DW) met interested women, confirmed their eligibility, and obtained their consent forms. After baseline data collection, the researchers (JZ and DW) randomly allocated women to BCS program plus care as usual (BCS+CAU) or CAU-alone group with allocation ratio as 1:1 and provided 30 min of program training for BCS+CAU participants before their first cycle of chemotherapy. The research assistants (RAs) collected data at baseline (T0), at 3 months (T1), and at 6 months (T2) of medical follow-ups with self-assessed paper questionnaires in the clinics. These time frames were chosen because greatest benefits of internet-based intervention were documented within 3 months [16], and some benefits might be sustained 6 months later [17]. Women were provided with a small gift (approximately US \$5) when they returned their questionnaires.

### Intervention

The process of BCS development was published in *Technology and Health Care* [18]. User-centric design was applied in BCS development, and the perceived ease of using the BCS program

was assessed [18]. The researchers (JZ and DW) helped BCS+CAU participants to download the app into their mobile phones and to register the BCS program. After approval by the first author from the app background thread, a unique username was generated with automated passport (changeable later). BCS+CAU participants did not need to pay for BCS access, and the usernames expired 12 weeks after activation.

Because 4 cycles of chemotherapy (3 weeks/cycle) are the minimum recommended standard [1], BCS program supported women for 12 weeks covering from the beginning of the 1st cycle to the end of the 4th cycle of chemotherapy. The BCS program (Figure 1) included 4 components: (1) a Learning forum; (2) a Discussion forum; (3) an Ask-the-Expert forum; and (4) a Personal Stories forum [11]. On the basis of Bandura's self-efficacy theory (direct mastery experiences, vicarious experiences, verbal persuasion, and arousal state) [12], the Learning forum provided knowledge related to breast cancer and symptom management strategies to address the women's direct mastery experiences. All knowledge was evidence-based and validated by multidisciplinary Chinese oncology professionals. The Discussion forum and Ask-the-Expert forum offered opportunities for women to interact with peers and health care professionals where verbal persuasion and modification of the women's perceptions of arousal states occurred. The Personal Stories forum involved 5 video-recorded encouraging stories to enhance the women's vicarious experiences. Guided by the social exchange theory (structural and functional support) [13], the Discussion forum and Ask-the-Expert forum increased the women's structural social networks, and the interaction within these 2 forums conveyed various functional support.

On the basis of the questions and concerns put forward in the BCS program, the Learning forum was updated with new knowledge every 2 weeks. The moderator, an experienced health care professional, moderated the Discussion forum by reading all messages daily and providing expert advice if requested. To protect the women's privacy, access to the questions and response in the Ask-the-Expert forum were restricted to the individual posing the question and health care professionals. Eight doctors from the participating hospitals joined the BCS program. The moderator sent reminder message to the corresponding doctors with incoming questions, and the doctors answered women's questions in the Ask-the-Expert forum within 24 hours. With the women's permission, some valuable questions and answers, which might be interesting for others, were added to the Discussion forum to facilitate communication. Technical assistance was available to the women during the workday. It was up to women how often and how long they made use of the BCS program.

### Comparator

Women receiving CAU alone did not have BCS access. For both conditions, CAU consisted of health supportive care while receiving chemotherapy as an inpatient. There were no restrictions in both groups in terms of performing other internet searches for information or social support.

### Outcomes

Women self-reported sociodemographic and clinical variables at T0. The medical records were checked if doubts existed regarding the clinical variables.

The primary outcome was self-efficacy at 3 months comparing the intervention and control arms. Self-efficacy was assessed using the Chinese version of the Stanford Inventory of Cancer Patient Adjustment (SICPA), which is a 38-item instrument to evaluate women's belief in their ability to manage problems related to cancer [19]. The total score of SICPA ranges from 0 to 380, with higher total scores indicating higher level of self-efficacy. The baseline internal consistency of SICPA for this study was good (Cronbach alpha=.87).

Secondary outcomes measured the women's social support, symptom distress, QoL, and anxiety and depression. Social support was assessed using the Chinese version of the Multidimensional Scale of Perceived Social Support (MSPSS), which is a 12-item self-report instrument to evaluate women's perception of support [20]. The item score ranges from 1 to 7, with a higher mean score indicating better social support. In this study, the baseline internal consistency of the MSPSS was .89.

Symptom distress was assessed using the Chinese version of the MD Anderson Symptom Inventory, which consists of a 13-item symptom severity subscale to measure the severity of each symptom and a 6-item symptom interference subscale to evaluate the extent to which the symptoms interfere with the patients' daily life [21]. The item score ranges from 1 to 10, with a higher mean score indicating severer symptom distress. In this study, the baseline internal consistency for symptom severity and symptom interference were .77 and .84, respectively.

QoL was assessed with a Chinese version of the Functional Assessment of Cancer Treatment-B (FACT-B), which is a 37-item instrument to evaluate the impact of breast cancer and its chemotherapy on dimension of QoL [22]. The total score of FACT-B ranges from 0 to 148, with higher total scores indicating better QoL. FACT-B had good baseline internal consistency in this study (Cronbach alpha=.77).

Anxiety and depression were assessed using the Chinese version of the Hospital Anxiety and Depression Scale, which consists of a 7-item anxiety subscale and a 7-item depression subscale [23]. The total score of each subscale ranges from 0 to 21, with higher total scores indicates greater anxiety or depression. In this study, the baseline internal consistencies were .81 and .73 for the anxiety and depression subscales, respectively.

Twelve weeks' usage data, including log-in frequency and usage duration of the whole BCS program, were tracked in the app's statistics module of background thread on individual basis. Log-in frequency was recorded as the number of times a participant logged into the app during 12 weeks. The total usage duration was recorded as the sum of all time in minutes between logging in and logging out. If women forgot logging out of the app, the app ran as the background operation mode no matter women were surfing on other websites or the mobile phones were in standby modes. App running as the background

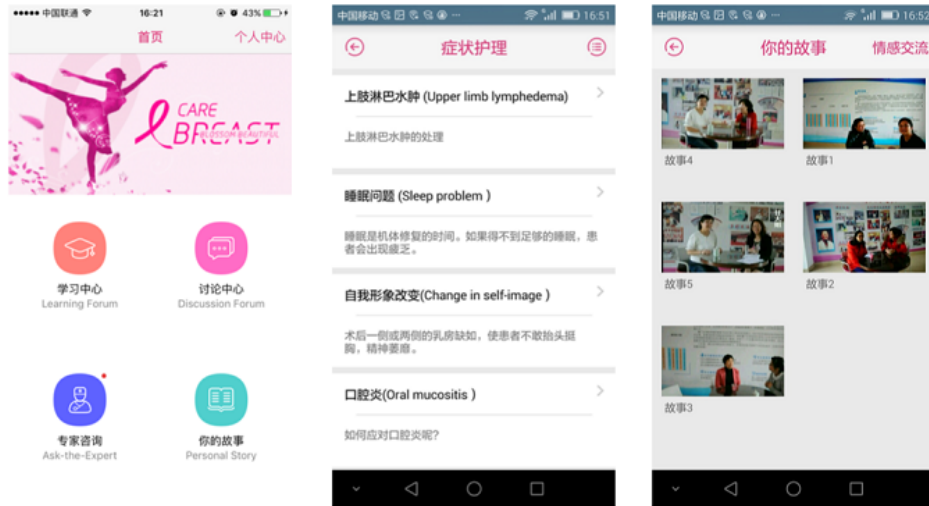
operation mode was regarded as app being logged out in the app's statistics module when recording the usage duration.

**Random Assignments and Masking**

Women with breast cancer were randomly assigned to BCS+CAU or CAU alone with an allocation ratio as 1:1. For

each hospital, a permuted block randomized design was used with Research Randomizer (Urbaniak and Plous) [24]. A variety of randomly selected block sizes of 4, 6, and 8 ensured blinded allocation. The health care team and RAs collecting data were blinded to the women's group allocation.

**Figure 1.** Screenshots of the breast cancer e-support (BCS) program home page and the 4s forums.



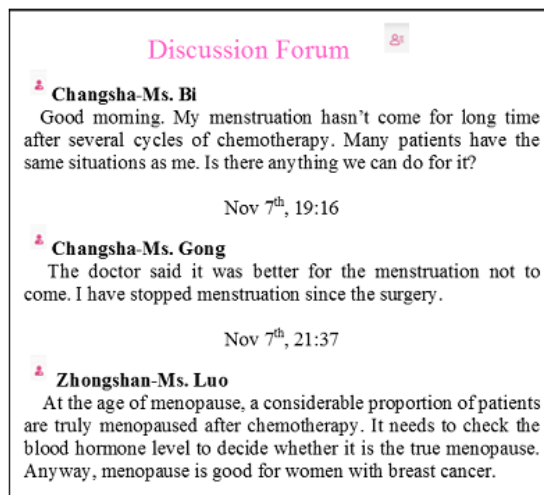
Home page

Learning forum

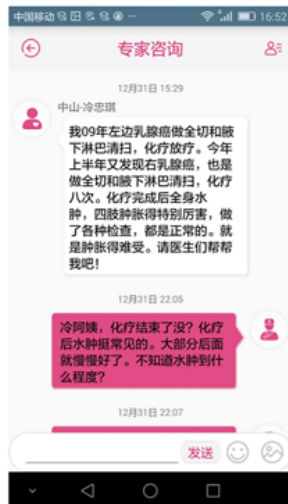
Personal stories forum



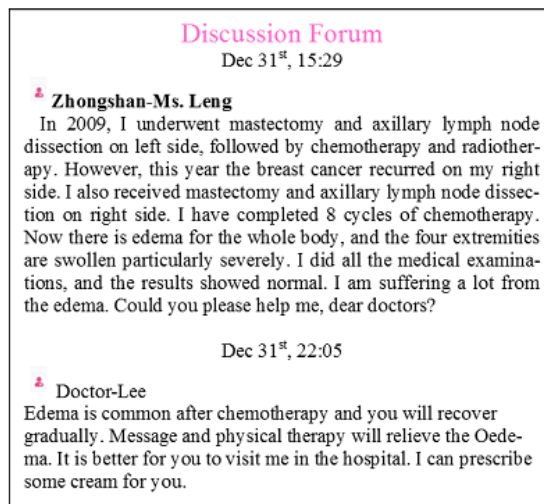
Discussion forum



Translation



Ask the Expert forum



Translation



## Sample Size Calculation

The study sample size was determined by the primary outcome of self-efficacy, with the standardized effect size of 0.60 reported in a previous psychosocial trial [25]. A sample of 108 participants (54 participants per group) was needed to detect an effect size of at least 0.60, with 80% power, two-sided  $P < .05$ , and 20% attrition. A dropout rate ranging from 10% to 20% was reported in previous studies involving an app-based study [9,26]. Finally, the recruitment numbered 114 participants in total (57 participants per group).

## Statistical Analysis

IBM SPSS Statistics 22.0 (IBM Corp, New York, USA) was used to analyze the data [27]. Intention-to-treat analysis with the last observation carried forward was applied to account for missing data. All baseline demographic characteristics, clinical variables, and baseline outcomes were compared using independent samples  $t$  test for continuous variables and chi-square test or Fisher exact test for categorical variables between the randomized assigned groups, as well as between participants who completed all follow-ups and who dropped out. The effectiveness of intervention on the primary and secondary outcomes was tested using repeated measures multivariate analysis of covariance with a group as a between-subject factor, time as a within-subject factor, and the interaction between group and time, adjusted by baseline corresponding outcomes. Because the women were randomly assigned at each hospital, the hospital site was not included as a random effect. The adjusted mean difference (95% CI) between groups at each of the following-up points are reported, with the adjusted mean (SDs), significance level, and effect size (Cohen  $d$ ). The adjusted means and pooled SD were used to calculate the effect size Cohen  $d$  for independent groups. With the caveat that only for women in the intervention group, the mean (SD), median, interquartile range (IQR), and maximum were used to describe log-in frequency and usage duration of the BCS program. Due to the highly skewed nature of the BCS usage data, Spearman rank-order correlation was calculated between the women's BCS usage data and unadjusted outcome variables at three time points.  $P < .05$  was considered statistically significant.

## Results

### Participant Characteristics

Between May 2016 and August 2016, 163 women were assessed for eligibility: 32 women (19.6%) were ineligible, 17 women (10.4%) refused, and 114 women (69.9%) underwent random assignment. Of the 114 women randomly assigned, 44 women (38.6%) were recruited from ZSH, and 70 women (61.4%) were recruited from HCH. Data collection was finalized in February 2017. Figure 2 presents the Consolidated Standard of Reporting Trials flowchart [28].

The two groups were comparable at baseline regarding demographic, clinical-related, and outcome measures (Table 1). There were more participants with missing data at T1 among

the CAU participants ( $n=7$ ) than among the BCS+CAU participants ( $n=1$ ), but the difference was not significant ( $P=.06$ ). Baseline variables in Table 1 did not show a significant difference between participants who completed all follow-ups ( $n=104$ ) and who dropped out ( $n=10$ ). A total of 96% of BCS+CAU participants ( $n=55$ ) and 86% of CAU participants ( $n=49$ ) completed the follow-up assessments.

### Effectiveness of the Breast Cancer e-Support Program

Regarding the primary outcomes, the women's self-efficacy in both groups was reduced after chemotherapy began. Adjusted for the baseline self-efficacy, the decrease in self-efficacy at T1 was significantly less for BCS+CAU participants than for CAU participants, with a medium effect size ( $P=.03$ ;  $d=0.53$ ; adjusted mean difference=21.05; 95% CI 1.87-40.22; Table 2).

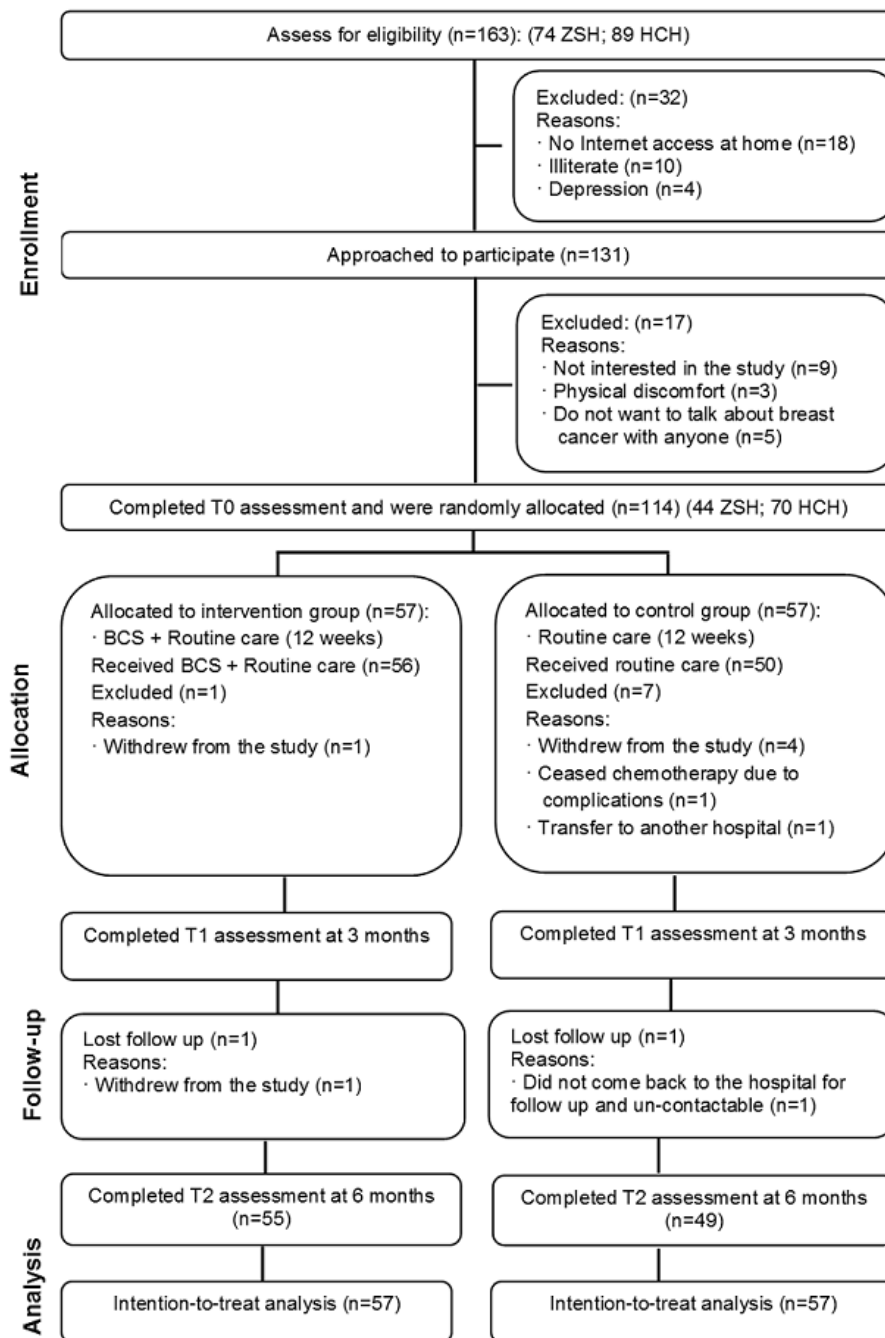
Regarding the secondary outcomes, both symptom severity and symptom interference increased from T0 to T1. Adjusted for baseline symptom interference, the increase in symptom interference at T1 was significantly less for BCS+CAU participants than for CAU participants, with a medium effect size ( $P=.02$ ;  $d=-0.51$ ; adjusted mean difference=-.73; 95% CI -1.35 to -.11; Table 2). No such difference in symptom severity was found. The QoL declined following the commencement of chemotherapy. Controlled for baseline QoL, the drop in QoL for BCS+CAU participants was significantly less than that for CAU participants, with a small to medium effect size ( $P=.03$ ,  $d=0.46$ ; adjusted mean difference=6.64; 95% CI 0.77-12.50; Table 2). There was no significant group difference for social support, anxiety, and depression from T0 to T1. At the 6-month follow-up, our intervention did not lead to significant improvement in any health outcomes from T1 to T2. Figure 3 presents a graphical representation of the mean percentage change in health outcomes. The hypothesis that the intervention could enhance health outcomes was partially supported.

### Association Between the Breast Cancer e-Support Usage Data and Health Outcomes

BCS usage varied considerably. During the 12-week intervention, the log-in frequency ranged from 0 to 774 times (mean 54.7; SD 131.4; median 11; IQR 5-27), and the total usage duration ranged from 0 to 9371 min (mean 1072.3; SD 2359.5; median 100; IQR 27-279). Two BCS+CAU participants never logged into the BCS program. The association between log-in frequency and outcomes variables was not found in this study.

BCS usage duration was correlated with different health outcomes at three time points. At T0, self-efficacy ( $r=.439$ ,  $P=.001$ ) and QoL ( $r=.313$ ,  $P=.02$ ) showed a positive correlation with the BCS usage duration, whereas symptom severity ( $r=-.297$ ,  $P=.03$ ) was inversely related to the women's BCS usage duration. At T1, self-efficacy ( $r=.290$ ,  $P=.03$ ), social support ( $r=.320$ ,  $P=.02$ ), and QoL ( $r=.273$ ,  $P=.04$ ) were positively related to the BCS usage duration. At T2, self-efficacy was still correlated with the BCS usage duration ( $r=.329$ ,  $P=.01$ ), whereas anxiety was inversely correlated with the BCS usage duration at T2 ( $r=-.300$ ,  $P=.03$ ).

**Figure 2.** Consolidated Standard of Reporting Trials (CONSORT) diagram of Breast Cancer e-Support program (BCS) program. HCH: Central South University affiliated Hunan Cancer Hospital; ZSH: Xiamen University affiliated Zhong Shan Hospital.



**Table 1.** Comparison of demographic/clinical characteristics and baseline outcomes between the groups (n=114).

Demographic/clinical characteristics and baseline outcomes <sup>a</sup>	Total (N=114)	BCS <sup>b</sup> +CAU <sup>c</sup> participants (N=57)	CAU participants (N=57)
Age in years, mean (SD)	47.2 (8.3)	46.2 (8.5)	48.2 (8.1)
<b>Marital status, n (%)</b>			
Married	111 (97.4)	57 (100)	54 (95)
Single	2 (1.8)	0 (0)	2 (1)
Divorce	1 (0.9)	0 (0)	1 (1)
<b>Education level, n (%)</b>			
No education	17 (14.9)	8 (14)	9 (16)
Elementary school	31 (27.2)	13 (23)	18 (32)
Junior middle school	33 (28.9)	16 (28)	17 (30)
High school	21 (18.4)	12 (21)	9 (16)
University or above	12 (10.5)	8 (14)	4 (7)
<b>Monthly family income (USD)<sup>d</sup>, n (%)</b>			
≤148	22 (19.3)	14 (25)	8 (14)
149-442	60 (52.6)	24 (42)	36 (63)
443-738	17 (14.9)	10 (18)	7 (12)
≥739	14 (12.3)	8 (14)	6 (11)
Missing data	1 (0.9)	1 (2)	0 (0.0)
<b>Currently employment<sup>d</sup>, n (%)</b>			
Yes	19 (16.7)	10 (18)	9 (16)
No	86 (75.4)	44 (77)	42 (74)
Missing data	9 (7.9)	3 (5)	6 (11)
Body mass index (kg/m <sup>2</sup> ), mean (SD)	23.4 (2.9)	23.0 (2.6)	23.7 (3.2)
<b>Cancer stage, n (%)</b>			
1	21 (18.4)	9 (16)	12 (21)
2	49 (43.0)	28 (49)	21 (37)
3	42 (36.8)	19 (33)	23 (40)
4	2 (1.8)	1 (2)	1 (2)
<b>Surgery, n (%)</b>			
Breast conserving surgery	5 (4.4)	3 (5)	2 (4)
Mastectomy	97 (85.1)	45 (79)	52 (91)
Others	12 (10.5)	9 (16)	3 (5)
<b>Comorbidity, n (%)</b>			
Yes	3 (2.6)	1 (2)	2 (4)
No	111 (97.4)	56 (98)	55 (96)
<b>Complication, n (%)</b>			
Yes	1 (0.9)	0 (0)	1 (2)
No	113 (99.1)	57 (100)	56 (98)
<b>Cycles of chemotherapy, n (%)</b>			
Four cycles	18 (15.7)	9 (16)	9 (16)
Six cycles	27 (23.7)	11 (19)	16 (28)
Eight cycles	69 (60.5)	37 (65)	32 (56)

Demographic/clinical characteristics and baseline outcomes <sup>a</sup>	Total (N=114)	BCS <sup>b</sup> +CAU <sup>c</sup> participants (N=57)	CAU participants (N=57)
<b>Chemotherapy regimen, n (%)</b>			
Cyclophosphamide+Epirubicin+Docetaxel	47 (41.2)	25 (44)	22 (39)
Docetaxel+Cyclophosphamide+Herceptin	18 (15.8)	9 (16)	9 (16)
Theprubicine+Cyclophosphamide+Docetaxel+Herceptin	17 (14.9)	8 (14)	9 (16)
Liposomal doxorubicin or Pharmorubicin+Cyclophosphamide	14 (12.3)	5 (9)	9 (16)
Herceptin	8 (7.0)	4 (7)	4 (7)
Vinorelbine+Cisplatin or Lobaplatin	7 (6.1)	4 (7)	3 (5)
Others	3 (2.6)	2 (4)	1 (2)
<b>Health outcomes, mean (SD)</b>			
Self-efficacy	224.7 (59.2)	235.3 (64.6)	214.1 (51.7)
Social support	5.5 (0.7)	5.6 (0.7)	5.4 (0.8)
Symptom severity	3.5 (2.0)	3.3 (2.0)	3.7 (2.0)
Symptom interference	3.1 (1.9)	2.8 (1.8)	3.3 (2.1)
Quality of life	92.8 (18.4)	94.6 (19.5)	90.9 (17.3)
Anxiety	9.9 (2.4)	10.3 (2.4)	9.5 (2.3)
Depression	12.6 (2.2)	12.6 (2.0)	12.6 (2.4)

<sup>a</sup>No significant difference were found between two groups ( $P>.05$ ).  $P$  values were calculated using independent samples  $t$  test for continuous variables and chi-square tests or Fisher exact test for categorical variables.

<sup>b</sup>BCS: breast cancer e-support program.

<sup>c</sup>CAU: care as usual.

<sup>d</sup>Missing data present.

**Table 2.** Effect of breast cancer e-support (BCS) program (intention-to-treat analysis) on primary and secondary outcomes at 3 months (T1) and 6 months (T2); N=114.

Treatment effect	Mean (SD)		Adjusted mean difference (95% CI)	P value <sup>a</sup>	Effect size (Cohen <i>d</i> )
	BCS+CAU <sup>b</sup> participants (n=57)	CAU participants (n=57)			
<b>Primary outcomes</b>					
<b>Self-efficacy (SICPA<sup>c</sup>) [19]</b>					
T1	227.12 (66.80)	197.07 (43.44)	21.05 (1.87 to 40.22)	.03	0.53
T2	232.09 (69.01)	220.91 (56.32)	3.40 (-19.05 to 25.86)	.76	0.18
<b>Secondary outcomes</b>					
<b>Social support (MSPSS<sup>d</sup>) [20]</b>					
T1	5.24 (1.00)	5.47 (2.75)	-0.39 (-1.15 to 0.38)	.32	-0.11
T2	5.62 (.65)	5.42 (.80)	0.14 (-0.13 to 0.41)	.31	0.27
<b>Symptom severity (MDASI<sup>e</sup>) [21]</b>					
T1	3.79 (1.81)	4.17 (1.71)	-0.21 (-0.72 to 0.31)	.42	-0.22
T2	3.67 (2.21)	4.30 (1.89)	-0.26 (-0.88 to 0.36)	.41	-0.31
<b>Symptom interference (MDASI) [21]</b>					
T1	2.99 (1.78)	3.93 (1.91)	-0.73 (-1.35 to -0.11)	.02	0.51
T2	3.11 (2.01)	3.84 (1.95)	-0.57 (-1.27 to 0.13)	.11	-0.37
<b>Quality of life (FACT-B<sup>f</sup>) [22]</b>					
T1	92.87 (21.39)	84.09 (15.99)	6.64 (0.77 to 12.50)	.03	0.46
T2	92.16 (21.24)	85.66 (15.58)	5.23 (-1.34 to 11.80)	.12	0.35
<b>Anxiety (HADS<sup>g</sup>) [23]</b>					
T1	9.93 (2.72)	10.28 (2.46)	-0.77 (-1.62 to 0.08)	.07	-0.14
T2	10.58 (2.87)	10.26 (2.39)	-0.05 (-0.96 to 0.86)	.92	0.12
<b>Depression (HADS) [23]</b>					
T1	12.75 (1.57)	12.58 (2.15)	0.17 (-0.52 to 0.87)	.62	0.09
T2	13.28 (2.02)	12.65 (2.53)	0.63 (-0.20 to 1.45)	.14	0.28

<sup>a</sup>All *P* values were calculated using an analysis of covariance with adjustment for baseline value of the corresponding questionnaire.

<sup>b</sup>CAU: care as usual.

<sup>c</sup>SICPA: Stanford Inventory of Cancer Patient Adjustment.

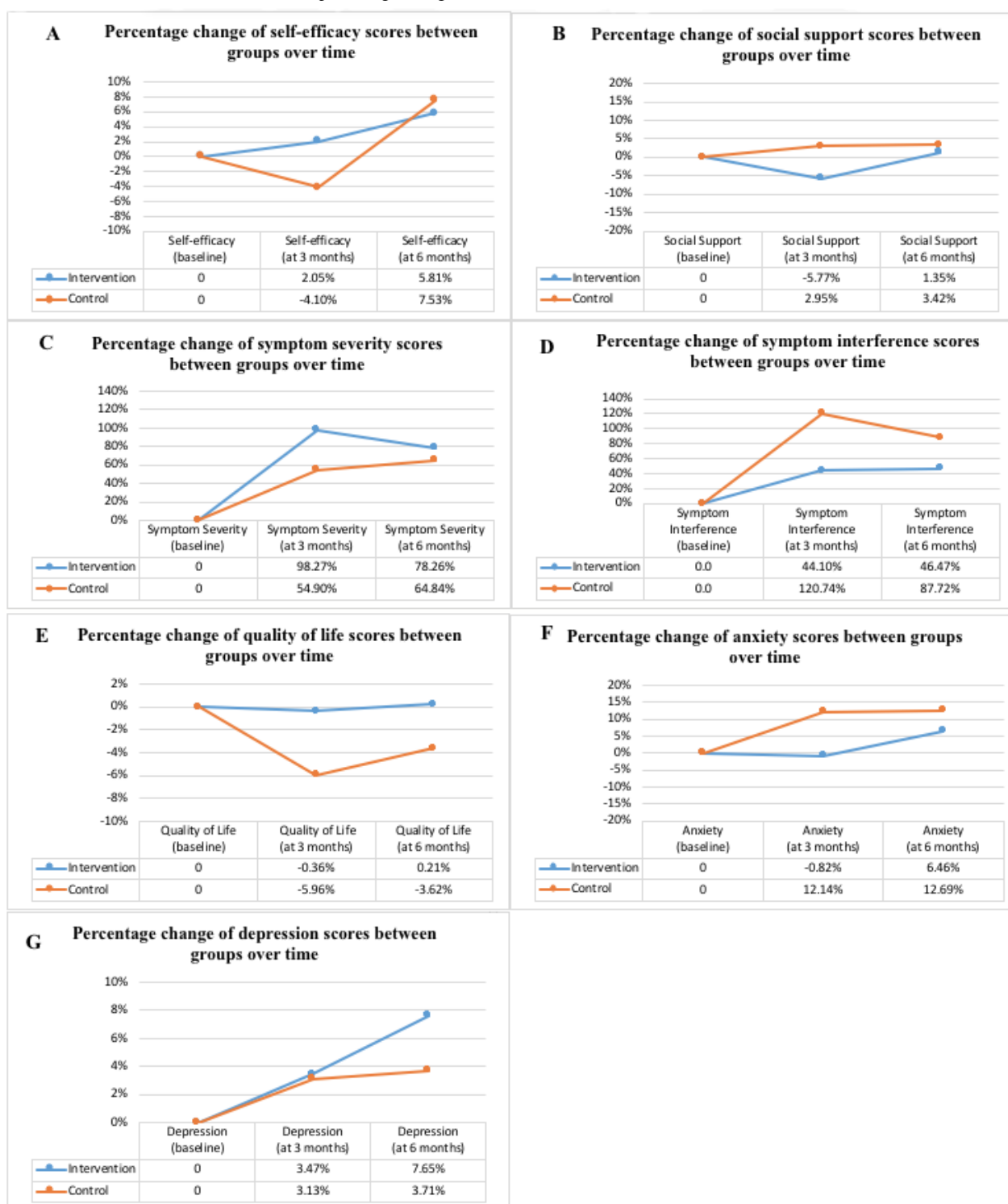
<sup>d</sup>MSPSS: Multidimensional Scale of Perceived Social Support.

<sup>e</sup>MDASI: MD Anderson Symptom Inventory.

<sup>f</sup>FACT-B: Functional Assessment of Cancer Treatment-B.

<sup>g</sup>HADS: Hospital Anxiety and Depression Scale.

**Figure 3.** Mean percentage changes of health outcomes from baseline to posttests (n=114). Score at 3 months percentage change=(score at 3 months-score at baseline)/score at baseline; Score at 6 months percentage change=(score at 6 months-score at baseline)/score at baseline.



## Discussion

### Principal Findings

The strength of this study included health-focused theoretical underpinnings that support the design of the BCS program and the study's methodological rigor in data collection and analysis. This study found that, when women are in the midst of early struggle with breast cancer and chemotherapy, 12-week access

to BCS program plus CAU resulted in significant better health outcomes regarding self-efficacy, symptom interference, and QoL compared with CAU alone at 3 months. However, these beneficial effects were not sustained at 6 months. Access to BCS did not influence social support, symptom severity, anxiety, and depression at follow-ups. The BCS usage duration was positively correlated with self-efficacy, social support, and QoL at 3 months.

BCS participants reported significantly better self-efficacy at 3 months compared with control participants. In addition, a positive relationship was found between self-efficacy and the BCS usage duration at baseline, 3 months, and 6 months of follow-ups. Self-efficacy determines whether the women would initiate the actions, how much effort they exerted, and how long they sustained the effort when encountered with obstacles [12]. Consistent with prior research [14,25], we demonstrated that the self-efficacy theory and social exchange theory are usable in guiding the development of an app-based program to enhance self-efficacy.

BCS+CAU participants showed better QoL at 3 months. Furthermore, BCS usage duration was positive related with QoL at baseline and 3 months. Similarly, Gustafson et al [29] reported that the Comprehensive Health Enhancement Support System (CHESS) had a positive impact on QoL for women with breast cancer. CHESS is a computer-based program involving an information module, a communication module, and an interactive coaching module [16], which are, currently, easy to install and use through apps. Our BCS program indicated that the app-based BCS program could provide comparative functionality and achieve similar effectiveness as computer-based programs [29], whereas women could enjoy the advantage of convenience and easy access of apps.

This study achieved a significant group difference in symptom distress only for the subscale of symptom interference, not for the subscale of symptom severity, at 3 months. Decreased symptom distress is a critical indicator of successful health support [30]. BCS program may modify women's interpretation of the extent to which symptoms interfered with their daily lives. In this study, symptom severity was inversely correlated with BCS usage duration at baseline. Some women might have experienced high levels of symptoms such as pain or fatigue that hindered their BCS engagement, potentially diluting the results. Future app-based studies might involve caregivers using the app to support the patients when the patients are experiencing severe symptoms.

BCS program did not significantly change social support relative to the effect of CAU alone at 3 months. In China, there are many existing popular mobile phone-based chat platforms, such as Wechat and QQ, which women in both groups were more familiar with and used for seeking social support, thus potentially competing for the impact of BCS program on social support. However, among BCS+CAU participants, our study found that women's BCS usage duration was positively associated with the perceived social support at 3 months, indicating that the longer women used the BCS program, the higher women perceived social support. The BCS superiority to other online chat platform is the credibility of information provided and medical consultation from experts, which should be addressed to promote engagement with BCS.

In addition, the study found that the BCS program did not significantly reduce the BCS+CAU participants' anxiety and depression at 3 months. Access to a wide variety of knowledge related to breast cancer and chemotherapy may not relieve the women's anxiety and depression [31]. Moreover, literature shows inconsistent findings regarding the effects of eHealth on

anxiety and depression for cancer patients [32], which needs to be addressed in the future research.

This study found no long-term effects for women at 6 months. This may be because women could access the BCS program for 12 weeks only, and the BCS program may produce little residual advantage at 6 months. However, the physical and psychosocial symptoms may persist for 12 months or even longer after the completion of the chemotherapy [33]. Thus, allowing women to retain BCS access longer may have revealed different outcomes at 6 months. Moreover, the majority of participating women had completed chemotherapy and were experiencing physical, psychological, and social recovery at 6 months. It is possible that BCS program focuses on chemotherapy support and does not include sufficient knowledge for adjustment after completion of the treatment, which should be addressed for future app-based studies to achieve long-term effect.

Women's engagement in the BCS program needs to improve. In our study, the median of usage data showed that the BCS engagement was relatively low, and the big difference between mean and median indicated usage polarization among BCS participants. Meanwhile, our study found that the BCS usage duration was positively related to self-efficacy, social support, and QoL for BCS participants at 3 months, indicating that women drew more benefits if they used the BCS program more often. These usage data could be helpful to explain why the BCS program achieves or fails in the desired outcomes [34]. The design of the BCS program needs to be improved to encourage engagement for a more effective app-based program. In our qualitative process evaluation, women suggested to add message reminders to prompt instant communication and add search engine to help locate information more quickly [15], which could lead to more engagement and should be addressed in the future trial.

Due to time and resource limitations, the participants of this study were recruited from 2 university-affiliated hospitals. Our sample characteristics, such as the participants' mean age, marital status, educational level, cancer stage at diagnosis, and treatment type were comparable to the national clinical epidemiological data on breast cancer [1,35]. Their current employment status and family income of the participants in this study were also similar to other studies on patients with breast cancer or other cancers during chemotherapy [25,36]. Thus, our study could generalize to women with breast cancer in China with similar characteristics. However, further multicenter studies are needed to provide more conclusive results.

## Limitations

This study possessed several limitations. The requirement of mobile phone internet access may have resulted in a more tech-savvy population who were more comfortable with mobile phone use, potentially limiting the generalization of this study. However, in future, more women will be able to use apps, and the BCS application may be greater. The BCS engagement shows scope of improvement and warrants attention. No long-term effect was found. Future app-based studies should explore different strategies to reduce potential barriers such as the involvement of the caregivers in the app use, to promote

engagement by addressing the benefits of this credible resource and health care professionals' involvement, and to extend the access time to 12 months after the completion of medical treatment to test the long-term follow-up effect. Moreover, the app has not been designed to track women's usage data on a weekly or monthly basis. The lack of BCS dynamic usage data means that it is not possible to inform how often and how long the BCS program should be used to have a short-term and long-term effect [17]. Continued research is warranted considering the promising findings of this trial.

### Conclusions

The BCS program demonstrates its potential for dissemination globally to support women with breast cancer during chemotherapy. The application of this app seems to be promising

for Chinese women with breast cancer in the world. This app also has the potential to be translated to other languages for culturally and linguistically diverse groups. Health care professionals are in a prime position to incorporate app-based program as a routine care to enhance health outcomes for women with breast cancer undergoing chemotherapy, as well as for other cancer patients. This study provides evidence for policy makers and hospital administrators to allocate resources for development and implementation of apps related to health promotion to further advance this effort. This is crucial because mobile apps are being increasingly utilized as supplementary interventions for individuals when the feasibility of face-to-face interventions is challenged by physical limitations or geographic distance [37].

### Acknowledgments

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### Authors' Contributions

JZ, LE, and SW-CC contributed to conception and design of the study. JZ also contributed to acquisition of data, analysis of data, funding acquisition, writing of the original draft and revision, and final approval the submitted version. LE further contributed to writing or reviewing and editing for important intellectual content, and final approval the submitted version. XL contributed to acquisition of data, writing or reviewing and editing for important intellectual content, and final approval the submitted version. DW contributed to acquisition of data, writing or reviewing and editing for important intellectual content, and final approval the submitted version. SW-CC contributed to project administration, writing or reviewing and editing for important intellectual content, and final approval the submitted version.

### Conflicts of Interest

None declared.

### Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 814KB - [mhealth\\_v6i4e104\\_app1.pdf](#)]

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## Abbreviations

**BCS:** breast cancer e-support  
**CAU:** care as usual  
**CHESS:** Comprehensive Health Enhancement Support System  
**FACT-B:** functional assessment of cancer treatment-B  
**HADS:** Hospital Anxiety and Depression Scale  
**HCH:** Central South University affiliated Hunan Cancer Hospital  
**IQR:** interquartile range  
**MDASI:** MD Anderson Symptom Inventory  
**MSPSS:** Multidimensional Scale of Perceived Social Support  
**QoL:** quality of life  
**RCT:** randomized controlled trial  
**SICPA:** the Stanford Inventory of Cancer Patient Adjustment  
**ZSH:** Xiamen University affiliated Zhong Shan Hospital

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Original Paper

# A Behavioral Lifestyle Intervention Enhanced With Multiple-Behavior Self-Monitoring Using Mobile and Connected Tools for Underserved Individuals With Type 2 Diabetes and Comorbid Overweight or Obesity: Pilot Comparative Effectiveness Trial

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## Abstract

**Background:** Self-monitoring is a cornerstone of behavioral lifestyle interventions for obesity and type 2 diabetes mellitus. Mobile technology has the potential to improve adherence to self-monitoring and patient outcomes. However, no study has tested the use of a smartphone to facilitate self-monitoring in overweight or obese adults with type 2 diabetes mellitus living in the underserved community.

**Objective:** The aim of this study was to examine the feasibility of and compare preliminary efficacy of a behavioral lifestyle intervention using smartphone- or paper-based self-monitoring of multiple behaviors on weight loss and glycemic control in a sample of overweight or obese adults with type 2 diabetes mellitus living in underserved communities.

**Methods:** We conducted a randomized controlled trial to examine the feasibility and preliminary efficacy of a behavioral lifestyle intervention. Overweight or obese patients with type 2 diabetes mellitus were recruited from an underserved minority community health center in Houston, Texas. They were randomly assigned to one of the three groups: (1) behavior intervention with smartphone-based self-monitoring, (2) behavior intervention with paper diary-based self-monitoring, and (3) usual care group. Both the mobile and paper groups received a total of 11 face-to-face group sessions in a 6-month intervention. The mobile group received an Android-based smartphone with 2 apps loaded to help them record their diet, physical activity, weight, and blood glucose, along with a connected glucometer, whereas the paper group used paper diaries for these recordings. Primary outcomes of the study included percentage weight loss and glycated hemoglobin (HbA<sub>1c</sub>) changes over 6 months.

**Results:** A total of 26 patients were enrolled: 11 in the mobile group, 9 in the paper group, and 6 in the control group. We had 92% (24/26) retention rate at 6 months. The sample is predominantly African Americans with an average age of 56.4 years and body mass index of 38.1. Participants lost an average of 2.73% (mobile group) and 0.13% (paper group) weight at 6 months, whereas the control group had an average 0.49% weight gain. Their HbA<sub>1c</sub> changed from 8% to 7% in mobile group, 10% to 9% in paper group, and maintained at 9% for the control group. We found a significant difference on HbA<sub>1c</sub> at 6 months among the 3 groups ( $P=.01$ ). We did not find statistical group significance on percentage weight loss ( $P=.20$ ) and HbA<sub>1c</sub> changes ( $P=.44$ ) overtime; however, we found a large effect size of 0.40 for weight loss and a medium effect size of 0.28 for glycemic control.

**Conclusions:** Delivering a simplified behavioral lifestyle intervention using mobile health–based self-monitoring in an underserved community is feasible and acceptable and shows higher preliminary efficacy, as compared with paper-based self-monitoring. A full-scale randomized controlled trial is needed to confirm the findings in this pilot study.

**Trial Registration:** ClinicalTrials.gov NCT02858648; <https://clinicaltrials.gov/ct2/show/NCT02858648> (Archived by WebCite at <http://www.webcitation.org/6ySidjmT7>)

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## KEYWORDS

self-monitoring; diabetes; obesity; mobile health; behavior change; connected health; patient-generated health data; lifestyle; patient engagement; comparative effectiveness trial

## Introduction

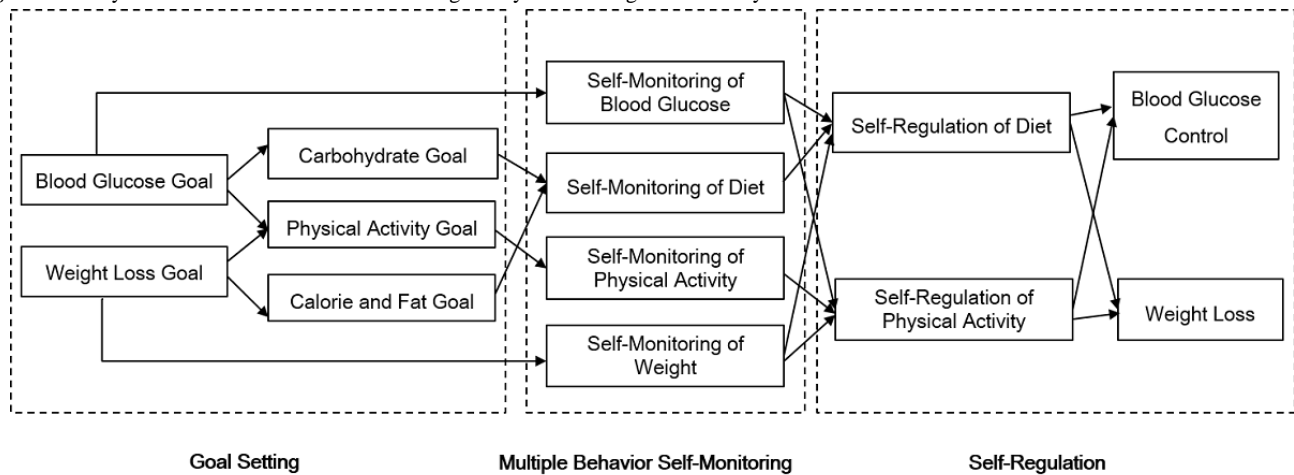
More than two-thirds of American adults are overweight or obese [1]. New statistics show that obesity rates are on the rise [2]. Among adults in the United States with diabetes, 80.3% were overweight or obese (body mass index, BMI>25) [3]. Overweight and obesity are major contributors to increased incidence of type 2 diabetes mellitus (T2DM) [4], which is associated with serious comorbid conditions including long-term damage from micro and macrovascular diseases to multiple organs (eg, eyes, kidneys, nerves, heart, and blood vessels) [5]. Strong evidence supports the efficacy of a behavioral lifestyle modification for weight loss, glucose control, and cardiovascular disease (CVD) risk reduction in overweight or obese adults with T2DM [6,7]. The landmark Look AHEAD (Action for Health in Diabetes) trial demonstrated the efficacy of an intensive lifestyle intervention in achieving clinically significant weight loss, glucose control, and CVD risk reduction in overweight or obese adults with T2DM [7]. However, although a recent meta-analysis showed that achieving a weight loss of >5% did demonstrate improvement in metabolic parameters, most studies did not show a weight loss in this range [8]. In particular, few studies provided evidence to support the effectiveness of behavioral lifestyle interventions among underserved populations. A systematic review evaluating behavioral interventions for African Americans with T2DM suggested that clinical trials are needed to tailor interventions to this largely underserved population [9].

Medically underserved populations or patients from medically underserved areas, as defined and designated by the Health Resources and Services Administration [10], are typically older or face barriers to good health and health care based on their income, education, race or ethnicity, or other social and economic factors. Diabetes self-management has been a challenge for all diabetes patients, especially underserved individuals [11,12]. Trief and colleagues found that adherence to diabetes self-management is particularly poor for older minority patients from underserved areas, and adherence is a significant mediator of glycemic control for this population [13]. More innovative and practical strategies are needed to address such disparity and improve glycemic control for underserved T2DM patients.

Self-monitoring of dietary calorie and fat intake and physical activity (PA) was emphasized as a key strategy in the two

landmark behavioral lifestyle intervention studies, the Diabetes Prevention Program and the Look AHEAD study [14,15]. In a recent systematic review [16], daily self-monitoring of weight was found to be effective in weight loss without causing negative psychological outcomes. Self-monitoring of carbohydrate intake and self-monitoring of blood glucose (SMBG) are standard practice in diabetes self-management education. However, whether SMBG is effective in the management of T2DM for persons not receiving insulin remains controversial [17]. A systematic review of 30 trials suggested that not using SMBG results to guide corresponding lifestyle behavior changes might have contributed to the inconclusive findings on the effect of SMBG. Thus, we hypothesized that enhancing patients' problem-solving skills using SMBG results through reflecting, self-monitoring, and regulating diet, activity, and weight could increase the effectiveness of SMBG. Daily self-monitoring of carbohydrate intake, along with self-monitoring of weight and blood glucose, was not part of the included in the two landmark behavioral lifestyle intervention studies [14,15] but holds promise in further improving patient outcomes when used alongside diet and activity self-monitoring.

Although traditional paper diaries were used for self-monitoring in the two landmark behavioral intervention studies, researchers have tested the use of electronic diaries for self-monitoring [18-20] and found these as effective as paper diaries and less burdensome and time consuming. Initially, Burke and colleagues examined the use of personal digital assistants (PDAs) for self-monitoring [18,19] to strengthen the effect of a behavioral weight loss intervention and found PDAs to be a viable alternative that is convenient to use. As technological advances have rendered PDAs obsolete, more recent research tested smartphones to reduce patient burden in self-monitoring and in counting calories using a booklet. Current research comparing the effectiveness of mobile health (mHealth) technology such as PDAs or smartphone apps vs paper diaries to support self-monitoring did not find significant difference on weight loss outcome in several behavioral weight loss trials [21,22]. Moreover, these weight loss trials focused on obese populations only [21,22]; no study compared the two modalities in T2DM patients with comorbid overweight or obesity. Although there are studies testing the use of mHealth tools for diet, PA, and blood glucose self-monitoring as part of a health coaching intervention in T2DM patients [23,24], none of these studies compared the two self-monitoring modalities.

**Figure 1.** Study model modified from social learning theory and self-regulation theory.

Thus, we propose to fill the scientific gap in testing a behavioral lifestyle intervention for underserved T2DM patients using mHealth tools to enhance multiple-behavior self-monitoring of diet, PA, weight, and blood glucose in a pilot comparative effectiveness trial. On the basis of self-regulation theory, we hypothesized that monitoring multiple behaviors (ie, calorie and fat consumption, exercise, and carbohydrate intake) and associated health outcomes (ie, weight and blood glucose levels) simultaneously can result in behavior change through better self-awareness of how eating and exercise play a role in both weight and glycemic control (Figure 1). In this study, we sought to assess the feasibility of this mHealth-enhanced intervention and compare its preliminary efficacy with that of paper-based multiple-behavior monitoring and standard diabetes care and education in improving glycemic outcomes among overweight or obese adults with T2DM living in underserved communities.

## Methods

### Study Design

We conducted a three-group pilot randomized controlled clinical trial comparing the efficacy of a behavioral lifestyle intervention modified for underserved populations using either (1) mobile or (2) paper-based tools for self-monitoring of diet, PA, weight, and blood glucose and (3) usual diabetes care and education on glycemic control and weight loss at 3 and 6 months. We used a mixed-method design with quantitative measures to evaluate the feasibility and preliminary efficacy of the intervention and conducted focus groups to assess participants' acceptability of the intervention. We are reporting the quantitative study findings in this paper. The study is approved by the institutional review board at the University of Texas Health Science Center at Houston. Consolidated Standards of Reporting Trials (CONSORT) of Electronic and Mobile Health Applications and onLine TeleHealth was used to guide the reporting of this study; a checklist was uploaded as [Multimedia Appendix 1](#) in this paper [25].

### Sample and Sample Size

Participant inclusion and exclusion criteria are shown in [Textboxes 1](#) and [2](#).

We used the age criteria from the Look AHEAD clinical trial and limited the exclusion criteria to include a general clinical population with a goal to be pragmatic in the nature of this study. To obtain a more representative sample of the underserved population, we included patients with amputations as long as they were able to perform regular activity such as walking. Due to the nature of this study being a pilot and feasibility study, we aimed to recruit 30 patients with 10 patients in each group.

### Setting

Participants were recruited from an American Diabetes Association certified diabetes education program located in a community health center primarily serving uninsured or underinsured individuals living in Harris County, Texas. Flyers were distributed to the patients attending diabetes self-management education classes by their diabetes educators.

### Enrollment and Randomization

If patients showed interest in this study and approached the study team for more details, they were screened for eligibility based on the inclusion and exclusion criteria; their diagnosis of T2DM was confirmed via chart review. Informed consent was obtained from all eligible study participants before enrollment. The study participants were aware of the differences among the three randomization groups during the consenting process. After consent and enrollment, we assigned each patient with a study ID number. The study statistician generated a randomization sheet with the group assignment for each study ID. Study participants were then randomly assigned to one of the three study groups based on the randomization sheet.

### Intervention

#### Intervention Overview

To increase study replicability, key differences among the three randomization groups and the behavioral lifestyle intervention in the landmark Look AHEAD trial (intervention materials are publicly available at look ahead trial website) are presented in [Table 1](#).

**Textbox 1.** Inclusion criteria.

<p>Individuals were included if they</p> <ul style="list-style-type: none"> <li>• had a diagnosis of type 2 diabetes mellitus (T2DM) for at least 6 months by self-report and later confirmed in the electronic health records</li> <li>• were overweight or obese (body mass index, BMI&gt;25)</li> <li>• were aged 21 to 75 years</li> <li>• were able to read and write in English</li> <li>• had completed or were about to complete the basic diabetes self-management education offered at the recruitment site</li> </ul>
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**Textbox 2.** Exclusion criteria.

<p>Individuals were excluded if they</p> <ul style="list-style-type: none"> <li>• had a history of severe psychiatric disorders (eg, bipolar disorder or schizophrenia)</li> <li>• were unable to perform regular activity</li> <li>• were currently or planned to be pregnant or nursing in the next 6 months</li> <li>• had a planned vacation in the next 6 months</li> <li>• had previously participated in an intensive behavioral lifestyle intervention</li> <li>• had substance abuse in the past year</li> </ul>
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**Table 1.** Comparison of key intervention components among three randomization groups and standard behavioral lifestyle intervention used in the landmark Look AHEAD (Action for Health in Diabetes) trial. SMBG: self-monitoring of blood glucose.

Intervention components	Look AHEAD (Action for Health in Diabetes)	Paper group	Mobile group	Usual care and education
<b>Self-monitoring</b>				
Self-monitoring of diet	Paper diaries given to monitor meals, calories, fat goals	In addition to Look AHEAD protocol, add a focus on self-monitoring of carb intake, SMBG, and self-monitoring of weight	Use smartphone app with connected glucometer to monitor the same parameters as the paper group	No, diabetes educator may do one dietary recall during an education visit or give general recommendations to carb counting
Self-monitoring of physical activity	Paper diaries given to monitor exercise minutes, calories burned	Same as Look AHEAD group	Smartphone app	No
Daily self-monitoring of weight	Not part of the intervention	Yes, a weight scale, and place in a paper diary to document	Provide a wireless weight scale and its companion smartphone app for daily weight monitoring	No
Self-monitoring of blood glucose	Not part of the intervention	Recommend every other day at the recruiting center, free glucometer and strips once every other day, our study will supplement strips for daily SMBG	Provide wireless glucometer and its companion smartphone app and strips for daily SMBG	Recommend every other day at the recruiting center, free glucometer and strips once every other day, our study will supplement strips for daily SMBG
Behavioral intervention sessions	Month 1-6, weekly sessions (3 group + 1 individual)	11 group sessions + 1 individual session in the first 6 months	Same as paper group	No
Usual care and diabetes education		Same as usual care and education group	Same as usual care and education group	3 group classes and follow up classes as needed with diabetes educators, physician visit about every 6 months depending on condition
Meal replacement	Yes	No	No	Not recommended at the recruitment site

### Usual Diabetes Care and Education Group

Participants in the control group received usual care and diabetes education from their primary care physicians and diabetes educators. The recruiting community health centers offer a diabetes education program for all diabetes patients. The diabetes education program consists of individual visits or a series of two interactive group classes taught by registered dietitians or nurses who are certified diabetes educators. The topics covered in the sessions are as follows: SMBG skills, carbohydrate counting, healthy eating and exercise, and the risk and management of hyperglycemic and hypoglycemic situations. Patients are not typically asked to self-monitor diet, activity, and weight on a daily basis in diabetes education. During diabetes education, patients typically set one to three behavioral goals centered on nutrition, PA, risk prevention, SBMG, or medication.

### Group and Individual Behavioral Lifestyle Intervention Sessions for Both the Mobile and Paper Groups

In addition to receiving usual diabetes care and education at the recruiting community center, both the mobile and paper groups received a standard behavioral lifestyle intervention comprising 11 group sessions—weekly for month 1, biweekly for months 2 and 3, and monthly for months 4 to 6—and an individual session after month 3. The group sessions were held at the recruiting community health center and included a grocery shopping trip. Pedometers, weight scales, and food scales were distributed in the sessions. The topics for the 11 sessions were as follows: (1) Welcome to the Program; (2) Be a Fat and Calorie Detective; (3) Healthy Eating; (4) Grocery Shopping and Cooking; (5) Move Those Muscles, Jump Start Your Activity Plan; (6) Tip the Calorie Balance, Take Charge of What's Around You; (7) Problem Solving, Stress, and Time Management; (8) Four Keys to Healthy Eating Out, Make Social Cues Work for You; (9) Slippery Slope of Lifestyle Change, Ways to Stay Motivated; (10) Prepare for Long-Term Self-Management, More Volume or Fewer Calories; and (11) Balance Your Thoughts, Strengthen Your Exercise Program. Each session took approximately 1 to 2 hours.

Two lifestyle counselors were trained using publicly available materials and a digital optical disc and printed training materials from the Group Lifestyle Balance (GLB) program and the Look AHEAD intervention. On the basis of GLB and Look AHEAD intervention principles, a standard behavioral intervention program typically includes group sessions focused on the following behavioral strategies: (1) goal setting, (2) feedback, (3) portion control, (4) cooking class, (5) field trip, (6) social support, (7) incentives, (8) problem solving, (9) relapse prevention, and (10) self-monitoring. All of these strategies in the original 12 core sessions and four transition sessions in the first 6 months of the GLB program were integrated and delivered in the 11 group sessions. An individual intervention was added ad hoc to evaluate individualized goals and behavior change plans; review individual weight loss goals, current weight, and diaries; how to tip the calories; and develop specific diet and PA goals to reach weight loss goal.

To adapt the intervention for the underserved population, all intervention materials were modified to be at 9th grade reading

level. Intervention sessions were delivered at the recruiting community health center that is close to most of the participants' homes. The grocery shopping trip was also conducted in the neighborhood where the participants typically shop.

### Multiple-Behavior Self-Monitoring Intervention for the Mobile and Paper Groups

Participants received training on how to self-monitor their diet and exercise habits, weight, and blood glucose in the first two sessions. Specifically, both groups were instructed to record their exercise activities (minutes and type of activity) and specify the foods they ate; the amount eaten; the number of calories, fat grams, and carbohydrates; their weight; and their blood glucose using a paper diary or an electronic diary depending on their group randomization.

Mobile group: for those who did not have a smartphone, we provided a smartphone for use over 6 months. None of the participants assigned to this group owned a smartphone, so all study participants in the group were given a smartphone with two apps downloaded by the study team. The participants used the LoseIt! (FitNow, Inc, Boston, Massachusetts) smartphone app for self-monitoring of diet, PA, and weight and the Diabetes Connect app (PHRQL Inc, Pittsburgh, Pennsylvania) connected with MyGlucoHealth, a Bluetooth-enabled glucometer (Entra Health Systems LLC, San Diego, California). There were no prompts or reminders embedded in these apps; however, we discussed self-monitoring results and encouraged participants to share experience using them during the 11 face-to-face group sessions.

Paper group: we provided CalorieKing food and exercise journals to study participants to write down their daily dietary intake and exercise. We instructed them to record their weight and blood glucose levels on the same pages, with the goal of helping them make connections between their diet, PA, weight, and glucose outcomes. Free stand-alone glucometers were provided to all patients at the recruitment sites. A CalorieKing counter, calculator, food scale, and food measuring set was provided to each participant in the paper group to measure their food portions; look up calorie, fat, and carbohydrate content; and calculate the total numbers for dietary self-monitoring.

### Treatment Fidelity

A checklist was developed and used for each group and individual session to track the content delivered. The principal investigator (PI) attended at least 80% of the group sessions for both paper and mobile groups to ensure treatment fidelity. Training of the two lifestyle counselors (their backgrounds were in public health and kinesiology) occurred 4 months before the study. Mock sessions were conducted on weekly meetings where lifestyle counselors developed PowerPoint slides, delivered mock intervention sessions, and reviewed the checklist for each session.

### Missed Sessions

Individual or group make-up sessions were scheduled for those who had to miss any group or individual sessions.

## Measures

### **Feasibility: Retention, Group Session Attendance, and Adherence**

Study feasibility was evaluated using retention rates at 3 and 6 months, group session attendance rates, and adherence to self-monitoring for both intervention groups. Participants in both intervention groups were asked to assess the acceptability of the 6-month behavioral intervention. Focus groups were conducted at the end of the intervention to learn about participants' experiences and satisfaction with the intervention.

### **Preliminary Efficacy**

All of the outcome measures were administered at baseline, 3 months, and 6 months. The study was completed in 2015. Physical measurements and a blood samples were obtained at the study sites.

### **Primary Outcome Measure-Glycemic Control**

Glycemic control was determined by glycated hemoglobin (HbA<sub>1c</sub>) levels. Patients were asked to fast for at least 8 hours before the scheduled data collection visits for venipuncture. A healthy breakfast including fresh fruits and breakfast bars was offered after blood draws. Blood samples were then transferred to a biological laboratory for analysis.

### **Secondary Outcome Measure-Weight**

We used a Tanita scale and body fat analyzer (Tanita Corporation of America Inc, Illinois, United States) to measure weight and body composition while subjects wore light clothing and stood erect with their bare feet on the scale's footpads.

### **Sociodemographic and General Health Information**

Participants' age, gender, ethnicity, race, marital status, education level, employment status, weight, and diabetes history were collected in a sociodemographic questionnaire. Details about their personal health and medical history (eg, comorbid conditions) were collected in a general health history form.

### **Data Management**

The recruitment, feasibility, and tracking forms were collected and stored in the PI's office at the Cizik School of Nursing at The University of Texas Health Science Center at Houston for data processing. Oracle (version 9i, Oracle Corporation, Redwood Shores, California) was used for data management. Form design, data entry, and data verification were performed in TeleForm (version 10.0, Verity Inc, Sunnyvale, California) for automated data entry or verification. All forms were precoded to minimize coding errors. During data collection, forms were screened upon receipt for completeness of response. Once verified, data were exported to the Oracle database for further data processing before being exported to SAS (SAS Institute) for data analysis.

### **Statistical Analysis**

Intention-to-treat (ITT) analyses were performed on the primary and secondary outcomes. Descriptive statistics (frequency and percentage for categorical variables and mean and SD or median and interquartile range for continuous variables) were reported

for retention at 6 month of the intervention, attending group sessions, and adherent to the multiple-behavior self-monitoring. For continuous variables with skewed distribution (eg, retention rates and group session attendance rates), nonparametric Mann-Whitney *U* tests were conducted for comparison between the mobile and paper groups. For the primary outcome, the percentages of weight change over time were compared by Kruskal-Wallis test, and the percentages of HbA<sub>1c</sub> change over time were compared by analysis of variance. Sensitivity analyses were conducted using last observation carried forward (LOCF) method to impute the missing data for participants who withdrew or were lost to follow-up.

## Results

### **Sociodemographic Characteristics**

Demographic characteristics of the sample by randomization group are presented in Table 2. The average age of the participants was 56.4 years, and the average years of education were 12.15 years (SD 1.22). A total of 62% (16/26) of the sample were female, and 69% (18/26) were African Americans. The BMI ranged from 27.4 to 51.1, with average of 38.1 at baseline. The majority of the sample had no health insurance or received only Medicare or county-assisted insurance in Harris County, Texas. All of the study participants were uninsured or underinsured. The household income for all study participants was below US \$30,000, and 92% (24/26) had a household income lower than US \$20,000. Age ( $P=.04$ ) and gender ( $P=.07$ ) differed significantly among the three randomization groups, but no statistically significant differences were found among other demographic variables.

### **Feasibility**

#### **Retention and Group Session Attendance**

One person dropped out of the study before the intervention started because of a schedule conflict for group sessions. The retention rate at 3 months was 96% (25/26) and 92% (24/26) at 6 months. Retention rates were not significantly different in the three randomization groups ( $P>.05$ ). The CONSORT diagram depicting patient retention is in Figure 2.

The median rate of session attendance at the 11 group sessions was 100% (range from 54.5%-100%) for the mobile group and 81.8% (range from 27.3%-100%) for the paper group. The nonparametric Mann-Whitney *U* test showed a statistically significant difference in group session attendance between the mobile and paper groups ( $P=.01$ ).

#### **Patient Engagement and Adherence to Self-Monitoring**

In the mobile group, the median percentage of days with at least one self-monitoring entry for diet, PA, weight, and glucose was 96.6%, 37.3%, 49.7%, and 72.7%, respectively, whereas the corresponding median adherence rates for the paper group were 8.1%, 1.2%, 2.5%, and 2.5%. Nonparametric Mann-Whitney *U* tests showed that there were significant differences between the mobile and paper group in all four self-monitoring variables ( $P \leq .001$  for diet and PA,  $P=.007$  for weight, and  $P=.003$  for glucose).



**Table 2.** Demographic characteristics by three groups.

Variables	Mobile group (N=11)	Paper group (N=9)	Control group (N=6)
Age (years), mean (SD)	58.8 (5.9)	56.1 (5.4)	49.2 (10.2)
Female, n (%)	9 (82)	5 (56)	1 (20)
Body mass index, mean (SD)	38.9 (9)	40.1 (7.0)	33.7 (2.7)
<b>Ethnicity, n (%)</b>			
Not Hispanic	9 (73)	7 (67)	4 (67)
Hispanic	2 (18)	2 (22)	2 (33)
<b>Race, n (%)</b>			
White	3 (27)	2 (22.2)	2 (3)
Black	7 (64)	6 (67)	4 (80)
American Indian	0 (0)	1 (11)	0 (0)
Asian	1 (11)	0 (0)	0 (0)
<b>Employment status, n (%)</b>			
Full time	2 (18)	1 (11)	0 (0)
Part time	0 (0)	2 (22)	2 (33)
Laid off	2 (18)	0 (0)	0 (0)
Retired	3 (27)	1 (11)	1 (17)
Disabled or unable to work	2 (18)	5 (56)	1 (17)
Full time homemaker	2 (18)	0 (0)	1 (17)
Student	0 (0)	0 (0)	1 (17)
<b>Insurance coverage, yes, n (%)</b>			
	7 (64)	4 (44)	1 (17)
<b>Insurance type, n (%)</b>			
Medicare	5 (71)	3 (60)	0 (0)
Gold Card, Harris County	2 (29)	2 (40)	2 (100)
<b>Income (USD), n (%)</b>			
Under \$10,000	1 (10)	3 (33)	2 (33)
\$10,000-\$13,000	5 (50)	0 (0)	1 (17)
\$13,000-\$20,000	3 (30)	6 (67)	2 (33)
\$20,00-\$30,000	1 (10)	0 (0)	1 (17)
Years of education, mean (SD)	12.3 (1.0)	11.8 (1.5)	12.5 (1.2)

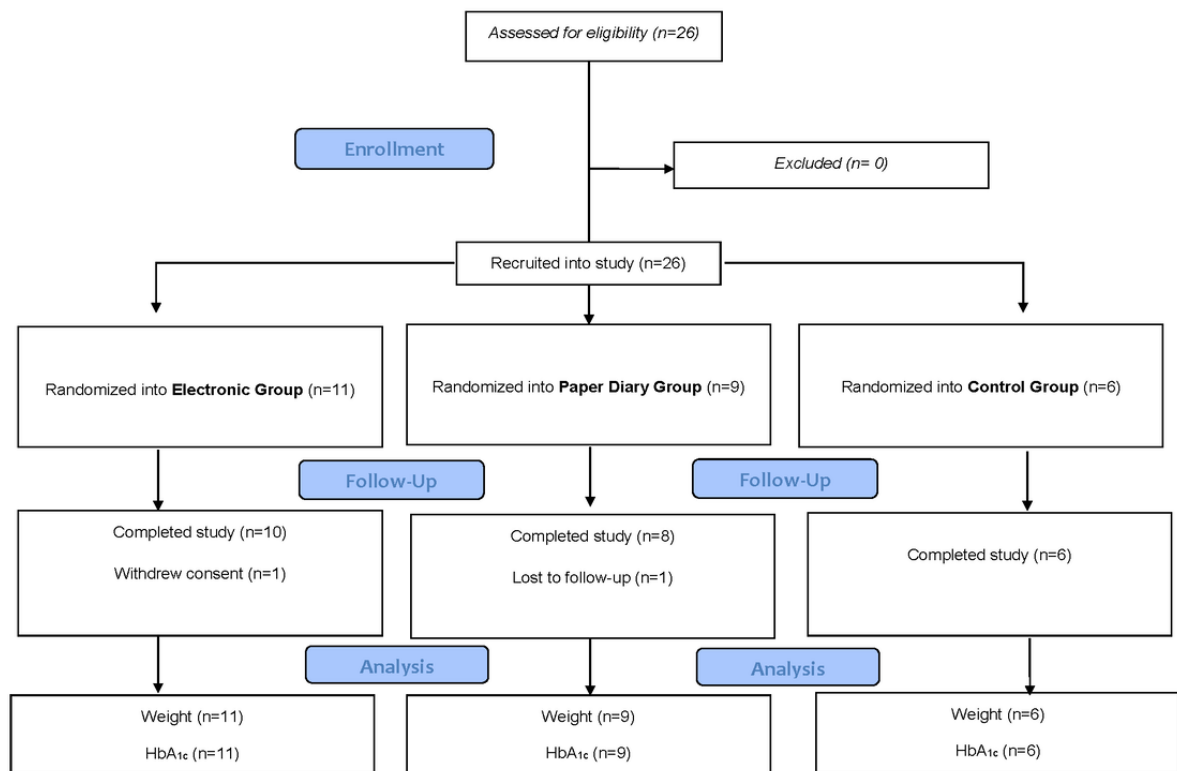
Figure 3 depicts the frequency of days on which each of the four self-monitoring variables was reported for each of the 10 study participants in the mobile group and for each of the 6 study participants in the paper diary group.

### Evaluation of Intervention on Outcomes (Preliminary Efficacy)

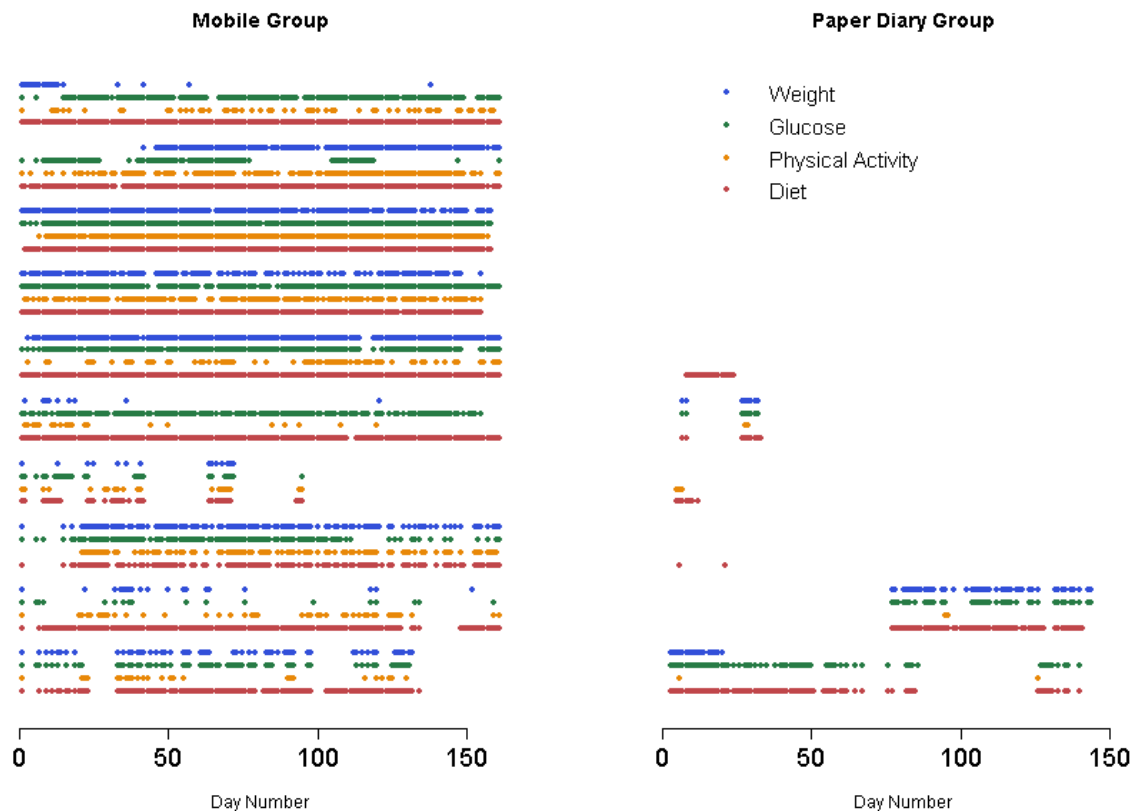
Descriptive findings on HbA<sub>1c</sub> and weight outcomes at each study data collection time point (baseline, 3 months, and 6 months) are summarized in Table 3. At baseline, there were no statistical significant differences on HbA<sub>1c</sub> among the three randomization groups; at 6 months, a statistical significant difference on HbA<sub>1c</sub> was found among the three groups, with mobile group having an average HbA<sub>1c</sub> level <7%, whereas the paper group and control group had an average HbA<sub>1c</sub> level

around 9%. Results from the ITT analysis on the primary outcome of HbA<sub>1c</sub> showed that there were no statistical significant group differences on HbA<sub>1c</sub> level change over 6 months ( $P=.44$ ); however, a medium effect size of Cohen  $d=0.28$  was detected for HbA<sub>1c</sub> changes. At 6 months, participants in the mobile group had an average weight loss of 1.8%, whereas the paper group had an average of 4% weight gain, and the control group had an average of 1.6% weight gain. There were no statistical significant differences among the three groups on weight changes over time ( $P=.20$ ). A medium effect size of Cohen  $d=0.40$  was found for changes on weight outcomes over time. Sensitivity analysis using LOCF for imputations did not show any statistically significant differences on the HbA<sub>1c</sub> and weight outcomes.

**Figure 2.** Consolidated Standards of Reporting Trials (CONSORT) diagram. HbA<sub>1c</sub>: glycated hemoglobin.



**Figure 3.** Adherence to self-monitoring of multiple behaviors in the intervention groups.



**Table 3.** Descriptive values for weight and glycated hemoglobin (HbA<sub>1c</sub>) levels at each visit by group. Q1: 25<sup>th</sup> percentile; Q3: 75<sup>th</sup> percentile.

Variables	Mobile group (N=11)	Paper group (N=9)	Control group (N=6)	<i>P</i> value
<b>HbA<sub>1c</sub>, mean (SD)</b>				
Baseline	8.4 (2.3)	10.4 (2.4)	8.9 (2.4)	.20
3 months	7.3 (1.1)	8.5 (1.4)	8.5 (1.7)	.13
6 months	6.9 (1.0)	9.1 (1.8)	8.9 (1.6)	.01
<b>Weight, median (Q1, Q3)</b>				
Baseline	233.6 (179.8, 295.4)	243.6 (222.2, 321.8)	201.2 (195.8, 213.8)	.48 <sup>a</sup>
Percentage weight change at 3 months, median (Q1, Q3)	0.5 (-2.9, 2.2)	-1.0 (-1.6, -0.1)	2.1 (0.1, 4.2)	.16 <sup>a</sup>
Percentage weight change at 6 months, median (Q1, Q3)	-1.8 (-4.2, -0.3)	0.4 (-2.3, 1.5)	1.6 (-4.1, 3.8)	.16 <sup>a</sup>

<sup>a</sup>Denotes *P* values obtained from Kruskal-Wallis test; other *P* values were obtained from analysis of variance.

## Discussion

### Principal Findings

To our knowledge, this pilot study is the first to report the feasibility and acceptability of using mobile and connected tools to enhance an evidence-based behavioral lifestyle intervention for the underserved community. We compared the efficacy of standard diabetes care and education with behavioral lifestyle interventions enhanced with either using smartphone apps and a Bluetooth-connected glucometer for self-monitoring of multiple behaviors or paper diaries on improving glycemic outcomes among overweight or obese adults with T2DM living in underserved communities. The feasibility and acceptability of the study were demonstrated by the high retention rates at 3 and 6 months and high rates of patient engagement in using the mobile apps. In fact, our retention rates of 96% at 3 months and 92% at 6 months were higher than those reported in most of the previous behavioral lifestyle interventions mediated by technology in obesity and T2DM [26,27], including those in medically underserved communities [28].

The comparative findings revealed the mobile group participants had higher group session attendance and higher patient engagement and adherence to self-monitoring of multiple behaviors than the paper group, which was consistent with previous studies reporting higher adherence to self-monitoring rates using electronic diaries compared with paper diaries among overweight or obese populations [29,30]. As compared with the diabetes population, a study planning to use a mobile app to support patient self-management did not recruit enough patients [31]. We recruited our 27 patients in less than 1 month, and those who participated in the mobile group had high adherence rates to all components of the intervention over 6 months. This may suggest that a mobile app alone does not interest patients as much as a hybrid of face-to-face sessions using mobile apps to support self-monitoring.

Although the previous literature comparing electronic diaries and paper diaries for self-monitoring of diet and PA did not reveal significant differences in weight loss outcomes [21,32], our study not only showed significantly better adherence to self-monitoring in the mobile group but also a trend for greater weight loss and glycemic control with medium effect sizes in

the mobile group. Furthermore, the mobile group had significantly lower HbA<sub>1c</sub> levels at 6 months than the paper group. A meta-analysis of lifestyle weight loss interventions in overweight and obese adults with T2DM revealed that the majority of the trials did find <5% weight loss; however, they did not reveal significant beneficial effects on glycemic control [33]. The self-monitoring intervention in these lifestyle weight loss interventions focused on self-monitoring of diet and PA only, with a few of them adding self-monitoring of weight, whereas our study used a holistic approach to introduce SMBG and weight, along with self-monitoring of diet and PA behaviors to help patients understand the relationship between their behaviors and outcomes.

To our knowledge, our study is the first to combine self-monitoring of diet, PA, and weight using a mobile app that are used in behavioral weight loss interventions along with a connected glucometer to help patients learn their behavioral patterns in association with their weight and blood glucose outcomes. Previous studies had used either connected glucometers along with access to a live certified diabetes educator coach [34] or personalized feedback messages based on connected glucometer results [35] for general T2DM patients, not specifically targeting overweight or obese T2DM patients from underserved communities.

Several limitations to this study should be acknowledged. First, the study sample was recruited from an underserved community in an urban setting, so the study findings may not be generalizable to underserved communities in rural areas. Second, the focus of this study was feasibility and acceptability; thus, the study did not have sufficient power to detect group differences. Third, we provided smartphones and Bluetooth-enabled glucometers to the participants because none of the study participants reported owning a smartphone; the adherence to self-monitoring may be different for those who previously owned a smartphone. Fourth, our measure on adherence to self-monitoring of PA depended on patient adherence to the recommended PA behaviors. Although this approach has been used in several other studies [29,36], it may underestimate the actual adherence to self-monitoring of PA. For example, our adherence to self-monitoring of PA was lower than adherence dietary self-monitoring, which could suggest

that participants did not exercise at all on that particular day, they did not bother to enter 0 for exercise minutes, and instead, they left it blank. Future research should examine the difference between adherence to self-monitoring and adherence to the actual behavior separately. Fifth, our study only looked at the short term outcomes; maintaining long-term effect may be a different challenge that future studies should consider examining.

## Conclusions

Delivering a behavioral lifestyle intervention enhanced with multiple-behavior self-monitoring using smartphone apps and a connected Bluetooth glucometer in an underserved community is feasible and acceptable, and using mobile tools including smartphone apps and connected glucometers has the potential to increase patient adherence to self-monitoring of multiple behaviors and improve glycemic control among underserved populations. A full-scale randomized controlled trial is needed to confirm the findings of this feasibility trial.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[\[PDF File \(Adobe PDF File\), 851KB - mhealth\\_v6i4e92\\_app1.pdf\]](#)

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## Abbreviations

**BMI:** body mass index  
**CONSORT:** Consolidated Standards of Reporting Trials  
**CVD:** cardiovascular disease  
**GLB:** Group Lifestyle Balance  
**HbA<sub>1c</sub>:** glycated hemoglobin  
**ITT:** intention-to-treat  
**LOCF:** last observation carried forward  
**AHEAD:** Action for Health in Diabetes  
**mHealth:** mobile health  
**PA:** physical activity  
**PDA:** personal digital assistant  
**PI:** principal investigator  
**SMBG:** self-monitoring of blood glucose  
**T2DM:** type 2 diabetes mellitus

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Original Paper

# How Mobile App Design Impacts User Responses to Mixed Self-Tracking Outcomes: Randomized Online Experiment to Explore the Role of Spatial Distance for Hedonic Editing

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## Abstract

**Background:** Goal setting is among the most common behavioral change techniques employed in contemporary self-tracking apps. For these techniques to be effective, it is relevant to understand how the visual presentation of goal-related outcomes employed in the app design affects users' responses to their self-tracking outcomes.

**Objective:** This study examined whether a spatially close (vs distant) presentation of mixed positive and negative self-tracking outcomes from multiple domains (ie, activity, diet) on a digital device's screen can provide users the opportunity to hedonically edit their self-tracking outcome profile (ie, to view their mixed self-tracking outcomes in the most positive light). Further, this study examined how the opportunity to hedonically edit one's self-tracking outcome profile relates to users' future health behavior intentions.

**Methods:** To assess users' responses to a spatially close (vs distant) presentation of a mixed-gain (vs mixed-loss) self-tracking outcome profile, a randomized 2×2 between-subjects online experiment with a final sample of 397 participants (mean age 27.4, SD 7.2 years; 71.5%, 284/397 female) was conducted in Germany. The experiment started with a cover story about a fictitious self-tracking app. Thereafter, participants saw one of four manipulated self-tracking outcome profiles. Variables of interest measured were health behavior intentions, compensatory health beliefs, health motivation, and recall of the outcome profile. We analyzed data using chi-square tests (SPSS version 23) and moderated mediation analyses with the PROCESS macro 2.16.1.

**Results:** Spatial distance facilitated hedonic editing, which was indicated by systematic memory biases in users' recall of positive and negative self-tracking outcomes. In the case of a mixed-gain outcome profile, a spatially close (vs distant) presentation tended to increase the underestimation of the negative outcome ( $P=.06$ ). In the case of a mixed-loss outcome profile, a spatially distant (vs close) presentation facilitated the exact recognition of the positive outcome ( $P=.04$ ). When the presentation of self-tracking outcomes provided the opportunity for hedonic editing, users with a low (vs high) health motivation produced compensatory health beliefs, which led to lower health behavior intentions (index of moderated mediation=0.0352, 95% CI 0.0011-0.0923).

**Conclusions:** When spatial distance between the presentations of mixed self-tracking outcomes provided the opportunity to hedonically edit one's self-tracking outcome profile, users recalled their self-tracking outcomes in a more positive light. Especially for users with lower health motivation, the opportunity to hedonically edit one's mixed self-tracking outcome profile led to reduced health behavior intentions. To prevent the occurrence of hedonic editing in users' responses to visually presented self-tracking outcome profiles, further research is necessary to determine the ideal distance that should be employed in the app design for the presentation of mixed self-tracking outcomes on a digital device's screen.

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**KEYWORDS**

mobile apps; self-tracking; user interaction design; goal setting

## Introduction

### Background

Given the growing spread of wearable technological devices and mobile phones alongside with mobile apps, consumers nowadays increasingly practice digital forms of self-tracking [1,2], which is the systematic recording of “information about one’s diet, health, or activities...so as to discover behavioral patterns that may then be adjusted to help improve one’s physical or mental well-being” [3]. The rise of apps encouraging the self-tracking of physical activity and diet [4], such as the popular “Lose It!” or “MyFitnessPal” apps, enable consumers to easily keep a digital record of calorie burn and consumption. Commonly, these apps allow users to set a daily caloric goal and to monitor the amount of calories burned compared to the amount of calories consumed. Through this, these apps aim to spur users to live a healthy life and to facilitate the pursuit of personal health goals such as weight loss or weight maintenance [5,6]. Also, researchers advocate that apps might be promising tools that can contribute to the promotion and improvement of people’s overall health [7,8].

So far, existing studies have examined the effectiveness of health-related mobile phone interventions and technology-enhanced interventions in general [9-15] or have assessed the prevalence and effectiveness of behavioral change techniques employed in the app design in particular [16,17]. The use of a tracking app in general has been associated with increased behavioral intentions [18], and goal setting is one of the behavioral change techniques commonly employed in self-tracking apps [7,8,19], yet little is known about how the presentation of goal-related outcomes from different domains (eg, activity, diet) employed in a self-tracking app impacts users’ self-reflection of the collected data.

This lack of research is surprising, considering that users’ reflections of their self-tracking outcomes most likely will

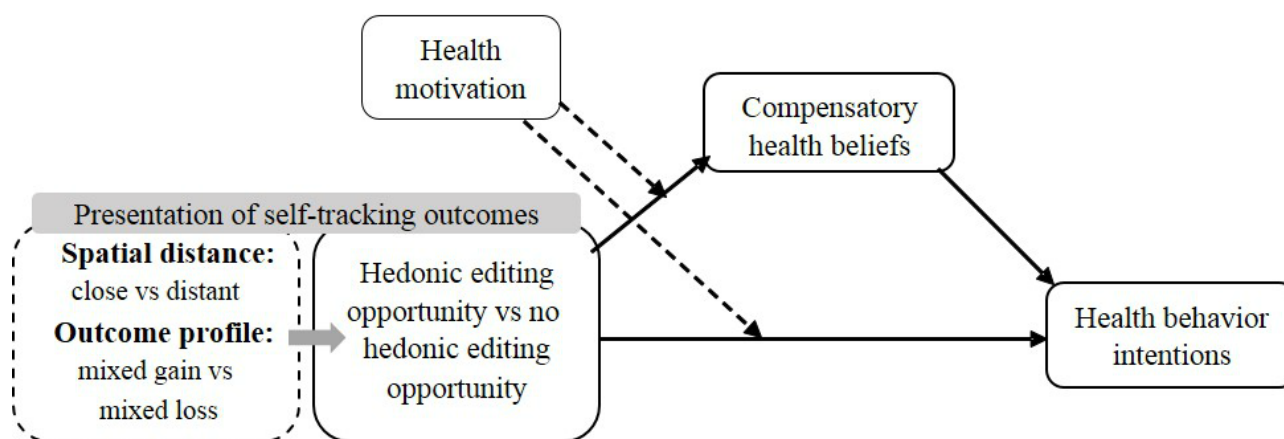
determine their health-related intentions and actions [20]. Accordingly, it is relevant to understand how features of outcome presentation, such as the spatial distance between goal-related outcomes on a digital device’s screen as it is employed in the app design, can affect how users respond to their self-tracking outcomes. In view of the lack of health behavior theory integration in the development of health apps in general [21,22], this research transfers mental accounting principles of hedonic editing [23], originally from the field of economics, to the context of self-tracking. Based on this theoretical approach, the objective of this research is to examine whether, depending on the overall outcome profile, a spatially close compared to a distant presentation of mixed positive and negative self-tracking outcomes from the domains of physical activity and diet can provide users the opportunity to hedonically edit their self-tracking outcome profile (ie, to view their mixed self-tracking outcomes in the most positive light). This study further provides a motivated cognitive justification account to examine how the opportunity to hedonically edit one’s self-tracking outcome profile relates to users’ future health behavior intentions. For an overview of the study’s framework, see Figure 1.

### Theory and Hypotheses Development

#### Mental Accounting and Principles of Hedonic Editing in the Context of Self-Tracking

First, to apply principles of mental accounting—originally used to describe how consumers mentally code, categorize, and evaluate multiple economic outcomes [23,24]—to the context of self-tracking, we argue that when physical activity and dietary self-tracking outcomes are measured along the same dimension (ie, calories), this allows for the combination of both outcomes within a mental account of health. This argument is based on the reason that outcomes from both domains influence one’s total energy balance, which relates to overall health.

**Figure 1.** Proposed model of how hedonic editing opportunity as a function of spatial distance and self-tracking outcome profile influences users’ health behavior intentions. The self-tracking outcome profile is a mixed gain if there is a positive outcome in one domain and a smaller negative outcome in the other domain. Conversely, in a mixed-loss outcome profile, there is a large negative outcome in one domain and a smaller positive outcome in the other domain.





Second, to describe how consumers mentally combine multiple outcomes within a single account, Thaler [23] draws on the shape of prospect theory's value function [25] and proposes that consumers perceive their outcomes relative to a reference point either as gains or losses. Accordingly, in a self-tracking context, setting caloric goals in the domain of physical activity as well as diet can serve as reference outcomes relative to which mobile self-tracking app users classify each of their self-tracking outcomes either as a gain (positive outcome; eg, burning more calories from physical activity than the caloric goal) or a loss (negative outcome; eg, burning less calories from physical activity than the caloric goal). We propose that a mixed outcome profile—such as a positive outcome in one domain and a negative outcome in the other domain—is inherently ambiguous and thus leaves some scope for users' subjective evaluation.

Third, to explain how consumers evaluate combinations of positive and negative outcomes, Thaler [23,24] has derived principles of hedonic editing that are based on the shape of the value function. According to Thaler's [23] principles of hedonic editing, consumers prefer to evaluate mixed outcomes either jointly (integration) or separately (segregation) to maximize their happiness. As such, principles of hedonic editing predict that when the combined outcome is a mixed gain, which is the case if there is a positive outcome in one domain and a smaller negative outcome in the other domain, users strive to integrate the negative with the positive outcome [23]. This is because the integration of the small negative outcome into the positive outcome allows one to cancel out the pain from the negative outcome and reduces the recognition of the loss [26]. Conversely, if the combined outcome is a mixed loss, which is the case if there is a large negative outcome in one domain and a smaller positive outcome in the other domain, hedonic editing principles suggest that users strive to segregate the positive from the negative outcome [23]. This is because the small positive outcome becomes a "silver lining" in the face of the large negative outcome and segregation versus integration allows consumers to appreciate the positive outcome even when the combined result is negative [23,26]. Taken together, principles of hedonic editing suggest that when self-tracking app users experience an overall mixed-gain self-tracking outcome profile, they would look for ways to integrate the small negative outcome. Conversely, when users experience an overall mixed-loss outcome profile, they would look for ways to segregate the small positive outcome.

### ***Spatial Distance and Hedonic Editing of Self-Tracking Outcomes***

Regarding the influence of spatial distance on the use of hedonic editing strategies, we draw on previous research, which suggests that temporal distance between the occurrence of a positive and negative outcome facilitates hedonic editing [26,27]. As such, temporal separation facilitates the recognition of the positive event as a distinct occurrence, whereas temporal closeness provides the opportunity to integrate and cancel out the negative occurrence [26]. Consistent with this reasoning, we propose that spatial distance in the presentation of multiple self-tracking outcomes can facilitate hedonic editing. In particular, we assume that in the case of a mixed-gain outcome, a close versus distant presentation of self-tracking outcomes will help integrate the

small negative outcome into the larger positive outcome and provide the opportunity to hedonically edit one's self-tracking outcomes. Conversely, in the case of a mixed-loss outcome profile, a distant versus close presentation of self-tracking outcomes will help segregate the small positive outcome from the larger negative outcome and provide the opportunity for hedonic editing.

Following the reasoning of Cowley [26], we propose that hedonic editing is indicated by users' allocation of attention and the resulting accuracy when recalling the caloric values of the small negative outcome or the small positive outcome, respectively. As such, in case of a mixed-gain outcome profile, a close compared to a distant presentation of self-tracking outcomes should facilitate hedonic editing (ie, the integration of the small negative outcome into the larger positive outcome), which would be reflected by an underestimation of the small negative outcome. Conversely, in the case of a mixed-loss outcome profile, a distant compared to a close presentation of self-tracking outcomes should segregate the small positive outcome from the larger negative outcome and hedonic editing would be indicated by a more accurate recall of the small positive outcome.

Therefore, our first hypothesis is that, in the case of a mixed-gain outcome profile, a close (vs distant) presentation of self-tracking outcomes will lead to an underestimation (vs accurate estimation or overestimation) of the recalled small negative outcome and that, in the case of a mixed-loss outcome profile, a distant (vs close) presentation of self-tracking outcomes will lead to a more accurate (vs overestimation or underestimation) memory of the small positive outcome.

### ***Hedonic Editing Opportunity and User Responses to Self-Tracking Outcomes***

Because mental accounts are considered to function as self-regulatory mechanisms [28], the opportunity to hedonically edit one's mixed self-tracking outcomes might affect users' responses to their self-tracking outcomes such as their health behavior intentions (eg, intending to do more sports or to eat healthier in the future). We propose that when the opportunity to hedonically edit mixed self-tracking outcomes arises (vs not), users—particularly users who have lower health motivation—will respond to this opportunity and reflect their outcomes in the best possible light, which will result in lower health behavior intentions.

We suggest that this effect might be explained by a motivated cognitive justification mechanism. We argue that particularly users with a low as opposed to a high health motivation may—probably unconsciously—justify using the opportunity to hedonically edit their self-tracking outcomes, which allows them to have lower health behavior intentions in response to their tracking results. One way to cognitively justify reduced health behavior intentions in response to the hedonic editing opportunity is the formation of compensatory health beliefs, which are "beliefs that the negative effects of an unhealthy behavior can be compensated for, or 'neutralized,' by engaging in a healthy behavior" ([29], p 607) and thus enable users "to justify unhealthy behavior choices" ([29], p 608). Therefore, we propose that users with a lower health motivation will have

reduced health behavior intentions when the presentation of the outcome profile provides the opportunity for hedonic editing and that this effect occurs due to the activation of compensatory health beliefs. Formally, we hypothesize that users' levels of health motivation will moderate the direct effect of hedonic editing opportunity on health behavior intentions as well as the indirect effect of hedonic editing opportunity on health behavior intentions through compensatory health beliefs.

## Methods

### Aims of the Study

This study aimed to establish that spatial distance in the presentation of self-tracking outcomes facilitates hedonic editing and examined whether a close compared to a distant presentation of self-tracking outcomes in the case of a mixed-gain or a mixed-loss outcome profile biased users' memory of self-tracking outcomes as proposed by hedonic editing principles. Further, this study examined how the opportunity to hedonically edit one's outcome profile affected users' health behavior intentions. To investigate our hypotheses, we conducted a 2 (spatial distance: close vs distant)  $\times$  2 (outcome profile: mixed gain vs mixed loss) between-subjects online experiment.

### Recruitment

The experiment was designed in the German language using SoSci Survey, a software package for conducting online surveys. We tested the technical functionality of the electronic questionnaire and the correctness of electronic data recording as well as the transmission of collected data before making the online experiment public. A convenience sample was used because the invitation link to the open online survey was distributed in various groups of social media networks and shared on two survey websites. Consequences of this procedure for the survey population with respect to the sex (ie, more females) and age (ie, relatively young) were expected. We recruited participants from December 2016 to January 2017. The study was approved by the Head of the Department of Retailing and Customer Management, University of Cologne, Germany, to confirm compliance with ethical standards. As such, before beginning of the survey, participants were informed on the entry page about the general topic, purpose, and procedure of the study, and that their participation was voluntary and the data would be treated anonymously. Participants had to give their consent by clicking on the button "I agree" to continue with the study. No incentives were offered.

### Design and Procedure

The study employed a 2 (spatial distance: close vs distant)  $\times$  2 (outcome profile: mixed gain vs mixed loss) between-subjects design and questionnaires with the respective experimental condition were randomly displayed by the survey software. The

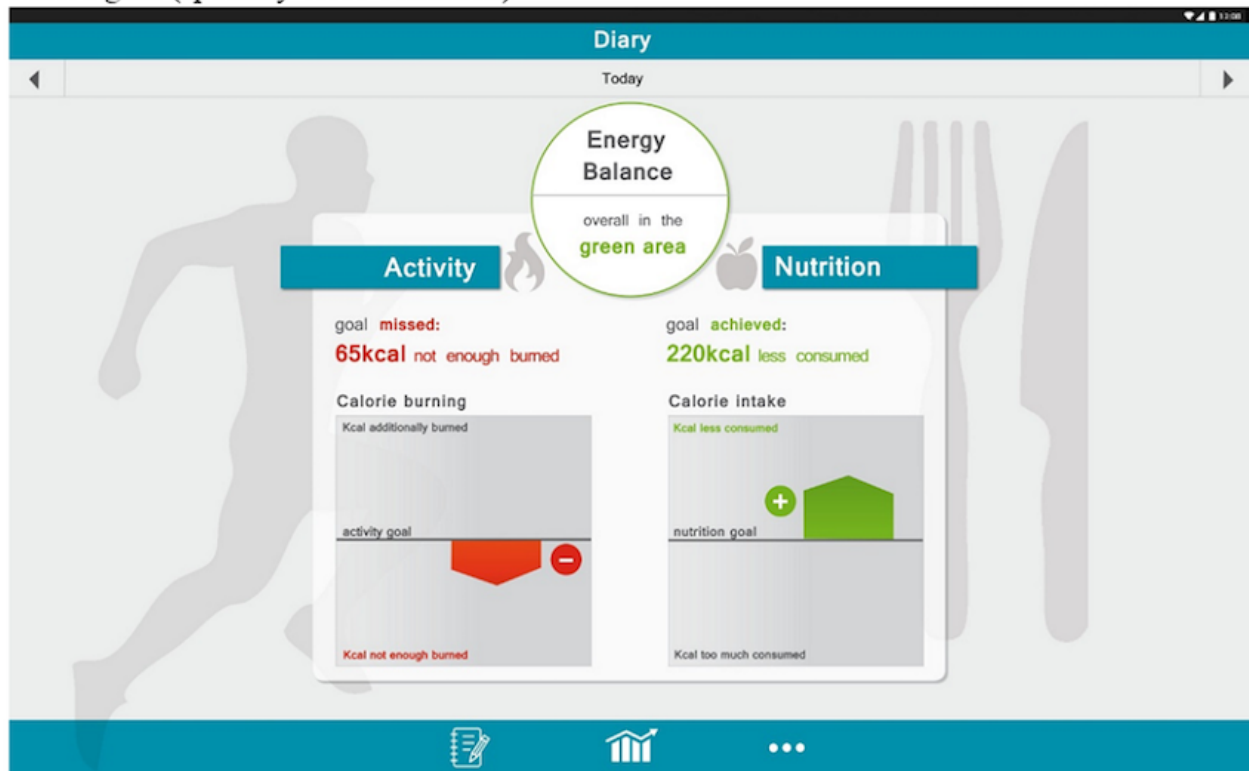
cover story explained that the study's aim was to optimize the design of a yet-unreleased self-tracking app that measures health-related information so that users can easily monitor their activity, diet, and overall energy balance. The instruction sheet stated that the study sought to find out how comprehensible the app layout was. We briefed participants about the integral elements of the fictitious self-tracking app and explained that they will see an illustration of self-tracking results as they were obtained at the end of a certain day, containing information about activity (calories burned from physical exercise), diet (calories consumed from food and drinks), and overall energy balance (difference between calorie burning and consumption). We told participants that the app sets daily caloric goals based on individual needs for the domain of activity (minimum amount of calories that should be burned from activity during the day) and diet (maximum amount of calories that should be consumed during the day). These goals should be achieved or surpassed to obtain an overall even energy balance, where calorie consumption does not exceed calorie burning. Thereafter, participants saw a fictive self-tracking outcome profile including the display of goal achievement in the domains of activity, diet, and overall energy balance. We asked participants to imagine that they themselves had obtained the depicted self-tracking outcomes at the end of a certain day.

We presented participants either a mixed-gain or mixed-loss self-tracking outcome profile with the outcomes in the domains of activity and diet being either spatially close to or distant from one another. The four different self-tracking outputs were designed with the graphic program Adobe InDesign CS6 (see [Figure 2](#)).

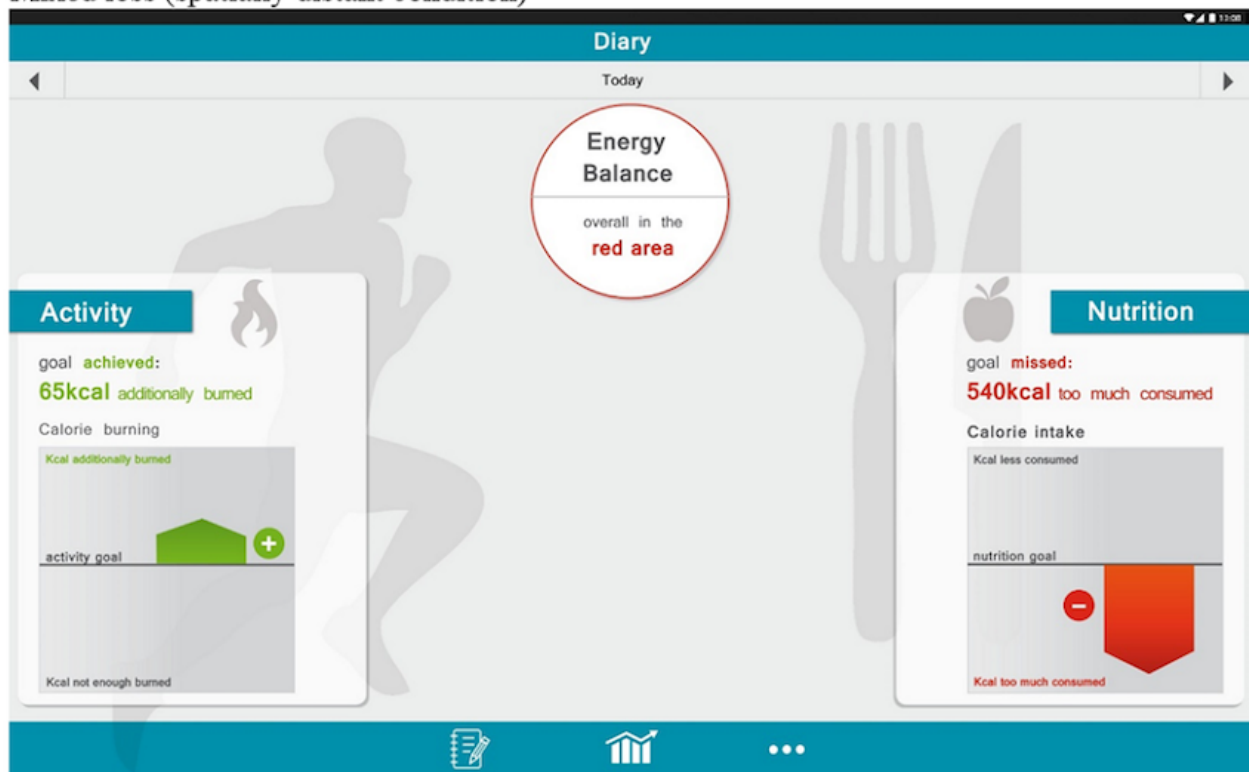
In the mixed-gain condition, the self-tracking results showed participants that they had underscored their caloric activity goal by 65 kcal and achieved their caloric diet goal by consuming 220 kcal less than the target amount of calories, hence having an overall positive energy balance. In the mixed-loss condition, the self-tracking results showed participants that they had exceeded their caloric activity goal by 65 kcal, but that they had failed to achieve their caloric dietary goal by consuming 540 kcal too much, hence having an overall negative energy balance. The exact goal value was not indicated to prevent participants from comparing the fictitious goal with their own needs or their own set goals. The outcomes of activity and nutrition were highlighted graphically through bar graphs and marked with plus or minus signs. The colors green and red were used for the plus and minus signs, respectively, and were consistently used in the output design to enable fast recognition of gains or losses. Spatial distance between self-tracking outcomes from the domain of activity and diet in the close condition was set to 94 pixels and in the distant condition to 667 pixels. Further, the output included information about the overall energy balance to prompt a mental connection between activity and nutrition.

Figure 2. Illustration of mixed-gain and mixed-loss self-tracking stimuli.

Mixed gain (spatially close condition)



Mixed loss (spatially distant condition)



Measures

All measures took place immediately after participants had seen the self-tracking outcome profile. The questionnaire assessed participants' health behavior intentions by asking how likely it

was that they had activity-related and diet-related behavioral intentions in response to their self-tracking outcomes (four items on a 7-point scale anchored visually at 1=very unlikely and 7=very likely): "I want to be more active in the near future," "I want to do more sports in the near future," "I want to eat

healthier in the near future,” and “I want to eat less high-caloric in the near future” ( $\alpha=.70$ ). Similar to previous work [29], participants’ compensatory health beliefs were measured by five items (on a 7-point scale anchored visually at 1=don’t agree at all and 7=totally agree): “If I eat less or more healthily, it is not necessary to do a lot of sports,” “It is okay to eat an unhealthy snack after having had a hard workout,” “It is okay to eat more during lunch and dinner if one has skipped breakfast in the morning,” “Skipping exercising in one week can be compensated for by exercising twice the next week,” and “Eating dessert is okay if one restrains eating during the main dish” ( $\alpha=.68$ ). To assess participants’ level of health motivation, we asked about the importance of activity and diet in their life (on a 7-point scale anchored visually at 1=don’t agree at all and 7=totally agree): “Doing sports is an important element in my life,” “I can easily live without doing sports” (reverse coded), “A healthy diet is important to me,” and “I eat unhealthy fast food very often” (reverse coded) (last item was excluded to increase  $\alpha$  to .69). To test for a bias of participants’ attention focus and a consequential hedonic editing memory bias, participants were asked to recall the absolute caloric deviation from the activity as well as diet goal (open answer format). The questionnaire contained further measures on participants’ feelings and perceptions of the app as well as personal and demographic information (for details on measures, see [Multimedia Appendix 1](#)).

### Statistical Analysis

We analyzed our data using the statistical package of SPSS version 23 (IBM Corp, Armonk, NY, USA). All effects are reported as significant at  $P<.05$ . First, to test the first hypothesis, we analyzed whether spatial distance affected participants’ accuracy of recalled absolute deviations (open answers in kcal) from the determined goal in the domain of activity in line with hedonic editing principles. In the mixed-gain conditions, users had a small negative outcome in the domain of activity (65 kcal less burned than the set goal) and we examined whether a close compared to a distant presentation of self-tracking outcomes resulted in an underestimation (vs accurate estimation or overestimation) of the recalled small negative outcome. For this analysis, we binary coded the recalled kcal scores into whether they underestimated the caloric deviation of the small loss (<65 kcal) or whether they exactly matched or overestimated the caloric deviation ( $\geq 65$  kcal). In the mixed-loss conditions, users had a small positive outcome in the domain of activity (65 kcal more burned than the set goal) and we tested whether a distant compared to a close presentation of self-tracking outcomes resulted in a more accurate (vs overestimation or underestimation) recall of the small positive outcome. For this analysis, we binary coded the recalled kcal scores into whether they exactly matched the caloric deviation (=65 kcal) or whether they either underestimated or overestimated the caloric deviation (<65 kcal or >65 kcal). For the mixed-gain and the mixed-loss conditions, a Pearson chi-square test with spatial distance and the according binary-coded response variable was conducted

to examine whether users’ accuracy of recalled self-tracking outcomes changed as an effect of spatial distance in line with hedonic editing principles. We report the asymptotic two-sided significance of this test.

Second, to test our second hypothesis, we analyzed whether users’ levels of health motivation moderated the direct effect of self-tracking outcome presentation that either does or does not provide the opportunity for hedonic editing on health behavior intentions as well as the indirect effect of self-tracking outcome presentation on health behavior intentions through compensatory health beliefs. To simultaneously test both the moderator and mediator, we used the PROCESS macro version 2.16.1 for SPSS, which is suited for conducting a moderated mediation analysis (moderated mediation; model 8 [30]). We used bias - corrected bootstrap confidence intervals based on 10,000 resamples and the significance of the indirect effect was based on a 95% confidence interval. If the range of the upper and lower level confidence intervals does not include zero, the analysis indicates significance. The independent variable was coded 1 when the outcome profile provided the opportunity to hedonically edit one’s self-tracking outcomes (ie, mixed gain/close presentation and mixed loss/distant presentation) and was coded 0 when no hedonic editing opportunity was given (ie, mixed gain/distant presentation and mixed loss/close presentation). We set users’ level of health motivation as the moderator and compensatory health beliefs as the mediator. Users’ health behavior intentions served as the dependent variable.

## Results

### Sample

A total of 584 participants completed the online experiment. Manipulation checks served to exclude 187 participants who indicated they remembered a wrong outcome profile as well as participants who indicated they remembered an extremely high or low deviation from the determined caloric goals in the domain of activity (kcal values  $\leq 10$  and  $\geq 450$ ) or diet (kcal values  $\leq 10$  and  $\geq 1000$ ) in the free recall question on their goal deviation (kcal value). The final sample consisted of 397 participants with cell sizes ranging between  $n=84$  and  $n=113$ . The sample consisted of 71.5% (284/397) female participants and the mean age was 27.4 (SD 7.2) years. In terms of the highest educational level attained, of the 397 participants, 2 (0.5%) had a lower secondary school leaving certificate, 33 (8.3%) had an intermediate or general secondary school leaving certificate, 154 (38.8%) had a general or subject-linked higher education entrance qualification, 133 (33.5%) had a bachelor’s degree, 73 (18.4%) had a master’s degree or a diploma, and 2 (0.5%) had a doctoral degree. We used participants’ voluntary information about body weight (in kg) as well as body size (in cm) to calculate the body mass index (BMI). For the 354 participants who voluntarily provided information, the mean BMI was 23.7 (SD 3.9)  $\text{kg/m}^2$ .

Figure 3. Recall of the small loss in the mixed-gain outcome conditions.

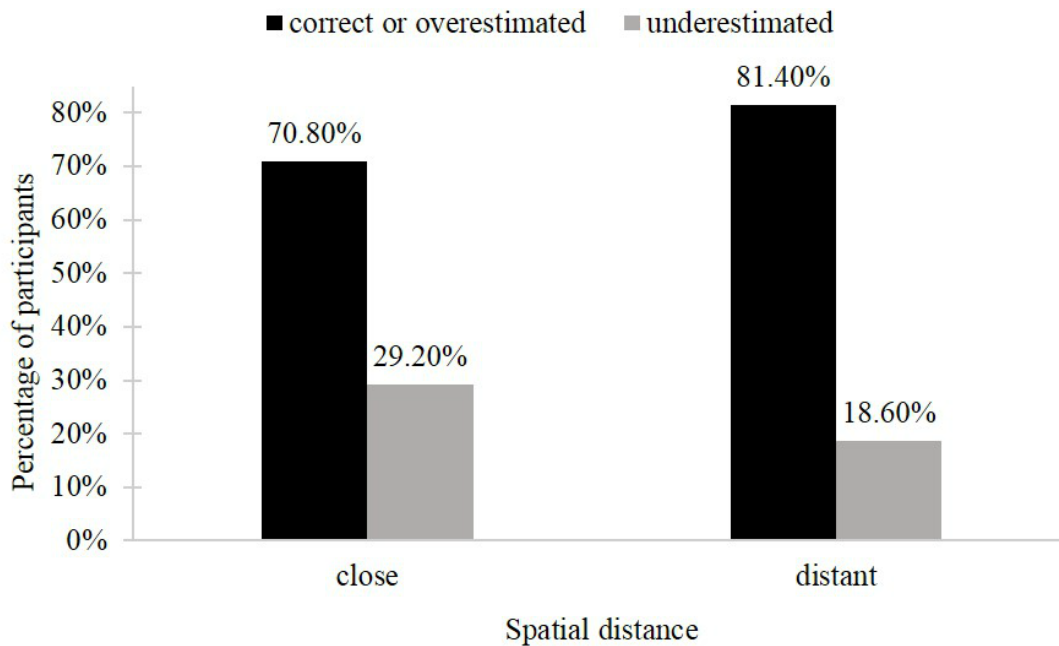
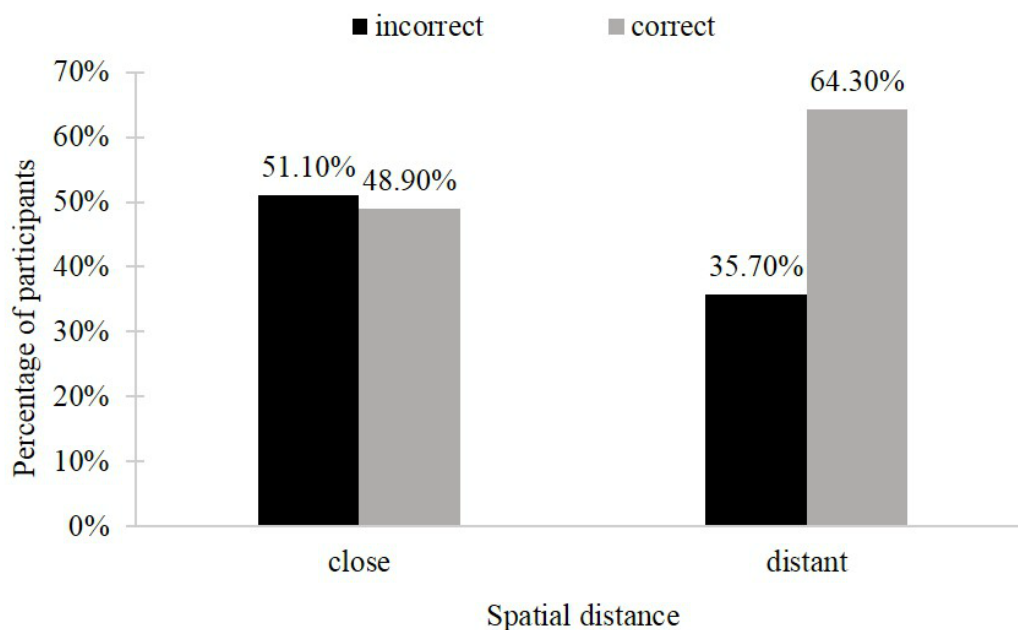


Figure 4. Recall of the small gain in the mixed-loss outcome condition.



### Hedonic Editing of Self-Tracking Outcomes

The first hypothesis assumed that for a mixed-gain outcome profile, a close rather than a distant presentation of self-tracking outcomes would lead to an underestimation versus an accurate estimation or overestimation of the recalled small negative outcome. The chi-square test was marginally significant and showed that when mixed-gain outcomes were presented close to (vs distant from) one another, a higher proportion of participants underestimated the small loss (31/106, 29.2% vs 21/113, 18.6%) and a lower proportion of participants exactly recalled or overestimated the small loss (75/106, 70.8% vs 92/113, 81.4%;  $\chi^2_1=3.4, P=.06$ ). The second part of the first

hypothesis proposed that for a mixed-loss outcome profile, a distant rather than a close presentation of self-tracking outcomes would lead to an accurate estimate versus an overestimation or underestimation of the recalled small positive outcome. The chi-square test revealed a significant effect of spatial distance on accuracy of recalled kcal scores. The analysis indicated that in the distant (vs the close) mixed-loss condition 64.3% (54/84; vs 46/94, 48.9%) of participants recalled the small gain correctly and that 35.7% (30/84; vs 48/94, 51.1%) of participants recalled the small gain incorrectly ( $\chi^2_1=4.2, P=.04$ ). Figures 3 and 4 illustrate the results and display the percentage of participants underestimating the small loss in the mixed-gain condition and

the percentage of participants correctly recognizing the small gain in the mixed-loss outcome conditions, respectively.

### Effect of Hedonic Editing Opportunity on Health Behavior Intentions

To test the second hypothesis of how the opportunity to hedonically edit one's self-tracking outcome affects participants' health behavior intentions, we examined the mediating role of compensatory health beliefs and the moderating role of health motivation (moderated mediation analysis, Table 1).

The analysis revealed that health motivation was a marginally significant moderator of the association between hedonic editing opportunity and compensatory health beliefs (estimate of interaction = -0.17;  $P = .07$ ), but not of the direct effect of the hedonic editing opportunity on health behavior intentions (estimate of interaction = 0.02;  $P = .83$ ). Further, the results

showed that compensatory health beliefs were negatively related to health behavior intentions ( $b = -.21$ ;  $P < .001$ ). Results indicated that the effect of hedonic editing opportunity on health behavior intentions was moderated by health motivation and mediated by compensatory health beliefs (index of moderated mediation = 0.0352, 95% CI 0.0011-0.0923). Results confirmed that especially users with a lower level of health motivation produce compensatory health beliefs in response to the hedonic editing opportunity, which decreased health behavior intentions. As such, in support of our second hypothesis, the conditional indirect effect of hedonic editing opportunity on health behavior intentions through compensatory health beliefs was significant at low levels of health motivation (indirect effect = -0.0902, 95% CI -0.1985 to -0.0237), but not at high levels of health motivation (indirect effect = -0.0045, 95% CI -0.0797 to 0.0615; see Figure 5).

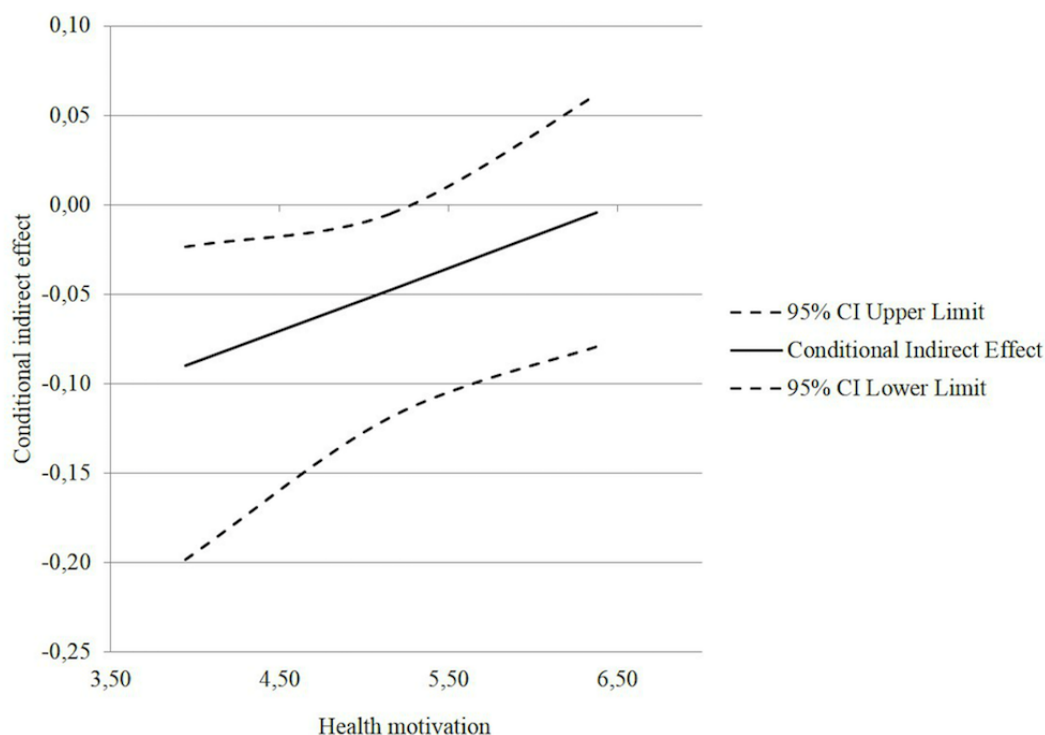
**Table 1.** Results of the moderated mediation analysis (not mean-centered).

Source	Coeff/Effect (SE) <sup>a</sup>	95% CI	<i>t</i> (df)	<i>P</i> value
<b>Outcome variables</b>				
<b>Compensatory health beliefs</b>				
Constant	3.30 (0.32)	2.67, 3.93	10.30 (393)	<.001
Hedonic editing opportunity	1.11 (0.49)	0.14, 2.08	2.24 (393)	.03
Health motivation	-0.04 (0.06)	-0.16, 0.08	-0.69 (393)	.49
Hedonic editing opportunity × health motivation	-0.17 (0.09)	-0.35, 0.01	-1.82 (393)	.07
<b>Health behavior intentions</b>				
Constant	5.38 (0.37)	4.66, 6.10	14.66 (392)	<.001
Compensatory health beliefs	-0.21 (0.05)	-0.31, -0.11	-4.04 (392)	<.001
Hedonic editing opportunity	-0.28 (0.50)	-1.27, 0.71	-0.56 (392)	.58
Health motivation	0.10 (0.06)	-0.02, 0.22	1.59 (392)	.11
Hedonic editing opportunity × health motivation	0.02 (0.10)	-0.17, 0.21	0.22 (392)	.83
<b>Conditional indirect effect<sup>b</sup></b>				
<b>Value of the moderator</b>				
Low health motivation (mean-1SD=3.94)	-0.09 (0.04)	-0.20, -0.02		
Health motivation (mean=5.16)	-0.05 (0.03)	-0.12, -0.00		
High health motivation (mean+1SD=6.38)	-0.00 (0.03)	-0.08, 0.06		
<b>Index of moderated mediation</b>	0.04 (0.02)	0.00, 0.09		

<sup>a</sup>Coefficient for outcome variables and effect for conditional indirect effect.

<sup>b</sup>Of hedonic editing opportunity on health behavior intentions through compensatory health beliefs at values of the moderator health motivation.

**Figure 5.** Conditional indirect effect of hedonic editing opportunity on health behavior intentions at values of the moderator health motivation through compensatory health beliefs.



## Discussion

### Principal Findings

Despite the growing popularity of digital self-tracking apps, to our knowledge this study is the first one exploring how spatial distance in the presentation of multiple self-tracking outcomes (physical activity and diet) affects users' responses to their self-tracking outcomes. Building on principles of hedonic editing [23], this study has provided initial evidence that a spatially close presentation of mixed-gain self-tracking outcomes or a spatially distant presentation of mixed-loss self-tracking outcomes facilitate hedonic editing of one's self-tracking outcomes. Highlighting potentially negative consequences of hedonic editing, this research has demonstrated that, particularly for users with low health motivation, the opportunity to hedonically edit one's self-tracking outcomes reduces future health behavior intentions through the formation of compensatory health beliefs.

Specifically, we found that spatial distance affects users' attention allocation and resulting memory of self-tracking outcomes consistent with principles of hedonic editing [23]. As such, in the case of a mixed-gain outcome profile, participants tended to systematically underestimate the small negative outcome when the outcomes were presented spatially close to versus distant from one another. In the case of a mixed-loss outcome profile, participants recalled the small positive outcome more accurately when the outcomes were presented spatially distant versus close to one another. This memory bias indicates that spatial distance between mixed self-tracking outcomes facilitates hedonic editing (ie, the mental integration of the small loss into the larger gain in the case of a mixed-gain outcome as

well as the segregation of the small gain from the large loss in the case of a mixed-loss outcome and indicates that spatial distance facilitates to view one's self-tracking outcomes in the most positive light). This finding is in line with previous research, which has proposed that attention allocation is a necessary condition of hedonic editing and has shown a systematic hedonic editing bias in users' memory of temporally close or separate gains and losses in the context of gambling [26]. This study extends this previous work by demonstrating a hedonic editing bias for the memory of spatially close or separate gains and losses in the context of self-tracking, hence generalizing the finding to another type of experience and distance manipulation.

Moreover, this research offers a novel explanation of how a hedonic editing opportunity might affect users' health-related behavioral intentions. Specifically, we provide initial evidence for a motivated cognitive justification mechanism and showed that particularly users' with a lower health motivation form compensatory health beliefs in response to the opportunity to hedonically edit their outcome, hence leading to reduced health behavior intentions. Thus, for users with a lower health motivation, compensatory health beliefs help to legitimate the hedonic reflection of their self-tracking outcomes and accordingly to justify their reduced intentions for future health-related behaviors in response to their self-tracking outcomes. This finding supports the assumption that "there may be individual differences in the employment of hedonic editing strategies" ([26], p 82; see also [31]) and addresses the call for research to include measures of motivation in order to explain differences in the occurrence of hedonic editing and resulting justification processes of irresponsible behavior [26]. The finding that users' levels of health motivation moderated the

association between hedonic editing opportunity and compensatory health beliefs extends previous research that has provided evidence for the compensatory health beliefs model [32] in a dietary context and documented that autonomous weight-loss motivation decreases compensatory dietary beliefs [33].

This research adds to initial work exploring the effectiveness of self-tracking apps to encourage health behavior change [18] and contributes to literature on hedonic editing [23,24]. As such, this research transfers hedonic editing principles to a novel context, namely the context of self-tracking, and thus extends previous work that has investigated the use and consequences of hedonic editing principles in the context of price changes [34], emotionally impactful events [35], multiple time losses [36], or the evaluation of a gambling experience [26]. Moreover, this study extends previous research examining the influence of temporal distance on hedonic editing [26,27] by examining whether spatial distance can also facilitate the segregation or integration of outcomes as postulated by hedonic editing principles.

### Limitations and Future Research

The limitations of our study offer various avenues for future research. First, we used fictive self-tracking outcomes to create standardized experimental conditions. However, it would be interesting to know whether the observed effects also occur when users view their actual self-tracking outcomes. Second, our study focused on the immediate effects of spatial distance on hedonic editing biases and resulting health behavior intentions and thus cannot provide insights on longitudinal or actual behavioral effects. Accordingly, future research should investigate how spatial distance in the presentation of goal-related outcomes affects health behavior intentions over time and/or how it affects actual physical activity or dietary behavior. Third, we considered self-tracking outcomes from multiple domains that are measured along the same dimension (ie, calories). It would be interesting to examine if multiple self-tracking outcomes that are measured along different measurement units (eg, step count for physical activity and calories burned for dietary behavior) would yield similar hedonic editing effects. Fourth, the participants in our study were not made aware of the possibility that they may experience a hedonic editing bias. To provide insights regarding how the potential negative effect of hedonic editing opportunity on health behavior intentions might be mitigated, it would be worthwhile to investigate whether making users with low health motivation aware of their hedonic editing bias and the potential activation of compensatory health beliefs would attenuate the negative effect of hedonic editing opportunity on health behavior intentions. Fifth, with respect to the manipulation of spatial distance, this study only employed one potential way of presenting goal-related outcomes. In this regard, future research could investigate the integration/segregation of self-tracking outcomes in conditions where spatial distance is even greater (eg, using two separate domain-specific apps) or smaller (eg, one compound chart) than in this study. Finally, the characteristics of our sample limit the generalizability of our research's findings. Our study employed a convenience online sample and shows how especially younger, majority female,

normally weighted, and well-educated users respond to a close compared to distant presentation of mixed self-tracking outcomes and to the opportunity to hedonically edit one's self-tracking outcomes. Accordingly, further studies might examine whether the observed effects change for older users or users who are less educated or heavily overweight.

### Implications

Considering that self-tracking apps constitute a promising, cost-effective tool to improve physical activity or dietary behaviors and to promote overall health outcomes [37], the findings of this research should be of interest for app designers and might be considered by health insurance providers, doctors, or even by app users. For example, designers of physical activity and diet tracking apps might consider developing an adaptive outcome presentation tool that aims to prevent hedonic editing biases by automatically maximizing the spatial distance between the presentation of both outcomes on the screen in the case of an overall mixed gain and by minimizing the spatial distance in case of an overall mixed loss. Spatial distance might be manipulated by displaying goal feedback horizontally compared to vertically or by presenting goal feedback separately in domain-specific halves of the screen or in two distinct user menu points compared to an integrative presentation. App designers might try to develop a tool that identifies users' health motivations and accordingly adapt the app's goal-related outcome presentation format for users with low health motivation. If the spatial distance in the app is difficult to adjust, app designers can think about integrating tools that assess users' health motivation and that warns users with low health motivation about a possible hedonic editing bias when they encounter an outcome profile that would be conducive for such a bias.

### Conclusions

Our findings suggest that app design features such as spatial distance between the presentation of mixed positive and negative goal-related outcomes can provide users the opportunity to hedonically edit their self-tracking outcome profile (ie, to recall their self-tracking outcomes in a more positive light). As such, if users have a positive outcome in one domain and a smaller negative outcome in the other domain, a spatially close versus distant presentation of self-tracking outcomes could facilitate that users tend to recall the small negative outcome as being smaller than it actually was. Likewise, if users have a large negative outcome in one domain and a small positive outcome in the other domain, a spatially distant versus close presentation of self-tracking outcomes could facilitate that users recall the small positive outcome more accurately. Importantly, particularly among users with lower health motivation, the opportunity to hedonically edit one's mixed self-tracking outcome profile leads to reduced health behavior intentions. Thus, to improve the effectiveness of self-tracking apps that employ goal-setting techniques for multiple domains, further studies are needed to determine the ideal distance between the presentation of mixed self-tracking outcomes on a digital device's screen because it is conducive to prevent the occurrence of hedonic editing biases among users and to encourage health behavior intentions.



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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Details on measures and participant exclusion criteria.

[[PDF File \(Adobe PDF File\), 273KB - mhealth\\_v6i4e81\\_app1.pdf](#)]

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## Abbreviations

**BMI:** body mass index

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Original Paper

# Findings of the Chronic Obstructive Pulmonary Disease-Sitting and Exacerbations Trial (COPD-SEAT) in Reducing Sedentary Time Using Wearable and Mobile Technologies With Educational Support: Randomized Controlled Feasibility Trial

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## Abstract

**Background:** Targeting sedentary time post exacerbation may be more relevant than targeting structured exercise for individuals with chronic obstructive pulmonary disease. Focusing interventions on sitting less and moving more after an exacerbation may act as a stepping stone to increase uptake to pulmonary rehabilitation.

**Objective:** The aim of this paper was to conduct a randomized trial examining trial feasibility and the acceptability of an education and self-monitoring intervention using wearable technology to reduce sedentary behavior for individuals with chronic obstructive pulmonary disease admitted to hospital for an acute exacerbation.

**Methods:** Participants were recruited and randomized in hospital into 3 groups, with the intervention lasting 2 weeks post discharge. The Education group received verbal and written information about reducing their time in sedentary behavior, sitting face-to-face with a study researcher. The Education+Feedback group received the same education component along with real-time feedback on their sitting time, stand-ups, and steps at home through a waist-worn inclinometer linked to an app. Patients were shown how to use the technology by the same study researcher. The inclinometer also provided vibration prompts to encourage movement at patient-defined intervals of time. Patients and health care professionals involved in chronic obstructive pulmonary disease exacerbation care were interviewed to investigate trial feasibility and acceptability of trial design and methods. Main quantitative outcomes of trial feasibility were eligibility, uptake, and retention, and for acceptability, were behavioral responses to the vibration prompts.

**Results:** In total, 111 patients were approached with 33 patients recruited (11 Control, 10 Education, and 12 Education+Feedback). Retention at 2-week follow-up was 52% (17/33; n=6 for Control, n=3 for Education, and n=8 for Education+Feedback). No study-related adverse events occurred. Collectively, patients responded to 106 out of 325 vibration prompts from the waist-worn inclinometer (32.62%). Within 5 min of the prompt, 41% of responses occurred, with patients standing for a mean 1.4 (SD 0.8) min and walking for 0.4 (SD 0.3) min (21, SD 11, steps). Interviews indicated that being unwell and overwhelmed after an

exacerbation was the main reason for not engaging with the intervention. Health care staff considered reducing sedentary behavior potentially attractive for patients but suggested starting the intervention as an inpatient.

**Conclusions:** Although the data support that it was feasible to conduct the trial, modifications are needed to improve participant retention. The intervention was acceptable to most patients and health care professionals.

**Trial Registration:** International Standard Randomized Controlled Trial Number (ISRCTN) 13790881; <http://www.isrctn.com/ISRCTN13790881> (Archived by WebCite at <http://www.webcitation.org/6xmnRGjFf>)

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## KEYWORDS

chronic obstructive pulmonary disease; feasibility; fitness trackers; intervention; physical activity; sedentary lifestyle; sedentary time; self-monitoring; wearable electronic devices

## Introduction

Postacute exacerbation interventions for people with chronic obstructive pulmonary disease (COPD), including pulmonary rehabilitation within 4 weeks of discharge, have been found to reduce COPD-related readmissions [1]. An acute exacerbation is characterized by a “sustained worsening of the patient’s condition, from the stable state and beyond normal day-to-day variation that is acute in onset and may warrant additional treatment in a patient with underlying COPD” [2]. Despite the benefits, postdischarge pulmonary rehabilitation is sparsely taken up at the point of discharge (9.6% of all hospital discharges) [3]. One reason for this may be that increasing physical activity or exercise can be a daunting prospect for many patients and may seem counterintuitive to managing their breathlessness [4]. Therefore, an intervention aiming to reduce patients’ sedentary behavior when they return home from hospital may be more relevant than exercise for some individuals with COPD [5,6]. In turn, this may act as a stepping stone in helping patients prepare for pulmonary rehabilitation. Sedentary behavior is defined as “any waking behaviour characterized by an energy expenditure  $\leq 1.5$  metabolic equivalents, while in a sitting, reclining or lying posture” [7]. It is currently unknown whether targeting reductions in sedentary behavior at home immediately following discharge from hospital following an acute exacerbation is feasible and acceptable to individuals with COPD.

Wearable technology may help patients engage with their health [8], and although there is evidence suggesting that wearables, such as pedometers, help individuals with COPD to increase their physical activity [9,10], no studies have specifically targeted sedentary behavior. Haptic feedback provided as vibration prompts has been used successfully in a range of contexts, including sports coaching [11], gait and balance training for older adults [12], and learning new skills [13]. The use of vibration prompts in behavior change interventions is gaining momentum and has been found to be an acceptable approach to reducing sitting time in sedentary men [14]. The Chronic Obstructive Pulmonary Disease Sitting and Exacerbations Trial (COPD-SEAT) aimed to examine the feasibility of the trial and acceptability of the intervention to reduce sedentary behavior at home in patients with COPD following hospitalization for an acute exacerbation. Furthermore, we interviewed patients and health care professionals involved

in COPD exacerbation care to understand their perspectives of reducing patients’ sedentary behavior in this context.

## Methods

### Design

The study design was a 3-armed feasibility randomized controlled trial (RCT) lasting 2 weeks following discharge from hospital, with 1:1:1 allocation. A detailed description of the study protocol has been published previously [15]. The trial is reported in accordance with CONSORT-EHEALTH (Multimedia Appendix 1). The study was approved by Research Ethics Committee East Midlands Leicester Central and all participants provided written informed consent (15/EM/0433).

### Recruitment

Individuals admitted to Glenfield Hospital (Leicester, UK), between February and June 2016, were screened for eligibility by COPD Specialist Nurses. Inclusion criteria were: aged 40 to 85 years; confirmed COPD diagnosis as described in patient notes; confirmed acute exacerbation of COPD as the reason for hospitalization; fewer than 4 exacerbations requiring emergency admission to hospital in the previous year, and deemed by the COPD Specialist Nurses to be physically able to participate in light-intensity physical activity. Patients were invited to take part during their hospital stay, face-to-face by a study researcher (MO), after being seen by a COPD Specialist Nurse as part of usual care. Eligible patients were given a verbal description of the study, participant information sheet, and expression of interest form. The researcher revisited patients at the bedside at an agreed time to collect the expression of interest. For patients wishing to take part in the study, written informed consent was obtained. The timing of these procedures varied based on expected discharge. Participants were not required to have access to the Internet to take part and were not paid for taking part.

### Randomization

Block randomization was conducted using sequentially numbered sealed envelopes by an individual independent of the research team. Due to limited study team members and logistical barriers, researchers were made aware of group allocation before obtaining consent. Patients were informed of their group allocation after providing informed consent.

## Intervention and Control Groups

Patients were randomized in-hospital to one of the 3 groups: “Control,” “Education,” or “Education+Feedback.” Study interventions were delivered in-hospital (face-to-face) by a researcher (MO). The Education group received verbal and written information about reducing sedentary behavior in the form of a booklet entitled *Sit Less, Move More, Live Healthier*, adapted for COPD from *On Your Feet to Earn Your Seat* [16,17]. The researcher went through the material with each participant at the hospital bedside, discussing the importance of breaking up prolonged sitting and how this could be done at home. The booklet contained 7 main suggestions: leave the house daily; make advertisement breaks active; stand-ups (eg, when the kettle is boiling); tiptoe through the queue; increase your steps; sit to stand with no hands; and treat the seat as a treat. The Education+Feedback group received the same educational component plus real-time feedback on their step count, sitting, standing, lying down, and sit-to-stand transitions via an inclinometer linked to a smart device application provided for them. Additionally, these patients received haptic feedback (vibration prompts) from the inclinometer when they were sedentary for a prolonged period of time. This feature was modified from the original purpose of the device, which was to vibrate when the user was in poor posture. The timings of the vibration prompts (eg, after 30 min of sitting) were determined by the patient in-hospital. The setting of how long patients could be sedentary for before the prompt could not be altered after patients were discharged from hospital (eg, they could change from 30 min to 40 min). No changes to the education booklet, inclinometer, or smart device application were made during the study. Patients took part in the interventions for 2 weeks following discharge and were not prompted to engage with the intervention during that time.

All patients in the trial received the discharge bundle as part of usual care (control condition). The care bundle comprised advice about doing regular exercise (no actual supervised exercise conducted with patients), attending pulmonary rehabilitation, medication advice, inhaler training, mobility physiotherapy input, and in-hospital physical function discharge assessments [18]. Patients were provided with telephone contact details of the COPD Specialist Nurses.

## Feasibility of the Trial

### Recruitment and Retention

Patient eligibility, uptake, and retention were recorded. Patients not wishing to take part were asked for their main reason for this. To monitor intervention safety, adverse events were recorded for each patient during their time in the study. Readmissions for an acute exacerbation were not considered adverse events as up to 43% of patients may be readmitted within 3 months in any case [19]. Descriptive characteristics were compared between those who did and did not attend the 2-week follow-up appointment.

### Intervention Fidelity

Deliveries of the Education and Education+Feedback components of the intervention were audio recorded. Details of the intervention components (education booklet, application,

and vibration prompts) have been previously reported [15]. Each component was coded separately by 2 trained, independent assessors using dichotomous scales (present or absent) for consistency and ordinal scales (poor, adequate, or excellent) for quality of delivery.

### Dropout Interviews

Dropout telephone interviews were conducted to explore reasons why patients did not attend the follow-up appointment. The questions asked included what they thought of the study, how they were feeling and what had been going on during the study, and their reasons for withdrawal.

### Health Care Professional Interviews

Semistructured interviews with doctors, COPD Specialist Nurses, ward nurses, and physiotherapists were conducted to examine the perspectives of staff involved in the COPD care pathway and provided insights on suggestions for and the potential barriers of conducting a full-scale RCT. They were asked about their thoughts on the intervention itself, reducing sedentary behavior for this patient population, and the education material and technology.

## Acceptability of the Intervention

### Wear Adherence, Charging Compliance, and Missing Data

All participants were asked to wear the inclinometer for 14 consecutive days, with discharge date considered as day 0. The number of days the inclinometer was worn by participants was examined. One overnight charging occurrence per 24 hours (13 in total) was considered 100% charging compliance. Charging was automatically detected by the inclinometer. Patients were asked to charge the inclinometer every day to remove the need for patients to check the battery status manually. The battery life of the inclinometer typically lasts for 2 to 3 days before charging is required. Missing data were examined to determine whether this was caused by a depleted battery or from being manually switched off.

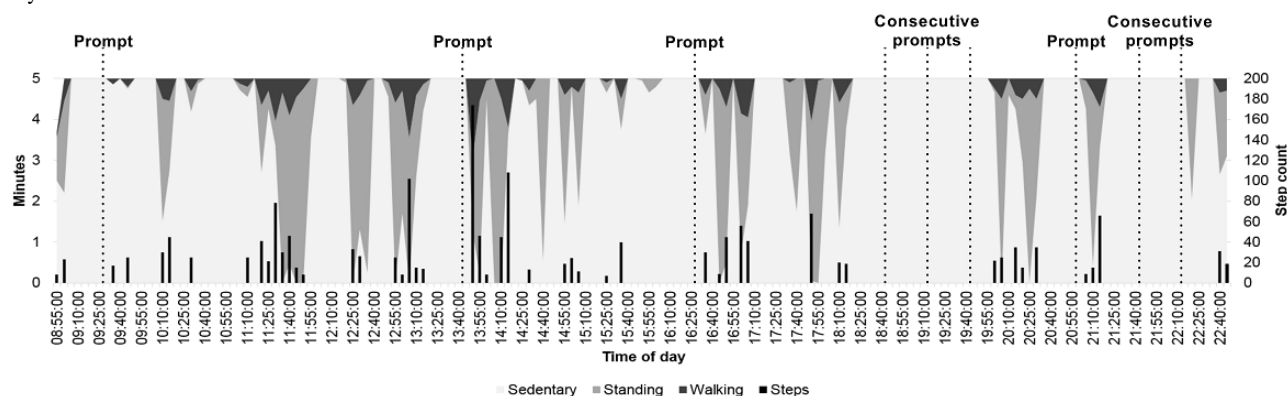
### Engagement With Smart Application

Patient engagement with the LUMOback app was quantified using Flurry Analytics [20], which registered, offline, each swipe and tap performed by patients for the sitting time, stand-ups, and step count panels.

### Responses to Vibration Prompts

Vibration prompt identification was based on periods of consecutive time spent sedentary as per patients' choice of vibration setting. After time-stamped vibration prompts were identified, the subsequent 15 min were analyzed to examine whether patients responded to the vibration prompt and, if they did, how long it took and what they decided to do. A concept diagram using real data for when vibration prompts occurred is provided in Figure 1. From the figure, it can be seen that prompts occurring at 9:30, 14:45, 16:30, 21:00, and 22:15 were followed by physical activity within 5 min of the prompt taking place, whereas 3 consecutive prompts at 18:45, 19:15, and 19:45 and a prompt at 21:45 were not followed by physical activity.

**Figure 1.** A concept diagram demonstrating where vibration prompts (set for 30 consecutive minutes sedentary) would occur during the course of a day. The dashed lines indicate where a vibration prompt would have occurred. The darker shaded areas depict where a patient has interrupted their sedentary time with standing and/or walking, and the black bars represent step count. Prompts at 9:30, 14:45, 16:30, 21:00 and 22:15 are followed by physical activity within 5 min of the prompt taking place. Prompts at 18:45, 19:15, 19:45 (3 consecutive prompts) and 21:45 are not followed by physical activity.



### End-of-Study Interviews

Semistructured interviews with patients in the intervention groups were conducted during the follow-up appointment at Glenfield Hospital, United Kingdom. Interviews explored patients' experiences of the self-monitoring technology, vibration prompt, application, education booklet, and the study overall.

### Attendance at Pulmonary Rehabilitation

Past and present pulmonary rehabilitation referral and attendance information was obtained through the Hospital Information Support System on-site at Glenfield Hospital, United Kingdom. The proportion of patients attending the pulmonary rehabilitation clinic assessment as part of usual postexacerbation care, the proportion of patients who agree to take part, and the proportion of patients to go on to attend are reported.

### Sample Descriptive Measures

Measures were obtained during the hospital stay to describe the study sample. Symptom burden was self-reported using the COPD Assessment Test [21] and usual modified Medical Research Council dyspnea grade [22]. Fatigue was self-reported using Functional Assessment of Chronic Illness Therapy-Fatigue with a score <30 indicating severe fatigue [23]. Anxiety and depression were examined using the Hospital Anxiety and Depression Scale [24] with a normal score considered as 0 to 7, borderline abnormal level considered 8 to 10, and abnormally high anxiety/depression considered 11 to 21 [25]. Fear of falling was self-reported by Falls Efficacy Scale-International (0-64, with higher score denoting more fear of falling) [26]. Self-reported usual time spent sitting was obtained from the Marshall Sitting Time questionnaire [27]. Information on the ownership and usage of computers and smartphones was self-reported. Index of Multiple Deprivation, which ranks the relative deprivation of postcodes in England was used. At the follow-up appointment, height, weight, and waist circumference were measured. Body mass index (BMI) was calculated, and patients were categorized as either underweight (<18.5 kg/m<sup>2</sup>), normal weight (≥18.5 and <25.0 kg/m<sup>2</sup>), overweight (≥25.0 and <30.0 kg/m<sup>2</sup>), or obese (≥30.0 kg/m<sup>2</sup>) [28]. Patients completed

the short physical performance battery (SPPB) with a score <10 points considered the threshold for mobility limitation [29].

### Assessment of Physical Activity and Stationary Time

Participants were asked to wear an ActiGraph wGT3X-BT accelerometer (ActiGraph, Pensacola, FL) on the right anterior hip during waking hours for 14 days following discharge (full methodology in Multimedia Appendix 2). Steps and intensity of physical activity undertaken during the study period were reported with stationary time classified as <100 counts per min [30]. A valid day was considered ≥8 hours of valid waking wear time, with patients providing ≥4 valid days out of 7 for both weeks included in the analyses [31].

### Quantitative Analyses

Comparisons between groups and between patients who did or did not complete the study were performed using independent *t* tests and analysis of variance. Categorical data were analyzed using chi-square (*n*≥5) or Fisher exact test (*n*<5). Analyses were conducted using SPSS version 22.0 for Windows (SPSS Inc., Chicago, IL), with alpha set to .05. The datasets used and/or analyzed during this study are available from the corresponding author on reasonable request.

### Qualitative Analyses

Interviews were conducted by a trained social scientist (AW), audio-recorded, and transcribed. Transcripts were analyzed initially by AW, for themes pertinent to the feasibility of the study and acceptability of the intervention [32], using constant comparison [33] and facilitated by NVivo 10 qualitative software (QSR International, Cambridge, MA). Themes were discussed against the material with PS and JD.

## Results

### Feasibility of the Trial

#### Eligibility, Uptake, and Retention

Participant flow through the trial is presented in Figure 2. Of the 300 patients screened, 212 (70.7%) were eligible to take part in the study. Of these, 100 (47.2%) were discharged before the researcher could approach them, and the study team were

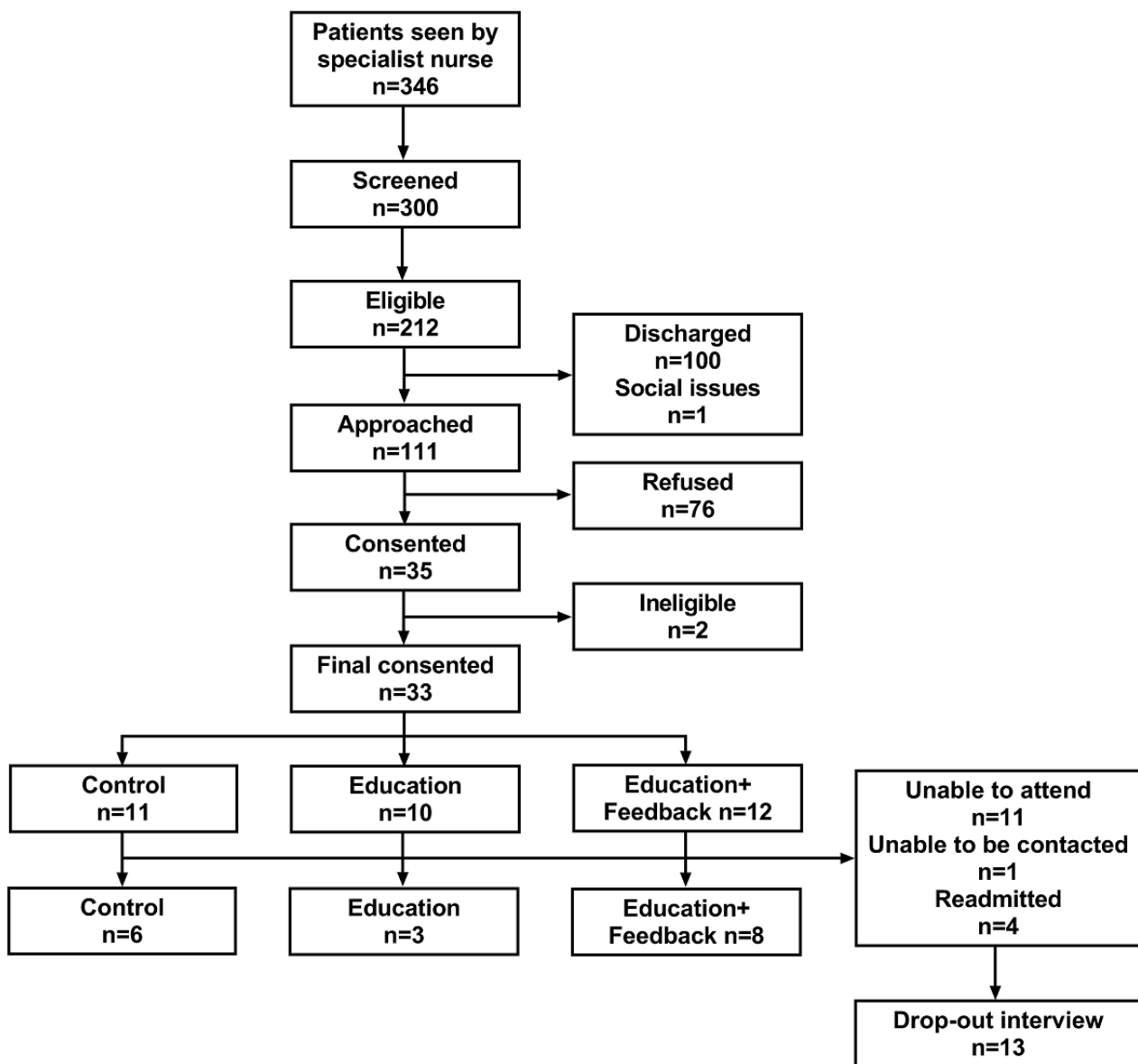
advised not to approach one patient because of a complicated social situation. Finally, 111 patients (52.4% of eligible patients) were approached to take part in the study, with 35 (31.5%) consenting to participate. However, 2 patients were identified as having early-stage dementia, leaving 33 patients (11 Control, 10 Education, and 12 Education+Feedback). Of these, 17 (51.5%; 6 Control, 3 Education, and 8 Education+Feedback) attended the follow-up appointment. Rate of recruitment averaged 2.2 patients per week.

**Patient Characteristics**

The sample comprised mostly female (23/33, 70%), retired (25/33, 76%), former smokers (21/33, 66%) who self-reported sitting for an average of 9.2 (SD 4.2) hours/day (Table 1). The majority (25/33, 76%) of participants did not own a smartphone

but did own a computer (20/33, 61%). Of the total sample, 30% of patients (10/33) were classified as having abnormally high depression scores, 39% (13/33) were classified as having abnormally higher anxiety scores, and 81.8% (27/33) of patients were classified as having severe fatigue. All patients who completed the study completed all questionnaires. On the basis of follow-up data of patients who completed the study, 65% of patients (11/17) were overweight or obese, 6% (1/17) were underweight, and 96% (16/17) had mobility limitation (SPPB <10 points). Control completers had significantly greater BMI and waist circumference than Education and Education+Feedback completers (eg, 21.3, SD 3.2, vs 37.3, SD 9.7, vs 28.8, SD 3.8 kg/m<sup>2</sup>, respectively). Noncompleters had higher levels of postcode deprivation and had more readmissions during the study period than those who completed the study.

**Figure 2.** Consolidated Standards of Reporting Trials (CONSORT) diagram.





**Table 1.** Patient characteristics for the whole sample and stratified by attendance at the 2-week follow-up appointment. COPD: chronic obstructive pulmonary disease.

Descriptor	Whole sample (N=33)	Completed (N=17)	Not completed (N=16)
Age in years, mean (SD)	71.0 (20.0)	66.6 (9.6)	69.5 (11.2)
Female sex, n (%)	23 (70)	12 (71)	11 (69)
Index of Multiple Deprivation decile, mean (SD)	4.5 (3.2)	5.8 (3.1)	3.0 (2.6); <i>P</i> =.008
<b>Employment status, n (%)</b>			
Retired	25 (76)	12 (71)	13 (81)
Unemployed	5 (15)	4 (24)	1 (6)
Employed	3 (9)	1 (6)	2 (13)
<b>Smoking status<sup>a</sup>, n (%)</b>			
Current	11 (34)	4 (24)	7 (44)
Former	21 (66)	12 (71)	9 (56)
Pack years, mean (SD)	46.7 (25.6)	44.3 (26.5)	49.5 (25.1)
Usual modified Medical Research Council grade, mean (SD)	2.6 (1.2)	2.7 (1.1)	2.6 (1.3)
Home oxygen, n (%)	3 (9)	2 (12)	1 (6)
Number of comorbidities, mean (SD)	3 (3)	2 (3)	4 (3)
Acute exacerbation of COPD readmissions, n (%)	4 (12)	0 (0)	4 (25); <i>P</i> =.043
COPD assessment test score, mean (SD)	24.9 (7.5)	24.5 (7.4)	25.4 (7.8)
Fatigue score, mean (SD)	19.8 (11.8)	21.0 (12.2)	18.1 (11.7)
Hospital Anxiety and Depression Scale depression score, mean (SD)	8.2 (4.7)	7.4 (5.2)	9.3 (3.9)
Hospital Anxiety and Depression Scale anxiety score, mean (SD)	9.2 (5.8)	8.9 (5.5)	9.6 (6.2)
Falls Efficacy Scale-International score, mean (SD)	33.4 (13.7)	31.5 (13.5)	35.4 (14.2)
Self-reported daily sitting time in min/day, mean (SD)	553.0 (253.6)	603.1 (257.4)	487.9 (245.9)

<sup>a</sup>Missing n=1.

### Reasons for Ineligibility and Nonparticipation

The most common reasons for ineligibility were as follows: too severe comorbidities (36.4%), more than 4 exacerbations in the previous year (20.5%), and taking part in other research (14.8%). The most common reasons for not taking part in the study were as follows: feeling too unwell or having too many health-related issues/commitments (40.0%) and considering themselves sufficiently active (12.9%). Two patients (2.4%) were put off by the activity monitors.

### Readmissions and Adverse Events

Two patients (6%; Education) were readmitted to hospital for at least one overnight stay for respiratory (n=1) and nonrespiratory (n=1) issues. Although not considered an adverse event in this study, 4 patients (12%; 1 Control, 3 Education+Feedback; withdrawn from the study) were readmitted for an acute exacerbation of COPD during the 2-week follow-up. No hospital admissions were study-related, and no participants died during the trial.

### Intervention Fidelity

We delivered 21 (95%) interventions as planned. However, one intervention (Education) was not delivered verbally because of the patient being discharged. A full breakdown of intervention fidelity is provided in [Multimedia Appendix 3](#). Overall

consistency of the intervention delivery was 77.3%, with 0.2%, 9.4%, and 90.4% for “poor,” “good,” and “excellent” quality ratings, respectively.

### Reasons for Patients Dropping out of the Study

When 13 participants (81% of those who dropped out) were asked about their reasons for dropping out of the study, patients stated they were too unwell and overwhelmed after experiencing an exacerbation, sometimes dealing with comorbidities (eg, urinary tract infection and heart failure), medications, hospital appointments, readmission for another exacerbation, and lack of support from friends and family ([Textbox 1](#)). When asked what would help them to sit less, patients responded with answers such as “getting better.” Patients did not suggest any specific changes to the study and were often disappointed or apologetic with not being able to give it a go, indicating they would have liked to try the intervention at a later date when symptoms are more stable.

### Views of Health Care Professionals

Health care staff reported in interviews that decreasing sedentary behavior would be a good way to increase patients’ activity levels and prevent them from being readmitted ([Textbox 2](#)). Although a few thought the timing of the study was good because it encouraged movement at home, many suggested

starting the intervention during the patients' hospital stay because it would help motivate them to move in hospital, where they often became bedbound. Staff also noted that they could help patients get used to the device during hospital stay but also remarked that this would increase workload. Nearly all the health care staff felt that the technology was a good idea, as it would give patients something to focus on and encourage them to sit less. However, staff noted that the patients, the majority of whom were older adults, might have limited technological ability and that the more severely ill patients might find the concept overwhelming.

### Acceptability of the Intervention

#### *Wear Adherence, Charging Compliance, and Missing Data*

Patients wore the inclinometer for 11.8 (SD 2.3) days over the 14-day period. Of those who participated, 67% of the patients charged the device on  $\geq 7$  days and 47% charged the device on  $\geq 10$  days; 20% of the participants experienced a device malfunction. Two types of malfunction were reported: the smart device would not turn on, which meant patients were unable to use the mobile app (the vibration prompt remained functional), and a delay in communication between the inclinometer and the app. Missing data occurred for 3 participants: 1 turned the inclinometer off for 1 day, 1 had 8 missing days (battery died

for 5 days and turned off for 3 days), and 1 had 12 missing days (turned off).

#### *Engagement With Smart Application*

Three patients (25%) actively engaged with the LUMOback app during the 2-week follow-up. One male patient used the app on day 1 to look at the sitting time summary (131 seconds), the stand-ups summary (3 seconds), and step count summary (6 seconds) and detailed step count information (8 seconds). This patient experienced a device malfunction on day 2. Despite a replacement sensor being provided, it was not possible to obtain further app interaction data. The other 2 patients did not engage with the app beyond the use of the summary tile automatically on show when unlocking the smart device (unknown durations as no swipes or taps on the screen occurred).

#### *Responses to Vibration Prompts*

Of the 12 patients randomized to the Education+Feedback group, 6 chose for the vibration to occur after 30 min (4 completers), 1 after 45 min (1 completer), and 5 after 60 min of consecutive sitting (3 completers). Collectively for the 8 patients who completed the study, 325 vibration prompts occurred. Patients did not respond to 67% of the prompts. When patients did respond to the prompts, 40.6% responses occurred within 5 min of the prompt, with patients spending 1.4 (SD 0.8) min standing and 0.4 (SD 0.3) min walking, taking 21.2 (SD 11.0) steps (Figure 3).

**Textbox 1.** Patient panel: illustrative quotes from patient dropout interviews.

"I am really disappointed, but it's just the way it is, I have so much on my plate right now, and the heart failure thing really knocked me." [Female, Education 009]

"I had an awful lot of hospital appointments and doctors' appointments, and it was like. Do you know what, I'm getting fed up with this. It was too much for me, I just wanted to relax and get better." [Female, Education 021]

"I'll try again, I want to do it, but maybe when I feel a bit better." [Female, Education 027]

**Textbox 2.** Health care panel: illustrative quotes from health care qualitative interviews about the feasibility of the trial.

#### Views on study design

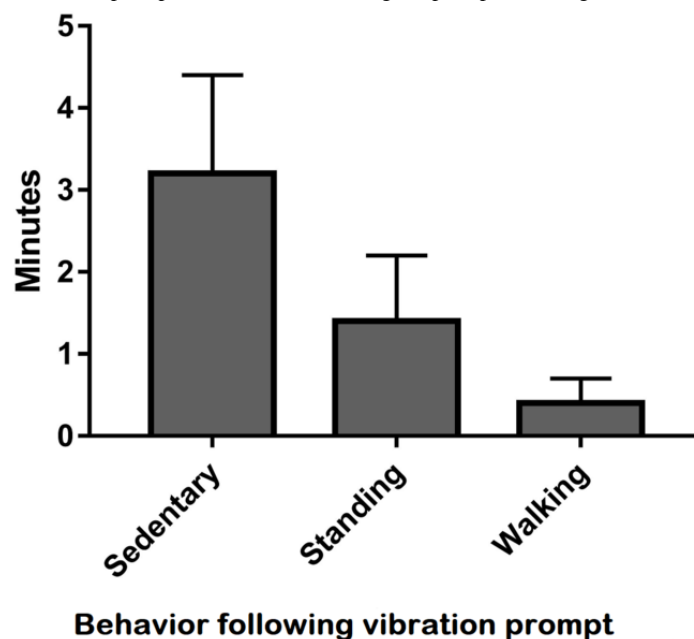
- "I think that's a really good idea. It will give them something to focus on. It may give them a bit of drive, a bit of focus, and it encourages people to become active, cuz obviously a lot of these patients who get very breathless and they can't walk too far, so that will prompt them just to do small bits of exercise." [HC020]
- "They are looking forward to getting home and getting back to some kind of normality, but hopefully they are thinking to themselves, I don't wanna do that again anytime soon, so what's gonna help me not do that again, and this study could help with that." [HC011]

#### Perspectives on timing

- "There's nothing wrong with the timing it's just the amount of information, I think, because when you're not well yourself and to be bombarded with a lot of information to take on board you're sitting there listening but how much do you take in." [HC006]
- "Round the ward would be good to encourage them to move, but if it was in the ward, the limitation would be those who can't move without our help, and we don't have enough nurses to go to bed 1 or 2, but it would help them regain confidence before going home." [HC021]

#### Views on technology

- "I think it would be a good prompt to remind them to move and exercise, and it might help them focus, I think it's a good idea." [HC026]
- "Some patients, maybe the older ones possibly who are just not very technologically savvy, they may struggle with something like this, and maybe the ones who are more end stage COPD, they might not see the point or be too overwhelmed possibly." [HC022]

**Figure 3.** Behavioral responses to the vibration prompt for the 5 min following the prompt occurring.

The proportion of days prompted were similar between patients who chose a 30-min prompt setting and patients who chose a 60-min prompt setting (76% and 77% of days, respectively). Patients who chose the 30-min setting were prompted more frequently than those who chose the 60-min prompt setting (5.5 and 1.6 prompts per day, respectively), but the proportion of nonresponses and responses within 5 min of the prompt occurring were similar (53% vs 59% nonresponses and 19% vs 23% responses within 5 min, respectively).

### **Views of Patients Who Completed the Study**

Three themes pertinent to the acceptability of the intervention were identified from the interviews: (1) being too unwell and overwhelmed, (2) engaging with the intervention when it fitted with routines, and (3) perspectives on leaflet and wearable technology. Supporting quotes for the themes identified are provided in [Textbox 3](#).

#### **Being Too Unwell and Overwhelmed**

Many patients still felt unwell after their exacerbation and talked about being too overwhelmed with hospital appointments and medications to be able to fully engage with the intervention. They discussed about struggling to do normal daily activities and not engaging with the study intervention but instead preferred sitting and relaxing to make themselves feel better. A few patients were readmitted for their COPD within a week of their discharge, and a few also experienced newly diagnosed or ongoing comorbidities. Patients talked about the study not being their priority while illnesses and treatments were on their agenda.

#### **Engaging With the Intervention When It Fitted With Routines**

Patients who engaged with the intervention described that they typically reduced their sitting time when it fitted with their

routines. For example, they responded to the vibration prompt by getting up to make tea or walk the dog. When the prompts interrupted an activity deemed important/enjoyable to the patient, such as watching an interesting program on TV, the prompt was experienced as disruptive and annoying.

A couple of patients reported adopting new routines, such as walking to the bottom of the garden in response to the vibration. Several participants mentioned that they made more of an effort to reduce their sedentary time in the second week rather than the first, when they felt better.

#### **Leaflet and Technology Use**

Most participants found the technology fairly easy to use and wore and interacted with it. With regard to the educational component, many did not recall the leaflet, some mentioned they had read but forgotten it, or felt that it was not relevant or useful to them, and many said they did not really sit anyway and they found the tips were not applicable for them. However, some patients mentioned that they had read it and it made them think about sitting, and they thought the overall concept was a good idea. Many said the waistband was uncomfortable and suggested that a wristband would have been easier to use. The study in general appealed to most participants, with many saying they had good intentions and considered that they might gain some knowledge from it for themselves and others.

#### **Pulmonary Rehabilitation**

Of the 33 patients who took part in the trial, 14 (42%) attended the clinic assessment, 7 (21%) agreed to attend, and 4 (12%) went on to attend pulmonary rehabilitation ([Table 2](#)); 9% of patients in the Control group, 10% of patients in the Education group, and 17% of patients in the Education+Feedback group went on to attend pulmonary rehabilitation.

**Textbox 3.** Patient panel: illustrative quotes from patient qualitative interviews.

<p>Too unwell and overwhelmed</p> <ul style="list-style-type: none"> <li>• “I’ve had to sit a lot. There’s a lot going on with my health, and I just can’t cope sometimes. I’m struggling with even my normal stuff.” [Female, Feedback 017]</li> <li>• “You need so much energy to get through the day, it’s difficult when you get home, and you’re trying to recover and getting up is sort of difficult then, you just want to sit and relax and get better.” [Female, Feedback 026]</li> </ul> <p>Fitting with routine</p> <ul style="list-style-type: none"> <li>• “You feel it buzz on your back, so I just get up and walk in the kitchen or go and put the kettle on.” [Male, Feedback 010]</li> <li>• “It does give you a sense of purpose, you know, it goes off and you walk the dogs or go round to the neighbours or something like that. It clocks it up.” [Male, Feedback 010]</li> <li>• “I was annoyed that this thing was poking me in the back every half an hour, cause I didn’t want to move, I was watching something.” [Female, Feedback 020]</li> <li>• “The first week was dreadful, I just wasn’t feeling myself. Anyway the next week I started feeling a lot better, started doing my normal things again.” [Female, Feedback 029]</li> </ul> <p>Leaflet and technology use</p> <ul style="list-style-type: none"> <li>• “It [the device] was fine. No problem, fairly easy to use really. I put it on in the morning and left it on all day until I went to bed at night.” [Female, Feedback 020]</li> <li>• “I read it [the leaflet]. Forgot it. It didn’t really have anything in it that interested me, I don’t watch much TV or anything.” [Female, Education 012]</li> <li>• “It’s been a bit uncomfortable, because it’s been hot, you know, and I couldn’t put any thin trousers on because I’m wearing it, but it’s been alright, yeah. Maybe a wrist thing would have been better for me.” [Female, Feedback 029]</li> <li>• “I think it’s a good study, it gives insight, doesn’t it, to other people and for me too really.” [Female, Education 008]</li> </ul>
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**Table 2.** Uptake to pulmonary rehabilitation (PR) stratified by study group.

Stage of pulmonary rehabilitation	Whole sample (N=33)	Control (N=11)	Education (N=10)	Education+Feedback (N=12)
Attended clinic assessment, n (%)	14 (42)	8 (73)	3 (30)	3 (25)
Agreed to take part in PR, n (%)	7 (21)	3 (27)	2 (20)	2 (17)
Attended PR, n (%)	4 (12)	1 (9)	1 (10)	2 (17)

### **Changes in Physical Activity and Stationary Time**

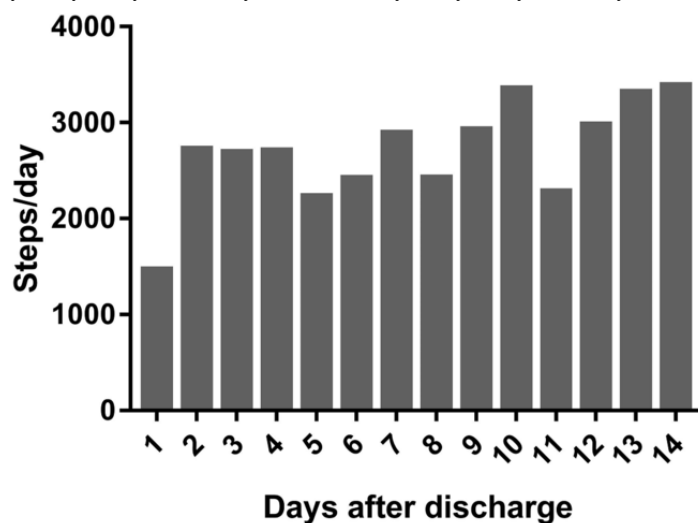
A total of 14 patients (42%) provided at least 1 day of valid accelerometer data for both the first and second week post discharge reducing to 5 patients (15%) providing 6 valid days for both the first and second week post discharge (total 12 days). On the basis of 8 patients (24%) who provided at least 4 days of valid accelerometer data for both the first and second week post discharge (total  $\geq 8$  days; 3 Control, 1 Education, 4 Education+Feedback), step count increased on average by 1920 steps per day (+43%) from the first day after discharge to day 14 (Figure 4). The proportion of stationary time, light activity, and moderate to vigorous physical activity did not change over the 2-week period, with stationary time ranging from 63% to

77% and MVPA ranging from 0.3 to 0.9% of patients’ waking day (Figure 5).

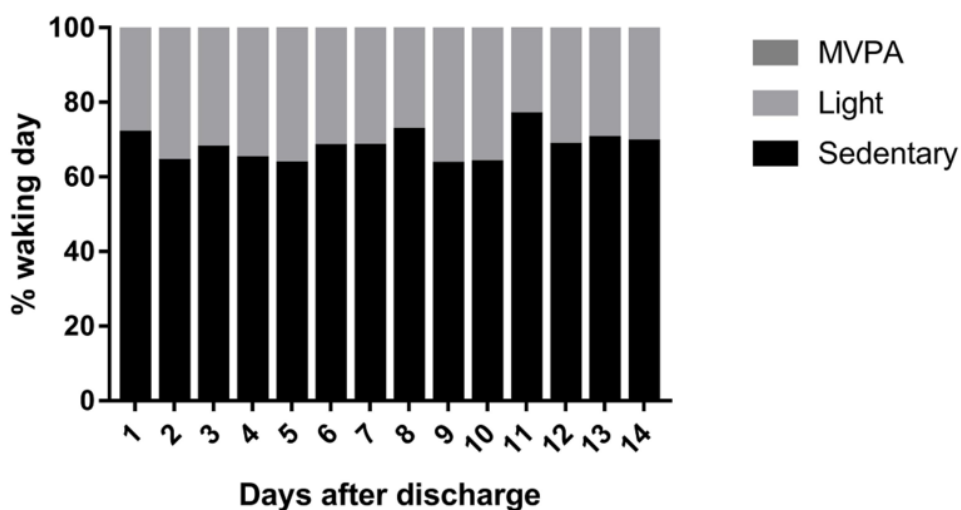
### **Changes in Self-Reported Health Questionnaires**

A comparison of baseline versus 2-week follow-up responses with health questionnaires for patients with complete data (6 Controls, 3 Education, and 8 Education+Feedback) is provided in Multimedia Appendix 4. No statistically significant changes over time were observed for all groups for COPD symptoms (COPD Assessment Test), fatigue, anxiety, depression, or fear of falling (Falls Efficacy Scale-International score). The proportion of patients reporting severe fatigue reduced from 71% to 41% for the whole sample over the 2 weeks, which can be attributed to the natural postexacerbation recovery of patients.

**Figure 4.** Daily step count during the 14-day study period for patients with valid data ( $\geq 4$  day out of a possible 7 for each of the 2 weeks). N=8 for day 7 and day 8; N=7 for day 2, day 3, day 4, day 9, day 12, and day 13; N=6 for day 1, day 5, day 6, and day 11; and N=5 for day 10.



**Figure 5.** Proportion of each waking day spent being stationary, in light activity and in moderate to vigorous physical activity (MVPA) during the 14-day study period for patients with  $\geq 4$  valid days for each of the 2 weeks. N=8 for day 7 and day 8; N=7 for day 2, day 3, day 4, day 9, day 12, and day 13; N=6 for day 1, day 5, day 6 and day 11; and N=5 for day 10.



## Discussion

### Principal Findings

This study examined trial feasibility and the acceptability of an education and self-monitoring intervention using wearable technology to reduce sedentary behavior for individuals with COPD hospitalized for an acute exacerbation. Approximately one-third of patients who were offered the study took part, and of these, around half attended their follow-up appointment at 2 weeks. Reasons for deciding not to take part were predominantly being too unwell or being readmitted. Patients responded to approximately one-third of the vibration prompts provided by the wearable technology, of which approximately 40% occurred within 5 min, resulting in approximately 1.5 additional min standing, approximately 0.5 min of walking, and approximately 21 extra steps per response.

### Feasibility of the Trial

The trial seems feasible with the proportion of eligible patients (70.7%) comparable with early pulmonary rehabilitation (63.8%

eligible) [3]. This study's uptake (31.5%) was also similar to that of a periexacerbation pulmonary rehabilitation study (32.3%) conducted in the same hospital [34], and the rate of recruitment was faster than a physical activity intervention using wearable technology (Fitbit Ultra) at a similar time point (average of 2.2 vs 0.6 patients per week) [35]. Retention of participants to the 2-week follow-up appointment (51.2%) was lower than the proportion of patients completing early pulmonary rehabilitation (71.7% of patients attending rehabilitation) [3]. However, for patients in the Education+Feedback group, retention (75%) was comparable to a previous behavioral telehealth intervention in this population [36], suggesting that receiving haptic feedback did not contribute significantly to the observed attrition. The relatively poor retention rate overall may be related to the length of the follow-up. When patients are discharged from hospital, symptoms remain elevated and it takes time for patients to return (or get close) to their normal activities and symptom severity [37,38]. The qualitative dropout and end-of-study interviews illustrated that many participants struggled to engage with the

intervention immediately after being discharged because of multiple issues related to coping with health, which was also intimated by some of the health care staff, who suggested offering patients more support with the intervention during the hospital stay.

The recruitment method was only able to invite a proportion (47%) of admitted patients to take part in the study. This was because patients were discharged between screening and approach. Usual care, required to determine eligibility and conducted by COPD Specialist Nurses, was provided to all patients. With pressure for wards to discharge patients and variable patient recovery rates, this usual care cannot always be conducted in the early days of admission. In addition, 45% of patients are admitted and discharged within 3 days [39]. Therefore, with 1 person recruiting for this study (after usual care was completed), it was not always possible to approach eligible patients before they were discharged. Additional opportunities for patients to engage with lifestyle program may be warranted. For example, the future iteration of this trial could offer multiple opportunities for patients to take part when they feel well enough, including during their hospital stay, once they have returned home, and before attending pulmonary rehabilitation. If in the next trial it is not possible to approach patients during their hospital stay, patients could be sent study information by post and contacted via telephone. The challenge for future work will be to maintain contact with the patient and intervene regardless of whether or not the patient is still in hospital. This is because the discharge date is often influenced by other factors such as the need for family or social support.

### Acceptability of the Intervention

Overall, participants adhered to wearing and charging the waist-worn inclinometer. However, with an increasing recognition of the importance of capturing the 24-hour day for understanding behavior and health outcomes [40], there is a need to shift the traditional locations for activity monitoring (eg, the waist) toward locations facilitating better compliance (eg, the wrist). Interviews highlighted that most patients found the inclinometer easy to use and were more engaged with it than the educational booklet and app; however, several noted that they found the waist location uncomfortable. Therefore, future work should consider moving activity monitoring to a more desirable location on the body.

Participants rarely talked about the usefulness or relevance of the specific components of the education booklet, although some mentioned they did not find some of the tips relevant as they did not relate to their habitual activities, for example, they did not watch television. Matei and colleagues [17] observed good adherence to most suggestions (eg, 61% for “making ad breaks active” and 55% adhering to “leave the house daily”) in older adults recruited from sheltered housing sites. Other tips were adhered to less, with 15% adhering to “tiptoe through the queue” [17]. This highlights the need to individually tailor the education component to the specific sedentary behaviors of patients and to capture adherence rates to the education components in future work.

In addition, the lack of engagement with the app may reflect the additional effort required to use unfamiliar technology (only

24% owned a smartphone) and, as described by patients during the interviews, to comprehend and act on information at a time when they were still unwell and struggling to cope with their COPD and comorbid conditions. This study did not offer training on using the smart device, which may have contributed to the poor engagement with the app. The next iteration of the trial should account for the variability between patients in their confidence and ability to use technology. With time, a greater proportion of patients are likely to own smart devices and be more comfortable using such technology.

The proportion of positive behavioral responses to the vibration prompts and the resulting additional physical activity were promising (eg, 21, SD 11, extra steps per positive response). It is perhaps unrealistic to expect patients to respond to all vibration prompts as some of the unheeded nudges may have been the result of poor timing as the technology was not “context aware.” For example, prompts could have gone off while a patient was in their car. The interviews illustrated that patients often responded to the prompts when this naturally fitted with their routines; furthermore, some chose to ignore the vibration when they interrupted enjoyable activities. In this respect, our participants did not easily introduce new behaviors, as in the study by Matei and colleagues [17] focusing on healthy older adults and offering tips to reduce sedentary time. This may have been because patients in this study had a chronic condition, were acutely unwell, and had returned home following hospitalization, but may have also been because they were asked to engage with a wearable monitor that interrupted everyday routines. Patients chose how long they could be sedentary before being prompted, with half choosing to be prompted after 30 min of sitting. The range in patient preferences of vibration prompt occurrence supports future work offering this choice to patients. However, the unstandardized prompt frequencies between patients must be accounted for in the future efficacy trial. Due to usage restrictions placed on the smart device, the choice of vibration setting could not be changed during the 14 days. Additional flexibility permitting patients to alter the frequency of the feedback may facilitate greater engagement with the intervention in the context of their recovery, as highlighted in the qualitative interviews.

### Pulmonary Rehabilitation Participation

Although the small sample size must be considered, the proportion of participants going on to attend pulmonary rehabilitation was similar to what would be expected (approximately 14%) [3], but the proportion of patients attending from the Education+Feedback group (17%) was higher than attendance rates from the Education and Control groups (10% and 9%, respectively). Therefore, findings support the idea of providing a behavioral intervention post discharge as a stepping-stone approach to encouraging pulmonary rehabilitation participation.

### Strengths and Limitations

Strengths of the study include the use of qualitative and quantitative methods to examine trial feasibility and intervention acceptability, the use of novel wearable technology to provide behavior-specific nudges, asking for the perspectives of hospital staff involved in COPD care, and delivering the intervention at

the bedside in accordance with the discharge care bundle. Limitations beyond those pertinent to the feasibility nature of this study included the relatively small sample size and short follow-up period, limiting the conclusions that could be drawn from statistical analyses. For example, COPD symptoms, fatigue, anxiety, depression, and fear of falling did not appear to improve over the 2-week period (however, the study was underpowered). Although we present the first intervention specifically targeting reductions in sedentary behavior for individuals with COPD, testing such an intervention in the stable state will permit an easier assessment of efficacy compared with the acute state where patients will naturally recover. No further reinforcement to attend pulmonary rehabilitation was provided during patients' involvement in the trial and no extra support or training on the technology was provided to patients once discharged. However, these limitations are because of the "light-touch" design of the study to better reflect what future implementation may look like. Assessor and patient blinding to group allocations was not possible. The use of the ActiGraph accelerometer limited our assessment of sedentary behavior to "stationary time" rather than specific postures such as lying down, sitting, and standing. The self-monitoring technology

used in this study is no longer being manufactured, an important notion to consider when examining commercially available devices and the fast-moving wearable technology industry.

## Conclusions

The data show that it is feasible to conduct a trial targeting reduction in sedentary time for individuals with COPD hospitalized for an acute exacerbation. Important areas for future work have been highlighted as follows: (1) taking a pragmatic approach of offering behavioral interventions at multiple time points; (2) improving patient stratification to identify who may need more support during behavior change interventions; (3) exploring alternative locations for objective physical activity and sedentary time intervention tools; and (4) haptic feedback using wearable technology in clinical populations. Modifications specifically required for this study include the following: (1) improved recruitment resources and methodology to approach a higher proportion of eligible patients and (2) increased flexibility of patients' ability to engage with the intervention tool (eg, changing the vibration setting). The use of wearable technology was overall acceptable to patients and health care professionals. Responding positively to the vibration prompts resulted in meaningful increases in physical activity.

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## Authors' Contributions

All authors have contributed to the design of the work, acquisition, analysis, and interpretation of the data. MO, AW, PS, DE, LS, and SS were involved in the development of the intervention and design of the trial. All authors have been involved in drafting the work or revising it critically for important intellectual content. All authors have read and approved the final manuscript for publication.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 575KB - mhealth\\_v6i4e84\\_app1.pdf](#) ]

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## Multimedia Appendix 2

Accelerometry data collection and analytical procedures.

[[PDF File \(Adobe PDF File\), 63KB - mhealth\\_v6i4e84\\_app2.pdf](#) ]

### Multimedia Appendix 3

Intervention fidelity for education and feedback components.

[[PDF File \(Adobe PDF File\), 75KB - mhealth\\_v6i4e84\\_app3.pdf](#)]

### Multimedia Appendix 4

Comparison of baseline versus follow-up responses to health questionnaires, stratified by study group, reported as mean (SD) unless otherwise stated.

[[PDF File \(Adobe PDF File\), 70KB - mhealth\\_v6i4e84\\_app4.pdf](#)]

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## Abbreviations

**BMI:** body mass index

**BRC:** Biomedical Research Centre

**CERS:** Centre for Exercise and Rehabilitation Science

**COPD:** Chronic Obstructive Pulmonary Disease

**COPD-SEAT:** Chronic Obstructive Pulmonary Disease Sitting and Exacerbations Trial

**NIHR:** National Institute for Health Research

**PR:** pulmonary rehabilitation

**RCT:** randomized controlled trial

**SPPB:** short physical performance battery

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Original Paper

# Relationship Between Weekly Patterns of Caloric Intake and Reported Weight Loss Outcomes: Retrospective Cohort Study

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## Abstract

**Background:** Although millions of overweight and obese adults use mobile phone apps for weight loss, little is known about the predictors of success.

**Objective:** The objective of this study was to understand the relationship between weight loss outcomes and weekly patterns of caloric intake among overweight and obese adults using a mobile phone app for weight loss.

**Methods:** We examined the relationship between weekly patterns of caloric intake and weight loss outcomes among adults who began using a weight loss app in January 2016 and continued consistent use for at least 5 months (N=7007). Unadjusted and adjusted linear regression analyses were used to evaluate the predictors of percentage of bodyweight lost for women and men separately, including age, body mass index category, weight loss plan, and difference in daily calories consumed on weekend days (Saturday and Sunday) versus Monday.

**Results:** In adjusted linear regression, percentage of bodyweight lost was significantly associated with age (for women), body mass index (for men), weight loss plan, and differences in daily caloric intake on Mondays versus weekend days. Compared with women consuming at least 500 calories more on weekend days than on Mondays, those who consumed 50 to 250 calories more on weekend days or those with balanced consumption ( $\pm 50$  calories) lost 1.64% more and 1.82% more bodyweight, respectively. Women consuming 250 to 500 calories or more than 500 calories more on Mondays than on weekend days lost 1.35% more and 3.58% more bodyweight, respectively. Compared with men consuming at least 500 calories more on weekend days than on Mondays, those consuming 250 to 500 calories or more than 500 calories more on Mondays than on weekend days lost 2.27% and 3.42% less bodyweight, respectively.

**Conclusions:** Consistent caloric intake on weekend days and Mondays or consuming slightly fewer calories per day on Mondays versus weekend days was associated with more successful weight loss.

**Trial Registration:** ClinicalTrials.gov NCT03136692; <https://clinicaltrials.gov/ct2/show/NCT03136692> (Archived by WebCite at <http://www.webcitation.org/6y9JvHya4>)

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**KEYWORDS**

mobile apps; weight reduction; caloric restriction; diet habits

## Introduction

### Weekly Patterns in General Health-Related Behaviors

Past research has demonstrated that behavioral differences between weekdays and weekends have a significant impact on health-related and dietary decisions. In particular, studies have found a common pattern of increased caloric intake and decreased physical activity on the weekend as compared with weekdays [1-4]. This circaseptan periodicity is not only limited to consumption but also seems to affect information-seeking behaviors. Google searches containing the word *healthy* are highest on Monday and Tuesday, as people remotivate themselves after the weekend, and thereafter, their motivation declines until rebounding again on Sunday [5]. Similar patterns have been detected in information-seeking behaviors specific to smoking cessation [6] and in some HIV-related behaviors [7]. This renewed interest in health at the start of the week is sometimes referred to as the “Monday effect” or the “Monday phenomenon” [8,9].

### Weekly Patterns in Weight Loss Behaviors

Previous research has demonstrated that these weekly intake patterns may contribute to a slower rate of weight loss due to cessation of weight loss on weekend days as well as long-term weight gain [10]. However, other research suggests that fluctuating caloric intake across the week is not associated with weight gain over time. This is due to compensatory patterns of decreased caloric intake that often take place when the weekend ends. In one study, those that compensated the most for their weekend behavior during the week were the most likely to maintain their weight rather than gain [11]. A small trial (n=27) revealed that participants tended to gain weight during high-risk periods, such as weekends, but “weight losers” were more likely to compensate for this gain beginning on Mondays. Weight losers were also more likely to show a pattern of weekly weight gain and loss surrounding the weekend than nonlosers [12]. Whether or not cyclic patterns affect weight loss has not yet been clarified in a large sample of adults. Thus, we examined a large dataset from a mobile phone app to understand the influence of weekly patterns of caloric intake on weight loss success.

This study analyzes data logged by 7007 new users of *Lose It!*, a weight loss mobile phone app designed for easy caloric tracking [13]. *Lose It!* provides a free mobile and Web interface for users to construct a customized weight loss plan by entering their goal weight and desired weekly weight loss. Using the user’s height, current weight, gender, and age, the app generates a daily caloric budget designed for the user to reach their goal. Users can then log their caloric intake, exercise, and weight to track progress toward their goal. Our hypothesis was that users with inconsistent caloric intake on Mondays versus weekends would be less successful in their weight loss efforts.

## Methods

### Recruitment

FitNow Inc provided deidentified *Lose It!* data to researchers at the Johns Hopkins Bloomberg School of Public Health for

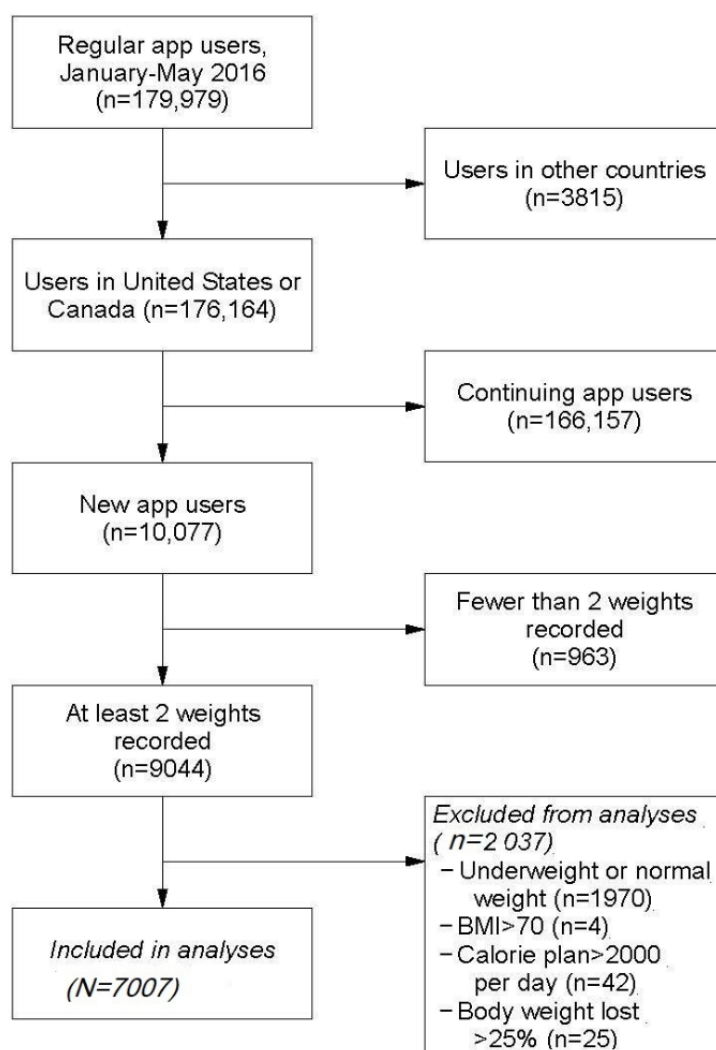
analysis (ClinicalTrials.gov NCT03136692b). The dataset included users who actively used the app each month from January to May 2016. Specifically, the dataset was limited to users who logged food at least 8 times during the first or second half of each month (ie, January, February, March, April, and May). We further limited the sample to new users located in United States and Canada, between 18 and 80 years of age, and who are overweight (ie,  $25 < \text{body mass index [BMI]} < 30$ ) or obese (ie,  $\text{BMI} > 30$ ). The obtained data included: user ID number, sex, age, height, weight, number of times the user logged weight, number of days the user logged food, number of days the user logged exercise, number of food calories logged each day, number of exercise calories logged each day, daily caloric budget (for chosen weight loss plan), estimated energy requirement, and whether or not the user purchased the premium version of the app. Data cleaning consisted of eliminating duplicates and placing valid ranges on each variable.

Among 176,164 individuals in the United States or Canada who were regular users of *Lose It!* from January through May 2016, we identified 10,007 as new users. Among them, 90.37% (9044/10,007) had at least two weigh-ins recorded, and 78.26% (7078/9044) of those were overweight or obese by BMI criteria. Finally, an additional 1.00% (71/7078) were excluded for either having a BMI greater than 70, having a weight loss plan with a caloric budget greater than 2000 calories per day, or reporting weight loss of more than 25% of starting bodyweight, yielding a final sample size of 7007 users (see Figure 1).

### Statistical Analysis

The primary outcome was the percentage of bodyweight lost over the 5-month window (January 2016 through May 2016) and was calculated by subtracting the final weight measurement from the first weight measurement and dividing the resulting value by the first weight measurement. The primary predictor of interest was the difference in reported calorie consumption between weekend days and Mondays, and this was calculated by subtracting the mean calories consumed on Mondays from the mean calories consumed on weekend days (Saturdays and Sundays). Thus, negative values indicated that more calories were consumed on Mondays than weekend days, whereas positive values indicated that fewer calories were consumed on Mondays than weekend days. This difference in calorie intake was then categorized into the following groups: less than -500 kcal, -500 kcal to -250 kcal, -250 kcal to -50 kcal, -50 kcal to 50 kcal, 50 kcal to 250 kcal, 250 kcal to 500 kcal, and more than 500 kcal. In regression analyses, additional covariates include years of age (ie, 18-24 years, 25-34 years, 35-44 years, 45-54 years, 55-64 years, and 65-80 years), sex, BMI category (ie, overweight, obesity I, obesity II, and extreme obesity), and user weight loss plan in pounds per week (<1 lb,  $\geq 1$  to <1.5 lb,  $\geq 1.5$  to <2 lb, and  $\geq 2$  to <4 lb). We did not include independent variables as continuous as many did not have linear relationships with the outcome variable, percent bodyweight lost. We categorized the predictors to allow non-linearity and for ease of interpretation.

**Figure 1.** Inclusion of regular Lose It! app users between 18 and 80 years of age in analyses. Regular users are defined as users logging food at least 8 times during the first or second half of each month (January, February, March, April, and May). BMI: body mass index.



Preliminary analyses described the distributions of mean daily calories consumed and calories consumed on Mondays relative to weekend days. Because women and men tend to differ in mean caloric intake [14], we presented descriptive data for women and men separately. We also estimated the associations between the predictor variables and the percentage of bodyweight lost for women and men. We performed two sets of linear regression of the percentage of weight loss. The first consisted of unadjusted regressions that included only one predictor (age, sex, initial BMI category, weight loss plan, or calories consumed on Mondays vs weekend days). Subsequently, an adjusted linear regression model was performed that included all of these predictors.

As we wanted to make statistical comparisons between the coefficient estimates for women and men, we estimated the coefficients in joint models. This approach produced coefficient estimates identical to running separate models for men and women, but allowed for direct statistical comparison of coefficients for men and women. All analyses were conducted using Stata/SE 14.2 (College Station, TX) [15]. All findings

reported as “significant” have a  $P$  value of  $<.001$ , unless otherwise stated.

## Results

All US states, the District of Columbia, and all of the Canadian provinces were represented among the 7007 *Lose It!* users included in these analyses. Two-thirds (67.10%, 4702/7007) of users were identified as women, and the distributions of covariates for women and men and their relationships with mean daily calories were presented (see Table 1). The distributions of age, initial BMI category, weight loss plan, and daily calories consumed on Mondays relative to weekend days were significantly different between women and men. Women in the age groups of 18-24 years and 25-34 years tended to consume more similar amounts of calories on Mondays and weekend days than men did. Women were more likely to be overweight, whereas men were more likely to be in the lowest obesity category (Obesity I). Additionally, men were inclined to adopt more aggressive weight loss plans, as measured in pounds per week. Regarding the mobile phone app use, the mean number of recorded weigh-ins was 19.7 (SD 21.8, range 2-123).

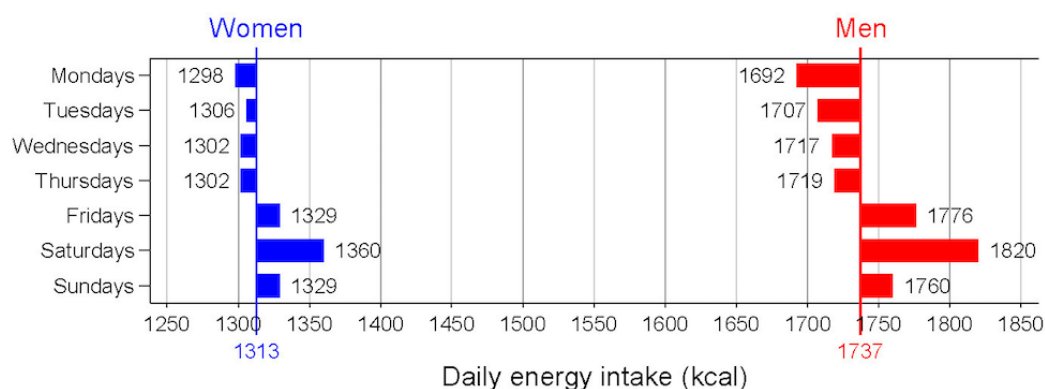
**Table 1.** Individual characteristics and daily caloric intake for women and men using the *Lose It!* mobile phone app (N=7007). BMI: body mass index.

Characteristics	Distributions		Kcal per day	
	Women, n (%)	Men, n (%)	Women, mean (SD)	Men, mean (SD)
Total sample	4702 (100.00)	2305 (100.00)	1313 (302)	1737 (399)
<b>Age (years)</b>				
18-24	643 (13.68)	217 (9.41)	1329 (311)	1727 (391)
25-34	1110 (23.61)	486 (21.08)	1364 (308)	1841 (418)
35-44	1119 (23.80)	588 (25.51)	1345 (315)	1802 (401)
45-54	956 (20.33)	497 (21.56)	1284 (282)	1696 (395)
55-64	620 (13.19)	347 (15.05)	1241 (275)	1647 (354)
65-80	254 (5.40)	170 (7.38)	1196 (246)	1530 (302)
<b>BMI classification</b>				
Overweight	2083 (44.30)	897 (38.92)	1275 (273)	1726 (358)
Obesity I	1348 (28.67)	812 (35.23)	1308 (298)	1698 (393)
Obesity II	715 (15.21)	344 (14.92)	1330 (311)	1769 (432)
Extreme obesity	556 (11.82)	252 (10.93)	1447 (358)	1861 (477)
<b>Weight loss plan (lb/week)</b>				
<1	157 (3.34)	91 (3.95)	1531 (328)	2022 (482)
1 to <1.5	1405 (29.88)	538 (23.34)	1385 (292)	1829 (408)
1.5 to <2	1318 (28.03)	507 (22.00)	1299 (275)	1749 (362)
2 to <4	1822 (38.75)	1169 (50.72)	1249 (306)	1668 (384)
<b>Daily calories on Mondays versus weekend days</b>				
More than 500 on weekend days	89 (1.89)	140 (6.07)	1489 (327)	1955 (389)
More than 250 to 500 on weekend days	415 (8.83)	381 (16.53)	1418 (290)	1818 (408)
More than 50 to 250 on weekend days	1617 (34.39)	742 (32.19)	1317 (299)	1696 (377)
More than or less than 50 calories	1230 (26.16)	422 (18.31)	1267 (292)	1679 (388)
More than 50 to 250 on Mondays	1029 (21.88)	447 (19.39)	1296 (300)	1703 (401)
More than 250 to 500 on Mondays	204 (4.34)	129 (5.60)	1392 (309)	1785 (377)
More than 500 on Mondays	40 (0.85)	33 (1.43)	1444 (300)	1945 (490)

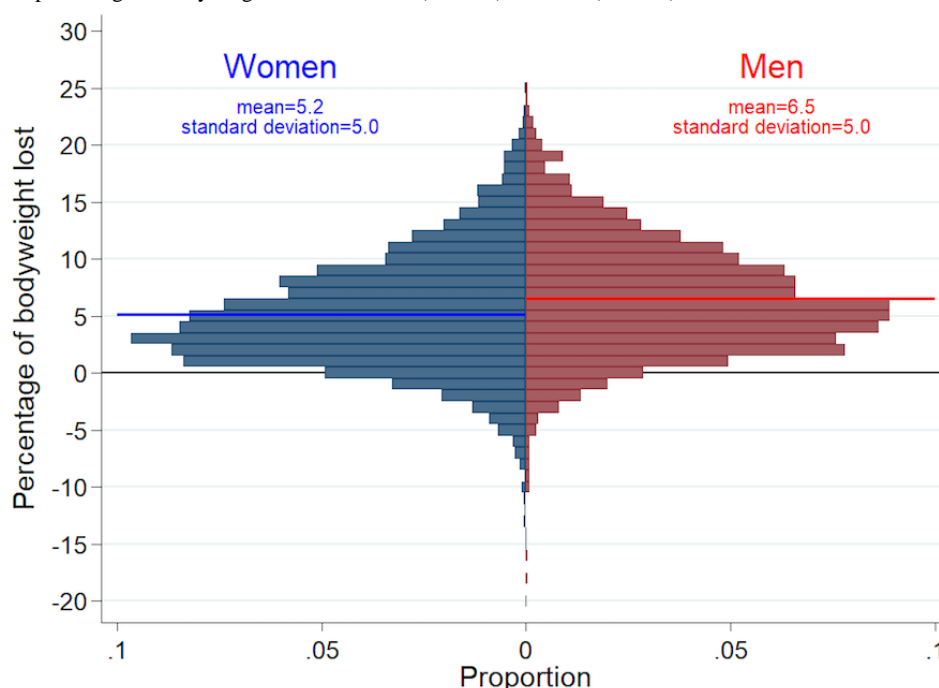
Women consumed significantly fewer calories per day than men (1313 vs 1737), but the relationships between individual characteristics and caloric intake were similar for women and men. For both, the highest mean caloric consumption was seen in those in the age group of 25-34 years, and caloric intake decreased in the older age groups. For both, mean caloric intake increased with initial BMI category, and decreased with the aggressiveness of the individual weight loss plan. For both, mean caloric intake was lower with similar caloric intake on Mondays and weekend days, and mean caloric intake increased as the imbalance between Mondays and weekend days increased. For both women and men, mean daily caloric intake was lowest on Mondays (1298 vs 1692) and highest on Saturdays (1360 vs 1820; see [Figure 2](#)). For women, compared with mean caloric intake on Mondays, caloric intake was within 8 calories on

Tuesdays, Wednesdays, and Thursdays, was 31 calories higher on Fridays and Sundays, and was 62 calories higher on Saturdays. Men followed a similar, but more extreme, pattern: compared with mean caloric intake on Mondays, caloric intake was within 27 calories on Tuesdays, Wednesdays, and Thursdays, was 84 calories higher on Fridays, was 128 calories higher on Saturdays, and was 68 calories higher on Sundays. [Figure 3](#) presents the distributions of percentage of bodyweight lost for women and men at the end of the 5-month period. Among women, 1.40% (66/4702) had no weight change, 10.80% (508/4702) gained weight, and 87.79% (4128/4702) lost weight, with a mean of 5.2 (SD 5.0) percent bodyweight lost. Among men, 0.78% (18/2305) had no weight change, 5.98% (138/2305) gained weight, and 93.18% (2148/2305) lost weight, with a mean 6.5 (SD 5.0) percent bodyweight lost.

**Figure 2.** Caloric intake by day of the week relative to mean caloric intake for women (n=4702) and men (n=2305) who used the *Lose It!* mobile phone app.



**Figure 3.** Distribution of percentage of bodyweight lost for women (n=4702) and men (n=2305) who used the *Lose It!* mobile phone app.



In unadjusted analyses, all 4 predictors (age, BMI, weight loss plan, and daily calories on Mondays vs weekend days) were significantly associated with percentage of weight lost for both women and men (see Table 2). For women, percentage of weight lost was lower in the youngest (18-24 years) and oldest (65-80 years) age groups, and highest in the age group of 45-54 years. For men, percentage of weight lost was lowest in the age group of 65-80 years. For both women and men, weight loss was lowest among participants who were classified in the BMI category as overweight versus those classified as obese, and percentage of weight lost increased with more aggressive weight loss plans.

Compared with the women with caloric intake of more than 500 calories more on weekend days than Mondays, those consuming 50 to 250 more calories on weekend days relative to Mondays or similar calories on weekend days and Mondays ( $\pm 50$  calories) lost a significantly higher percentage of bodyweight, 1.64% (95% CI 0.59-2.69) and 1.83% (95% CI 0.77-2.89), respectively. Women consuming 250 or more calories on Mondays than on weekend days lost a significantly

lower percentage of bodyweight, including 1.38% less (95% CI -2.61 to -0.16) for those consuming 250 to 500 more on Mondays and 3.45% less (95% CI -5.29 to -1.61) for those consuming at least 500 calories more on Mondays. Compared with the men consuming more than 500 calories more on weekend days than on Mondays, there was no significant difference in percentage of bodyweight lost until caloric intake on Mondays was at least 50 calories higher than on weekend days: 50 to 250 calories more on Mondays -1.17%, 95% CI -2.11 to -0.24), 250 to 500 calories more on Mondays (-2.52%, 95% CI -3.69 to -1.34), and at least 500 calories more on Mondays (-3.37%, 95% CI -5.24 to -1.50).

In contrast to unadjusted analyses (see Table 3), there were no significant differences ( $P < .05$ ) between women and men in the associations between factors and percentage of weight lost. In general, the patterns of association between these predictors and weight lost were similar for men and women. Only in the BMI category, the coefficients of the joint test were significantly different for women and men, with initial BMI appearing to affect men greater than it affected women.

**Table 2.** Unadjusted linear regressions of percentage of bodyweight lost among women and men who used the *Lose It!* mobile app (sex-specific intercepts for models are not reported; N=7007). Estimates in italics are significant at  $P<.05$ . BMI: body mass index. Ref: reference category.

Characteristics	Women			Men		
	Regression coefficient	Standard error	<i>P</i> value	Regression coefficient	Standard error	<i>P</i> value
<b>Age (years)<sup>a</sup></b>						
18-24	Ref			Ref		
25-34	.75	0.25	.003	.41	0.41	.32
35-44	.65	0.25	.009	.20	0.40	.62
45-54	1.04	0.25	<.001	-.05	0.41	.91
55-64	.85	0.28	.003	.04	0.43	.93
65-80	-.03	0.37	.93	-1.03	0.51	.05
<b>BMI classification<sup>a,b</sup></b>						
Overweight	Ref			Ref		
Obesity I	.34	0.17	.05	1.27	0.24	<.001
Obesity II	.84	0.22	<.001	1.16	0.32	<.001
Extreme obesity	.82	0.24	.001	1.49	0.36	<.001
<b>Weight loss plan (lb/week)<sup>a</sup></b>						
<1	Ref			Ref		
1 to <1.5	1.11	0.42	.008	.12	0.56	.82
1.5 to <2	1.36	0.42	.001	.51	0.56	.36
2 to <4	2.33	0.41	<.001	2.04	0.54	<.001
<b>Daily calories on Mondays versus weekend days<sup>a</sup></b>						
More than 500 calories on weekend days	Ref			Ref		
More than 250 to 500 calories on weekend days	.39	0.58	.50	-.52	0.49	.28
More than 50 to 250 calories on weekend days	1.64	0.54	<.001	.17	0.45	.71
More than or less than 50 calories	1.83	0.54	<.001	.11	0.48	.82
More than 50 to 250 calories on Mondays	.50	0.54	.36	-1.17	0.48	.01
More than 250 to 500 calories on Mondays	-1.38	0.63	0.03	-2.52	0.60	<.001
More than 500 calories on Mondays	-3.45	0.94	<.001	-3.37	0.95	<.001

<sup>a</sup>Factor significantly associated ( $P<.001$ ) with percentage of weight loss for that sex.

<sup>b</sup>Joint test comparing matching coefficients for women and men for a given factor is statistically significant ( $P<.001$ ).



**Table 3.** Adjusted linear regression of percentage of bodyweight lost among women and men using the *Lose It!* mobile app (N=7007). Estimates in italics are significant at  $P<.05$ . BMI: body mass index. Ref: reference category.

Characteristics	Women			Men		
	Regression coefficient	Standard error	<i>P</i> value	Regression coefficient	Standard error	<i>P</i> value
<b>Age (years)<sup>a</sup></b>						
18-24	Ref			Ref		
25-34	.73	0.25	.003	.15	0.40	.71
35-44	.48	0.25	.05	.02	0.39	.95
45-54	.82	0.26	.001	-.31	0.41	.44
55-64	.70	0.28	.01	-.26	0.43	.55
65-80	-.08	0.37	.84	11.04	0.51	.04
<b>BMI classification<sup>a</sup></b>						
Overweight	Ref			Ref		
Obesity I	.20	0.17	.24	1.03	0.24	.001
Obesity II	.44	0.22	.05	0.76	0.32	.02
Extreme obesity	.42	0.25	.09	.93	0.37	.01
<b>Weight loss plan (lb/week)<sup>a</sup></b>						
<1	Ref			Ref		
1 to <1.5	.89	0.42	.03	-.18	0.56	.75
1.5 to <2	1.11	0.42	.01	0.09	0.56	.87
2 to <4	2.07	0.42	<.001	1.37	0.55	.01
<b>Daily calories on Mondays versus weekend days<sup>a</sup></b>						
More than 500 calories on weekend days	Ref			Ref		
More than 250 to 500 calories on weekend days	.46	0.57	.42	-.34	0.48	.48
More than 50 to 250 calories on weekend days	1.64	0.53	.002	.48	0.45	.29
More than or less than 50 calories	1.82	0.54	.001	.42	0.48	.39
More than 50 to 250 calories on Mondays	.54	0.54	.32	-.87	0.47	.07
More than 250 to 500 calories on Mondays	-1.35	0.62	.03	-2.27	0.60	<.001
More than 500 calories on Mondays	-3.58	0.93	<.001	-3.42	0.94	<.001
Intercept	3.83	0.46	<.001	6.02	0.65	<.001

<sup>a</sup>Factor significantly associated ( $P<.05$ ) with percentage of weight lost for that sex.

Table 3 presents the coefficient estimates from the adjusted linear regression models, which included all four predictors and the joint tests comparing the coefficients for each factor between women and men, which revealed no significant differences. However, each factor was significantly associated with percentage of weight lost for women, men, or both. Age was significantly associated with weight loss for women but not for men, and the initial BMI category was significantly associated with percentage of weight lost for men, but not for women. For both women and men, the aggressiveness of weight loss plan and the caloric intake on Mondays versus weekend days were associated with percentage of weight lost.

For women, the patterns of association for the categories of caloric intake on Mondays versus weekend days were very similar in the adjusted and unadjusted analyses, with negligible

difference in the magnitude of the coefficients. In the adjusted analyses, as compared with the women consuming 500 or more calories more on weekend days than Mondays, those consuming 50 to 250 more calories on weekend days or a similar amount of calories on both weekend days and Mondays ( $\pm 50$  calories) lost more body weight, with regression coefficients of 1.64 (95% CI 0.60-2.68) and 1.82 (95% CI 0.77 to 2.87), respectively; those consuming 250 to 500 calories and more than 500 calories more on Mondays than weekend days lost lesser bodyweight, with regression coefficients of -1.53 (95% CI -2.56 to -0.14) and -3.58 (95% CI -5.40 to -1.76) respectively.

For men, the magnitude of the coefficients for the associations between caloric imbalance and weight loss were also of similar magnitudes in the unadjusted and adjusted analyses. In the

adjusted analyses, compared with men consuming 500 or more calories more on weekend days than Mondays, those consuming 250 to 500 calories and more than 500 calories more on Mondays than weekend days lost lesser bodyweight, with regression coefficients of -2.27 (95% CI -3.44 to -1.10) and -3.42 (95% CI -5.27 to -1.58), which are similar to the estimates in the unadjusted analyses. In contrast to the unadjusted analyses, percentage of bodyweight lost among those consuming more than 50 to 250 calories on Mondays than weekend days was no longer significantly different from those consuming at least 500 calories more on weekend days than Mondays.

## Discussion

### Principal Findings

In this sample of mobile phone app users for consistent weight loss, the lowest mean caloric intake was reported on Mondays and the highest was reported on Saturdays for both men and women. The results of this study indicate that consuming a consistent amount of calories per day throughout the week, or consuming slightly fewer calories per day on Mondays versus weekend days, are the most beneficial weekly patterns of caloric intake for weight loss. Consuming considerably more calories on weekend days versus Mondays was associated with less weight loss for women, but this association was weak for men. Conversely, consuming more calories per day on Mondays than on the weekends has negative implications for weight loss that increase with the magnitude of the difference in calories consumed. This negative association is particularly strong for women, with consuming 500 or more calories more on Mondays versus weekend days associated with at least 3% less bodyweight lost. For men, consuming 250 or more calories on Mondays versus weekend days was associated with 2.3% to 3.4% less bodyweight lost. These associations are also independent of the other variables examined. In particular, the initial BMI category and the aggressiveness of a weight loss plan had little effect on the observed associations between calories consumed on Mondays versus weekend days and percentage of bodyweight lost. Furthermore, the associations with percentage of weight lost were of greater magnitude for weekly patterns of intake than for other categories including age, initial BMI, and weight loss plan.

Potential mechanisms for this association have not been established. Possible explanations include associations between imbalanced caloric intake across the week and greater overall intake, macronutrient imbalance, energy expenditure patterns, or metabolism. Differences between weekday and weekend eating patterns may reflect differential eating triggers, such as eating out versus eating self-prepared meals, or differences between weekday and weekend lifestyle routines. Consistency in intake across the week may reflect higher self-monitoring or awareness of intake.

Caloric intake on Monday and the 3 consecutive weekdays were correlated (data not presented), and it is possible that moderated intake on Monday may set the tone for these subsequent weekdays. Therefore, Mondays might serve as an important reset point for the upcoming week.

### Limitations

This study has several limitations. First, caloric intake and bodyweight measurements are largely based on self-reporting. Some individuals may have used “smart” scales that connect to the *Lose It!* app, but we did not explore this. Most users did not record calories on a daily basis, and if days with missing data had systematically higher or lower consumption, this would have introduced reporting bias. Second, our analyses do not reflect caloric expenditure through physical activity. Although some users reported physical activity, this was not consistently recorded. Third, we do not know whether the observed associations would hold true for other *Lose It!* users or for dieters who do not use this app. The study sample consisted of consistent users, and different patterns of consumption and weight loss may occur for those with sporadic use, with short-term use, or who do not use the app at all. Fourth, although caloric balance may have a causal effect on weight loss, the observed association may be due to unmeasured confounding variables. For example, consistent caloric intake on Mondays versus weekend days may be associated with individuals having more consistent routines in general, such as regular exercise.

Additional research on the accuracy of self-reporting of caloric data through apps would be beneficial for research in this burgeoning area. With respect to the Monday effect, examining the associations among weekly variations, the diet compositions, and the weight loss outcomes may provide insights into potentially important and modifiable behaviors. As weekly variation was found to be an important predictor of weight loss, understanding factors that shape such a variation may provide another important avenue for promoting weight loss.

### Conclusions

The results of this study present an understanding of eating behaviors and obesity by explicating weekly patterns of caloric consumption and their association for successful weight control. By using mHealth in this way, we also gain a preliminary understanding of how engagement and effectiveness correspond with the users’ goals and the days of week. The size of the dataset contributes to the novelty and applicability of the study, and the study findings are valuable for obesity prevention because they further elucidate human behavior patterns with respect to weight loss and caloric decision-making. By increasing our understanding of these weight-determining factors, we can create relevant interventions and prevention schemes. The results of this study indicate the importance of weekly patterns of caloric intake for successful weight loss. Subsequently, diet and weight-related apps and interventions, such as *Lose It!*, can be designed and promoted. Ongoing prompts to engage or motivate users on Mondays may be well received among individuals who tend to demonstrate increased compliance to their diet plans following less-restricted eating habits on weekends. Similarly, a Monday reminder in the app may serve to retain lapsed users by appealing to their interest in health early in the week. Our analysis indicates that greater caloric intake on Mondays relative to weekend days is associated with poorer weight-loss outcomes, and that this pattern demonstrates a dose-response relationship. By reminding users of their goal each Monday, it may also be possible to limit

exposure to this potentially damaging pattern among users who have previously shown signs of increased caloric intake at the beginning of the week.

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## Authors' Contributions

All authors designed the research; BWW analyzed data; CH, BWW, LJC, and LWF wrote the paper; and BWW, LJC, and LWF had primary responsibility for final content. All authors read and approved the final manuscript.

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## Conflicts of Interest

None declared.

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## Abbreviations

**BMI:** body mass index

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Original Paper

# General Practitioners' Perspective on eHealth and Lifestyle Change: Qualitative Interview Study

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## Abstract

**Background:** Wearables, fitness apps, and patient home monitoring devices are used increasingly by patients and other individuals with lifestyle challenges. All Danish general practitioners (GPs) use digital health records and electronic health (eHealth) consultations on a daily basis, but how they perceive the increasing demand for lifestyle advice and whether they see eHealth as part of their lifestyle support should be explored further.

**Objective:** This study aimed to explore GPs' perspectives on eHealth devices and apps and the use of eHealth in supporting healthy lifestyle behavior for their patients and themselves.

**Methods:** A total of 10 (5 female and 5 male) GPs were recruited by purposive sampling, aged 38 to 69 years (mean 51 years), of which 4 had an urban uptake of patients and 6 a rural uptake. All of them worked in the region of Southern Denmark where GPs typically work alone or in partnership with 1 to 4 colleagues and all use electronic patient health records for prescription, referral, and asynchronous electronic consultations. We performed qualitative, semistructured, individual in-depth interviews with the GPs in their own office about how they used eHealth and mHealth devices to help patients challenged with lifestyle issues and themselves. We also interviewed how they treated lifestyle-challenged patients in general and how they imagined eHealth could be used in the future.

**Results:** All GPs had smartphones or tablets, and everyone communicated on a daily basis with patients about disease and medicine via their electronic health record and the internet. We identified 3 themes concerning the use of eHealth: (1) how eHealth is used for patients; (2) general practitioners' own experience with improving lifestyle and eHealth support; and (3) relevant coaching techniques for transformation into eHealth.

**Conclusions:** GPs used eHealth frequently for themselves but only infrequently for their patients. GPs are familiar with behavioral change techniques and are ready to use them in eHealth if they are used to optimize processes and not hinder other treatments. Looking ahead, education of GPs and recognizing patients' ability and preference to use eHealth with regard to a healthy living are needed.

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**KEYWORDS**

general practice; primary care; technology; motivational interviewing; telemedicine; mentoring

## Introduction

Wearables, fitness apps, and patient home monitoring devices are increasingly used by the general population. A recent study showed that 96% of a representative sample of 1004 Danes between 40 and 60 years prefers lifestyle change to medication [1], and outcomes for patients engaging in medical treatment has shown to be significantly affected by patients' engagement [2].

Internet and mobile interventions have the ability to improve lifestyle behaviors for patients when behavior change elements are used by health professionals [3]. However, teams with both medical doctors and lifestyle coaches did not perform better than teams without medical doctors [4]. General practitioners (GPs) are central in the Danish health care system and have specialization certificates equal to other specialties for medical doctors. Close to 85% of all Danes see a GP at least once annually [5], and the GP is the patient's primary contact point to the health care system. The GPs have a 5-year postgraduate specializing degree and act as gatekeepers between the primary levels and the specialized health care system, covering hospitals, private hospitals, and specialists.

We have previously described a collaborative electronic health (eHealth) solution that supported lifestyle coaching by establishing a relationship and providing behavioral change (weight loss of 7.0 kg for 20 months) through monitoring and empathic, relevant, and individualized feedback in a general practice setting [6]. These findings were replicated in a later version of the solution in a municipality setting in the region of North East England in Durham and Darlington County for men with type 2 diabetes in a pilot randomized controlled trial where patients lost an average of 5.4 kg compared with a control group that received usual care and lost 2.8 kg. In that same study, in-depth interviews with participating patients revealed that meeting face to face was important for the patients [7], and a recent qualitative study has shown that building a relationship to a health care professional using collaborative eHealth for lifestyle change is probably the most important driver for successful long-term outcome [8].

The role of GPs with regard to support of patients with lifestyle challenges and use of eHealth has not yet been explored. Hence, we aimed to identify factors important to GPs assisting patients undergoing lifestyle changes. Of particular focus was how the GPs see eHealth as a part of their own and their patients' struggle to live a healthier life.

## Methods

### Context

We performed semistructured in-depth individual interviews with 10 GPs in the Region of Southern Denmark. In 2017, there were approximately 3500 GPs in Denmark covered by the collective agreement with the public health care system. On average, each GP had 1600 patients. In the Region of Southern Denmark, there were 786 full-time employed GPs working in 378 shared or solo practices [5]. GPs were paid partly by a per capita remuneration (30%) and partly a fee for service offering

(70%) such as fees for consultations (20 €), telephone consultations (3,5 €), asynchronous e-consultations (6 €), various blood tests, and other relevant GP tasks. GPs did not receive remuneration for receiving or interpreting patient-registered outcome measurements (PROMs). Patients were generally quite loyal to their GP and change doctor rarely.

### Sampling

Purposeful sampling was conducted comprising 10 GPs recruited by email or phone. The criteria were gender, seniority, age, registration as sole practitioner or in a shared medical practice, and patient recruitment area. In total, 11 GPs were invited and 1 declined to participate. After 9 interviews, no new themes or subthemes emerged, and an additional tenth interview confirmed that saturation was met [9]. GP characteristics were 5 females and 5 males, and with a mean age of 51 years ranging from 38 to 69 years. The GPs' patient recruitment area was rural for 6 and urban for 4 of the GPs; see [Multimedia Appendix 1](#).

### Interview Procedure

The semistructured interviews followed an interview guide, which allowed an iterative approach, where emerging themes and perspectives could be explored in the interviews with subsequent participants [10]; see [Table 1](#) for an overview of the themes and probing questions in the interview guide. The interview guide was made with inspiration from a study on GPs attitude toward the treatment of cardiovascular disease [11] and a previous study exploring the patients' perspective of using eHealth in changing lifestyle [8].

The interviews were held in Danish and carried out from March to May 2017 in the GPs' offices and took 45-60 min each. All interviews were performed by CJB, who has worked as a GP for more than 10 years and with different eHealth solutions for more than 15 years. The GPs were asked to describe examples from their own experience and were encouraged to reflect upon them to explore the various aspects of the topics evolving.

### Analysis

The 10 interviews were digitally recorded and transcribed verbatim. The transcripts were analyzed by the researchers (CJB, GIS, JC, JBN, and JS) using thematic analysis. To systematically uncover important themes and to get a rich, straightforward description of the concepts and latent variables, the explorative approach of systematic text condensation was applied [12,13]. The transcripts were read thoroughly to get an overall impression of the material before the initial coding. A priori coding was done by using QSR NVivo 11 software [14] for each transcript. Themes were identified, and the data were coded, sorted, and categorized into themes and subthemes by identifying similar expressions, patterns, and sequences. Data from each theme were condensed and summarized into generalized descriptions and concepts concerning GPs' perspectives on the use of eHealth in relation to improving lifestyle for their patients and themselves. During the analytical process, the extracted information was related to the full transcripts to preserve the original context. The identified themes were compared between the different researchers. Coinciding themes of importance was identified and consistency was reached.

**Table 1.** Interview guide. GP: general practitioner.

Themes	Probing questions
Experience with handling of patients with lifestyle challenges in their GP center	I will ask you to remember one consultation that went well. Please describe the consultation. What happened? What went well? What do you think a patient would choose given the choice between one pill or lifestyle change involving 30 min more daily exercise, healthier diet, and smoking cessation?
Their own lifestyle experiences	Have you ever taken the initiative to improve or change your lifestyle? Who has helped you with your health challenges?
Experience with eHealth in relation to their own and patients' health challenges	Have you ever used apps or internet in relation to your own health or well-being? Have you communicated with your patients using digital tools? How? Have you ever received patient-registered objective measurements via digital tools? How do you use them?

Finally, quotes were selected to illustrate each theme and its related subthemes and translated from Danish to English. The two researchers, CJB and GIS, compared their individual translations, agreeing on wording and meaning. The remaining authors then reviewed the quotes in Danish and English, and changes were made if all authors agreed on it. In the text, interview quotes are followed by a unique participant identifier called GP1 to GP10 ([Multimedia Appendix 1](#)). The authors CJB and GIS were the only ones aware of the true identity of the GPs.

### Ethical Considerations

The study has been approved by the local Ethics Committee of Southern Denmark. Before initiating an interview with a GP, the nature of the research was briefly explained by CJB, any questions regarding the study were answered, and a description of the study in layman's terms was provided. CJB explained that the interview data would be anonymized, the GPs were informed of their rights as participants, and informed consent documents were signed both by the GP and CJB.

## Results

### Themes Concerning Improving Lifestyle Using eHealth

We identified 3 themes with related subthemes concerning the use of eHealth in relation to improving lifestyle: (1) how eHealth is used for patients; (2) GPs own experience with improving lifestyle and eHealth support and (3) relevant coaching techniques for transformation into eHealth; see [Table 2](#) for themes and related subthemes.

### How eHealth Is Used for Patients

All GPs used smartphones or tablets. All GPs used local electronic health record systems and asynchronous e-consultations daily related to exchange of laboratory results and simple health questions, which are embedded in the local health record system, but only 1 had experience with PROM delivered to the GP via eHealth solutions in the form of home-registered blood pressure. Most eHealth communication reported was one-way such as showing results on the GP's computer screen, or the GP recommending websites and apps to the patient.

### One-Way Information About Health and Lifestyle in the Consultation

A total of 9 out of the 10 GPs only used one-way information about health and lifestyle in the consultation. Typically the GPs used their computer screen when showing patients the development of objective risk factors/lifestyle measures such as HbA1c, cholesterol, or weight. One GP stated:

*I use numbers and figures from my computer screen to explain to the patients how they are doing. [GP1]*

### Recommendation of Websites That Patients Could Use on Their Own

Recommendation about eHealth for patients' personal use most often consisted of websites with relevant information that they found matched the patient. One of the GPs said:

*It could be concrete sleep hygiene advice and instructions. Either from me or if it is a younger person, from websites they can visit. [GP9]*

### Recommendation of Apps That GPs Had Used Themselves or Learned About From Other Patients

In addition, 5 GPs recommended apps that they had used themselves or learned about from other patients:

*Well, sometimes they bring something up. For example, the one called "7 Minute Workout"; I could recommend that one to some of my other patients, because the vast majority can do that...But, sometimes it is the patient, who tells me about something smart, which I also think is smart. [GP3]*

### Attitude to Lifestyle Intervention, Use of eHealth, Workflow, and Data Security

All GPs underestimated their patients' preference for lifestyle improvement over medicine. Most thought 50% would prefer medicine to lifestyle intervention. Most GPs were very positive when discussing how they could follow patients' lifestyle through smartphones with step counts, etc:

*If I had problems completing something that would improve my health and it could be supported broadly by electronics, apps or pulse clock or...then I think I would benefit from it. [GP6]*

**Table 2.** Themes and subthemes for general practitioners' (GP) perception of electronic health (eHealth) in relation to lifestyle improvement.

Theme 1. How eHealth is used for patients	Theme 2. GPs own experience with improving lifestyle and eHealth support	Theme 3. Relevant coaching techniques for transformation into eHealth
One-way information about health and lifestyle in the consultation	Mirroring own personal health situation and procedural knowledge	Mutual understanding of patient challenges is key
Recommendation of websites that patients could use on their own	Realistic goal setting	Realistic goal setting
Recommendation of apps that GPs had used themselves or learned about from other patients	Measurable outcome and reinforcement	Measurable outcomes
Attitude to lifestyle intervention, use of eHealth, workflow, and data security	Support from family and peers	Social and structural barriers

Concerns were mainly aimed at how to integrate the eHealth data without disturbing other tasks that needed attention or exposing sensitive data:

*I'm afraid it will take up too much time.* [GP1]

One GP expressed concerns related to security of data:

*Is the data security good enough?* [GP3]

### General Practitioners' Own Experience With Improving Lifestyle and eHealth Support

#### *Mirroring Own Personal Health Situation*

A total of 9 out of the 10 GPs said they wanted to live healthier than they did, and many explained how eHealth supported them in their daily healthy lifestyle choices:

*Using a pedometer, while working in the clinic, we suddenly realized, that we actually walked less than we thought.* [GP3]

#### *Realistic Goal Setting and Procedural Knowledge*

One of the major barriers for the GPs was setting up realistic plans for themselves and following them. Some had used apps to support their health plan:

*...fulfill the app's needs in a way. In some way, it needs to know whether you have made your push-ups today, and then you get a need to say yes to it.* [GP2]

#### *Measurable Outcome and Reinforcement*

Most of the GPs explained how they valued being able to measure their progress and being recognized for their effort:

*It is important to praise the patients...I need to be recognized in one way or another every time I exercise. If I forget my phone I don't exercise.* [GP4]

#### *Support From Family and Peers*

Most GPs found themselves or their spouse to be the most important support for healthier living:

*No, well the wife indirectly...And again, that is the competitive element that kicks in, you should not underestimate the value it has, if you are into that. I remember one day, when she worked late and we couldn't walk the dog together as we usually do, then I was ahead of her stepwise (laughing). I enjoyed that because usually she lies ahead of me.* [GP4]

The majority of GPs would not share health improvement data on Facebook, but held positive viewpoints of sharing data online with other persons having the same health issues as themselves:

*...a group, you just sign up for, it is about getting the support in order to live healthier, to be around someone, who has the same problem and then meet regularly.* [GP2]

### Relevant Coaching Techniques for Transformation Into eHealth

All GPs used motivational interviewing in their communication with patients about lifestyle.

#### *Mutual Understanding of Patient Challenges Is Key*

All the GPs highly valued the relationship with the patient, and the majority found they needed to know the reasons behind lifestyle choices and that could only be learned from the patient:

*...understanding, the patient's starting point, getting to know a little more about their specific situation, and also getting to know their conceptual framework of different things.* [GP6]

Many of the GPs could explain how they had learned this from their own experience with changing lifestyle:

*...but if you then hear someone, who talks about skinny-fat, eg, then you catch the message, right? Because then it becomes—what should I call it—something I can identify myself with...It becomes relevant to me.* [GP4]

*...and we actually made motivational interviewing about exercise for each other, after which I also started cycling to work on a daily basis (laughing), and it also changed the way I looked at motivational interviewing, because I think it worked annoyingly good, also on me.* [GP2]

With regard to eHealth, for patients with chronic health issues who GPs knew were challenged with their health, eHealth was viewed as to not “lose them for follow-up”:

*...we have, ie, chronic patients with hypertension, COPD, diabetes, and we need to have a waterproof system. A system to ensure that, when they are in the system, they don't leave without a scheduled appointment, and if we catch them in an exacerbation (Editor's note: if the patient's condition worsens), then we get them back on the tracks again etc., but*



*we don't have a system, ie, this female patient, who cancelled an appointment and then she was lost again.* [GP6]

### **Realistic Goal Setting**

The GPs found it important that it is the patients who set the goals:

*It must be them, who are setting the goals. They have to have ownership, else it won't work at all...what they are doing has to be of great importance for them, and it has to be what they find utmost important, and at the same time what they think they can complete and what they find realistic to integrate in their everyday life.* [GP3]

This was an experience they could relate to in different ways:

*I have also tried to lose weight. It has helped a lot that I bought an electric bike, because then I get, then I am much more motivated to get out and go for a ride on the bike.* [GP9]

Furthermore, by using eHealth:

*Well... You can see it on the watch, the way it looks, there is a number especially women, who wear accelerometers in watches and then I see, that it is an ongoing motivation, that they wear it, they walk more and go for extra walks consciously.* [GP6]

### **Measurable Outcomes**

PROM data were used by all GPs in the form of paper notes brought to the GP by the patient to facilitate discussions in the consultation room:

*Sometimes I think, and we have been doing that for many years, for example if it concerns such a thing as a weight loss, that I simply start out by giving them a paper, with a table drawn on it, covering all the week days, and then it says: breakfast, snack, lunch, snack, dinner. And then they simply have to fill in what they eat at all times, so that we can use it as a starting point.* [GP5]

And more specific with relevance for eHealth:

*Yes, sure I do that (Editor's note: use PROM) It is often blood glucose measurements (written on paper, red). Steps (information about steps. red.) could also be a possibility, but then it is more unspecific, there are not many who measure their function so specific, not among our patients anyway. Then it is more like: "I walk two kilometers so and so." So it could very well be more specified, actually, I think. And then I would use it, then you actually could use it, if they could say: "Yesterday I walked exactly..." then you, as a GP, would use it if they came in with their measurements. Because often it gets very unspecific.* [GP7]

### **Social and Structural Barriers**

It was important for all GPs to get to know their patients and learn what barriers they experienced in their lives that prevented

them from making lifestyle choices that were most healthy for them. Many explained how they helped the patient to find possibilities in their daily life to fit in more exercise:

*It is not something you have to decide in the evening, Monday evening, whether you want to go out for a spinning hour or not. It is more like, now I leave work to go home, I do not have a ticket for the bus, so now I walk home. Or, now I am going home from work, and my bike is outside, so now I am riding the bike home.* [GP2]

GPs, especially those with many years of experience, found that some life events were so important to patients that lifestyle change became inevitable:

*Patients with myocardial infarction are easy to assist in smoking cessation.* [GP8]

*Actually, sometimes I am surprised by how much people are capable of changing their lifestyle because they are getting diagnosed.* [GP9]

Some GPs pointed out that eHealth might be a way to support collaborations with lifestyle coaching specialists:

*I think if we had some places we could refer them to, or someone who came to the clinic and offered exercise, diet counseling and such things, because in a regular consultation where we take care of the medicine and everything else about the disease and its consequences, eyes, legs, then there is not much time left for other things that really fill up.* [GP10]

## **Discussion**

### **Principal Findings**

eHealth solutions were generally not used when communicating with patients, and if used, they were used only as one-way recommendations from GP to patient; however, they play an important role for the majority of the GPs' own lifestyle choices. Furthermore, our study showed that GPs used motivational interviewing, were positive to new technology, and gave many insights into how coaching techniques could be included in their patient communication for lifestyle improvement.

### **Comparison With Prior Work**

#### **eHealth Use for Patient Communication**

Our finding that GPs only used eHealth one way is in alignment with a recent study including interviews with 3 GPs and 9 other health care professionals, demonstrating that GPs and health care professionals most often used eHealth by recommending websites, even though they saw eHealth enabling patients to participate in balanced two-way conversations in face-to-face consultations [15].

The lack of more advanced eHealth use can both be due to patients' preconception of what they expect from their GP as well as GPs' reluctance in using new technology. Bowes et al [16] found that patients who had found information on the internet prioritized the opinion from their doctor higher than information found on the internet, except when the doctors were disinterested, dismissive, or patronizing. Then, the doctor-patient

relationship was damaged, and patients would seek information from alternative routes. Creating space for eHealth in GPs' patient communication is a two-way street. A Danish study suggests that GPs have a fundamental different perspective of what digital interaction can be used for compared with patients' perspective. Patients often expected a dialogue with room for discussion, whereas GPs mostly saw e-consultation as a tool for short closed information, which might be due to a lower remuneration for e-consultations for the GPs compared with face-to-face consultations [17]. Furthermore, GPs often have a strong relationship with their patients, which we anticipate could be of importance for developing new collaborating eHealth solutions, where adherence to agreed treatment based on an existing relationship is often an issue [18]. Studies have shown that quality of both websites and apps vary [16,19], which might also play a role in the GPs lack of eHealth use in addition to the GPs explaining that it was difficult to know what to recommend. Generally, however, along with other studies, we also found that GPs as health professionals are positive to the use of eHealth solutions [15,20]. All GPs in our study underestimated the patients' wish for lifestyle advice [1]. One of the main challenges seems to be to fit eHealth and lifestyle talks into the known workflow, highlighting that competing priorities might be one of the major obstacles [15,21]. Asynchronous e-consultations have been used for more than 10 years by GPs in Denmark, and concerns of security of data were only raised by one GP, a concern that seemed to be more prominent in other studies [22].

### ***GPs' Personal Experience Improving Lifestyle and eHealth***

GPs recognized the positive effects of wearables, apps, and internet for their own personal health and how it animated them to live healthier in accordance with known behavioral change theories [23]. GPs found that eHealth monitoring through measurable outcomes helped them to set realistic goals and reminded them of how even small steps could help them live healthier in accordance with studies looking into a number of behavioral change techniques used in eHealth [24]. GPs also explained how patients gave them ideas to use different apps for benefiting their own health. A trend that was also noted in an English study on the role of GPs, finding that this could be understood in an Eliasian framework as the functional-democratization of patient-doctor relations via civilizing processes [25]. As a GP, you have to take up different roles. An Australian study from 2016 has described how GPs on help lines not being able to see patients face to face have to take a new role [26]. A total of 9 out of the 10 GPs wanted to live healthier, and eHealth solutions gave the GPs the opportunity as private persons to live healthier. GPs experienced that being supported both from family and peers mattered. Maybe GPs when discussing lifestyle with patients should take

a new role and discuss GPs as human beings also have to make lifestyle choices on a daily basis to stay healthy, mainly because it opens for a respectful empathic dialogue, which is important for patients' long-term successful lifestyle improvement [8].

### ***Future Use of eHealth in Patient Lifestyle Coaching***

Transforming knowledge into action is not trivial, and the GPs were positive in regard to empowering patients through increasing the patient's capacity to think critically and make autonomous, informed decisions, which is in accordance with Anderson and Funnell [27], but contrary to another recent study where GPs expressed nervousness for patients performing self-care [28]. The GPs told how they used coaching techniques such as motivational interviewing to set realistic goals, focusing on measurable outcomes, overcoming structural barriers, and having patients commit to concrete realistic contracts using pen and paper [23]. GPs expressed the will to assist patients in healthy lifestyle choices and deep reflection monitored through PROM delivered via eHealth. Studies show that PROM data could be supported by algorithms based on eHealth [29] and through patient-centered care [30,31], giving space for the patient to act. Adding machine learning or artificial intelligence to PROM data could potentially strengthen the GPs' ability to assist patients cost efficiently in conjunction with other health care professionals, which is being tested in specific patient groups [32], but will need substantially more research.

### **Strengths and Limitations of This Study**

This is the first qualitative research study to analyze how GPs using eHealth perceive eHealth in relation to successful lifestyle change among patients and themselves. However, even though the findings of this study are relevant and seem generalizable to future implementations of eHealth solutions involving GPs, it will not be applicable to all health care systems.

A limitation of this study is also the lack of methodological triangulation: why further studies using questionnaires and more quantitative outcomes are needed. Another limitation is that we only interviewed GPs. Data from patients could have revealed other aspects of the GPs' role in assisting patients' lifestyle change.

### **Conclusions**

GPs used eHealth for their own health but did not translate that into lifestyle change guidance for their patients, although they had been inspired themselves from discussions with patients. eHealth has the potential to become an important tool for the GPs in future work to improve the health of their patients. Education is needed, remuneration structures may need to be revisited, and more research is needed on how GPs can become active in developing behavioral change eHealth solutions that will create the future framework for collaboration among general practice, local authorities, and patients.

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## Conflicts of Interest

The corresponding author CJB owns shares in Liva Healthcare AS, the company that developed the behavioral change platform, LIVA. The other authors have no conflicts of interest to declare.

## Multimedia Appendix 1

General practitioner characteristics.

[\[PDF File \(Adobe PDF File\), 22KB - mhealth\\_v6i4e88\\_app1.pdf\]](#)

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## Abbreviations

- eHealth:** electronic health  
**GP:** general practitioner  
**PROM:** patient-reported outcome measures

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Original Paper

# Mobile App Usage Patterns of Patients Prescribed a Smoking Cessation Medicine: Prospective Observational Study

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## Abstract

**Background:** Cigarette smoking is the leading preventable cause of death and is responsible for more than 480,000 deaths per year in the United States. Smoking cessation is challenging for many patients. Regardless of available treatment options, most quit attempts are unaided, and it takes multiple attempts before a patient is successful. With the ever-increasing use of smartphones, mobile apps hold promise in supporting cessation efforts. This study evaluates the ease of use and user satisfaction with the Pfizer Meds app to support smoking cessation among patients prescribed varenicline (Chantix).

**Objective:** Study participants included varenicline users who downloaded and used the app on their personal smartphone. The main objectives were to report mobile app download frequency and usage details and to describe the participant-reported satisfaction with and usefulness of the app over the 14-week follow-up study period.

**Methods:** Adults aged 18 years or older who had been prescribed varenicline were identified from the Express Scripts Incorporated pharmacy claims database. After meeting privacy restrictions, subjects were sent an invitation letter and second reminder letter with instructions on how to download the Pfizer Meds mobile app. Participants received a push notification to complete a smartphone-enabled survey regarding the utility of the app 12 weeks after downloading the app. Descriptive statistics summarized sociodemographics, use of varenicline, and details of use and satisfaction with the mobile app.

**Results:** Of the 38,129 varenicline users who were sent invitation letters, 1281 participants (3.35%) downloaded the Pfizer Meds app. Of the 1032 users with demographic and other data, 585 (56.68%) were females, and 446 (43.22%) were males; mean age was 46.4 years (SD 10.8). The mean number of app sessions per participant was 4.0 (SD 6.8). The end-of-study survey was completed by 131 survey respondents (10.23%, 131/1281); a large number of participants (117/131, 89.3%) reported being extremely, very, or moderately satisfied with the app. A total of 97 survey respondents (97/131, 74.0%) reported setting up a quit date in the app. Of those, 74 (74/97, 76%) reported quitting on their quit date.

**Conclusions:** Positive patient engagement was observed in this study based on app download and usage. This study quantified how the Pfizer Meds app performed in an observational real-world data setting. The findings demonstrate the willingness of participants to set a quit date and use the app for support in medication adherence, refill reminders, and information regarding how to take the medication. This study provides real-world evidence of the contribution apps can make to the continued encouragement of smokers to improve their health by smoking cessation.

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**KEYWORDS**

smartphone; mobile apps; technology; patient engagement; patient satisfaction; patient adherence; surveys; smoking cessation

## Introduction

### Background

Cigarette smoking is the leading cause of premature death, causing approximately 480,000 deaths annually in the United States [1]. Although the negative health effects of smoking are well known, it remains a major preventable public health issue. It is estimated that approximately 16% of US adults aged 18 years and older currently smoke [2].

Although many smokers state a desire to quit, few are able to do so without help. Regardless of the available treatment options, more than half (52%) of quit attempts by US smokers are unaided attempts, with an average success rate as low as 5% [3]. A large number of studies have demonstrated the efficacy of medication and counseling to support smoking cessation [4].

### Smoking Cessation Apps

Mobile apps have been developed to assist with smoking cessation. Abrams et al systematically evaluated 47 iPhone apps for smoking cessation [5], characterizing them by app type (eg, calculator, rationing, or other), level of adherence to the US Public Health Service's 2008 Clinical Practice Guideline for Treating Tobacco Use and Dependence [6], frequency of downloads, and app price. The authors found that as a group, the iPhone smoking cessation apps generally failed to follow the guidelines, to ask users for their tobacco use status, assess their willingness to quit, arrange for a follow-up, recommend the use of approved medications, and the use of counseling and medication to quit smoking.

Another group of investigators similarly reviewed the attributes of Facebook apps for smoking cessation [7]. A smaller group of apps (9) both met the search criteria and were available on Facebook. Similar to the findings from the iPhone app review, Facebook apps had a low level of adherence to the US Public Health Service's 2008 Clinical Practice Guideline for Treating Tobacco Use and Dependence.

Using a different approach, Haskins et al [8] reviewed published research articles related to smoking cessation apps and looked in app stores for the apps that were evaluated in the literature. Using this approach, they were able to identify the available evidence-based apps, finding a total of 6 that were available in the app stores. The authors concluded that the process of finding evidence-based smoking cessation apps was quite difficult, and there is a need to continue to advance techniques to find technology-based health interventions.

To investigate the contents of smoking cessation apps in South Korea, Choi et al [9] searched Google Play and the Apple iTunes store for keywords "smoking" and "smoking cessation" in either Korean or English. Applying a priori criteria (eg, apps were selected if targeted to general consumers rather than physicians, not for hypnosis, not for simulation of smoking), they found a total of 309 apps to evaluate, and of these, they randomly selected 175 apps. Apps were then coded based on self-determination theory (focuses on stimulation of autonomous motivation). On the basis of their review, the authors concluded that smoking cessation apps generally might not sufficiently

stimulate autonomous motivation (ie, autonomy, competence, and relatedness).

### Smoking Cessation Treatment

Pharmacotherapeutic approaches also play a key role in smoking cessation. This study was based on varenicline users, so it was important to consider the use of the app in patients prescribed varenicline. Varenicline is used as an aid to support smoking cessation, and its efficacy has been demonstrated in a number of randomized, controlled clinical studies, most recently in a large, prospective, randomized, double-blind, active- and placebo-controlled pharmacotherapy trial, which evaluated the neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine replacement therapy (NRT) patch versus placebo; varenicline showed superior efficacy to placebo ( $P<.001$ ) and both bupropion and NRT patch ( $P<.001$ ) at the end of treatment (weeks 9 through 12) and follow-up (weeks 9-24). Bupropion showed similar efficacy to NRT patch ( $P=.60$ ), and both showed superior efficacy versus placebo ( $P<.001$ ) [10]. Although pharmacological approaches have proven efficacy and are supported in the 2008 US Public Health Service (PHS) Guidelines on treating tobacco use and dependence, additional recommendations include combination therapy and social or behavioral support to increase cessation rates [6]. Therefore, it is prudent that clinicians understand and use multiple approaches, particularly to enhance and support the success of a smoking cessation attempt.

With the increasing convenience and wide reach of smartphones during the last decade [11], an increasing number of people are now taking advantage of smartphones to tackle health issues. Smartphones are mobile phones with advanced functionality and features. Mobile health (mHealth) apps have risen in popularity, providing new opportunities to change health-related behaviors and manage chronic conditions [12,13]. The World Health Organization defined mHealth as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices [14]. These health apps can provide immediate access to health information, medication reminders, as well as help track progress toward a health-related goal such as a weight loss regimen; however, many factors related to smartphone health and wellness app use are not yet fully understood.

Globally, smartphones are increasingly used in health information and health care delivery. As of 2016, the global number of mHealth apps had reached 259,000 apps. Today, there are more than 59,000 mHealth app publishers on the main app stores worldwide, and the trend is quickly rising [15]. In a wide range of countries, smoking cessation services are using mobile phones to help deliver support, particularly in conjunction with other services [16]. The potential benefits of mobile phone-based smoking cessation interventions include ease of use anywhere at any time; cost-effective delivery and scalability to large populations, regardless of location; and the ability to link the user with others for social support.

Concurrent with the rise in smartphone use to advance health goals such as smoking cessation, there has been increased emphasis on patient empowerment [17]. Patient educational

programs have proliferated to provide health and wellness support through tools such as apps and including a focus on improving adherence to medications [18-23]. High levels of medication adherence are associated with better clinical outcomes, greater treatment satisfaction, better quality of life, and lower overall health care costs [24]. A recent publication by Laffer and Feldman indicates that some patients proactively seek out ways to improve their medication adherence, and this has included the use of reminder services and third-party apps on their mobile devices [25]. Such devices are becoming popular patient-driven routes of accessing information. However, limited information exists on patient access, use, and outcomes of product-specific mobile apps.

In support of smoking cessation, Pfizer developed a mobile app for use by varenicline users to provide educational information and support on quitting smoking with varenicline, including how to take the medication, possible side effects, and safety considerations in addition to motivational support. Before deciding to launch the app broadly in the United States, this study was conducted to better understand the utility of the app in the real-world setting. The objective of this pilot study was to characterize the participant population of varenicline users who opted to use the app and evaluate the app's functional attributes by analyzing mobile app download frequency and usage as well as describe participant-reported satisfaction with and usefulness of the app over the approximate 14-week follow-up study period.

## Methods

### Study Design

This was a noninterventive, prospective study of individuals prescribed varenicline for use as an aid to smoking cessation treatment. Pharmacy claims data were gathered from the database of a pharmacy benefits manager Express Scripts Incorporated (ESI) to identify varenicline users to be sent an invitation letter for participation. Outreach was restricted to ESI client organizations who have agreed to the use of their members' data for research purposes. Potential participants were provided a unique alphanumeric code in the invitation letter with instructions on how to download the mobile app from Google Play (app store for Android products) or iTunes (app store for iOS, iPhone Operating System, or Apple products). Once the app was downloaded by a potential study participant, the code was required to unlock app functionality.

Participants were excluded from the study if they were younger than age of majority at study enrollment (eg, aged <19 years in Alabama and Nebraska and aged <21 years in Puerto Rico) or if the participant did not agree to the Pfizer Meds Mobile App Informed Consent Document (ICD) and Privacy Notice (PN). After downloading the app and entering the unique code, informed consent for study participation was presented in the app screen window. Without agreement to ICD and PN, the participant was not able to progress further and unlock the full app functionality. Participants must also have agreed to the End User License Agreement (EULA) by scrolling to the bottom of the screen and checking the box next to the acceptance statement. Study participants received an invitation to complete

a smartphone-enabled survey regarding the utility of the app after 12 weeks of use of the app.

### Data Sources and Measurement

There were four sources of study participant data, which included the following:

1. *Pfizer Meds mobile app downloads*: The number of downloads of the app was tracked by App Figures. App Figures is a product that provides download data for apps available on the Google Play and Apple iTunes stores.
2. *Pfizer Meds mobile app use*: The app captured metrics via Google Analytics related to the type of material the participant accessed and level and dates of activity within the app. Google Analytics provided mobile analytics reporting for all activities occurring within the Pfizer Meds app. All activities were associated with the user's unique alphanumeric code and time stamped. Google Analytics used a number of components to ensure proper tracking of measurements of user interactions. Google Analytics tracked app installation, active users and demographics, screens and user engagements, and crashes and exceptions.
3. *ESI pharmacy claims*: Anonymized pharmacy claims data were analyzed via the ESI claims database and included age, gender, varenicline fill date(s), number of varenicline days' supply per fill and refill, dose per fill and refill, and refill indicator. Varenicline claims data were collected and analyzed for the participant-specific study period.
4. *Participant smartphone-enabled survey responses*: The one-time survey was taken at a minimum of 12 weeks after enrollment and included questions related to participant sociodemographic characteristics (including ethnicity and race), varenicline knowledge, satisfaction with and usefulness of the app and information provided therein, smoking history, current smoking status, additional support services used to quit smoking, comorbid conditions, and intention to continue using the app after completion of the survey. Furthermore [26], the survey was reviewed and approved by the institutional review board. Before launching the survey, a thorough testing of its programming was conducted to ensure skip patterns were followed, question branching logic properly working, and data validations and error messages accurately programmed. As part of the survey development, test data were used to check data tabulations for validity. The survey programming was also tested using 2 methods to ensure accuracy: systematic and stochastic testing. Survey programmers followed a testing plan and tested the skip patterns and branching logic. Systematic testing was followed by a process of automated stochastic testing, which avoids assumptions of user bias, where testing software randomly chooses responses in an effort to test the scripting logic from end to end. Following the aforementioned testing, a live link to the survey was provided to testers who subsequently verified the content and presentation of the survey based on comparison with written plans.

Survey participants were a convenience sample, as individuals voluntarily took part in the follow-up survey. No personal information was collected or stored.



Data were reviewed following written data review guidelines that specified the visual data review to be performed on the listings and tabulations of participant survey data. Data were reviewed before database lock to exclude data if needed as a result of straight-line or overly rapid responses. Due to the cross-sectional nature and mode of administration of the survey, as well as protection of participant privacy, survey data were used as reported by participants (participants were not contacted to clarify responses).

### Patient Recruitment

Participant recruitment was done via the ESI pharmacy claims database; ESI is the largest pharmacy benefits manager in the United States, covering approximately 1 in 4 Americans. Their pharmacy claims database houses all pharmacy claims adjudicated for participants who have ESI as their pharmacy benefits manager. Only pharmacy claims for ESI clients that allow for deidentified data for use in mining activities, statistical compilation, or research were used in this study.

ESI identified all members, aged 18 years or older, who had received varenicline via mail order or retail pharmacy within the previous 30 days. This was the defined “lookback” period for participant recruitment. All such participants were issued a study invitation by email. These identified “index claims” were not required to be the first varenicline claim for the participant and may have been a refill prescription. This process was completed monthly for a period of 5 months, targeting different potential participants each month. Invitees received a second invitation (reminder) letter during the subsequent mailing.

### Study Period

The recruitment period started on the date of the first mailed study invitation letter and continued for 5 months. All eligible participants were invited to download the Pfizer Meds mobile app and to complete a cross-sectional smartphone-enabled survey no earlier than 12 weeks after the app download date. Moreover, 12 weeks correspond to the approved treatment length of varenicline [27].

The expected time from agreement with the ICD and PN to survey completion was 12-14 weeks for the last enrolled participant; those who enrolled earlier had a longer window for survey completion. The survey was closed after 14 weeks following enrollment of the last participant; as of that time, no further survey reminders were issued through the app.

### Study Size

The target sample size was set for up to 1000 enrolled participants. Up to 100,000 participants in the United States were planned to be invited to participate in this study to reach the target sample size. The projected response rate of 1% was considered a conservative estimate and was based on results of similar studies that used the same study recruitment method (mailed letter sent to nonblocked ESI members; personal communication LISA GRIBBLE, July 15, 2017). Recruitment rate was closely monitored, and number of mailed invitations was adjusted in case the target sample size of 1000 enrolled participants was reached before the end of recruitment.

### App Content and Functionality

The app included 20 unique pages, including set-up, a main screen, reminders, savings calculator, an information vault, badges, and notifications. Examples of some of the most frequently visited pages can be seen in [Multimedia Appendix 1](#).

### Statistical Methods

Descriptive statistics, including mean, SD, minimum, first quartile, median, third quartile, and maximum values for continuous variables and numbers and percentages for categorical variables, were calculated to characterize study subjects who downloaded the app, including their use of and satisfaction with the mobile app.

The proportion of invited participants who downloaded the mobile app was calculated and summarized. Participants comprising the numerator were defined as those invitees who had unlocked the app with their unique ID and had made it through to the welcome screen, having accepted the terms of the ICD and PN and the EULA.

### Results

#### Express Scripts Incorporated Varenicline Users, Invitation Letters, and Pfizer Meds App Downloads

A total of 38,129 initial invitation letters and 35,541 reminder letters were mailed to ESI varenicline users between September 2015 and February 2016 (see [Figure 1](#)). Of these, a total of 1281 participants downloaded the Pfizer Meds app (overall response rate of 3.36%). Of note, claims data could only be obtained from 1027 participants due to a change in the ESI policy during the study period.

Among the 1281 participants who downloaded the app, females represented a larger percentage (585/1281, 45.67%) compared with males (446/1281, 34.82%), and gender was missing for 19.52% (250/1281). For the 1032 users with known age, the mean age was 46.4 years (range 19-85 years), with the majority in the 35- to 65-year age group (671/1032, 65.02%).

#### Pfizer Meds App Use Metrics

A key objective of this study was to evaluate features of the app. The Pfizer Meds app use metrics are provided in [Table 1](#). The My Pfizer Meds page, the main screen that is displayed when the app is opened, was visited the most frequently, at an average of 4.1 times among the 1220 participants who ever visited that screen. From this page, the participant could swipe through product images and view content on how to take the medication, the full prescribing information, medication guide, and full safety information. The next most frequently visited pages (and the number of times visited on average) were My Info Vault (3.8), Unlock (3.3), Reminder Display (2.8), and Reminder Set (2.7).

The “my information vault” page, the central repository of patient educational information, was viewed by approximately half of the enrolled population (51.52%, 660/1281). Those participants who viewed “my information vault” primarily accessed slip-ups, tips for handling urges, and also celebrating

quitting windows. Participants rarely viewed windows associated with medication-related items, such as how to take my medication, starting my medication, and the most important safety information I should know about my medication. This could be due in part to the recruitment methodology whereby patients were identified for potential participation based on a filled claim for varenicline. Therefore, it is expected that most participants had already decided to start medication or started taking their medication before downloading the mobile app. In addition, this also reflects the challenge of smoking cessation and support patients may need during their quit attempt with medication.

Participants generally displayed a positive level of engagement to various app features. A large proportion of participants set up a quit date (1086/1281, 84.77%) and refill reminder at 1 month (1134/1281, 88.52%). More than half of enrolled participants (717/1281, 55.967%) set up motivational notifications. In contrast, dosing reminder activity utilization within the app was relatively low (109/1281, 8.51%).

Badges were earned as milestones and were reached for prespecified activity in the app. Badges were most often earned for designating a quit date (925/1281, 72.21%) and setting a reminder to take meds (679/1281, 53.01%).

**Twelve-Week Postenrollment Survey Results**

A total of 131 respondents (131/1281, 10.23%) completed the end-of-study survey. Table 2 provides data on survey respondents' smoking history and smoking status. The mean number of years smoked by survey respondents was 22.1 (SD 9.9) years. The majority of respondents (55.0%) indicated that aside from the current attempt, they previously tried to quit

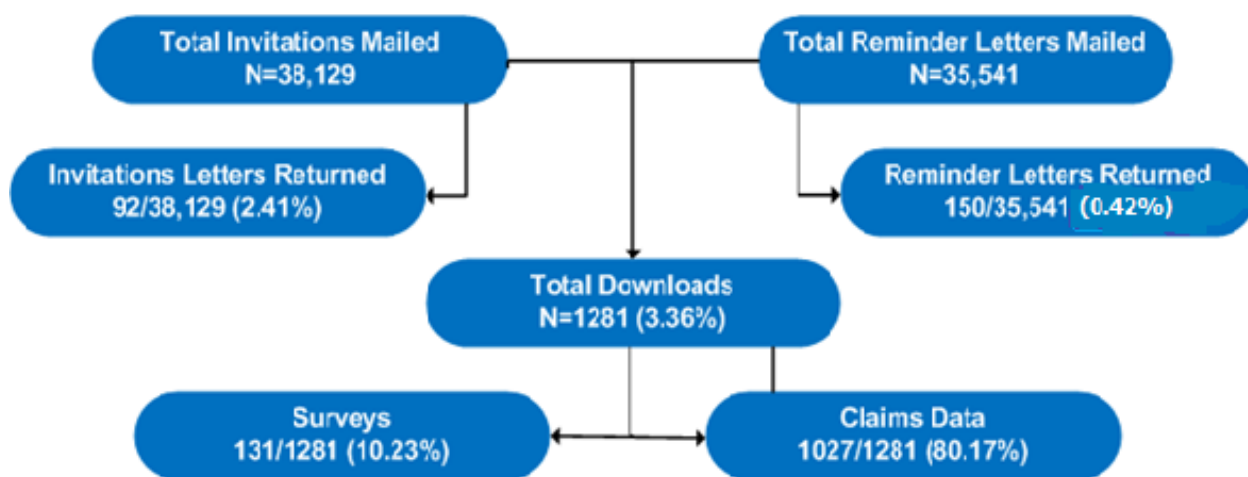
smoking fewer than 6 times. In addition to varenicline and the Pfizer Meds app, participants reported using family and friends (58.8%) and health care providers (HCPs; 40/131, 30.5%) as additional quit smoking support resources; 22.9% (30/131) of respondents only used the Pfizer Meds app.

When asked about their satisfaction with the Pfizer Meds app, a large proportion of participants (89.3%, 117/131) reported being extremely, very, or moderately satisfied with the app. In addition, 54.2% (71/131) rated the usefulness of the app in terms of supporting their smoking cessation goal as extremely or very useful. Only one subject indicated that the app was not at all useful.

In response to questions regarding the assessment of the usefulness of various components of the Pfizer Meds app, more than half of the 131 survey respondents found reminders to take the medication, medication refill reminders, and information about how to take the medication (78/131, 59.6%; 70/131, 53.4%; and 76/131, 58.1%, respectively) to be extremely or very useful. A similar number of respondents found the savings calculator and the message notifications (77/131, 58.8%, and 76/131, 58.0%, respectively) to be extremely or very useful. When asked about potential future use, 60.3% (79/131) of respondents reported planning to continue using the app in the future.

A total of 97 survey respondents (97/131, 74.0%) reported setting up a quit date in the app. Of those, 74 (74/97, 76%) reported to have stopped smoking on the chosen quit date. Regarding intentions, 68.7% (90/131) of survey respondents who set up a quit date reported feeling extremely or very confident that this quit attempt will be successful.

**Figure 1.** Study participation subgroups. Claims data were available for 1027 of the 1281 download participants' data due to a change in Express Scripts Incorporated (ESI) policy during the study period.



**Table 1.** Frequency of use metrics of the Pfizer Meds app. iOS: iPhone Operating System; OS: operating system.

Variable	Participant utilization (N=1281)
<b>Type of mobile on OS, n (%)<sup>a</sup></b>	
Android	672 (52.46)
iOS	612 (47.78)
<b>Number of sessions per participant</b>	
n (%)	1281 (100.00)
Mean (SD)	4.0 (6.8)
Median (min, max)	1.0 (1, 89)
<b>Number of times my medication page viewed per participant</b>	
n (%)	1220 (95.24)
Mean (SD)	4.1 (5.9)
Median (min, max)	2.0 (1, 87)
<b>Number of times reminder set/user settings up page viewed per participant</b>	
n (%)	1259 (98.28)
Mean (SD)	2.7 (1.9)
Median (min, max)	2.0 (1, 17)
<b>Number of times reminder display page viewed per participant</b>	
n (%)	672 (52.26)
Mean (SD)	2.8 (4.2)
Median (min, max)	1.0 (1, 68)
<b>Number of times savings calculator set up page viewed per participant</b>	
n (%)	1210 (94.46)
Mean (SD)	1.3 (0.9)
Median (min, max)	1.0 (1, 9)
<b>Number of times savings calculator graph viewed per participant</b>	
n (%)	1175 (91.73)
Mean (SD)	1.4 (1.0)
Median (min, max)	1.0 (1, 11)
<b>Number of times main my information vault page viewed per participant</b>	
n (%)	660 (51.52)
Mean (SD)	3.8 (4.1)
Median (min, max)	2.0 (1, 40)
<b>Number of times product images viewed per participant</b>	
n (%)	425 (33.18)
Mean (SD)	1.3 (0.6)
Median (min, max)	1.0 (1, 4)
<b>Number of times important safety information expanded per participant</b>	
n (%)	262 (20.45)
Mean (SD)	1.1 (0.4)
Median (min, max)	1.0 (1, 4)
<b>Number of times badges page viewed per participant</b>	
n (%)	498 (38.88)
Mean (SD)	2.3 (3.0)

Variable	Participant utilization (N=1281)
Median (min, max)	1.0 (1, 30)

<sup>a</sup>Percentages can sum to more than 100% because a participant can report more than one type of mobile OS.

**Table 2.** Smoking history and smoking status among survey respondents.

Variable	Survey respondents (N=131)
<b>What is the approximate total number of years you have smoked in your lifetime?</b>	
n (%)	131 (100%)
Mean (SD)	22.1 (9.9)
Median (min, max)	20.0 (2, 45)
<b>In your lifetime, how many times have you tried to quit smoking (not including this time)? n (%)</b>	
0 times, this is my first attempt at quitting	3 (2.3)
Fewer than 6 times	72 (55.0)
6-10 times	41 (31.3)
More than 10 times	15 (11.5)
<b>Which of the following methods have you used in the past to help you quit smoking? (Select all that apply), n (%)</b>	
Prescription medication	70 (53.4)
Nicotine patches	63 (48.1)
Nicotine gum	49 (37.4)
Nicotine lozenges	13 (9.9)
Nicotine inhaler	4 (3.1)
Nicotine nasal spray	1 (0.8)
E-cigarette	54 (41.2)
Counseling advice	17 (13.0)
Helpline	9 (6.9)
Self-help materials	13 (9.9)
Others (eg, hypnosis, acupuncture)	16 (12.2)
Nothing (I quit "cold turkey")	30 (22.9)
<b>What types of support resources did you use during this quit attempt in addition to the Pfizer Meds Mobile App? (Select all that apply), n (%)</b>	
Family and friends	77 (58.8)
Support group	12 (9.2)
Health care professional (doctor, nurse, pharmacist)	40 (30.5)
Quitline	9 (6.9)
Self-help materials	24 (18.3)
Program through my employer	9 (6.9)
Web-based resources	15 (11.5)
Another smartphone app	11 (8.4)
Hypnosis	3 (2.3)
Acupuncture	1 (0.8)
Others	5 (3.8)
None	30 (22.9)

## Discussion

### Principal Findings

This pilot study combined several data sources to capture and quantify real-world usage patterns of a patient-focused app among subjects prescribed a smoking cessation medication. The study successfully enrolled 1281 participants, achieving an overall response higher than the expected (3.36% vs 1% per protocol based on similar studies conducted within the pharmacy benefits manager).

Most commonly, participants earned badges for designating a quit date and setting up a dosing reminder for medication, highlighting interest in this type of functionality of the app. Interaction of participants with the app was less with medication activity-related pages. For example, 467 participants (36.46%) accessed how to take varenicline medication. It is worth noting that, according to the varenicline prescribing information, before initiating medication, patients are instructed to set a quit date and are advised to initiate varenicline about 1 week before the quit date. These results are aligned with the support motivated smokers need to reach their smoking cessation goal. The lower level of interaction with medication-specific app content might suggest that patients feel a level of comfort and reliability of using the set-up reminders to adjust and take the medication. This may also be a reflection of positive patient counseling by HCPs on prescribing the medication as well as the dispensing package of the product with instructions on how to take the medication.

Counseling and support is a critical component of smoking cessation. The 2008 US PHS guidelines [6] encourage behavioral support and patient engagement. The guidelines also state that “There is a need for innovative and more effective counseling strategies.” The results of this study indicate that the use of a branded mobile app for smoking cessation may support engagement for motivated smokers.

This study was unique in that it was a proof of concept pilot for the Branded Pfizer Meds mobile app, providing data on its use and participant-reported satisfaction in a real-world setting. Although patients were on a prescription product, the intervention was the delivery of educational material and support with the mobile app. The app was available for both iOS and Android platforms and has subsequently been removed.

A diverse array of data sources was used in this analysis. First, this study used the pharmacy claims data from ESI, the largest pharmacy benefit manager in the United States, allowing the study team to reach a diverse sample of potential participants. The study also collected a large volume of quantitative and qualitative information by combining data from various sources (Google Analytics, anonymized Express Scripts pharmacy claims data, and participant smartphone-enabled survey responses ) to fulfill the study objectives.

Advantages associated with the smartphone-enabled survey that was accessible via the Pfizer Meds app included increased accuracy of data entry relative to paper surveys, timely collection of participant responses, and a relative cost reduction

compared with survey administration by a separate stand-alone data source.

### Limitations

There are a few limitations to be mentioned. This study was not fully representative of smokers who wish to stop smoking, in large part due to the protocol’s inclusion criteria. In addition to being an adult, to be included in this study, a participant must have had access to a smartphone, been in the ESI sampling frame that included claims (primarily employer-based plans), and be able to download a mobile app. The percentage of participants who were mailed an invitation letter and who had access to and use smartphone technology is unknown.

In addition, the study period varied per participant, with those who enrolled earlier having a longer window for survey completion, which in turn may increase the probability of recall bias. In addition, participants who disabled their screen notifications either on their mobile device or within the app did not receive the notifications regarding survey completion. The usefulness of the participant survey data in relation to their experience with the mobile app may be limited for participants who were less active within the mobile app.

Another limitation of this study was that the Pfizer Meds app was only available in the English language and was only available to Android and Apple device users. Although these operating systems (OSs) account for 90% of the market share [15], this limited availability of the app excluded the participation of those using mobile devices under the umbrella of Windows and Blackberry (OS).

The smaller (n=131) group of participants who took the end-of-study survey were self-selected, and the majority of survey participants were of white ethnicity (88.5%). This may be a limit to generalizability, although these findings are in accordance with a cohort study that looked at predictors of cessation intervention websites use showing that non-Hispanic whites are more likely to visit and participate in Web-based smoking cessation programs [28]. Future studies should consider including attempts to reach varenicline users who were contacted but did not download the app to evaluate differences between participants and non-participants that may have impacted smoking cessation behaviors.

### Conclusions

Smoking is the leading preventable cause of death in the United States [29]. Various approaches to smoking cessation are available to assist smokers who wish to quit. A systematic review of literature regarding the effectiveness of approaches to smoking cessation was the basis of the US Preventive Services Task Force recommendations that include such interventions as pharmacological intervention, brief counseling by HCPs, and use of mobile apps for smoking cessation support [30].

This study is innovative in seeking to gain insight into usage patterns in a smoking cessation app designed to be used in conjunction with varenicline. The 3.4% response rate of downloading the app is encouraging, given the potential

advantage of supplementing smoking cessation medication with more personalized patient education through this app.

The findings demonstrate the willingness of participants to set a quit date and use the app for support in medication adherence, refill reminders, and information regarding how to take the medication. A subset of smokers who wish to quit will benefit

from the availability and continual refinement of educational apps. Using metrics available from smartphone use and a patient survey at 12 weeks after enrollment, this study quantified how this app performed in a real-world data setting and may guide further refinement to the app. Specifically, modifications may include improved app functionality and features that this work has found to be important to users with health information needs.

## Acknowledgments

Jim Young (United BioSource Corporation, UBC) provided the statistical analysis plan and completed the analytics, Holly Patterson (UBC) coordinated the study, Ron Segal (Pfizer Medical Business Technology) coordinated app and survey development and deployment to app stores, and Karan Lazan (Pfizer Global Director of Brand Development & Innovation) created and curated patient educational information and resources for the app and led efforts to ensure optimal consumer experience.

## Conflicts of Interest

This study was sponsored by Pfizer. During the study, MB, MW, CLB, BE, EC, and MC were employees and stockholders of Pfizer Inc. CS and AP are employees of UBC, who were paid consultants to Pfizer in connection with the development of this manuscript. UBC is a contract research organization and a subsidiary of Express Scripts Incorporated. Pfizer sponsored the smoking cessation app for mobile phones that was evaluated in the study and this manuscript.

## Multimedia Appendix 1

Screenshots of Pfizer Meds App.

[[PDF File \(Adobe PDF File\), 397KB - mhealth\\_v6i4e97\\_app1.pdf](#)]

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## Abbreviations

**ESI:** Express Scripts Incorporated  
**EULA:** End-User Licensing Agreement  
**HCPs:** health care providers  
**ICD:** informed consent document  
**iOS:** iPhone operating system  
**mHealth:** mobile health  
**OS:** operating system  
**PHS:** public health service

PN: privacy notice

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Original Paper

# Evaluation of Two Mobile Health Apps in the Context of Smoking Cessation: Qualitative Study of Cognitive Behavioral Therapy (CBT) Versus Non-CBT-Based Digital Solutions

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## Abstract

**Background:** Mobile health (mHealth) apps can offer users numerous benefits, representing a feasible and acceptable means of administering health interventions such as cognitive behavioral therapy (CBT). CBT is commonly used in the treatment of mental health conditions, where it has a strong evidence base, suggesting that it represents an effective method to elicit health behavior change. More importantly, CBT has proved to be effective in smoking cessation, in the context of smoking-related costs to the National Health Service (NHS) having been estimated to be as high as £2.6bn in 2015. Although the evidence base for computerized CBT in mental health is strong, there is limited literature on its use in smoking cessation. This, combined with the cost-effectiveness of mHealth interventions, advocates a need for research into the effectiveness of CBT-based smoking cessation apps.

**Objective:** The objective of this study was, first, to explore participants' perceptions of 2 mHealth apps, a CBT-based app, Quit Genius, and a non-CBT-based app, NHS Smokefree, over a variety of themes. Second, the study aimed to investigate the perceptions and health behavior of users of each app with respect to smoking cessation.

**Methods:** A qualitative short-term longitudinal study was conducted, using a sample of 29 smokers allocated to one of the 2 apps, Quit Genius or Smokefree. Each user underwent 2 one-to-one semistructured interviews, 1 week apart. Thematic analysis was carried out, and important themes were identified. Descriptive statistics regarding participants' perceptions and health behavior in relation to smoking cessation are also provided.

**Results:** The thematic analysis resulted in five higher themes and several subthemes. Participants were generally more positive about Quit Genius's features, as well as about its design and information engagement and quality. Quit Genius users reported increased motivation to quit smoking, as well as greater willingness to continue using their allocated app after 1 week. Moreover, these participants demonstrated preliminary changes in their smoking behavior, although this was in the context of our limited sample, not yet allowing for the finding to be generalizable.

**Conclusions:** Our findings underscore the use of CBT in the context of mHealth apps as a feasible and potentially effective smoking cessation tool. mHealth apps must be well developed, preferably with an underlying behavioral change mechanism, to promote positive health behavior change. Digital CBT has the potential to become a powerful tool in overcoming current health care challenges. The present results should be replicated in a wider sample using the apps for a longer period so as to allow for generalizability. Further research is also needed to focus on the effect of greater personalization on behavioral change and on understanding the psychological barriers to the adoption of new mHealth solutions.

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## KEYWORDS

smoking cessation; mHealth; mobile health; health behavior change; cognitive behavioral therapy; public health; health policy

## Introduction

### Background

There is general consensus worldwide that health care organizations have historically struggled to embrace the use of information technology to increase productivity and the quality of care delivered [1]. However, the technological landscape is rapidly being transformed with the emergence of the digital revolution. A number of leading health care organizations worldwide have begun to exploit some of the opportunities for novel health care solutions [2,3]; however, there appear to be many further opportunities to be unlocked in this space, in particular in the context of digital mobile technologies.

Smartphones are considered to be one of the 8 key technologies contributing to the digital revolution [4]. The number of smartphone users has been increasing rapidly. In 2014, there were 1.57 billion smartphone users worldwide, and this is predicted to increase to 2.87 billion by 2020; the upshot is that in 2017, 96% of UK respondents aged between 16 and 34 years reported owning a smartphone [5].

Mobile health (mHealth) is a critical part of the digital transformation of health care. The Global Observatory for eHealth defined mHealth as medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices [6]. Technological advances, coupled with the unique ability of mobile apps to reach all smartphone owners at a relatively low cost, have accelerated the market growth for mHealth apps [7], such that in 2016, there were more than 259,000 mHealth apps available on the major app stores. It is predicted that by 2020, 2.6 billion people will have downloaded an mHealth app at least once—551 million of these will be active users [8].

mHealth apps can offer a number of benefits for users, such as improved treatment accessibility, real-time symptom and activity monitoring, treatment progress tracking, personalized feedback, motivational support, portability, and flexibility [9,10]. They seem to represent a feasible and acceptable means of administering health interventions [11] and have the potential to be effective in eliciting health improvements in conditions ranging from diabetes [12] to depressive symptoms [13]. Conversely, there are also a number of notable drawbacks of mHealth apps that need to be considered. These include technical problems, data security, patient privacy, timely management of assistance from a medical professional [14], as

well as psychological barriers to adoption and effective user engagement.

The World Health Organization reported in 2017 that noncommunicable diseases (NCDs) are the cause of 70% of all global deaths. Cardiovascular disease, cancer, respiratory diseases, and diabetes are the biggest contributors to NCD deaths equating to 81% thereof. Risk factors such as frequent tobacco use, alcohol abuse, poor diet, and physical inactivity increase likelihood of NCDs [15]. A number of smartphone apps address these issues using behavioral change mechanisms to modify behavior and promote a healthier lifestyle.

The cognitive behavioral therapy (CBT) model is based on the idea that thoughts, emotions, and behavior interact with and influence each other. CBT is commonly used in the treatment of mental health disorders especially because of its ability to alleviate distress caused by unhelpful cognitions and reframe these cognitions to lead to more adaptive behaviors [16]. This type of psychotherapy has been incorporated within clinical guidelines because of its strong evidence base [17], which supports the idea that it represents an effective method to elicit health behavior change [18-20]. Importantly, with nearly three-fourths of current smokers reporting that they wanted to give up smoking [21], CBT has also shown to be effective in smoking cessation [22,23].

The evidence base for the efficacy of computerized low-intensity psychological CBT interventions for anxiety and depression is particularly strong [24,25]. Moreover, evidence has shown that, alongside CBT provided through a computer-based platform, CBT delivered via mobile apps could significantly improve outcomes for patients [26]. However, limited research on its use in smoking cessation exists. This, combined with the cost-effectiveness of this intervention, advocates a need for research investigating its effectiveness in this context.

### Objectives

The purpose of this study was, therefore, first, to explore users' perceptions of two mHealth apps, one CBT-based app, Quit Genius (QG), and one non-CBT-based app, National Health Service (NHS) Smokefree (SF), over a variety of critical themes. Second, the study also sought to investigate the perceptions and health behavior with respect to smoking cessation for users of each app. To do so, a qualitative short-term longitudinal study was conducted based on semistructured interviews with users, followed by a thematic analysis, which resulted in several higher themes and subthemes. Descriptive statistics regarding participants' willingness to continue using each of the apps, as

well as perceptions and health behavior in relation to smoking cessation, were also calculated.

## Methods

### Participants

A total of 45 participants were recruited for the study, to account for any dropouts. This sample size was chosen in accordance with the recommendations for qualitative studies present in the literature, which indicate a sample size of 5 to 50 [27] to achieve saturation of results [28]. The following inclusion criteria were used: (1) smoker who intends to quit, (2) Apple iPhone smartphone user, (3) access to English App Store, (4) English speaker, (5) age >18 years, (6) has mental capacity, (7) has some experience/knowledge regarding mobile apps. Application of the inclusion criteria led to an initial sample of 45 users. Users were randomly allocated to one of 2 apps, resulting in 18 users allocated to QG and 27 users allocated to SF.

Three participants dropped out of the QG arm, and 13 dropped out of the SF arm. The final sample was thus composed of 15 participants in the QG arm and 14 in the SF arm. Demographic data of the final sample of participants were also collected (Table 1).

The NHS/HSC Research and Development Offices granted ethics approval. Fully informed written consent was gained from all participants before interview.

### Study Design

A qualitative short-term longitudinal study based on one-to-one semistructured interviews with users allocated to one of the 2 selected apps was conducted. The literature investigating the

use of CBT in smoking cessation, specifically via a mobile digital platform, is limited. Due to this, an exploratory approach was used, setting out to gather data around the topic, the analysis of which would facilitate the emergence of research questions and theory. Thus, a qualitative, inductive approach was adopted. From the primary data collected, thematic analysis was carried out using a 6-phase framework [29]. This was used to generate themes from ideas that emerged during the interviews. Descriptive statistics based on quantitative data gathered as part of the interviews are also provided.

### Apps

The rationale behind the choice of apps was to compare a smoking cessation app that uses CBT against one that does not. Therefore, QG (Figure 1) and NHS SF (Figure 2) were chosen. Figures 1 and 2 represent screenshots of the app interfaces at the time of the data collection. Both apps are gamified, smoking cessation, smartphone apps and offer a number of different features (see Table 2). Gamification refers to the introduction of game-like elements and principles to nongame contexts, with a view to encouraging participation and involvement [30,31].

### Interview Procedure

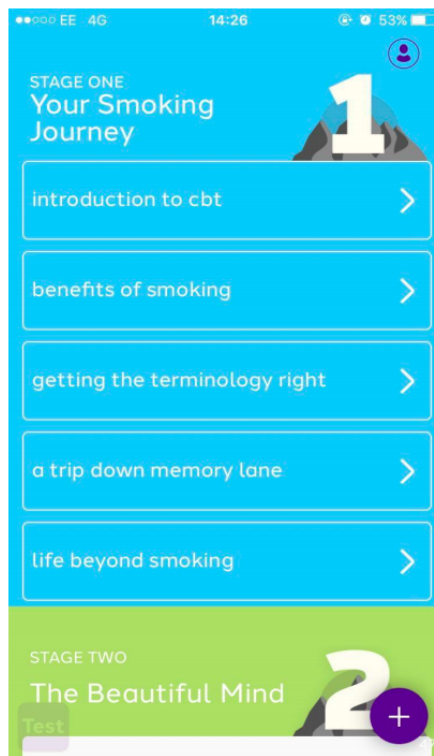
Each participant was interviewed twice, 1 week apart, before and after they had used their allocated app. Interviews included mostly qualitative, but also a small number of quantitative (ie, 1-10 rating scales) elements. The first interview provided a short, baseline assessment of the individual's smoking habits and history, as well as of their perceptions of digital therapeutics and mobile apps in health care. Participants were also given standardized instructions regarding app use. Interviewers were instructed to neither encourage nor discourage the participants' smoking behavior, to minimize bias.

**Table 1.** Demographic data of the final sample of participants. NHS: National Health Service.

Characteristics	Quit Genius users	NHS Smokefree users
Number of participants, N	15	14
Mean age, in years	25.07	24.21
<b>Gender, n</b>		
Male	13	12
Female	2	2
<b>Occupation, n</b>		
Student	11	8
Employed <sup>a</sup>	4	6
<b>Cultural background, n</b>		
Caucasian	3	9
Asian	12	4
British Arab	0	1
Quitting for the first time, n	6	6
Average number of cigarettes per day	7.9	7.8
Average number of times participant opened app between interviews 1 and 2	9.2	6.1

<sup>a</sup>PhD students were included in the "Employed" category as their financial status and daily working schedule is closer to being employed than being an undergraduate student.

**Figure 1.** Screenshot of the Quit Genius interface. CBT: cognitive behavioral therapy.



**Figure 2.** Screenshot of the NHS SmokeFree interface.



**Table 2.** Characteristics and features offered by the Quit Genius and Smokefree apps. CBT: cognitive behavioral therapy; NHS: National Health Service.

Characteristics/features	Quit Genius	NHS Smokefree
Length of program	8 weeks	4 weeks
Characteristics of program	CBT-based, customized, personalized; involves the following: self-reflection, changing unhelpful thinking patterns and behaviors, development of personal coping strategies, problem-solving, and mindfulness	Non-CBT-based, involves the following: support messages to increase motivation, practical support, encouragement, tailored advice, and success tips and content
Features	Four-stage “journey” with several steps per stage, involving audio sessions and transcripts, quizzes, and interactive exercises, as well as a smoking diary	Daily support messages; badges rewarding progress, craving button with tips and content, savings calculator, personalized motivation; success tips
Gamification elements	Presenting the program as a journey with achievements, progress bars, time-based challenges	Progress tracking, badges rewarding progress, and savings calculator

The second interview assessed users’ evaluation of their allocated app, as well as the effects the use of each app had on smoking-related perceptions and behaviors.

Interview questions were initially prepared, then piloted using 4 independent participants. Adjustments to the interview questions were made based on findings from these pilot interviews. The pilot study confirmed the suitability of the 2 chosen apps. The results of the pilot were not included in the final study.

Verbal consent was gained from all participants to record interviews on a smartphone or laptop software.

### Thematic Analysis

Braun and Clarke’s [29] 6-phase framework was used for our thematic analysis. An inductive approach was adopted during the coding process; all concepts and ideas that arose were coded, regardless of relevance to the original research question. A manual coding process was undertaken. The transcripts were printed, and individual codes were highlighted and transferred onto post-it notes, in the process of identifying segments of the data. The post-it notes were color-coded to facilitate easy visualization of codes for the development of themes. Once coded, each transcript was then reread by a second researcher to check the rigor of coding and to increase the conformability of the codes created. The codes were analyzed to form overarching themes, and ambiguities were resolved via discussion among members of the research team.

### Descriptive Statistics

Descriptive statistics regarding the willingness to generally use a smoking cessation mHealth app, as well as motivation to quit smoking and different aspects of smoking behavior of users of each app, were also calculated.

## Results

### Thematic Analysis

The thematic analysis resulted in five overarching (higher) themes that influenced the impact of the interventions on health behavior. Three of the higher themes were associated with several subthemes (Figure 3). The themes were explored with a view to determining the relationship and differences between

the 2 apps. The five higher themes were not exclusively related to smoking cessation.

### App Features

#### Specific Features

One user commented positively on QG’s “memory lane” as their favorite feature. Multiple participants also spoke positively of the smoking diary feature that allowed them to log every cigarette they had and reminded them to open the app:

*You can see the pattern of why you’ve been having cigarettes.*

SF users spoke poorly of the “lapse” feature, as it made them feel guilty disengaging them from the app. One of the users commented:

*The [SF] app makes you feel like you’ve failed if you relapse.*

SF users were also wary of the sharing capabilities of the app, specifically with social media. They did not feel comfortable with the option, and the thought of doing so made them feel insecure. One user said:

*Don’t want to share progress on social media in case you fail.*

Multiple users also mentioned that the SF “savings” feature was inaccurate, and this led to a lack of trust in the app, making users question the integrity of all aspects of its design. Conversely, other users appreciated the existence of the “savings” feature and used it as motivation to continue with the program.

#### General Features

Participants commented on the idea of personalization in both QG and SF. It was agreed that the ability to tailor the app to your personal situation was pivotal for engagement. One participant stated:

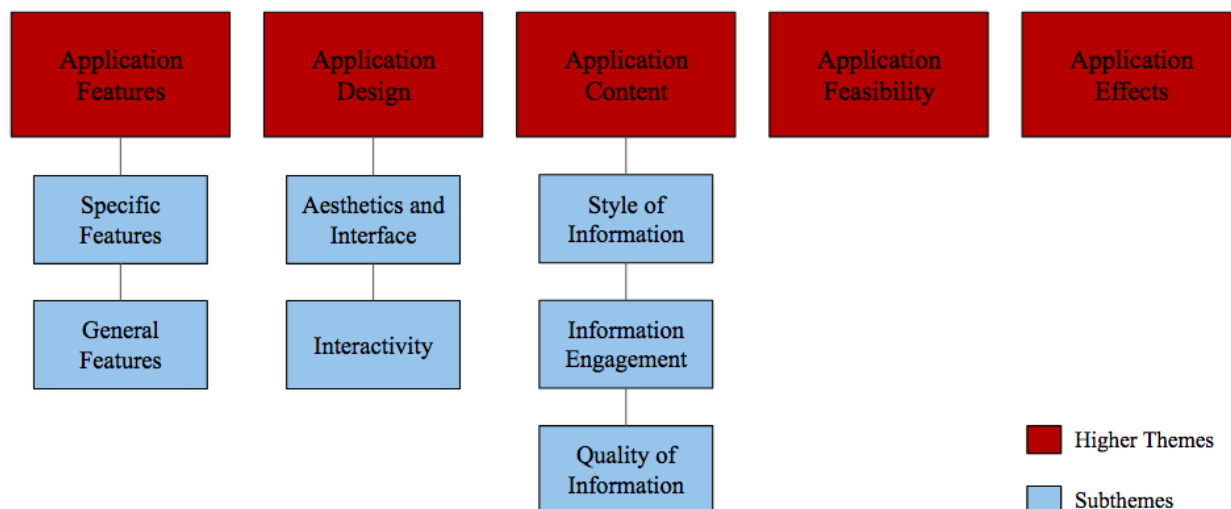
*...it’s like a personal kind of message to yourself to say...so it’s like in a motivation rather than someone else telling you what to do.*

QG participants found that the QG notifications were motivational and engaging:

*I liked how it gave notifications, like every day I've got a notification saying; You're on day four of your smoking quitting history. You could do this, don't give*

*up. Stay loyal and stuff like that. That was quite impressive.*

**Figure 3.** Visual representation of the five overarching themes and their respective subthemes, which resulted from the thematic analysis.



On the other hand, a significant number of SF users commented that the SF tips functions and notifications were generic and not useful, some even choosing to ignore them all together. Some, however, found the tips function useful, helping them commit to their goals.

Users also mentioned that they enjoyed the multimedia functionality of QG. They commented particularly on the audio feature being soothing and engaging. Multiple QG users also commented on the quizzes, suggesting that they helped reinforce the knowledge that the app provided. One of the users said:

*The quizzes are pretty useful and there's a sense of achievement from getting them right.*

## App Design

### *Aesthetics and Interface*

The majority of participants found the QG app's aesthetics and layout favorable, with a positive, bright color scheme. Multiple users also appreciated that the QG app did not appear too clinical:

*[QG has a] simple design...it looks like a professional app.*

SF was identified as aesthetically appealing by a few participants; a positive response to the color scheme was exhibited. However, other participants were less enticed by the aesthetics of SF. One of the participants commented:

*[SF] made me feel childish...it's a little bit Mickey Mouse.*

A number of QG users were frustrated by a bug in the app regarding the progress bar:

*[The QG] progress bar at bottom doesn't always work, [you] have to refresh the app.*

Nearly, all SF participants noted that the app was very easy to use and navigate. The lack of technical issues such as bugs or

slow response times resulted in minimal effects on overall experience. One user stated:

*[SF is] simple, easy to use, user-friendly.*

Although the QG app's steps were quite extensive, participants felt they were well instructed and given sufficient guidance when operating the app.

On the other hand, SF participants reported that the interface provided poor instructions and guidance:

*It doesn't really instruct you what to do next.*

### *Interactivity*

QG was found to be highly interactive, with generally positive responses regarding engagement. Participants were especially engaged by the audio narrations:

*[I] felt interactive with the speaker.*

Notably, this was not always observed, as a small minority of users struggled to engage with QG, expressing a sense of boredom because of perceived lack of captivating material. One of the users stated:

*[I] would prefer some kind of like visual effects.*

A number of participants highlighted the lack of interactivity in SF, which caused boredom and a decreased desire to use the app. One participant said:

*It just needs to be made more interactive.*

## App Content

### *Style of Information*

Multiple participants appreciated how QG could be listened to, with audio being considered more insightful than just reading text on a screen. Some even associated the benefits of audio with convenience, as it can be carried out while performing other activities. However, some users preferred using the

transcript alone as it allowed them to set their own pace. This is evident from the following statements:

*I just listened to this thing...because I don't like reading.*

*It's good because it's audio so you can just listen to it while you're in the train...you don't actually have to be physically on your phone.*

The terminology of the information was also shown to make a difference in the effectiveness of the content. One of the participants commented:

*I think a lot of the initial sessions were set out really well, so actually understanding a bit about CBT and the things about getting the terminology right, I think that's important to understand the rest of the app.*

Furthermore, there was also particular appreciation for when information was delivered concisely and not presented in large chunks, minimizing information overload:

*[QG] starts and stops so you can only do progress at certain stages. That's good, because it limits the amount of information you get all at one go.*

Users of SF did not comment on the style of information, as it provided a more traditional app style.

### Information Engagement

The majority of QG participants found the information and the introductory video, in particular, engaging:

*I find it really engaging, I suppose that's why I stuck with it.*

Building on that, participants noted that when engaged, they enjoyed learning, and it helped them understand the consequences of smoking:

*I...enjoy learning something new. It's quite informative and makes you think about what you're doing.*

*[QG] helps you to understand a bit more about what's going on...what could go wrong by continuing (to smoke).*

Some QG users reported difficulty in engagement as the app required time commitment for the audio features. Furthermore, repetition was conducive to loss of interest. One participant said:

*Three to four minutes...doesn't seem long at all but when you're listening to the guy it seems on for ages.*

Overall, a minority of SF participants found the SF information engaging. The participants noted that if they were engaged, they wanted to know what happened next in the app:

*I was just interested to see what badge came next...that's quite interesting in itself.*

However, SF users felt bored using the app:

*Bit bored by it and [did] not want to use it.*

### Quality of Information

Overall, the majority of QG participants were impressed by the quality of information. The QG content went beyond what the users expected, helping them understand the consequences of smoking. It was also well received when the content was found to be relatable, as users felt a more personal connection:

*It obviously isn't a tailored app to each person, but it gives enough information that each person can relate to it in a tailored way.*

Furthermore, it was also noted that when information debunked common myths, it had a larger impact on the user:

*They're talking about debunk a lot of the myths that tobacco companies put across, or corporate greed.*

Several SF participants stated displeasure in the quality of information provided in the app. SF users lost interest in the app when provided with information they already knew. Poor information quality seemed to leave a lasting impression on the participants:

*I think everyone has heard that information many times.*

*It's actually quite patronizing...shallow stuff, not hard hitting useful facts.*

### App Feasibility

Multiple users spoke favorably of the potential of mobile apps in providing therapy, commenting that apps are easy to access and use without the need for previous training or advice. The time commitment required is generally less than in the case of other treatment forms. It was further reported that mobile apps have the advantage of being low cost with a wide reach. Users also identified benefits because of the fact that one can receive treatment on one's own terms, independently, and with an element of privacy. This is echoed by the following statements:

*It's in your pocket, easily accessible. Available to a lot of people, all the time.*

*Less time commitment with a greater focus on the modern use of technology. It's the way to quit smoking that best fits into a modern person's life.*

Some users, however, identified that apps on phones are easily forgettable, and engagement often reduces over time. Moreover, the lack of human contact from a physician deemed mobile apps to be a less attractive option. One user said:

*I probably wouldn't want to use an app but would want to have personal contact with the doctor or trained physician.*

### App Effects

QG users noted a significant number of *changes in their perceptions*. Most participants reported that they had changed the way they thought about smoking to some degree. Many users appreciated the purpose of CBT and valued the way that CBT provided information and tools to make their own decisions and trained the brain to think in new ways. Participants reported that the app helped them explore their own smoking journeys

and was valuable in understanding psychological triggers and cues of why they smoked and reevaluate their smoking behavior:

*It links your thoughts to your behaviour. It worked. It questions why you do things rather than just when you just do it you just do it.*

*It's training your brain to think in new ways, to not associate certain things with certain things.*

*...this [QG] changes your mind.*

QG increased confidence in users who had previously perceived quitting as an impossible task such that they reported that quitting now seemed more feasible. Many QG users identified how the app had improved their willpower to quit smoking. In contrast, relatively few users reported decreased motivation to quit after the week, with one user reporting they felt a lot of effort needed to be inputted to feel engaged by the app:

*It has made me realise that it's more feasible to quit. It's not impossible.*

Some QG participants noted that labeling themselves as “non-smokers” as opposed to “ex-smokers” increased their confidence in their ability to quit smoking. One user stated:

*Yes it has given me confidence to stop smoking and focus on being a non-smoker not an ex-smoker.*

A small number of participants also displayed successful internalization as they reported that they applied a visualization exercise provided by the app in their day-to-day life. These participants emphasized that doing the exercise did not require direct access to the app. Referring to this exercise, one of the participants said:

*There is an exercise that you imagine yourself as a non-smoker and that you're going to an event - and everybody there is a non-smoker and you put yourself there. I really like that bit so I can actually take that exercise in my head and do that anywhere.*

The majority of participants expressed their desire to continue to use the QG app. Users reported talking about the app to friends and family:

*I found myself talking about it with the people as well trying to explain to them how it describes smoking and why would you do it and what it actually chemically does you know. This is almost like you're reeling off facts but they're quite interesting.*

A small number noted they were less likely to continue using the app, as mobile apps, in general, are easy to forget:

*It's not a thing that I'll remember daily.*

Users also reported enjoyment in using the QG app and in learning:

*I actually really enjoyed it.*

A number of SF users reported that they experienced no positive behavior changes after the use of the app. Most SF users stated that they would not continue to use the app further:

*I wouldn't say it's hugely changed my smoking habits.*

One user quit smoking on the first day of the study, reporting that they felt highly motivated to stop so that they could log being “smoke free” on the app. A few participants reported that the SF app itself increased the urge to smoke, resulting in an increase in smoking:

*[SF] can cause the urge to smoke.*

Most SF users reported the app to be ineffective with lack of impact. The lapse feature recurrently reminding users of slips in their smoking cessation journeys resulted in negative emotions. One participant stated:

*You feel a little bit like a loser.*

## App Improvements

Users of both apps recommended adding more personalized features to the apps. Such features included customized motivation scales or tailoring tips and a progress monitoring feature. One user stated:

*The tips are not necessarily very tailored to the person.*

QG users suggested improvements to the audio clips, some requesting shorter, more concise clips, and others suggesting videos for any text-heavy topics.

Many QG users recommended the addition of an in-app forum whereby users could have the opportunity to interact with other users for motivational reinforcement. One of the participants said:

*So having some sort of platform where everyone can just say, “This is how I stopped” or “This is how I'm trying to stop” and then other people giving feedback saying, “This is good” or, “This is not.”*

A few participants reported that a gaming aspect in the SF app would be a desirable attribute:

*Maybe if they had prior to like some type of like a mini game or something in there that would keep the mind occupied rather than telling you, “Don't smoke.”*

The SF users specified several individual improvements. Visualization, such as a graphical representations monitoring health, was deemed to be a key feature of an ideal app with a number of SF users. Some users also suggested regular health news updates such as smoking taxes and bans.

## Descriptive Statistics

Users of QG were, on average, more willing to use a smoking cessation app to manage their health, in comparison to SF users (Table 3).

In addition, participants having used QG for 1 week reported, on average, several positive behavior changes, such as increased motivation to quit smoking and reduction in the number of cigarettes smoked per day (Table 4). QG participants were similarly more likely to recommend the app, compared with SF participants.



**Table 3.** Numbers of users whose willingness to use a smoking cessation app to manage their health was high, moderate, or low, for each app. NHS: National Health Service.

Willingness to use smoking cessation app to manage health	Quit Genius (N)	NHS Smokefree (N)
High (increased willingness)	10	5
Moderate (no change in willingness)	4	4
Low (decreased willingness)	1	5

**Table 4.** Overall patterns of users' perceptions and health behavior change in relation to smoking cessation for each app.

Number of participants who:	Quit Genius, n (%)	NHS Smokefree, n (%)
Decreased number of cigarettes/day	8 (53)	2 (14)
Increased number of cigarettes/day	0 (0)	3 (21)
Showed increased motivation to quit smoking	8 (53)	5 (36)
Expressed desire to continue using app	10 (67)	5 (36)
Recommend the app	11 (73)	5 (36)

## Discussion

### Principal Findings

Five higher themes and several subthemes resulted from the thematic analysis. QG users were generally more positive and receptive with regard to the app's features, design, as well as information engagement and quality, compared with SF users. QG users also reported changing their perceptions and way of thinking with respect to smoking. It is possible that the root of this effect may lie in CBT, which gives users the opportunity to explore and change their thoughts and perceptions related to smoking.

On average, QG users also noted an increased willingness to use a smoking cessation app in general to manage health. They also showed increased motivation to quit smoking, as well as more willingness to continue using their allocated app after 1 week. These participants also showed changes in their smoking behavior although this was in the context of our limited sample, not allowing for the finding to be generalizable as of yet.

Several findings emerged in terms of the features of the apps and their relationship to behavior change.

A change in the manner of thinking about smoking was deemed important by participants with regard to a possible change in behavior. This was prominent in QG users, and it is possible that this is because of the app's use of CBT. Users reported that the app allowed them to question why they smoke, what smoking means to them, as well as their thoughts about quitting and why this is something they want to achieve. QG also allowed users to reframe the way they thought about themselves and their behavior in relation to smoking. For example, several QG users reported that perception-altering exercises such as labeling themselves as "nonsmokers" as opposed to "ex-smokers" helped them dissociate themselves from the behavior and contributed to a reduction in smoking in these users. No such effects were reported by the SF users.

QG users also reported that the CBT method contributed to their intrinsic motivation to quit, making them perceive themselves

at the source of their decisions and therefore feel empowered to take control of their own actions in relation to their journey to smoking cessation. This coincided not only with an increase in self-efficacy, that is, one's belief in one's ability to succeed in specific situations or accomplish a task [32] but also with an increase in behavioral control, that is, the level of difficulty an individual associates with a behavior [33]. Specifically, QG users reported that they believed the app had equipped them with increased confidence in their ability to quit, making the concept of quitting seems easier, more realistic, and thus more achievable. SF users did not report such a change in their belief related to their ability to quit smoking; many noted that the advice and tips provided by the app were already known and too generic. However, some SF users noted that just by downloading the app, they felt more equipped to quit than previously.

Although users of both apps understood and reported some of the benefits of smoking cessation, such as better health and saving money, SF users mostly felt that their knowledge was left unchanged, as the information provided, for example, regarding the harms of smoking, was generic and well known. Therefore, this had no impact on their understanding of the consequences of smoking. Conversely, QG users were positive about the effect on their knowledge, mentioning that reinforcement of the consequences at multiple points during the progress gave them greater motivation to quit smoking. This fits well with the health belief model [34-36], in which the perceived threat (in this case, the health hazards associated with smoking) plays a vital part in the individual's likelihood to engage in health-promoting behavior. Generally, users reported feeling bored using SF, which provided information already known to the users, whereas QG was seen as novel and informative. This is not surprising, as implementing CBT in such a gamified app is a new concept.

Users also highly commended QG for not using scare tactics to drive change in behavior but instead supporting and guiding users gently through the process. This goes against common literature that suggested fear-appeal and antismoking tactics are effective in promoting smoking cessation [37-39]. A possible

explanation in this study may be related to the fact that a large proportion of our participants were relatively young and, therefore, identified scare tactics as an out-of-date strategy, preferring to be given the information and opportunities to make their own decisions. Another reason may be that scare tactics make reference to information that is already vastly known to people about the dangers of smoking, but these tactics do not acknowledge the great difficulties associated with nicotine addiction and fail to provide practical support.

### Implications to Practice and Barriers to Implementation

The findings of this study suggest that a mobile app based on CBT was favorably perceived by users in terms of features, design, as well as information engagement and quality, in the context of smoking cessation. This was associated with changes in users' perception and thinking manner with regard to smoking. On average, users of the gamified CBT-based app also showed increased willingness to use a smoking cessation app, in general, to manage health, as well as increased motivation to quit smoking and positive changes in smoking behavior. A non-CBT-based mobile app was less favorably perceived, yet some users viewed some features and the app's interface as useful. Other apps based on therapeutic principles such as acceptance and commitment therapy (ACT), which has common elements with CBT, have also been developed and shown to be effective in smoking cessation [40].

Given the significant estimated smoking-related cost to the NHS (£2.6bn in 2015; [41]), the possibility of using mobile apps to influence health behavior may have implications in the current economic climate of health care, contributing to the growing use of mobile apps in this domain. Specifically, exploiting such advances in technology could contribute to the needed efficiency savings of 2% to 3%, compared with the current 0.8%, noted in the NHS England Five Year Forward Review, in the context of the £30 billion funding gap predicted to occur by 2020/2021 [42].

Further advantages of apps include opportunities for scalability across the NHS and eliminating postcode lottery issues, as well as the possibility of increased adherence to interventions because of the convenience of use. Indeed, the review suggested expanding the set of NHS-accredited health apps available to patients [43], whereby apps may even be prescribed as treatment or part thereof in the future.

However, reengineering processes to implement mHealth apps into daily medical practice, such as first-line treatment recommendations, will involve a rigorous change management process. A crucial aspect of this is ensuring that apps are compliant with privacy standards, as illustrated by the release and subsequent withdrawal of the NHS mHealth Applications Library pilot in 2013 because of noncompliance. mHealth apps have the capability to collect a vast amount of data, which can then be used to improve medical care in the future via predictive analytics and artificial intelligence. However, extensive security and privacy systems need to be put in place before apps can be confidently recommended.

Another possible barrier to wider use of mHealth apps is that of digital exclusion. A significant proportion of the population lacks Internet access or has low digital literacy. These tend to be the elderly, disabled, and ethnic minorities [43]. These populations require health care the most, hence exemplifying the inverse care law [44]. This barrier is continuously being tackled through the work of the Tinder Foundation, providing online resource training to 220,000 people [42].

Furthermore, even with Internet access and a sufficient level of digital literacy so as to be open to using a healthy living app, as is the case of 37% of UK individuals, only 3% use them [45]. This highlights that more research needs to be undertaken in exploring the factors that influence individuals' attitudes and behavioral intentions to use such apps. For example, previous research has shown that gamification, "the use of game design elements in nongame contexts" [46], can represent a highly effective way to engage users with mHealth apps [47]. Another important consideration is that, in the present study, users of not only SF but also QG stated that the lack of human contact from a trained health care worker made mobile apps less attractive as a single therapy form for them. This raises important questions in terms of the overall capabilities of CBT delivered via mobile apps. Such findings suggest the need for a study investigating both objective and subjective measures, as well as their interaction.

### Limitations and Future Research

There are a number of limitations to this study. First, because of time constraints, participants were only able to use and evaluate the apps for the duration of 1 week. Although it allowed for participants to form opinions on the themes explored, this short period prevented users from completing the programs offered by each of the 2 apps (8 weeks for QG and 4 weeks for SF), which would possibly have provided them with a more comprehensive impression of the apps and their effects. This period may also have been insufficient to determine the sustained effects of the apps. Therefore, the descriptive statistics we report are not necessarily an appropriate representation of the expected behavioral and perceptual effects which would be anticipated with the completion of the programs. Second, convenience sampling was used, where recruitment took place on a university campus, resulting in a sample of mostly university students with a mean age of 24.66 years. This may have led to a misrepresentation of the overall population, thereby bringing into question the transferability and generalizability of the conclusions. Third, the study lacked a control condition, against which the effects of each app on users' positive behavior change could be compared, so as to evaluate these effects more accurately.

Therefore, future studies should consider using a randomized controlled trial design in a larger, more representative sample with more varied demographic characteristics, running over a longer period of time, allowing for the completion of the programs offered by each of the apps. This would produce more generalizable, conclusive, and reliable results. After this, more in-depth research could address any differences in behavioral changes elicited by the use of the app(s), as well as the effect of increased options for tailoring and personalization on

measures of behavioral change and adherence. Numerous health care offerings are being digitally transformed. Yet, important questions remain about effective user engagement across different digital platforms [48,49], and the potential of digital health solutions [50] for improving people's lives and enhancing their willingness to recommend new digital solutions to family, friends, and colleagues [51,52]. Additional research into the understanding of psychological barriers to adoption of new mHealth solutions and technologies that can inform the design and communication of new mobile health care solutions to facilitate behavior change is richly deserving.

### Conclusions

In conclusion, investigating the results of the thematic analysis carried out in this study revealed a generally more positive attitude of QG users with regard to the app's features, design, as well as information engagement and quality, compared with SF users. QG users also reported changing their perceptions and way of thinking with respect to smoking, and noted, on average, increased willingness to use a smoking cessation app

in general to manage health, as well as increased willingness to continue using their allocated app, and increased motivation to quit smoking after 1 week of app use. On average, these participants also showed changes in their smoking behavior although, of note, this was in the context of our limited sample, not allowing for the finding to be generalizable as of yet. It is possible that the root of these effects may lie in CBT, which gives users the opportunity to explore and change their thoughts and perceptions related to smoking.

This suggests that CBT has the potential to work effectively in the context of a gamified mobile app for smoking cessation; however, future research involving wider distributed samples and longer periods is required to draw more generalizable conclusions. The findings also suggest that a mobile app must be well developed, preferably with an underlying behavioral change mechanism, to promote positive perceptual and health behavior change in the context of smoking cessation. The potential of digital CBT delivered through a gamified mobile platform should be seen as a powerful tool to overcome current health care challenges.

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### Authors' Contributions

NA, MC, MJ, KK, VK, TP, and MS collected, coded, and synthesized the qualitative study data and wrote a preliminary version of the manuscript. CT-S, RR, MN, and YL edited the manuscript. MA, YS, SS, and ABE provided valuable suggestions and input on improving the manuscript. YS, MA, SS, and CT-S were not involved in collecting, coding, and synthesizing qualitative study data.

### Conflicts of Interest

YS, MA, and SS are cofounders of Digital Therapeutics Ltd. CT-S is an employee of Digital Therapeutics Ltd.

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## Abbreviations

- ACT:** acceptance and commitment therapy
- mHealth:** mobile health
- NCD:** noncommunicable disease
- CBT:** cognitive behavioral therapy
- NHS:** National Health Service
- QG:** Quit Genius

**SF: NHS Smokefree**

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Original Paper

# Incorporating a Static Versus Supportive Mobile Phone App Into a Partial Meal Replacement Program With Face-to-Face Support: Randomized Controlled Trial

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## Abstract

**Background:** Mobile phone apps may be acceptable to users and could improve retention and adherence over more traditional methods, but there is mixed literature supporting their efficacy. In the weight management space, very little is known about how a mobile phone app integrating features beyond text messaging (short message service) can affect behavior, particularly when combined with face-to-face support.

**Objective:** The objective of this study was to examine the effectiveness of a mobile phone app when combined with a partial meal replacement program including face-to-face support. This paper compares a static versus supportive app over a 6-month randomized trial for effects on weight loss, weight-related biomarkers, and psychological outcomes.

**Methods:** Overweight and obese adults (71.2% female, 104/146; mean 48.11, SD 11.75 years) were recruited to participate in the weight loss study, and they were randomized on a 1:1 basis using a computer algorithm. The supportive app (n=75) provided information, food intake recording, rewards, prompts for regular interaction through reminders, and the opportunity to review personal compliance with the dietary program. The static app (n=71) included only recipes and weight loss information. Both groups received equal amounts of face-to-face support in addition to app.

**Results:** The overall reduction in app usage over 24 weeks was lower for the supportive app in comparison with the static app; approximately 39.0% (57/146) of the users were still using the app at week 24. Despite the promising results for app usage, there were no differences in weight loss between groups ( $F_{1,128.12}=0.83$ ,  $P=.36$ ). However, it should be noted that almost 60% (49/84) of all participants lost 5% or more of body weight during the trial. No weight-related biomarkers were significantly different between groups. Both groups experienced an increase in positive mood, but this was significantly higher for those who received the static app ( $F_{1,118.12}=4.93$ ,  $P=.03$ ).

**Conclusions:** Although the supportive app was well received by users, we found little evidence of the added benefit of this versus the static app in combination with face-to-face support in a community-delivered weight loss program. Future versions of the app may incorporate more unique behavioral techniques beyond those provided by the consultant to improve the potency of the app.

**Trial Registration:** Australian New Zealand Clinical Trials Registry ACTRN12613000547741; <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=364187> (Archived by WebCite <http://www.webcitation.org/6yivwfmI9>)

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**KEYWORDS**

mHealth; weight loss; diet

## Introduction

### Mobile Phones and Weight Loss

There is growing interest in the possible role mobile phones could play in supporting health behavior change [1,2]. A review of literature suggests that text messaging (short message service) could be effective as an adjunct to behavior change interventions [3]. In the domain of weight control, results reported from a year-long study were promising, with close to 3.5 kg higher weight loss in an intervention group receiving mobile support relative to a no intervention control [4].

Mobile phone apps may be acceptable to users and could improve retention and adherence over more traditional methods of weight loss [5], but there is mixed evidence supporting their efficacy [6,7]. A 12-month intervention using a personal digital assistant (PDA) to support a standard weight loss program reported 3.1% more weight loss in the intervention group when compared with a standard care group [8]. Unlike other trials that included no in-person support [6,7], this intervention included face-to-face support in addition to mobile support through the PDA. Other studies also suggest that combining in-person support with technology may be an effective method for delivering weight management programs. Over 30 months, Svetkey et al [9] observed that the effect of technology looked promising during the early stages but described this effect as “transient” with brief, regular personal contact ultimately more effective at assisting participants with sustained weight loss. Therefore, it is unclear whether apps can be a useful adjunct for weight loss interventions when combined with face-to-face or in-person support.

### Combining Mobile Phones With Traditional Methods

Incorporating mobile phone technology with face-to-face contact does potentially minimize cost-effectiveness and reach associated with exclusively technology-driven programs. However, if outcomes can be improved, and the face-to-face contact can be delivered using a method maximizing reach, then this may balance the advantages and disadvantages of both modes of program delivery. A pharmacy environment provides a practical solution as they are readily accessible for a large number of people [10]. Therefore, it was our aim to develop a supportive weight control program that incorporated in-pharmacy delivery through a trained pharmacy assistant as well as a mobile phone app designed to be an adjunct to the wider program by assisting users in monitoring their progress and staying motivated between face-to-face visits. This paper will describe the mobile phone app and the results comparing a supportive versus static app during a 6-month trial of the weight loss program. It is hypothesized that for a group of dieters following a partial meal replacement program including face-to-face support, an interactive and supportive app will be more effective for weight loss than a static app. A partial meal replacement program was chosen as the basis for the weight control program because these diets provide simple dietary prescriptions and demonstrate good weight loss results [11]. At the same time, these programs can also be challenging because they provide little flexibility and limited variety (most meals are in the form of milkshakes). Therefore, the addition of

electronic support could have an effect on the overall efficacy of these programs.

## Methods

### Description of the Trial

This study was a 24-week randomized controlled trial (ACTRN12613000547741), including a 12-week active intervention period followed by a 12-week free-living period. The research was approved by the CSIRO Human Research Ethics Committee (Approval 12/14). All participants signed formal consent forms before their participation in this trial.

A detailed description of the method has been published elsewhere [12]. Briefly, participants were asked to follow a partial meal replacement program, and during the initial active period, they received personalized advice from a trained consultant about how to incorporate high-protein meal replacement shakes (manufactured by Probiotec Pty Ltd) and high-protein meals into their lifestyle. Meal replacements were provided for the first 4 weeks, and then the participants were required to purchase them (Aus \$1 per sachet) for the remainder of the study period to attempt to better simulate a pharmacy environment. Participants were randomized to one of the 2 groups that received mobile phone apps differing in the number of monitoring tools and supportive features they contained (described in detail below). Both groups received the same level of face-to-face support and the same weight control program. Apps were purpose-designed for the trial and installed manually on the participants' phones at their first visit.

### Conditions

#### *Intervention and Supportive App*

The Weight Management Program (WMP) app was designed to support participants' behavior modification during the partial meal replacement program by providing information, simplifying food intake recording, rewarding positive behavior, and prompting regular interaction through reminders. The features included were selected based on both behavioral theory and successful behavior change techniques, as well as dietetic methods associated specifically with weight loss programs (ie, dietary compliance feedback) and app design features known to improve engagement, such as gamification, through the award of medals.

For purposes of the trial, the prototype WMP was implemented as a native app for iPhones running iOS 6 or later. Upon download, users set up an account entering a username, their starting weight, a weight loss goal, and by when they wish to achieve the goal.

The WMP home screen included a dashboard access to the tools and services provided in the app (Figure 1). At log-in, each day the users were presented with a randomly selected motivational message or thought for the day on the home screen. Some of these messages were as follows: “Planning ahead will help you to stick to your goals,” “Don't focus on your failures, learn from them,” and “All great achievements take time. Hang in there.” These messages were developed based on the health action process approach of behavior change and included messages to



initiate behavior (action-planning) and manage setbacks (coping planning) [13].

The home screen showed a summary of progress, including weight loss and medals received. Dietary information specific to the program was presented in the Information section of the app indicated by the “i” icon on the top left-hand side (Figure 1).

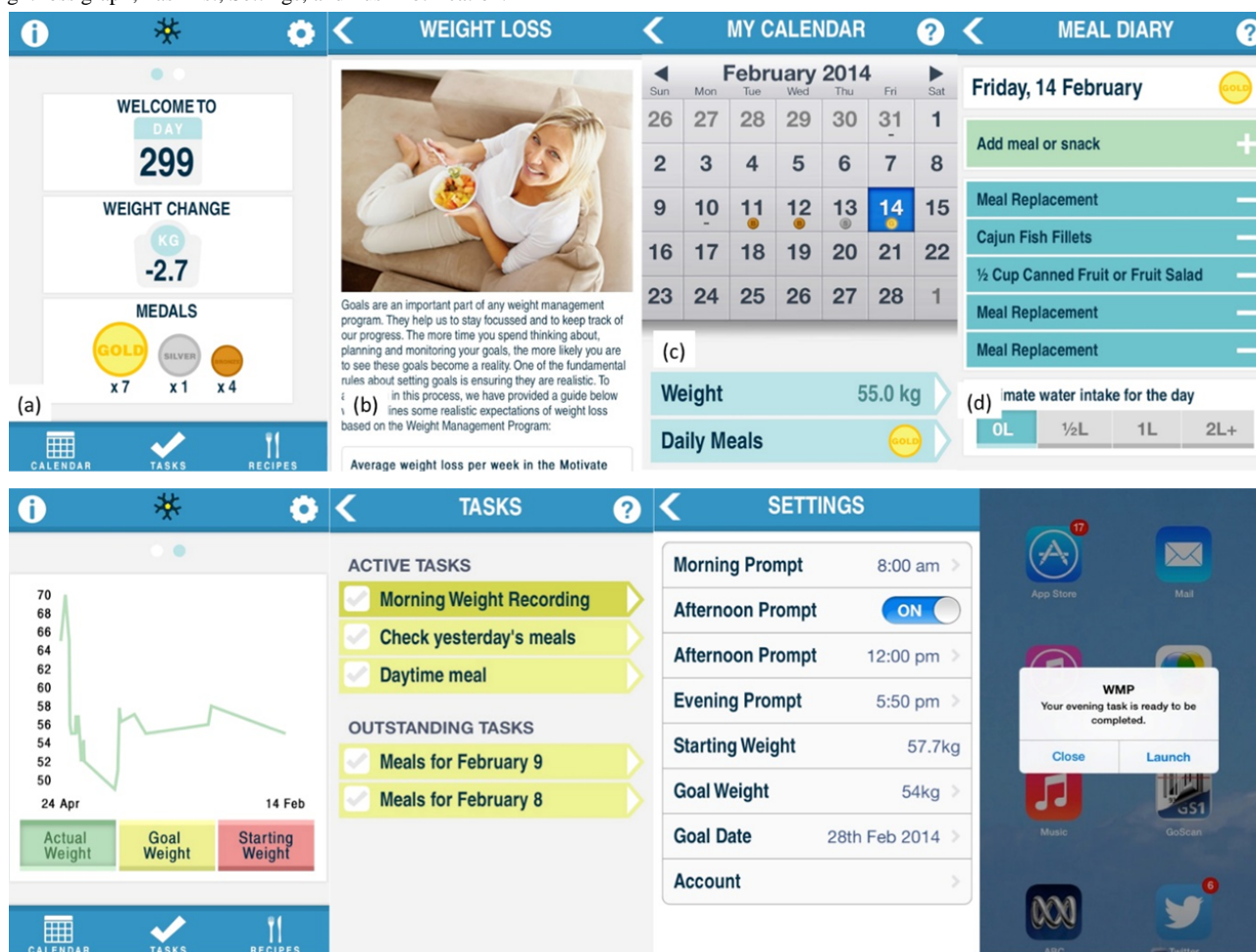
The WMP app provided monitoring tools for weight and food, and it communicated weight loss progress and compliance visually and through virtual rewards. Self-monitoring is considered one of the most effective strategies for behavior change [14]. Recording meals involved the selection of menu items from a list of categories, including Program Meal, Non-program Meal, Meal Replacement, Program Snack, Mini Program Snack, Non-program Snack, and Treat, as outlined in the dietary program. The app included a recipe library of program compliant meals and snacks.

Daily compliance is an essential part of any weight management program. Compliance to the partial meal replacement program was communicated to users through the receipt of gold, silver, and bronze medals, which reflect how well the recorded food intake met the daily guidelines specified by the weight control

diet (Figure 1). Medals were also used to add an element of gamification, which has been shown to improve user engagement in other behavioral domains [15]. A gold medal indicated that the guidelines were met, a silver medal indicated that the intake was close to the guidelines, and a bronze medal indicated that some progress toward the guidelines was made. No medal was rewarded if a minimal amount of information was entered, or if a user was well short of the dietary prescriptions. A snapshot of daily intake was shown on the Calendar screen. Users’ weight loss was summarized on the home screen for convenient reflection and presented graphically in a separate section (Figure 1).

The app generated 3 daily task prompts (morning, afternoon, and evening) to encourage self-monitoring. Morning tasks required completion of the meal diary for the previous day and the recording of weight. The afternoon and evening tasks asked the users to update their food diary (Figure 1). Prompt times for tasks were customizable, and afternoon tasks could be disabled by the user. These prompts were all designed to promote closer self-monitoring of progress (weight) and compliance (food diary), and they appeared through push notifications.

**Figure 1.** Screenshots of the supportive app showing the Weight Management Program (WMP) home screen; Information; Calendar; Meal diary; Weight loss graph; Task list; Settings; and Push notification.



### **Control App**

The control/static app did not include any recording tools (weight or food) or any tasks. It provided information about the program only, including the detailed recipes. It had the same visual appearance as the home screen on the intervention app with only the recipes button, the day number, and the information button.

### **Participants and Outcome Measurements**

Overweight and obese adults (aged 18 years and above) were recruited via an established clinic database and local media in Adelaide, South Australia, between March and August 2013. The recruitment process has been published in detail elsewhere [12]. Based on our previous pilot study [6], 61 completers were required to have 80% power to detect a 2.5% difference in weight loss between the 2 groups. To account for participant withdrawals, more than 122 participants were recruited. Based on a drop-out of 20% [6], we aimed to recruit 148 overweight or obese adults. A screening questionnaire was reviewed against eligibility criteria, which included having a body mass index (BMI) greater than 25 kg/m<sup>2</sup> (based on the self-reported height and weight), access to an iPhone, and willingness to have a pin-prick blood glucose and lipids assessment on 4 occasions at the purpose-built trial clinic. This clinic was designed to replicate a pharmacy environment. On the basis of responses to a medical screener administered by the trial manager, people with known medical conditions, such as diabetes and cancer, were excluded from the study.

### **Objective Outcomes**

The primary outcome measures were percentage weight loss from baseline and changes in blood pressure, fasting blood glucose, and fasting blood lipids (total cholesterol, low-density lipoprotein [LDL], high-density lipoprotein [HDL], and triglycerides). These were measured at baseline; week 2 (weight only); and weeks 4, 12, and 24 (Figure 2). The point-of-care measures were all assessed via a finger prick using AccuCheck devices (Roche Diagnostics Australia, New South Wales, Australia).

### **Psychological Measures**

Given the supportive nature of the intervention app, a series of psychological outcomes were included to assess any differences between the 2 apps in terms of changes in mood (positive and

negative affect schedule [16]) and stress levels (Perceived Subjective Stress Scale [17]). Given their potential to drive behavior according to the theory of planned behavior, changes in intention and perceived control [18] for continuing the diet program and the intention to continue using the app were also compared between apps.

### **App Usage**

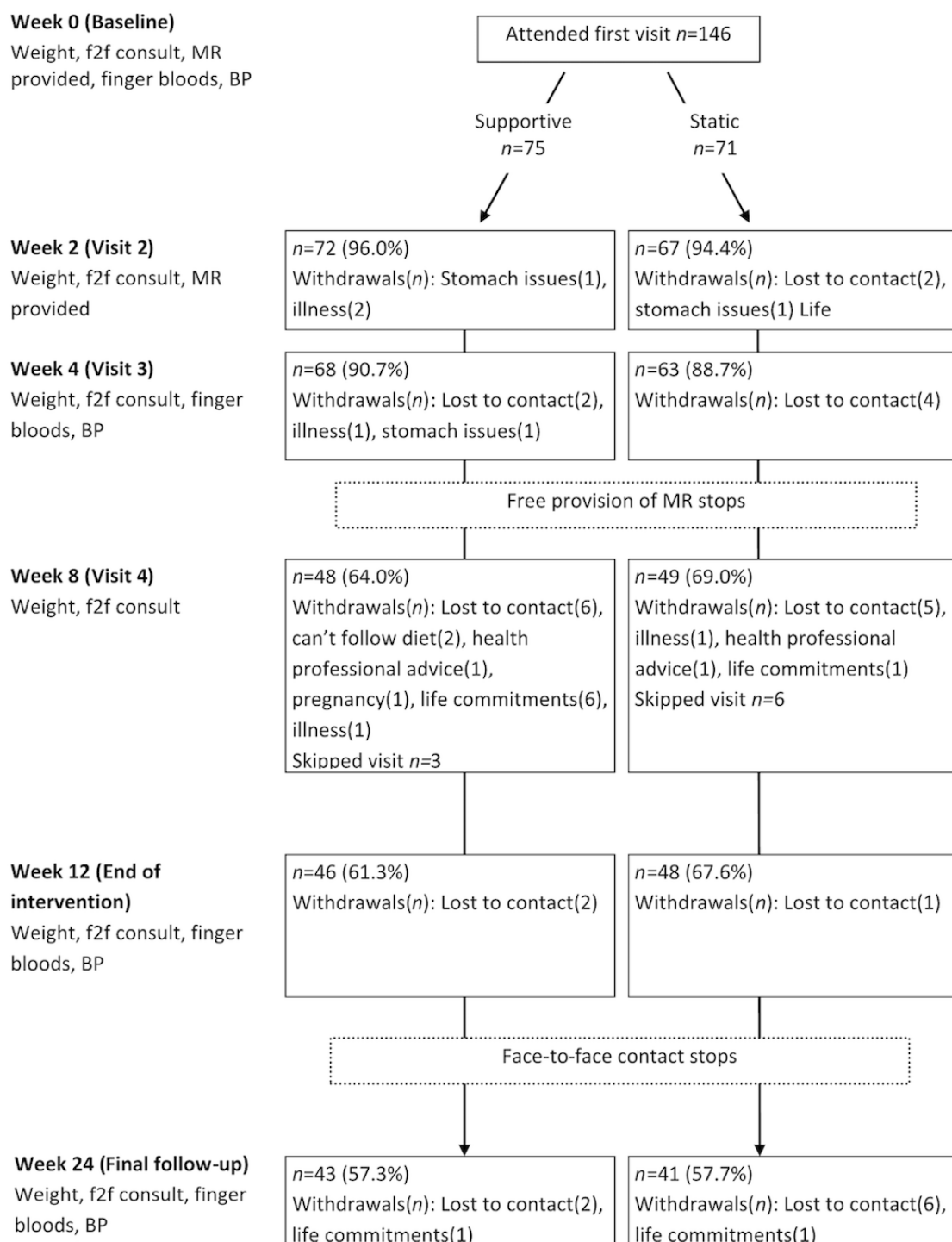
These data were collected objectively through the logs and database associated with the apps.

### **Statistical Methods**

All analyses were performed in SPSS version 23 (IBM, Armonk, New York, US). Usage data were aggregated and analyzed using descriptive methods and then compared using general linear models, where appropriate. Mixed models were used to answer the primary hypothesis. These models were designed to assess differences between app condition (main effect) and the interaction between app condition and study week for outcomes, including percentage change from baseline weight, self-reported frequency of weighing, self-reported dietary compliance, and changes in psychological and blood measures (from baseline). All mixed models controlled for participants' sex, baseline weight (percentage weight change model excepted), and age (in years). Mixed models included all available data and, therefore, were considered an intention-to-treat method of analysis. The numbers presented in the results section are means with standard errors unless otherwise stated. Significance tests were set at  $P < .05$ . Due to errors in readings, 3 recordings of cholesterol and 1 for blood glucose were deleted from the final analyses and entered as missing values.

### **App Bugs During the Trial**

Two major technical errors occurred while the trial was underway. Database errors occurred during the first weekend of the trial, which affected only those in the intervention group. Seven users reported problems relating to this. This issue was resolved within 5 days of the initial report. The second technical fault occurred approximately 7-8 weeks after the trial commencement and affected all users. It pertained to an expired enterprise certificate. Five users reported errors relating to this. This fault was resolved within 5 days, and users were asked to reinstall an updated version of the app. They could do this remotely during their visit to the clinic.

**Figure 2.** Participant flow diagram. BP: blood pressure; f2f: face-to-face; MR: meal replacement.

## Results

### Participant Description

None of the participant demographics were significantly different between the 2 app groups (Table 1). Most participants were female, had a diploma or a technical certificate, had owned an iPhone for 12 months or longer, and were classed as obesity category 2 according to BMI.

Dropout by the end of week 24 was 42.5% (58/146; Figure 2). There were no differences in attrition between app groups at any week of the study. The greatest dropout occurred after

cessation of the provision of free meal replacements. Most dropouts (42%, 24/58) were lost to contact and, therefore, provided no reason for stopping their participation. In total, 14 visits were skipped throughout the trial. This meant that participants returned after missing a visit and, therefore, had missing data for these skipped visits.

### System Usage

Half of the control group was still using the app at week 12 compared with 72% of those using the intervention app. During the free-living period, usage of the app continued to fall in both groups, with approximately 39% and 9% of the intervention

and control groups, respectively, still using the app by the final week of the study (Figure 3). According to univariate analysis of variance, the percentage of days that people interacted with the app (days with interactions/total trial days) was significantly different between groups, with this number higher in the intervention group (43.1%) compared with the control group (11.1%;  $F_{1,144}=83.30$ ,  $P<.001$ ).

Negative binomial models suggested that the total number of days an interaction occurred varied significantly between the groups (Wald  $\chi^2_{1,144}=64.9$ ,  $P<.001$ ), with the intervention group having an average of 72.4 (SE 8.4) days and the control group having 18.7 (SE 2.3) days out of a possible 168 days of interaction (Figure 4). The recipes were the central feature of the control app, but the intervention group actually viewed the recipes on more days (23.5 [SE 2.8] vs 8.5 [SE 1.1]; Wald  $\chi^2_{1,144}=35.0$ ,  $P<.001$ ). There was no difference between groups for the number of views of the content providing information on the weight control program, which generally had a low average uptake across the sample (8.90 [SE 0.63]). For the

intervention group, the most commonly used features were weight entry and food diary (Figure 5).

To compare engagement levels between the 2 apps, the number of views of the weight control program information and the recipes were compared between groups because these were the only actions that appeared in both apps. The number of active days (a day where a recipe- or information-viewing action occurred) was plotted against users' membership duration (the number of days between enrolment and last logged use of the app). For both groups, there was a positive trend—the longer the membership, the more days with interactions (Figure 6). Users of the supportive app showed higher viewing activity of the recipes and information content.

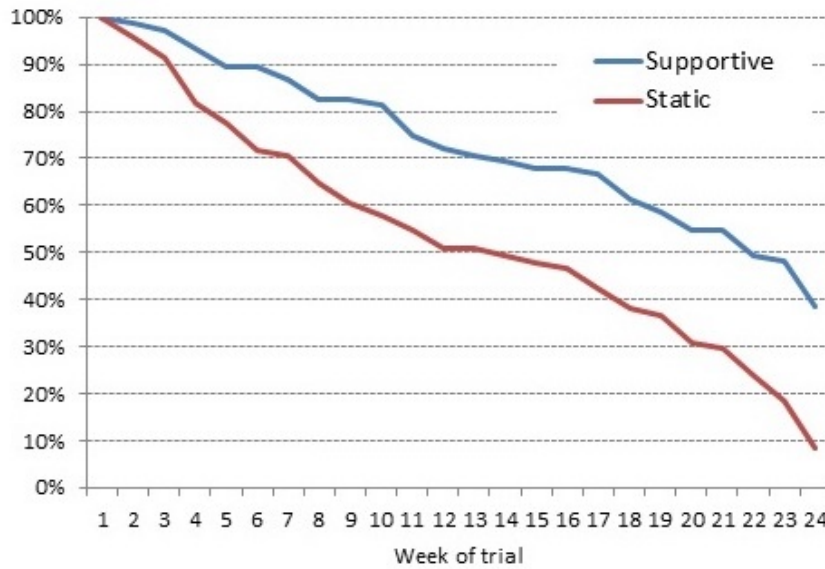
### Motivation to Use the App

Corresponding to higher usage data, those with the supportive app also had a smaller pooled decrease in their intention to use the app provided (−0.90 [SE 0.22]) relative to those in the control condition (−2.89 [SE 0.21];  $F_{1,113.72}=46.53$ ,  $P<.001$ ). This effect did not interact with week of the trial ( $F_{3,90.34}=1.36$ ,  $P=.26$ ).

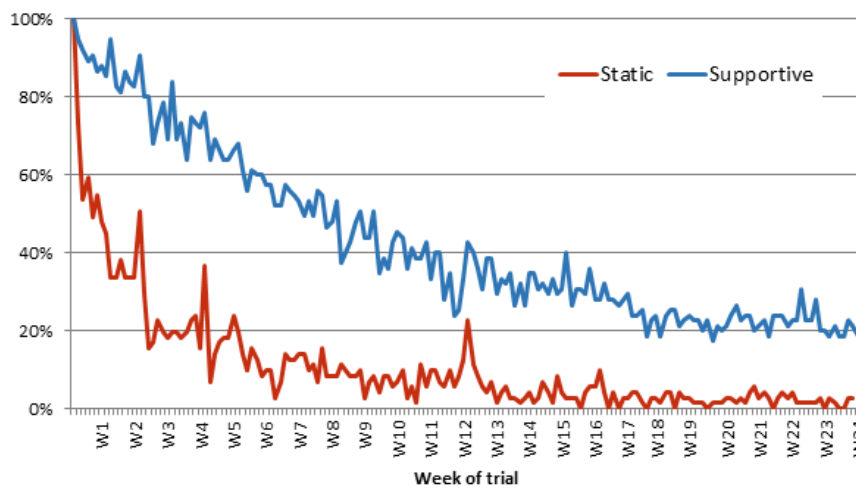
**Table 1.** Participant demographics and starting characteristics. DPB: diastolic blood pressure; HDL: high-density lipoprotein; LDL: low-density lipoprotein; SBP: systolic blood pressure.

Characteristics	Supportive app (n=75)	Static app (n=71)	Total (n=146)
Sex (female), n (%)	55 (73)	49 (69)	104 (71.2)
Age in years, mean (SE)	48.57 (1.30)	47.76 (1.46)	48.18 (0.98)
<b>Education, n (%)</b>			
Below secondary school	1 (1)	1 (1)	2 (1.4)
Secondary school	17 (22)	22 (31)	39 (26.7)
Technical certificate/Diploma	30 (40)	25 (35)	55 (37.7)
Bachelor's degree	16 (21)	12 (17)	28 (19.2)
Postgraduate degree	11 (15)	11 (16)	22 (15.1)
Owned phone for >12 months, n (%)	61 (81)	50 (70)	111 (76.0)
<b>BMI category, n (%)</b>			
Overweight (25-30)	15 (20)	12 (17)	27 (18.5)
Obese category 1 (30-35)	22 (29)	29 (41)	51 (34.9)
Obese category 2 (35+)	38 (51)	30 (42)	68 (46.6)
<b>Starting measures, mean (SE)</b>			
Weight (kg)	100.68 (2.16)	99.14 (2.38)	99.93 (1.60)
DPB (mmol/Hg)	80.14 (1.12)	77.84 (1.13)	79.02 (0.80)
SBP (mmol/Hg)	128.43 (1.70)	127.76 (1.72)	128.10 (1.21)
Total cholesterol (mmol/L)	4.55 (0.14)	4.90 (0.16)	4.72 (0.11)
Triglycerides (mmol/L)	1.13 (0.07)	1.20 (0.07)	1.16 (0.05)
LDL (mmol/L)	2.68 (0.10)	2.92 (0.10)	2.80 (0.07)
HDL (mmol/L)	1.37 (0.05)	1.36 (0.05)	1.36 (0.04)
Glucose (mmol/L)	4.78 (0.11)	4.52 (0.12)	4.65 (0.08)

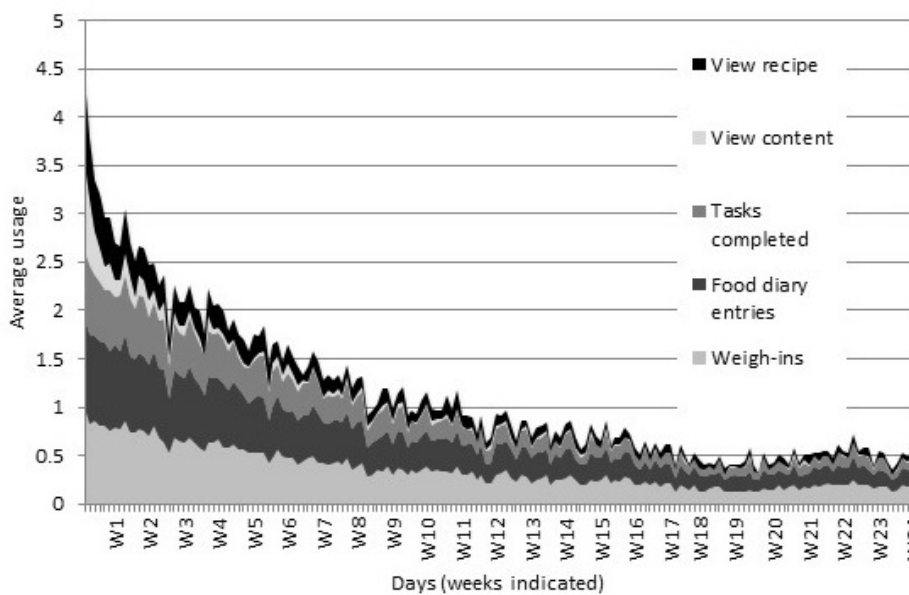
**Figure 3.** Nonuse attrition of users by app condition throughout the 24 weeks of the trial.



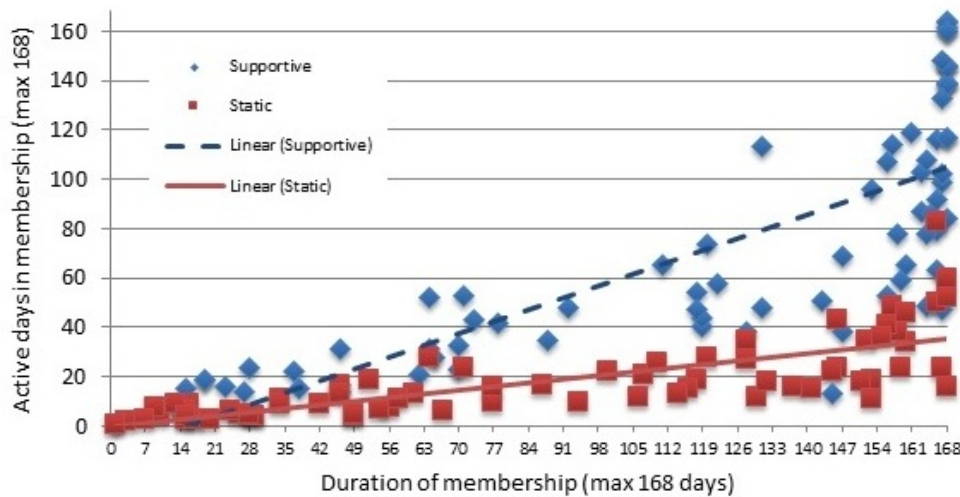
**Figure 4.** Number of active sample logging in for each day of the trial presented by app condition as a percentage of active (not-withdrawn) users.



**Figure 5.** Consumption of different app features for the supportive and intervention app throughout the 24 weeks of the trial.



**Figure 6.** User engagement for both app conditions over the membership duration (number of days between enrollment and last logged use of app).



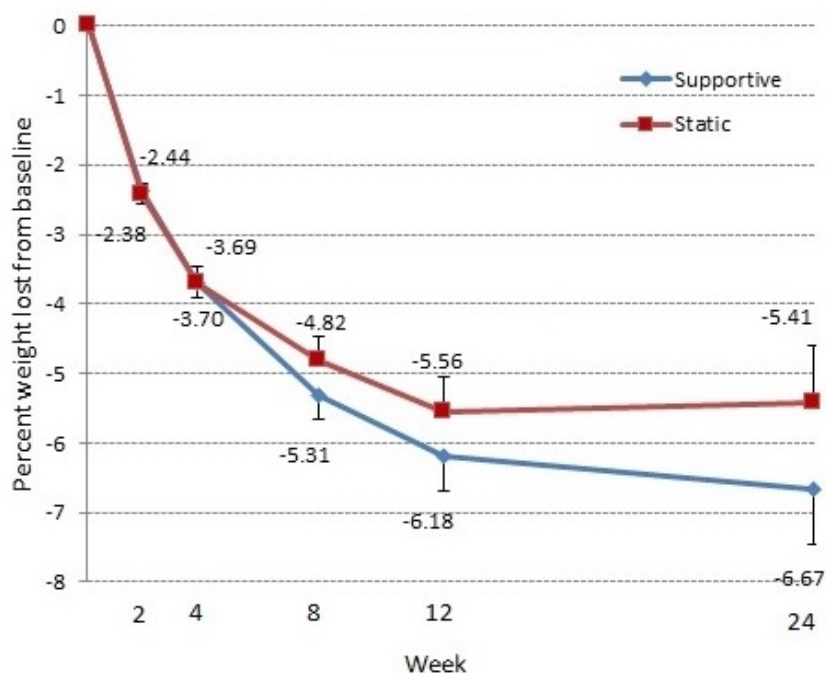
**Percent Weight Change From Baseline**

By week 24, those in the supportive and static app conditions lost 6.67% and 5.41% of their baseline weight, respectively (Figure 7). There were no differences in weight by the different app condition ( $F_{1,128,12}=0.83, P=.36$ ) or for the interaction between week and app condition ( $F_{4,99,94}=0.86, P=.49$ ). There was a main effect for sex with males (5.01 [SE 0.32]) losing more weight than females (4.22 [SE 0.26];  $F_{1,135,06}=8.88, P=.003$ ). The number of people losing 5% or more of their body weight (a clinically relevant amount of weight) also did not vary by app condition ( $\chi^2_{1,83}=0.2, P=.69$ ). Of the 84 completers, 58% ( $n=49/84$ ) lost 5% or more of their body weight. Those with the supportive app (3.67 [SE 0.10]) reported weighing themselves more frequently than those with the control app (2.90 [SE 0.21];  $F_{1,129,27}=29.74, P<.001$ ).

**Dietary Compliance**

Perceived dietary compliance (score out of 10) decreased steadily throughout the trial (week 2=9.26 [SE 0.16]; week 4=8.48 [SE 0.19]; week 8=7.47 [SE 0.28]; week 12=7.1.8 [SE 0.27]; and week 24=6.08 [SE 0.28]) but did not vary by app condition ( $F_{1,117,84}=0.92, P=.34$ ). It was possible to receive dietary compliance feedback daily over the 24-week intervention period (a possible 168 days). Those in the intervention group received some form of dietary compliance feedback (a gold medal, a silver medal, a bronze medal, or no medal) on an average of 76 days. Of all the medals awarded, 26.6% were gold. Interestingly, the number of gold medals received throughout the trial was moderately associated with weight loss at the end of the trial ( $r=.461, P<.002$ ).

**Figure 7.** Percentage weight loss from baseline results for each condition presented for each clinic visit throughout the trial. Bars represent 1 standard error.



**Table 2.** Adjusted means for changes in study outcomes for each of the app conditions and results from mixed models for the main effect of treatment and the interaction effect of treatment and study week. DPB: diastolic blood pressure; HDL: high-density lipoprotein; LDL: low-density lipoprotein; SBP: systolic blood pressure.

Measures	Supportive <sup>a</sup>	Static <sup>a</sup>	Treatment		Treatment by week	
	Mean (SE)	Mean (SE)	F (degrees of freedom)	P value	F (degrees of freedom)	P value
<b>Blood-related</b>						
SBP (mmol/Hg)	-5.81 (1.03)	-5.76 (1.02)	≤ 0.00 (1,109.54)	.97	0.50 (2,95.88)	.61
DBP (mmol/Hg)	-2.72(0.94)	-2.56 (0.93)	0.02 (1,107.89)	.90	1.88 (2,92.95)	.16
Total cholesterol (mmol/L)	-0.51 (0.09)	-0.49 (0.09)	0.03 (1,108.75)	.86	0.10 (2,88.81)	.90
Blood glucose (mmol/L)	-0.07 (0.07)	-0.21 (0.07)	2.34 (1,114.96)	.13	0.44 (2,91.42)	.64
Triglycerides (mmol/L)	-0.07 (0.04)	-0.13 (0.04)	1.42 (1,104.50)	.24	3.00 (2,81.47)	.06
LDL (mmol/L)	-0.22 (0.07)	-0.24 (0.07)	0.04 (1,94.44)	.84	0.02 (2,78.28)	.98
HDL (mmol/L)	-0.14 (0.03)	-0.11 (0.03)	0.45 (1,120.36)	.50	0.42 (2,83.35)	.66
<b>Psychological</b>						
Intention (diet)	-0.77 (0.16)	-0.67 (0.16)	0.23 (1,116.57)	.63	0.80 (3,86.68)	.50
Behavioral control (diet)	-0.31 (0.09)	-0.07 (0.09)	3.72 (1,99.07)	.06	0.78 (3,91.59)	.51
Positive affect	0.09 (0.69)	2.17 (0.69)	4.93 (1,118.12)	.03	1.33 (3,92.67)	.27
Negative affect	-1.61 (0.69)	-0.87 (0.68)	0.64 (1,104.85)	.43	0.73 (3,88.16)	.54
Weight loss self-efficacy	25.68 (3.1)	23.81 (3.12)	0.20 (1,122.18)	.66	0.99 (3,91.51)	.40
Subjective stress	-1.08 (0.63)	-1.16 (0.63)	0.01 (1,119.33)	.93	2.35 (3,93.56)	.08

<sup>a</sup>Means are presented with 1 standard error. Means are adjusted for participant age and sex and baseline weight.

## Blood Measures

None of the blood outcomes were significantly different in any of the mixed models (Table 2).

## Psychological Measures

Overall, changes from baseline suggested a consistent decrease in perceived behavioral control and intention to stay on the diet. However, app condition had no differential influence on these outcomes (Table 2). The only psychological measure to be significantly associated with app condition was positive affect. Adjusted mean values suggested that those receiving the static app had a larger increase in positive affect than those with the supportive app.

## Discussion

The aim of this randomized controlled trial was to compare the effect of 2 apps included as part of a weight control program to assess whether a supportive app could improve participant outcomes, including weight, risk factor indicators (such as cholesterol), psychological outcomes (such as mood and motivation), and app engagement. Despite promising results for user engagement (higher usage of the supportive app relative to the static app), we found few differences in the other outcomes assessed between the 2 apps over the 6-month trial.

## Key Findings

The app was one part of a much larger weight control intervention, which also involved face-to-face support and a prescriptive diet program [12]. It may be the case that the additional benefit of the face-to-face contact in the context of

the current program limited the ability of the app to have a significant influence on the outcomes assessed. Although positive results have been previously reported using PDAs [8], it is difficult to determine how useful additional mobile phone support is for a variety of styles of weight management programs (calorie counting, group-based, etc).

The apps had significantly different effects on positive affect. Both groups experienced an overall increase in positive affect. However, this was significantly higher for those who were allocated to receive the static app. The direction of this difference was opposite to that seen when comparing similar apps in a previous study [6] and therefore puzzling—especially when paired with objective user data that suggest that those with the static app were not using their app, and subjective reports indicating lower intent to use the app in the control group. Virtual support through apps and other electronic health (eHealth) tools may be the most effective at different stages of behavior change, with face-to-face support being more effective at other times [9]. It may be the case that participants in the static group relied more heavily on the in-person support. All the consultants were trained to provide standard care to each participant. Unfortunately, the amount of face-to-face support that participants received was not recorded or evaluated as part of this trial.

The study retention below 60% and nonuse attrition (less than half still using the app by the end of the study) warrant discussion. We attempted to better replicate a pharmacy environment by including a small cost impediment after an initial weight loss period of 4 weeks. We witnessed a spike in attrition at this point, and this may have inflated our total

dropout rate relative to other trials. Including a cost impediment for the meal replacements may have also reduced the weight loss observed as the provision of free products can improve weight outcomes [19]. Fortunately, dropout did not differ between the app groups. Furthermore, the use of intention-to-treat analysis method optimizes statistical power by accounting for missing data. Although nonuse attrition appears high for both of our apps, other studies have seen similar rates in more sophisticated Web-based programs [20]. Indeed, weight management programs, in general, suffer from poor retention and engagement [21].

### Study Strengths and Weaknesses

This study has various strengths that help establish the integrity of its findings. It was a randomized trial, which assessed multiple outcomes through tightly controlled standard operating procedures, and used mostly validated and objective measures. The study also included a variety of outcomes relating directly and indirectly to weight management. Finally, despite witnessing minimal differences between the 2 app conditions, the participants appeared to lose weight, with a majority of completers losing 5% or more of their body weight (a clinically significant amount) by the end of the trial. This suggests that the wider weight control program was successful at promoting weight loss for those retained.

The app targeted specific, evidence-based behavior change techniques considered absent in many commercially available apps [22]. There is little doubt that weight self-monitoring is related to successful weight management [23], and there was a suggestion that the intervention app improved the frequency of weighing. Likewise, the intervention app also successfully targeted diet monitoring—also considered important for weight management [24]. Yet, these behaviors did not translate to

observable differences in weight, contrary to previous studies [25]. Weight monitoring may be most effective when combined with feedback [26]. We provided graphical weight summaries to users, but minimal other feedback relating to the weight entries. A future app could target additional behavioral techniques such as contingency planning and problem solving to improve outcomes [27]. Elements of user experience are also likely to improve engagement and, therefore, weight loss. Mining of large amounts of data from a health app also suggests that weight loss success is greater when users can customize features within an app [28]. However, only future controlled trials will reveal the efficacy of these techniques in combination with face-to-face support.

The limitations of this study, such as the restriction to iPhone users, its focus on dietary intervention (more so than exercise) and the primarily female sample have been reported in other similar trials [6] and are unlikely to account for the null effects observed. Although additional features may improve the potency of the supportive app in the future, it remains possible that a supportive app alone is not enough to dramatically influence weight-related outcomes when combined with the support provided in person. Future trials will need to assess the effect of combining multiple forms of support relative to usual care in a community-delivered weight management program.

### Conclusions

We found little evidence of the added benefit of a supportive versus static app in combination with face-to-face support in a clinically delivered weight loss program. Future versions of the app may incorporate more, unique behavioral techniques beyond those provided by the consultant in an effort to improve the potency of the app.

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The authors wish to thank all the consultants for assisting in delivering the intervention and the trial manager (Cathy Whitely) and research dietitian (Pennie Taylor) for assisting in training the consultants and the delivery of the intervention.

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### Authors' Contributions

All authors were involved in the design of the study and/or development of app components. EB and GAH helped perform data collection. EB conducted the data analysis and was primarily responsible for preparing the manuscript. All authors contributed to and reviewed the final manuscript.

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### Conflicts of Interest

Commonwealth Scientific and Industrial Research Organisation (CSIRO) has an ongoing research partnership with Probiotec to develop the Impromy program. Probiotec had no input into the final version of this paper and only offered advice on the trial design regarding the plausibility of the program in a commercial setting. The app was developed by the authors and remains the property of CSIRO. Meal replacements were provided in kind by Probiotec. Probiotec also paid for the commercial development of the app.

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### Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 1MB - [mhealth\\_v6i4e41\\_app1.pdf](#) ]

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## Abbreviations

**BMI:** body mass index  
**DPB:** diastolic blood pressure  
**HDL:** high-density lipoprotein  
**LDL:** low-density lipoprotein  
**PDA:** personal digital assistant  
**SBP:** systolic blood pressure  
**WMP:** Weight Management Program

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Original Paper

# Key Lessons and Impact of the Growing Healthy mHealth Program on Milk Feeding, Timing of Introduction of Solids, and Infant Growth: Quasi-Experimental Study

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## Abstract

**Background:** The first year of life is an important window to initiate healthy infant feeding practices to promote healthy growth. Interventions delivered by mobile phone (mHealth) provide a novel approach for reaching parents; however, little is known about the effectiveness of mHealth for child obesity prevention.

**Objective:** The objective of this study was to determine the feasibility and effectiveness of an mHealth obesity prevention intervention in terms of reach, acceptability, and impact on key infant feeding outcomes.

**Methods:** A quasi-experimental study was conducted with an mHealth intervention group (Growing healthy) and a nonrandomized comparison group (Baby's First Food). The intervention group received access to a free app and website containing information on infant feeding, sleep and settling, and general support for parents with infants aged 0 to 9 months. App-generated notifications directed parents to age- and feeding-specific content within the app. Both groups completed Web-based surveys when infants were less than 3 months old (T1), at 6 months of age (T2), and 9 months of age (T3). Survival analysis was used to examine the duration of any breastfeeding and formula introduction, and cox proportional hazard regression was performed to examine the hazard ratio for ceasing breast feeding between the two groups. Multivariate logistic regression with adjustment for a range of child and parental factors was used to compare the exclusive breastfeeding, formula feeding behaviors, and timing of solid introduction between the 2 groups. Mixed effect polynomial regression models were performed to examine the group differences in growth trajectory from birth to T3.

**Results:** A total of 909 parents initiated the enrollment process, and a final sample of 645 parents (Growing healthy=301, Baby's First Food=344) met the eligibility criteria. Most mothers were Australian born and just under half had completed a university education. Retention of participants was high (80.3%, 518/645) in both groups. Most parents (226/260, 86.9%) downloaded and used the app; however, usage declined over time. There was a high level of satisfaction with the program, with 86.1% (143/166)

reporting that they trusted the information in the app and 84.6% (170/201) claiming that they would recommend it to a friend. However, some technical problems were encountered with just over a quarter of parents reporting that the app failed to work at times. There were no significant differences between groups in any of the target behaviors. Growth trajectories also did not differ between the 2 groups.

**Conclusions:** An mHealth intervention using a smartphone app to promote healthy infant feeding behaviors is a feasible and acceptable mode for delivering obesity prevention intervention to parents; however, app usage declined over time. Learnings from this study will be used to further enhance the program so as to improve its potential for changing infant feeding behaviors.

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## KEYWORDS

mHealth; obesity prevention; infancy; parents; breastfeeding; complementary feeding; formula feeding

## Introduction

The World Health Organization has identified the prevention of obesity in early life as a key priority [1]. Children are becoming overweight at a relatively young age, with 22.8% of Australian children aged 2 to 4 years already overweight or obese [2] with substantial health and economic consequences [3]. Infants who are at the highest end of the distribution for body mass index (BMI) or who grow rapidly during infancy are at increased risk of subsequent obesity in both childhood and adulthood [4,5].

Infant feeding practices, including the duration of breastfeeding, formula feeding practices [6-8], when solid food is introduced [9], and whether a baby is predominantly fed on a schedule or according to their hunger and satiety cues, are associated with rapid weight gain [10,11]. Australian and international infant feeding guidelines recommend that infants are exclusively breastfed to around 6 months of age when solid foods should be introduced and that breastfeeding continue for 12 months or longer [12,13]. However, Australian data indicate that only 15% of infants are exclusively breastfed until 6 months of age, with 40% of infants having at least some formula by 1 month of age [14]. Similar numbers are found in the United States where national rates of exclusive breastfeeding at 6 months are 22% [15]. Furthermore, over a quarter (28.4%) of Australian infants are introduced to solids by 4 months of age and over half (56.2%) by 5 months [14]. This clearly highlights the need for interventions to promote recommended infant feeding practices.

There is increasing evidence that children from low socioeconomic backgrounds have higher rates of overweight and obesity [16], and socioeconomic disparities begin early in life [17]. A recent review found that a strong socioeconomic gradient exists for the majority of early life risk factors for child obesity [18], suggesting that early intervention is critical in reducing socioeconomic inequalities in overweight and obesity in childhood and related chronic diseases in adulthood. However, socioeconomically disadvantaged families are often more difficult to reach and may be less likely to participate in traditional programs that support healthy behaviors [19].

One emerging and promising area to facilitate parent engagement at a low cost is the provision of support for parents through electronic media such as the Internet or smartphones. Smartphone ownership is increasing worldwide, with Australians having the highest rate (93%) of access to smartphones [20].

Women aged 18 to 49 years (many of whom are mothers) spend on average 21 hours a week on their smartphone [21]. Well-designed smartphone apps can provide around the clock high-quality information, as well as personalized and tailored support at low cost [22]. Evidence suggests that although parents increasingly rely on the Internet for information on infant feeding and care [23-27], less research has been conducted on the use of smartphone apps in the postpartum period. One study reported that low-income women commonly use apps during pregnancy, but not in the postpartum period because of the limited availability of high-quality apps, creating a postpartum app gap [28]. This is in line with our own research where we found that infant feeding apps available in Australia are generally of low quality [29].

Early research on the effectiveness of mHealth interventions in changing health behavior is promising [30-32]; however, this is the first study, to our knowledge, to investigate the effectiveness of mHealth interventions in influencing parents' infant feeding behaviors. The Growing healthy (GH) study aimed to explore the feasibility of providing information and support to parents for healthy infant feeding practices using an mHealth program. This paper reports on the effectiveness of GH in terms of reach, use, acceptability, and several key infant feeding outcomes including the promotion of exclusive or continued breastfeeding, best practice formula feeding, timing of introduction of solids, and infant growth.

## Methods

The study utilized a quasi-experimental design with an mHealth intervention group and a concurrent nonrandomized comparison group. A detailed description of the development of the GH program and the methods of the feasibility study has been previously published [33]. Key components related to this paper are described below.

### Study Participants

The eligibility criteria for participation in the intervention group (GH) included being pregnant (30+ weeks gestation) or parent or main carer of an infant younger than 3 months, ownership of any type of mobile phone, ability to speak and read English, age 18 years or older, and residing in Australia. Participants were recruited using 3 methods: via their primary care providers in socioeconomically disadvantaged communities in 2 Australian states; face-to-face by researchers in first-time parent groups; or Web-based advertising. A concurrent nonrandomized

comparison group (Baby's First Food, BFF) was recruited via online forums, social networking sites, and blogs and received usual care. The eligibility criteria for participation were the same as the intervention arm with the exception that participants were not required to own a mobile phone. Enrollment to both groups of the study involved the completion of a Web-based screening form, a consent form, and a baseline survey. Further details of the recruitment process and outcomes have been published elsewhere [34].

### **The Growing Healthy Program**

In brief, the GH program aimed to encourage parents to engage in infant feeding practices that promote healthy rather than excess weight gain, with a focus on socioeconomically disadvantaged parents. The aims of the program were as follows:

- Promote breastfeeding.
- If breastfeeding was not possible, promote best practice formula feeding.
- Delay the introduction of solids to around 6 months of age but not before 4 months.
- Promote healthy first foods.
- Promote healthy infant feeding practices (including feeding to appetite, repeated neutral exposure to healthy food, and avoiding using food as a reward).
- Optimize infant dietary exposure to fruits and vegetables.

The main delivery media for the program were an app and website, which provided parents with evidence-based article and videos containing practical advice and strategies consistent with national guidelines on infant feeding from birth until 9 months of age. The development of the program was guided by the Behaviour Change Wheel and the Capability, Opportunity and Motivation model of behavior change [35]. For each program aim (target behavior), key determinants were identified using prior formative work [36,37] and literature and mapped to intervention strategies. Participants received 3 personalized push notifications or text messages (short message service, SMS) per week targeting specific intervention strategies and behavior change techniques as detailed in our protocol paper [33]. Push notifications were also tailored to each infant's age and stage of development as well as their feeding mode (breast, formula, or mixed feeding), directing them to relevant content in the app. A weekly email was also sent that included the 3 messages for the week with links to the website. This was introduced part way through the intervention in response to the low number of push notifications being opened. Participants were also invited to join a Facebook group where one feeding message per week was posted by a moderator, and participants were encouraged to discuss practical experiences around infant feeding.

### **Data Collection**

Data were collected at 3 time points via a Web-based survey: when infants were less than 3 months old (T1), when the infant was 6 months of age (T2), and when the infant was 9 months of age (T3). To compensate participants for the time involved in completing surveys, GH participants received a gift voucher worth Aus \$20 per survey completed, and BFF participants received Aus \$40 for the completion of 2 or more surveys.

Nonresponders to the survey were sent 3 email reminders, 1 week apart. We also collected data from analytics within the app.

### **Assessment of Breastfeeding Duration and Exclusivity**

At T1, T2, and T3, parents were asked to report if their infant was currently breastfed and the infant's age in weeks when breastfeeding ceased if they were no longer breastfeeding. At T3, they were also asked about what they were feeding their infant: (1) breast milk, solids, and water or juices; (2) infant formula, solids, and water or juices; or (3) a combination of breast milk, infant formula, solids, and water or juices. Exclusive breastfeeding at T2 was determined by the question "Does baby have other fluids or food apart from breast milk?" All of those participants who were breastfeeding were asked additional questions at T1 and T2 about introduction of infant formula and the child's age at introduction of formula.

### **Assessment of Best Practice Formula Feeding**

Formula preparation was assessed at each time point using a valid and reliable questionnaire [38] including the following items: follows instructions on the tin for loosely packed level scoops, adds water to the bottle first, and never adds more formula than the specifications on the tin. Additional questions about formula feeding practices were asked at each time point, including whether cereal was added to the bottle to ensure baby slept longer or stayed fuller longer, whether participants held their baby when feeding with a bottle, whether participants believed it was important for the baby to finish all the formula in the bottle, and whether participants allowed their baby's appetite to guide feeding. These questions were taken from the previously validated infant feeding questionnaire [39].

### **Assessment of Timing of Solid Introduction**

At T1 and T2, parents were asked whether solids had been introduced and, if so, the infant's age in weeks at introduction.

### **Assessment of Child Anthropometrics**

At each time point, the parent was asked to provide the most recent weight and length data from their infant's health record.

### **Assessment of Demographic Characteristics**

The infant's sociodemographic characteristics including age, gender, birth order, and whether infants were Aboriginal or Torres Strait Islander were collected in the survey at T1. Also collected at T1 were parental characteristics, including primary carer's age, country of birth, relationship status, self-rated health, employment status, education level, and annual household income.

### **Assessment of App Usage**

Participants' app usage was extracted from the GH activity log hosted on the Azure cloud in Southeast Australia. The key metrics collected included number of pages viewed per session (1 session=each day they accessed the app), number of sessions from the point participants activated the app until 9 months of the infant's age, and the number of push notifications opened. Furthermore, participants' device type (Android/iPhone) was also collected.

### Assessment of App Acceptability

At T3, participants were asked 25 questions relating to feasibility, acceptability, ease of use, and perceived usefulness of the app (and website) and the program overall. These survey questions were adapted from EMPOWER, an Australian mHealth intervention aimed at weight loss in adults [40], and the app quality assessment tool [29].

### Statistical Analysis

Basic descriptive analysis and cross-tabulations were calculated. Baseline characteristic comparisons were made using chi-square test and *t* test as appropriate to the variable type. Survival analysis was used to assess the difference in timing of feeding practices, including duration of any breastfeeding, timing of introduction of infant formula, and timing of solids introduction between the 2 groups—GH and BFF. Kaplan-Meier survival curves were used to assess the mean and median of breastfeeding duration and the timing of introduction of solids. Differences between the groups were assessed using Breslow test. Those cases where the child was reported as still being breastfed at T3 were classed as censored observations in the breastfeeding duration analysis. Cox proportional hazards regression models in the analysis of breastfeeding duration and time to solids introduction were used to account for covariates such as child's gender, whether first born, dummy use, maternal smoking status, mother's country of birth, parental education and work status, household income, and maternal age and prepregnancy BMI. Mother's self-rated health and possession of a health card were considered but due to high correlation with other covariates were excluded from the final analysis. Evaluation of the log-minus-log survival curves provided no evidence that the assumptions of proportional hazards were not met.

Multivariate logistic regression was used in the analysis of differences between GH and BFF for binary outcomes, including proportion exclusively breastfeeding; formula feeding outcomes; and proportion who had introduced solids before 4 months, after 6 months, and at 4, 4.5, 5, 5.5, and 6 months.

Differences between GH and BFF group continuous variables, which included child BMI z-score, weight, and length at time points between birth and T3, were assessed using mixed effect polynomial regression models with an unstructured covariance structure. A random intercept and a random slope for age to allow individual growth rates were fitted. Quadratic and cubic age variables to model nonlinear growth were included. Covariates included in the model were child's gender, whether first born, dummy use, maternal smoking status, mother's country of birth, parental education and work status, household income, and maternal age and prepregnancy BMI. All statistical

analysis was performed using IBM Corporation SPSS version 24 [41].

## Results

### Study Participants

A total of 909 subjects commenced enrollment into the study; however, 264 were ineligible predominately because they did not complete the baseline survey or their baby was older than 15 weeks or born prematurely (Figure 1). The final sample included 645 carer/child dyads at baseline (GH: 301; BFF: 344). Retention to the study was high at T2 (84.7%) and T3 (80.3%; Figure 1).

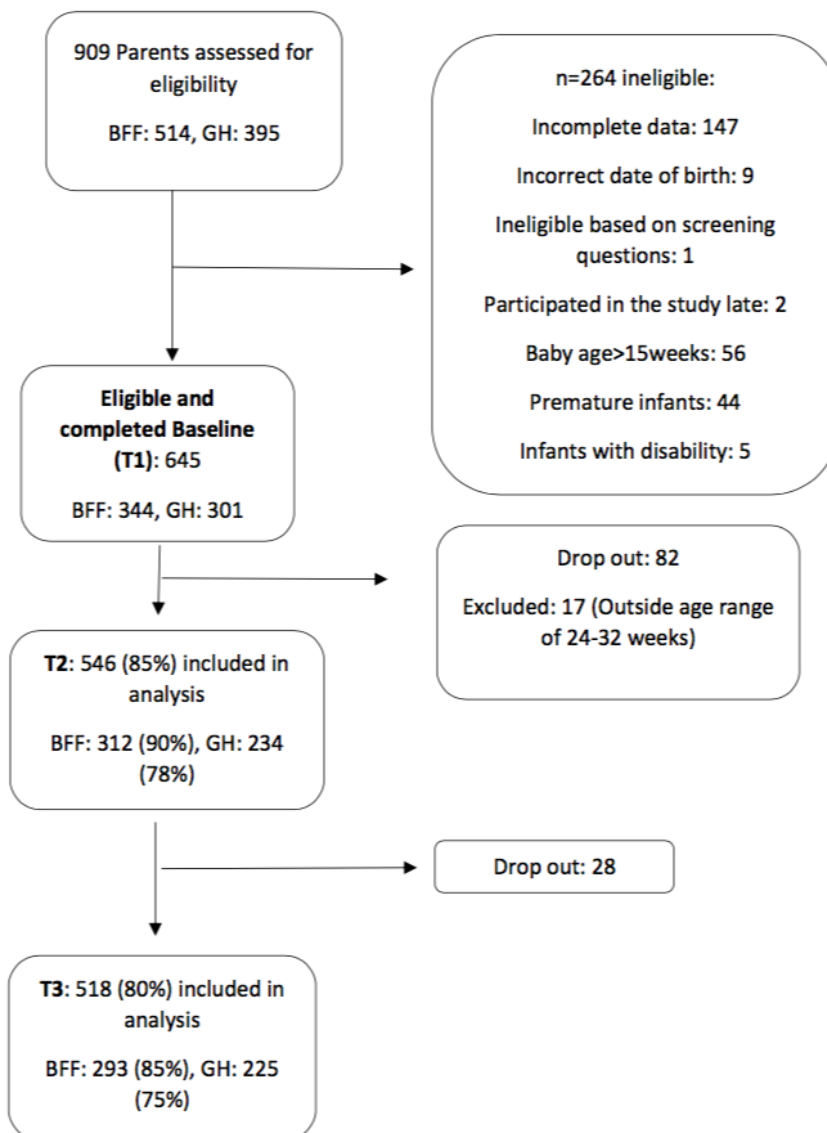
### Baseline Characteristics

At enrollment, the mean age of the children in the GH group was significantly younger than the BFF group (7.0 weeks compared with 7.9 weeks). Furthermore, the GH group compared with the BFF group contained a significantly higher proportion of first-born children, with GH mothers being younger (30.4 years compared with 31.2 years), a lower proportion of GH mothers being Australian born (84.1% vs 90.1%), and a lower proportion in the highest household income category (29.4% vs 36.8%). GH also contained a lower proportion of breastfeeding mothers and higher proportion of formula and mixed feeding mothers at baseline when compared with BFF ( $P < .001$ ). Other characteristics considered were not found to be significantly different at baseline between the 2 groups. Details of the baseline characteristics of study participants are provided in Table 1.

### App Usage

Of the 301 participants, 260 (86.4%) opted to access the program via the app, and 41 (13.6%) via the website/SMS. App participants were provided with a code to enable them to download the app from either Google Play or the App Store, and 74.8% (225/301) of participants downloaded the app. More than half of the sample used iPhones (71.6%), with 28.4% using Android phones and 11.9% website and SMS. Of app users, Android phone usage was higher among non-university-educated participants (31.7%) compared with university-educated participants (24.5%). App users were sent 3 push notifications each week, and on average, 11 push notifications were opened over the time of the study (8.0% of all notifications). App usage declined over time from 92.0% using the app at least once on enrollment to 38.2% at study completion when infants were aged 8 to 9 months of age (Figure 2), with a similar decline in the mean number of sessions using the app across the duration of the study (Figure 3).

Figure 1. Flowchart detailing study participants.



**Table 1.** Baseline characteristics of study participants by intervention group.

Characteristics	Growing healthy (n=301)	Baby's First Food (n=344)	P value
<b>Child factors</b>			
Age (weeks)	7.0 (3.7)	7.9 (3.8)	.001
<b>Gender, n (%)</b>			
Boys	150 (49.8)	167 (48.5)	.74
Girls	151 (50.2)	177 (51.5)	
<b>Aboriginality, n (%)</b>			
Nonaboriginal nor Torres Strait Islanders	294 (97.7)	335 (97.4)	.81
Aboriginal and/or Torres Strait Islanders	7(2.3)	9 (2.6)	
First-born baby, n (%)	173 (57.5)	133 (38.7)	<.001
Dummy use at baseline, n (%)	164 (54.5)	163 (47.4)	.07
<b>Parental factors</b>			
Mother's age, years, mean (SD)	30.4 (4.7)	31.2 (4.4)	.04
Mother prepregnancy body mass index, kg/m <sup>2</sup> mean (SD)	26.6 (5.7)	27.2 (6.8)	.23
Maternal current smoking status, n (%)	18 (6.0)	15 (4.4)	.35
Maternal country of birth—Australian born, n (%)	253 (84.1)	310 (90.1)	.02
Relationship status—married, n (%)	289 (96.0)	332 (96.5)	.74
Health care card holder, n (%)	48 (15.9)	53 (15.4)	.85
<b>Maternal self-rated health, n (%)</b>			
Poor/fair	30 (10.0)	28 (8.1)	.51
Good	116 (38.5)	152 (44.2)	
Very good	124 (41.2)	131 (38.1)	
Excellent	31 (10.3)	33 (9.6)	
<b>Maternal education, n (%)</b>			
	<b>n=289</b>	<b>n=332</b>	
Low	61 (21.1)	56 (16.4)	.29
Medium	88 (30.5)	115 (33.6)	
High	140 (48.4)	171 (60.0)	
<b>Maternal working status, n (%)</b>			
	<b>n=301</b>	<b>n=342</b>	
Not working	261 (86.7)	298 (86.6)	.87
Working	40 (13.3)	44 (12.8)	
<b>Paternal education, n (%)</b>			
	<b>n=289</b>	<b>n=332</b>	
Low	56 (19.4)	64 (19.3)	.56
Medium	144 (49.8)	153 (46.1)	
High	89 (30.8)	115 (34.6)	
<b>Paternal working status, n (%)</b>			
	<b>n=289</b>	<b>n=331</b>	
Not working	12 (4.2)	7 (2.1)	.14
Working	277 (95.8)	324 (97.9)	
<b>Annual house income, Aus \$, n (%)</b>			
	<b>n=301</b>	<b>n=288</b>	
≤51,999	35 (13.7)	44 (15.3)	.02
52,000-77,999	79 (31.0)	57 (19.8)	
78,000-99,999	81 (25.9)	66 (28.1)	
100,000 or more	75 (29.4)	106 (36.8)	
<b>Feeding groups, n (%)</b>			

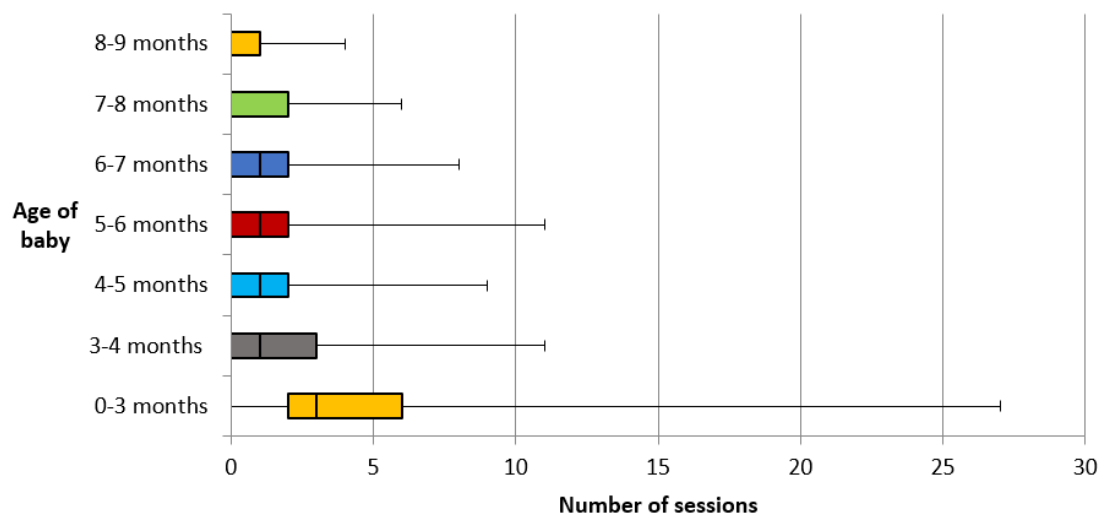


Characteristics	Growing healthy (n=301)	Baby's First Food (n=344)	P value
Breastfeeding	196 (65.1)	245 (71.2)	<.001
Formula feeding	52 (17.3)	48 (14.0)	
Mixed feeding	53 (17.6)	51 (14.8)	

**Figure 2.** The percentage of participants who used the Growing healthy app throughout the 9-month program.



**Figure 3.** Participants' frequency of using the Growing healthy app throughout the 9-month program.



### Acceptability

Overall, participants reported high levels of satisfaction with the program, with 88.1% agreeing that they liked the program and 84.6% informing that they would recommend it to a friend (Table 2). Most parents (86.1%) reported that the app provided trustworthy information and was easy to understand (91.0%) and use (78.3%), with less than 5% of parents expressing concern about data usage when using the app. However, just

over a quarter of parents reported that the app failed to work at times. Nearly 20% of participants who completed T3 reported disabling push notifications on their phone. For those receiving push notifications, a majority found them helpful, well suited to their baby's age and stage of development, and appropriate in terms of number and timing of messages. However, just over a third reported that the messages disappeared before they read them, and nearly 40% were unsure how to retrieve push notifications once they had disappeared from the screen.

**Table 2.** Participant satisfaction with the Growing healthy program.

Satisfaction item	Agree or strongly agree, n (%)
<b>Overall program (n=201)</b>	
Overall I liked the Growing healthy program	177 (88.1)
I would recommend the Growing healthy program to a friend	170 (84.6)
Covered all I needed on feeding	134 (66.7)
<b>Growing healthy app (n=166)</b>	
Using the app was an enjoyable experience	125 (75.3)
I can trust the information in the app	143 (86.1)
The app did everything I expected it to do	128 (77.1)
I liked the layout/look of the app	131 (78.9)
The language used in the app was easy to understand	151 (91.0)
I found the Growing healthy app easy to use	130 (78.3)
I was concerned about data usage/costs when using the app	7 (4.2)
Hard to navigate	20 (12.0)
The Growing healthy app failed to work at times, n=166	43 (25.9)
<b>Push notifications (n=126)</b>	
Push notifications often disappeared before I had a chance to open them	43 (34.1)
I did not know how to retrieve push notifications once they disappeared from the screen	50 (39.7)
I would prefer to receive text messages than push notifications	37 (29.4)
<b>Push notifications and text messages (n=201)</b>	
I was happy with the number of push notifications/texts received each week	127 (63.2)
I was happy with the timing of push notifications/texts	134 (66.7)
I found the push notifications/texts helpful	127 (63.2)
I found the push notifications suited my baby's age and stage of development	138 (68.7)

## Feeding Outcomes

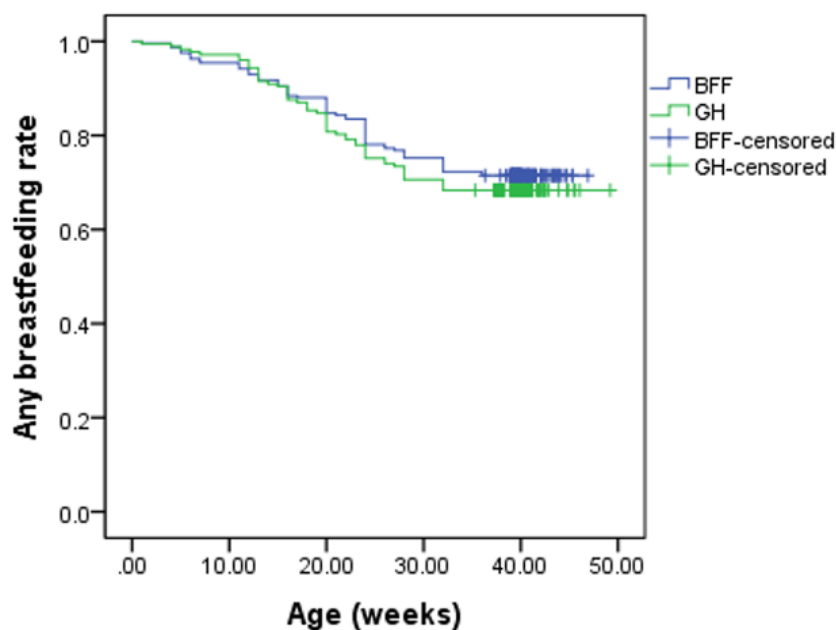
### Breastfeeding

The percentage of breastfeeding and mixed feeding mothers who reported having stopped breastfeeding by T3 was 31.6% and 28.5% for GH and BFF, respectively (Figure 4). The mean duration of any breastfeeding at T3 for GH was 39.6 weeks (95% CI 37.5-41.8) compared with 39.0 weeks (95% CI 37.3-40.7) for BFF. There was no statistically significant difference in the mean duration of any breastfeeding between the 2 groups ( $P=.46$ ). The hazard ratio for ceasing any breastfeeding in GH compared with BFF was not significantly different (hazard ratio 1.13; 95% CI 0.74-1.74;  $P=.57$ ). Stratified analysis by whether child first born (first-time vs non-first-time mothers) suggested that duration of any breastfeeding were not significantly different between GH and BFF, regardless of whether the child was first born or not. However, across both groups, the median duration of any breastfeeding for

non-first-time mothers (41.9 weeks) were significantly longer than that of first-time mothers (37 weeks) ( $P=.02$ ). Cox hazard regression also revealed that first-time mothers were more likely to cease breastfeeding at T3 when compared with non-first-time mothers (hazard ratio 1.63; 95% CI 1.06-2.52;  $P=.03$ ). For maternal education, no differential effects on any breastfeeding duration were found.

The proportion of breastfeeding mothers who were exclusively breastfeeding at baseline was 84% (GH) and 83% (BFF). At 6 months, the proportion of exclusive breastfeeding among the GH and BFF groups was 9% and 13%, respectively, which after adjustment for covariates showed no statistically significant difference between the groups (adjusted odds ratio, AOR 1.25; 95% CI 0.46-3.32;  $P=.65$ ). Among exclusive breastfeeding mothers, the mean duration of any breastfeeding was also similar between the 2 groups, with a mean duration of any breastfeeding for GH of 43.4 weeks (95% CI 41.4-45.4) and for BFF of 41.0 weeks (95% CI 39.7-42.4).

**Figure 4.** Rates of any breastfeeding duration by intervention group (BFF: Baby's First Food; GH: Growing healthy).



### Formula Feeding

At all 3 time points, there was a trend for a higher proportion of GH participants preparing formula correctly compared with BFF group (Table 3). After adjusting for all covariates, formula preparation practice was not significantly different between groups (AOR 1.00; 95% CI 0.48-2.10) at baseline. At T2 and T3, GH participants had slightly higher odds of preparing formula correctly in comparison with BFF (AOR of 1.25 at T2 and 1.67 at T3); however, neither was statistically significant. Most participants (99%) from both GH and BFF did not add cereal to bottle during formula preparation (data not shown). At T3, parents in the GH group were less likely to hold their baby when giving a bottle compared with mothers in the BFF group (odds ratio 0.45, 95% CI 0.20-0.95). At T2, but not baseline or T3, a higher proportion of mothers in GH than that of BFF believed that it is important to finish all formula in the bottle (AOR 2.65, 95% CI 1.04-6.71). No significant difference was found for other formula feeding behaviors such as parents' attitude toward letting baby's appetite guide feeding (Table 3).

### Introduction of Solid Food

The median age for solid introduction was 21.0 weeks for both GH and BFF (GH: 95% CI 20.4-21.6; BFF: 95% CI 20.3-21.6).

There was not a statistically significant difference in hazard rates for solid introduction timing between the 2 groups (hazard ratio 0.946; 95% CI 0.76-1.18). No statistically significant difference was found in the proportion introducing solids at different ages between GH and BFF groups (Table 3). Parents in the GH group were less likely to introduce solids before 4.5 months when compared with those in the BFF group (AOR 0.54-0.66); however, statistical significance was not reached ( $P=.09$ ). Few babies in either the GH or the BFF group received solid food before 4 months (Table 4).

### Infant Growth Trajectories

Pairwise comparisons of predicted child BMI z-score, weight, and length at each time point from the mixed effect polynomial regression model between GH and BFF are shown in Table 5. BMI z-score of GH children from birth to T3 were similar to those in the BFF group ( $P \geq .05$ ). GH children compared with BFF children had lower weight from T1 to T3, but the mean difference was small (0.12-0.32 kg). Similarly, the height of GH children was also slightly shorter than BFF children from T1 to T3 (mean difference 0.47-1.11 cm). Growth trajectories of BMI z-score, weight, and length were not significantly different between GH and BFF ( $P > .05$ ; Multimedia Appendix 1).

**Table 3.** Comparison of infant feeding practices by intervention group.

Variables	Intervention (Growing healthy)	Control (Baby's First Food)	Total	Adjusted odds ratio <sup>a</sup> (95% CI)	P value
<b>Exclusive breastfeeding</b>					
<b>T1, n</b>	195	246	441		
Yes, n (%)	164 (84.1)	202 (82.1)	366 (82.9)	1.37 (0.72-2.66)	.34
<b>T2, n</b>	111	160	271		
Yes, n (%)	10 (9.0)	20 (12.5)	31 (11.4)	1.22 (0.46-3.32)	.69
<b>Prepared formula correctly</b>					
<b>T1, n</b>	105	99	204		
Yes, n (%)	48 (45.7)	38 (38.4)	86 (42.2)	1.00 (0.48-2.10)	>.99.
<b>T2, n</b>	101	116	217		
Yes, n (%)	58 (57.4)	56 (48.3)	114 (52.5)	1.25 (0.64-2.44)	.52
<b>T3, n</b>	108	137	245		
Yes, n (%)	66 (61.1)	71 (51.8)	137 (55.9)	1.67 (0.87-3.20)	.13
<b>Held baby when giving a bottle</b>					
<b>T1, n</b>	105	99	204		
Yes, n (%)	103 (98.1)	96 (97.0)	199 (97.5)	1.71 (0.28-10.64)	.57
<b>T2 (N=217) n</b>	101	116	217		
Yes, n (%)	87 (86.1)	103 (88.8)	190 (87.6)	0.73 (0.27-1.97)	.54
<b>T3, n</b>	115	137	252		
Yes, n (%)	73 (63.5)	102 (74.5)	175 (69.4)	0.48 (0.23-1.00)	.05
<b>Important to finish all formula in the bottle</b>					
<b>T1, n</b>	105	99	204		
Yes, n (%)	20 (19.1)	24 (24.2)	44 (21.6)	0.72 (0.3-1.69)	.45
<b>T2, n</b>	n=101	n=116	217		
Yes, n (%)	26 (25.7)	15 (12.9)	41 (18.9)	2.65 (1.04-6.71)	.04
<b>T3, n</b>	n=115	n=121	252		
Yes, n (%)	21 (18.1)	16 (13.2)	37 (14.7)	1.60 (0.66-3.88)	.30
<b>Let baby's appetite guide feeding</b>					
<b>T1, n</b>	53	51	104		
Yes, n (%)	46 (86.8)	44 (86.3)	90 (86.5)	0.87 (0.12-6.48)	.89
<b>T2, n</b>	n=30	n=33	63		
Yes, n (%)	22 (73.3)	23 (69.7)	45 (71.4)	2.32 (0.29-18.24)	.43

<sup>a</sup>Logistic regression adjusted for child age, gender, whether first born, dummy use, maternal age, smoking status, country of birth, maternal and paternal education, maternal and paternal working status, maternal prepregnancy body mass index, and house income.

**Table 4.** Comparison of age at which solid foods were introduced by intervention group.

Variables	Total, (n=481)	Intervention (Growing healthy), n=208	Control (Baby's First Food), n=273	Adjusted odds ratio <sup>a</sup> (95% CI)	P value
<b>Age at which solids were introduced</b>					
Before 4 months (0-15 weeks), n (%)	21 (4.4)	10 (4.8)	11 (4.0)	0.46 (0.12-1.77)	.26
At 4 months (0-16 weeks), n (%)	64 (13.3)	28 (13.5)	36 (13.2)	0.54 (0.26-1.09)	.09
At 4.5 months (0-18 weeks), n (%)	134 (27.9)	56 (26.9)	78 (28.6)	0.63 (0.38-1.06)	.08
At 5 months (0-20 weeks)	234 (48.6)	104 (50.0)	130 (47.6%)	0.92 (0.58-1.44)	.70
At 5.5 months (0-22 weeks), n (%)	304 (63.2)	145 (69.7)	159 (58.2)	1.42 (0.89-2.26)	.14
At 6 months (0-24 weeks), n (%)	409 (85.0)	184 (88.5)	225 (82.4)	1.14(0.61-2.11)	.68
After 6 months (0-25 weeks), n (%)	433 (90.0)	194 (93.3)	239 (87.5)	1.22(0.57-2.62)	.61

<sup>a</sup>Logistic regression adjusted for child age, gender, whether first born, dummy use, maternal age, smoking status, country of birth, maternal and paternal education, maternal and paternal working status, maternal prepregnancy body mass index, and house income.

**Table 5.** Predicted mean child body mass index (BMI) z-score, weight, and length of Growing healthy (GH) and Baby's First Food (BFF) at birth, 3 months (T1), 6 months (T2), and 9 months (T3).

Anthropometry	Growing healthy, predicted mean <sup>a</sup> (95% CI)	Baby's First Food, predicted mean <sup>a</sup> (95% CI)	P value
<b>BMI<sup>b</sup> z-score</b>			
Birth	0.22 (0.22-0.34)	0.33 (0.22-0.44)	.21
T1	1.57 (1.45-1.69)	1.71 (1.59-1.83)	.11
T2	0.44 (0.31-0.57)	0.26 (0.14-0.38)	.05
T3	0.24 (0.09-0.38)	0.28 (0.16-0.41)	.61
<b>Weight</b>			
Birth	3.49 (3.43-3.56)	3.55 (3.48-3.61)	.26
T1	4.62 (4.55-4.69)	4.76 (4.70-4.82)	.003
T2	7.23 (7.15-7.30)	7.55 (7.48-7.61)	<.001
T3	8.62 (8.54-8.70)	8.78 (8.71-8.85)	.003
<b>Length</b>			
Birth	50.55 (50.28-50.82)	50.71 (50.46-50.97)	.39
T1	54.97 (54.70-55.25)	55.51 (55.25-55.77)	.01
T2	64.97 (64.67-65.27)	66.08 (65.81-66.36)	<.001
T3	69.78 (69.46-70.10)	70.25 (69.97-70.53)	.03

<sup>a</sup>Predicted means derived from mixed effect polynomial regression model with adjustment for child age, gender, whether first born, dummy use, maternal age, smoking status, country of birth, maternal and paternal education, maternal and paternal working status, maternal prepregnancy body mass index, and household income.

<sup>b</sup>BMI: body mass index.

## Discussion

### Principal Findings

This is the first study, to our knowledge, to report on the feasibility and effectiveness of an mHealth intervention for prevention of obesity in infancy. Our findings support the use of mHealth as a feasible and acceptable mode of delivery of an intervention targeting parents' infant feeding behaviors due to participants' high levels of reported satisfaction and retention to the program, despite some technical difficulties using the app and decline in engagement over time. We were, however, unable to demonstrate any impact of the intervention on the target

behaviors and outcomes of breastfeeding duration or exclusivity, timing of introduction of solids, or infant growth trajectories. The findings suggest that the GH intervention may have positively impacted on formula preparation practices, although this was not significant in fully adjusted models and requires confirmation in an adequately powered randomized controlled trial.

The findings of this study support mHealth as an acceptable mode of delivery for obesity prevention interventions in infancy, particularly those targeting infant feeding, with high rates of recruitment [42] and a retention rate of 80% at 9 months follow-up. It is important to acknowledge that the high retention

rates might reflect, in part, the payment offered for survey completion and the use of 3 reminders. Acceptability of the program is supported by the high rates of reported user satisfaction with the program. This is consistent with findings from our qualitative follow-up interviews with parents [43] where they reported engagement with the program was promoted by the credibility of the program source, the user-friendly interface, and tailoring of content and push notifications to the baby's age and key transition points. Our findings are congruent with existing research, which suggests that parents are increasingly relying on online source of information for infant feeding and care [23-27].

However, a number of factors may have reduced engagement with the program. Over a quarter of participants reported that the app failed to work at times. Technical problems did arise in the study, including operating system updates for both iOS and Android systems disabling the app for a short period of time. Parents who changed mobile phones during the study were required to contact the research team to obtain another code to access the app, which may have further reduced app usage. Furthermore, although push notifications were perceived to be relevant and timely, nearly 40% of participants were unsure how to retrieve push notifications once they had disappeared from the screen. This might explain the relatively low proportion (8%) of push notifications opened. Given that push notifications were the primary mechanism to drive parents to engage with the app content, this was very likely to have limited the dose of the intervention received and its subsequent impact on infant feeding behaviors and outcomes. This is further supported by app analytics data, which indicate that the use of the app did indeed decline over the duration of the study.

Understanding factors influencing engagement with mHealth programs and how these can be maximized over time is critical to program effectiveness. Our quantitative analysis of app usage [44] revealed higher engagement with the program among those recruited by their health practitioner, those who registered when their infant was younger, those who were first-time mothers, and those using both the app and website (via email links) compared with those using the app alone. This suggests that, to maximize engagement and potential impact, consideration should be given in the future to focus on recruiting first-time parents, with the help of health practitioners during the early postnatal or antenatal period. Future iterations of the program should include design features to improve access to push notifications and to maximize engagement over time using multiple methods (eg, email and push notifications) as well as the inclusion of more interactive features such as a forum and other tools to promote ongoing engagement. Technical issues also need to be addressed in a timely manner, including accommodating any operating system updates to ensure the program is functional at all times.

In addition to intervention dose, the lack of intervention effect may also be because of the sample size of this feasibility study, which was not powered to detect differences between groups but rather inform sample size calculations for a subsequent larger randomized controlled trial. The study was limited by the significant difference in a number of baseline characteristics between the study groups. Although baseline differences were

controlled for in the statistical analysis, this reduces the power to detect differences in key outcomes between the groups.

The timing of the intervention may have contributed to the program's limited impact on outcomes, particularly for breastfeeding. The average age of infants at the time of enrollment was 7 to 8 weeks, suggesting that the intervention missed the critical period for breastfeeding support, with national data indicating that 40% of mothers introduce formula by 1 month of age [14]. Research has also indicated that plans about whether a mother will breastfeed and for how long are made antenatally [45], and this was consistent with our qualitative findings [43] where mothers reported that plans for feeding their infant were made before enrolling in the program. This highlights the importance of commencing the program before birth and providing very early postnatal breastfeeding support to influence breastfeeding outcomes.

The GH program specifically targeted socioeconomically disadvantaged parents due to the socioeconomic disparities in obesity risk emerging in early infancy [17]. Our findings suggest that we had some limited success in reaching these parents, with just over half of mothers (51.6%) and nearly 70% of fathers not having a university-level education, with education commonly used as a proxy for socioeconomic position [46]. This is similar to the national average [47] but higher than that reported in other group-based obesity prevention trials in infancy. For example, the proportion of mothers without a university education was 46% in the InFANT trial [48] and 42% in the NOURISH trial [49]. However, a home-visiting trial in disadvantaged communities managed to recruit three-quarters of participants without a university education [50]. Surprisingly, we found no difference in the education levels of mothers when recruited by primary health care practitioners in disadvantaged communities and those recruited via social media [42]. It may be that primary health care practitioners were more selective in offering the program to less vulnerable parents. Our findings indicate the importance of catering for Android phone users if mHealth programs target socioeconomically disadvantaged parents, with higher Android phone usage among those without a university education compared with university-educated mothers in our sample. Given the greater need in socioeconomically disadvantaged parents, further research is required to ascertain how best to engage these parents in obesity prevention interventions and indeed whether mHealth programs provide a useful mode of delivery.

The use of mHealth for obesity prevention in early childhood is a rapidly growing field, with a number of trials underway [51-54]. However, we are unaware of any other studies reporting the outcomes of a mobile phone app targeting parents' healthy infant feeding practices. A recent meta-analysis of 16 studies in developed countries has shown e-technologies (including SMS, Web, and interactive computer agent) to be effective in improving rates of breastfeeding initiation, duration, and exclusivity [55]. This review however did not include any studies utilizing a mobile phone app. Only one other published study [56] has reported the effectiveness of an mHealth program targeting infant feeding. That study [56], by Jiang et al in Shanghai, China, found that a weekly SMS from third trimester of pregnancy to 12 months postpartum resulted in a significantly

higher rate of exclusive breastfeeding at 6 months and a significantly lower rate of the introduction of solid foods before 4 months. However, the intervention had no effect on other infant feeding practices, including taking a bottle to bed, drinking from a cup, or using food as a reward.

### Strengths and Limitations

The key strength of this study was that the intervention was informed by behavior change theory and extensive formative work and had high rates of retention. The use of a quasi-experimental study design was a limitation with a number of baseline differences between the intervention and the comparison groups; however, these differences were controlled for in the statistical analysis. There was also a likely selection bias in that the mothers who took part in both groups may have been more interested and motivated to achieve desirable infant feeding practices by virtue of their interest in this research despite having similar levels of education as national average [47]. This is supported by the high rates of exclusive breastfeeding at baseline (84% in BFF and 82% in GH compared with national average of 48% in infants less than 3 months of age [14]) and low proportion introducing solids early (13% at 4 months in both groups compared with national average of 35% [14]). This may have limited the ability to detect intervention effect. A randomized recruitment strategy with a more representative sample of mothers might offer more potential to show improvements in infant feeding practices.

Measurement of infant feeding behaviors based on self-report in both groups was no doubt subject to social desirability bias. Parental report of weight and length may be subject to transcription errors and would be more accurately collected by investigators.

### Conclusions

Our study design was feasible in that there was an excellent retention rate over time for participants who completed the enrollment survey, and the results provide a useful estimate on which to base a sample size calculation for a larger study. An mHealth intervention using a smartphone app to promote healthy infant feeding behaviors is a feasible and acceptable mode for delivering obesity prevention intervention to parents but further work is required to sustained engagement and use over time. The limited impact of the program on key measureable infant feeding outcomes may reflect that some participants received a low intervention dose because of unforeseen technical problems, the timing of the program, participant selection bias, and/or limitations in the study design. It is recommended that mHealth programs targeting infant feeding commence antenatally and future iterations of the program have contingencies in place to address technical issues in a timely manner and design features to maximize engagement over time. Future research using larger randomized controlled trial designs are required to determine the effectiveness of mHealth programs for obesity prevention in infancy.

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### Authors' Contributions

RL, EDW, ST, CGR, RE, and KC all contributed to the conceptualization of the study and development of the app content. KL developed the programming behind the app and website and measurement of program analytics. EL managed the data collection, whereas MZ undertook the data analysis, with input from SL. RL and EDW wrote the first draft of the paper. All authors reviewed and contributed to drafts of the paper and approved the final manuscript.

### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Mixed effects polynomial regression model for BMI z-score, weight, and length trajectories.

[PDF File (Adobe PDF File), 29KB - [mhealth\\_v6i4e78\\_app1.pdf](#) ]

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## Abbreviations

- AOR:** adjusted odds ratio  
**BFF:** Baby's First Food  
**BMI:** body mass index  
**GH:** Growing healthy  
**SMS:** short message service

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Original Paper

# Measuring Risky Driving Behavior Using an mHealth Smartphone App: Development and Evaluation of gForce

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## Abstract

**Background:** Naturalistic driving studies, designed to objectively assess driving behavior and outcomes, are conducted by equipping vehicles with dedicated instrumentation (eg, accelerometers, gyroscopes, Global Positioning System, and cameras) that provide continuous recording of acceleration, location, videos, and still images for eventual retrieval and analyses. However, this research is limited by several factors: the cost of equipment installation; management and storage of the large amounts of data collected; and data reduction, coding, and analyses. Modern smartphone technology includes accelerometers built into phones, and the vast, global proliferation of smartphones could provide a possible low-cost alternative for assessing kinematic risky driving.

**Objective:** We evaluated an in-house developed iPhone app (gForce) for detecting elevated g-force events by comparing the iPhone linear acceleration measurements with corresponding acceleration measurements obtained with both a custom Android app and the in-vehicle miniDAS data acquisition system (DAS; Virginia Tech Transportation Institute).

**Methods:** The iPhone and Android devices were dashboard-mounted in a vehicle equipped with the DAS instrumentation. The experimental protocol consisted of driving maneuvers on a test track, such as cornering, braking, and turning that were performed at different acceleration levels (ie, mild, moderate, or hard). The iPhone gForce app recorded linear acceleration (ie, gravity-corrected). The Android app recorded gravity-corrected and uncorrected acceleration measurements, and the DAS device recorded gravity-uncorrected acceleration measurements. Lateral and longitudinal acceleration measures were compared.

**Results:** The correlation coefficients between the iPhone and DAS acceleration measurements were slightly lower compared to the correlation coefficients between the Android and DAS, possibly due to the gravity correction on the iPhone. Averaging the correlation coefficients for all maneuvers, the longitudinal and lateral acceleration measurements between iPhone and DAS were  $r_{\text{lng}}=0.71$  and  $r_{\text{lat}}=0.83$ , respectively, while the corresponding acceleration measurements between Android and DAS were  $r_{\text{lng}}=0.95$  and  $r_{\text{lat}}=0.97$ . The correlation coefficients between lateral accelerations on all three devices were higher than with the corresponding longitudinal accelerations for most maneuvers.

**Conclusions:** The gForce iPhone app reliably assessed elevated g-force events compared to the DAS. Collectively, the gForce app and iPhone platform have the potential to serve as feature-rich, inexpensive, scalable, and open-source tool for assessment of kinematic risky driving events, with potential for research and feedback forms of intervention.

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**KEYWORDS**

kinematic risky driving behavior; naturalistic driving studies; elevated g-force; lateral acceleration; longitudinal acceleration; iPhone

## Introduction

Teenage drivers, compared to other age groups, have the highest risk of fatal automobile crashes per driven mile [1]. In 2015, there were 221,313 teenage drivers admitted to hospital emergency rooms, which resulted in 2333 fatalities (Centers for Disease Control statistics, average of 6 per day) [2]. Contributing factors to teenage crashes include night-time driving, speeding, impairment due to alcohol or other drugs, and secondary task engagement such as mobile phone use, teenage passenger presence, and eating [3,4].

While there is substantial individual variability in risk [5] and rapid improvement in driving outcomes with age and experience, the first year of driving is particularly risky [6,7]. The high risk among novice teenage drivers has been attributed to young age, inexperience, and risky driving behaviors [7]. A unique characteristic of teenage risky driving is a high rate of elevated acceleration (g-force) events due to hard stops, rapid starts, sharp turns, and over-correction maneuvers, reflecting poor speed control or volitionally erratic driving [8]. The rate of elevated g-force events, termed kinematic risky driving (KRD), are 4-5 times higher among young drivers than adults [8] and are prospectively associated with crash likelihood [9]. KRD can be assessed by accelerometers installed in vehicles in naturalistic driving studies (NDSs) and are sometimes employed to provide driving performance feedback to teenage drivers and their parents [10]. NDSs [11,12], designed to objectively assess driving behavior and outcomes, are conducted by equipping vehicles with dedicated instrumentation (eg, accelerometers, gyroscopes, Global Positioning System [GPS], and cameras) that provide continuous recording of acceleration, location, videos, and still images for eventual retrieval and analyses. However, this research is limited by several factors: the cost of equipment installation; management and storage of the large amounts of data collected; and data reduction, coding, and analyses. Modern smartphone technology includes accelerometers built into phones, and the vast, global proliferation of smartphones could provide a possible low-cost alternative for assessing KRD.

Research to date on driver-monitoring smartphone apps have mainly focused on monitoring driver behavior as indicated by vehicle lateral and longitudinal accelerometer data [13-16]. Unfortunately, most of these apps do not provide features (eg, video capture, event selectivity, real-time feedback) or tools (eg, downstream data collection, processing, and reporting) for a comprehensive analysis of events. Currently, smartphone video capability has only been used for driver fatigue detection, disregarding other driver distractions such as eating or drinking. Applying these existing apps to driving research presents significant challenges, including the following: (1) proprietary code (eg, not open source, therefore not modifiable); and (2) data accessibility, scalability, and research suitability (eg, provide raw data) for innovative data analysis and development

of methods to provide feedback as a means of preventive intervention.

Advances in mHealth solutions and data-centralization methods, including smartphone assessments, could result in reduced cost and complexity associated with collecting comprehensive driving data, and enabling increased and innovative driving research. Additionally, driving data could be collected by smartphones from previously unmeasured populations (eg, lower socio-economic strata, low-income countries), which could result in further app diversification, research insights, and a wider impact on driving safety.

A recent survey confirmed the continued popularity and dominant market share of the iPhone among teenagers; 81% of surveyed US teenagers owned an iPhone, and this number is projected to grow [17]. However, no research has reported the utility of the iPhone for assessing KRD. The purpose of this work was to evaluate the utility of a simple, nonproprietary iPhone app to assess teenage KRD behavior. The research evaluates the feasibility of using iPhone devices as a research tool for NDS by comparing linear acceleration acquired with iPhone devices to acceleration measurements obtained simultaneously with an Android smartphone (Samsung Galaxy S5) and the in-vehicle miniDAS data acquisition system (DAS) developed at the Virginia Tech Transportation Institute (VTTI).

## Methods

### Overview

The smartphone Application to Measure Risky Driving Behavior and Predict Crashes (gForce App), was developed in Swift, which is a general-purpose, multi-platform, programming language for iOS using an Xcode environment (Apple, Inc). The gForce App was tested on the iPhone 6 (Apple, Inc) running iOS 10.3.1. The iPhone incorporates the Sensortec BMA280 3-axis accelerometer and the InvenSense MP67B 6-axis accelerometer, gyroscope, and magnetometer combined sensor with an on-chip digital motion processor (DMP) with sensor-fusion capabilities. Sensor-fusion is a technology (ie, firmware) that algorithmically combines data from multiple sensors to mitigate the limitations of the individual sensors to more accurately calculate the real-time position and orientation of the iPhone device. In addition, but not part of this research, the gForce app utilizes the iPhone dual cameras (ie, front and back cameras). The front camera records a video of the driver, while the back camera captures still images outside the vehicle.

The gForce App is designed to continuously record (ie, 10 Hz nominal sampling rate) linear acceleration (acceleration of the device, excluding the effect of gravity on the device) and rotation data for the x, y, and z axes. Immediately, the gForce App calculates a directionless g-force by combining the linear acceleration data from all three axes. The data is stamped with Coordinated Universal Time and GPS location. Other app features include: an audio warning when a g-force event is

triggered, a capability of uploading JSON formatted files to a centralized database, and a fully integrated navigation solution.

This navigation feature may reduce the driver's desire to switch to another app, which, due to iOS limitations, would effectively disable gForce camera acquisitions even though the app would continue to run otherwise (eg. measure and upload g-forces).

The iPhone acceleration measurements were compared with the acceleration values acquired by a custom-built app on a Galaxy S5 (Samsung, Inc) running Android 4.5.2 (Google, Inc), and the DAS. Similar to the iPhone gForce App, the Android app and DAS system continuously record acceleration and rotation measurements along three axes, stamped with time and location. The Galaxy S5 utilizes a InvenSense MP65M 6-axis gyroscope, accelerometer, and magnetometer-combined sensor with a DMP. The DAS device is equipped with a STMicroelectronics LSM303DLM sensor module, which includes a 3-axis

accelerometer and three-axis magnetometer. The DAS device does not provide onboard sensor-fusion technology. Similar to the iPhone gForce App, the Android app features wireless uploading of data to a centralized database in JSON and, in addition, CSV file format. The DAS system requires data transfer via a Secure Digital card. The Android app was pilot tested and refined based in small-scale field tests in Washington D.C. and was compared to the DAS in a previous experiment [18]. The DAS has been widely employed in NDSs and is considered to provide reliable g-force measures [9,12].

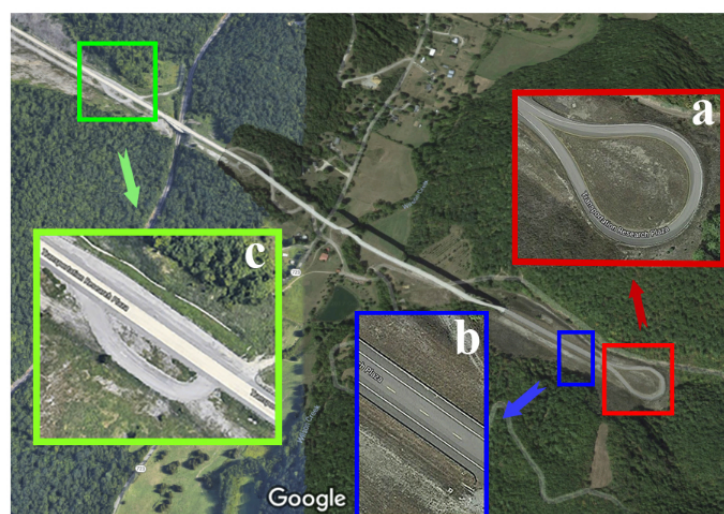
### Procedures

Device testing consisted of the following two parts: (1) test track driving on the Virginia Smart Road research facility, which is managed by VTTI and owned and maintained by the Virginia Department of Transportation; and (2) street driving in Christiansburg, VA.

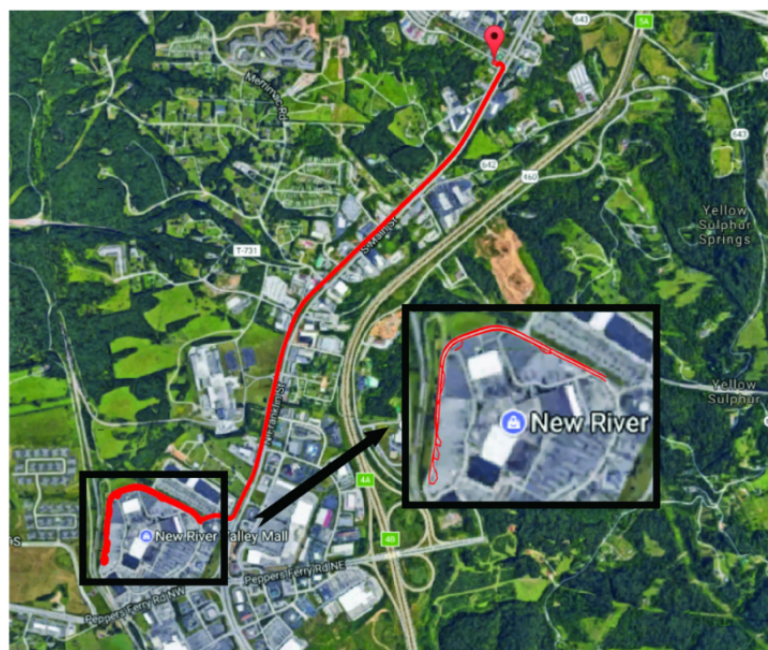
**Figure 1.** Smartphones used for the Virginia Tech Transportation Institute road test: iPhone devices are #2 and 3; Android devices are #1, 4, and 5; Virginia Tech Transportation Institute permanently vehicle-installed instrumentation #6.



**Figure 2.** Virginia Smart Road: a) roundabout used for cornering; b) straight portion of the road used for braking and acceleration; c) turnout lane used for turning left and right.



**Figure 3.** The street-driving phase of the test in Christiansburg, VA. Driving over speedbumps, potholes and U-turns was performed on the loop around New River Valley Mall (black box).



## Experimental Protocol

Figure 1 shows the orientation and location of the devices used in this study. These devices included an Android phone (#1) and two iPhones (#2 and #3) mounted on the dashboard, two Android phones (#4 and #5) mounted on the windshield, and the permanently installed DAS device (#6). A fourth Android phone (not shown) provided the driver with a g-force estimation during each maneuver, which helped to ensure the desired g-forces were generated. Experimental testing on the Smart Road consisted of consecutive groups of driving maneuvers, including: 10 moderate and 5 hard cornering for each left and right directions on a roundabout (Figure 2 a), braking (15 hard) and acceleration (5 mild) driving in a straight line (Figure 2 b), and 12 moderate and 6 hard turning maneuvers in each left and right directions (Figure 2 c). The street-driving phase of the test (Christiansburg, VA, Figure 3) was comprised of normal driving maneuvers and road conditions, such as: 3 stop signs, 2 traffic lights, 2 left and 6 right turns, 4 left and 2 right U-turns, 7 left and 5 right cornering, 14 speedbumps, and 8 potholes. The duration of the test was 10 minutes 14 seconds. There were four passengers in the car.

## Data Processing and Analysis

Postprocessing was performed in MATLAB (MathWorks, Inc). To reduce noise and the number of false positives (ie, g-force events associated with speedbumps and potholes), a second-order low-pass Butterworth digital filter with a cutoff frequency of 0.4 Hz was applied to iPhone and Android measurements. DAS sensor data was processed on the device with a 5 Hz low-pass filter, followed by a MATLAB low-pass filter with parameters identical to iPhone and Android data post-processing. The Pearson correlation coefficients,  $r$ , for acceleration along x (lateral,  $r_{lat}$ ), y, and z (longitudinal,  $r_{lng}$ ) axes were estimated for the iPhone (the average of two iPhones)

versus DAS, and Android (the average of two Androids) versus DAS.

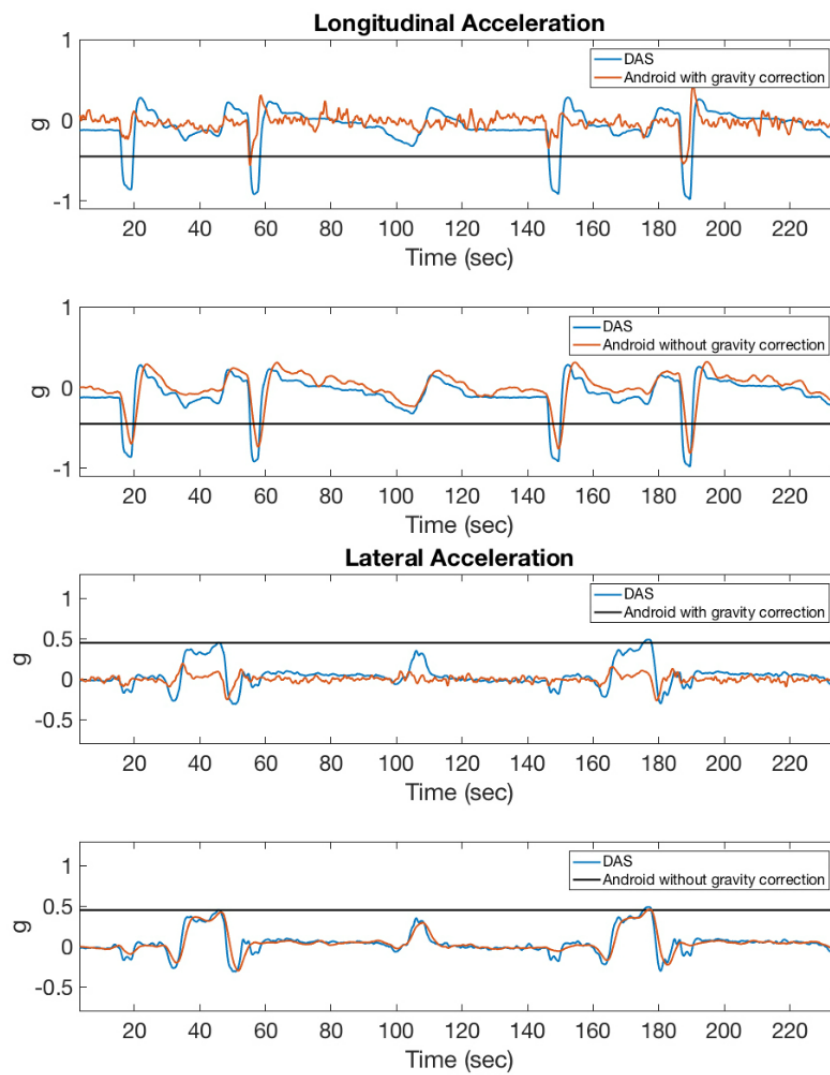
Lateral (ie, x-axis) acceleration corresponds to sideways movement in relationship to the direction of travel, while longitudinal (ie, z-axis) acceleration corresponds to acceleration in the direction of travel. In this work, we report correlation coefficients for the longitudinal and lateral acceleration measurements only. The average duration of the g-force events over 0.45 g were estimated for each device. This threshold was selected for all events to provide consistent values for analyses.

## Results

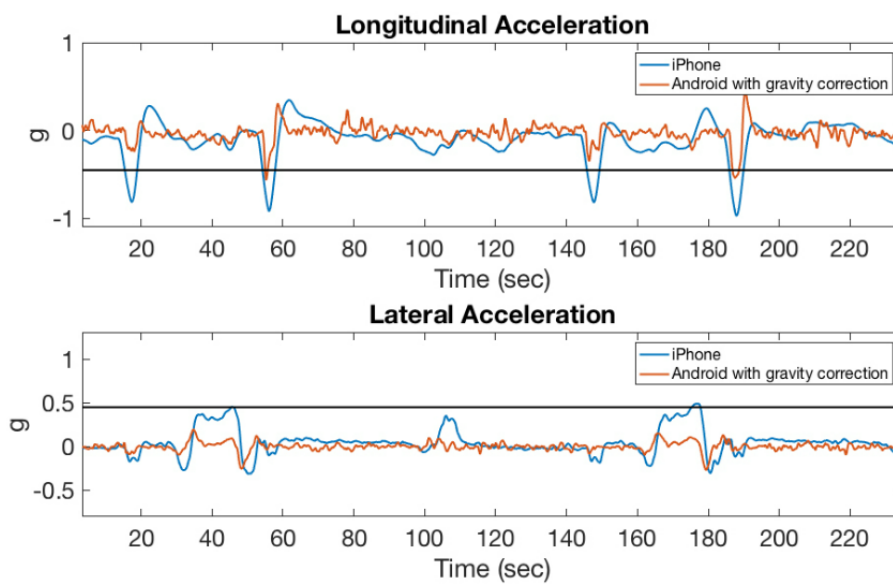
### Gravity Correction on the Android and Data Acquisition System

Preliminary analyses indicated a poor correlation between the Android linear acceleration and the DAS acceleration measurements. In addition, the amplitude of the signal consistently below the threshold of 0.45 g for all maneuvers revealed that the gravity correction on the Android device was ineffective in correctly adjusting for the effect of gravity. This gravity correction issue was especially pronounced during the braking maneuvers where the correlation coefficients between the Android linear longitudinal (Figure 4 a) and lateral (Figure 4 b) acceleration and DAS acceleration measurements were  $r_{lng}=0.05$  and  $r_{lat}=0.10$ , respectively, while the correlation coefficients for the same maneuvers without gravity correction on the Android device were  $r_{lng}=0.93$  and  $r_{lat}=0.89$  for the longitudinal and lateral acceleration measurements, respectively. Figure 5 shows a similar trend between the Android and iPhone gravity-corrected acceleration measurements. Therefore, in this work, the Android acceleration measurements without gravity correction were used for estimating correlation coefficients between the Android and DAS devices.

**Figure 4.** Comparison of gravity-corrected and uncorrected Android acceleration measurements with data acquisition system (DAS; gravity-uncorrected).



**Figure 5.** Comparison of gravity-corrected Android acceleration measurements with iPhone (inherently gravity-corrected).





### Effect of Weight Distribution on Kinematic Measures

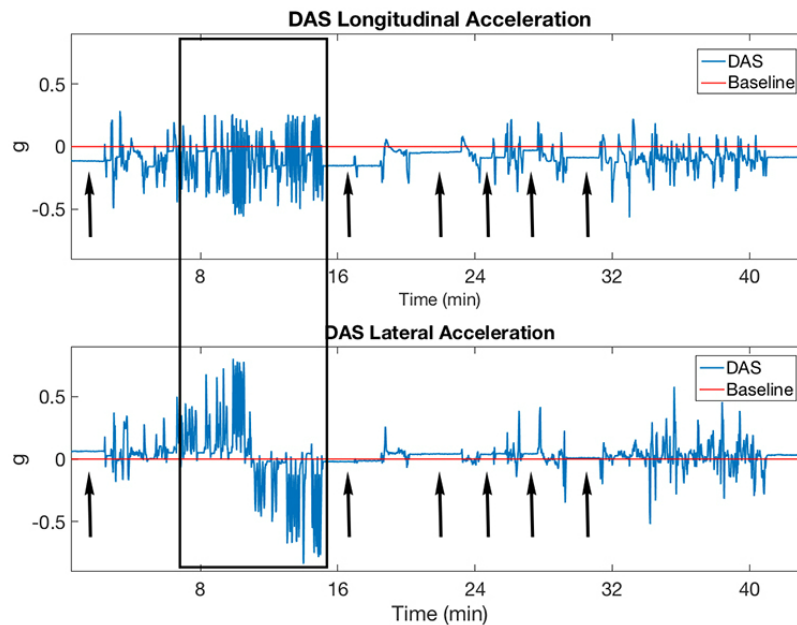
The weight distribution (ie, vehicle lean) within the vehicle (ie, number of passengers and their location) had an effect on the DAS acceleration measurements. As seen in Figure 6, the baseline offset shifted (black arrows) as passengers entered or exited the vehicle. Figure 7 shows the Android acceleration measurements were similarly affected by weight distribution, while the iPhone baseline offset correctly remained at zero.

Figure 6 and Figure 7 show that in the absence of gravity correction, the DAS and Android acceleration amplitude measurements were either overestimated or underestimated, depending on the baseline offset. The iPhone acceleration amplitude measurements were not affected by the changing weight distribution within the vehicle (Figure 7).

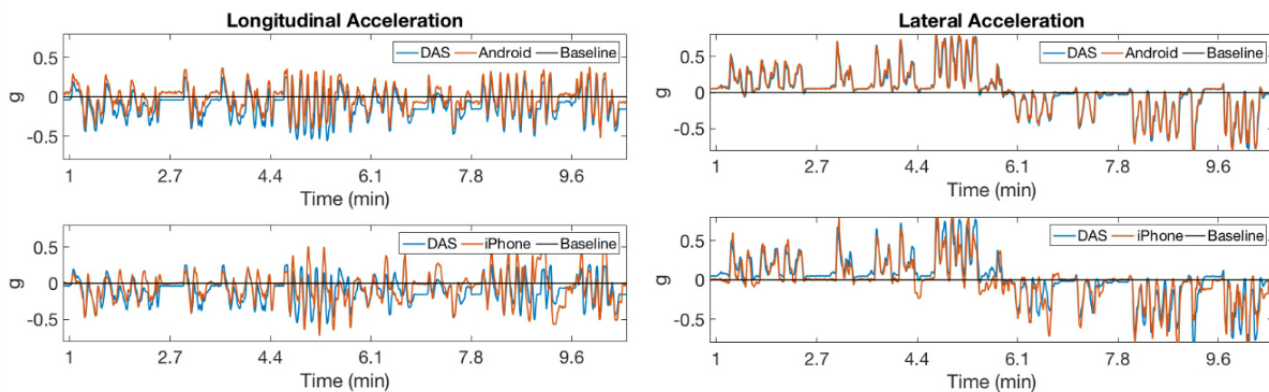
### Correlations of Acceleration Measures

In the test track assessment, the correlation coefficients between acceleration measurements acquired with DAS and Android devices were consistently higher than the correlation between DAS and iPhone devices for the same measurement, possibly because neither of these devices correct for gravity (Figures 8, 9, and 10). Averaging all maneuvers, the correlation coefficients between longitudinal and lateral accelerations between iPhone and DAS were  $r_{\text{lng}}=0.71$  and  $r_{\text{lat}}=0.83$ , respectively, while the corresponding acceleration measurements between Android and DAS were  $r_{\text{lng}}=0.95$  and  $r_{\text{lat}}=0.97$  (Table 1). This study also revealed that the correlation coefficients between the iPhone and DAS lateral accelerations were higher than the corresponding longitudinal accelerations for most maneuvers (Table 1). A similar lateral versus longitudinal correlation difference was observed between the Android and DAS measurements (Table 1).

**Figure 6.** The effects of in-vehicle weight distribution on baseline acceleration measurements. The acceleration measurements offset from the baseline varied (arrows) based on the number of passengers/weight distribution inside the vehicle. Comparison with the Android and iPhone devices within the black box is show in Figure 7. DAS: data acquisition system.



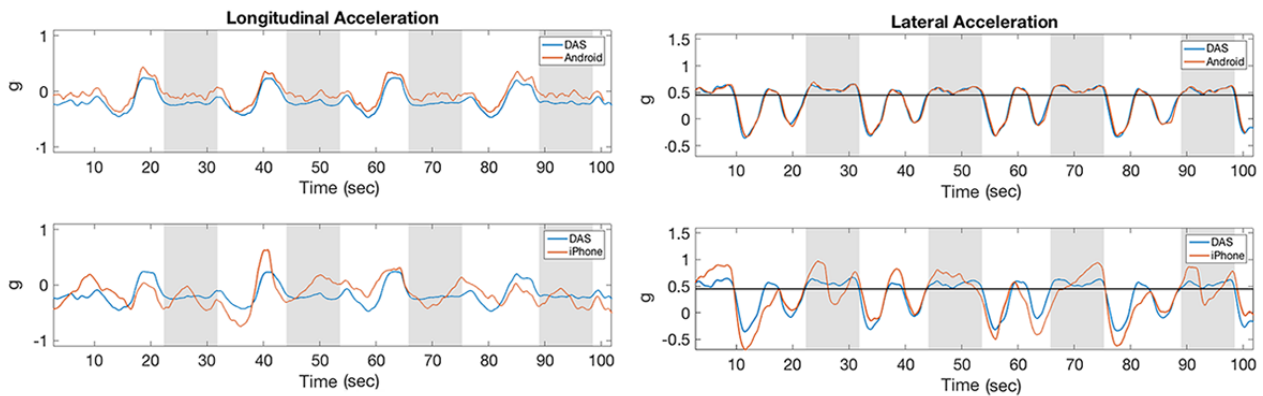
**Figure 7.** The effects of in-vehicle weight distribution on baseline acceleration measurements. While vehicle is stationary, the acceleration measurements should be zero. DAS: data acquisition system.



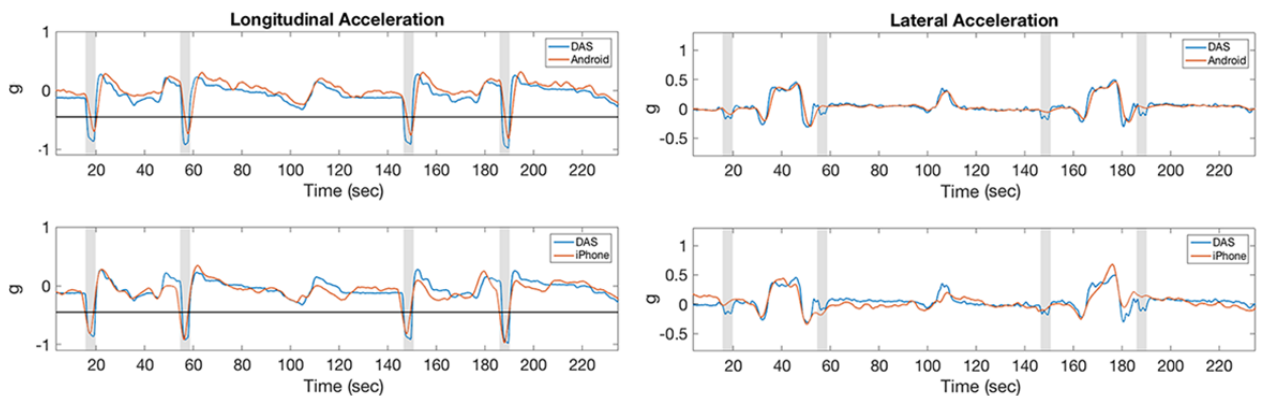
As shown in Table 2, the average duration of the g-force events above 0.45 g for the hard cornering maneuvers in the lateral direction were 9.5, 8.4, and 9.5 seconds for the DAS, iPhone, and Android devices, respectively. Similarly, the average duration of the hard-braking maneuvers above threshold were 3.5, 3.4, and 3.1 seconds for the DAS, iPhone, and Android devices, respectively. The average duration of the g-force events above 0.45 g during the hard turns were 3.9, 2.7, and 3.6 seconds for the DAS, iPhone, and Android devices, respectively.

In the street driving phase, the correlation coefficients (Figure 11 and Figure 12) were lower than those for the data obtained during experimental testing on the Smart Road, perhaps due to false positives (eg, speedbumps and potholes). The correlation coefficient between the iPhone and DAS longitudinal and lateral accelerations were  $r_{lng}=0.62$  and  $r_{lat}=0.71$ , respectively; the corresponding correlation coefficients between the Android and DAS measurements where  $r_{lng}=0.86$  and  $r_{lat}=0.91$ .

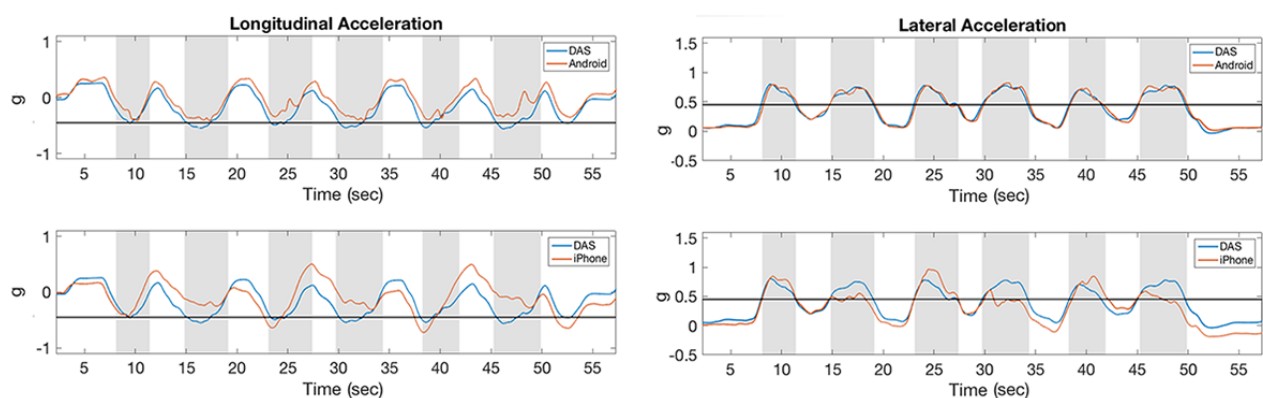
**Figure 8.** Acceleration measurements for hard left cornering maneuvers. The horizontal line along lateral acceleration represents the threshold of 0.45 g. Shaded stripes identify the approximate time of the cornering maneuvers. DAS: data acquisition system.



**Figure 9.** Acceleration measurements for hard braking maneuvers. The horizontal line along longitudinal acceleration represents the threshold of -0.45 g. Shaded stripes identify the approximate time of the braking maneuvers. DAS: data acquisition system.



**Figure 10.** Acceleration measurements for hard left turning maneuvers. The horizontal line along longitudinal and lateral accelerations represents thresholds of -0.45 g and 0.45 g, respectively. Shaded stripes identify the approximate time of the turning maneuvers. DAS: data acquisition system.



**Table 1.** Correlation coefficients between data acquisition system (DAS)/iPhone and DAS/Android devices.

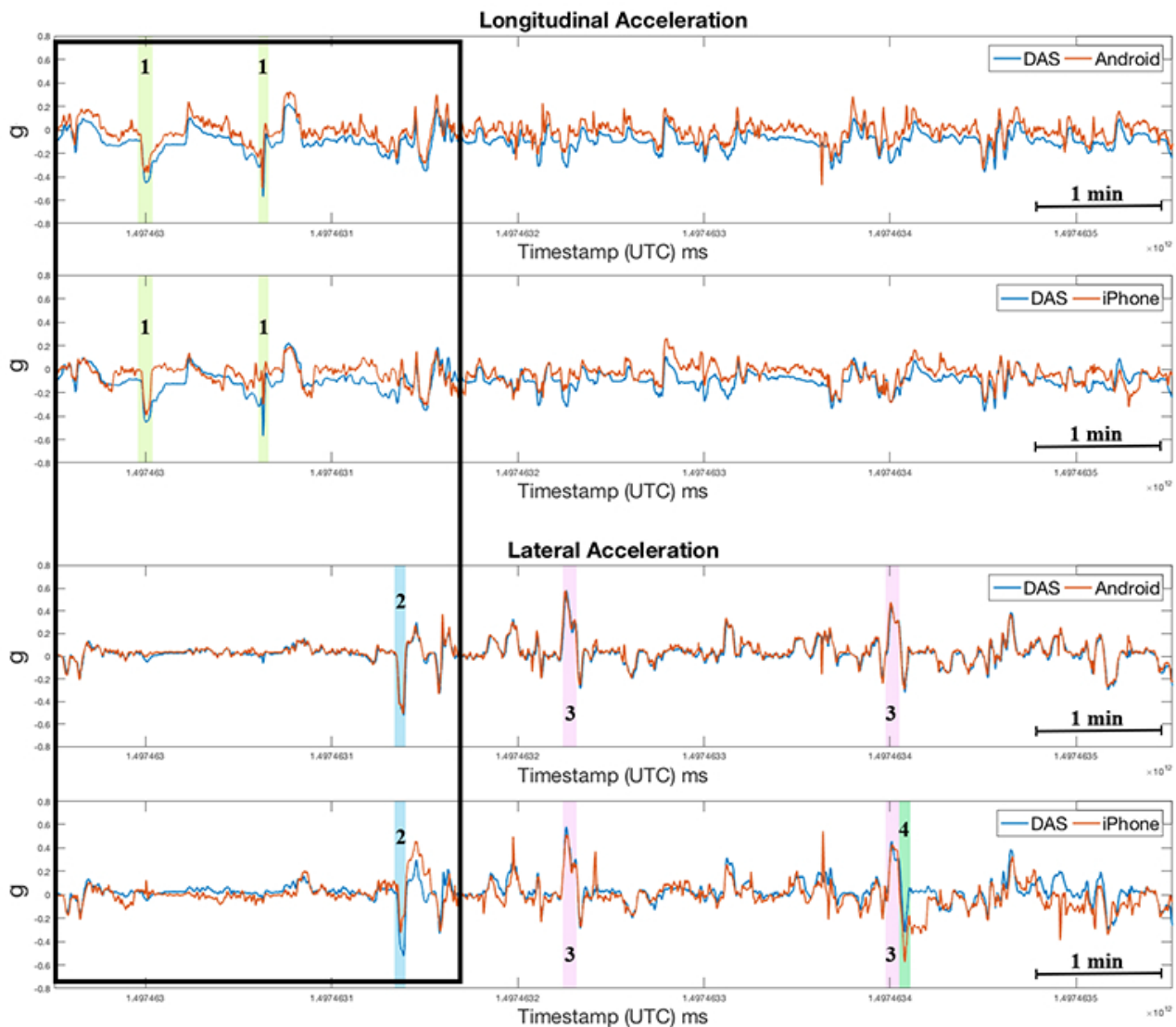
Driving maneuver	$r_{lat}^a$		$r_{lng}^a$	
	iPhone	Android	iPhone	Android
<b>Cornering</b>				
Left hard (>0.45 g)	0.86	0.94	0.65	0.88
Left	0.82	0.99	0.58	0.93
Right hard (>0.45 g)	0.78	0.97	0.63	0.98
Right	0.80	0.99	0.77	0.96
Braking hard (>0.45 g)	0.76	0.93	0.84	0.89
<b>Turning</b>				
Left hard (>0.45 g)	0.87	0.99	0.90	0.93
Left	0.90	0.97	0.69	0.95
Right hard (>0.45 g)	0.85	0.98	0.75	0.96
Right	0.84	0.99	0.63	0.97
Average	0.83	0.97	0.71	0.95

<sup>a</sup>Pearson correlation coefficients,  $r$ , for acceleration along x (lateral,  $r_{lat}$ ) and z (longitudinal,  $r_{lng}$ ) axes.

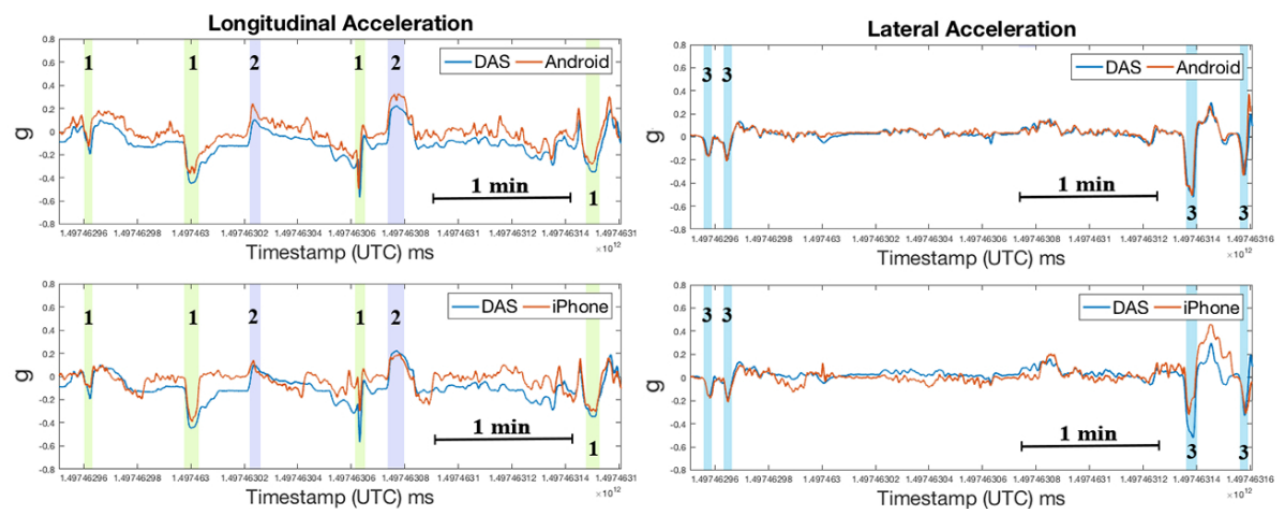
**Table 2.** Average duration of the g-force events over 0.45 g threshold (seconds).

Driving maneuver	Lateral			Longitudinal		
	iPhone	Android	Average	iPhone	Android	Average
<b>Cornering hard</b>						
Left	9.8	8.0	9.9	0	0	0
Right	9.2	8.8	9.1	0	0	0
Braking hard	0	0	0	3.5	3.4	3.1
<b>Turning hard</b>						
Left	4.2	3.1	3.8	2.0	2.1	0
Right	3.6	2.2	3.4	0	0	0

**Figure 11.** Acceleration measurements acquired during street driving in Christiansburg, VA. Highlighted are maneuvers that exceeded 0.45 g threshold: hard brake (1), hard right turn (2), hard left U-turn (3), and pothole (4). Details during first 3.4 minutes of driving within the black box are annotated in Figure 12. DAS: data acquisition system; UTC: Coordinated Universal Time.



**Figure 12.** Acceleration measurements acquired during first 3.4 minutes of street driving in Christiansburg, VA (black box in Figure 11): brake (1), acceleration (2), and right turn (3). DAS: data acquisition system; UTC: Coordinated Universal Time.



## Discussion

### Principal Findings

The main objective of this study was to evaluate performance of a custom-built gForce iPhone app as a potential research tool. This evaluation compared the iPhone gForce acceleration measurements with data collected with the DAS device, which is the standard equipment in on-road NDSs. The findings indicated that correlations between measures of elevated g-forces from the iPhone gForce App and the DAS were reasonably high, ranging from  $r=0.78$  to  $0.81$ . This finding suggests that the iPhone 6 with integral sensor-fusion technology may be a viable data acquisition platform for detecting elevated g-forces, with the added benefit of decoupling measurements from gravity (ie, vehicle orientation relative to gravity). In comparison, Android and DAS measurements were highly sensitive not only to road topography (eg, road lateral slope or banking), but also to the weight distribution within the vehicle (ie, vehicle lean), thus altering acceleration amplitudes along individual axes. Due to this sensitivity, the average durations of the elevated g-force events captured with the iPhone device differed from the corresponding durations acquired with DAS and Android devices. This effect was especially pronounced during cornering and turning, since the vehicle was leaning during these maneuvers. In contrast, the highest similarity between the

average durations of the elevated g-force events for all three devices was observed during braking, since this maneuver was less susceptible to vehicle leaning.

Future research will examine the association between g-forces collected by the iPhone and a device that includes in-built gravity adjustment, and is unaffected by weight distribution in the vehicle. Beyond this, the utility of the app would be assessed by recruiting participants to use the app while driving their own vehicles under usual driving. In this context, participant preferences for downloading an app on their existing iPhone device or using a dedicated device for data collection would need to be established. Given the sophistication of the iPhone and iOS development platform, the capabilities of the app could be extended to include video capture, real-time driver feedback, and cloud-based data aggregation and analyses. Finally, machine learning-based methods will be needed for automated maneuver identification and improved rejection of false positive g-force events not associated with a risky driving behavior.

### Conclusions

The gForce iPhone app reliably assessed elevated g-force events compared to the DAS. Collectively, the gForce app and iPhone platform have the potential to serve as feature-rich, inexpensive, scalable, and open-source tool for assessment of KRD events, with potential for research and feedback forms of intervention.

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### Conflicts of Interest

None declared.

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## Abbreviations

- DAS:** data acquisition system  
**DMP:** digital motion processor  
**GPS:** Global Positioning System  
**KRD:** kinematic risky driving  
**NDS:** naturalistic driving study  
**VTTI:** Virginia Tech Transportation Institute

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Original Paper

# Digital Inequalities in the Use of Self-Tracking Diet and Fitness Apps: Interview Study on the Influence of Social, Economic, and Cultural Factors

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## Abstract

**Background:** Digital devices are driving economic and social transformations, but assessing the uses, perceptions, and impact of these new technologies on diet and physical activity remains a major societal challenge.

**Objective:** We aimed to determine under which social, economic, and cultural conditions individuals in France were more likely to be actively invested in the use of self-tracking diet and fitness apps for better health behaviors.

**Methods:** Existing users of 3 diet and fitness self-tracking apps (Weight Watchers, MyFitnessPal, and sport apps) were recruited from 3 regions of France. We interviewed 79 individuals (Weight Watchers, n=37; MyFitnessPal, n=20; sport apps, n=22). In-depth semistructured interviews were conducted with each participant, using open-ended questions about their use of diet and fitness apps. A triangulation of methods (content, textual, and quantitative analyses) was performed.

**Results:** We found 3 clusters of interviewees who differed by social background and curative goal linked to use under constraint versus preventive goal linked to chosen use, and intensity of their self-quantification efforts and participation in social networks. Interviewees used the apps for a diversity of uses, including measurement, tracking, quantification, and participation in digital communities. A digital divide was highlighted, comprising a major social gap. Social conditions for appropriation of self-tracking devices included sociodemographic factors, life course stages, and cross-cutting factors of heterogeneity.

**Conclusions:** Individuals from affluent or intermediate social milieus were most likely to use the apps and to participate in the associated online social networks. These interviewees also demonstrated a preventive approach to a healthy lifestyle. Individuals from lower milieus were more reluctant to use digital devices relating to diet and physical activity or to participate in self-quantification. The results of the study have major implications for public health: the digital self-quantification device is intrinsically less important than the way the individual uses it, in terms of adoption of successful health behaviors.

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**KEYWORDS**

diet; digital divide; fitness trackers; France; healthy diet; physical activity; social networking; social participation; weight loss

## Introduction

### A Digital Society

We have entered a digital society. Digital technologies are driving economic and social transformations, particularly in the areas of diet and fitness. Self-tracking devices are becoming increasingly prevalent and are changing how individuals monitor their health to a more preventive approach, allowing the general public wide access to data related to health and personalized recommendations [1]. Personal physiological self-tracking has therefore become a very commonplace activity [2].

An increasing number of health-related apps are available for download, and the majority relate to diet, weight, and physical exercise [3]. In the United States, 60% of US adults track their weight, diet, and physical activity on a daily basis [4]. In France, within the context of increasing diet and health inequalities and a reduced habit of quantification, 24% of the population in 2016 used a digital device for their health [5].

Research on diet- and health-related digital devices has produced contrasting results, some studies demonstrating the positive effects of digital devices on dietary behavior change, weight loss, or physical activity [6-9] and others highlighting the limits of such digital devices [10]. Moreover, research has not yet precisely determined the social circumstances under which such apps are beneficial, particularly as active engagement of users is a major issue in digital health [11].

More recently, studies have been conducted among the general public to determine how social differences influence the use of digital self-tracking devices [12]. Ng et al [13], for instance, reported that physical activity trackers are used more by adolescents from affluent milieus. Sociological research has taken a particular interest in how digital devices form a new mode of self-governance and self-measurement. Lupton's central analysis was of digital devices in the context of the health imperative of contemporary societies [14]. The findings of this study underscored the risks of standardizing practices and warned against the surveillance and self-control aspects of digital devices, which form the basis of new efforts to normalize and standardize behavior [15].

### Daily Uses of Self-Tracking Apps

Regardless, research that provides field data on how these tools are used by individuals in their everyday lives, particularly in the area of dietary habits, is limited. Yet, the question of use is decisive: effectiveness of digital devices may depend less on the tool and more on how the individual uses it [16]. Indeed, digital devices offer several functionalities: measuring (food intake or physical activity), recording (keeping a written record), quantifying (expressing content numerically in digital format rather than in words [2]), and participating in social networks (sharing, commenting on, and comparing data).

The goal of this paper was to analyze the uses and perceptions of digital diet and fitness devices in daily life and their links to social status. The paper will address the following questions: Why do some individuals turn to self-tracking tools at a given moment in their lives? What functionalities do users favor and how do they make use of the digital communities? Finally, what

economic, social, and cultural conditions lead individuals to use digital devices actively to attain better health behaviors?

## Methods

To understand the diversity of practices and perceptions and the individual experiences of the participants, our study was based on a qualitative survey. We used the 32-item Consolidated Criteria for Reporting Qualitative Research checklist [17].

### Study Design and Participants

We conducted in-depth, individual, semistructured interviews with 79 individuals. Participants were asked open-ended questions about their use of digital devices in daily life: reasons for choosing the particular device, frequency and circumstances of use, functionalities used, information taken into account when using the device, and effect of use on dietary or sporting habits.

The inclusion criterion was use of at least one of the following self-tracking tools: sport apps (n=22), MyFitnessPal (n=20), or Weight Watchers app (n=37). The 22 individuals in the sport apps group were characterized by the use of common self-tracking tools accessible via cell phone apps, bracelets or watches with accelerometers, and instruments equipped with global positioning system. MyFitnessPal, one of the most popular diet apps [18], is an online calorie counter based on a food diary model. In addition to recording and quantify food intakes, the app determines a recommended daily calorie intake based on the user's profile (height, weight, gender, daily activity level, and personal objectives in terms of weight).

Both sport devices and MyFitnessPal enable users to store and share data and also to facilitate community discussions, either on the app's website or via websites for athletes, such as Strava.

Members of Weight Watchers France, a private company that has developed weight loss programs, follow a dietary plan and attend weekly support group meetings [19]. They are offered a mobile app that calculates and records meals via a points system and scans products. They have access to the Weight Watchers website (recipes and discussion forums). Furthermore, members have the option to choose between a digital or paper Weight Watchers program, enabling us to evaluate reasons for choosing a digital app.

The sample was chosen to compare the social status of participants, based on the declared profession, according to the National Institute of Statistics and Economic Studies classification. To do this, interviews were conducted in Paris (n=35), which provided access to high- and middle-income earners residing in urban areas; in and around La Rochelle, Western France, which provided access to middle-income earners (n=13); and, in Eastern France around Thionville, in small towns impacted by the de-industrialization crisis (n=13), versus a wealthy city (n=13)

Participants were recruited from sports clubs or while participating in sporting activities (face-to-face approach), via snowball sampling on the MyFitnessPal social network (initial participants were recruited via the forum and the messaging systems), and via our participation in Weight Watchers meetings.



They were interviewed for 1-2 hours, most often in their own home. We conducted 5 interviews by phone because of the wide geographic distribution of MyFitnessPal participants (ie, more than 3 hours away from Paris, Thionville, or La Rochelle).

All interviews were recorded, transcribed, and anonymized. The transcription was realized by a team of transcription consultants, trained for homogeneity in the processing. The researcher who conducted the field survey was helped by 1 sociologist consultant trained in the processing of semistructured interviews. She was warmly welcomed by participants who were excited to relate their perspective on digital devices. The researcher's lack of knowledge in the field of self-tracking was a positive characteristic, encouraging participants to adopt the position of expert in the field. Moreover, the researcher's nonjudgmental attitude toward losing weight enabled participants with weight issues to feel confident.

Interviews were completed with ethnographic observations regarding the uses of digital apps (participants explained their personal health or fitness data, showed us how they had evolved through time, and explained in practical terms how their app worked). Qualitative data were also collected from field notes. The size of the sample made it possible to achieve sufficient saturation, that is, each new participant in each group did not bring any new substantial, relevant knowledge to the survey, and provide enough internal variation to draw solid conclusions regarding differences between practices and perceptions in relation to the social status of individuals.

### Ethics

The goals of the research were explained to the interviewees and their consent was obtained for recording. The Weight Watchers field work was carried out with the approval of the management of Weight Watchers France. All the interviews were strictly anonymized, and interviewees were given fictitious names. The interviewees were thanked with a gift card (€15).

### Quantitative Analysis of Practices

Analysis was based on a triangulation of methods [20]: content, textual, and quantitative analyses. We considered 25 different practices (see [Table 1](#)) deriving from the corpus of 79 interviews generating 759,240 words. This corpus was first submitted for content analysis: the data were coded, following the themes of the interview guide and including new themes derived from the data collection (eg, a search for precision vs trend). The content analysis leads to the identification of 6 main themes (functionalities used, uses, engagement in the digital network, relation to publishing, familiarity with information and communication technology (ICT), and reasons for use; sample quotes are given for each theme in [Table 1](#)).

The content analysis was double-checked with Hyperbase, based on the specificity tables drawn up for each interview by

Hyperbase, using Z-scores which measured the over- or under-representativeness of a word in an interview with respect to the corpus as a whole.

These 6 identified themes lead to the characterization of 25 different practices, measured as dichotomous variables ([Table 1](#)). A principal component analysis was carried out using Stata software on the 25 active variables determined by practice. As a robustness check, we conducted a multiple correspondence analysis that produced very similar results. The first 2 axes, accounting in total for 26% of the total variance of the sample, generated a correlation circle [21], representing the 25 active variables ([Multimedia Appendix 1](#)); the illustrative (sociodemographic) variables are represented on the principal plan ([Multimedia Appendix 1](#)).

Beyond the 2 first dimensions of the factor analysis, we retained 4 additional axes on the basis of differences in variance (other choices did not substantially affect results). These first 6 scoring axes, which accounted for 54% of the variance, were used as active variables of a hierarchical ascending classification (Ward method, squared Euclidean distance) designed to provide a coherent grouping of the population on the basis of their practices. The clusters are represented on the principal plan of the principal component analysis, and the significance of the correlation between cluster group and the 25 active variables (Phi coefficient) is presented in [Multimedia Appendix 1](#).

### Sociodemographic Characteristics

The sample included 60 women, which was attributable to the high proportion of women enrolled in Weight Watchers and using MyFitnessPal. The majority of sport app users were men. Interviewees were aged between 23 and 70 years, with a mean age of 43 years. Most of them were employed in intermediate professions, such as technicians or nurses (31/79, 39%), or were clerical workers (21/79, 27%). Interviewees also had diverse social profiles, in terms of occupational status, associated with their respective self-tracking device. Sport app users tended to belong to high-income milieus, users of MyFitnessPal to the intermediate categories, and Weight Watchers members to intermediate- to low-income milieus ([Table 2](#)). Among sport app users, we found that 8 participants used watches (Garmin, Suunto), 5 used mobile phone apps (Runkeeper, Runtastic), 2 used Fitbit wristbands, 6 used 2 devices (mostly a watch plus a smartphone app), and 1 used connected running shoes. We found that 39 individuals used several digital apps at the same time: one to monitor food and another to monitor physical activity. More than half of the Weight Watchers members (20/37, 54%) and 70% (14/20) of MyFitnessPal users used a physical activity tracker. Among sport app users, 23% (5/22) used or had previously used MyFitnessPal.

**Table 1.** Twenty-five variables determined by different uses, categorized by theme and examples of quotes. ICT: information and communication technology; WW: Weight Watchers.

Theme and quote	Variable	Abbreviation
<b>Functionalities</b>		
“I don’t use MyFitnessPal to count calories.”	Quantification	Quantific
“The top functionality, it’s the scan.”	Scan	Scan
“The recipe’s calculator is really great!”	Recipes	Recipes
“When we cook, we publish our recipes (...) mainly on Facebook (...) because the internet community...chatting with people I don’t know, well...no.”	Facebook_WW	Facebook
<b>Uses</b>		
“It’s more for myself, to improve over previous years.”	Improvement_self	Improv_self
“You know what you have to beat [the record of the guy on the segment] so it’s pretty fun.”	Challenge	Comparison
“I wanted to know if it (commuting to work via bicycle) took me 32 minutes, which days it’d take 31, when it’d take 28.”	Precision	Precision
“It gave me a general idea of whether it was a good or not-so-good session.”	Trend	Trend
“It’s good to be able to compare from one time to another one.”	Correlate_data	Correl_data
<b>Digital network</b>		
“I was totally focused on the community.”	Community_yes	Com._yes
“No, I don’t use the forum, I’m not active.”	Community_no	Com._no
“At the beginning, I was on the forum, but I only read (the posts).”	Passive_engagement in digital social network	Passiv_eng
“So, I did publish much.”	Active_engagement in digital social network	Active_eng
“The community is awesome.”	Support	Support
<b>Relation to publishing</b>		
“When I was a child, I trained in a club, and yes, we used to fill out our cycle rides, with the number of kilometers, on a calendar.”	Anteriority of written record keeping	Anteriority
“I have my little... my little Weight Watchers booklet (...) I wrote on my little paper notebook.”	PaperWW	PaperWW
“I mean, you never know with Internet or apps, so I prefer being careful.”	Fear	Fear
<b>Familiarity with information and communication technology</b>		
“I work in an office...I’m an accountant so we’re used to working with Excel, with Word, with several types of software.”	ICT_familiarity without self-quantification	ICT_fam
“But at home, I don’t use a computer...nor a laptop, except for online games, in the evenings to relax.”	Digital_Entertainment without self-quantification	E_entertain
<b>Reasons for use</b>		
“I consider my body as an unfinished piece of art (...) that you constantly try to improve, to shape, to sculpt.”	Esthetic	Esthetic
“I have never had health issues because of my weight. It’s for prevention.”	Preventive	Preventive
“I suffer from diabetes (...) I had to give my doctor my food diary (...) With the app (MyFitnessPal) I took screenshots and I printed them.”	Chronic illness_management	Chronic
“I wanted to lose weight,” “I really wanted to lose weight.”	Curative_weight	Curative
“The marathon was my target.”	Performance_sport	Performance
“I went back to running last February.”	Restart_sport	Restart

**Table 2.** Sociodemographic characteristics of the participants. Values with statistically significant overrepresentation ( $P < .05$ ) are italicized.

Tool	Sport apps	MyFitnessPal	Weight Watchers	Total
Population size, n	22	20	37	79
<b>Gender, n (%)</b>				
Men	<i>14 (64)</i>	4 (20)	1 (3)	19 (24)
Women	8 (36)	<i>16 (80)</i>	<i>36 (97)</i>	60 (76)
<b>Age in years, n (%)</b>				
20-29	3 (14)	<i>7 (35)</i>	1 (3)	11 (14)
30-39	<i>10 (45)</i>	<i>8 (40)</i>	5 (13)	23 (29)
40-49	<i>9 (41)</i>	4 (20)	11 (30)	24 (30)
50+	0 (0)	1 (5)	<i>20 (54)</i>	21 (27)
Total	22 (100)	20 (100)	37 (100)	79 (100)
<b>Occupation, n (%)</b>				
Self-employed	1 (5)	0 (0)	2 (5)	3 (4)
Upper management, experts, and professionals	<i>11 (50)</i>	4 (20)	2 (5)	17 (21)
Intermediate professions	6 (27)	<i>10 (50)</i>	15 (41)	31 (39)
Clerical	3 (14)	3 (15)	<i>15 (41)</i>	21 (27)
Manual workers	0 (0)	<i>2 (10)</i>	1 (3)	3 (4)
Unemployed	1 (5)	1 (5)	2 (5)	4 (5)
Total	22 (100)	20 (100)	37 (100)	79 (100)

## Results

### Three Types of Users

Three clusters differed in their habits of self-quantification app use (Figure 1). Quadrants of Figure 1 labeled “Resistant,” “For self-improvement,” and “For sharing” indicate the position of the 3 clusters along the 2 axes (reluctance vs adhesion to self-tracking [axis 1] and rejection vs integration in the digital community [axis 2]) and the participants’ main sociodemographic characteristics. The device did not determine the use: the relationships between and within the clusters and the sample based on device used (sport app, Weight Watchers, or MyFitnessPal) represent the diversity of uses in the various classes of the typology (Multimedia Appendix 1). Between the 3 clusters, several lines of differentiation emerge (Figure 1). On axis 1 (“adhesion to self-tracking”), differences are found between the individuals most resistant to digital devices and the self-quantification process (on the left) and the individuals most connected and focused on monitoring and counting. There is an overlap between those who used self-tracking tools under constraint (on the left) and those who chose to use them (on the right). Indeed, this divide reflects the opposition between individuals who used digital devices to manage their weight gain or for a curative aim and those who used them for prevention or control of previous conditions, such as bulimia or anorexia, to thwart another trigger.

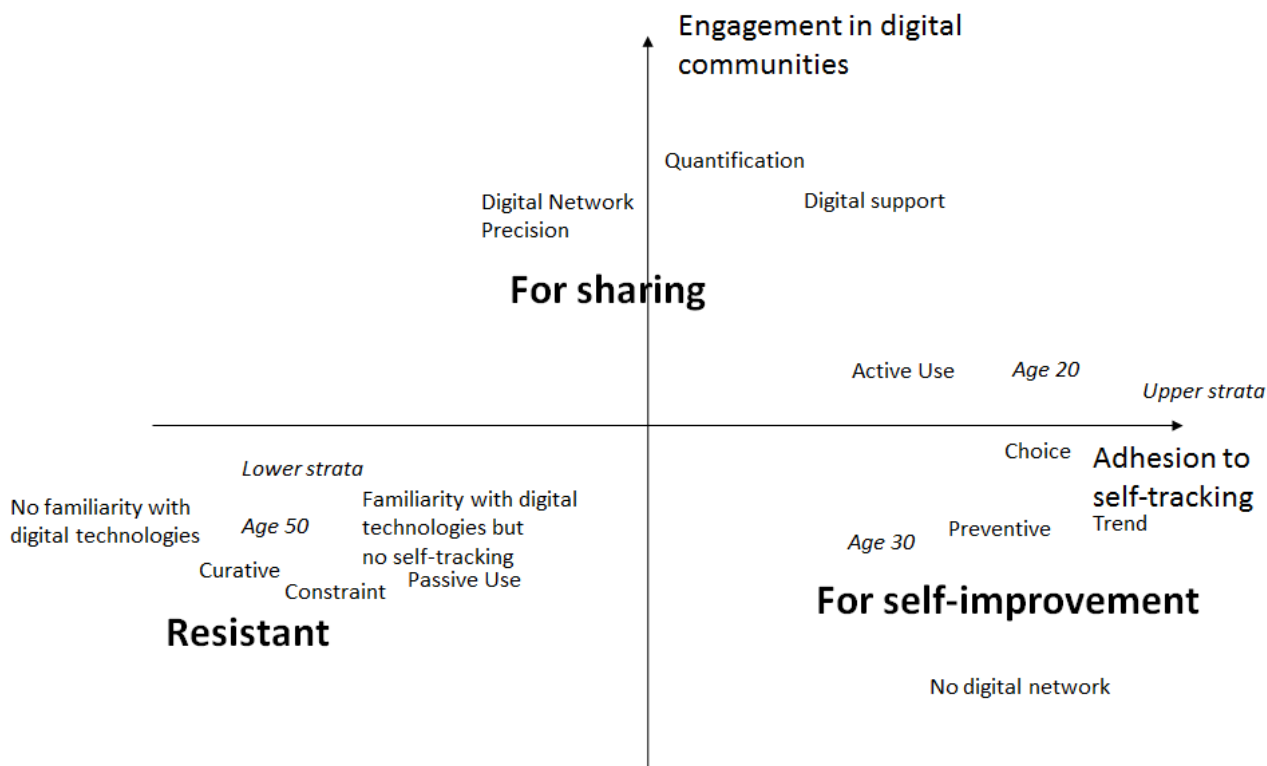
This differentiation corresponds to the opposition between poorer categories (manual and clerical workers on the left) and wealthier categories (executives on the right). Axis 2 shows the opposition between the individuals most resistant to entering a digital online community (at the bottom) and the individuals most integrated into online social media, who were also the most active contributors (at the top).

The “resistant” cluster was not only merely associated with reluctance regarding digital devices or self-quantification but also showed strong reluctance regarding online participation. The “for self-improvement” cluster combined adhesion to self-quantification, rejection of online social media, and preventive goals. The “for sharing” cluster was defined predominantly by the intense use of and active participation in a digital community that motivated, encouraged, and supported users.

### Individuals Resistant to Self-Tracking

The first cluster (“Resistant”) consisted of individuals with little inclination to use digital devices, particularly those associated with self-quantification. The majority of these individuals were women (28/32, 88%), who, with an average age of 50 years, were older than average and belonged predominantly to intermediate and clerical sociodemographic categories (Table 2).

Figure 1. Three types of users.



These individuals monitored their diet (weighed food) or physical activity (notably with pedometers) and weighed themselves, but recorded little on the apps and were not familiar with the quantification processes. The majority of these individuals were Weight Watchers members living in deprived areas and former users of MyFitnessPal or physical activity trackers, who used these tools temporarily as a result of lassitude, disinterest, boredom, or meeting their goal of losing weight. For example, 1 individual was annoyed with the mobile Weight Watchers app, referring to it as “fiddle-faddle” (aged 68 years, retired), whereas someone else, who had lost weight with Weight Watchers (aged 47 years, intermediate profession) stated:

*I'll admit that since I know it by heart...I'm not really addicted to numbers and, so...well, it's been a while since I've counted my points.*

Among this “Resistant” group, 2 subgroups emerged. The first and larger group (23 out of 32) was composed of individuals resistant to digital apps and devices in general, with a more specific reluctance to engage in online social media, and who were unfamiliar with digital technologies: “I don’t know how,” explained Marguerite (Weight Watchers, aged 67 years, nursing assistant), although she had a tablet. However, when it came to digital devices, she cited her profession and her age as a hindrance, saying it did not allow her to familiarize herself with computers and the Internet.

These individuals seldom participated in the digital communities linked to the 3 types of apps, and, if they did, they often participated in discussion forums as spectators:

*I look...just to tell myself “well, yes, we are all the same, you know.” [Weight Watchers, aged 55 years, intermediate profession]*

The second subgroup (9 out of 32 individuals) consisted of individuals who were resistant to the self-quantification process but familiar with digital technologies (eg, through their jobs) or in areas other than diet and fitness, such as gaming or online. Of the Weight Watchers members in this group, the nonuse of the digital app reflected their lack of motivation to follow the program. For instance, Michel (Weight Watchers, aged 58 years, self-employed) has several apps (for wine, to track his dog, and a Garmin global positioning system for his vacation itinerary), but because he was not very enthusiastic about exercise, he did not have a “fitness” app. He hardly showed any interest in trying the Weight Watchers digital program and used it inconsistently (“just the general gist”), a euphemism we interpreted to mean that he no longer really followed the program and he would soon discontinue.

### Self-Tracking Devices for Self-Improvement

The second cluster (“For self-improvement”) used self-tracking devices for self-improvement. This cluster consisted predominantly of sport app and MyFitnessPal users, who particularly appreciated the self-quantification approach because it enabled them to measure, record, and quantify themselves. This group contained more men (9/22, 41%) than the other 2 groups and, with a median age of 38 years, individuals were younger than the survey average and tended to be executives or have intermediate professions.

Individuals in this group shared the characteristics of wanting to use self-quantification tools and refusing to join a social media network: they were more concerned with personal

progress than comparing their results with others. As 1 individual stated:

*It's more for myself, to improve over previous years.*  
[Mathieu, Fitness tracker, aged 23 years, higher managerial profession]

Similarly, another individual emphasized his dislike of competing with others:

*Challenges don't [do it for me], not at all. I hate that. I don't have anything to prove except to myself. So, I'm relatively individualistic...I note my progress.*  
[Guy, MyFitnessPal, aged 49 years, manual worker]

These individuals did not compete with others, but rather measured their success by exceeding a personal goal set by themselves on the app. Some of these individuals looked for personal victories elsewhere, such as sporting competitions (9 out of the 22 individuals in this cluster); however, they still were unwilling to publish their performance data.

In addition, these individuals were motivated by congratulatory actions. Although members of the first cluster felt that the comments were intrusive or condescending (“stupid” or “silly”), members of the second cluster saw these comments as a real source of motivation:

*Everyone congratulates you, comments on your activity so it makes you want to continue.* [Ophélie, MyFitnessPal, aged 29 years, clerical]

Finally, in this cluster, the self-tracking tool monitored the individuals' activities, whether starting or restarting a sporting activity or preventing a wellness risk, such as weight gain. Thus, within this framework, the digital device was a very useful accessory, but only as a means of self-improvement.

### Self-Tracking for Sharing

The third cluster (“For sharing”) was composed of participants who had intense recourse to the digital community (22 out of 25), were significantly associated with active or passive engagement in the digital network, and who tended to have intermediate professions and be in their 40s. For most of these individuals, this involvement was active: they published their data, had online friends or subscriptions, were followed by other users, or regularly participated in discussion forums. Their second common characteristic was their love of quantification (significantly associated with this cluster), making them complete users of self-tracking devices (they measured, recorded, quantified, and participated in the digital community).

Twice as many individuals (12 out of 20) in this cluster than in the other clusters viewed online communities as a support system. Thus, these individuals used self-tracking tools constantly to manage their physical activities or diet on a daily basis.

In this cluster, some of the individuals looked for the most precise self-measurements possible, often reducing quantification down to the minute, second, or nearest gram (precision is significantly associated with this cluster; see [Multimedia Appendix 1](#)).

Furthermore, sporting activities or weight loss efforts were central to the lives of the individuals in this group, with many of them exhibiting strong motivation to achieve their goals. The largest weight loss “successes” (up to 45 kilos) were found in this cluster. So far, it is difficult to assess the sense of the causality: the use of digital device led to success or the most motivated interviewees took advantage of all their device's functionalities. Digital devices and self-quantification tools were ends in themselves.

### Diversity of Uses and Motivations

The utilization of digital devices differed drastically from one individual to another, whether in regard to the functionalities used, data taken into account, or integration in a digital community. Between individuals, measuring, recording, quantifying, and communicating were done very differently.

### Converting Measurements to Written Records

The reasons why individuals measured dietary intake or physical activity were diverse. Among the Weight Watchers members, weight loss was the ultimate goal for esthetic or health reasons. Users of MyFitnessPal had more varied goals; in most cases, although, the aim was a slimmer physique. With this aim, the app was either used for a long period of time (several months) or for a short period of time, ranging from 2 to 3 weeks, possibly several times a year. Some individuals used the devices to gain muscle, whereas others used them to monitor a medical condition, such as diabetes or an eating disorder (anorexia or bulimia), using the app as a safeguard to ensure they neither ate too much nor too little. Sport app users used the digital devices either to accompany the start or restart of sporting activities or to improve their performance at multiple levels, particularly in individual sports, such as running, cycling, and swimming.

Analysis showed that users had diverse reasons for recording their food intake or physical activity. Counting, recording, and writing are central tools in the Weight Watchers program [22]. The awareness afforded by converting measurements into a written record was evoked more broadly by the users of the 3 apps studied. Taking notes was also an obligation to control oneself (“a little police officer in your pocket,” said Clémence, MyFitnessPal, aged 41 years, intermediate profession).

MyFitnessPal is based on keeping a food diary. Differences between uses were found, eg, in the recording of excess. Some users published their excesses as a way to actualize and recognize them; however, others preferred to keep their excesses private. Differences were also found in the measurements scrutinized by the users, with some users reviewing overall calorie intake, and others attentively examining all nutritional data, such as calories, protein, carbohydrates, sodium, potassium, cholesterol, vitamins, and calcium.

Recording all food intakes was not seen as a time-consuming or fastidious constraint. Information was recorded after each meal, at the end of the day, or even at the start of the day when meals were being planned or during a spare minute or designated moment. For many, this recording session was seen as a way to make time for oneself outside of domestic or professional obligations. During this process, the speed and automation offered by digital support were widely viewed as an advantage,

whether in calculating points or calories or in populating the database.

Use of sport apps varied widely and was strongly linked to the intensity of the users' sporting activities. Some individuals, mostly the least athletic, used the tool daily to measure and record all of their physical activity (total number of steps, going up the stairs at home, etc), showing an interest in accumulating data on all movements made. Other, more athletic individuals, only measured what they considered to be true physical activity (an activity for which a specific time was allocated and for which real physical effort was implicated). The data used were also variable: distance, speed, incline, improvement from one session to the next, and heart rate are available. Some users, mostly the most active, would consult all current and past data, analyzing all parameters with precision. Conversely, other users were content with the basic use of the device to measure average speed and distance covered.

### Quantification: The Power of Numbers

Quantification capabilities offer several key benefits to individuals. First, numerical measurement provides objectivation: for instance, Christian was able to monitor and "match objective data to a personal feeling" (sport app, aged 49 years, intermediate profession). Participants greatly appreciated presentation in graphical format because it was easier to read and detect objective trends. Representing activities using mathematical expressions, such as curves, graphs, diagrams, or evolutions over time, also lent a scientific appearance to a mundane activity, such as walking, running, or weighing oneself, and thus appeared more valuable.

Second, numbers are authoritative. One user, Laurent, explained:

*The numbers are there...They are certain.* [sport app, aged 31 years, higher managerial profession]

This certainty was just as important to him as his weight gain, as ceasing participation in sports to start an intense job caused him to lose confidence in himself despite his excellent professional profile. For some, measuring even went as far as giving the activity its value—its very existence. As stated by one user who would occasionally forget his cardio belt or leave his watch at home:

*When I do, I'm working in the dark. I mean, without information.* [sport app, aged 44 years, higher managerial profession]

In these cases, an activity not measured by the device did not count, as if it never happened, although it could have been recorded manually and thus counted.

Quantification is a way to manage or prevent a condition. For example, one user wanted to "get ahead" of age-related weight gain:

*At some point, you see the years piling up and start to think: it's time to get your act together...After all, I'm a little scared of...I'm trying to make sure I don't put on that one invisible kilo every year for 10 years when I'll realize there are all those 10 kilos.* [Benoit sport app, aged 38 years, higher managerial profession]

Another user expressed the need to start exercising after a heart attack:

*I need to exercise for my health, but exercise is annoying. That's just the way it is. When you're a kid, you exercise for fun, and when you're old you exercise because you need to take care of yourself.* [Emile, sport app, aged 44 years, higher managerial profession]

Finally, the quantification process applied to 2 types of profiles that differed along a trend versus precision axis (see quotes in Table 1). The first profile consisted of individuals who simply wanted to see trends, whereas the second profile consisted of individuals who wanted numerical precision.

### Sharing: Engagement in Social Networks

In the digital domain, there is a high diversity of engagement levels: the majority of users are passive readers, some are spectators, a small number are occasional participants who become involved based on their interests, and an even smaller number are active contributors [23]. Engagement paths were taken: at first, an individual read the forum content, looked at other users' performances, observed, and then started posting after a familiarization process that leads to self-exposure by publishing one's own words or data.

The online community was a major source of motivation for 3 different reasons. First, the community provided support: discussions with friends or even the encouraging messages from the app provided motivation because individuals with the same concerns, interests (sports), or struggles (excess weight) were brought together. As stated by one user, the community was seen as "benevolent":

*I was really feeling down, and it lifted me up...The community is extremely caring.* [Elisabeth, Weight Watchers, aged 45 years, intermediate profession]

The community was based on a collective identity. Therefore, discussions with others proved particularly useful when users faced difficulties, such as giving into temptation or hitting a weight-loss plateau.

The community also provided positive identification models and access to shared experiences:

*Going to a community and meeting people who are in the same situation as you or who started MyFitnessPal two years ago and have lost 35 kilos, those are the people you want to follow; it's their advice you want to have.* [Valentine, MyFitnessPal, aged 29 years, higher managerial profession]

The digital community was also a source of knowledge. The transformation of an individual into an expert on his or her own health is triggered by recourse to the Internet with a health perspective and leads to an increasing digital divide [24]. Individuals in the upper and middle groups received or gave advice, read discussions, and, after a personal information selection process, assimilated their own knowledge. Ophélie (MyFitnessPal, aged 27 years, intermediate profession), who lost 20 kg, found a lot of information on the Internet, but the

community gave her access to opinions. Experience was what she trusted:

*And after, it was thanks to the forum, where everyone shares their meal plans, their ratios, so I experimented a lot until I found what I liked...*

Finally, and specifically for the sport apps users, the community was a source of emulation because it formed a pool of rivals who fueled some users' taste for competition, a rather masculine attitude [25]. Competing with others—known or strangers—sharpens practice: the social network offers a challenge. Sport apps' users published their results to advertise their performances, gaining a sense of satisfaction and perseverance by beating others and in proving their skills through sports data sharing sites, such as Strava. As stated by one participant, with Strava:

*You know what you have to beat [the record of the guy on the segment] so it's pretty fun. [sport app, aged 42 years, self-employed]*

Thus, the question is raised as to what extent these various uses can be explained by social factors.

## Discussion

### Digital Inequalities

With the increase in digital technologies and health inequalities, the notion of the digital divide in relation to social status [26] must be examined (Textbox 1).

The use of self-tracking tools was socially divided: the individuals most adept at self-quantification were also those who belonged to the more affluent milieus. This divide corresponds to axis 1 of the factor analysis, which corresponds to the central dichotomy between high-income socioeconomic categories and poorer categories.

This study expands research on digital inequalities. Belonging to an affluent social milieu intrinsically involves elements that encourage self-tracking (Textbox 1): owning efficient tools that limit technological hindrances (slow connection and session interruptions, with some studies showing that the interaction speed of apps has a significant effect on user satisfaction [27]), familiarity (through work or education) with the Internet and new technologies, concern for recommended healthy lifestyles [28], and tracking food and weight from a perspective of prevention, with the connection of health to daily diet being viewed as a long-term relationship [29].

Although self-tracking is not a practice reserved for elite members of society, it is often seen as one, and it is appreciated by members of intermediate professions; by imitating members of the elite, the middle class perceives the use of self-tracking as a way to access the practices of the next highest social group to which they aspire. "Personalized" self-tracking tools allow

them to avoid, particularly when they are overweight, the gaze of those who dominate them socially or of medical bodies supervising them.

Conversely, in poorer milieus, some individuals evoked their lack of technical skills, a hindrance frequently mentioned to explain why they did not use digital devices.

Blank and Reisdorf [30] have explained active and passive attitudes to publishing on the Web: the 2 most decisive variables are the ease of publishing data on the Internet versus uncertainty in one's ability to publish one's own data on the Internet. Our results suggest that this uncertainty can be interpreted as a feeling of cultural illegitimacy [31] about using digital devices among members of poorer milieus, who may feel that using ICT oversteps their social position.

### Dynamic Dimensions: Life-Course Transitions and Turning Points

Dynamic dimensions linked to life course provided additional insight (Textbox 1). The youngest individuals (aged 18-24 years) and those in the highest social category are most likely to have mobile phones and most frequently use an Internet connection. Hence, the most resistant to digital devices in our survey were also the oldest interviewees, and these findings confirmed previous observations [32].

However, the average age of users for whom digital devices were most central was 40 years. Thus, our study showed that recourse to self-tracking tools was more linked to a specific position in life course, a factor which exercises a fundamental influence on food choices [33] and body governance, now in the area of new technologies. Some individuals turned to digital devices after a turning point in their life course (new job, new home, or divorce), which led to major changes in dietary and sporting practices. Quantifying and tracking data were therefore ways to bring order back to a life that had been temporarily disrupted [2].

For other individuals, the use of digital devices was prompted by a "midlife" transition, which implied small adjustments in food choices or physical activity to prevent weight gain. In these cases, self-tracking tools were used, either regularly or constantly, by individuals who were approximately aged 40 years.

These concerns were more distant for younger individuals in their 20s, who viewed the bodily horizon in much more serene terms. Their use of smart watches was more irregular, and, in their opinion, less necessary: the pleasure they found in physical activity dominated.

Finally, the perception of a health risk that was directly linked to a family member's illness or a life course turning point could incentivize interviewees to monitor their diets or physical activity.

**Textbox 1.** Social factors in the use of self-tracking tools.

<p><b>Hierarchical factors</b></p> <ul style="list-style-type: none"> <li>• Efficient equipment</li> <li>• Digital familiarity and cultural legitimacy</li> <li>• Diet, a health factor</li> <li>• Preventive aim</li> </ul> <p><b>Dynamic factors</b></p> <ul style="list-style-type: none"> <li>• Age</li> <li>• Midlife transition</li> <li>• Life-course turning points</li> </ul> <p><b>Heterogeneity factors</b></p> <ul style="list-style-type: none"> <li>• Social integration and cultural intermediaries</li> <li>• Anteriority of written record-keeping</li> <li>• Awareness of a risk</li> </ul>
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### Cross-Cutting Factors of Heterogeneity

Cross-cutting factors moderated the ascription of social status (Textbox 1). The degree of social integration was a major factor that either promoted or hindered the use of digital apps. Indeed, good social integration facilitated the spread of an innovation by imitation. Our results extended previous research: good social integration also fosters the adoption of new ideas and objects because of the intervention of the opinion leader [34], who is close to individuals from a social standpoint, but still retains a slightly higher position. As cultural intermediaries, they are seen as experts and further the spread of new practices linked to digital technologies.

Regardless of social milieu, the use of digital self-quantification tools was associated in part with previous acts of keeping written records or quantification. Of the people surveyed in this study, one-fourth mentioned previous habits of keeping a written record of physical activity or a food diary.

### A Divide in Terms of Uses

Although we corroborated previous studies [24] and found a digital divide, it was less associated with equipment and more with type of use. Indeed, the emergence of digital diet and fitness tools coincided with the preoccupation of members of intermediate and higher sociodemographic categories, who had similar characteristics in terms of food, health care, and body care, with controlling their diets and physical activity. Self-tracking tools gave them a new, faster, more precise, and often more enjoyable way to monitor and control their diets and physical activity. Conversely, in poorer milieus, neither health through diet nor weight control nor physical exercise were priorities.

For all these reasons, self-tracking tools definitely increased motivation for people who wanted to lose weight or be more physically active. However, although individuals who lost a lot of weight or were very physically active used digital apps, sometimes intensely, it cannot be concluded that the use of these

tools was the reason for their success. Rather, using a self-tracking tool was a reflection of the motivation to control one's weight or exercise.

### Limitations

The survey was predominantly conducted among current users of digital devices, who were willing to share their experiences because they were satisfied with the outcomes. Further research is needed among former users and intermittent users, and among those who are reluctant to implement digital technologies and self-quantification practices in all social milieus, to augment the research presented here.

### Strengths

A particular strength of our research is that it is one of the few qualitative studies on digital apps based on such a large sample of in-depth interviews [35]. Another strength of our study was the reliability of our data (number of interviews, ethnographic observations, quantitative analysis, and triangulation of methods).

### Conclusions

The results of this study have major implications for public health. Two major divides were highlighted, with significant social implications. Those most willing to use self-tracking tools belonged to affluent milieus, for whom self-care of the body was an ethic, and intermediate milieus, where the cultural desire to "eat better" or "move more" was made practical thanks to digital devices. In both cases, a preventive outlook when it came to healthy lifestyles was a motivator to use self-quantification devices. Among low-income milieus, there was more frequent reluctance, either to digital devices in general or to the self-tracking process. Moreover, members of poorer milieus showed more marked reluctance to speak out in digital communities, whereas members of the middle class found motivation, support, and an arena for expression in digital communities. Our final major finding was that it was neither intrinsically the digital device nor the app that motivated



individuals to modify their diet or physical activity toward improved health behaviors: it was rather the active way in which engaged individuals used the devices and apps.

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## Authors' Contributions

FR secured the funding, conceived the protocol, conducted the field survey, and wrote the manuscript. LC conducted the statistical analysis, based on anonymized statistical data sets, and participated in drafting the results and writing the manuscript. Both authors read and approved the final manuscript and consent to publication in this journal.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Supplementary tables and legends.

[[PDF File \(Adobe PDF File\), 107KB - mhealth\\_v6i4e101\\_app1.pdf](#)]

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## Abbreviations

**ICT:** information and communication technology

**WW:** Weight Watchers

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Original Paper

# Development of a Healthy Lifestyle Mobile App for Overweight Pregnant Women: Qualitative Study

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## Abstract

**Background:** Mobile apps are becoming an increasingly ubiquitous platform for delivery of health behavior interventions among overweight and obese perinatal women. However, only a few methodological guidelines on integrating theory, evidence, and qualitative research for their designs are available.

**Objective:** The aim of this study was to develop a theory-based, evidence-driven, and user-centered healthy lifestyle app targeting overweight and obese multiethnic pregnant women.

**Methods:** This paper illustrates how intervention development may be enriched with theoretical basis, systematic review, and qualitative study. An individual face-to-face interview was performed to incorporate the user's involvement in the design. These interviews were audiotaped and transcribed. Thematic analysis technique was used for emerging themes.

**Results:** Integrated concepts of social cognitive theory of self-regulation, self-regulation model, and strength model of self-control were selected as bases of the intervention. Evidence from our systematic review and meta-analysis provided the strongest evidence for the development of intervention. We invited 16 obese or overweight pregnant women to participate in a semistructured interview. The following key themes emerged: content, platform, interactivity, format, and functionality. Apps are a favorable technology platform for healthy diet advice, appropriate physical exercise, and weight management because they are user-friendly and convenient. The app used in this study contains culture-specific, pregnancy-related, and credible contents, including educational, professional and peer support, and self-monitoring domains. The design should include aesthetic appeal, visualized features, and interactive multimedia.

**Conclusions:** A 3-step process integrating theoretical basis, evidence from systematic review, and research findings from target users can be considered a guide for future app development.

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**KEYWORDS**

mobile apps; overweight; obesity

## Introduction

### Background

With obesity as a worldwide epidemic [1], perinatal overweightness and obesity have been widely considered [1]. Approximately 50% of women experience excessive gestational weight gain (GWG) [2], which shows a consistent relation to postpartum weight retention [3] and a substantially increased risk of being obese. Perinatal overweightness and obesity are linked to adverse maternal and infant outcomes, including obstetric, intrapartum complications, instrumental delivery, babies who are large for their gestational age, and macrosomia [2,4,5]. Unhealthy lifestyle patterns are critical factors influencing perinatal overweightness and obesity [6]. Behavioral change depends on the discontinuation of an unhealthy lifestyle and the formation of a new healthy lifestyle [7]. Pregnancy is a crucial stage to remain healthy for the sake of pregnant women and their unborn baby [8]. Healthy eating during pregnancy is critical, and pregnant women require 2000 kcal/day [9]. To obtain a balanced diet, pregnant women should eat a variety of food, including fruits, vegetables, rice, meat, and milk and its alternatives [9]. With regard to physical activity, pregnant women should walk 10,000 steps a day (4-5 miles, depending on stride length) or do a minimum of 30-min moderate physical activity for 5 to 7 days a week [10]. The Institute of Medicine guidelines recommend a total weight gain during pregnancy based on the prepregnancy body mass index (BMI) as follows: normal, 11.5 to 16 kg; overweight, 7 to 11.5 kg; and obese, 5 to 9 kg [11]. Consequently, new and effective lifestyle interventions that promote healthy outcomes are necessary.

Mobile apps create new opportunities to set behavioral goals, provide healthy lifestyle counseling, and facilitate self-monitoring of pregnant women's goal-directed behavior [12]. Apps have become increasingly relevant to health care. Apps have been successfully integrated into interventions that target diet, physical activity, and weight management in overweight and obese individuals [13]. Apps also use a tracking system to improve adherence by automatic alert or notification or graphic progress by monitoring devices for reminders and regular interactions. The advantages of using apps include cost-effectiveness, accessibility, and timely delivery to multiple regions and various populations [13,14]. Perinatal women actively use apps to search for pregnancy health-related information, discuss issues with peers, and seek advice from professionals to guide their pregnancy decision making [15,16]. Nonetheless, the market for health care apps is considerably fragmented because many of them are designed for highly specific contexts, and they lack theoretical content. A systematic review on quality assessment for apps [17] is varied. Results showed that only 10 studies from 606 articles satisfy the inclusion criteria. According to the quality criteria, the mean score is 5.05 out of 8 [17]. Thus, the development of a quality and evidence-based app for overweight or obese perinatal women is necessary.

Theoretical-based intervention helps guide intervention designers in identifying theoretical constructs to target in an intervention to elicit behavioral change [18]. In addition,

theoretical foundation provides guidance on mobile health behavior intervention development [19]. The Template for Intervention Description and Replication (TIDieR) guideline [20] recommended the use of theoretical frameworks in designing interventions. More importantly, theory-informed development facilitates the functionality of an intervention [21]. Evidence from systematic review and meta-analysis is used as a basis to develop recommendations for mobile app development [22]. Systematic review is the reference standard in synthesizing evidence in health care [23]. Moreover, a meta-analytic approach is considered the strongest evidence because of its methodological rigor [24]. User-centered design is a well-established approach to develop a mobile app. This design is strategically important because of its insights on users and their context of use [25]. Advantages of user-based design include the promotion of autonomy, competence, positive emotional experience, and sense of relatedness for users [26]. User-based design focuses on target audience through an iterative design process that engages users in conceptualization, design, and development of an app [27]. User involvement increases appeal and user-friendliness [28]. Target population can select tailored information about their preferred form, which is essential to maximize the acceptability and effectiveness of interventions [26]. User-centered development method can assist in understanding the preference of potential users for content, platform, and format, thereby resulting in a remarkably effective program.

### Objectives

With potential benefits of low cost, high accessibility, and good adherence, this study aims to develop a mobile app (mHELP) for a healthy lifestyle program among overweight or obese multiethnic pregnant women using a theory-based, evidence-driven, and user-centered approach.

## Methods

With regard to mHELP development, we used a 3-step process by integrating theoretical basis, evidence from our systematic review, and research findings from our target users.

### Step 1: Theory-Informed Development

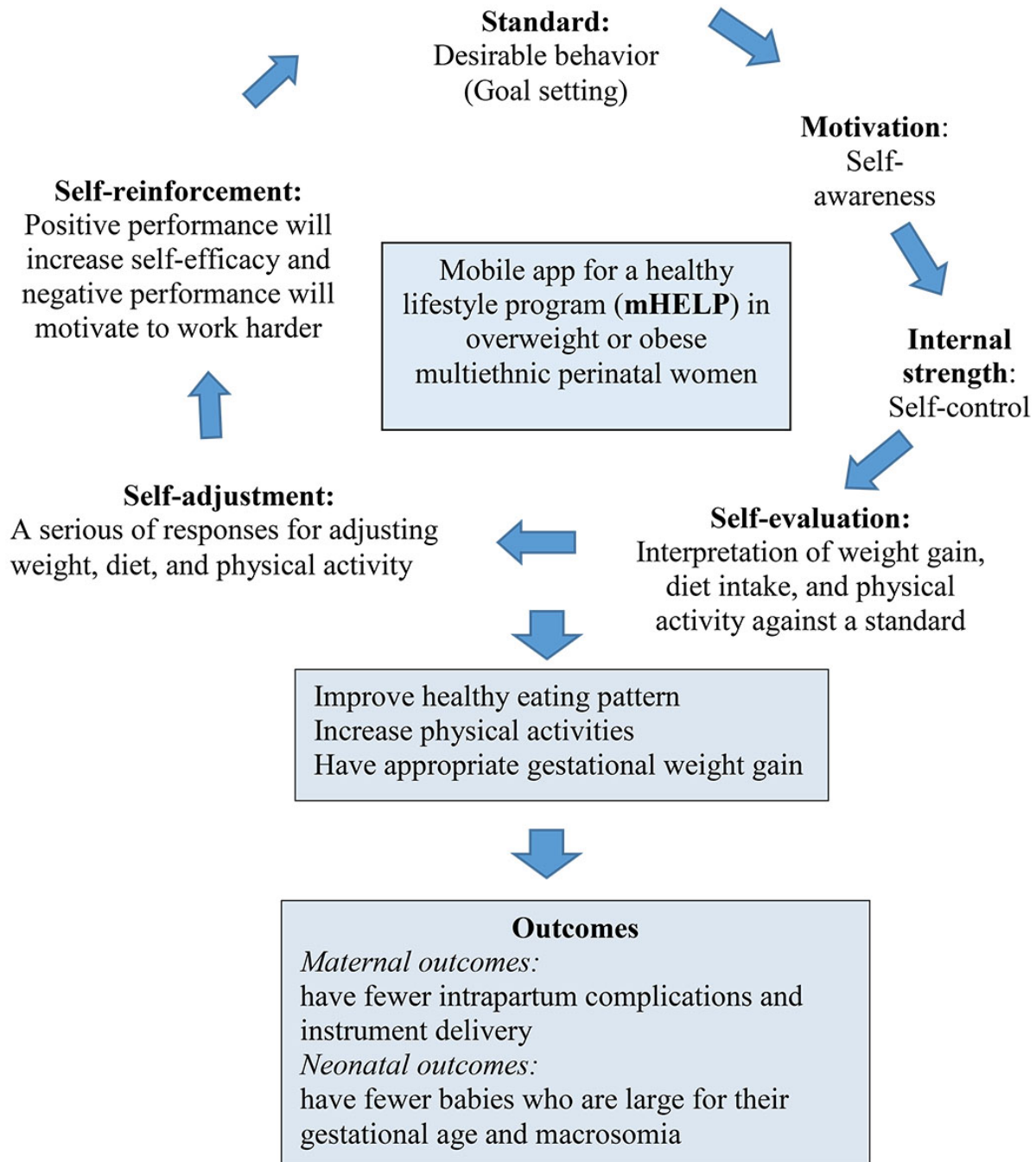
Intervention development by using a theoretical basis can substantially improve health behavior [18]. Hence, mHELP development was based on the integrated concepts of social cognitive theory of self-regulation [29], self-regulation model [30], and strength model of self-control [31]. The social cognitive theory of self-regulation emphasizes the major self-regulative mechanism through the 3 principal subfunctions, including self-monitoring of individual behavior (its determinants and its effects), evaluation of individual behavior in relation to personal standards and environmental circumstances, and affective self-reaction [29]. The self-regulation model focuses on a 5-stage self-regulation, including specification of goals, establishment of commitments to change, physical and environmental management to facilitate pursuit of goals, and execution of self-regulation components to achieve the goal [30]. The strength model of self-control consists of the following components: standard of desirable behavior, motivation to satisfy standards, monitoring of

situations that achieve the standards, and internal strength to control urges [31]. Self-control is a central function of an individual. This function is an important key to succeed in life [31] because it alters the individual’s responses. In particular, self-control aligns an individual with standards and supports the pursuit of a long-term goal. The conceptual framework (as shown in Figure 1) illustrates the relationships between mHELP and health outcomes.

trigger a self-evaluation response, which involves the interpretation of the condition of an individual against a goal or a standard. In addition, a series of responses can be determined after self-evaluation as a result of self-adjustment and self-reinforcement [30] to improve healthy diet pattern, increase physical activities, and obtain appropriate GWG. Consequently, women who participated in using the mHELP app will probably obtain improved maternal and neonatal outcomes.

In this conceptual model, self-regulation involves self-awareness of the current overweight and obese status. Awareness can

Figure 1. Conceptual framework.



## Step 2: Evidence From Our Systematic Review and Meta-Analysis

To obtain the most significant available evidence to design mHELP, our research team conducted a systematic review and meta-analysis to evaluate the effectiveness of electronic-based (e-based) lifestyle interventions in overweight or obese perinatal women [32]. Seven electronic databases, including the Cumulative Index to Nursing and Allied Health Literature, Cochrane Library, Excerpta Medica database, ProQuest Dissertations and Theses, PsycINFO, PubMed, and Scopus, were searched from their inception to July 13, 2016. We selected 14 randomized controlled trials (RCT) in 17 publications among the 1145 available studies [32]. Our review found that e-based lifestyle intervention is an acceptable approach to limit GWG, lose postnatal weight, increase the moderate and vigorous physical activity, and reduce the calorie intake after intervention [32].

Different e-based delivery formats were observed in 14 selected RCTs; these formats include app [12], website [33], the internet [34], email [35], short message services [36], computers [37], and interactive videos [38]. Physical activity, diet, and weight management are essential components in designing healthy lifestyle interventions [32]. Promising strategies play key roles in promoting healthy lifestyle. These strategies include setting of behavioral goals, undergoing lifestyle counseling or skills training, regular self-monitoring, and receiving reinforcement through feedback from health care professionals. Intervention starts in the first trimester of pregnancy until postpartum periods to broaden the beneficial effect of intervention [39]. E-based platforms incorporating in-person and phone session for professional consultation are effective in reducing GWG [32] because synchronous interpersonal interactions may be beneficial in improving the effectiveness of the intervention [40]. Social networking among peer support is vital in promoting healthy behavior [41]. Monitoring device for physical activity [42], image-assisted dietary assessment [43], and anthropometric measures for nutritional status [44] are considered accurate outcome measurements. Table 1 summarizes the suggested recommendations from our systematic review [32]. These recommendations can guide our study in exploring the subsequent step in designing a lifestyle program for overweight and obese perinatal women.

**Table 1.** Recommendations from the systematic review and meta-analysis.

Aspect	Recommendations
Component	Physical activity, diet, and weight management
Period	First trimester to postnatal period
Platform	E-based platform incorporating in-person and phone session
Strategies	Setting behavioral goals, undergoing lifestyle counseling or skill training, regular self-monitoring, and receiving reinforcement through feedback
Outcome measures	Monitoring device for physical activity, image-assisted dietary assessment for dietary intake, and anthropometric measures for nutritional status
Interactivity	Online peer discussion forum, texting, email, or phone for professional consultation
Functionality	Graphs for progress report, navigation, search feature, goal tracking, notification or reminder, and link to remote device

## Step 3: Use of Qualitative Research to Inform User-Centered Design

A qualitative methodology involving end users in the design process was used [25]. Qualitative research method is important because it provides useful insights for initial elicitation to design and develop mHELP [45]. A user-centered approach helps explore the needs and preferences of content, platform, and format of mHELP among overweight or obese multiethnic perinatal women [25]. The outcomes of this qualitative research may facilitate in tailoring the intervention, thereby increasing its acceptability and effectiveness.

### Sample and Setting

We purposively recruited 16 participants among multiethnic overweight and obese pregnant women in 2 outpatient clinics in a hospital, which is a 1160-bed, university-affiliated hospital that serves more than 670,000 outpatients and 49,000 inpatients. This hospital provides comprehensive obstetric care for different demographic and socioeconomic groups in Singapore, with a delivery rate of 3233 deliveries/year. The inclusion criteria for participating in the study included pregnant women aged  $\geq 21$  years with prepregnancy BMI of  $\geq 25.0$  kg/m<sup>2</sup> and having a singleton uncomplicated pregnancy at no more than 30 weeks of gestation.

### Data Collection

Data collection was conducted from July 2016 to January 2017 after obtaining approval from the Domain Specific Review Board (Reference No: NHG DSRB 2016/00654). A research assistant approached the target pregnant women during antenatal clinic visits, and eligibility screening was performed in a private area. Participants were informed about the purpose of the study, and information sheet was given. This initial contact was followed up by a telephone interview to establish their interest and consent to participate. Informed written consent was obtained, and participants' profiles were collected. A qualified research assistant, who was trained to conduct qualitative face-to-face interviews, carried out all individual interviews to ensure a high level of consistency. A semistructured interview guide (Textbox 1) with open-ended questions was used to explore the needs and preferences of participants in terms of the content, platform, and format for a healthy lifestyle intervention.

**Textbox 1.** Semistructured interview guide for face-to-face individual interview.

What do you think about the healthy lifestyle intervention for perinatal women?

What is the most important content you need to know in a healthy lifestyle intervention?

Do you have any other suggestion regarding the specific contents for a healthy lifestyle intervention?

How do you feel in using electronic technology to deliver healthy lifestyle intervention?

What are your experiences in accessing information from electronic-based platform?

Tell me about how you choose preferable technology platform to receive healthy lifestyle information and why?

What do you think about the favored way to receive information about healthy lifestyle?

What do you think about the favored format for interactivity with peers?

What format do you prefer in communicating with health care professionals?

What is your preferred presentation format using multimedia?

What are the essential aspects of design that will engage you in electronic-based intervention?

Do you have any additional thought that you have not expressed in the presented questions?

Finally, is it alright to contact you for some follow-up questions if necessary?

This interview technique allowed participants to express their answers freely in their own words. The interview questions and prompt were developed according to a framework for a qualitative semistructured interview guide [27]. All interviews were conducted in a private room at the convenience of the participant, either before or after the scheduled follow-up at 2 outpatient clinics. The interview lasted for 20 to 40 min. All interviews were audio-recorded, and field notes were taken. We provided each participant \$20 (Singapore dollar) as a token of appreciation for their time.

**Data Analysis**

Descriptive statistics summarized the participants' characteristics. Data were audio-recorded and transcribed verbatim. We used thematic analysis following the methods of Braun and Clarke [46]. This method was selected because of its flexibility, freedom from specific theoretical framework, ability to explore a rich set of data, and identification and analysis of repeated themes [46]. This analytic process is a theoretically flexible method with 6 recommended steps [46], including (1) familiarization with data by reading and rereading the transcripts, (2) initial coding by systematically identifying and naming units of meaning with codes, (3) searching for themes among the initial codes according to data patterns, (4) reviewing themes by organizing the data that may best fit together as subthemes, (5) defining and naming final major themes, (6) producing the report. The themes identified on a semantic level were closely linked to the data using an inductive approach. Constant comparative analysis was performed to iterate the variation between theme occurrences across different participants [47]. Thematic saturation was achieved at the 16th interview as determined by 2 research team members (YL and LJC) during concurrent analysis. Illustrative verbatim quotations were selected to support the validity of data generation.

**Methodological Rigor**

Credibility, dependability, confirmability, and transferability establish the methodological rigor [48]. To ensure the credibility

of data sources, prolonged engagement and member checks were used. We repeatedly viewed the audio recording, transcription, and field notes for accuracy. We sent the transcriptions to the participants to validate the information through the member-checking procedure [49]. Dependability was achieved by auditing. Audit trails were developed using reflexive memos and codebooks throughout the research process to keep track of any bias and assumption [50]. For confirmability, we involved coresearchers in the analysis. Two research members (YL and LJC) independently participated in a multiphase process, including initial coding, theme development, review, and definition [46]. Two members verified this process for accuracy and appropriateness. Any discrepancy was discussed and resolved for consensual validation. Our research team facilitated transferability by providing details of demographic and obstetric descriptions and using relevant quotations from different participants [48].

**Results****Overview**

We invited 20 eligible women, but 4 women refused to join because of lack of time and planning to deliver in another hospital. A total of 16 eligible women (response rate=80%) agreed to participate; of these, 8 were recruited from a general outpatient clinic, and 8 were from a private outpatient clinic. [Table 2](#) presents a summary of the demographics and obstetric characteristics of all participants. The participants' BMI ranged between 25 kg/m<sup>2</sup> and 38 kg/m<sup>2</sup>. Majority of the participants were married and with complete tertiary education.

After a 6-step thematic analysis, 5 key themes related to the domains of content, platform, interactivity, format, and functionality emerged. These 5 themes captured the meaning of narratives offering contextual insights into the development of mHELP. Summaries of the key themes, subthemes, and recommendation are presented in [Table 3](#).



**Table 2.** Characteristics of interview participants (N=16).

Characteristics	n (%)
<b>Ethnicity</b>	
Chinese	3 (19)
Malay	6 (37)
Indian	4 (25)
Burmese	1 (6)
Hispanic	1 (6)
Bangladeshi	1 (6)
<b>Age, in years</b>	
25-34	11 (69)
35-45	5 (31)
<b>Marital status</b>	
Married	15 (94)
Divorced	1 (6)
<b>Education</b>	
Degree and above	11 (69)
Diploma and below	5 (31)
<b>Employment status</b>	
Full time or part time	11 (69)
Unemployed or housewife	5 (31)
<b>Body mass index, in kg/m<sup>2</sup></b>	
25-30 (overweight)	10 (62)
31-38 (obese)	6 (38)
<b>Number of pregnancies</b>	
1	7 (44)
2-4	9 (56)
<b>Number of babies</b>	
0	7 (44)
1	5 (31)
2-3	4 (25)

## Theme 1: Content

### Subtheme 1.1: Culturally Tailored and Specific to Pregnancy

Most participants said that they were highly attracted to engage in the intervention if it can provide them with a culture-specific diet plan. Some participants expressed their opinions as follows:

*Maybe something related to like different culture. Because I am Malay...maybe the meal plan should be customized to race or culture so that I do not need to adapt diet from other culture. [Participant 7]*

*Whatever I can search pregnant-related information from the internet is mostly developed by the western*

*countries...so the baby size, the body weight of the baby and mother is very much westernized. So I think maybe I should cater to Asian mother and the baby. [Participant 3]*

Some participants wanted pregnant-specific healthy lifestyle. They stated:

*I like all provided information is pregnancy-based, any suggested activities should be pregnancy-friendly. [Participant 1]*

*We are pregnant so it is slightly different from the normal people...so I think information will be very helpful only for the pregnant women. [Participant 3]*

**Table 3.** Key themes, subthemes, and recommendations. SMS: short message service.

Themes	Recommendation
<b>Content</b>	
Culturally tailored and specific to pregnancy	Culture-specific, pregnancy-related, and credible educational support for diet, exercise, and weight advices for perinatal women
Multicomponent	
Credibility	
<b>Platform</b>	
Use of mobile app	Mobile app is used in a user-friendly design
Convenient and user-friendly	
<b>Interactivity</b>	
Flexible communication with health care professionals	Professional support via email, SMS text messaging, and hotline for individual consultation
Importance and value of peer support	Peer sharing and support using online peer discussion forum
<b>Format</b>	
Aesthetic appeal	Interactive multimedia, including video, animations, game, and Web-based quiz
Visualized features	
Interactive multimedia	
	External link for further resources, such as websites, text, news, and articles
<b>Functionality</b>	
Self-monitoring for individualized goal setting	Graphs for progress report using tracking and notification
Progress monitoring	Incorporated with remote device (pedometer)
Regular update	Easy navigation and automatic update

### **Subtheme 1.2: Multicomponent Content**

The participants also suggested that multicomponent content possesses a key role in designing the content of intervention according to different educational needs. Intervention components should highly emphasize on appropriate exercises, dietary advices, and weight management. Participants' preference is illustrated in the following statements:

*Usually it's very helpful to know like which type of food, how many calories or what kinds of food I can eat for controlling my weight.* [Participant 5]

*I actually don't know to what extend I can exercise. What is suitable exercise for different period of pregnancy?...How much exercise per day or per week that I should do that is good for my body weight?* [Participant 7]

### **Subtheme 1.3: Credibility**

Participants raised the issue about the intervention's credibility. They felt comfortable with obtaining information from reputable sources, such as their doctors, nurses, university, or hospital, rather than from unknown sources regarding the authorship or institution of origin. Two participants shared their experiences:

*Some websites do not provide any information about themselves and I don't believe it. I like information*

*from doctors or nurses that I can trust.* [Participant 7]

*I think if information source comes from hospital or university, accuracy is the first thing I would expect and credibility is already there.* [Participant 8]

## **Theme 2: Platform**

### **Subtheme 2.1: Use of Mobile App**

Most participants expressed that the use of mobile app is a preferable technology platform. The main advantage of using mobile apps is that it is handy and easy to navigate; it can be accessed anywhere at any time. Participants stated the following:

*Personally, I tried out a number of pregnancy apps. I found mobile phone is quite handy and mobile app is easy to download.* [Participant 4]

*Nowadays, everybody uses mobile phone and everything is on the app. App likes a one-stop place for everyone and I can access anywhere at any time. App can provide hyperlinks that I could click on if I wanted to.* [Participant 12]

### **Subtheme 2.2: Convenient and User-Friendly**

The participants mentioned that the platform should be convenient and user-friendly. They stated:

*For me, user-friendly is very important because I like a simple, user-friendly and direct way to see things.*

*I want to go straight down the page and get where I want to go.* [Participant 8]

*User-friendly is good! That we can easy to use to read, key in, and find things.* [Participant 14]

### Theme 3: Interactivity

#### Subtheme 3.1: Flexible Communication With Health Care Professionals

Participants agreed that Web-based consultation is crucial to provide helpful advice and suggestion. Participants also tend to interact with health care professionals in a flexible manner through different delivery modes. Participants stated:

*I want some experts provide professional advices on appropriate exercise and balanced diet so online consultation should be very helpful.* [Participant 11]

*I might not be able to make the interaction in person because of transportation issue or I might have my work. It's easier for me to consult them through phone, email or Skype if there is any misunderstanding I can ask for clarifications.* [Participant 7]

#### Subtheme 3.2: Importance and Value of Peer Support

Participants felt that intervention can potentially provide professional support and emphasized the importance of peer support from online discussion forums. They stated:

*It is a good to have our online discussion forums with other pregnant women and we can exchange our views or maybe even get some information and some help through online discussion forum.* [Participant 2]

*I enjoy online chatting with other pregnant women and it can offer tips and suggestions for my pregnancy. Honestly, I want reassurance about my status during pregnancy and it means a lot to me if someone's back up.* [Participant 11]

### Theme 4: Format

#### Subtheme 4.1: Aesthetic Appeal

Most of the participants pointed out that the aesthetic appeal of the intervention is a major determinant in their usage of the app. Thus, considering a colorful and attractive interface is essential. Two typical answers are shown below:

*Of course bright color as it can attract people to look at it...so it is easy to catch attention and facilitate learning.* [Participant 3]

*I prefer colorful design such as pastel color. Generally, I relate pastel color to baby. Pink for girls and baby blue for boy.* [Participant 4]

#### Subtheme 4.2: Visualized Features

Visual information regarding the quantity and type of food to eat during pregnancy is also an important consideration. Visualized features improve the ability of women to grasp their progress and recognize their food intake. Participants commented:

*I like more visuals and graphics for knowing my condition.* [Participant 3]

*It is really good to show me what a standard serving size is supposed to look like because I want to see it.* [Participant 10]

#### Subtheme 4.3: Interactive Multimedia

The general preference of the participants is the use of interactive multimedia, including short video scripts, graphs, photos, Web-based quizzes, and animation, to make the app highly engaging. Some participants commented that they appreciate the option of using different multimedia to engage in the intervention, as echoed in the quotes below:

*Short video for suggested exercise, health tips and the recommended diet would be interesting and useful.* [Participant 6]

*Personally, I prefer more photos, animation and graphics. I feel online quiz is an awesome part. Once I read the information, then I just check whether I have understood it correctly through quizzes.* [Participant 8]

### Theme 5: Functionality

#### Subtheme 5.1: Self-Monitoring for Individualized Goal Setting

The participants recognized that each pregnancy presents distinct challenges. They want content in terms of healthy lifestyle tailored to their needs and expectations. A general consensus by the respondents indicated that the program should possess functions that will allow self-monitoring. Two participants shared their ideas as follows:

*I would like to have some graphs for monitoring my diet, activities and weight that is good.* [Participant 7]

*I can insert my personal information for the doctor to see using the graph or the chart to monitor how well do I manage, the things to do prior to the next appointment so that the doctor can review.* [Participant 10]

#### Subtheme 5.2: Monitoring the Progress

Participants felt that the contents should motivate and remind the users of their progress. The participants expressed a desire to monitor their food intake, physical activities, and weight. This result corresponded to other statements from other participants, as evidenced by the quotes below:

*I need to motivate and remind myself. It is really good if the intervention can give me notification to keep on track.* [Participant 4]

*Hoping to have simple diet, weight and exercise device or tool to monitor my progression and a routine pop-up message is helpful for reminding me.* [Participant 14]

### **Subtheme 5.3: Regular Update**

Given the rapid change in knowledge, regular updating of content is considerably important. Participants requested for a regular update on the app as a part of the functionality of the intervention. Two participants commented as follows:

*I like to read current research and know the latest perinatal diet advice or suggested exercise.*  
[Participant 7]

*It will be good if weekly update from intervention to get more updated knowledge.* [Participant 8]

### **Translating Theory, Evidence, and User Needs Into Intervention**

On the basis of the results from the theoretical basis and recommendations of our systematic review and qualitative research findings with target users, the program content, platform, and format of mHELP were formulated. A multidisciplinary research team was formed. This team included a computing expert, a professional app designer, an obstetrician, a dietician, a physiotherapist, a nursing specialist, and a researcher to design mHELP. mHELP aims to improve the neonatal and maternal outcomes in overweight or obese multiethnic perinatal women. To design a highly automated mobile app with a user-friendly interface, mHELP's user interface and features were designed by a computer expert and a professional app designer. The app can be preinstalled on phones and delivered as a Web app to provide online colorful features, such as social networking and tracking within a Web browser. The software program was used in multiple mobile platforms, such as Android and iOS (iPad and iPhone). A visual

graphing function was designed to allow the user to configure their starting weight, food intake, and physical activity throughout the pregnancy. Real-time feedback and automatic notification were also developed in the app. Our research team will incorporate social functionality in a large, open-source software hosting service GitHub that makes a developer's identity, so that mHELP can be publicly visible across a wide community.

mHELP content consists of healthy diet advice, appropriate physical exercise, and weight management starting from 12 weeks of gestation to 6 months postpartum, as shown in [Textbox 2](#). Users can access mHELP in their own time and at their own pace. They can also revisit the contents without time limitation. This app contains culture-specific, pregnancy-related, and credible contents, including educational, professional and peer support, and self-monitoring domains. Educational support aims to motivate participants by determining the importance of changing their diet and physical activity to maintain appropriate weight gain. Peer support aims to mediate interaction of participants with one another using a pseudonym via online peer-to-peer communities, which are used to mobilize and raise collective awareness [51]. Professional support aims to achieve adherence and enhance healthy lifestyle knowledge through asynchronous and synchronous feedback [52]. Self-monitoring aims to encourage users to self-regulate their lifestyle behavior according to their goals and reinforce any change made. If the result is below or above the range, then the system provides a notification through the app. The user story box and mock-up screenshots of mHELP are illustrated in [Figures 2](#) and [3](#), respectively, and its description is presented in [Textbox 2](#).

**Textbox 2.** mHELP description.

- **Technology platform:** mHELP is a responsive Web app that can be used on personal computers, tablets, or smartphone devices through common Web browsers and operating systems
- **User interface:** colorful and user-friendly
- **Content:** multicomponent with 4 domains

**Domain 1: Educational support**

## 1. Content

- Content is obtained from national guidelines, theory, evidence, and experts.
- Information is updated and contents are constantly updated to maintain the user's interest
- Mobile app incorporating in-person communication via Skype, email, short message services (SMS), and phone session

## 2. Pregnancy-related physical activity

- Safety issue for physical activity during perinatal period
- Aerobic exercise: (1) walking, (2) swimming, and (3) yoga
- Strength training: (1) foot and ankle exercise, (2) calf stretch, (3) pelvic floor exercise, and (4) pelvic tilting

## 3. Culture-specific healthy diet

- Appropriated weight gain
- Healthy diet plan in Chinese, Indian, and Malay styles
- Additional nutrient needs during pregnancy
- Pregnancy food myths

## 4. Format and security

- Interactive multimedia, including short video scripts, animations, illustrations, games, and online quizzes
- External link to credible resources
- Customizable details and user settings
- Password-protected to ensure online security
- User portal via a privacy compliant–shared record platform

**Domain 2: Professional support**

## 1. Content

- Feedback from health care professionals (obstetrician, dietician, physiotherapist, and nurse) will improve the compliance and knowledge.

## 2. Interactivity

- Online forum for group consultation
- Users can contact through email, SMS, and/or telephone for individual advice from experts if needed
- Content-related questions are addressed promptly

**Domain 3: Peer support**

## 1. Content

- Provide a forum for the participants to converse with one another

## 2. Interactivity

- Online peer-directed forum for sharing and support
- User can see how others responded to the poll questions about healthy lifestyle
- User can read posts by other participants; they can also contribute responses in the online forum

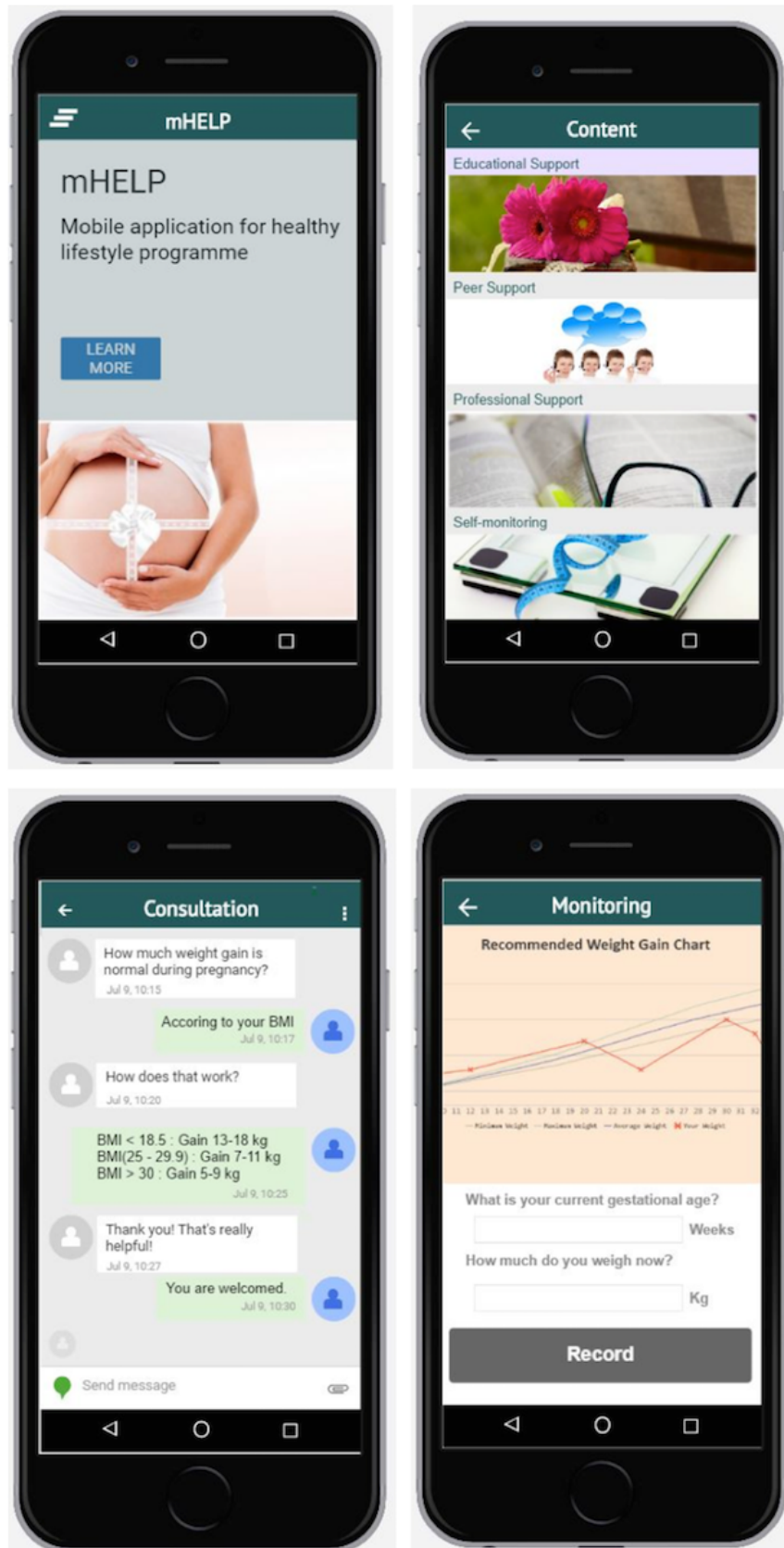
**Domain 4: Self-monitoring**

1. Individualized goal setting
  - Physical activity: engaging in 30 min of moderate to vigorous physical activity at least 5 days per week or walking 10,000 steps a day
  - Dietary: improving or maintaining the nutritional quality of their diets by consuming 5 servings of fruits and vegetables per day based on the 2000 kcal/day requirement and avoiding excess sugar and fat intake and emotional eating
  - Weight: following Institute of Medicine–recommended weight gain during pregnancy
2. Functionality
  - Users set individualized behavioral goals, and goal achievement triggers onscreen congratulatory feedback. Generate a list of goals in the form of action plan per week and archived goal content
  - Offer visualization tools, such as graphic progress chart and food image–assisted dietary advice or assessment
  - Navigation, tracking, and notification
  - Synchronized with remote monitoring devices (pedometer)
  - Tailored messages displayed on app and delivered via SMS or email according to the user’s preference
  - Regularly updating app with current content
  - Auto-update function for app system

**Figure 2.** User story box of the mHELP.



Figure 3. Mock-up screenshots of mHELP.



## Discussion

### Overview

To our knowledge, this study is the first to use a theory-informed, evidence-driven approach, and user involvement in developing a mobile app for a healthy lifestyle program in overweight or obese multiethnic perinatal women. We provide the description of a 3-step process by integrating theoretical basis, evidence from our systematic review, and research findings from target users. In addition, multidisciplinary research team was formed to provide expert advice and contribute practical and clinical considerations in designing mHELP.

### Principal Findings

We developed a theory-based intervention following the TIDieR intervention guideline [20]. Integrated concepts from social cognitive theory of self-regulation [29], self-regulation model [30], and strength model of self-control [31] were used to provide theoretical guidance on the app's development. Our systematic review and meta-analysis synthesized the most remarkable evidence using 14 RCTs [32] to provide valuable recommendations on component, period, platform, strategies, outcome measures, interactivity, and functionality of the intervention. With consideration that meta-analysis is the strongest and highest quality of evidence [24], mHELP suggested an evidence-based design. Furthermore, our qualitative study among potential users builds on our previous systematic review and meta-analysis [32] to explore the needs and preferences to design a tailored intervention. The use of a qualitative approach to elicit the user's views during intervention development is considered a good practice [45]. This user-centered design is tailor-made to the end-user perspectives because it can ensure that the app is desirable and suitable for end users [26] by selecting preferable content, technology platform, user interface, interactivity, and functionality.

Themes that emerged from our qualitative study suggested that culturally tailored, pregnancy-specific, multifaceted, and credible contents are particularly important. Given the multiethnic groups in Singapore, we considered to make the content culturally sensitive by matching health information to the observable characteristics of a target group. This effort involves translations to Chinese, Malay, and Indian using pictures of pregnant women with various ethnic backgrounds and using food items familiar to and preferred by pregnant women in those cultures. Users are likely to engage actively in mHELP if they perceive that the intervention is relevant to pregnancy. Multifaceted contents provide a first exposure to educational information in virtual learning environment to satisfy educational needs. Educational support may motivate active learning; in addition, the overall concept is that the users take ownership of their learning [53]. Design format should include aesthetic appeal, visualized features, and interactive multimedia. Multimedia features can accommodate different learning styles [54]. Data visualization improves the user's ability to comprehend their progress and monitor their food intake [43]. Contents should provide realistic goals and practical strategies to initiate change in the target behaviors [18].

Among a range of technology platforms, our mobile app satisfies the need for ubiquitous technology resulting from our qualitative study because of its convenient and user-friendly interface. The widespread use of mobile technology, along with the availability of efficient mobile broadband connections, offers a distinct opportunity to develop an innovative learning method [55]. Users can learn about healthy diet, appropriate physical activity, and weight management by using short interactive videos, animations, games, or Web-based quizzes [55,56]. Mobile app has gained popularity among perinatal women [57] because of its handy features, easy usage, and multifunctional attributes. Mobile apps also offer self-regulatory features, which may promote personal awareness of health behaviors in users [13,14]. With regard to interactivity, users preferred flexible communication with health care professionals through the provision of Web-based discussion and access to individualized expert advice. Cloud computing offers flexible dissemination channels between health settings and health care providers [58]. Peer support is an important element of the intervention, which allows users to share their experiences, knowledge, and emotional, social, or practical support with one another [51]. Furthermore, we need to update the content and system continually to ensure that the content is updated and credible. Optimizing and maintaining user engagement remain a considerable challenge. Hence, engagement strategies are essential to app designs. These strategies include ease of use, aesthetic design, feedback function, ability to change designs to suit an individual's preference, tailored information, and distinct mobile phone features [59].

### Implications

We demonstrated that a 3-step approach can be applied to develop mHELP for overweight or obese multiethnic perinatal women. Results are useful to design a culture-specific, multifaceted, and user-friendly app. The ubiquity of app facilitates the dissemination of information, supports a broad range of audience, and allows the tailoring of information and support according to users' characteristics and experiences [60]. The popularity of technological advancement can indicate a shift toward maternal empowerment within the maternity care provision [14]. Overweight and obese perinatal women can access mHELP at any time and place. Hence, mHELP can provide support for perinatal women between consultation visits, thereby reducing the number of required outpatient clinic visits [61].

### Limitations

Our study presents several limitations. First, the purposive, regional, and small sample in one hospital may limit the generalizability of our findings. Second, the time to develop a 3-step process is long, and time lags may also occur because of the changeable consumer profiles and fast-paced technological development. Third, app intervention development, including time, labor, facility, equipment, and training, is considerably resource-intensive. Thus, policy makers should consider providing financial support, manpower, protected time, and logistic support for app development.



## Future Work

This paper supports the use of a 3-step process as evidence of the usefulness of this approach. We accommodated the perspective of potential user with theoretical basis and evidence for mHELP development. Further work is needed to perform beta test in the feasibility study before RCT. In beta testing, we will evaluate the clarity of language, ease of screen navigation, technical bugs, corrupt hyperlinks, and typographical errors in various internet browsers. In addition, we will conduct a qualitative study to elicit the users' experiences after intervention. Further application and refinement will help establish evidence about the acceptability, usability, adherence, sustainability, and cost-effectiveness of mHELP. After mHELP refinement, we will evaluate its effectiveness in large and

well-designed RCTs in different settings. Hence, mHELP is tailored as a culturally relevant app for obese and overweight perinatal women.

## Conclusions

With the growth of smartphone devices, a series of mobile apps has been developed to provide education, information, and support concerning health problems. Theory, evidence, and user needs are vital in intervention development. The iterative process allows the incorporation of end-user feedback, theories, and systematic reviews to formulate the content, platform, and format of mHELP, which is tailored to the user's preferences. Our 3-step developmental process is a useful guide for researchers or app developers for future app development.

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## Authors' Contributions

YL designed the research. LJC and YL collected the data. SSTHL and CC coordinated the study. YL, KLT, and WW designed interface of intervention. CT, KWO, and CC designed the content of intervention. YL and LJC analyzed and interpreted the data. YL wrote the manuscript. LJC prepared figures and tables. All authors approved the final manuscript.

## Conflicts of Interest

None declared.

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## Abbreviations

**BMI:** body mass index  
**e-based:** electronic-based  
**GWG:** gestational weight gain  
**RCT:** randomized controlled trial  
**SMS:** short message service  
**TIDieR:** Template for Intervention Description and Replication

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Review

# The Usability and Effectiveness of Mobile Health Technology–Based Lifestyle and Medical Intervention Apps Supporting Health Care During Pregnancy: Systematic Review

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## Abstract

**Background:** A growing number of mobile health (mHealth) technology–based apps are being developed for personal lifestyle and medical health care support, of which several apps are related to pregnancy. Evidence on usability and effectiveness is limited but crucial for successful implementation.

**Objective:** This study aimed to evaluate the usability, that is, feasibility and acceptability, as well as effectiveness of mHealth lifestyle and medical apps to support health care during pregnancy in high-income countries. Feasibility was defined as the actual use, interest, intention, and continued use; perceived suitability; and ability of users to carry out the activities of the app. Acceptability was assessed by user satisfaction, appreciation, and the recommendation of the app to others.

**Methods:** We performed a systematic review searching the following electronic databases for studies on mHealth technology–based apps in maternal health care in developed countries: EMBASE, MEDLINE Epub (Ovid), Cochrane Library, Web of Science, and Google Scholar. All included studies were scored on quality, using the ErasmusAGE Quality Score or the consolidated criteria for reporting qualitative research. Main outcome measures were usability and effectiveness of mHealth lifestyle and medical health care support apps related to pregnancy. All studies were screened by 2 reviewers individually, and the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement were followed.

**Results:** Our search identified 4204 titles and abstracts, of which 2487 original studies remained after removing duplicates. We performed full-text screening of 217 studies, of which 29 were included in our study. In total, 19 out of 29 studies reported on mHealth apps to adopt healthy lifestyles and 10 out of 29 studies to support medical care. The lifestyle apps evaluated in 19 studies reported on usability and effectiveness: 10 studies reported positive on acceptability, and 14 studies reported on feasibility with positive results except one study. In total, 4 out of 19 studies evaluating effectiveness showed significant results on weight gain restriction during pregnancy, intake of vegetables and fruits, and smoking cessation. The 10 studies on medical mHealth apps involved asthma care, diabetic treatment, and encouraging vaccination. Only one study on diabetic treatment reported on acceptability with a positive user satisfaction. In total, 9 out of 10 studies reported on effectiveness. Moreover, the power of most studies was inadequate to show significant effects.

**Conclusions:** Most studies on mHealth apps to support lifestyle and medical care for high-income countries reveal the usability of these apps to reduce gestational weight gain, increase intakes of vegetables and fruit, to quit smoking cessation, and to support health care for prevention of asthma and infections during pregnancy. In general, the evidence on effectiveness of these apps is limited and needs further investigation before implementation in medical health care.

**KEYWORDS**

mHealth; pregnancy; lifestyle; health care; maternal health

## Introduction

### Mobile Health in Developed Countries

Mobile health (mHealth) technology-based apps are becoming rapidly available, especially in high-income countries. mHealth was defined by the World Health Organization as the use of mobile devices (mobile phones, patient monitoring devices, and personal digital assistants) for medical and public health practice [1]. Most of the mHealth apps aim to adopt healthy lifestyles such as nutrition, weight control, and smoking cessation, or to support medical health care such as the control of glucose levels to support diabetic care [2,3]. The benefits of mHealth apps include that they can be delivered to an individual anywhere at any time and provide opportunities for interaction and tailoring of specific domains and target groups. Several mHealth apps have been developed related to pregnancy and as such have the potential to improve maternal health care [4].

The use of mobile phones is increasing worldwide [5]. It is estimated that in 2020, 90% of the worldwide population will own a mobile phone [5]. In 2015, about 94% of the Dutch population aged between 25 and 45 years owned a smartphone with internet access offering opportunities for a broad use of mobile apps including health apps [6]. Carroll et al showed that main users of health apps were healthy, young, higher-educated persons with a higher income. However, they also showed that in general, determinants such as gender, age, and education were less suitable for predicting the use of mobile and health apps, which is in contradiction with the profile of main users of health apps [5].

### Mobile Health During Pregnancy

There are more apps available to support pregnancy than for any other medical domain [7]. Apps can contribute to healthy lifestyle during pregnancy, as pregnancy is a critical teachable period in the lives of young women [8]. App use is often associated with intentions to change diet and physical activity. However, the quality, reliability, and effectiveness of current available pregnancy apps are undetermined. Therefore, exposure to potential harmful apps or participation in research with nonevidence-based mobile apps should be carefully considered, especially during pregnancy when women are more sensitive for external influences [9]. Moreover, unnecessary information and advice on lifestyle and health care can lead to more worrying and stress during pregnancy. Therefore, information on usability and effectiveness is crucial for implementation of new apps in maternal health care. This was underlined by an evaluation of 10 popular, free maternal and baby-health apps by Scott et al [9]. A health professional was involved in the development of only 4 apps, and the content was evidence-based in 3 apps. Bert et al found that only less than half of the reviewed apps presented a privacy policy statement, whereas a scientific board was mentioned in a third of the apps [8].

From this background, we conducted a systematic review to provide evidence on the usability, that is, feasibility and acceptability, and effectiveness of mHealth lifestyle and medical apps to support health care during pregnancy in high-income countries. We used the United Nations Country classification to establish which countries are considered high income [10].

## Methods

The review protocol was registered on PROSPERO (registration number CRD42016053325). The authors followed the guidelines for Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement [11].

### Search Method

We conducted a systematic review of studies on mobile lifestyle and medical apps to support health care during pregnancy in developed countries. In our study, all text messaging services, intervention, or monitoring system with the intention to improve maternal health during pregnancy were considered apps. We searched the databases EMBASE (1947-2017), MEDLINE Epub (Ovid) (1946-2017), Cochrane Library (1992-2017), Web of Science (1900-2017), and Google Scholar, using a combination of Medical Subject Headings topics and free text terms. The literature search was performed in February 2016 according to a predefined protocol with the aid of a librarian of the Erasmus MC, the Netherlands, and updated in February 2017. A copy of the complete search strategy including search terms is available in [Multimedia Appendix 1](#). The search was limited to human studies, reported in the English language, and no time restrictions were applied.

### Inclusion and Exclusion Criteria

We included original research and qualitative health care research studies on mHealth technology-based apps for pregnant women with the aim to support lifestyle and health care during pregnancy. The inclusion criteria were (1) pregnant women and partner; (2) an app or text message service during pregnancy; (3) studies that were randomized (controlled) trials, pilot studies, prospective or retrospective cohort studies, surveys, and qualitative health care research; (4) original research; and (5) outcomes include information on feasibility, acceptability, and the effectiveness of mHealth apps.

The exclusion criteria were as follows: (1) apps for professionals; (2) studies in developing countries; (3) apps or text message service starting before or after pregnancy; (4) use of mobile phone only for contacting health care providers; and (5) review articles, editorials, letters, comments, and textbook articles.

### Study Selection

To evaluate the feasibility and acceptability, we established definitions for these terms to be able to uniformly compare the evidence of the included studies. These definitions were based

on the study by Bowen et al in 2010 and adjusted for our research on apps [12]. Feasibility was defined as actual use, interest, intention, and continued use, perceived appropriateness, and ability of users to carry out the activities of the app. Acceptability was assessed by user satisfaction, appreciation, and the recommendation of the app to others.

**Data Extraction and Quality Assessment**

Studies were selected in a 2-stage process. First, 2 reviewers (AV and SO) independently screened the titles and abstracts for relevance to our criteria. Hence, the full manuscripts were studied by the same reviewers. In case full text was not available, the corresponding author was contacted to request for the article. Discrepancies were resolved by a third senior reviewer (AR). We completed our search by checking the references of the included articles for studies not found in the search of the included articles. For data extraction, a standardized form, adjusted for this particular study, was used. Data extraction was performed by both reviewers individually. Differences were resolved by consensus.

The ErasmusAGE quality assessment tool for systematic reviews was used to assess the quality of the intervention and observational studies. This quality score for systematic reviews is enclosed in the Multimedia Appendix 2. The ErasmusAGE quality score is composed of 5 items. Each item is allocated 0, 1, or 2 points [13-15]. This summarizes a total score between

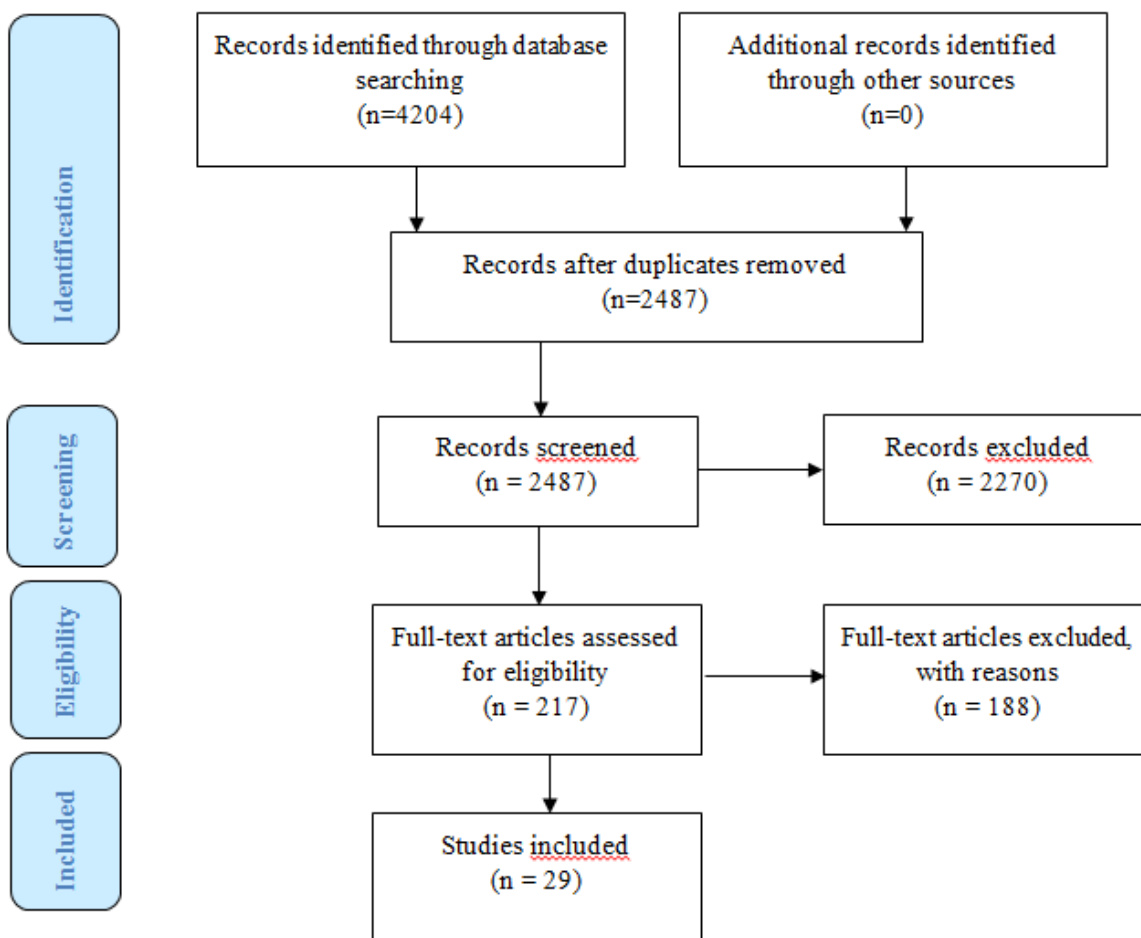
0 and 10 points in which 10 points represent the highest quality. For the qualitative research articles, the consolidated criteria for reporting qualitative research (COREQ) was used to evaluate the quality [16].

**Results**

**Study Selection**

We identified 4204 titles and abstracts of which 2487 original articles remained after removing duplicates (Figure 1). In total, 217 of the articles were assessed for eligibility by full-text screening. The full-length articles were assessed by both reviewers. Some studies used the same app within an identical study population. In this case, only the most recent and/or most complete study was selected for data extraction. After full-text screening, 28 articles were included. There was some doubt about 1 full-text article, which was therefore presented to the third reviewer. The study had a different design but did focus on a wide array of lifestyle factors. Patients could use mobile phones to text pregnancy-related questions to a programmed system after which the patient received either a direct answer or encouragement to seek answers from health care providers. The third reviewer concluded that the design of the study (texting questions to a programmed system and reporting a follow-up of the effectiveness of the text messages) conformed to the inclusion criteria and therefore the study was included.

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



This resulted in 29 included articles for further evaluation. Manual searching of the reference list of the included papers did not yield additional papers for inclusion in our analysis.

### Data Extraction

All original papers were analyzed on the 2 outcome measures usability, that is, feasibility and acceptability, and effectiveness of mHealth lifestyle apps and medical apps related to pregnancy. In total, 19 studies reported on the usability and effectiveness of mHealth lifestyle and 10 studies on medical apps. The study characteristics of the studies reported on mHealth lifestyle apps are presented in [Multimedia Appendix 3](#), and the study characteristics of the studies reported on mHealth medical apps are reported in [Multimedia Appendix 4](#). We report first the results on feasibility, followed by acceptability and effectiveness.

### Principal Findings of the Studies on Usability and Effectiveness of mHealth Lifestyle Apps

A complete overview of the results on mHealth lifestyle apps can be found in [Multimedia Appendix 5](#). This appendix provides detailed information such as country, sample size, study design, study setting, etc.

#### *Results on Feasibility of mHealth Lifestyle Apps*

##### Actual Use

In total, 9 studies reporting on lifestyle behaviors paid attention to the actual use of the mHealth app. These studies focused on smoking cessation [17-25], nutrition [17,18], weight control [23], and physical activity [20]. All studies reported that the study participants opened and responded to the messages they received; however, responding to the messages varied from 59 to 100% of all participants in the study.

##### Interest or Intention to Use or (Intent) Continued Use

In total, 8 studies reported on interest or intention to use of the app offered by the mHealth app [19,20,22,24,26-29]. These studies focused on nutrition [19,26], vitamin use [26], smoking cessation [22,24,29], to stop alcohol consumption [19,26], physical activity [20], weight control [27,28], and mental health [24]. Participants agreed that they were interested in the service and that they planned to continue being enrolled; however, the study by Choi et al showed that the response rate dropped to 24% after 10 weeks of participation. This study focused on stimulating physical activity by sending daily messages.

##### (Perceived) Suitability

In total, 4 studies reported on suitability [22,25,29,30]. In total, 3 studies focused on smoking cessation by sending informative text messages [22,25,29]. The study by Song et al had a different design that focused on a wide array of lifestyle factors, that is, vitamin intake, morning sickness, nutrition, and abdominal pains [30]. Patients could use mobile phones to text pregnancy-related questions to a programmed system after which the patient received either a direct answer or encouragement to seek answers from health care providers.

Regarding the smoking cessation studies, 24% of the participants in the MiQuit study thought that the texts were annoying and 26% felt they had received too many messages [22]. Most

participants (88%) of the study by Abrams et al judged the number of received messages “just right” [25]. The second study by Naughton et al reported that the approach of participants by the app was appropriate [29].

##### Ability of Participants to Carry out Intervention Activities

In total, 6 studies reported on the ability to use the mHealth app. These studies concentrated on nutrition, folic acid supplement use, to stop alcohol consumption [17,19,30], physical activity [19], weight control [27], smoking [24,29], and mental health [24]. Most participants agreed that the app was simple to use, easy to understand, or user-friendly ([Multimedia Appendix 6](#)).

#### *Results on Acceptability of mHealth Lifestyle Apps*

##### User Satisfaction

In total, 8 studies reported on users' satisfaction. For smoking cessation [22-26] as well as for nutrition [26] and weight control [21,27,31], the satisfaction of the participants was high. Participants described the app as helpful or useful. In the study by Herring et al [31], participants reported that the intervention was extremely successful in changing eating habits.

##### Suitability

In total, 7 studies reported on (perceived) suitability. These studies focused on smoking cessation [17,23,25,26], nutrition [17,26], vitamin supplement use [17,26], to stop alcoholic consumption [17,26], and weight control [27,28]. Suitability of the app was described by participants as acceptable, liked, reliable, enjoyed the app, and very or somewhat interesting. The study by Bot et al showed a 78% rate of high or intermediate appropriation [18]. The intervention in the study by Soltani et al was liked because of the holistic nature of the program [28]. Within this study, participants received daily text messages supported with appointments with healthy lifestyle midwives, diet and activity goal setting, and self-monitoring diaries.

##### Recommendation to Others

In total, 3 studies reported whether participants would recommend the app to others [21,23,25]. The study by Pollak et al, which focused on weight control by short message service (SMS)-texting interventions, was recommended by 80% of the participants to others [21]. An earlier study by Pollak et al reached a recommendation rate of 78% by all participants. In this study, SMS-delivered support messages were compared with support messages plus a scheduled gradual reduction of smoking. In both arms of the study, the recommendation of the intervention was high [23].

[Multimedia Appendix 7](#) gives an overview of the results of the review on acceptability of mHealth lifestyle apps by summarizing the results per first author, year of publication, used technique of the app, focus of the reported study, and acceptability by study participants, defined as user satisfaction, suitability, and recommendation.

#### *Results on Effectiveness of mHealth Lifestyle Apps*

In total, 10 studies reported on effectiveness of the app [20-23,28,31-35]. Moreover, 5 studies reported on smoking cessation [22,23,32,33,35]. Naughton et al could not show significant differences, and Pollak et al could not do any



statistical analysis due to small groups but showed a lower prevalence of smoking cessation in the intervention group [22,23]. Women enrolled in the study by Moniz et al received 12 weekly text messages encouraging preventive health behaviors. An improvement in self-reported health behaviors was observed between baseline and follow-up, including decreased tobacco use, more prenatal vitamin intake, and more frequent healthy food intake [33].

Fuijoka et al showed significant decreases of carbon monoxide exhalation levels of the participants within 3 months of participation in the study [32].

In total, 3 studies reported on controlled gestational weight gain during pregnancy [21,28,31]. Pollak et al showed a nonsignificant difference in the mean gestational weight gain of 6 pounds less for women who completed the intervention [21]. Soltani et al could not do any statistical analysis due to a small sample size, but the mean gestational weight gain in the intervention group was 6.65 kg vs 9.74 in the control group [28]. Herring et al showed significant differences in gestational weight gain in the intervention group vs the control group ( $P=.03$ ) [31].

Physical activity and nutrition were reported in 2 studies [20,35]. Choi et al compared the use of Fitbit only vs an app plus Fitbit in a group of pregnant women. The intervention group tended to increase in daily steps compared with the Fitbit-only group; however, the difference was not significant [20].

Van Dijk et al reached 1275 couples contemplating pregnancy and 603 pregnant couples. Lifestyle behaviors, ie, folic acid, tobacco and alcohol use, and inadequate nutrition, ie, fruits and vegetables intake, were identified at baseline [35]. After this, a Web-based coaching was created for each user on the most prevalent inadequate nutrition and lifestyle behaviors for 6 months. After 6 months of coaching, intakes increased by 26.3% and 38.4% for vegetable and fruit intake, 56.3% for folic acid supplement use, and 35.1% and 41.9% for reduced tobacco use and alcohol consumption. The program showed the strongest success in women of participating couples.

Evans et al used the Text4baby program, consisting of 3 text messages per week additional to the regular Text4baby program, tailored by the date of enrollment and gestational age. They showed only a significantly lower alcohol consumption in the high-dose intervention group, that is, patients receiving

the maximum number of messages, but not on other health behaviors, including taking prenatal vitamins, eating 5 or more fruits and vegetables daily, and smoking behavior [34].

In total, 2 studies evaluated the effectiveness of text messages promoting healthy lifestyle behavior in general during pregnancy [33,34].

[Multimedia Appendix 8](#) gives an overview of the results of the review on the effectiveness of mHealth lifestyle apps by summarizing the results per first author, year of publication, used technique of the app, focus of the reported study, and effectiveness based on patient-reported questionnaires. Van Dijk et al, Herring et al, and Fuijoka et al showed significant results on effectiveness of the lifestyle mHealth app. All other studies reported nonsignificant differences [35,31,32].

### Principal Findings of the Studies on mHealth Medical Apps

A complete overview of the results on mHealth medical apps can be found in [Multimedia Appendix 9](#).

### Results on Feasibility of Medical Apps

[Table 1](#) gives an overview of studies reporting on the feasibility of medical apps by summarizing the results per first author, year of publication, used technique of the app, focus of the reported study, and feasibility reported by patients. Thereafter, we discuss the actual use, interest or intention to use or (intent to) continued use, perceived suitability, and ability of participants to carry out intervention activities of the included studies. In this case, only 1 study reported on the actual use and interest of the app in medical health care [33].

#### Actual Use

Nicholson showed that 65% of the participants logged in to the website at least 3 times during pregnancy. Women with gestational diabetes used the gestational management system (GooDMomS) in which they received Web lessons, self-tracking of weight and glucose, automated feedback, and access to a message board for peer support [36].

#### Interest or Intention to Use or (intent to) Continued Use

Most women in the study by Nicholson did not have experiences with this kind of medical apps, but they were willing to give it a try as participating would not be harmful and maybe others may know more than themselves [36].

**Table 1.** Overview of studies reporting on medical (interventions) apps related to pregnancy: feasibility.

Author and year	Technique	Focus	Feasibility			
			Actual use	Interest	Suitability	Ability
Nicholson et al, 2016 [36]	Web lessons, self-tracking of weight and glucose, automated feedback, and access to a message board for peer support	Diabetes	In total, 65% of the participants logged in to the website at least 3 times during pregnancy	“Using this program would probably... would be the first for me because I don’t do the message boards and things of that nature, but I’m willing to give it a try, just, you know, because somebody may know something more than I do, and it never hurts to ask.”	-	Most participants ( $n=8$ ) thought the website was user-friendly and easy to access

### (Perceived) Suitability

This outcome was not reported in any of the studies about medical apps.

### Ability of Participants to Carry out Intervention Activities

Participants in the study by Nicholson et al thought the website was user-friendly and easy to access but logging into the system was sometimes challenging. Access through mobile phone could enhance their ability to login consistently [36].

### Results on Acceptability of Medical Apps

Table 2 gives an overview of studies reporting on the acceptability of medical apps by summarizing the results per first author, year of publication, used technique of the app, focus of the reported study, and acceptability reported by patients. Thereafter, we discuss the user satisfaction, appreciation, and recommendation of the included studies.

In total, 2 studies reported on acceptability of the medical apps [33,34].

### User Satisfaction

Hirst et al described an interactive, smartphone-based remote blood glucose monitoring system [37]. Women with gestational diabetes reported their blood glucose levels by telephone on a secure website to a diabetes midwife or physician. This website was checked at least 3 times a week. If required, the midwife or physician contacted the women via SMS or a phone call. In total, 45 out of 49 women agreed their care was satisfactory and the best for them, 47 out of 49 and 43 out of 49 agreed the equipment was convenient and reliable, respectively. Moreover, 42 out of 49 agreed that gestational diabetes mellitus (GDM) health fitted into their lifestyle, and 46 out of 49 agreed that they had a good relationship with their care team [37].

### Appreciation

In the study by Hirst et al, 83% of the participants agreed or strongly agreed the management system was reliable [37]. In the study by Nicholson et al, women expressed that the intervention materials were useful, well received, and led to a better understanding of how gestational weight gain during pregnancy might affect their child. Logging into the system was sometimes challenging [36].

### Recommendation

No studies reported recommendations of the medical apps.

### Effectiveness of Medical Apps

One study involved a telehealth program developed to manage asthma in pregnancy. It involved care of respiratory function, supported by a handheld respiratory device and a smartphone app. The primary outcome was change in asthma control as measured by the 7-item Asthma Control Questionnaire-7 at 3 and 6 months. At 6 months, the telehealth program group had significantly better asthma control compared with usual care group ( $P=.02$ ) [38].

In total, 5 studies described an app for pregnant women with diabetes mellitus (type 1 or 2) or GDM [36,39-42]. All studies in this subgroup evaluated an internet-based telemedicine system to monitor and transmit results to a health care professional. In all systems used in this subgroup, a form of personal interaction with a health care professional was possible, mostly by means of text messaging. All 4 studies used blood glucose and/or HbA1C as an outcome measure. Some also assessed insulin use and neonatal outcomes. Carral et al found less insulin use and fewer health care visits in the intervention group; however, there was no significant difference in HbA1C [42]. Homko et al found no significant difference in blood glucose and HbA1C [39]. In contrast to Carral et al, they did find that the proportion of women needing insulin therapy was significantly higher ( $P<.05$ ) in the intervention group. A later study by Homko et al reported no significant differences in glucose values or infant weight [41].

Perez-Ferre et al did not find any differences in HbA1C and blood glucoses or neonatal outcomes [40]. In total, 3 studies evaluated the effectiveness of an app to encourage pregnant women to receive an influenza vaccination during pregnancy [43-45]. In the study by Stockwell et al, a sequence of 5 weekly, automated text messages providing information and reminders about the influenza vaccine were sent [43]. The intervention in the study by Jordan et al used text reminders and tailored education [44]. The study by Yudin et al used 2 weekly sent text messages, during a period of 4 weeks [45].

**Table 2.** Overview of studies reporting on medical (interventions) apps related to pregnancy: acceptability.

Author and year	Technique	Focus	Acceptability	
			User satisfaction	Appreciation
Hirst et al, 2015 [37]	Using a GDM <sup>a</sup> health system for monitoring all blood glucoses and communication with the research team	Diabetes	In total, 90% of the participants agreed or strongly agreed the management system is convenient	In total, 83% of the participants agreed or strongly agreed the management system is reliable
Nicholson et al, 2016 [36]	Web lessons, self-tracking of weight and glucose, automated feedback, and access to a message board for peer support	Diabetes	-	Women reported little to no experience with online discussion groups, but expressed a willingness to use a message board to communicate with other women with GDM

<sup>a</sup>GDM: gestational diabetes monitoring.

Jordan et al showed an increase of continued intention to be vaccinated as a result of the encouraging messages with an adjusted odds ratio of 2.1 (95% CI 1.4-3.1) but no increased odds of vaccination at follow-up [44]. Stockwell et al reported a higher vaccination-rate, with an adjusted odds ratio of 1.3 (95% CI 1.003-1.69) in favor of the intervention group [43]. Yudin et al did not find significant differences in vaccination rate between the intervention and control group [45] (Table 3).

### Quality of Evidence

Only studies that evaluated a clinical outcome were assessed on quality by the ErasmusAGE quality assessment tool (Table 4). We aimed to evaluate the quality of qualitative research articles by the COREQ. Unfortunately, this was not possible because none of the included studies mentioned reporting according to this guideline [16].

**Table 3.** Overview of studies reporting on medical (interventions) apps related to pregnancy: effectiveness.

Author and year	Technique	Focus	Effectiveness
Zairina et al, 2015 [38]	Telehealth program in which daily lung functions were recorded and uploaded, and then, the participant's health care professional was contacted by a member of the research team if any medication changes or unscheduled asthma-related visits were needed	Asthma	The changes in ACQ <sup>a</sup> score from baseline to 3 months for MASTERY and usual care groups were 0.01±0.11 and 0.16±0.09, respectively. No significant difference in lung function was observed
Homko et al, 2007 [39]	Daily monitoring of blood glucose levels, recording insulin levels and episodes of hypoglycemia, and transmission of the measures to the diabetes health network (with health care providers involved in this network) at least 3 times a week	Diabetes	There was no significant difference between the 2 groups' blood glucose values and HbA1c levels. Significantly more women in the internet group received insulin therapy (31% vs 4%; <i>P</i> <.05). There were no significant differences in pregnancy and neonatal outcomes between the 2 groups
Perez-Ferre et al, 2010 [40]	A telemedicine system for the transmission of capillary glucose data and short text messages with weekly professional feedback	Diabetes	There was no difference in maternal metabolic parameters or in pregnancy outcomes
Homko et al, 2012 [41]	Data transfer from patient to practice and practice to patient to send blood glucose and other health data directly to health care providers to receive information or advice from the health care provider via the internet or phone	Diabetes	There were no significant differences between the 2 groups with regard to maternal blood glucose values or infant birth weight
Carral et al, 2015 [42]	Website which allows remote and bidirectional communication between health care professionals and patients with diabetes, offering the patient the possibility of sending blood glucose values, insulin doses, and other health data that can be evaluated remotely by doctors and nurses in an asynchronous manner	Diabetes	There was no significant difference in HbA1c levels. Significantly less insulin treatment and less health care visits in intervention group were observed
Nicholson et al, 2016 [36]	Web lessons, self-tracking of weight and glucose, automated feedback, and access to a message board for peer support	Diabetes	Average gestational weight gain for all participants was 19.9±13.2 lb. There was no statistically significant difference between baseline and 36 weeks of gestation in HbA1c levels
Stockwell et al, 2014 [43]	In total, 5 weekly text messages regarding influenza vaccination and 2 text message appointment reminders (intervention group); invitation for vaccination through the health care provider (control group)	Vaccination	Women in the intervention group were more likely to receive an influenza vaccination (adjusted odds ratio, AOR 1.3, CI 1.003-1.69)
Jordan et al, 2015 [44]	An encouragement message or an encouragement messages plus the opportunity to schedule a reminder	Vaccination	There was no significant increase of the odds of vaccination at follow-up. Significant increase of continued intent to be vaccinated later in the season (AOR 2.1, 95% CI 1.4-3.1)
Yudin et al, 2017 [45]	In total, 2 messages weekly for 4 consecutive weeks reinforcing that the influenza vaccine is recommended for all pregnant women and safe during pregnancy and breastfeeding vs no messages	Vaccination	There was no significant difference between the intervention and control group

<sup>a</sup>ACQ: Asthma Control Questionnaire.

**Table 4.** Quality scores included studies evaluated on effectiveness in review.

Author (year)	Design	Size	Exposure	Outcome	Adjustment	Total
Carral (2015) [42]	2	2	0	2	0	6
Choi (2016) [20]	2	0	0	2	1	5
Evans (2015) [34]	2	2	0	1	2	7
Fujioka (2012) [32]	1	0	0	2	0	3
Herring (2016) [31]	2	2	0	2	2	8
Homko (2007) [39]	2	1	0	1	0	4
Homko (2012) [41]	2	1	0	1	0	4
Jordan (2015) [44]	2	2	0	1	2	7
Moniz (2015) [33]	1	1	0	1	0	3
Nicholson (2016) [36]	2	0	0	2	0	4
Perez-Ferre (2010) [40]	2	1	0	2	0	5
Pollak (2014) [21]	2	0	0	1	0	3
Soltani (2015) [28]	2	0	0	0	0	2
Stockwell (2014) [43]	2	2	1	2	2	9
van Dijk (2016) [35]	2	2	1	2	0	7
Yudin (2017) [45]	2	2	0	2	0	6

## Discussion

### Purpose of This Review

The purpose of this systematic review was to provide information on the usability, defined as feasibility and acceptability, and effectiveness of both mHealth lifestyle and medical apps related to pregnancy in high-income countries.

### mHealth Lifestyle Apps

The results of this review clearly show the feasibility of most lifestyle apps, according to the criteria defined for this review. After activation, there is an adequate short- and long-term use as well as intention to use these apps [17-25]. This is in line with the perceived suitability of the apps that are often judged as good, easy, and simple to use. Moreover, the lifestyle apps with a target on improvement of health behavior, less gestational weight gain, and smoking cessation showed positive results on effectiveness. However, due to small sample size, significances could often not be demonstrated [21-23,27,28,31-35]. These results are in line with the systematic review by Badawy et al, which evaluated texting and apps for preventive behavior in adolescents [46]. They concluded that most studies reported positive on feasibility with high acceptability and satisfaction. This review included studies focusing on clinic attendance, contraceptive use, oral health, physical activity and weight management, sun protection, human papillomavirus vaccination, smoking cessation, and sexual health.

We observed high dropout rates among users of several apps [17,18,20]. This is in line with qualitative research by Dennison et al who found that participants lacked commitment using any particular app and seemed likely to engage in only transient, casual use [47]. These findings could be of concern for apps that aim to support long-term lifestyle interventions. For

pregnancy apps, this is not necessarily a barrier as the use of these apps is narrowed by a limited time frame.

We were surprised to find only 1 study involving also male partners in the intervention of adopting healthy nutrition and lifestyle [35]. This study clearly showed that women whose partners also participated showed the strongest positive change of these behaviors, which was significantly associated with a higher chance of achieving a pregnancy (adjusted hazard ratio 0.75, 95% CI 0.61-0.91).

### mHealth Medical Apps

In contrast to the mHealth lifestyle apps, the feasibility and acceptability of the medical apps was only reported in 2 studies concerning diabetes management and judged as good [36,37]. The evaluation of 5 studies on effectiveness of diabetes treatment during pregnancy could be judged properly because of objective outcome measures.

The effectiveness of mHealth medical apps in improving asthma management [38] and vaccination rates [43-45] is promising. However, not all studies showed significant outcomes, due to small sample sizes.

The study by Nes et al found that their mobile app for self-management of type 2 diabetes is feasible because of a high response rate. The intervention was evaluated as supportive and meaningful [48]. Hayashi et al tested the feasibility and usability of a self-management support system for dialysis patients and concluded that the completion rate was good, and most patients appreciated the system and intended to continue using the system [49].

Ming et al [50] evaluated 7 randomized controlled trials on telemedicine in gestational diabetes in a meta-analysis. A modest but statistically significant improvement in HbA1c associated

with the use of a telemedicine technology was demonstrated; however, there was insufficient evidence that other clinical endpoints were affected. In agreement with our results and due to lack of trials with large sample size and the variations of technologies used, it is not possible to draw a strong conclusion on the genuine benefits of the apps.

### Combination of mHealth Lifestyle and Medical Apps

Rehman et al reviewed the literature on the combination of mHealth apps involving smoking cessation and general diabetes management [51]. The authors reported low absolute smoking cessation rates, even though in some studies, intervention groups performed better than controls. They showed that mHealth could play a potential role in diabetes management; for example, text messages showed mixed results on HbA1c levels, which is in line with our results [36,39-41].

### Strength and Limitations

The main strength of this systematic review is that we evaluated both the feasibility and acceptability as well as the effectiveness of mHealth apps with a focus on lifestyle and medical domains. We limited our systematic review to apps for high-income countries and have made this choice because the needs and populations are very different between high- and low-middle-income countries. Hence, a broad view is given of existing evidence on factors influencing the implementation of new mHealth apps. The field of mHealth is fast growing with increasing evidence to support benefits for patients improving health outcomes as well as quality of health care. Furthermore, we used a systematic search method assisted by a clinical librarian.

Our study has also some limitations. The qualitative studies fail quality assessment using the predefined quality assessment (COREQ) [16]. With regard to the interpretation and validity of the results, we encountered a poor quality of most studies due to small sample sizes, high dropout rates after randomization for unknown reasons (cave selection bias), and the use of subjective outcome measures [23,40].

Therefore, an overestimation of the outcomes is very likely because it is known that, in particular, motivated women most often apply and continue the use of the intervention. Another issue of concern is the lack of objectivity of the data in most studies, because of the self-reporting of questionnaire data.

We did not include “adherence to medication” and “security” in our search. However, it is very worthwhile to address the

systematic review by Badawy et al, showing the feasibility, acceptability, and efficacy of mHealth apps to improve adherence to medication use in adolescents with chronic health conditions [52]. The barriers of security and privacy issues of mHealth technology are not often addressed. Kotz et al [53] is warning about the fact that many health care organizations lack the technology and expertise to secure patient data for cyberattacks in medical devices. Only the study by Hirst et al reported on a secured website for communication and transmission of confidential data [37]. It is possible that security issues influence the feasibility and acceptability as well as the effectiveness of mHealth apps. This raises the discussion whether the quality of these mHealth apps developed for health care have to be certified, such as a *Conformité Européenne* (CE, meaning European Conformity) certification. The advantage will be that the quality of all apps will be controlled and improved and the implementation of poor-quality apps will be limited.

### Conclusion and Practical Implications

This review outlines that most mHealth lifestyle and medical apps for pregnant women seem to be feasible and acceptable. mHealth crosses the boundaries of many related health fields, such as pediatrics, internal medicine, and social medicine. Therefore, future research should also focus on the impact of mHealth on related health conditions, clinical practice, and cost-effectiveness. This is supported by Badawy et al, showing that there is plenty room for further research in particular with regard to cost savings of mHealth by improving, eg, adherence to medication use [54].

We found modest evidence on effectiveness because most intervention studies evaluated small study groups, resulting in only a tendency toward positive results in the intervention groups and rarely significant improvements. We recommend that the development as well as the examination of feasibility and acceptability of new mHealth apps for (maternal) health care and lifestyle support should be done together with the target group. A clear definition of feasibility and acceptability within the focus of the app must be maintained as, for example, maternity care asks other definitions as antenatal care.

Finally, we and others are convinced that it is necessary to thoroughly guarantee security and privacy of the mHealth apps used in health care and beyond. Therefore, we strongly plea for the development of formal guidelines for quality certification of the apps before introduction.

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### Conflicts of Interest

From 2016, RST is CEO of eHealth Care Solutions and CSO of Slimmere Zorg BV. Other authors have no conflicts of interests to declare.

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### Multimedia Appendix 1

Search strategy.

[[PDF File \(Adobe PDF File\), 51KB - mhealth\\_v6i4e109\\_app1.pdf](#)]

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### Multimedia Appendix 2

Quality score for systematic reviews.

[[PDF File \(Adobe PDF File\), 35KB - mhealth\\_v6i4e109\\_app2.pdf](#)]

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### Multimedia Appendix 3

Study characteristics of mHealth lifestyle apps.

[[PDF File \(Adobe PDF File\), 47KB - mhealth\\_v6i4e109\\_app3.pdf](#)]

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### Multimedia Appendix 4

Study characteristics of mHealth medical apps.

[[PDF File \(Adobe PDF File\), 43KB - mhealth\\_v6i4e109\\_app4.pdf](#)]

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### Multimedia Appendix 5

Complete overview of results on mHealth lifestyle apps.

[[PDF File \(Adobe PDF File\), 59KB - mhealth\\_v6i4e109\\_app5.pdf](#)]

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### Multimedia Appendix 6

Overview of studies reporting on lifestyle mHealth apps: feasibility.

[[PDF File \(Adobe PDF File\), 47KB - mhealth\\_v6i4e109\\_app6.pdf](#)]

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### Multimedia Appendix 7

Overview of studies reporting on lifestyle mHealth apps: acceptability.

[[PDF File \(Adobe PDF File\), 43KB - mhealth\\_v6i4e109\\_app7.pdf](#)]

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### Multimedia Appendix 8

Overview of studies reporting on lifestyle mHealth apps: effectiveness.

[[PDF File \(Adobe PDF File\), 35KB - mhealth\\_v6i4e109\\_app8.pdf](#)]

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### Multimedia Appendix 9

Complete overview of results on mHealth medical apps.

[[PDF File \(Adobe PDF File\), 48KB - mhealth\\_v6i4e109\\_app9.pdf](#)]

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## Abbreviations

**COREQ:** consolidated criteria for reporting qualitative research

**GDM:** gestational diabetes mellitus

**mHealth:** mobile health

**SMS:** short message service

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Original Paper

# Impact of the Growing Healthy mHealth Program on Maternal Feeding Practices, Infant Food Preferences, and Satiety Responsiveness: Quasi-Experimental Study

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## Abstract

**Background:** Infancy is an important life stage for obesity prevention efforts. Parents' infant feeding practices influence the development of infants' food preferences and eating behaviors and subsequently diet and weight. Mobile health (mHealth) may provide a feasible medium through which to deliver programs to promote healthy infant feeding as it allows low cost and easy access to tailored content.

**Objective:** The objective of this study was to describe the effects of an mHealth intervention on parental feeding practices, infant food preferences, and infant satiety responsiveness.

**Methods:** A quasi-experimental study was conducted with an mHealth intervention group (Growing Healthy) and a nonrandomized comparison group ("Baby's First Food"). The intervention group received access to a free app with age-appropriate push notifications, a website, and an online forum that provided them with evidence-based advice on infant feeding for healthy growth from birth until 9 months of age. Behavior change techniques were selected using the Behaviour Change Wheel framework. Participants in both groups completed three Web-based surveys, first when their infants were less than 3 months old (baseline, T1), then at 6 months (time 2, T2), and 9 months of age (time 3, T3). Surveys included questions on infant feeding practices and beliefs (Infant Feeding Questionnaire, IFQ), satiety responsiveness (Baby Eating Behaviour Questionnaire), and infant's food exposure and liking. Multivariate linear regression models, estimated using maximum likelihood with bootstrapped standard errors, were fitted to compare continuous outcomes between the intervention groups, with adjustment for relevant covariates. Multivariate logistic regression adjusting for the same covariates was performed for categorical outcomes.

**Results:** A total of 645 parents (Growing Healthy: n=301, Baby's First Food: n=344) met the eligibility criteria and were included in the study, reducing to a sample size of 546 (Growing Healthy: n=234, Baby's First Food: n=312) at T2 and a sample size of 518 (Growing Healthy: n=225, Baby's First Food: n=293) at T3. There were approximately equal numbers of boy and girl infants, and infants were aged less than 3 months at baseline (Growing Healthy: mean 7.0, SD 3.7 weeks; Baby's First Food: mean 7.9, SD 3.8 weeks), with Growing Healthy infants being slightly younger than Baby's First Food infants ( $P=.001$ ). All but one (IFQ subscale "concerns about infant overeating or becoming overweight" at T2) of the measured outcomes did not differ between Growing Healthy and Baby's First Food.

**Conclusions:** Although mHealth can be effective in promoting some health behaviors and offers many advantages in health promotion, the results of this study suggest that design and delivery characteristics needed to maximize the impact of mHealth interventions on infant feeding are uncertain. The sensitivity of available measurement tools and differences in baseline characteristics of participants may have also affected the results.

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## KEYWORDS

mHealth; obesity; infant; parents; food preferences; appetite; pediatric obesity; feeding behavior; overweight; eating; health promotion

## Introduction

### Context

Childhood obesity is a strong risk factor for adult overweight or obesity [1,2] and is associated with numerous medical, psychosocial, and economic costs [3-5]. Primary prevention is therefore an important public health priority, particularly given the high prevalence in numerous societies [6,7], including Australia, where approximately one-quarter of children are overweight or obese [8]. Rapid growth in infancy has a strong positive association with being overweight in childhood [9,10] and is therefore an important target for prevention efforts. The World Health Organization's (WHO) Commission on Ending Childhood Obesity [11] notes that to reverse worldwide trends in childhood obesity, approaches for addressing the complex range of risk factors in a range of population groups is needed [12]. The World Health Organization urges "Member States to develop national responses, strategies and plans to end infant, child and adolescent obesity" [13]. One modifiable risk factor is parental feeding practices that encompass those food- or eating-specific behaviors or strategies that parents use to influence children's or infants' eating.

### The Importance of Parental Feeding Practices and Cognitions to Infant Eating and Weight

Parental feeding practices affect infants' and children's food intakes, as well as the development of their food preferences and eating behaviors (such as responding to the hunger and satiety cues) [14-16]. They are important intervention targets because they influence healthy eating and weight in both the short and long term. Feeding practices likely to promote healthy eating and weight outcomes for children or infants typically incorporate responsive feeding (ie, recognizing and responding to an infant's hunger and satiety cues and needs in appropriate ways) with a flexible feeding or mealtime structure (ie, providing consistency in what, when, and how food is provided) [17-20]. Conversely, nonresponsive feeding practices include those that are controlling or pressuring, which can elevate a child's risk of weight gain [21]. These feeding practices are characterized by a higher disregard for an infant or child's

hunger and satiety cues and attempts to promote either higher or lower consumption of particular foods through, for example, restricting children's access to or consumption of particular foods. These types of feeding practices can disrupt an infant's or child's ability to effectively self-regulate their caloric intake, leading to excess calorie intake and weight gain [22]. However, there are still many gaps in our understanding of such relationships.

Parental cognitions such as concerns about an infant eating too much, or that a child is at risk of becoming overweight, may affect their feeding practices. Parents who are concerned about their infant or child being or becoming underweight or not gaining enough weight are more likely to use pressuring feeding practices to promote greater consumption [23,24]. Conversely, parents who are concerned about their child being or becoming overweight are more likely to restrict access to foods [25]. These concerns and perceptions may arise partly in reaction to the characteristics of the infant (eg, birth weight, speed of eating, or gender), as well as those of the caregiver such as the mother's education level and her own weight status [26,27].

### The Importance of Food Preferences to Eating and Weight

Also significant in the development of weight status are children's emerging food preferences: these are an important determinant of whether children consume particular foods or avoid them [28,29], especially vegetables [30]. Repeated exposure is a core determinant of food liking in children and infants, with higher exposure typically linked to higher liking [31]. The types of foods that infants and children are exposed to will have a lasting influence on their developing food preferences and whether they are likely to consume healthy diets in the future [32,33]. Consequently, it is important that parents repeatedly expose infants to core foods that are associated with healthy weight gain and growth and avoid noncore foods that are associated with poorer diets and health. Parental feeding practices, parental feeding cognitions, and children's food preferences are three potentially modifiable domains that may influence child weight outcomes.

## Approaches to Promoting Healthy Feeding and Eating in Infancy

Despite the range of studies now indicating that particular parental feeding practices and associated cognitions in early stages of children's lives are important for children's healthy weight gain, there are still substantial gaps in our understanding of the most effective approaches for helping parents to achieve this [34]. Available evidence suggests that by providing guidance to parents, some, but not all, feeding practices and beliefs can be shifted to healthier patterns [34]. Evidence for this comes from multicomponent behavioral interventions that broadly aimed to increase parents' knowledge and skills about infant feeding in face-to-face individual or group settings [34]. Due to the delivery mode, these interventions are necessarily resource intensive and are therefore less able to be provided to a wide range of potential participants. Mobile health (mHealth), in contrast, provides the advantages of flexibility in how and when information is accessed by participants at relatively low cost of use and dissemination. Given the high penetration of mobile phones [35], mHealth interventions may be more likely to be used by a wide range of sociodemographic groups, including those typically hard to reach with face-to-face interventions such as parents of lower socioeconomic position.

mHealth programs also offer advantages over traditional approaches in the types of behavior change approaches that can be employed, which may enhance intervention effectiveness. For instance, content can be readily tailored to participants' individual needs (eg, infant's age and whether breast- or formula-feeding), and because they offer programming flexibility, numerous behavior change techniques (BCTs) can be readily utilized (eg, video demonstrations and feedback on behaviors) or features be incorporated (eg, prompts). For these reasons, mHealth approaches to health promotion provide an attractive medium through which interventions could be delivered to time-poor groups such as new parents. Available evidence from the wider mHealth field suggests that mHealth interventions are more effective in promoting some health behaviors than others [36-38]. A recent review found that their capacity to influence infant or child eating or weight through parents as an agent of change is, however, uncertain [39].

To this end, this paper reports on data from the *Growing Healthy* program, an mHealth intervention that aimed to promote infant feeding practices consistent with national guidelines from birth until 9 months of age [40]. The purpose of this paper is to describe whether parents participating in this mHealth intervention were more likely than those in a nonrandomized comparison group to (1) use feeding practices associated with healthy weight outcomes in infants or children; (2) be more likely to expose infants to core, as opposed to noncore foods, (3) have infants who like more core foods and like fewer noncore foods, and (4) have infants who are better at responding to internal hunger and fullness cues.

## Methods

### Overview

Details of the study design are reported elsewhere [40]. In brief, the study used a quasi-experimental study design with an mHealth intervention group and a nonrandomized comparison group. Ethics approval was provided by Deakin University and University of Technology Sydney.

### Study Participants

Eligibility criteria for participation in the intervention group (*Growing Healthy*) included pregnant (30+ weeks gestation) or parent or main caregiver of an infant aged under 3 months, owned any type of mobile phone, spoke and read English, aged 18 years or older, and lived in Australia. Participants were recruited three ways: via their primary health care providers in socioeconomically disadvantaged communities in two Australian states (New South Wales and Victoria), face-to-face by researchers, and through Web advertising. Enrollment to the study included completion of a Web-based screening form, a consent form, and a baseline survey. A concurrent nonrandomized comparison group (*Baby's First Food*) was recruited via Web forums, social networking sites, and blogs and received usual care that involves regular face-to-face appointments with a maternal and child nurse to monitor and advise on the infant's health, growth, and development. Further details can be found in the study by Laws et al [41].

### Intervention: The Growing Healthy Program

The *Growing Healthy* program consisted of an app, website, and Web-based forum, providing parents with evidence-based advice on infant feeding for healthy growth from birth until 9 months of age. The program aims included promoting healthy infant feeding practices (eg, recognizing and appropriately responding to infant cues of hunger and satiety) and promoting high exposure to fruits and vegetables [40]. Participants received three push notifications via their *Growing Healthy* app (or via email for those without a mobile phone) for each week of the intervention on infant feeding topics tailored to their infant's age and feeding mode (whether breast-, formula-, mixed-feeding, alone or in combination with solid-feeding). The push notifications and emails provided links to further related information on the app or website. The app and website contained enriched information delivered in a variety of formats (eg, video, text, and imagery), a range of communication functions (eg, capacity to share with others), and a Web-based forum. Detailed information on the intervention and its development is reported elsewhere [40]. BCTs were selected using the Behaviour Change Wheel (BCW) framework [42] as a guide. That is, the BCW was used to identify determinants of the target behaviors and their alternatives (less desirable behaviors) and to map these to BCTs using the behavior change taxonomy (see [43,44]).

### Data Collection

Participants in *Growing Healthy* and *Baby's First Food* completed a baseline survey when their infant was between 2 weeks and 3 months of age, a follow up survey when infants were approximately 6 months of age, and a final survey when

infants were approximately 9 months. The baseline survey collected information on sociodemographics, including the child's age and gender and the mothers' age, country of birth (Australia or overseas born), relationship status (single or married), employment status (currently employed or unemployed), education level (low: no formal education or high school; medium: certificate or diploma; high: university degree and higher), and annual household income (Aus \$≤51,999, 52,000-77,999, 78,000-99,999, ≥100,000). Mothers also self-reported their prepregnancy weight in kilograms and current height in centimeters. Maternal prepregnancy body mass index (BMI) was calculated as prepregnancy weight divided by height squared ( $\text{kg}/\text{m}^2$ ). Feeding mode (exclusively breastfeeding, formula feeding, or mixed feeding) was also collected.

### **Assessment of Parental Feeding Practices and Beliefs**

Parental feeding practices and beliefs were collected at all three time points using questions from the Infant Feeding Questionnaire (IFQ) [45]. The IFQ consists of 20 items across the seven dimensions of: concern about infant undereating or becoming underweight (example item: do you worry that your baby is not eating enough?), concern about infant's hunger (example item: do you put cereal in his bottle so he stays full longer?), awareness of infant's hunger and satiety cues (example item: my baby knows when he is hungry), concern about infant overeating or becoming overweight (example item: I am worried that my baby would become overweight), feeding infant on a schedule (example item: do you feed your baby at set times?), using food to calm infant's fussiness (example item: feeding my baby is the best way to stop him being unsettled), and social interaction with the infant during feeding (example item: do you talk or sing to your baby when you feed him?). Behavioral items were measured on a 5-point frequency scale (0=never, 1=rarely, 2=sometimes, 3=often, and 4=always), whereas belief items were measured on the following scale: 0=disagree a lot, 1=disagree a little, 2=no strong feelings either way, 3=agree a little, and 4=agree a lot.

### **Assessment of Infant Satiety Responsiveness**

Respondents were also asked about perceptions of their infant's ability to respond to their internal satiety cues (*satiety responsiveness*), which was measured with three items from the Baby Eating Behaviour Questionnaire (BEBQ, [46]). In total, 6 of the 20 items were not used in all three variants of the survey at each time point, and for consistency, were therefore excluded from analyses.

### **Assessment of Infant Food Exposure and Parental Intentions to Offer Foods**

Frequency of food exposure, infant food preference, and parents' intentions to offer foods again were reported at time 3 (T3) with purpose-developed items. Thirty-two foods were included to provide a range of foods, typically available in the Australian food supply and being characteristic of foods recommended to be consumed in high or low amounts [47]. The 22 core foods were apple, banana, grape, orange, watermelon, mandarin, pear, rockmelon, kiwi, grapefruit, potato, carrot, pumpkin, broccoli, corn, tomato, mushroom, sweet potato, parsnip, eggplant, water, and cow's milk. The ten noncore foods were juice, other drinks,

flavored milk, cakes, sweet biscuits, savory biscuits, chocolate or lollies, salty snacks, pies, and hot chips (French fries). For each food item, parents were asked about the frequency at which they had offered the food (1=never, 2=less than once a month, 3=1-3 times a month, 4=once a week, 5=2-4 times a week, 6=5-6 times a week, and 7=once a day or more) and about their infant's liking of the food (question: does the child usually like this food? response categories: yes, no, and hasn't tried this food), as well as their intentions to reoffer foods (question text: will you offer this food again in the next six months? response categories: yes, no, and unsure). Additional questions on whether parents added sugar or salt into foods their infant would eat were also asked (response options: never, sometimes, often, and always).

### **Statistical Analysis**

For baseline characteristics, group comparisons were made using *t* tests for continuous characteristics and chi-square tests for categorical characteristics. Exploratory factor analysis (promax rotation) was performed on the 14 IFQ at all three time points. At each time point, five main factors were extracted and were consistent with the original IFQ structure [48]. These factors were as follows: (1) concern about infant undereating or becoming underweight (4 items), (2) awareness of infant hunger and satiety cues (3 items), (3) concern about infant overeating or becoming overweight (3 items), (4) feeding infant on a schedule (2 items), and (5) using food to calm infant fussiness (2 items). The scores of these five outcomes were calculated as the sum of the corresponding subitems, with higher scores representing stronger beliefs or more frequent behaviors for each factor. For the *satiety responsiveness* score from the BEBQ, the three items were added. The list of items included in each outcome is provided in [Multimedia Appendix 1](#).

To assess infants' food exposure, we calculated core and noncore food offering frequency scores and variety scores. Frequency of consumption of each food item was converted to daily equivalent scores (never=0, less than once a month=0.017, 1-3 times a month=0.067, once a week=0.143, 2-4 times a week=0.429, 5-6 times a week=0.786, and once a day or more=1). Adding daily equivalent scores of the 22 core food categories and ten noncore food categories, respectively, generated core and noncore food frequency scores. For the food variety score, frequency of consumption of each item was first coded into a binary variable indicating offered or not offered. Core and noncore food variety scores were created by adding individual binary variables together, resulting in a score ranging from 0 to 22 for core foods and 0 to 10 for noncore foods. Similarly, by adding binary variables (offer again yes or no) of individual foods together, the number of core or noncore foods that parent will offer again was also obtained. For infants who disliked one or more core foods, a score was created for the proportion of disliked core foods that the parent intended to offer again in the next 6 months. For infant food preferences, individual food item preference was coded as either yes or no, with "has not tried" coded to missing. The proportions of core and noncore foods that the infant tasted and disliked, as well as the proportion of disliked core foods the parent intended to offer again, were dichotomized into all versus not all. Questions asking whether parents added sugar or salt to baby foods were

combined into a single outcome and dichotomized as never versus some of the time (sometimes or often or always).

Descriptive analyses (ie, means and SDs for continuous variables and percentages for categorical variables) were conducted to compare baseline characteristics between the two groups. Multivariate linear regression models, estimated using maximum likelihood with bootstrapped standard errors, were fitted to compare continuous outcomes between the intervention groups, with adjustment for baseline parental feeding practice and belief variables, and covariates including infant's age, maternal age, maternal BMI, whether first born, maternal country of birth, and feeding method. These covariates were chosen as they each differed between Growing Healthy and Baby's First Food groups and were associated with at least one outcome variable with  $P < .25$ , allowing for the inclusion of potentially important confounders. Multivariate logistic regression adjusting for the same aforementioned covariates was performed for categorical outcomes. As noncore food exposure (frequency scores) residuals of linear regression analyses were right skewed, this variable was also analyzed as a dichotomized variable: whether parents offer noncore foods to their infant (never or some). Attrition analysis was performed to examine baseline characteristics of those who remained in the study and those who dropped out. All analyses were conducted in Stata (Release 14; StataCorpLP).

## Results

### Retention and Recruitment

There were 645 eligible participants at baseline (Growing Healthy: 301, Baby's First Food: 344), reducing to a sample size of 546 (Growing Healthy:  $n=234$ , Baby's First Food:  $n=312$ ) at time 2 (T2) and a sample size of 518 (Growing Healthy:  $n=225$ , Baby's First Food:  $n=293$ ) at T3. Thus 82 participants (82/645, 12.7%) dropped out between baseline and T2, and a further 28 participants (making a total of 110 [28/645, 17%]) dropped out between T2 and T3. Most (151/301, 50.3%) of the intervention group was recruited via the Web, 7.7% (23/301) through face-to-face methods, 29.3% (88/301) via practitioners, and the remainder (38/301, 12.7%) via word of mouth. Further details are described in the papers by Laws et al [41,49].

### Study Participants at Baseline

Details of recruitment and retention of study participants are reported elsewhere [41]. As shown in Table 1, baseline infant characteristics between two groups were similar, with exception of infant age and proportion of first-born infants: the mean infant age in Growing Healthy (7.0, SD 3.7, weeks) was younger than those in Baby's First Food (7.9, SD 3.8, weeks), and there was a greater proportion of first-born infants in Growing Healthy (173/301, 57.5%) than in Baby's First Food (133/344, 38.7%). The proportion of boys in both groups was similar (150/301, 49.8% in Growing Healthy and 167/344, 48.5% in Baby's First Food). The distribution of feeding mode also differed between the two groups, with a lower proportion of exclusive breastfeeding mothers in Growing Healthy (196/301, 65.1%)

than in Baby's First Food (245/344, 71.2%). For parental characteristics, apart from Growing Healthy mothers being younger (Growing Healthy: mean 30.4, SD 4.7 years vs Baby's First Food: mean 31.2, SD 4.4 years), a lower proportion being Australian born (Growing Healthy: 253/301, 84.1% vs Baby's First Food: 310/344, 90.1%), and a higher proportion coming from middle household income categories (Growing Healthy: 145/301, 56.9% vs Baby's First Food: 138/344, 47.9%), other parental factors such as mother's smoking status, prepregnancy BMI, parental education, and employment status were not statistically different. The entire sample at baseline ( $n=645$ ) and 93% (510/546) at T2 completed the survey questions pertaining to parental feeding practices and beliefs (IFQ). Ninety-three percent of participants (480/518) at T3 completed questions relating to dietary exposure, infant food preferences, and intentions to reoffer disliked foods, in addition to the IFQ. Baseline parental IFQ and infant *satiety responsiveness* (BEBQ) scores by intervention groups are shown in Table 2. No significant between-group differences were observed at baseline. Details of the individual items comprising the IFQ factors and the Cronbach alphas for each IFQ factor at baseline, T2 and T3 are in Multimedia Appendix 1.

There were some statistically significant differences between the retained samples and study dropouts with respect to baseline characteristics. Participants who had dropped out by T2 had lower baby birth weight (mean 3321.6, SD 738.4 g vs mean 3485.6, SD 644.3) than the retained T2 sample. Participants who had dropped out by T3 had lower baby birth weight (mean 3350.6, SD 776.3 vs mean 3492.7, SD 624.1), parents perceived them to have an easier or better baby temperament (mean 2.2, SD 0.9 vs mean 2.4, SD 0.8), greater awareness of infant hunger and satiety cues (mean 13.0, SD 2.1 vs mean 12.6, SD 2.0), were less likely to be married (118/127, 92.3% vs 503/518, 97.1%), more likely to have a health care card (28/127, 22.1% vs 73/518, 14.1%), and less likely to be tertiary educated (48/124, 38.7% vs 263/507, 51.9%) than the retained T3 sample.

### Outcomes at Time 2

Five outcomes relating to parental feeding practice and belief outcomes and one outcome on infant satiety responsiveness scores were examined at T2 when infant mean age was 6 months (26.6 weeks). Comparison of these outcomes by intervention groups is presented in Table 3. Adjusted mean differences between the two groups were not significantly different for any of the outcomes examined with the exception of IFQ subscale "Concerns about infant overeating or becoming overweight," which was higher in Growing Healthy. The median score for the IFQ subscale "Concerns about infant undereating or becoming underweight" was 7.0 for both groups. Median score of the IFQ subscale "Awareness of infant hunger and satiety cues" was not significantly different between Baby's First Food (14.0) and Growing Healthy (13.0). Both groups had similar median score for the IFQ subscales "Feeding infant on a schedule" (7.0), "Using food to calm infant fussiness" (6.0), and the BEBQ infant "Satiety responsiveness score" (7.0).

**Table 1.** Sociodemographic characteristics of the Baby's First Food and Growing Healthy samples at baseline.

Characteristics	Growing Healthy (n=301)	Baby's First Food (n=344)	P value
<b>Child factors</b>			
Age (weeks)	7.0 (3.7)	7.9 (3.8)	.001
<b>Gender, n (%)</b>			
Boys	150 (49.8)	167 (48.5)	.74
Girls	151 (50.2)	177 (51.5)	
First born baby, n (%)	173 (57.5)	133 (38.7)	<.001
<b>Parental factors</b>			
Mother's age (years)	30.4 (4.7)	31.2 (4.4)	.04
Mother prepregnancy body mass index (kg/m <sup>2</sup> ), mean (SD)	26.6 (5.7)	27.2 (6.8)	.23
Maternal smoking status (currently smoking), n (%)	18 (6.0)	15 (4.4)	.35
Maternal country of birth (Australian born), n (%)	253 (84.1)	310 (90.1)	.02
Relationship status (married), n (%)	289 (96.0)	332 (96.5)	.74
Health care card (yes), n (%)	48 (16.0)	53 (15.4)	.85
<b>Maternal self-rated health, n (%)</b>			
Poor or fair	30 (10.0)	28 (8.1)	.51
Good	116 (38.5)	152 (44.2)	
Very Good	124 (41.2)	131 (38.1)	
Excellent	31 (10.3)	33 (9.6)	
<b>Maternal education, n (%)</b>			
Low	61 (21.1)	56 (16.4)	.29
Medium	88 (30.5)	115 (33.6)	
High	140 (48.4)	171 (50.0)	
<b>Maternal working status, n (%)</b>			
Not working	261 (86.7)	298 (87.1)	.87
Working	40 (13.3)	44 (12.9)	
<b>Paternal education, n (%)</b>			
Low	56 (19.4)	64 (19.3)	.56
Medium	144 (49.8)	153 (46.1)	
High	89 (30.8)	115 (34.6)	
<b>Paternal working status, n (%)</b>			
Not working	12 (4.2)	7 (2.1)	.14
Working	277 (95.8)	324 (97.9)	
<b>Annual house income (AUD), n (%)</b>			
≤51,999	35 (13.7)	44 (15.3)	.02
52,000-77,999	79 (31.0)	57 (19.8)	
78,000-99,999	66 (25.9)	81 (28.1)	
≥100,000	75 (29.4)	106 (36.8)	
<b>Feeding groups, n (%)</b>			
Exclusive breastfeeding	196 (65.1)	245 (71.2)	<.001
Formula feeding	52 (17.3)	48 (14.0)	
Mixed feeding	53 (17.6)	51 (14.8)	

**Table 2.** Baseline parental feeding practice and beliefs (Infant Feeding Questionnaire) and infant satiety responsiveness (Baby Eating Behaviour Questionnaire) in the Baby's First Food and Growing Healthy samples. IQR: interquartile range.

Baseline (mean infant age: 7.4 weeks)	Baby's First Food (n=344)			Growing Healthy (n=301)		
	n	Mean (SD)	Median (IQR)	n	Mean (SD)	Median (IQR)
Concerns about infant undereating or becoming underweight (4 items, maximum score 20)	343	7.1 (2.8)	6.0 (5.0-8.0)	301	7.3 (2.7)	7.0 (5.0-9.0)
Awareness of infant hunger and satiety cues (3 items, maximum score 15)	344	12.8 (2.1)	13.0 (12.0-15.0)	301	12.6 (2.0)	13.0 (11.0-14.0)
Concerns about infant overeating or becoming overweight (3 items, maximum score 15)	344	5.0 (2.1)	4.0 (3.0-6.0)	301	5.3 (2.0)	5.0 (4.0-7.0)
Feeding infant on a schedule (2 items, maximum score 10)	343	3.8 (1.8)	3.0 (2.0-5.0)	301	3.8 (1.7)	3.0 (2.0-5.0)
Using food to calm infant fussiness (2 items, maximum score 10)	344	6.8 (1.8)	7.0 (6.0-8.0)	301	6.6 (1.7)	7.0 (5.0-8.0)
Infant satiety responsiveness score (3 items, maximum score 15)	296	7.3 (2.0)	7.0 (6.0-9.0)	262	7.3 (2.0)	7.0 (6.0-9.0)

**Table 3.** Comparison of parent feeding practice and belief outcomes at time 2 between Baby's First Food and Growing Healthy. Mean difference coefficients estimated from linear regression analysis. IQR: interquartile range.

Parent feeding practice and belief items	Distribution of outcomes						Effects of intervention	
	Baby's First Food			Growing Healthy			Mean difference (95% CI)	P value
	n	Mean (SD)	Median (IQR)	n	Mean (SD)	Median (IQR)		
Concerns about infant undereating or becoming underweight (4 items)	281	7.2 (2.7)	7.0 (5.0-9.0)	229	7.2 (2.8)	7.0 (5.0-9.0)	-0.14 (-0.61 to 0.34)	.57
Awareness of infant hunger and satiety cues (3 items)	281	13.2 (1.9)	14.0 (12.0-15.0)	229	12.9 (2.1)	13.0 (12.0-15.0)	-0.11 (-0.44 to 0.23)	.54
Concerns about infant overeating or becoming overweight (3 items)	281	4.5 (1.7)	4.0 (3.0-6.0)	229	4.9 (2.0)	4.0 (3.0-6.0)	0.30 (0.01 to 0.59)	.04
Feeding infant on a schedule (2 items)	282	4.9 (2.2)	5.0 (3.0-7.0)	229	5.1 (2.2)	5.0 (3.0-7.0)	0.05 (-0.28 to 0.39)	.76
Using food to calm infant fussiness (2 items)	281	6.2 (1.9)	6.0 (5.0-8.0)	229	6.1 (1.9)	6.0 (5.0-7.0)	0.06 (-0.22 to 0.34)	.69
Infant satiety responsiveness score (3 items)	241	7.0 (2.4)	7.0 (5.0-8.0)	228	7.2 (2.2)	7.0 (6.0-8.0)	0.08 (-0.36 to 0.52)	.72

<sup>a</sup>Multivariate linear regression models, estimated using maximum likelihood with bootstrapped standard errors, were fitted to compare continuous outcomes between the intervention groups with adjustment for baseline parental feeding practice and belief variable, age, maternal age, maternal body mass index, whether first born, maternal country of birth, and feeding mode.

### Outcomes at Time 3

At T3, the IFQ and BEBQ satiety responsiveness scores were similar between the two groups (Table 4). Core and noncore food exposure represented by offer frequency scores and variety scores exhibited no significant between-group differences. Median core and noncore offer frequency scores were 5.0 and 0.1, respectively, indicating that infants were offered 5 core and 0.1 noncore foods per day. Similar median variety scores for core (15.0 out of a possible 22) and noncore (2.0 out of a possible 10) were also found for both groups. Of 22 core foods,

the median number of foods that parent intended to offer in the future was similar between two groups (19 for Baby's First Food, 20 for Growing Healthy). Of 10 noncore foods, the median number of foods that parent intended to offer in the future was 3.0 for both Baby's First Food and Growing Healthy. No significant differences were found in the analyses of between-group differences in whether parents offer noncore foods, reoffer rejected core foods, the proportion of core and noncore foods infants had tasted and they liked, and whether the parent added salt or sugar to the infant's foods (Table 5).



**Table 4.** Comparison of parent feeding practice and beliefs, dietary exposure, and infant food preference continuous outcomes at time 3 between Baby's First Food and Growing Healthy. Mean difference coefficients estimated from linear regression analysis. IQR: interquartile range.

Parent feeding practice and belief items	Distribution of outcomes						Effects of intervention	
	Baby's First Food			Growing Healthy			Mean difference (95% CI)	P value
	n	Mean (SD)	Median (IQR)	n	Mean (SD)	Median (IQR)		
Concerns about infant undereating or becoming underweight (4 items)	279	7.5 (3.0)	7.0 (5.0-9.0)	201	7.7 (3.2)	7.0 (5.0-10.0)	-0.02 (-0.59 to 0.54)	.94
Awareness of infant hunger and satiety cues (3 items)	279	13.0 (1.7)	13.0 (12.0-14.0)	201	12.6 (1.9)	13.0 (12.0-14.0)	-0.20 (-0.54 to 0.14)	.26
Concerns about infant overeating or becoming overweight (3 items)	279	4.6 (1.8)	4.0 (3.0-6.0)	202	4.7 (1.8)	4.0 (3.0-6.0)	-0.06 (-0.39 to 0.28)	.74
Feeding infant on a schedule (2 items)	279	5.4 (1.9)	6.0 (4.0-7.0)	202	5.5 (1.9)	5.0 (4.0-7.0)	-0.10 (-0.41 to 0.21)	.54
Using food to calm infant fussiness (2 items)	279	5.8 (1.9)	6.0 (4.0-7.0)	201	5.7 (1.8)	6.0 (4.0-7.0)	0.06 (-0.24 to 0.37)	.69
Infant satiety responsiveness score (3 items)	250	7.2 (2.1)	7.0 (6.0-8.0)	181	6.8 (2.1)	7.0 (6.0-8.0)	-0.21 (-0.62 to 0.19)	.30
Core food offer frequency score	276	5.2 (2.0)	5.0 (3.8-6.4)	202	5.1 (1.9)	5.0 (3.7-6.4)	-0.07 (-0.44 to 0.30)	.70
Non-core offer food frequency score	275	0.3 (0.5)	0.1 (0.0-0.5)	202	0.3 (0.4)	0.1 (0.0, 0.4)	-0.06 (-0.15 to 0.03)	.19
Core food variety score (0-22)	276	14.8 (3.1)	15.0 (13.0-17.0)	202	15.0 (3.0)	15.0 (13.0-17.0)	0.18 (-0.40 to 0.76)	.55
Non-core food variety score (0-10)	275	2.6 (2.0)	2.0 (1.0-4.0)	202	2.5 (2.2)	2.0 (1.0-4.0)	0.03 (-0.34 to 0.41)	.87
Number of core foods parent will offer again (0-22)	277	18.7 (2.7)	19.0 (17.0-21.0)	202	19.1 (2.4)	20.0 (18.0-21.0)	0.39 (-0.10 to 0.88)	.12
Number of non-core foods parent will offer again (0-10)	277	3.2 (2.3)	3.0 (1.0-5.0)	202	3.2 (2.5)	3.0 (1.0-5.0)	0.00 (-0.43 to 0.44)	.99

<sup>a</sup>Multivariate linear regression models, estimated using maximum likelihood with bootstrapped standard errors, were fitted to compare continuous outcomes between the intervention groups with adjustment for baseline parental feeding practice and beliefs variable, age, maternal age, maternal body mass index, whether first born, maternal country of birth, and feeding method.

**Table 5.** Comparison of parent feeding practice and belief binary outcomes at time 3 between Baby's First Food and Growing Healthy.

Parent feeding practice and belief items	Baby's First Food, n (%)	Growing Healthy, n (%)	Effects of intervention	
			Odds ratio (95% CI)	P value
<b>Did parent offer infant any noncore foods</b>			0.96 (0.59 to 1.55)	.81
No	54 (19.6)	44 (21.8)		
Yes	221 (80.4)	158 (78.2)		
<b>Proportion of core foods infant has tasted that they liked</b>			1.22 (0.83 to 1.80)	.36
Not all	162 (58.3)	111 (54.7)		
All	116 (41.7)	92 (45.3)		
<b>Proportion of noncore foods infant has tasted that they liked</b>			1.27 (0.67 to 2.41)	.46
Not all	35 (15.3)	19 (11.9)		
All	194 (84.7)	140 (88.1)		
<b>Proportion of disliked core foods the parent intended to offer again</b>			1.17 (0.64 to 2.14)	.61
Not all	42 (25.9)	26 (23.4)		
All	120 (74.1)	85 (76.6)		
<b>Does parent add salt or sugar to foods infant eats</b>			0.82 (0.48 to 1.41)	.47
Never	235 (84.8)	174 (86.1)		
Some of the time	42 (15.2)	28 (13.9)		

## Discussion

### Principal Findings

This study considered the effects of an mHealth intervention on parental feeding practices and cognitions, infants' food preferences, and infants' satiety responsiveness. In this study, we noted very few differences between the intervention and comparison groups in the measured outcomes, suggesting that although mHealth offers many advantages to both the researcher and participant over traditional approaches, further evidence on the most effective approaches for achieving and measuring outcomes in infant feeding are needed.

At each of the time points, just one of the tested relationships (concern about infant overeating or becoming overweight at T2) differed between the two groups. The majority of other studies using traditional intervention approaches (face-to-face) have been able to support parents to use some desirable infant feeding practices and eating outcomes for children, but not all. The NOURISH trial, for instance, which recruited first-time mothers and their 4- to 7-month old infants to a responsive feeding intervention, was able to influence infant satiety responsiveness [50] and only one of the IFQ subscales at 14 months [51]. In the Melbourne InFANT Program, a cluster randomized controlled trial (RCT) delivering diet and feeding education to first-time Australian mothers, differences in intervention and control group parents' use of *food as a reward* were observed, but no changes were seen for the other measured feeding practices at 18 months of age [52]. The POL.nz RCT also noted group differences in *pressure to eat* along with *child control* and *encourage nutrient-dense foods* but none of the other feeding practices after the provision of information and support on feeding and food [53]. The SLIMTIME study also showed effects on repeated exposure to vegetables, as well as

the number of feeds per day, but the latter only for breastfed infants when a responsive feeding intervention was administered to first-time American mothers [54]. The reasons underlying the effects of face-to-face multicomponent interventions on some feeding practices are unclear because of their heterogeneous designs and complex nature [55]. However, a recent intervention with slightly older children noted the important influence of children's innate individual characteristics (eg, temperament) on intervention effectiveness [56], and it is possible that further tailoring of intervention to these particular characteristics would enhance effectiveness.

In relation to the findings on food exposure, infants in the intervention group were equally likely as those in the comparison group to be exposed to and like core (as well as noncore) foods and were equally likely to be reoffered those foods that they initially disliked. The Growing Healthy program aimed to encourage parents to repeatedly expose their infants to core foods, even when initially rejected, and to avoid exposure to noncore foods. This could be a result of selection bias: it appeared that parents in both groups had similar intentions and behaviors, and in many (though not all) instances, these were close to ideal. For this reason, showing an effect of the intervention was challenging with the available sample size and measurement tools. Less ideal feeding practices may also only emerge later when children present more behavioral challenges such as a food neophobia or fussy eating at older ages [57,58], along with increasing independence and assertiveness such as in toddlerhood and beyond [59]. Furthermore, interventions targeting children or infants at high risk of (further) excess weight gain are likely to be more effective in producing change. Lioret et al [60], for instance, noted that changes in diet quality were only associated with reduced z-score BMI for school children who were already overweight at baseline. In this study,

it is possible that a subset of parents with higher risk behaviors existed, perhaps the approximately one-quarter of parents who did not intend to offer a disliked core food again, or the 14% to 15% who were adding salt or sugar to foods their infant ate at least some of the time.

The influence of the unique design features of the intervention on participants' behaviors may have also affected results. Health behavior programs delivered by mHealth are likely to be more effective when they meet several criteria including that they have a theoretical basis, suitable BCTs are employed over a suitable period of time, the content is appropriate, and the design characteristics and mode of delivery of the intervention are appealing to the participants [61,62], although many gaps exist in our understanding of effective design features for different behaviors and contexts [61]. Indeed the most effective features for child obesity prevention interventions (mHealth or otherwise) is still unclear [63]. It is also important that the program be tailored to the individual needs of the participants [61]. The Growing Healthy program was designed with these criteria in mind [40], and feedback from participants suggested that in many aspects, the program was able to meet participants' expectations and needs [43]. Retention across the study time frame was also high (80%), suggesting that there were benefits for participants in continuing to participate. However, preferred design and delivery characteristics differ across individuals and with different health behaviors. It could be that further tailoring of the intervention content to other characteristics of parent-infant dyads, such as their current knowledge around infant feeding, whether their child was a particularly avid eater or born at a high or low birth weight, or child temperament, may improve future studies. In Growing Healthy, a number of feeding behaviors were targeted (eg, breastfeeding, formula feeding, food exposure, and feeding to appetite) across a diverse sample of participants, and designing an intervention in such a way that it can optimally meet the diverse needs of all participants for all target behaviors is a challenge.

Another important consideration in explaining the effects reported here relates to the dose of the intervention. Although many of the challenges faced in an mHealth intervention of healthy infant feeding are similar to those faced in other parent feeding interventions (eg, effective BCTs and measurement of outcomes), there are some unique challenges associated with the mHealth delivery mode that may have affected the results. For instance, there were indications that improvements could be made to the delivery of the program: technical problems related to operating system upgrades that saw the app temporarily cease functioning likely affected the dose of the intervention received by some of the participants and consequently, may have reduced potential impact of the intervention. This may have affected participant engagement. Participant engagement describes how often participants accessed various elements of the app, read push notifications, participated in the forum, looked at the website, and over what period of time [64]. Engagement with mHealth programs is typically high upon joining the program and diminishes thereafter, and app analytics indicated that participants in Growing Healthy followed this pattern [43,64]. However, although overall engagement declined with time, the sections

of the program covering topics related to feeding and sleeping were among the most accessed by participants, suggesting that parents were interested in the topics and sought information regarding these constructs. It is unclear, then, whether the dose of the intervention received was lower than that needed to produce detectable changes in behaviors. A larger sample that enabled subgroup analyses based on engagement and interactions with particular design features may have provided some explanation.

The Growing Healthy program drew on the BCW framework and, as part of this, the Capability, Opportunity, Motivation, and Behavior (COM-B) framework to select BCTs likely to be effective in changing the target behaviors [42]. Available evidence on the likely relationships between the COM-B elements and the BCTs most likely to be effective in changing them was used; however, the effects of the many possible BCTs (eg, providing information about possible consequences, modeling [65], and their delivery [eg, videos and text]) on infant feeding have not previously been tested for their independent effects on COM-B, especially in an mHealth context. As such, it is difficult to know how successful each of these were in influencing target behaviors. Qualitative feedback from participants suggested that the program influenced some of the antecedents of behaviors (capability and opportunity in particular) [43]; however, the effects of these were not detected in the outcome measures. Interventions adhering to behavioral theories such as the BCW and who use particular BCTs are more likely to be effective than those that do not [66,67], although further work is needed to identify which components of such theories and which particular BCTs are likely to produce sustainable outcomes for different health behaviors in a range of contexts. It is possible, for instance, that alternative determinants of behaviors such as social norms could have had an influence on outcomes, and these were not addressed here but could be in the future with appropriate BCTs.

An additional challenge, common to all studies of parental feeding, is the effective measurement of parental feeding practices. In this study, the IFQ was used to measure parental infant feeding practices. At the time of designing the study, this was the only available self-reported measure of relevant parent infant feeding practices (to the authors' knowledge). The IFQ was developed with infants from 6 months of age. In this study though, parents were initially asked to complete it when their infant was aged less than 3 months, and it is not known how appropriate the IFQ is with younger infants. Furthermore, the IFQ has not been validated against observational measures of parental feeding, or against objective measures of infant's eating and weight, and therefore its capacity to accurately reflect parent's feeding practices and beliefs is unknown. Additionally, the measure of infant food liking and parental intentions to reoffer foods were purpose-developed for this study and has not been validated, although it is possible that parent measures of their infant feeding practices and their infant's food preferences are affected by social desirability and recall bias. Greater attention to validating measures of parent feeding practices and infant food preferences is urgently needed if the effects of interventions are to be confidently demonstrated.

A final but important consideration in interpretation of the results is that this study used a quasi-experimental design, and as such, the participants were not randomly assigned. Consequently, the two groups differed at baseline in some infant (eg, age) and parent (eg, parity) characteristics (although were similar in the majority of key criteria). The analyses took account of these differences; however, adequately powered RCTs are needed to confidently demonstrate effects.

### Conclusions

Although mHealth can be effective in promoting health behaviors and offers many advantages in health promotion, the

results of this study suggest that design and delivery characteristics needed to maximize the impact of mHealth interventions on infant feeding are uncertain. Further tailoring of content, including BCTs, to individual circumstances and characteristics may improve efficacy in different contexts. Furthermore, improved measures of outcomes, including those that are objectively measured or sensitive enough to reveal small changes in behaviors that are likely achieved by low-dose mHealth interventions, may be needed if the effects of mHealth interventions are to be detected.

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### Authors' Contributions

CGR, EDW, RL, ST, EL, and KC all contributed to the conceptualization of the study and development of the app content. KL developed the programming behind the app and website and measurement of program analytics. MZ and GA undertook the data analysis, with input from SL. CGR drafted the manuscript, and all authors reviewed and contributed to drafts of the paper and approved the final manuscript.

### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Items under each parental feeding practice and belief outcome and infant satiety responsive score and their Cronbach alpha.

[[PDF File \(Adobe PDF File\), 35KB - mhealth\\_v6i4e77\\_app1.pdf](#)]

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## Abbreviations

- BCT:** behavior change technique
- BCW:** Behaviour Change Wheel
- BEBQ:** Baby Eating Behaviour Questionnaire
- BMI:** body mass index
- COM-B:** Capability Opportunity Motivation and Behavior
- IFQ:** Infant Feeding Questionnaire
- IQR:** interquartile range
- mHealth:** mobile health
- RCT:** randomized controlled trial
- T1, T2, T3:** baseline, time 2, time 3

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Original Paper

# Long-Term Effectiveness of a Smartphone App for Improving Healthy Lifestyles in General Population in Primary Care: Randomized Controlled Trial (Evident II Study)

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## Abstract

**Background:** Information and communication technologies are currently among the supporting elements that may contribute to improving health and changing lifestyles.

**Objective:** The aim of this study was to evaluate the long-term effectiveness of adding an app to standardized counseling in order to increase physical activity (PA) and adherence to the Mediterranean diet and to analyze the effects of app adherence in lifestyle changes.

**Methods:** A randomized, multicenter clinical trial with a 12 month-follow up was conducted, involving 833 participants recruited by random sampling in 6 primary Spanish care centers (415 vs 418). Counseling on PA and the Mediterranean diet was given to both groups by a research nurse; however, the counseling + app group (intervention group) received additional training in the use of an app that was designed to promote the Mediterranean diet and PA over a 3-month period. Main outcomes and measures included PA by accelerometer and the 7-day Physical Activity Recall (PAR) questionnaire and adherence to the Mediterranean diet by an adherence screener questionnaire. We considered adherence to the app to be high when it was used for more than 60 days.

**Results:** The mean age was 51 years (SD 12) in the intervention group and 52.3 years (SD 12.0) in the counseling-only group; females predominated in both groups (60.0%, 249/415 and 64.1%, 268/418, respectively). PA by accelerometer declined in both groups at 12 months ( $P$  value for tendency in moderate to vigorous PA, [MVPA]=.15). The intervention subgroup with high app adherence had better behavior than the low adherence subgroup ( $P$  value for tendency in MVPA=.001). PA analyzed by 7-day PAR did not show changes at 12 months in any of the groups ( $P$  value for tendency=.25). In the Mediterranean diet, an increase in adherence was observed in both groups at 12 months with no differences between them ( $P$  value for tendency=.46). In these two cases, the group with high app adherence also had better behavior, although without reaching significance for the tendency ( $P>.05$ ).

**Conclusions:** The participants with strongest app adherence showed better outcomes in terms of maintenance of healthy lifestyles at 12 months than those with weaker adherence. Overall, however, we found no differences between intervention group and counseling-only group in PA increase and adherence to the Mediterranean diet in the long term.

**Trial Registration:** Clinicaltrials.gov NCT02016014; <https://clinicaltrials.gov/ct2/show/NCT02016014> (Archived by WebCite at <http://www.webcitation.org/6ymEXH6W4>)

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## KEYWORDS

exercise; Mediterranean diet; smartphone; vascular stiffness

## Introduction

### Background

Noncommunicable diseases have been major public health concerns in recent years [1], and the prevention of such diseases is a major public health goal worldwide [2]. Lifestyle is one of the main causes of noncommunicable diseases, and the improvement in parameters such as dietary composition, physical activity (PA), and sedentary lifestyle are determinants for reducing the frequency of this type of pathology [3]. Information and communication technologies (ICTs) are currently used as support tools that can contribute to a change in the population's lifestyle and thus improve their health [4].

A recent meta-analysis [5] found modest evidence for the efficacy of app interventions in dietary improvement, PA, and sedentary behaviors. The interventions that used an app in conjunction with other intervention strategies demonstrated improvements in behavioral and health outcomes compared with stand-alone app interventions [6]. These findings also showed that higher app usage was associated with improvements in PA and healthy eating [7], and low adherence rate was a major challenge in most of the studies, in particular, in studies with longer follow-up durations (>3 months) [8].

However, there are few studies that have analyzed the maintenance over time of the effect of an intervention with mobile apps once its use has ceased. Likewise, it does not seem to be clear to what extent greater or lesser adherence to the app affects the long-term maintenance of the beneficial lifestyle effects achieved during the time when the new technologies were being used. In the Evident II Project [9], an app was used for 3 months with the aim of achieving a change of lifestyle during this time with adherence to the Mediterranean diet (MD) and increased PA. We hoped that once acquired with the help of the app, the new habits would be maintained over time without the need for permanent reinforcement. This aspect does not seem to be sufficiently well clarified at present. In the analysis of short-term effectiveness, this study [10] showed that moderate -vigorous PA (MVPA) and adherence to MD increased

from baseline in both groups, but no differences were found when comparing the increases between them. The evidence on ICT effectiveness was derived mainly from short-term (<6 months) experimental studies with far less data on long-term effectiveness or sustainability [8]. Therefore, few studies have examined effectiveness in large population samples and long-term follow-up studies using an app combining PA and dietary habits, and more evidence from studies with longer duration of follow-up periods seems necessary.

### Objectives

This study evaluated the long-term effectiveness of adding an app over 3 months to support standardized counseling in increasing PA and adherence to MD, and analyzed the effects of the time of app use on lifestyle modifications, as well as the maintenance over time of lifestyle changes achieved.

## Methods

### Design

The *Evident II* study was a randomized, controlled, multicenter clinical trial with 2 parallel groups. It was carried out with a follow-up period of 12-months [9] ([Multimedia Appendix 1](#)). Between January 2014 and September 2016, evaluations were made at baseline and after the completion of 3 and 12 months.

### Setting, Participants, and Randomization

The study population was selected from the Evident I study [11] using random sampling from 6 primary care centers. We excluded participants aged >70 years. A detailed description of inclusion and exclusion criteria has been published elsewhere [9]. The reasons for exclusion are summarized in [Figure 1](#) (flowchart). Our study included 833 of the participants recruited in the Evident I study who were randomized in the ratio of 1:1 centrally from Salamanca using the Epidat 4.2 software package (Consellería de Sanidade, Xunta de Galicia, Spain) to assign them to the intervention group (IG, n=415) or the control group (CG, n=418). Due to the nature of the study, the participants could not be blinded to the intervention.

As reference committee, the Clinical Research Ethics Committee of the health care area of Salamanca approved the study (June 21, 2013), and the ethics committees of the 5 collaborating centers did likewise. All participants signed the informed consent form before inclusion in the study in accordance with the Declaration of Helsinki [12].

### Smartphone App for Evaluating Healthy Lifestyles

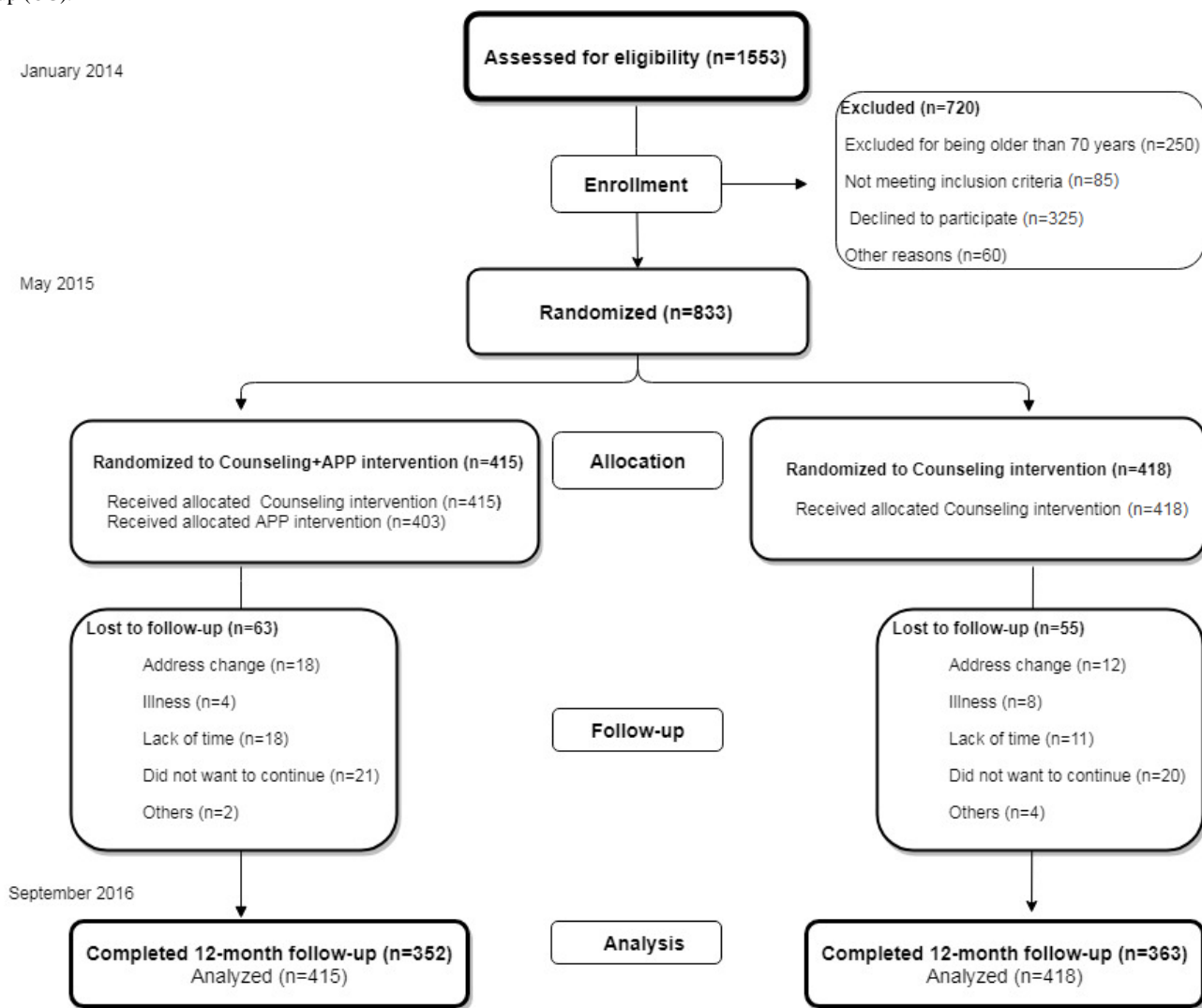
The smartphone app has a simple and user-friendly interface for daily recording of both portions of food eaten and PA performed (Multimedia Appendix 2) [9]. The app analyzed the user's portion logs, applying standardized criteria to assess the quantity and quality of the food eaten each day and generated a detailed report on the composition of the diet and the calories consumed. A pedometer included in the smartphone app recorded the PA, and the subject could add PA information when it was not possible to use the pedometer (eg, when swimming). The app then generated a report on all the PA performed. After a daily analysis, the app generated a plan of recommendations for the following days with the aim of improving eating habits and increasing PA toward the targeted

10,000 steps per day. The information was stored in the device and downloaded on the day of the control visits for subsequent analysis.

### Intervention

The common intervention consisted of a 30-min standardized PA and MD counseling session, the effectiveness of which had previously been demonstrated [13,14]. It was performed in both groups by a trained research nurse, and participants received printed support material (leaflets) on the session. The participants in the IG group also received training from a different investigator in the use of a smartphone app, designed to promote MD and increase PA. An initial 15-min visit was used to provide training in the use of the device, which was then employed daily for the full 3-month intervention period. A detailed description of the intervention and app utilities has been published elsewhere [9]. A second visit took place 1 week after supplying the device in order to confirm that it was being used correctly. Participants returned the smartphone after 3 months, coinciding with the common follow-up visit.

**Figure 1.** Flowchart of participants through of the Evident II trial comparing the counseling (intervention) + app group (IG) with the counseling-only group (CG).



## Outcome Measures and Follow-Up

The primary outcome measures were changes in PA, assessed by questionnaire and accelerometer, and adherence to MD, by questionnaire, at 12 months in IG compared with CG. Likewise, we analyzed PA changes and MD adherence in IG in relation to levels of app adherence. A detailed description of the method by which clinical data were collected has been published elsewhere [9].

## Physical Activity

The ActiGraph GT3X accelerometer (ActiGraph, Shalimar, FL, USA) [15] was used to objectively evaluate PA. For 7 consecutive days during routine PA, participants wore the accelerometer attached with an elastic strap to the right side of the waist except during bathing and performing water-related activities. The accelerometer was set to record PA data minute by minute. Inclusion criteria consisted of a minimum of 5 days of recordings, including at least 1 weekend day and at least 600 registered minutes per day. The first and last day data were excluded in order to analyze full days only, and the uptime was adjusted to 7 days. Activity “counts” were recorded to the internal memory of the accelerometers by converting acceleration units over a given period [16]. The main outcome variable from the activity monitor was the mean intensity of PA (counts per minute). The intensity of PA was rated according to the cutoff points proposed by Freedson [17].

PAR is a 7-day semistructured interview lasting 10 to 15 min in which participants provide an estimate of the number of hours dedicated to physical or occupational activities requiring at least moderate effort over the past 7 days [18,19]. The categories consisted of moderate, vigorous, and very vigorous PA. The dose of physical exercise was estimated in metabolic equivalent (MET) minutes per week.

## Nutrition

Adherence to MD as a nutrition primary endpoint was measured using the validated 14-point Mediterranean Diet Adherence Screener [20], developed by the PREDIMED study group. This 14-item screening questionnaire comprises 12 questions on food consumption frequency and 2 questions on food intake habits. Each question was scored as 0 or 1, and the total scores ranged from 0 to 14. A total score of  $\geq 9$  points represented adequate MD adherence.

## Adherence to the Smartphone App

In IG, adherence to the smartphone app was assessed through the number of recorded days in the device. We classified recordings into 4 categories, that were (1) 0 days, (2) 1 to 30 days, (3) 31 to 60 days, and (4)  $>60$  days. A food log of  $>60$  days in the 3 months that the participant had the smartphone represented high adherence, with  $\leq 60$  days equating to low adherence.

## Statistical Analysis

We estimated the sample size in relation to the main study endpoints. Assuming  $\alpha=.05$  and  $\beta=.20$  with an SD of 154 counts per min, in order to detect an increase of 30 counts per min in the IG versus CG groups we would have needed 828 participants (414 per group); for an SD of 2 points in MD, we

would have needed 504 participants (252 per group) in order to detect an increase of 0.5 points. We considered 833 participants sufficient to detect clinically relevant differences in the main study endpoints.

The results were expressed as mean and SD for quantitative variables and as the frequency distribution for qualitative variables. Analysis of the results was made on an intention-to-treat basis. Chi-square and Fisher exact tests were used to analyze the association between independent qualitative variables. Student *t* test was used for the comparison of means between 2 groups and the paired *t* test or McNemar test was applied to assess changes within the same group. In order to analyze the effects of the interventions, we compared the changes observed between IG and CG by analyzing covariance while adjusting for each variable's baseline measurements. To assess the effects of app adherence, we divided IG into high and low adherence categories according to specified criteria and performed the same analyses. In order to analyze the group effects with respect to MD adherence and PA increase, we performed a multivariate analysis of the variance of repeated measures adjusted by the baseline measure and analyzed the interaction of the main variables with the group (IG vs CG). Later, in order to evaluate the effects of app adherence, we performed the same analysis considering the day's app use as dichotomous and continuous variable. We also performed a Spearman ( $\rho$ ) correlation between the number of days of app use and the difference between 12-month and baseline measurements of the main variables to analyze the association between these variables. We used the Johnson-Neyman technique [21] to attempt to determine specific cutoff points (ie, the point at which the number of days of app use was significantly different on the dependent variable, using the motivation phase as a moderating variable).

The contrast in hypotheses established  $\alpha$  of .05. The data were analyzed using the SPSS version 23.0 (IBM Corp, Armonk, NY, USA).

## Results

### Baseline Characteristics of the Participants and Follow-Up

The flowchart (Figure 1) shows the subjects included in each group in addition to those who dropped out and the causes of this throughout the study. From a total of 118 subjects, 14.2% (118/833) dropped out, 15.2% (63/415) in the IG group and 13.2% (55/418) in the CG group. Table 1 describes the baseline characteristics of 833 participants.

### Changes in Physical Activity and Adherence to the Mediterranean Diet

In PA evaluated by accelerometer, there was a decrease in both groups with a greater decrease in IG without any interaction in the group effects (*P* value for tendency MVPA=.15), as you can see in Multimedia Appendix 3 and Figure 2. Regarding the 7-day PAR, no differences were found between the 2 groups in PA at 12 months (Table 2). Figure 2 shows METs per week, which were summary measures of the 7-day PAR at 12 months with no differences seen between them (*P* value for tendency

MET min per week=.25). In MD adherence, a similar increase was observed in both groups without differences between them ( $P$  value for tendency MD score=.46; see [Multimedia Appendix 4](#) and [Figure 2](#)).

### Adherence to the Smartphone App

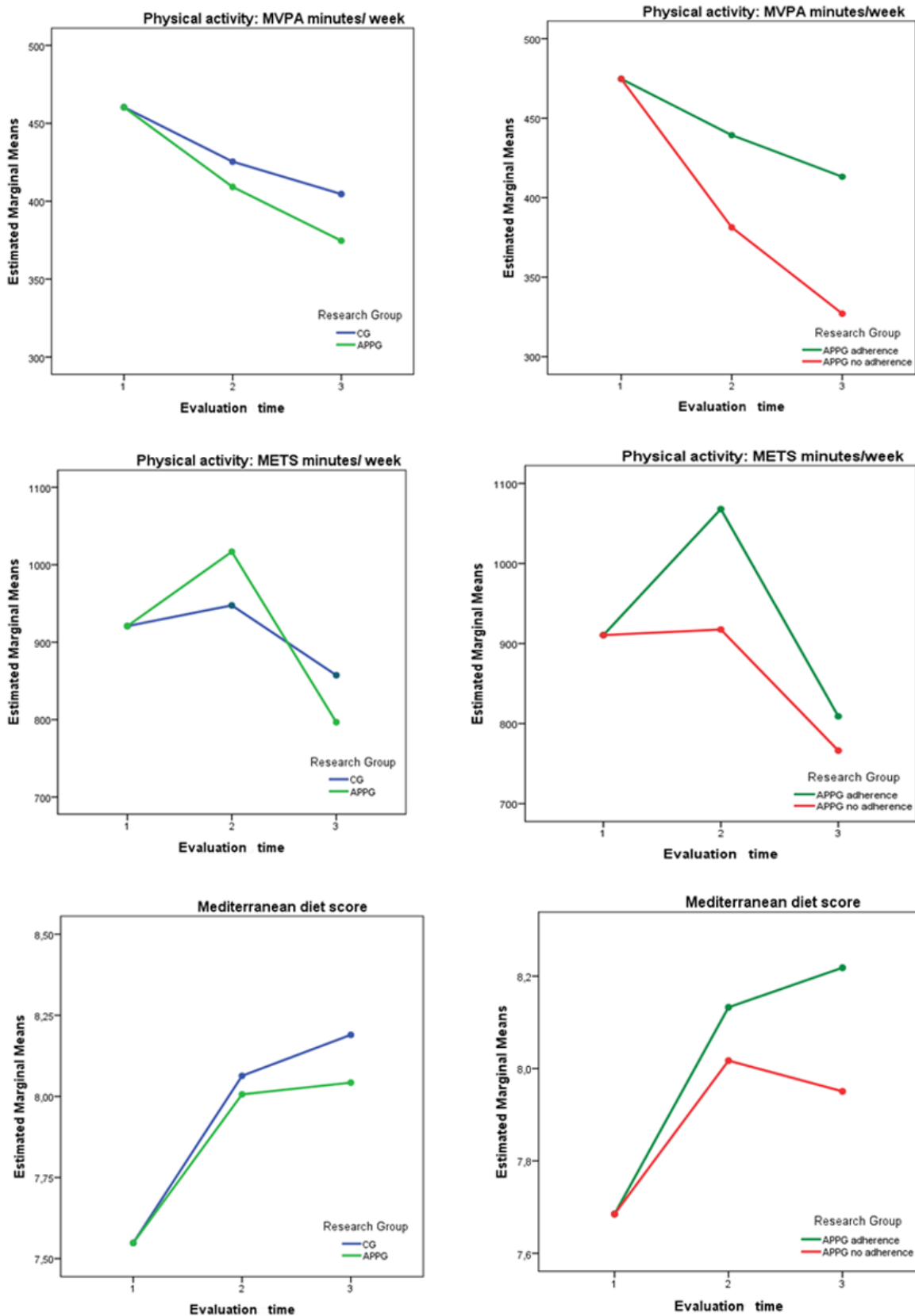
The median use of the app was 67 days. Some participants (56.8%, 236/415) in the IG group had high app adherence, and 28.2% (117/415) of the participants used it for less than a month ([Figure 3](#)). The participants with low adherence were younger (49.5 vs 52.9 years), and there was a higher proportion of smokers (54.3%, 51/179 vs 45.7%, 43/236), as shown in [Table 2](#).

We did not find a correlation between the number of days the app was used with the change at 12 months in the global score of the MD questionnaire, or with PA as measured with 7-day PAR. However, a correlation was found between the accelerometer changes in terms of steps per day ( $\rho=.114$ ,  $P=.046$ ), counts per minute ( $\rho=.126$ ,  $P=.03$ ), minutes of moderate activity ( $\rho=.112$ ,  $P=.049$ ), minutes of MVPA ( $\rho=.113$ ,  $P=.047$ ), and METS minutes per week ( $\rho=.120$ ,  $P=.04$ ). In the variance analysis of repeated measures, we found an interaction between the number of days of app use and MVPA with accelerometer ( $P$  value for tendency=.004), METS mins per week with 7-day PAR ( $P$  value for tendency=.03), and the MD adherence score ( $P$  value for tendency=.04).

**Table 1.** Baseline characteristics of the study population (N=833). Categorical variables are expressed as n (%) and continuous variables as mean (SD).

Variable	Counseling + app (n=415, 49.8%)	Counseling (n=418, 50.2%)
Age in years, mean (SD)	51.4 (12.1)	52.3 (12.0)
Gender (female), n (%)	249 (60.0)	268 (64.1)
<b>Work situation, n (%)</b>		
Works outside home	228 (54.9)	203 (48.6)
Homemaker	53 (12.8)	72 (17.2)
Retired	77 (18.6)	89 (21.3)
Student	10 (2.4)	8 (1.9)
Unemployed	47 (11.3)	46 (11.0)
<b>Educational level, n (%)</b>		
University studies	117 (28.2)	132 (31.6)
Middle or High school	208 (50.1)	208 (49.8)
Elementary school	90 (21.7)	78 (18.7)
<b>Smoking, n (%)</b>		
Nonsmoker	190 (45.8)	166 (39.7)
Smoker	94 (22.7)	108 (25.8)
Former smoker	131 (31.6)	144 (34.4)
<b>Alcohol, n (%)</b>		
Abstemious	86 (23.2)	88 (23.7)
Low risk	200 (53.9)	209 (56.3)
Moderate risk	46 (12.4)	34 (9.2)
High risk	39 (10.5)	40 (10.8)
Body mass index (kg/m <sup>2</sup> ), mean (SD)	28.1 (5.1)	27.6 (4.6)
Systolic blood pressure (mm Hg), mean (SD)	124 (16)	124 (17)
Diastolic blood pressure (mm Hg), mean (SD)	76 (10)	76 (10)
Total cholesterol (mg/dL), mean (SD)	202 (35)	206 (37)
Triglycerides (mg/dL), mean (SD)	112 (63)	107 (67)
Hypertension, n (%)	145 (34.9)	133 (31.8)
Dyslipidemia, n (%)	116 (28.2)	113 (27.3)
Diabetes, n (%)	32 (7.7)	30 (7.2)
Obesity, n (%)	126 (30.4)	114 (27.3)

**Figure 2.** Evolution of physical activity and adherence to the Mediterranean diet at 3 and 12 months. (A) Comparison of the evolution of counseling + app group (APPG) versus the control group (CG) showing (1) moderate to vigorous physical activity (MVPA) minutes per week by accelerometer (P value for tendency=.15), (2) Metabolic equivalents (METs) minutes per week by 7-day Physical Activity Recall or PAR (P value for tendency=.245), and (3) Score of adherence to the Mediterranean diet (MD) (P value for tendency=.465). (B) Comparison of the evolution of APPG with high adherence versus IG with low adherence showing (1) MVPA min per week by accelerometer (P for tendency=.001), (2) METS min per week by 7-day PAR (P for tendency=.38), and (3) Score of adherence to the MD (P for tendency=.31). 1: Baseline, 2: Three months, 3: Twelve months.



**Table 2.** Baseline characteristics of counseling + app group by adherence to the app.

Variable	Adherence to app groups		P value
	Low adherence (n=179, 43%)	High adherence (n=236, 57%)	
Age (years), mean (SD)	49.5 (12.5)	52.9 (11.6)	.004
<b>Gender, n (%)</b>			
Female	111 (44.6)	138 (55.4)	.47
Male	68 (41.0)	98 (59.0)	
<b>Civil status, n (%)</b>			
Single	33 (42.3)	45 (57.7)	.20
Married	122 (41.6)	171 (58.4)	
Separated	20 (62.5)	12 (37.5)	
Widower	3 (30.0)	7 (70.0)	
Others	1 (50.0)	1 (50.0)	
<b>Work situation, n (%)</b>			
Works outside of home	104 (45.6)	124 (54.4)	.25
Homemaker	20 (37.7)	33 (62.3)	
Retired	26 (33.8)	51 (66.2)	
Student	5 (50.0)	5 (50.0)	
Unemployed	24 (51.1)	23 (48.9)	
<b>Educational level, n (%)</b>			
University studies	48 (41.0)	69 (59.0)	.81
Middle or High school	90 (43.3)	118 (56.7)	
Elementary school	41 (45.6)	49 (54.4)	
<b>Smoker status, n (%)</b>			
Nonsmoker	78 (41.1)	112 (58.9)	.04
Current smoker	51 (54.3)	43 (45.7)	
Ex-smoker	50 (38.2)	81 (61.8)	
<b>Alcohol, n (%)</b>			
Abstemious	35 (40.7)	51 (59.3)	.33
Low risk	84 (42.0)	116 (58.0)	
Moderate risk	18 (39.1)	28 (60.9)	
High Risk	22 (56.4)	17 (43.6)	
Body mass index (kg/m <sup>2</sup> ), mean (SD)	28 (5)	28 (5)	.47
Systolic blood pressure (mm Hg), mean (SD)	122 (16)	125 (15)	.10
Diastolic blood pressure (mm Hg), mean (SD)	76 (10)	77 (10)	.10
Total cholesterol (mg/dL), mean (SD)	201 (35)	203 (35)	.44
Triglycerides (mg/dL), mean (SD)	114 (68)	111 (59)	.68
<b>Obesity, n (%)</b>			
No	118 (40.8)	171 (59.2)	.15
Yes	61 (48.4)	65 (51.6)	
<b>Hypertension, n (%)</b>			
No	123 (45.6)	147 (62.3)	.17
Yes	56 (38.6)	89 (37.7)	
<b>Dyslipidemia, n (%)</b>			

Variable	Adherence to app groups		P value
	Low adherence (n=179, 43%)	High adherence (n=236, 57%)	
No	133 (45.1)	162 (54.9)	.14
Yes	43 (37.1)	73 (62.9)	
<b>Diabetes, n (%)</b>			
No	161 (42.0)	222 (58.0)	.12
Yes	18 (56.3)	14 (43.8)	

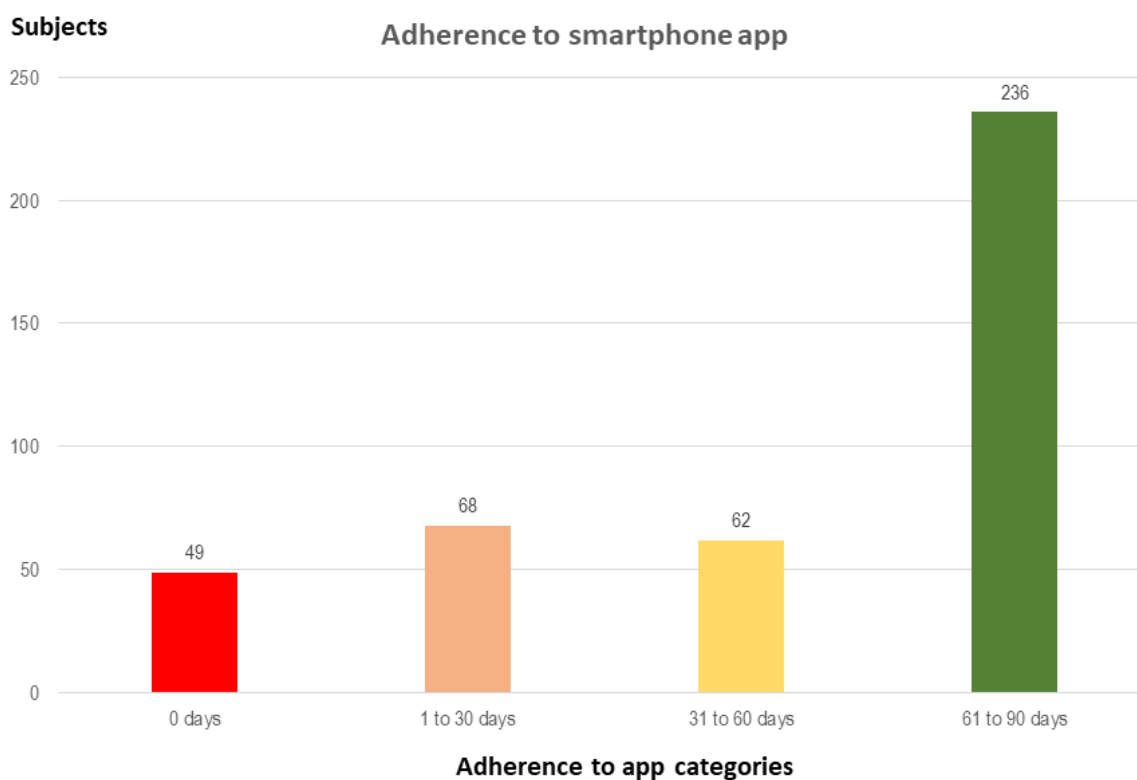
In [Figure 2](#), we can see that the low app adherence participants had worse PA behavior according to the accelerometer ( $P<.001$  for MVPA tendency). In [Multimedia Appendix 5](#), more favorable behavior ( $P<.05$ ) was observed among the high adherence participants in all parameters of the accelerometer except for light and vigorous or very vigorous PA. In the 7-day PAR, the high adherence participants were the ones who increased PA at 3 months but decreased at 12 months ( $P=.38$  for tendency MET min per week). We found no differences in any of the 7-day PAR parameters between the high and low adherence participants ([Multimedia Appendix 5](#)).

Regarding MD ([Multimedia Appendix 6](#)), participants in the high adherence category and CG had a similar behavior, whereas participants in the low adherence category were worse and showed a decline after 3 months, although this was not statistically significant ( $P=.31$  for tendency MD score). We

observed the best behavior among the high adherence participants, although statistical significance was only achieved after higher fruit and lower commercial dessert consumption.

In relation to Prochaska and Diclemente's stages of motivation for change, we found a greater number of days of app use among subjects during the preparation and maintenance stages for change in PA but not in eating habits ([Multimedia Appendix 7](#)). Likewise, in the multivariate analysis, we found that the intervention was more effective in the high app adherence group among subjects in the preparation ( $P$  value for tendency=.04) and maintenance ( $P$  value for tendency=.004) stages of PA measured by accelerometer and in the preparation stage ( $P$  value for tendency=.01) in the MD score. We did not find interaction between the number of days of app use and motivation stage in either PA ( $P=.91$ ) or in adherence to MD ( $P=.19$ ).

**Figure 3.** Adherence to the smartphone app (number of days with a record in the app). High adherence (>60 days)=57%; Low adherence ( $\leq$ 60 days)=43%.





## Analysis by Subgroups

In the multivariate analysis of repeated measures, including at baseline, 3, and 12 months for MVPA, as well as MET minutes per week, and MD, we did not find interaction of the study group in any of the subgroups analyzed, which included gender, age groups, educational level, employment status, and obesity.

## Discussion

### Principal Findings

The Evident II study is one of the largest studies of its kind worldwide, with one of the longest follow-up periods; this made it possible to analyze the long-term effects of smartphone apps in terms of lifestyle improvements. The main findings included an intervention based on counseling plus the use of a smartphone app during 3 months that did not increase accelerometry-evaluated PA after 12 months versus CG. After 12 months, both groups showed a decrease, mainly in IG subjects with low adherence to the app. With regard to PA evaluated with 7-day PAR, IG showed an increase after 3 months but only among participants with strong app adherence. This was followed by a decrease after 12 months, reaching levels similar to those seen in the other 2 subgroups. This finding suggests that the app may have contributed to more PA during the time it was used, with loss of the effect after discontinuation of the app use. In relation to MD, both groups experienced improved compliance that continued to increase after 3 months except among low app adherence participants who showed a slight decrease after 3 months.

The use of an app requires the users to spend some time each day to enter information about their food habits. This may constitute a barrier, particularly for those who are less motivated to change their living habits, favoring discontinuation of app use. In this context, following an initial period, the users may become accustomed to the messages generated by the app, with a subsequent loss of their added value. On the other hand, the low adherence participants are younger and smoke more; this group shows less desire to acquire healthy habits.

This could explain the poorer behavior among participants with low app adherence. Belonging to IG, which received the smartphone with the app, may have resulted in less attention paid to standardized counseling and subsequent adherence to it. Discontinuation of device use may likewise have caused these individuals to disregard the habits recommended by the app. Nevertheless, these data are consistent with the observations from other studies in which no clear evidence of the efficacy of ICTs in improving healthy habits has been observed [5,8].

### Comparison With Prior Work

Of the 23 studies analyzed in the systematic review published by Schoeppe et al [5] on the efficacy of apps in improving lifestyle, smartphones were only seen to have a favorable impact on food habits in 5 studies and resulted in increased PA in 9 studies. The methodologies used vary greatly, and the best techniques for modifying habits through the use of ICTs have not been identified to date. The results also showed that increased app use seemed to be associated with better outcomes in terms of both greater PA and healthier food habits [7,22,23].

These findings are consistent with our own data regarding app adherence. On the other hand, multicomponent interventions have been found to exert a greater effect than interventions involving the isolated use of an app [5]. In the review carried out by Flores-Mateo et al [24], the app group showed a decrease in body mass index and a slight increase in PA, although without differences between the groups. Similarly, an important recent trial with a follow-up period of 24 months recorded no effects in terms of weight loss or increased PA with the use of smartbands [25]. Direito et al [26] observed a decrease in the 2 groups after 8 weeks when comparing 2 apps and evaluating the effects on PA using accelerometry. Similar results were obtained by Wang et al [23] after examining the effects of a wearable sensor and short message service likewise using accelerometry. These findings were consistent with those from our study in which we used accelerometry to analyze PA. The first week was probably overestimated as a result of the Hawthorne effect, which gradually faded at the 3- and 12-month evaluations.

Using questionnaires, Meher et al [27] evaluated PA and observed an increase in PA in IG versus CG after 8 weeks, although this effect was lost by week 20 [27]. Similar results have been obtained by Safran-Naimark et al [28] in a clinical trial involving an app to promote increased PA and diet quality in which the outcomes were evaluated by a questionnaire. The authors observed an increase in PA and diet quality in IG versus CG, particularly in the subgroup with greatest app adherence. These results are consistent with our own findings with regard to the 7-day PAR. In general, this self-reporting method for assessing interventions appears to offer better outcomes, particularly in the short term, than when the outcomes are evaluated by accelerometry [9,27,28].

There is little evidence supporting the effectiveness of apps in improving food habits [29]. Elbert et al [30] evaluated the effect of 2 app-based interventions on the consumption of fruit and vegetables. The authors only observed an increase in fruit consumption in the group that received audio messages. In this regard, Mummah et al [31] were able to increase vegetable consumption as a result of an app designed to increase both the amount and variety of intake. Finally, Gullian et al [7] observed an association between app adherence and increased vegetable and fruit juice consumption. This finding reinforces the results from our study, in which improved behavior was observed with reference to both diet and PA among the participants with the strongest app adherence.

### Limitations

Our study also has several limitations. The main findings of the study were based on self-reported information about adherence to both MD and PA. The nature of the intervention precludes blinding of the participants, and this could have influenced the results. Certain populations may have experienced difficulties using the app and consequently decided to leave the study. Finally, the recorded loss rate of 14.2% (118/833) may have biased the final sample study composition.

## Conclusions

The participants with the strongest app adherence showed better outcomes in terms of maintenance of healthy lifestyles at 12 months than those with weaker adherence, especially among subjects in the preparation and maintenance motivation phases. Nevertheless, in global terms, no differences were found

between IG and CG in terms of increased PA and adherence to MD over long term. Further studies are needed to determine the optimum intervention time for facilitating adherence to the new technologies, in addition to identifying those population groups in which these interventions are more likely to be successful.

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## Authors' Contributions

LGO had full access to all of the data in the study and takes responsibility for the integrity of data and the accuracy of data analysis. LGO and JIRR contributed to conception and design of the study. LGO, MAGM, and ERS contributed to the drafting of the paper. LGO and JAMF contributed to the analysis and interpretation of the data. JIRR, JAMF, ERS, MAGM, and LGO contributed to the critical review of the paper for important intellectual content. MCPA and JAMF provided statistical expertise. JIRR, CAC, IRG, EPG, NGV, MSA, and YSG were responsible for collection and assembly of data. JIRR, CAC, JAMF, MCPA, ERS, MAGM, and LGO approved the final script. ERS and MAGM contributed equally to this work.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Study protocol Evident II.

[[PDF File \(Adobe PDF File\), 364KB - mhealth\\_v6i4e107\\_app1.pdf](#)]

## Multimedia Appendix 2

Main screens of the app.

[[PDF File \(Adobe PDF File\), 231KB - mhealth\\_v6i4e107\\_app2.pdf](#)]

### Multimedia Appendix 3

Changes in physical activity from baseline to 12 months. Groups: 1: Intervention; 2: Control. MET: metabolic equivalent; MVPA: moderate-to-vigorous physical activity. 7-day PAR: 7-day Physical Activity Recall.

[[PDF File \(Adobe PDF File\), 51KB - mhealth\\_v6i4e107\\_app3.pdf](#)]

### Multimedia Appendix 4

Changes of adherence to Mediterranean diet from baseline to 12 months. Groups: 1: Intervention; 2: Control.

[[PDF File \(Adobe PDF File\), 48KB - mhealth\\_v6i4e107\\_app4.pdf](#)]

### Multimedia Appendix 5

Changes in physical activity from baseline to 12 months of counseling + app group by adherence to app. Groups: 1: Adherent; 2: Not adherent. Analysis within group by t test pair and between groups by analysis of covariance (ANCOVA) test adjusted for baseline measures. High adherent group: use of app for >60 days. Low adherent group: use of app for ≤60 days. MET: metabolic equivalent; MVPA: moderate to vigorous physical activity. 7-day PAR: 7-day Physical Activity Recall.

[[PDF File \(Adobe PDF File\), 50KB - mhealth\\_v6i4e107\\_app5.pdf](#)]

### Multimedia Appendix 6

Changes in Mediterranean diet to 12 months counseling + app group by adherence to app. Groups: 1: Adherent; 2: Not adherent. Analysis within groups by t test pair and Friedman test and between groups by analysis of covariance (ANCOVA) test adjusted for baseline measures. High adherent group: use of app for >60 days. Low adherent group: use of app for ≤60 days.

[[PDF File \(Adobe PDF File\), 49KB - mhealth\\_v6i4e107\\_app6.pdf](#)]

### Multimedia Appendix 7

Prochaska and Diclemente's stages of motivation for change.

[[PDF File \(Adobe PDF File\), 184KB - mhealth\\_v6i4e107\\_app7.pdf](#)]

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## Abbreviations

**CG:** control group  
**ICT:** information and communication technology  
**IG:** intervention group  
**MD:** Mediterranean Diet  
**MET:** metabolic equivalent  
**MVPA:** moderate to vigorous physical activity  
**PA:** physical activity  
**PAR:** Physical Activity Recall

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Original Paper

# The Interactive Child Distress Screener: Development and Preliminary Feasibility Testing

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## Abstract

**Background:** Early identification of child emotional and behavioral concerns is essential for the prevention of mental health problems; however, few suitable child-reported screening measures are available. Digital tools offer an exciting opportunity for obtaining clinical information from the child's perspective.

**Objective:** The aim of this study was to describe the initial development and pilot testing of the Interactive Child Distress Screener (ICDS). The ICDS is a Web-based screening instrument for the early identification of emotional and behavioral problems in children aged between 5 and 12 years.

**Methods:** This paper utilized a mixed-methods approach to (1) develop and refine item content using an expert review process (study 1) and (2) develop and refine prototype animations and an app interface using codesign with child users (study 2). Study 1 involved an iterative process that comprised the following four steps: (1) the initial development of target constructs, (2) preliminary content validation (face validity, item importance, and suitability for animation) from an expert panel of researchers and psychologists (N=9), (3) item refinement, and (4) a follow-up validation with the same expert panel. Study 2 also comprised four steps, which are as follows: (1) the development of prototype animations, (2) the development of the app interface and a response format, (3) child interviews to determine feasibility and obtain feedback, and (4) refinement of animations and interface. Cognitive interviews were conducted with 18 children aged between 4 and 12 years who tested 3 prototype animated items. Children were asked to describe the target behavior, how well the animations captured the intended behavior, and provide suggestions for improvement. Their ability to understand the wording of instructions was also assessed, as well as the general acceptability of character and sound design.

**Results:** In study 1, a revised list of 15 constructs was generated from the first and second round of expert feedback. These were rated highly in terms of importance (mean 6.32, SD 0.42) and perceived compatibility of items (mean 6.41, SD 0.45) on a 7-point scale. In study 2, overall feedback regarding the character design and sounds was positive. Children's ability to understand intended behaviors varied according to target items, and feedback highlighted key objectives for improvements such as adding contextual cues or improving character detail. These design changes were incorporated through an iterative process, with examples presented.

**Conclusions:** The ICDS has potential to obtain clinical information from the child's perspective that may otherwise be overlooked. If effective, the ICDS will provide a quick, engaging, and easy-to-use screener that can be utilized in routine care settings. This project highlights the importance of involving an expert review and user codesign in the development of digital assessment tools for children.

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**KEYWORDS**

child; preschool; mental health; symptom assessment; self-assessment (psychology)

## Introduction

### Background

Behavioral and emotional problems are among the most common reported mental health difficulties in children younger than 12 years of age [1-3]. Such problems can interfere with a child's social and academic functioning and increase the risk of developing more severe problems such as depression, anxiety, and behavioral disorders [3-5]. As early intervention can alter the trajectory of disorder development and minimize the social, emotional, and economic burden of mental illness [3,6], universal screening for early identification is important. Dowdy et al [7] advocate a population-based approach to monitoring and addressing mental health difficulties in school-aged children, with universal screening as the first step in a multistage gating system. To this end, recommendations (eg, [8]) suggest that childhood screening instruments should meet 3 goals: (1) ability to identify behaviors that are known risk factors for further behavioral and emotional difficulties; (2) facilitate a timely assessment of children in an inexpensive manner; and (3) identify children at-risk and in need of further assessment, support, or intervention (ie, adequate specificity and sensitivity).

The assessment of general behavioral and emotional difficulties in children routinely relies on reports from parents, caregivers, and education professionals. Although information from these key informants is important, child self-report is a valuable source of clinical information that is often overlooked. Additionally, few self-report screening instruments exist that are suitable for primary school-aged children, particularly universal screeners with a focus on early detection and prevention. For example, in a recent review of instruments for children and adolescents, Deighton et al [9] identified only 11 instruments that included a self-report component, with only 8 of these suitable for children younger than 12 years, and 5 suitable for children aged 10 years and younger. Furthermore, of those measures suitable for younger ages, only 2 could be considered brief screeners, or containing fewer than 30 items—the KIDSCREEN 10 and 27-item versions [10] and the 25-item Youth Rating Scale from the Behavioral and Emotional Rating Scale-2 ([11]). Additionally, the Behavioral and Emotional Rating Scale is not free for research or clinical use and the European KIDSCREEN provides an index of health-related quality of life rather than emotional and behavioral difficulties, and to our knowledge is not suitable for use with children younger than 8 years of age.

Screening directly with children may facilitate quick identification of a range of social and behavioral indicators [9], while also having the potential to capture internalizing (emotional) difficulties that parents or caregivers have not been able to observe [12]. However, there are numerous administrative challenges that may preclude children from responding or impact the reliability of the information collected [13,14]. Children may find the traditional text-based rating scales difficult because of their limited attention spans or difficulties with reading, language, and item comprehension

[13,14], with these issues more pronounced in younger children (eg, 5-8 years). In addition, given there are significant developmental variations between the ages of 5 and 12 years, crafting items using appropriate language that is broadly suitable across various ages is a challenge for scale developers.

Despite this, researchers have demonstrated that when age-appropriate methods are used, valid and reliable self-report information can be obtained from children even as young as 5 or 6 years (eg, [13]). Much of this work has focused on adjusting the delivery modality (eg, clinical interviews), using novel stimuli (eg, interacting with puppets), or enhancing the traditional response scales with pictorial elements [15-18]. More recently, engaging and innovative approaches using digital technologies have been trialed. Examples include the Dominic Interactive [19], a computer-based diagnostic assessment that utilizes child-friendly (static) images, and maps onto 7 Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition disorders with demonstrated reliability and construct validity [20]; the Mood Assessment via Animated Characters [21], which uses digitally animated characters to assess internalized mood states (feelings) in young children aged between 4 and 11 years, and which has been shown to discriminate between anxious and nonanxious children [14]; and TickiT, a psychosocial screening app for adolescent youths that has been employed in hospital settings [22,23]. Similarly, a computer-administered, pictorial version of the Strengths and Difficulties Questionnaire (SDQ) has also been investigated with children aged between 8 and 15 years, with some evidence of clinical sensitivity (in children 11 years and older), higher user satisfaction ratings, and improved engagement compared with the standard pencil-and-paper version [24]. These efforts support the feasibility of digital assessment tools for children; however to our knowledge there are currently no digitally delivered, universal self-report screeners for emotional and behavioral difficulties that are suitable for primary-school children aged 5 to 12 years. There is also very little information available about how the aforementioned instruments were developed and which components were demonstrated to be effective.

### Objectives

This research describes the development process of the Interactive Child Distress Screener (ICDS), a new Web-based screening instrument for early identification of emotional and behavioral problems. The ICDS is designed to be easily administered within community settings, such as general practitioner clinics or education contexts, using modern touchscreen devices that are ubiquitous and familiar to most school-age children (eg, tablets and mobile phones), and with potential to facilitate rapid feedback to those administering the instrument (eg, educators or primary care professionals) through automated scoring. The ICDS differs from the aforementioned digital instruments in that it aims to provide brief, universal screening for general behavioral difficulties and emotional distress (nondiagnostic) and utilizes short, animated cartoons in place of text-based items to convey common childhood

difficulties in a way that is familiar, engaging, and relatable for even young children (eg, 5-6 years) while also remaining appealing to children in later primary-school (eg, 10-12 years).

To maximize the potential effectiveness of the ICDS, a thorough initial development and feasibility-testing process was implemented and reported here. The development process utilized a mixed-methods approach incorporating expert review to formulate and develop item content, along with user involvement from children to develop and evaluate the response format and working prototypes of both animations and user interface. Item content development and refinement is described in study 1, followed by animation and interface development and refinement which is described together in study 2. Lessons learned from this approach are presented in the Discussion.

## Methods

### Study 1: Item Content Development and Refinement

Content for the ICDS animations was drawn from 3 existing validated instruments used to assess general distress in children. We initially selected 2 parent-report measures—the SDQ [25] and the Child Behavior Checklist (CBCL) [26]—because they are frequently cited and widely used instruments for assessing general behavioral and emotional difficulties in children [27,28]. However, the CBCL is a longer instrument used primarily as a broad comprehensive assessment tool. Thus, we utilized its brief counterpart, the Brief Problem Monitor (BPM) [29], which includes original items from the CBCL. Further review of the literature revealed a brief, 16-item child self-report instrument, the Me and My School Questionnaire (M&MS) [30]. This scale has been validated with children as young as 8 years (ie, year 4 students) as well as in clinical and nonclinical samples [31] and has demonstrated a clear 2-factor structure (behavioral and emotional problems) and adequate internal consistency with both year 4 and year 7 students.

The initial task of developing a suite of animations representing children's behavioral and emotional difficulties required that we first identify key item groupings that best represent the primary constructs or domains covered by the validated instruments. Our aim was to identify a thematically common set of domains that had proved useful in previous screening instruments. Before proceeding to the animation development phase, there were 3 issues to consider regarding the content validity of the item groups and which formed the focus of study 1. The first consideration was whether our proposed item groupings (constructs) included items that were similar enough to each other to plausibly tap a global distress construct and to check whether item subgroupings were plausible. The second consideration was whether our proposed item groupings had potential to be depicted clearly through the use of brief animations, such that the target difficulty would be understood by primary school-age children. Relatedly, it was important to evaluate whether this was likely to be feasible using a single animation or whether multiple animations would be required. The third consideration was to identify the relative importance of each construct for inclusion in a broad screener of general behavioral and emotional difficulties in children.

To address these considerations, we sought a review of our proposed construct groupings from a small panel of experts, broadly adopting a strategy outlined by Kassam-Adams et al [32] regarding assessment of content validity through expert panel review. Though these guidelines were provided for evaluation of eHealth interventions, their approach to systematically assessing the relevance, effectiveness, and appropriateness of activity-target pairings (ie, item-construct pairings in our study) through mixed quantitative and qualitative expert responses was translatable to this study.

Item content development followed an iterative process and consisted of four steps, which are as follows: (1) initial construct development, (2) preliminary expert content validation, (3) item refinement, and (4) final expert validation.

#### *Step 1: Initial Construct Development*

We first collated all 60 items from the SDQ, BPM, and M&MS into an item pool. As there was a significant amount of overlap among items, these were grouped together by the first and second authors (both psychologists with prior experience in assessment with children) according to common themes. Some items had clear conceptual overlap (eg, "I am unhappy" from the M&MS and "Often unhappy, depressed or tearful" from the SDQ). Some items described related but potentially discrete problems (eg, the M&MS contains 2 sleep-related items: "I have problems sleeping" and "I wake up in the night") that we thought would be difficult to distinguish from each other through brief animations and thus were grouped together (eg, using a broader category of "sleep difficulties"). Differences in item phrasing arising from self-report (first person) versus parent-report measures (third person) were not considered relevant to this process as it was peripheral to our goal of identifying common themes indicative of behavioral and emotional difficulties in children. The outcomes of step 1 are presented in the Results section and [Multimedia Appendix 1](#).

#### *Step 2: Initial Expert Review of Constructs*

In step 2, we sourced 9 panel respondents (78%, 7/9 female) among the professional networks of the researchers. Respondents were invited based on identified clinical experience working with children (89%, 8/9), methodological expertise in the area of clinical research (67%, 6/9), or psychological assessment and measure validation (67%, 6/9), with some participants reporting expertise across multiple areas. Overall, the median level of experience across participants was 17 years in their respective fields (range, 7-35 years).

Respondents were presented with the list of 14 proposed domains along with the individual items that were grouped to form this construct (ranging from 2-8 items, as shown in [Multimedia Appendix 1](#)). For each grouping, respondents answered 3 questions using a 7-point Likert scale: (1) importance: "How important is the construct for inclusion in a brief screener of general emotional and behavioral difficulties in children?" (1=Not at all important to 7=Extremely important); (2) conceptual consistency: "How well do the individual items hang together as a common theme or construct?" (1=Very poorly to 7=Very well); and (3) identifiability: "How likely is it that a child could identify this behavior or difficulty if depicted in an



animation?" (1=Very unlikely to 7=Very likely). An open-ended text box was included after each conceptual group to allow respondents to provide a rationale for their ratings or any further reflections on the items or our proposed item groupings (eg, whether a group of items should be separated into 2 constructs).

### **Step 3: Refinement of Item Content**

In step 3, expert ratings and feedback were reviewed by the research team with special attention given to those domains that had the poorest ratings in any of the 3 categories ( $\geq 1$  SD below the overall mean). Qualitative feedback was also reviewed carefully for further insight. Constructs that had low conceptual consistency or were discussed qualitatively as not "fitting" together well were candidates for division into multiple constructs or for the removal of some items from one construct to be merged into another. Item groupings with lower ratings of importance, or viewed as likely to be especially difficult to depict using animations, were considered for removal. Decisions were data-informed and based on clinical relevance using an iterative process where changes were continually reviewed by the research team. This step produced a refined list of item groupings.

### **Step 4: Follow-Up Expert Review of Constructs**

In step 4, a follow-up expert review process was utilized to collect feedback on the refined list of item-construct groupings. Of 9 participants included in this study, 8 provided feedback at step 2 (75% female; 6/8); median years of experience in field was 17; clinical experience working with children: 88% (7/8); methodological expertise in the area of clinical psychology research: 75% (6/8); and psychological assessment and measure validation: 63% (5/8).

The procedure was similar to the first expert panel survey. Using the same scale, respondents provided ratings for the perceived importance of the refined constructs (see [Multimedia Appendix 1](#)), as well as face validity of the internal consistency (ie, how well items "hang" together). A separate section was included containing the list of constructs that had been removed following the first round of feedback (Nervous, Low self-worth or self-esteem, Internalizing, Illicit or covert behaviors, Immature, Impulsive behavior, and Caring or helpful), with respondents asked to rate their importance for inclusion. Respondents were not asked to rate the potential identifiability of constructs through animation as this was evaluated more directly through interviews with children using prototype animations (study 2).

## **Study 2: Animation and Interface Development and Refinement**

In addition to the initial expert review to confirm importance, conceptual consistency, and identifiability of items in study 1, we also conducted research with children to test and refine sample animations and the app interface. The aim was to determine whether the intended meaning of pilot animations could be accurately identified; whether the response instructions were understood; and whether the characters, sounds, and animation style were acceptable and engaging. Similar "codesign" approaches have been used successfully in the

development of innovative eHealth and mHealth technologies, where prospective users are involved collaboratively during design and development stages to provide valuable feedback and direction for ongoing development (eg, [22,23]).

This study consisted of four steps, which are as follows: (1) development of prototype animations, (2) development of the interface and response format, (3) child interviews to determine feasibility and obtain feedback, and (4) refinement of animations and interface.

### **Step 1: Development of Prototype Animations**

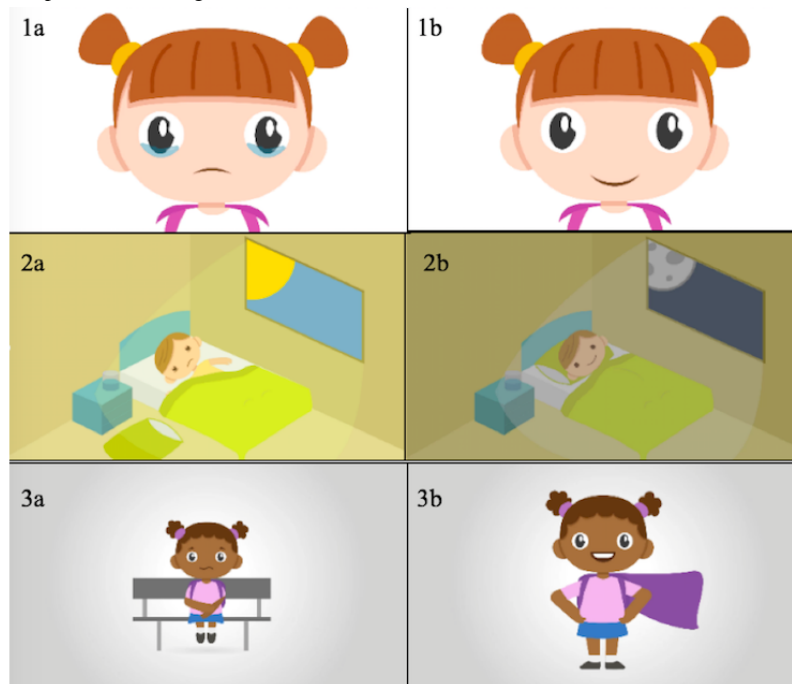
From the 15 revised constructs produced in study 1, the 3 following items were selected for development of prototype animations: (1) Sad or depressed, (2) Worried, and (3) Sleep problems. The constructs Sad or depressed and Worried were selected based on expert ratings of high importance, whereas sleep problems was considered particularly amenable to animation and provided us with a broader coverage of content areas for piloting with the respondent group.

For each construct, 2 prototype animations were developed; 1 "negative" animation showing a child experiencing the difficulty described by that construct and its candidate items (see [Figure 1](#)), and one "positive" animation indicating the absence of that difficulty or showing a child demonstrating a contrasting (ie, positive) behavior. This resulted in 6 pilot animations labeled: 1S (Sad) and 2H (Happy), 3SP (Sleep Poorly) and 4SW (Sleep Well), and 5W (Worried) and 6C (Not Worried). The rationale for the response format choice is explained below at step 2.

Animations were developed in consultation with an animator and a graphic designer. To encourage engagement, animations were designed to be brief (eg, 6-10 s), with each demonstrating a short, focused scenario showing either the positive or negative depiction of the intended construct. A mix of genders and ethnicities was used for the characters, but the same character was used in each animation pair for consistency and to minimize distraction. Stylistically, characters featured in the animations resembled cartoon children, which are easily relatable. Characters were given simple features with large eyes for expressiveness, and warm, bright colors for clothes and backgrounds. Contextual features were kept to a minimum so that children would not be distracted by nonessential information and so the target item was not specific to a context, with background objects only included if they enhanced the intended message (eg, an alarm clock and bed for the Sleep problems videos).

As a first step, the research team generated ideas for animating the item content based on common characteristics identified from the pooled items for each construct. A suggested storyboard was created for each animation detailing (1) the character's actions, (2) the scenery and objects to include or for the character to interact with, (3) sound effects that might enhance the message (eg, sound of a child crying), and (4) colors and other special effects that might further convey the construct's meaning.

**Figure 1.** Screenshots from early versions of the pilot animations. Images 1a and 1b show paired animations for the construct Sad or Depressed. Images 2a and 2b reflect the construct Sleep Problems. Images 3a and 3b reflect the construct Worried.



Storyboards were then shared with the animator, who prepared a first pass of animations that was reviewed by the research team. This iterative process continued for each animation until both parties were satisfied with the pilot version. Outcomes from step 1 are provided in the Results section.

### **Step 2: Development of the Interface and Response Format**

Development of the app and its interface required consideration of multiple factors, including (1) the response format, (2) the technology stack (eg, Web-based vs native app), (3) layout and colors, and (4) audio versus text-based instructions.

#### **Response Format**

We chose to develop a 2-stage response format in light of research suggesting younger children typically tend to respond at the extreme ends of rating scales and may perform better with dichotomous, forced-choice responses (eg, [33]). The app was developed such that after viewing both animations, children are asked to select one animation in response to the question “Which one is more like you?” To provide additional information, we also included a second follow-up question: “How much is this like you?” where children were asked to select either “A lot like me” or “A little like me.” The aim of this approach was to present children with simple dichotomous response options while maximizing the range of potential variability in response scores (ie, 1-4 for each item rather than binary responses). To our knowledge, the validity of such a response format has not yet been tested within digital screening instruments. As such, we decided to pilot this approach given that it would be trivial to later eliminate the second response stage, if it proved too complex or unreliable during administration.

#### **Technology Stack**

Although native apps written using a platform-specific code (eg, Swift for iOS, Java for Android) are typically considered

to have some advantages over Web-based apps in terms of speed and access to in-built device functions, for the pilot version of the ICDS we decided to harness the capabilities of modern Web-based technologies (eg, HTML5, JavaScript, and a responsive design) to ensure widespread accessibility. A PHP: hypertext preprocessor backend based on the open-source WordPress framework was utilized for administrative access, with data collected in a structured query language (SQL) database stored on a secure server within the host university’s research infrastructure. Using this combination of technologies, the app was enabled to be viewed through the Web-browser on any modern smart-device (eg, phone, tablet, personal computer), making it highly compatible and transferrable across testing scenarios.

#### **Interface (Layout, Colors, and Instructions)**

An iterative and collaborative development process involving the research team, the Web developer, and the graphic designer was utilized to develop an early working prototype of the app interface. The flow of the initial version of the app was developed as follows. Children are asked to select an avatar (or “buddy”) to accompany them through the app and then provide basic demographic information (age and gender). The following screens contain an animation pair (ie, one “item”), with both animations (positive and negative) presented side-by-side in a randomized order. Children play the highlighted video first, followed by the second video that is only available to view after the first animation finishes. Upon the completion of the second animation, verbal instructions commence asking children to answer the question “Which one is most like you?” For the first 2 items, written instructions are also displayed while being spoken by the child’s selected avatar that appears at the bottom of the screen. For subsequent items, instructions are not spoken or written unless the child taps the buddy helper for assistance.

After providing a response, the app automatically advances to the next item.

The interface was developed using a simple, clean design and a bold, bright color palette. The suite of avatars (buddies) introduced at the beginning of the screening instrument was designed to promote engagement and facilitate understanding and use of the app. Examples of the resulting interface are provided in the Results section.

### **Step 3: Qualitative Child Interviews**

Step 3 adopted a cognitive interviewing approach [34] to obtain feedback from children regarding the interpretability and acceptability of the animations, instructions, and response format. A convenience sample of children was recruited through personal networks. Eighteen children (10 females) aged between 4 and 12 years participated in the interviews. Of the 18 participants, 2 were “British Caucasian,” 3 were “South-East Asian (Philippines),” 2 were “New Zealand Caucasian,” and 11 were “Australian Caucasian.” Most ages were represented by at least 1 male and female (see Table 2 in Results). Qualitative data reached saturation at N=18 and therefore, we determined that sufficient information for refining and improving prototype animations had been gathered.

Both the child and a parent were required to provide consent to participate in the interviews that lasted between 15 and 30 min, with children permitted as much time as they required to answer all questions. Questions were asked verbally, with answers recorded verbatim by the interviewer along with other relevant descriptive information about the child’s demeanor or nonverbal responses (eg, “child shrugged” to indicate lack of understanding of the item). The interviews included questions that checked children’s understanding of animated items, understanding of instructions and response format, and acceptability of the prototype app.

### **Understanding of Animated Items**

Children were first shown each animation and asked “What do you think is happening for the boy or girl in this video?” Responses were noted and the interviewer made a judgment on the “correctness” of the response (ie, whether the child’s response matched the intended behavior that was being animated). If the child’s response was considered incorrect, the intended meaning of the animation was provided by the interviewer. Children were then asked to rate the pilot animation on how well they thought it captured the intended behavior, using a colored, cartoon visual analog scale from 1 to 5 (1=“NO! I HATE it. Change it completely”; 3=“OK. I kind of like it”; 5=“YES! I love it. It’s exactly right”). Children were then prompted to provide a “better” way of showing the intended target problem and whether they could think of a time when they (or someone they knew) felt the same as the character. The latter question was intended to determine how well children were able to relate the behaviors shown in the animations to their own experiences.

### **Understanding of Instructions and Response Format**

To evaluate the instructions and response format, children were asked if they could explain what was meant by the instruction “which video is most like you?” We then asked children to

describe what it means if the character is “a lot like you” or “a little like you.”

### **Acceptability**

Finally, we obtained general acceptability ratings of the characters, animation style, and sounds using a mix of open-ended verbal feedback (ie, “what did you like”, “what didn’t you like”) and quantitative ratings using the pictorial Likert scale described earlier (ie, “show me on the chart how much you liked it”). At the end of the interview, participants were also asked an open-ended question as to whether they had any other ideas that would make the animations easier to understand. Feedback from the child interviews regarding the characters, sounds, and behaviors depicted in the animations was collated and reviewed by the research team.

### **Step 4: Refinement of Animations**

In step 4, we focused particularly on feedback for the animations that were misinterpreted or not well-understood, along with suggestions from children that might help to improve the interpretability or likeability of animations in general. Suggestions for enhancing facial features and emotional expressiveness, along with increasing the contrast between paired animations, were deemed particularly important. In response to the feedback obtained, we developed new storyboard outlines to target the identified deficits in understanding and worked with the animator to implement these changes. Changes primarily included increasing the expressiveness of characters such as adding emphasis to the character’s eyes to make them twinkle or fill with tears, more exaggerated mouth movements, and adding eyebrows to enhance expression. Other details were also added to improve the interpretability of the intended behavior such as beads of sweat, tousled hair, and blinking eyes, whereas additional sounds and movement were incorporated such as giggling, crying, or shoulder movements to accentuate body language for laughing or sobbing.

Further context was also added by including new objects or symbols such as “thought bubbles,” a dream bubble of a jumping sheep, shadow creatures to represent a nightmare, an alarm clock with a grumpy face, and lightning bolts, as well as butterflies in the stomach area to represent worried, and a red heart shape beating quickly with sound effects. These revisions resulted in 3 new pairs of animations.

## **Results**

### **Study 1: Item Content Development and Refinement**

#### **Step 1: Initial Construct Development**

In Step 1, we conducted a preliminary review and grouping of the 60 items from the SDQ, BPM, and M&MS instruments. This resulted in the identification of 14 domains, which are outlined in [Multimedia Appendix 1](#).

#### **Step 2: Initial Expert Review of Constructs**

Mean ratings of perceived importance, internal conceptual consistency, and interpretability provided by panel experts were computed for each of the initial domains are shown in [Table 1](#), sorted in order of importance for inclusion in a screening tool

as rated by the panel. The panel considered areas pertaining to feeling sad or depressed, nervous or shy in social settings, and worried or anxious as being most important for a screener of general difficulties in children, followed by noncompliance and aggressive behavior problems. The panel also suggested that impulsive and inattentive behavior might be the most difficult areas for children to identify through animations.

Panel members provided a number of comments relating to the constructs, with the most common feedback being that some item groupings should be split into distinct constructs. For example, items originally grouped as “worried or anxious” were considered to tap into separate domains of “worried” and “fearful.” Similarly, the “irritable, argumentative, easily loses temper” domain was seen to contain both outward, externalizing behaviors (eg, “I get very angry,” “Argues a lot”) as well as internalized behaviors (eg, “I am calm,” “Stubborn, sullen, and irritable”), which were recommended to be considered distinct.

### **Step 3: Refinement of Item Content**

Analysis of expert ratings and qualitative feedback produced a refined list of item groupings in step 3 (see [Multimedia Appendix 1](#) and [Table 1](#)). The constructs initially labeled as Impulsive behavior, Helpful and considerate of others, and Illicit or covert behavior were removed due to low importance ratings (>1 SD below mean), along with agreement within the research team that these appeared to have less relevance for a broad, universal screener. The constructs labeled as Nervous or shy, Worried or anxious, Sad or depressed, Irritable or argumentative, and Social problems were separated into multiple groupings. For example, items originally grouped as Social problems were seen as mapping onto 2 converging but distinct ideas: Difficulty making friends and Bullied or teased by other children. Some items that no longer appeared to fit within any existing constructs were removed such as “feels worthless or inferior” which was previously grouped under the Sad or depressed construct.

### **Step 4: Follow-Up Expert Review of Constructs**

Results from the follow-up expert panel survey are presented in [Table 1](#). Other than Shy (mean=5.75) and Physical symptoms (mean=5.38), all constructs had a mean importance rating of at least 6 out of 7 (overall mean=6.32, SD 0.42). One respondent commented that targeting some physical symptoms such as “sickness” may not be a good indicator of emotional difficulties in children who have chronic illness. It was decided to retain this item for testing in the full ICDS. The constructs that had been removed (not shown in the table) received the lowest mean importance ratings overall (range, 1.50-4.25; mean=2.75, SD 0.92). In terms of perceived face validity of items informing each construct, these had high overall ratings (range, 5.50-6.88, mean=6.41, SD 0.45).

## **Study 2: Animation and Interface Development and Refinement**

### **Step 1: Development of Prototype Animations**

Still screenshots representing the early prototypes of the 6 pilot animations developed in step 1 are shown in [Figure 1](#). As an

example, for the construct Sleep problems, the first iteration of the animation showed a child tossing and turning in bed at night, unable to fall asleep, throwing his pillow on the ground, and waking up tired and grumpy the next morning with lines under the eyes and a frowning face. Its paired animation demonstrated a child yawning, falling asleep peacefully at night, and then waking up happy and refreshed in the morning when the sun rises.

### **Step 2: Interface Development**

[Figure 2](#) provides example screenshots from the prototype version of the app developed in step 2. A number of revisions were made to early versions of the interface based on internal review and testing, with a particular focus on issues that might limit the use and effectiveness of the app. For example, it was noted that animated videos would be clearer if presented as full screen pop-out videos rather than side-by-side animations. Thus, the app was amended so that each animation would use the full-screen window when viewed. Timing of responses was altered so that the child could not choose the response option until both videos had been played. It also became apparent that it would be beneficial to automatically play audio instructions for the first 2 items (rather than just the first item) to help ensure children remember what they were required to do beyond the first screen. Following the second item, the interface was further adapted such that instructions could be replayed on request by tapping on the buddy helper.

### **Step 3: Qualitative Child Interviews**

#### **Understanding Animated Items**

[Table 2](#) summarizes the number of children considered to have correctly interpreted each of the 3 items across each age. All children were able to correctly identify happy and sad or provided a similar response (eg, “upset”). Approximately half of the children correctly identified sleeping poorly and sleeping well, with no clear age-related pattern. Correct responses to these items included comments such as “he had a good sleep,” “the boy didn’t get enough sleep,” and “slept badly,” whereas incorrect responses included comments such as “tired and sleepy” or “sad in his bed.” For the worried and not worried pair of videos, none of the younger children (<8 years) were able to respond correctly, whereas the children who were 8 years and older had more success (54%, 6 out of 11 correct for worried; 45%, 5 out of 11 correct for not worried). Younger children provided comments such as “hungry,” “just a bit sad,” and “happy”; whereas older children responded with comments such as “anxious, worried, waiting,” “alone and anxious, waiting at a bus stop,” and “confident.”

When asked to rate each video on a scale of 1 to 5 for how well it captured the intended target, children tended to rate positive videos highest, suggesting their use of the rating scale in this context may have been more reflective of how “good” or “bad” the behavior was seen to be, rather than how well our animations did at capturing that behavior. These ratings are shown in [Table 2](#).

**Table 1.** Ratings for constructs based on initial expert panel review, ordered from most (7) to least (1) perceived importance for a screening instrument.

Domain label	Importance, mean (SD)	Hangs together <sup>a</sup> , mean (SD)	Identifiable, mean (SD)
<b>Survey 1: Preliminary domain label</b>			
Sad or Depressed	6.88 (0.35)	6.22 (1.09)	6.13 (0.35)
Worried or Anxious	6.63 (0.74)	6.00 (1.12)	5.00 (1.20)
Nervous or shy in social settings	6.63 (0.52)	6.11 (1.17)	4.88 (1.55)
Noncompliant behavior	6.63 (0.74)	6.56 (0.73)	4.75 (1.49)
Aggressive behavior	6.38 (1.06)	6.11 (1.05)	5.38 (1.30)
Irritable or argumentative or easily loses temper	6.38 (1.19)	5.56 (1.24)	6.25 (0.71)
Sleep problems	6.25 (1.16)	6.22 (1.3)	5.75 (1.39)
Hyperactive behavior	5.88 (1.13)	6.44 (1.01)	5.25 (1.04)
Inattentive behavior	5.88 (1.13)	5.78 (1.92)	3.75 (1.39)
Destructive behavior	5.63 (1.30)	6.11 (0.78)	5.25 (1.67)
Social problems <sup>b</sup>	5.60 (1.34)	4.80 (0.84)	6.60 (0.55)
Impulsive behavior	5.13 (1.73)	4.89 (1.69)	3.75 (1.39)
Helpful or considerate of others	5.13 (2.17)	6.44 (1.01)	5.38 (0.92)
Illicit or covert behavior	5.00 (1.20)	4.78 (1.99)	4.75 (1.04)
<b>Survey 2: Refined domain label</b>			
Angry	6.88 (0.35)	6.63 (0.74)	
Sad or depressed	6.88 (0.35)	6.13 (1.13)	
Worried	6.75 (0.46)	6.63 (0.74)	
Fearful	6.63 (0.52)	6.50 (0.93)	
Noncompliance (home)	6.50 (0.76)	6.75 (0.71)	
Difficulty making friends	6.50 (0.76)	6.13 (1.36)	
Physically aggressive	6.50 (0.53)	5.50 (1.41)	
Noncompliance (school)	6.38 (1.06)	6.88 (0.35)	
Argumentative	6.38 (1.06)	6.88 (0.35)	
Bullied or teased by other children	6.25 (1.04)	6.13 (1.36)	
Hyperactive behavior	6.00 (1.20)	6.75 (0.71)	
Inattentive behavior	6.00 (1.20)	6.50 (0.93)	
Sleep problems	6.00 (0.76)	5.50 (1.20)	
Shy	5.75 (1.28)	6.75 (0.46)	
Physical symptoms	5.38 (1.41)	6.50 (1.07)	

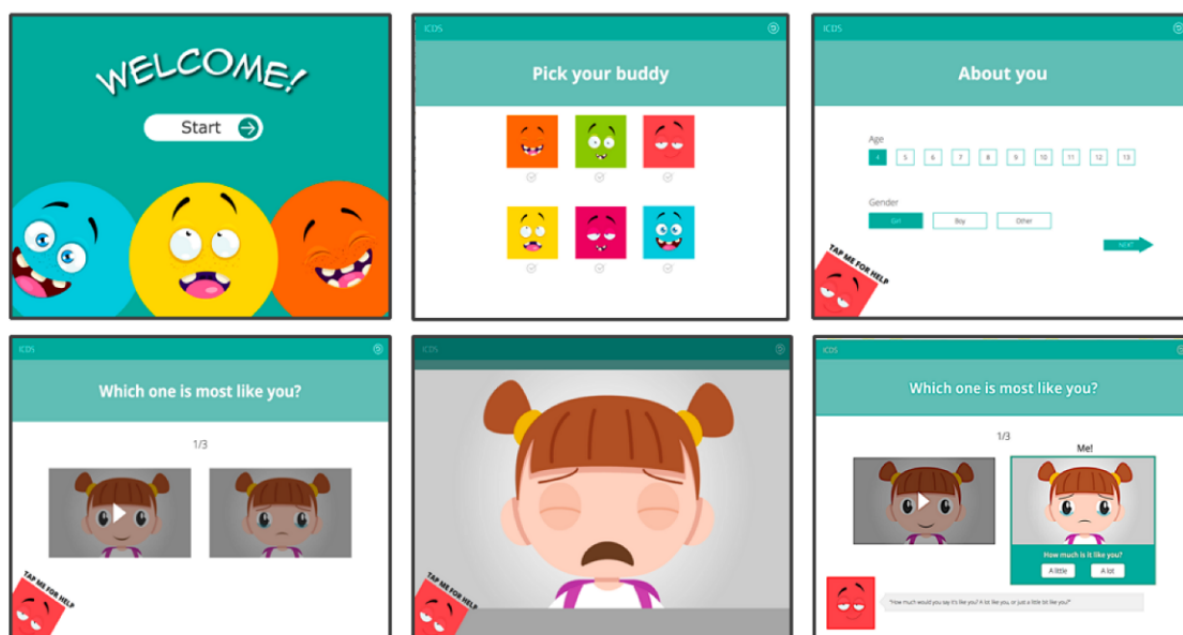
<sup>a</sup>How well individual items hang together as a common theme or construct.

<sup>b</sup>Four responses missing from Survey 1 for Social Problems due to technical error.

Regarding suggested changes to animations to better capture the intended behavior, most responses appeared to fall into one of 3 categories. First, some suggested changes for making the animations more exaggerated to more clearly capture the emotion (eg, “jumping up and down and looking excited”; “show him crying more”); others focused on adding more context to the videos, usually relating to a specific scenario or setting (eg “having fun on a playground”; “she can’t find her

Mum and Dad”; “getting a high score in a math’s test”); whereas others suggested the addition of iconic cartoon elements with which they may be familiar from other media such as thought or dream bubbles, looking like a “zombie,” or dropping ice cream on the floor and crying. Abbreviated responses to questions regarding interpretation and ways to improve animations for each child are presented in [Multimedia Appendix 2](#).

**Figure 2.** Screenshots from early prototype of the Interactive Child Distress Screener (ICDS) interface. From left to right: Top row: welcome screen, avatar (“buddy”) selection, and demographics. Bottom row: animation pairs, video pop-out, “How much is it like you?” selection with audiovisual instruction text spoken by the “buddy” helper.



**Table 2.** Descriptive statistics from child interviews showing age, gender, and response characteristics for participating children.

Variable	Child age (years)									Total (n)	Mean (SD) <sup>a</sup>	Choice (n) <sup>b</sup>
	4	5	6	7	8	9	10	11	12			
<b>Gender (n)</b>												
Male	1	1	1	0	1	1	0	2	1	8		
Female	1	1	1	1	0	3	0	2	1	10		
<b>Accuracy (n correct)<sup>c</sup></b>												
1a. Sad	2	2	2	1	1	4	— <sup>d</sup>	4	2	18	4.24 (0.75)	0
1b. Happy	2	2	2	1	1	4	—	4	2	18	4.53 (0.80)	18
2a. Sleep Poorly	1	1	0	1	1	1	—	1	2	8	3.65 (1.27)	4
2b. Sleep Well	1	1	0	1	1	2	—	1	1	8	4.29 (0.85)	13
3a. Worried	0	0	0	0	0	2	—	3	1	6	3.71 (1.05)	4
3b. Not Worried	0	0	0	0	1	1	—	2	1	5	4.12 (0.86)	14

<sup>a</sup>Average rating of how well the animation captured the intended behavior (scale 1-5).

<sup>b</sup>Total number of children endorsing the animation as “more like them” from the respective pair.

<sup>c</sup>Number of children who correctly identified each animation.

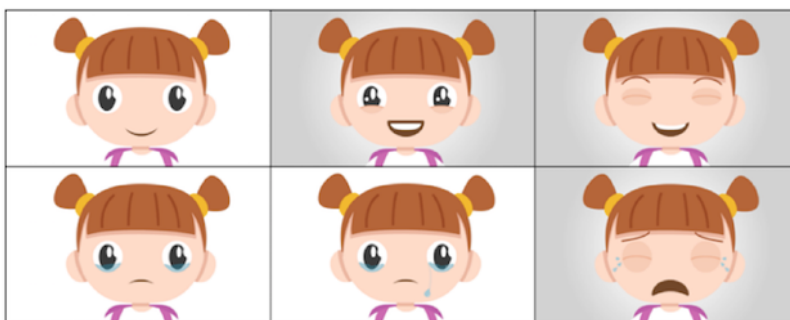
<sup>d</sup>Accuracy responses unavailable for 10-year olds as no children of this age were recruited in this sample.

In terms of children’s ability to identify personal moments and/or construct examples that portrayed the target behaviors depicted by animations, some interesting findings were noted. For example, for the Worried and Not Worried pair of videos where fewer children initially identified the target behavior correctly, more children were able to provide examples that reflected scenarios where it might be appropriate to feel worried or not worried (confident). This suggests that though some children initially had difficulty either identifying or verbally expressing the targeted difficulty from the video (perhaps due to vocabulary limitations), their internal representation of these targeted difficulties may be more developed.

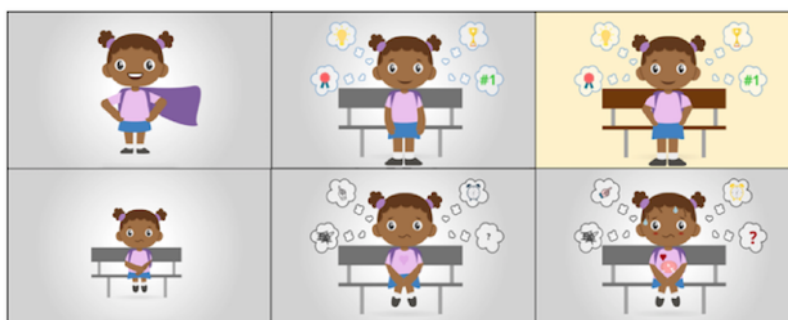
**Understanding Instructions**

Most children appeared to understand the question “which video is most like you” without further explanation. For example, children responded with comments such as “if you’re happy more days or not”; “what video I normally feel like”; and “what I’m feeling like most of the time.” Some younger children found it difficult to articulate a response to this question verbally, yet gave other nonverbal indications that they understood the question or were able to provide a response by pointing to one of the videos.

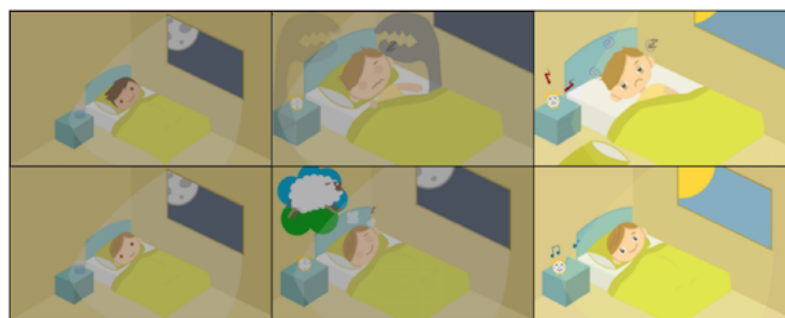
Figure 3. Screenshots showing refined pilot animations based on feedback from child interviews.



Panel A: Revised Happy/Sad animation pair



Panel B: Revised Worried/Not Worried animation pair



Panel C: Revised Sleeps Poorly/Sleeps Well animation pair

Of all children, 2 children (a 6 year old and an 11 year old) required some rephrasing of the question (eg, “which of these feelings do you feel most of the time?”) but then had no further difficulty. Only 1 child (a 4 year old) declined to choose a video from each pair that they thought was most like them. As outlined in Table 2, all children selected the positive video from the Happy or Sad pair, whereas 4 children selected the negative video from both the Sleeping and Worried or Confident video pairs. We note that this was a small sample of nonclinical children, so these figures are not considered representative of typical response patterns; nonetheless, they provide some indication that children may be willing to select the nonsocially desirable video when prompted to choose one or the other.

As expected, older children were more successful at articulating the difference between “a lot like you” and “a little like you.” Children provided responses such as “how often are you like that,” “how much are you like that feeling,” “is that how I am normally,” “do you have a little bit of that feeling in you or a lot,” and “are you always like this or only sometimes.” Of all responses, 2 responses (“when I feel the same emotions, I will

show the same expression as the cartoon”; “how you look when you’re expressing that emotion—sometimes you be sad but you act happy”) were less accurate, 3 children did not respond to this question, and the youngest children (ie, less than 6) were more likely to repeat the language from the question, for example, “it means is she a little bit like me or not.” Overall, it appeared that despite variation in their ability to articulate a response verbally, most children (13/18; 72%) responded in a way that indicated a general understanding of the question. Nonetheless, it was clear that further practical testing would be beneficial in the context of the full app and with a larger sample.

**Acceptability**

Responses were overall positive regarding the general acceptability of the characters, animation style, and sounds. On the 5-point scale, the mean rating for likability of characters was 4.33 (SD 0.50) and for likeability of sounds was 4.13 (SD 0.64) out of 5. Children reported that they liked that the characters were colorful, pretty or “cute,” and enjoyed the variety of characters. The majority of children indicated that

the sounds added to the videos made them easier to understand. Some children suggested adding more detail to the backgrounds to increase interest, which aligns with other suggestions that videos should include more context (eg, giving a speech in front of a class).

#### **Step 4: Refinement of Animations**

As a result of step 4, 3 new sets of animations were produced. Screenshots of the refined pilot animations are shown in [Figure 3](#).

## **Discussion**

### **Study Objectives**

When identified early and appropriate interventions received, the adverse consequences of emotional and behavioral difficulties in childhood can be prevented. Universal screening has the potential to identify at-risk individuals likely to benefit from further assessment or intervention. To date, such screening instruments rely largely on parent, caregiver, or teacher report, despite evidence that children may be capable of providing valuable and accurate clinical information via self-report (eg, [13]). This paper sought to describe the development and piloting process for an animation-based screening instrument for early identification of childhood emotional and behavioral problems. Specifically, it described the initial development and feasibility testing stages of the ICDS, utilizing the mixed-methods approach. It is hoped that this study will provide insights to inform the development of future digital instruments for young people.

### **Principal Findings**

As a result of this study, we have identified 15 constructs or item groupings that will form the ICDS and that (1) are considered by experts as important for a broad emotional and behavioral distress screener, (2) are amenable to animation, (3) are distinct enough to warrant representation as a separate construct, and (4) incorporate items similar enough to plausibly tap into a global distress construct. This project further demonstrated that a child-focused, digital delivery interface and prototype animation items representing these constructs were acceptable to children and that children were able to accurately identify emotions and behaviors under the right conditions. Thus, the preliminary feasibility of the ICDS was demonstrated.

The findings of this project also demonstrate the utility of using mixed-methods approaches in the development of digital assessment tools. The results of study 1 demonstrated the benefit of involving an expert panel to identify and refine the constructs necessary for inclusion in a brief screening instrument, as well as in the identification of target constructs that could be best translated into an animated and child-report format. Given that such an instrument has not yet been developed, the inclusion of the expert panel allowed us to confirm the validity of the item selection and item groupings and prompted refinement of ICDS constructs. Specifically, this process allowed us to identify items that could be grouped together in one animation pair (eg, sad or unhappy) and others that were required to be captured independently (eg, fearful and worried). It also allowed us to confirm constructs and items that were of less importance in a

broad screening instrument for childhood behavioral and emotional distress (eg, impulsive behavior, illicit and covert behavior). Expert review and iterative refinement in this way can be an important component in the development of new instruments, especially using new, innovative digital methods.

The second study sought to describe the development process at a step-by-step level to highlight the benefits of an iterative design and pilot testing in the end user group. Implementation of this method revealed a number of lessons regarding the development and use of digital animations in assessment tools for children. First, even at the first prototype stage, many children were able to understand the instructions and accurately identify the emotion or behavior being targeted in the animated items. This was more likely in target emotions and behaviors that are represented by clear external features such as sadness (tears) and sleeping difficulty (restlessness, looking tired) and less likely in complex emotions such as worry, where the emotion tends to be expressed inwardly (fearful thoughts, heart racing). The latter proved particularly challenging for younger children who may not understand labels such as “worry.” This highlights the careful consideration that must be given in translation of items into animated form and the necessity to review these with children of different ages. Although a strength of this study was its inclusion of a broad age range of youth, the small sample size within each age group requires these findings to be further examined in larger samples.

Second, findings suggested that even when children could not accurately label the target emotion or behavior, they were able to provide examples of similar behaviors or scenarios that suggested a more developed internal representation of these constructs. This reinforces the notion that using instruments that rely on a child’s cognitive and verbal ability to recognize and understand emotions may not provide reliable information. One benefit of a digital assessment tool such as the ICDS may be that concepts difficult for children to understand using verbal or written approaches may be more easily communicated through animations. In the ICDS, children merely need to recognize or relate to one of the visually depicted response options; this approach could be far easier than written descriptors (eg, I worry a lot) that may be too abstract and complicated to understand.

Third, findings from this development and testing process indicated that children could understand the instructions and requirement to choose which animation was more like them; however, older children were better at articulating the difference between levels of likeness (eg, “a lot like you” or “a little like you”). Fourth, the importance of using colorful and simple images and design was confirmed through participant acceptability and feedback. Such findings are not dissimilar to those in the child eHealth literature, which demonstrate the effectiveness of interventions that utilize eye-catching graphics, colors, stories, animations, and interactive activities [35-37]. Fifth, the importance of depicting strong, highly visible displays of the target problem was noted by many young people as a strategy for more clearly helping children to understand the target emotion or behavior. This may indicate that children find it difficult to identify the behavior or emotion at lower, more subtle levels of intensity.



Finally, children frequently cited the need to contextualize animations to achieve accurate understanding of target items. Contextualizing animated items presents both potential benefit and difficulty. Traditional pen-and-paper screening instruments typically remain vague and overly general in their item descriptions (eg, “I feel sad” or “I tend to worry about things”) so as not to imply a problem specific only to a certain context (eg, only at school, with parents). Given the known heterogeneity in which emotional and behavioral problems may manifest in children (eg, [38]), it is necessary to ensure that as many different representations of the target problem are represented as possible. We deliberately developed our prototype animations with sparse backgrounds to encourage children to focus on the general behavior or feeling being targeted, rather than associating it with a specific activity or context; yet child feedback suggests that this may be necessary in digital tools. Our refined animations addressed this by incorporating contextual information, for example, a park background in our worried or confident item, without adding elements that may be associated with specific forms of worrying such as a dog or other children. Assessing the match between animations and intended item meaning will be crucial to the development of future digital instruments for children.

### Implications and Future Research

The ICDS is intended for use as a screening instrument that can assist families and relevant professionals (eg, family health practitioners, teachers) to identify potential difficulties and guide decision making around referrals to formal assessment or interventions. The results of this project are being used to guide and inform the development of the remaining ICDS items, which will also be developed using an iterative codesign process. Future studies will confirm the utility of the ICDS in detecting childhood emotional and behavioral distress compared with

existing child- and parent-report instruments in community and clinical samples. This research will also allow the identification of “at-risk” cut-offs for different groups, which is necessary before widespread dissemination can occur. If effective, the ICDS will present a screening instrument that may be highly accepted by young people and provide valuable child clinical reports to inform further assessments and intervention referrals. An additional benefit of using modern Web-based technologies is the possibility of future over-the-air updates, allowing ongoing development to remain responsive to user feedback. Further, no specialist equipment or training will be necessary for the ICDS, thus providing a screening instrument that is easily disseminated and can have maximum prevention and early intervention capacity. Although this prototype has been developed only for English-speaking youth, future versions may be contextualized for other languages, as well as for specific emotional and behavioral disorders.

### Summary

This project described the development of an animated screening instrument for childhood emotional and behavioral distress, reporting on results of expert panel review and refinement of constructs, as well as pilot testing with children. The mixed-methods approach to development and testing revealed valuable information from experts and the target child group that assisted in the iterative refinement of the screener. The ICDS has potential to obtain clinical information from the child’s perspective, which may be missed through other observer report. There are very few child-reported screening instruments available for use, and if effective, the ICDS will provide a quick, engaging, and easy-to-use screener that can be utilized by families and in routine care settings. This project highlights the importance of involving expert review and user codesign in the development of digital assessments for children.

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### Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Preliminary and revised construct groupings, utilizing items from three brief measures of child emotional and behavioral difficulties.

[PDF File (Adobe PDF File), 102KB - [mhealth\\_v6i4e90\\_app1.pdf](#) ]

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### Multimedia Appendix 2

Verbatim feedback from children (by age and gender), including initial interpretation of items and whether considered correct by the interviewer; suggestions from child for improving animations to better convey intended meaning; and child’s personal story, identifying a time when they have felt like the character in the animation.

[PDF File (Adobe PDF File), 215KB - [mhealth\\_v6i4e90\\_app2.pdf](#) ]

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## Abbreviations

- BPM:** Brief Problem Monitor
- CBCL:** Child Behavior Checklist
- ICDS:** Interactive Child Distress Screener
- M&MS:** Me and My School Questionnaire
- SDQ:** Strengths and Difficulties Questionnaire
- SQL:** structured query language

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Original Paper

# Experiences of General Practitioners and Practice Support Staff Using a Health and Lifestyle Screening App in Primary Health Care: Implementation Case Study

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## Abstract

**Background:** Technology-based screening of young people for mental health disorders and health compromising behaviors in general practice increases the disclosure of sensitive health issues and improves patient-centered care. However, few studies investigate how general practitioners (GPs) and practice support staff (receptionists and practice managers) integrate screening technology into their routine work, including the problems that arise and how the staff surmount them.

**Objective:** The aim of this study was to investigate the implementation of a health and lifestyle screening app, Check Up GP, for young people aged 14 to 25 years attending an Australian general practice.

**Methods:** We conducted an in-depth implementation case study of Check Up GP in one general practice clinic, with methodology informed by action research. Semistructured interviews and focus groups were conducted with GPs and support staff at the end of the implementation period. Data were thematically analyzed and mapped to normalization process theory constructs. We also analyzed the number of times we supported staff, the location where young people completed Check Up GP, and whether they felt they had sufficient privacy and received a text messaging (short message service, SMS) link at the time of taking their appointment.

**Results:** A total of 4 GPs and 10 support staff at the clinic participated in the study, with all except 3 receptionists participating in the final interviews and focus groups. During the 2-month implementation period, the technology and administration of Check Up GP was iterated through 4 major quality improvement cycles in response to the needs of the staff. This resulted in a reduction in the average time taken to complete Check Up GP from 14 min to 10 min, improved SMS text messaging for young people, and a more consistent description of the app by receptionists to young people. In the first weeks of implementation, researchers needed to regularly support staff with the app's administration; however, this support decreased over time, even as usage rose slightly. The majority of young people (73/87, 84%) completed Check Up GP in the waiting room, with less than half (35/80, 44%) having received an SMS from the clinic with a link to the tool. Participating staff valued Check Up GP, particularly its facilitation of youth-friendly practice. However, there was at first a lack of organizational systems and capacity to implement the app and also initially a reliance on researchers to facilitate the process.

**Conclusions:** The implementation of a screening app in the dynamic and time-restricted general practice setting presents a range of technical and administrative challenges. Successful implementation of a screening app is possible but requires adequate time and intensive facilitation. More resources, external to staff, are needed to drive and support sustainable technology innovation and implementation in general practice settings.

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**KEYWORDS**

adolescent; primary health care; primary prevention; health behavior; quality improvement; telemedicine

**Introduction****Screening Young People for Mental Health Disorders and Health-Compromising Behaviors**

A range of mental health disorders and health-compromising behaviors emerge during adolescence and young adulthood, compromising current and future health and well-being [1]. Best practice guidelines recommend regular screening of young people for health and lifestyle issues in primary care to detect and intervene with problems early [2,3]. Screening increases appropriate referrals to specialty care [4] and the provision of health education materials [5] and may improve health outcomes [6]. However, many young people face barriers to disclosing health risks, and many clinicians run out of time or are concerned to ask about sensitive issues, especially if not directly related to the presenting issue [7,8]. Technology-based screening has the additional advantages of being engaging and efficient [9].

Our own prior research with 85 young people found that using a health and lifestyle screening app increased disclosure, patient-centered care, and preparedness of young people attending general practice. It created scope to address unmet health needs, without negatively affecting indicators of youth-friendly quality care, such as privacy and trust in their general practitioner (GP) [10]. In our study, we found that only 14.4% (30/209) of the eligible patients did not use the app, either because they did not want to use the app (n=24) or for no provided reason (n=6) [10]. We also found that young people rated this screening technology as highly acceptable and very easy to use, and most of them wanted to use the screening app regularly as part of their routine care with their GP [10]. However, despite the demonstrated benefits and need, the rate of using digital technology beyond a basic electronic health record in primary care settings is low [11,12].

**Implementation of Interventions to Improve Health in Primary Care**

Translating evidence and clinical guidelines into routine practice is typically slow and erratic and can result in suboptimal care and patient exposure to unnecessary risks [13]. A challenge for knowledge translation into primary care is the complexity of the setting, where multiple agents, such as patients, GPs, and practice support staff (receptionists and practice managers), are interacting at and across multiple levels, including organizationally and individually, and not always in a predictable manner [14]. The fit between an intervention and these dynamic contextual factors has been found to be critical in determining the success of an implementation in shortening the evidence-to-practice gap [15].

The Medical Research Council, which coordinates and funds medical research in the United Kingdom, recommends a staged and iterative process for the development, evaluation, and implementation of complex interventions to improve health [16,17]. Complex interventions comprise several components

which interact and do not necessarily relate linearly or predictably [16]. An iterative approach to tailoring interventions, repeatedly reflecting on results and refining, is particularly appropriate for the implementation of health technology, a complex intervention which is influenced by underlying and multifaceted interrelated technical, social, and organizational factors [18].

Reflecting the growth of implementation research, multiple theories exist to explain how and why implementation succeeds or fails [19]. Normalization process theory (NPT) provides a particularly appropriate theoretical lens to investigate the implementation of a screening technology in the primary care setting and has been widely used [20-22]. Unlike most other theories, NPT accounts for the important social aspects of the implementation of health technology, including the work required to make sense of the technology and its effects on roles and responsibilities [20]. NPT describes how complex practices and technology innovations become embedded and integrated into health care settings [23,24] and posits that implementation is operationalized in social contexts, including work settings, through 4 key mechanisms: coherence, how participants make sense of an intervention; cognitive participation, commitment and engagement by participants; collective action, the work participants do to make the intervention function; and reflexive action or how participants reflect in appraisal of the intervention after it has been in use.

**Experience of Clinicians and Support Staff in Implementing Technology-Based Screening for Young People in Primary Care**

Health care providers have reported that using a technology-based screening tool facilitates identification of and communication about risky behaviors [9], while pediatric primary care providers report that these tools improve visit organization and efficiency [25]. Little is known about how GPs integrate screening technology into the context of routine clinical care. One study found that using a quality improvement framework resulted in increased rates of comprehensive screening and counseling for adolescents [26], but this study was conducted in predominantly pediatric settings and did not use technology. In the United States, where young people may attend planned well-child consultations, which devote time to screening and intervention, less than 50% do so [27,28], which is why it is important to investigate whether primary care providers are able to use a technology-based screening tool during consultations in which young people present acutely with any health issue in a primary care setting. This investigation is even more pertinent for generalist primary care services which are a gateway to specialist services, such as general practice in the United Kingdom, Australia, New Zealand, and Canada, which treat patients of all age groups and thus have to balance patient care processes for each group.

In addition, as the interface between the health care system and the community [29], support staff are typically the staff responsible for administering screening tools required to be

completed by patients before the consultation. Support staff have highly demanding and complex roles [30], yet they also report having limited agency [31], which is known to impede implementation in primary care [15]. Despite their central role, there is a paucity of studies that explore the needs and experiences of support staff in implementing technology-based screening tools.

### Aim of This Study

The aim of this study was to investigate the implementation of a codesigned health and lifestyle screening tool (“app”), Check Up GP, for young people in an Australian general practice. We used NPT to explore both the experiences of support staff in administering an app to young patients and how GPs integrated the screening tool within their routine care of young people attending a general, rather than youth-specific primary health care setting. The codesign process for Check Up GP has been described in a previous conference publication and included input from young people, parents, support staff, and GPs [32].

## Methods

### Study Design

We conducted a 2-month in-depth implementation case study of Check Up GP in one general practice clinic, with methodology informed by the action research approach. Case study research is a particularly useful method for investigating complex social interventions and settings in health care [33], including technology-related innovations [34]. Action research aims to involve stakeholders in the implementation of change and generation of knowledge in a real-world setting through a cyclical process of collecting, feeding back, and reflecting on data [35,36]. A Plan-Do-Study-Act (PDSA) framework was used to help the clinic structure the iterative improvement of Check Up GP and its administration in rapid quality improvement cycles [37]. The PDSA framework has the advantage of being recommended to general practices to use in quality improvement activities by the Royal Australian College of General Practitioners, the peak accreditation body for GPs in Australia [3]. The 2-month length of the study was reached by agreement with the clinic before the commencement of the study. The study received ethics approval from the University of Melbourne (Ethics ID #1544281).

### Recruitment

The clinic was recruited through the Victorian Primary Care Practice-Based Research Network, managed by the Department of General Practice at the University of Melbourne. The 4 GP principal owners and all support staff participated in the study. The support staff consisted of a practice manager, a reception coordinator, and 8 receptionists, with all except 3 receptionists participating in the final interview.

The site chosen met 4 key criteria for selection in this case study. We wanted a traditional group practice that is run by GPs rather than a corporate chain practice, a community health center, or a bulk billing clinic (services covered by Australia’s Medicare system of free universal health insurance), as traditional group practices form the majority of primary care practices within Australia. We wanted a practice that was interested in young

people and saw enough young people in the age group of 14 to 25 years but was also a generalist practice caring for patients from cradle to grave. We wanted a practice that was comfortable with using technology and willing to work on integrating it but was not highly tech savvy as most of the practices in Australia have only a basic level of tech use (most only use technology for appointments, pathology, prescriptions, and billing [11,38]). We needed a site where most patients would be able to read and understand English, the language used in this prototype of the tool.

### Case Study Context

Using the macro, meso, and micro typology developed by Bronfenbrenner [39], the context of the case study is described below.

#### Macro Level Contextual Factors

The clinic is located in an inner urban suburb of Melbourne, Australia, just over 10 km east of Melbourne’s central business district. It is in a Local Government Area (LGA) ranked in the 98th percentile in Australia’s Index of Relative Socioeconomic Disadvantage [40], indicating a relative lack of economic and social disadvantage. Compared with the whole of Australia, the LGA has a similar mean age (LGA=37.7 years, Australia=37.2 years) [41] and proportion of young people aged 15 to 24 years (LGA=27,243 / 177,361; 15.36% [41], Australia=3,172,058 / 24,206,201; 13.01% [42]). However, the LGA has a higher median income (LGA=Aus \$56,451, Australia=Aus \$46,854) [41] and proportion of completion of secondary education (LGA=74.8%, Australia=51.8%) [41]. The unemployment rate of the LGA is similar to the national average (LGA=4.5%, Australia=5.6%) [41], though the proportion of people born overseas is lower (LGA=30.9%, Australia=35%).

#### Meso Level Contextual Factors

Established in 1902, the clinic is in a freestanding converted house located in a residential area at the edge of a local shopping village. Open 365 days per year, it is a large clinic with 12 GPs (4 principal owners and 8 GP employees or associates, totaling a full time equivalent (FTE) of 7.2), 5 registered nurses (FTE 2.15), a practice manager (PM; FTE 1.0), a reception coordinator (RC; FTE 1.0) and 8 receptionists (FTE 4.8). Colocated at the clinic are a podiatrist, dietitian, and a pathology service. It is a mixed private and bulk-billing practice with approximately 30% of patients being Health Care Card holders (the Health Care Card is provided by the Australian Government to those on certain government benefits, entitling the holder to concessions on the cost of health services and medicines). Those younger than 16 years, and pensioner and concession card holders (provided by the Australian Government to those receiving old age, carer, or disability pensions) are only bulk billed between 10:00 AM and 4:00 PM from Monday to Friday, though the GPs have the discretion to bulk bill during other times. As a general practice, every GP sees patients across the life span, including young people, and between 46 and 100 young people aged 14 to 25 years attend the clinic each week.

#### Micro Level Contextual Factors

The clinic uses a commercial clinical electronic health record software package for appointments and patient files. They have

recently started using the software's automated SMS text messaging (short message service, SMS) function to send bulk appointment reminders and health care recall messages to patients. Organizing these SMSs is the responsibility of one support staff member (the reception coordinator); so other receptionists neither use nor are familiar with using this SMS functionality. Before this study, neither the GPs nor support staff had prior experience with introducing new technology or apps into their work, though they were interested in the potential of technology to improve their work. Apart from new patient forms, receptionists did not have experience with asking patients to complete any offline or Web-based screening or other preappointment forms. The clinic does not have wireless Internet in the clinic, and new patient information is collected via paper forms and then transcribed by receptionists into their software. The GPs are used to checking clinical information, such as pathology results, before seeing their patients, though they do not typically navigate away from their clinical software to other websites during consultations.

The 4 GP principal owners are usually the instigators of change, and it is the PM's responsibility to show support and sustain momentum. The principal owners oversee the clinical function and are responsible for the GPs and nurses. The PM has complete autonomy over administration: receptionists report to the RC, and the RC reports to the PM. The PM and principal GP owners together form the senior management team. Clinical meetings involving all doctors are scheduled once in every 6 weeks, administration meetings (including one principal GP) are scheduled once in every 3 months.

As reported previously [10], the GPs rated highly their enthusiasm for seeing young people and their knowledge and confidence in consulting and communicating with young people and their confidence in exploring issues beyond the presenting problem.

## Measures

At the beginning of the study, GPs and support staff participants were asked to rate their technology adoption at home and at work on a scale (from 1=slow adopter to 5=innovator). At the end of the implementation, semistructured interviews and focus groups were conducted in-person with GPs and support staff by MW. The interview guide (Multimedia Appendix 1) was informed by the 4 core constructs of NPT to explore participants' experience of implementing Check Up GP. During the implementation period, researchers recorded the number of times that we needed to provide support to staff on using the app. Young people completed an exit survey immediately after their consultation. Results on what young people thought about using the app as part of their routine health care and the impact on their experience of care are reported in a previously published paper [10]. In this paper, we report on new data from young people concerning the implementation of the app: where they completed Check Up GP, if they received an SMS with a link to Check Up GP before attending the practice, and if they felt they had sufficient privacy.

## Intervention

The content and design features of Check Up GP are described in detail elsewhere [10]. In brief, the app consisted of 2 parts: the questionnaire answered by patients and the GP summary report. The questionnaire was adapted from the HEEDSSS (Home environment, Education and employment, Eating, peer-related Activities, Drugs, Sexuality, Suicide and depression, Safety from injury and violence) preventive health framework for interviewing adolescents [43,44], covering the range of mental, physical, and social issues and behaviors commonly experienced by young people. Questions from validated screening instruments were included to capture depression (Patient Health Questionnaire-2) [45], generalized anxiety disorder (Generalized Anxiety Disorder-2 scale) [46], eating disorders (Sick Control One stone Fat Food questionnaire) [47], and substance-related risks and problems (Car Relax Alone Forget Friends Trouble test) [48]. Youth responses to the questions in the app were immediately conveyed to their GP via a secure website. This summary highlighted areas of concern and strengths as well as tips on youth-friendly consultations and suggested actions to take on areas of concern, including referral options, information, and resources.

Receptionists were trained to inform young patients aged 14 to 25 years of participating GPs that Check Up GP was available when they phoned the clinic to take an appointment. The receptionist then created a flag in the clinical software signaling the reception coordinator to send the patient a link to Check Up GP via an SMS message (sent from the clinical software). When a young patient arrived at the clinic for their appointment, receptionists asked the young person if they had received the SMS; if not, the young person was given an Apple iPad and asked to complete the tool in the waiting room before their consultation. Once the tool was completed, the receptionist notified the GP via the clinical software that the GP summary report was available for checking.

## Procedure

At the start of the study period, all participating GPs and support staff met with the researchers (MW, GW, LS) and were given an overview of the study. In accordance with the iterative and participatory nature of the action research approach, we worked closely with staff during the intervention period to facilitate improvements to the process in rapid quality improvement cycles. A researcher was always present in the practice's waiting room during the intervention to collect exit surveys from young people immediately after the consultation and to provide implementation support to staff if requested. Also, at the beginning of the study period, because the clinic did not have wireless Internet, we set up a wireless dongle in the waiting room to enable patients to complete Check Up GP in the clinic and for the results to be immediately available to the GPs.

Young patients were recruited in the waiting room upon arrival to the clinic. If they were seeing a participating GP and aged 14 to 25 years, the researcher provided them with information about the study. If they agreed to participate, the young patient was asked to take a form into their consultation for their GP to assess their eligibility to participate in the study. Patients were excluded from the study if their GP assessed that their patient



was very unwell (eg, vomiting, weak, psychotic), unable to read or speak English, or if they were younger than 18 years and not a mature minor [49]. The patient handed the form back to the researcher on returning to the waiting room. Immediately after their consultation, each youth participant completed the short exit survey on a tablet in the waiting room with consent provided at the start of the survey.

During the 2-month implementation phase, the researchers communicated regularly with the PM and met twice with the GPs during a 30-min lunch break, using the PDSA framework as a structure for quality improvement discussion. At these meetings, we presented a summary of results from youth exit surveys to that date, including rates of youth-rated patient-centered care and disclosure. We then asked staff to reflect, identify, and resolve challenges or problems with either the implementation or the tool itself. These meetings also provided an opportunity to share feedback on initial findings, ensure the practice remained engaged, and celebrate successes. On the basis of staff needs, changes were made to the tool and how the tool was implemented by staff. We were unable to meet the receptionists as a group due to lack of availability, so ad hoc sessions were run with individual receptionists during quiet times in the waiting room. We also distributed a number of supporting documents to receptionists: a Frequently Asked Questions document to clarify and reiterate procedures, such as recommended phrases to use when informing young people about the tool and a summary of anonymized results from young people's exit surveys, including ratings of disclosure and patient-centered care.

The clinic received Aus \$2000 for their involvement (Aus \$1000 at the beginning and another Aus \$1000 at the end of the study), and each support staff received an Aus \$100 gift voucher at the end of the study in recognition of the additional work required of them to participate in the study. Involvement in the study was also an approved activity of the Quality Improvement and Continuing Professional Development program for GPs through the Royal Australian College of General Practitioners.

## Analysis

Interviews with GPs and support staff were audio-recorded and then transcribed verbatim by a professional transcription service. The first author listened to all interviews to ensure the transcripts accurately reflected the audio recordings. Transcripts were coded by the first author using NVivo 11 (QSR International, Melbourne) software. The second and third authors used this coding framework to independently code 2 transcripts: an interview with a GP and an interview with a receptionist. All authors then met to compare codes, revising the coding structure as required. The first author subsequently recoded all transcripts using the updated coding framework, before conducting a thematic analysis [50], with themes mapped to the corresponding core NPT constructs. The authors, of whom one is also a practicing GP (LS), met regularly to discuss emerging themes and resolve any differences until a final set of themes was agreed upon. Descriptive statistics were used to analyze results from

the youth exit survey (where young people used Check Up GP, whether they received an SMS with a link to it before attending the practice, and whether they felt they had sufficient privacy). Ratios were calculated of both usage and support provided to total eligible patients.

## Results

### Participant Characteristics

All 4 participating GPs were male, with three aged between 45 and 54 years and one aged between 55 and 64 years. All the 10 support staff who consented and participated were female. Of the 7 support staff who completed the demographic survey and participated in the final interviews, 2 were aged between 25 and 34 years, 1 was aged between 35 and 44 years, 2 were aged between 45 and 54 years, and 2 aged between 55 and 64 years. Compared with support staff (n=10), GPs (n=4) rated their technology adoption lower (between 1=slow adopter and 5=innovator) in both work and home settings (GP work mean=2.75, SD=1.26, GP home mean=3, SD=1.41, support staff work and home mean=3.9).

The characteristics of the young people who used Check Up GP are reported in detail in a previously published paper [10]. Briefly, of the 85 young participants who used the app, 54% (46/85) were female and the remaining 46% (39/85) were male. The mean age of youth participants was 19.9 years (SD 3.32). Just over half of young people (51/85, 59%) did not have a parent or guardian with them at the clinic.

### Implementation Activities

As shown in [Figure 1](#), during the implementation period, the design of Check Up GP was improved iteratively after 4 major PDSA quality improvement cycles in response to the needs of GPs and support staff. Changes that were made to the tool and its administration resulted in the following: a reduction in the average time taken to complete Check Up GP from 14 min to 10 min, an updated SMS message for young people, and a more consistent and improved description of the app for receptionists to use when speaking with young people.

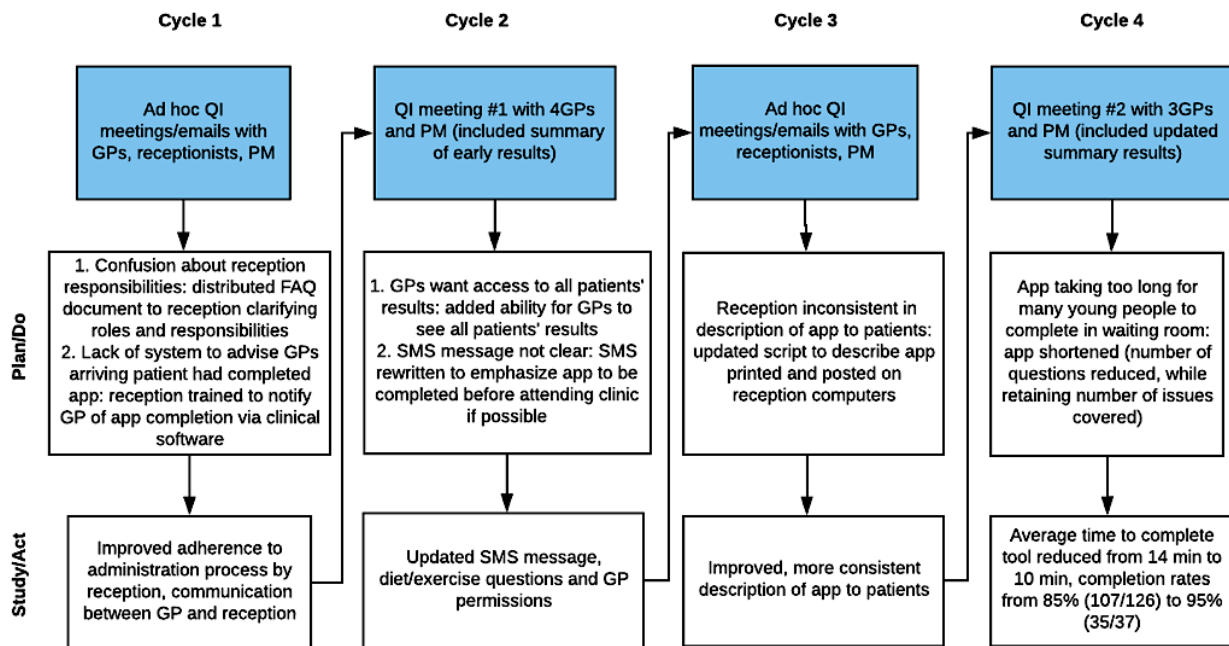
### Rates of Youth Usage and Support Provided to Staff

[Table 1](#) shows, in each week of the 2-month implementation period, the usage of Check Up GP by young patients, the number of times research assistants helped GPs and support staff with administering Check Up GP or technology problems, and the ratios of both usage and support to total eligible patients. The ratios show that, although the proportion of usage of Check Up GP by eligible patients increased slightly throughout the study period, the proportion of support required by staff to eligible patients declined.

### Postimplementation Staff Interviews and Focus Groups

Our findings from the staff interviews and focus groups conducted at the end of the intervention are structured here within the 4 core constructs of NPT.

**Figure 1.** Iterative cycles of quality improvement (QI) activities and results using the Plan-Do-Study-Act framework by general practitioners (GPs), practice manager (PM) and receptionists during the implementation of Check Up GP. FAQ: frequently asked questions; SMS: short message service.



**Table 1.** Check Up GP rates of patient usage and support provided to staff and ratios of usage and support provided to total number of eligible patients.

Patient usage and support provided to staff	Week 1 <sup>a</sup>	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8 <sup>a</sup>
Patient usage	7	18	10	9	13	6	12	9
Number of times support provided to staff	19	19	14	11	6	3	5	5
<b>Total number of eligible patients</b>	22	31	30	21	25	12	25	17
Usage: total eligible patients	0.3	0.6	0.3	0.4	0.5	0.5	0.5	0.5
Support: total eligible patients	0.7	0.6	0.5	0.5	0.2	0.2	0.2	0.3

<sup>a</sup>Week included 1 day of public holiday when only one GP worked and clinic opened for 4 hours instead of normal 12 hours.

**Coherence**

Both support staff and GPs could identify the purpose of Check Up GP and the potential benefits for young people using the tool. They felt that a key benefit of the tool was that young people’s comfort with technology would facilitate disclosure of health and lifestyle issues:

*I think it’s a user-friendly way for the young generation, who are so comfortable with electronics, to bring up topics that they don’t particularly feel comfortable doing face-to-face...it means the doctors find out more than they probably would have. [PM]*

*This is an amazing opportunity to speak to young people about all sorts of stuff that they would never ever have spoken about before. [GP 4]*

Although Check Up GP was viewed as being beneficial, GPs also speculated about 2 potential problems with using it. One GP felt that young people’s responses may be impetuous or fleeting and not necessarily provide an accurate reflection of their health and lifestyle:

*You’ve got the impulsivity of the kids as well coming in [saying] “Oh, this is how I feel this morning. I*

*don’t actually feel that bad, it’s just what I wrote because I got out of the wrong side of bed this morning.” [GP 4]*

The experience of another GP was that not all his patients were receptive or had a positive experience of using Check Up GP:

*There was a small number who didn’t really think it was very helpful or there were some who actually openly thought it may not be good but most were very open to it. [GP 1]*

Staff could make sense of the tool by comparing it with similar existing or previous interventions:

*We do the same thing with 45 to 49 year old health check...and it’s a little bit similar isn’t it. [GP 1]*

*We do surveys and things all the time. [Receptionist 1]*

**Cognitive Participation**

All staff interviewed felt that implementing Check Up GP was part of their existing job description and responsibilities. Support staff reflected that they were regularly required to integrate new systems or processes, which could originate from within the clinic, such as a new telephone system, or externally, such as

new billing requirements from Medicare (the Australia Government's public health insurance scheme). The staff's understanding of the purpose of Check Up GP also seemed to facilitate their acceptance and buy-in of using the tool. One of receptionists stated:

*It's just part and parcel of the job. I think we should be expected to do it. It's for patients and we're here to provide a service, so yeah.* [Receptionist 5]

Cognitive participation was evident in the way in which staff took initiative and invested time to improve the administration of Check Up GP throughout the implementation period. For example, it took some time for receptionists to normalize the correct script for describing Check Up GP to young people. One receptionist said:

*You [researcher] spoke to [the practice manager] at one point; you said let's get the receptionist to say this [how the app was described to the patient], I cut that out and I put it on my keyboard, and I stuck it down with sticky tape.* [Receptionist 2]

### Collective Action

We found that collective action was the biggest challenge for the implementation of Check Up GP. Administering the app presented significant additional work for support staff, who were already busy and had limited time to learn and integrate the new process into their work. For instance, the PM said:

*There was lot of stress from them about an additional task. They're constantly multi-tasking, there are a number of lines on hold, doctors who want attention right now. So it is a busy environment.* [PM]

The task of sending the link to Check Up GP by SMS, one of the core requirements of using the tool, was particularly time-consuming, creating a substantial amount of additional work for the RC. Unlike the automatic patient appointment reminders that are sent by the clinical software, the Check Up GP SMSs were not integrated with clinical software and had to be manually sent for each patient. In the words of an RC:

*You had to look at the upcoming appointments, check who fit into the category. Then you go into another screen on the computer and write up the message, and make sure that you send them to all. And then you go back into the name and you put under the alert that you note that you have send them the SMS... [The time it takes] depends how many patients you had on the day...at one stage we had about 12 that required a bit, that took at least almost 40 minutes to do.* [RC]

Lack of time was also a factor that influenced GPs use of Check Up GP. Using the app inherently added additional time to a consultation and GPs felt they had to rush to address all issues raised. For one GP who always ran to schedule, there was often not enough time for patients who did not arrive early to complete Check Up GP in the waiting room as this GP was not prepared to run even a little over time or to wait for young people to complete Check Up GP. Another GP felt that it was feasible to continue to use Check Up GP as part of young people's routine

care, though not at certain times, such as on weekends when only one GP works or during very busy periods.

Perhaps reflecting the time pressures and additional work, staff compliance with using Check Up GP was not always consistent, especially at the start of the implementation period. It took time for receptionists, particularly those working part-time, to understand what was required and to normalize the procedure. One of the receptionists stated:

*I found in the beginning it was quite overwhelming because I was here part-time...when you first started it, I'm thinking, "What is going on here?"* [Receptionist 1]

Inconsistent compliance by receptionists in administering Check Up GP required intervention by a GP at one point in the intervention:

*A couple of times we had to say [to receptionists]: "look, do you know what, this is not an optional thing, this is actually what we've chosen to do and it's important and this is part of the job."* [GP 1]

As well as time pressures, a lack of feedback was a factor that influenced the receptionists' collective action. One receptionist stated:

*I would have liked a bit of feedback [from the GPs] with whether they felt it was successful or not...because if they don't think it's good then why would we really do it...even if it was an email to say that this is the feedback that we found...or "Thank you, receptionist, for doing a great job."* [Receptionist 1]

One of the biggest facilitators of collective action was the support provided by researchers throughout the implementation period. This support was often practical, such as answering questions or reminding reception on the correct process of administering Check Up GP. As one receptionist said:

*Your staff were there, so if we did have issues and it got too busy we just go "hey, come out here" and "can you help."* [Receptionist 2]

As well as practical support, staff appreciated the feedback provided by researchers about the impact that using the tool was having on young people, as evidenced in improved ratings of disclosure and patient-centered care for those using Check Up GP compared with a treatment-as-usual group:

*It was good to have feedback from what we're participating in...it's good to know that that was helpful.* [Receptionist 3]

### Reflexive Monitoring

GPs felt Check Up GP had the potential to transform the experience of care, by expanding young people's understanding of the scope of what their GP can help them with. One of the GPs said:

*This very tool itself might give them the confidence to appreciate what is possible in the consultation...this is one of the truly significant advances, I think, in adolescent health.* [GP 4]

While the GPs were mostly positive about the impact of using Check Up GP on their care of young people, one GP reported that there were times when he felt ill-prepared to deal with an issue raised. There was an acknowledgment from GPs that further training was needed to equip them with the skills to help patients with raised issues:

*There were a few times I didn't know what to do with information...the kid who ticked "I often feel alone," okay, that's sad...it made me feel uncomfortable, that's not my kind of strength. [GP 3]*

*Upskilling might be useful for us to deal with specific problems...that would be a way of making it work because without the skillset in the GPs, it's all very nice but it isn't going to go anywhere. [GP 4]*

GPs were able to reflect on the impact of using Check Up GP on their care of young people. One key advantage was Check Up GP provided a reason to ask for time alone when young people were attending with a parent. One of the GPs stated:

*It made it easier to deal with the parents, it made it easier to throw them out of the room...It's not like, "oh, we've been talking about your presenting problem, and now I'm going to ask the parent to leave for some vague, nebulous kind of opportunistic waste of time that you don't have." It was like it forces you to do it. [GP 3]*

Both receptionists and GPs observed that there was often a lack of privacy using Check Up GP for young people attending the clinic with a parent. This lack of privacy had the potential to undermine the purpose of the tool, as is evident from the following statement:

*I found some of the mothers were quite intrusive. The kids were sitting there trying to do it...Like they're not going to answer something candidly, tick "Yes, I take party drugs" or "Have unprotected sex" with mum sitting on top of them, are they? So I felt that that might have influenced some of the answers to be done not honestly for the sake of offending their parents. [Receptionist 5]*

Both support staff and GPs felt that the implementation improved with time, as the process became embedded:

*We probably had a little bit more understanding as it went on what was happening. But I mean not that we weren't explained well enough, I think it's just getting used to doing that role. [Receptionist 3]*

*I think it's great. I think it does take a bit of time to get up and running with it, some months. So if you want to introduce it, you've got to be prepared to put that in. [GP 4]*

For sustained use both support staff and GPs felt the tool would need to be fully integrated and automated into their clinical software. One of the GPs said:

*I think because it was a trial that it didn't really worry us. I think, moving forward, I would like to see the information in the patient's file, because otherwise to then go looking, hunting for it amongst a scroll of*

*names is going to be really difficult...it's not going to be functional. [GP 4]*

Finally, despite the implementation challenges, GPs expressed a desire to continue using Check Up GP regularly with their young patients. Indeed, when the app was removed at the end of the study one GP reflected on how it would have saved time to assess a recent patient, who presented with a psychological issue:

*Certainly, the assumption is it worthwhile putting to routine [use]...it's hard to know how often you should be doing it but probably...at least [young people] being offered it every couple of years would be fabulous. [GP 1]*

Another GP said:

*Yes [it would have saved me time] because they're the questions I want to ask now. It would have been good if they [responses] were there and selected and she would have told me [about her] sexual health and all that. [GP 3]*

## Implementation Results From Young People

When asked where they completed Check Up GP, almost all (83/85, 98%) youth participants reported completing it in just one location. The majority of young people (73/87, 84%) completed Check Up GP in the waiting room, while 13% (11/87) completed it at home. Only a few completed it at work (2/87, 2%) or school/university (1/87, 1%). Of those who answered the question, 44% (35/80) of young people reported receiving an SMS from the clinic, 41% (33/80) did not receive an SMS, while 15% (15/80) could not remember. A large majority (79/85, 93%) of young people felt they had sufficient privacy completing Check Up GP, although the remaining 7% (6/85) felt they did not have enough privacy.

## Discussion

### Principal Findings

The aim of this study was to investigate the implementation of a codesigned health and lifestyle screening app for young people attending general practice for routine care. We conducted an in-depth implementation case study of Check Up GP, using a methodology informed by action research and NPT as a framework to guide our analysis. Overall, we found that, with appropriate time and intensive support from researchers, it is possible to implement a health and lifestyle screening app into the routine care of young people attending general practice.

One of the key challenges for GPs was the collective action, or operational work, required to implement Check Up GP. GPs expressed concern that they did not have time in routine consultations to sufficiently address all issues identified through Check Up GP, in addition to the presenting acute health issue. Given that the duration of a standard primary care consultation is approximately 10 min [51,52], this concern is understandable. There was also a concern from one GP that he did not always feel equipped to address some issues raised. Interestingly, these concerns were not reflected in young people's experience of using Check Up GP. As reported previously, the majority of

young people felt that their GP addressed the issues raised in Check Up GP either “quite a bit” or “very much [10].” It may be that young people were satisfied that any issues identified by the app were acknowledged and could be followed up in future consultations and did not expect an immediate lengthy discussion. This finding suggests that the perceptions of GPs are not necessarily reflected in the experience of patients and that patients offer important and unique insights into implementation.

Similar to GPs, support staff had high coherence and cognitive participation with the intervention, recognizing Check Up GP’s potential to improve the care of young people. However, it took time for them to normalize the administration of the app into their hectic day-to-day work routine, and improvements did not happen in a linear way, in keeping with the nature of complex interventions [16,53]. This normalization was impeded by the substantial additional time required by support staff to flag eligible patients in the clinical software, manually send individual SMSs, and then notify GPs when the tool was complete and the summary report available for viewing. Given this added work, it is not surprising that only 44% (35/80) of young people reported receiving an SMS with a link to the screening tool before arriving at the clinic. Although it was outside the scope of our study, automating this process and integrating the app within existing clinical software would facilitate implementation.

Not every issue was resolved by the end of the study. This suggests that full implementation, where the intervention is self-sustaining, was not achieved. Despite this, the implementation did improve over the 2-month study period, with youth relative usage remaining stable even as support required decreased. That full implementation was not achieved within the 2-month study period is not surprising given that successful implementation of new technology in primary care may take years [54,55]. It is also important to note that success in implementation is a dynamic and multidimensional concept, evolving over time [56,57]; so though using the app was not yet fully integrated into participants’ workflow, it was successful in terms of its acceptance, feasibility, and effectiveness.

An important facilitator for the implementation of Check Up GP, enabling collective action, was the intensive support provided by researchers onsite throughout the implementation period. Both support staff and GPs appreciated having a researcher at hand to troubleshoot issues that emerged after the clinic started using Check Up GP and to improve the implementation through rapid quality improvement cycles. This process enabled the intervention to better fit the context of a very busy primary care service where additional time to manage adoption of a new process that is a departure from usual process is slim. NPT does hold that implementation is easier when the new process blends easily with routine [24]. Dealing with these sorts of contextual issues is an important requirement in facilitating implementation in primary care [15]. Having the support of the researchers onsite meant that instead of having to pause the implementation for days or even weeks, most issues were able to be promptly investigated and resolved. Our role in facilitating the implementation of Check Up GP was, in essence, that of a practice facilitator. Practice facilitators assist

primary care practices with coordinating quality improvement activities and building capacity for those activities [58]. Practice facilitation has been shown to improve the adoption of evidence-based practices in primary care [59]. More research is needed to investigate the role of practice facilitators in helping primary care practices adopt new technology, but it does appear from our study that in very busy practices juggling competing demands, implementation is more effective if a facilitator is dedicated to the task.

Another factor that facilitated the extent of Check Up GP’s implementation was the context of our case study. The clinic did not have prior experience or systems to support the introduction of Check Up GP. However, it is likely that being located in an area of socioeconomic advantage provided greater scope for innovation compared with practices located in less-advantaged areas. As described by Hart’s Inverse Care Law [60] and supported in an analysis of Australian general practice data [61], people located in more-advantaged areas tend to receive longer consultations than those in more-disadvantaged areas, even though the frequency of care is similar. In addition, the business model of our practice may have facilitated innovation. Being a mixture of bulk billing and copayment may provide the practice with more money and time to see patients and scope to innovate compared with bulk billing only practices, which typically have very limited time and resources. Also, unlike corporate-owned practices, our clinic was privately owned by four of the practicing GPs, meaning implementation was not held up or dependent on approval of offsite management.

Strong organizational leadership and management support are important factors in the effective implementation of health technology [18,62]. Apart from the initial project orientation session run by the researchers, support staff and GPs did not manage to meet as a group to discuss implementation issues during the project. This might have been because they were expecting the researchers to manage the implementation given that was the aim of the research project. However, though support staff welcomed feedback from researchers about the impact of Check Up GP on young people’s experience of care, a number of these support staff expressed frustration at the lack of feedback and appreciation directly from the participating principal GPs. These findings suggest that there is a need for internal practice leadership to drive and support the implementation process in primary care; this is particularly important if the process is to succeed in the absence of external researchers.

Despite the challenges, GPs expressed a desire to continue using Check Up GP after the conclusion of the study. There was some discrepancy between GPs on how and when they wanted to use the tool in the future, for example, whether opportunistically in acute care as in this study or in a separate consultation. A separate appointment would be preferred by one GP, who was unwilling to run over time. Separate consultations for preventive screening may afford GPs more time but prior evidence shows low attendance of young people at dedicated preventive care well-child visits, particularly by the youth of low-income [27,28,63]. Furthermore, compared with planned well visits in the United States, dedicated to screening for health and lifestyle

issues, opportunistic screening is more effective at detecting issues in young people [64]. This suggests that integrating a screening opportunity into young people's routine acute care visits is the best way to maximize reach and detection. One option is for governments to subsidize a longer appointment to screen young people within routine consultations.

The willingness of support staff to continue to use the app sits in contrast to a previous study where receptionists developed negative views about administering a paper-based alcohol screening tool to an adult population over time [65]. A number of important methodological features in our study may have contributed to the more positive views of support staff toward continuing the implementation of Check Up GP. These features include involving support staff in iteratively improving the tool, regularly informing them about the positive impact using the tool was having on young people's experience of care, using a technology-based tool that was codesigned in part with input from support staff, and having researchers located at the clinic throughout the implementation period to troubleshoot administrative and technical issues. Given their unique and critical role and experience with this technology, support staff should be included not only in the codesign process of a tool which will affect their workflow but also in tailoring the implementation of a screening technology in primary care.

A particularly positive finding of our study was that using Check Up GP facilitated youth-friendly practice by making it easier for GPs to ask for consulting time alone with the adolescent. Having time alone with their GP is recommended as best practice for adolescent care [66], and young people who receive confidential care are more likely to discuss sensitive issues [67,68]. Despite this, the rates of young people seeing their GP alone are low [63,69]. Our findings suggest that the use of a health and screening app provides GPs with greater agency and confidence in asking for time alone and providing quality care.

Finally, our findings suggest that, not only users of a screening tool but parents attending with their child have the potential to undermine confidential care and influence the successful implementation of such a tool. Our GPs and support staff observed that many parents looked over the shoulder of their child when completing Check Up GP. This finding was reflected in the youth exit survey results where, although a minority, 7% (6/85) felt they did not have enough privacy completing Check Up GP. Privacy and confidential care is a core requirement of youth-friendly health care [70], so for a screening app to be useful and trusted it is essential that young people have sufficient privacy while using it. Future implementations of a screening tool need to ensure adequate privacy for young people, such as by providing an option of completing the app on their own smartphone, instead of a tablet, or by inviting them to use it on their own in a separate room. Another useful strategy for diverting parents' attention away from their child completing the screening tool would be giving parents their own survey to complete about any assistance they may need, an option

available through the American Academy of Pediatrics' Bright Futures Guidelines [2].

### Limitations

This study had a number of limitations. We conducted a single case study, implementing the tool at one English-speaking volunteer clinic in an area of relative socioeconomic advantage with GPs who identified as being enthusiastic, knowledgeable, and confident in consulting with young people. So, it is possible that a different type of clinic, such as a community health clinic, one with a predominantly multilingual or sociodisadvantaged population, or less youth-friendly GPs, may implement and use a tool such as Check Up GP differently to the practice in this study. As such, our findings may not be generalizable.

Another limitation is that due to the relatively brief study length and limited staff availability, we were only able to conduct in-depth interviews of GPs and support staff at the end of the implementation period. Thus, our analysis provided rich insights at only one moment in time. Conducting interviews at a number of time-points through implementation may have provided further insights; however, recording the support provided to staff throughout the implementation period provided valuable insights over time.

### Future Research

Although different general practices share similarities, they are diverse in a number of important ways, such as in size, location, opening hours, degree of corporatization, billing practices (free universal national health insurance versus fee for service), salaried versus nonsalaried GPs, and patient sociodemographic characteristics. Thus, further research is needed to investigate the implementation of a health and lifestyle screening tool in a range of clinics. We recommend that future projects should also ensure that the app is integrated within existing clinical software to minimize the additional work required by support staff and GPs to use this new technology.

### Conclusions

The implementation of technology in time-restricted and dynamic settings such as general practice presents a range of technical and administrative challenges. Our study reveals new insights into the impact of integrating a health and lifestyle screening app into the routine care of young people on the roles and responsibilities of both GPs and support staff. We present a rich picture of the practical problems that can arise when screening tools are introduced into busy clinics and the solutions that GPs and support staff devise in response to them. Our findings will benefit future researchers and practitioners seeking to implement screening tools in real-world settings. Successful implementation of this technology is possible but requires adequate time, intensive facilitation, organizational leadership, and cycles of iteration. More resources, external to staff, are needed to drive and support sustainable technology innovation and implementation in general practice settings.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Interview schedule for interviews with general practitioners and practice support staff.

[[PDF File \(Adobe PDF File\), 20KB - mhealth\\_v6i4e105\\_app1.pdf](#)]

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## Abbreviations

**FTE:** full time equivalent  
**GP:** general practitioner  
**LGA:** Local Government Area  
**NPT:** normalization process theory  
**PDSA:** Plan-Do-Study-Act  
**PM:** practice manager  
**RC:** reception coordinator  
**SMS:** short message service

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Original Paper

# Mobile Health to Maintain Continuity of Patient-Centered Care for Chronic Kidney Disease: Content Analysis of Apps

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## Abstract

**Background:** Chronic kidney disease (CKD) is a global health problem with a high economic burden, which is particularly prevalent in Taiwan. Mobile health apps have been widely used to maintain continuity of patient care for various chronic diseases. To slow the progression of CKD, continuity of care is vital for patients' self-management and cooperation with health care professionals. However, the literature provides a limited understanding of the use of mobile health apps to maintain continuity of patient-centered care for CKD.

**Objective:** This study identified apps related to the continuity of patient-centered care for CKD on the App Store, Google Play, and 360 Mobile Assistant, and explored the information and frequency of changes in these apps available to the public on different platforms. App functionalities, like patient self-management and patient management support for health care professionals, were also examined.

**Methods:** We used the CKD-related keywords "kidney," "renal," "nephro," "chronic kidney disease," "CKD," and "kidney disease" in traditional Chinese, simplified Chinese, and English to search 3 app platforms: App Store, Google Play, and 360 Mobile Assistant. A total of 2 reviewers reached consensus on coding guidelines and coded the contents and functionalities of the apps through content analysis. After coding, Microsoft Office Excel 2016 was used to calculate Cohen kappa coefficients and analyze the contents and functionalities of the apps.

**Results:** A total of 177 apps related to patient-centered care for CKD in any language were included. On the basis of their functionality and content, 67 apps were recommended for patients. Among them, the most common functionalities were CKD information and CKD self-management (38/67, 57%), e-consultation (17/67, 25%), CKD nutrition education (16/67, 24%), and estimated glomerular filtration rate (eGFR) calculators (13/67, 19%). In addition, 67 apps were recommended for health care professionals. The most common functionalities of these apps were comprehensive clinical calculators (including eGFR; 30/67; 45%), CKD medical professional information (16/67, 24%), stand-alone eGFR calculators (14/67, 21%), and CKD clinical decision support (14/67, 21%). A total of 43 apps with single- or multiple-indicator calculators were found to be suitable for health care professionals and patients. The aspects of patient care apps intended to support self-management of CKD patients were encouraging patients to actively participate in health care (92/110, 83.6%), recognizing and effectively responding to symptoms (56/110, 50.9%), and disease-specific knowledge (53/110, 48.2%). Only 13 apps contained consulting management functions, patient management functions or teleconsultation functions designed to support health care professionals in CKD patient management.

**Conclusions:** This study revealed that the continuity of patient-centered care for CKD provided by mobile health apps is inadequate for both CKD self-management by patients and patient care support for health care professionals. More comprehensive solutions are required to enhance the continuity of patient-centered care for CKD.

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## KEYWORDS

mobile apps; chronic kidney diseases; self-management; continuity of patient care; patient-centered care

## Introduction

### Continuity of Patient Care in Chronic Kidney Disease

Chronic kidney disease (CKD) is a global health problem with a high economic burden [1,2]. CKD is often accompanied by chronic vascular disease, diabetes, and other comorbidities associated with long-term conditions. Therefore, it is vital for patients with CKD to have continuity of care [3]. The prevalence of CKD globally is approximately 13.4% (11.7%-15.1%). However, the prevalence rate of CKD stages 3-5 is 10.6% (9.2%-12.2%) [4]. According to the latest US Renal Data System annual data report, the incidence and prevalence of end-stage renal disease in Taiwan was the highest in the world in 2015 [5]. Therefore, aggressive and effective interventions are especially crucial in Taiwan for managing patients with CKD.

Since 2001, the US Institute of Medicine has made “patient-centered” 1 of the 6 targets for improving health care [6]. CKD patient-centered medical services aim to improve the collaboration among the health care professionals (HCPs), patients, and primary caregivers to align patient care with patient values and preferences through shared decision-making. Such services focus on HCPs’, patients’, and primary caregivers’ perspectives [7-9]. Depending on the disease characteristics, care methods, and settings, the importance of each type of continuity also differs [10]. Improving continuity is an avenue worthy of exploration to improve patient-centered care for CKD.

### Mobile Apps for Chronic Disease Self-Management

Many systematic reviews have examined the effects of self-management strategies in care for chronic diseases, such as cystic fibrosis [11], osteoarthritis [12], chronic obstructive pulmonary disease [13,14], asthma [15], and chronic pain [16]. However, these studies have agreed that evidence supporting the self-management of chronic disease care as an effective strategy is insufficient. More rigorous studies are required for confirmation. Nevertheless, self-management strategies remain one of the most frequently recommended programs for CKD care [17,18]. Studies have found that CKD self-management education gradually incorporates a patient-centered and individualized management plan [8,19-21]. However, the effectiveness of these individual management plans for CKD care remains to be observed. Some studies have explored the views of all levels of HCPs on CKD patient management and found that primary HCPs feel more challenged when managing complex comorbidities or older patients with CKD. Therefore, enhancing the coordination and continuity of care and using a multidisciplinary team are necessary for improvements in care quality [22,23].

Mobile health apps are widely used for illness prevention, healthy lifestyles, finding HCPs or facilities, diagnosis, education, filling prescriptions, compliance, diabetes care, mental health and behavior disorders care, musculoskeletal system and connective tissue care, oncology care, nervous system care, women’s health care, and children’s health care [24]. A literature review of interactive telemedicine care has indicated that no difference exists between interactive telemedicine care and face-to-face or telephone interviewing in the management of heart failure, but the interactive telemedicine can improve the control of glycemic control for diabetics. However, due to limited data, the costs of an interactive telemedicine service and its acceptability to patients and HCPs remain unclear. The authors concluded that the outcomes of such studies depend on the participants, their disease histories, the severity of the diseases, and the chosen interventions [25]. This review indicated that, in addition to the application of technologies, patient-centered and individualized interventions may be critical factors influencing the effectiveness of mobile health or telemedicine.

### Mobile Information Technology for Chronic Kidney Disease

Meeting the care standards set by Kidney Disease Improving Global Outcomes is challenging under the often limited manpower available for CKD primary care. Consequently, applying information technology is vital to optimizing the management of CKD patients in primary care [26-28]. Some studies have used telemedicine in CKD care for patient education, interactive counseling for HCPs, monitoring the effectiveness of patient blood pressure control, and a small proportion of home-based case management [29-32]. Diamantidis and Becker reviewed the use of mobile technology in CKD patient care and revealed that, from early mobile messaging and internet connections to current mobile apps, accessibility of devices, usability of apps, and novelty were the primary factors affecting users’ willingness to continue using such technology. They observed that most CKD patients expected to increase their contact with physicians through an interactive system. Therefore, providing a HCP platform such as Happitque for patient education or patient management is becoming a requirement [33]. Developing an interactive telemedicine system that allows patients to communicate with health care providers is becoming a popular form of intervention through which personal health records, laboratory results, and appointment schedules can be obtained. Even wearable devices and apps that can measure renal function are under development [28]. CKD patient management with a mobile health app is thus a groundbreaking patient-centered approach to designing individualized management plans.

Havas et al explored what support CKD patients required for self-management. They summarized the following 10 aspects of CKD self-management: disease-specific knowledge, managing medications, engaging and sustaining social support, maintaining social and occupational roles, modifying lifestyle, developing and sustaining a positive attitude and caring for mental and physical well-being, building and sustaining effective relationships with health care providers, establishing routine and planning ahead, actively participating in health care, and recognizing and effectively responding to symptoms [8,21]. Many studies have explored the content and functionalities of apps for various diseases or health management [34-39]. However, no studies have specifically examined the functionalities of mobile health apps downloaded from popular mobile app platforms for the continuity of patient-centered care for CKD.

Thousands of health apps are available on popular mobile app platforms (eg, the App Store and Google Play). These platforms are the primary source for many patients or HCPs looking for self-management or disease management apps. In recent years, China's app market has rapidly developed [40], with 360 Mobile Assistant (25%), Tencent (25%), Baidu (17%), and Xiaomi (13%) occupying approximately 70% the market share among China's top 10 Android app stores [41]. Among these, 360 Mobile Assistant has gained attention for its security apps. However, the reference or validity descriptions of these apps are rarely displayed on these popular mobile app platforms. Therefore, users are unable to determine whether apps have reliable references and whether they are based on effective health management theories (eg, behavior change techniques). As a result, more studies have explored the gap between the functionalities of apps and evidence-based practice [36,42,43].

Many apps are short-lived; Larsen et al have conducted a longitudinal study of mental health apps and found that the environment for such apps is unstable. More than half of the studied apps were revised roughly every 4 months, and on average, 1 app was deleted for every 2.9 days [44]. Zaidan and Roehrer investigated diet and weight loss apps and discovered that some app developers on Google Play release apps with different names but identical content. They also noted that the search algorithm used by Google Play focused on titles and keywords of apps rather than content; however, titles and keywords may not always reflect the content of the apps [39]. This behavior may increase users' difficulty in selecting apps.

## Objective

This study aimed to: (1) identify the current apps related to the continuity of patient-centered care for CKD on the App Store, Google Play, and 360 Mobile Assistant and explore the information and frequency of changes in these apps available to the public on different platforms; (2) analyze the functionalities and recommended users of apps related to the continuity of patient-centered care for CKD; (3) compare the functionalities provided by apps related to the continuity of patient-centered care for CKD according to 10 aspects of requiring additional support in patient self-management for CKD and the functionalities supporting HCPs for implementing CKD patient management.

## Methods

### Identifying Apps Related to Patient-Centered Care for Chronic Kidney Disease

A total of 3 reviewers (YLL, YYC, and MHT) conducted this study. All reviewers are experts in nursing and mobile health care. Moreover, 2 were responsible for searching for apps as well as coding the features and functionalities. The third senior expert was responsible for monitoring and moderating the results of the data collection. From March to April 2016, 2 reviewers (YLL and YYC) searched 3 app platforms, namely, the App Store, Google Play, and 360 Mobile Assistant, using the CKD-related keywords "kidney," "renal," "nephro," "chronic kidney disease," "CKD," and "kidney disease" in traditional Chinese, simplified Chinese, and English. This study only included apps related to patient-centered care for CKD that could be used on mobile phones or tablets; those designed for journals, medical conference manuals, medical practice guidelines or reference materials, clinical comprehensive computers, and hemodialysis were excluded, as were those that could not be installed or operated.

### Developing Coding Guidelines

This study was conducted through content analysis. First, 1 reviewer (YLL) drafted coding guidelines according to the outlined aims and previous studies assessing health apps [38,39,45]. Following a review, iterative assessing, revising, and testing were conducted for 10 apps randomly selected from those identified in the first stage, and coding guidelines were confirmed (including the definition of each evaluation element and a coding example). The coding guide divided the evaluation elements into the following categories: (1) information provided by the developer, namely, app platform, language, price, content rating (Google Play and App Store only), installation times (Google Play and 360 Mobile Assistant only), privacy policy, registration requirements, last release date, current version, Android or iOS minimum version requirements, description for certification of medical grade app (such as the US Food and Drug Administration (FDA) [46] or MEDDEV 2.1/6 guidelines for medical devices in the European Union [47]); (2) users' rating, namely, current rating (Google Play and 360 Mobile Assistant only) and the total number of ratings (Google Play only); and (3) researchers evaluation, namely, the classification of the contents and functionalities, recommended users (HCPs, patients, or both), description of reference, and providers (eg, medical profession-related organizations).

### Coding the Features and Functionalities of Apps

Before formal coding, all reviewers obtained coding consensus according to the coding guidelines. First, 2 reviewers (YLL and YYC) identified the top 30 apps from the first stage, 23 for Google Play, 15 for 360 Mobile Assistant, 13 for the App Store, and 1 not included in the final sample. All information provided on the app platforms by their developers was documented. They then downloaded, installed, and operated the apps before coding independently according to the coding guidelines.

**Table 1.** Interrater reliability for all variables.

Variable	Cohen kappa coefficient
App platform	.67
Language	.77
Price	.83
Privacy policy	.71
Registration requirements	1
The classifications of the contents and functionalities	.65
Recommended users	.86
Description of reference	.81
Developers	.81
Description for certification of medical app	1

The apps that could not be registered and authorized were coded according to the screenshots and descriptions of features on the app platforms. The coding results were then recorded in an Excel worksheet.

After coding, the Cohen kappa coefficient of each variable was calculated using Microsoft Office Excel 2016 to test the interrater reliability (Table 1). The Cohen kappa coefficients ranged from .65 (the classifications of the contents and functionalities) to 1 (registration requirements and description for certification of medical app), and the levels of agreements were from moderate to strong [48]. For the differences, all reviewers discussed until consensus was reached and revised the latest coding guidelines accordingly.

After obtaining consensus, 2 reviewers (YLL and YYC) examined the contents and functionalities of all apps individually and encoded them according to the latest coding guidelines. After coding, the 2 reviewers (YLL and YYC) agreed on the coding results through comparison and discussion. If consensus could not be reached, the third senior expert (MHT) participated in the discussion to confirm the final coding.

The baseline survey was conducted between April and June 2016. To reveal the follow-up maintenance status and loss rate of apps included in the baseline survey, 1 reviewer (YLL) conducted a second survey in December 2016, a third survey in March 2017, and a fourth survey in June 2017. The follow-up surveys recorded whether the app was downloadable, the number of app downloads, the date of the last release, and the user rating from each app platform.

### Comparing Functionalities of Apps According to 10 Aspects of Chronic Kidney Disease Self-Management

To compare the functionalities of patient-centered care apps for CKD according to the 10 aspects of CKD self-management, 1 reviewer (YLL) categorized the 110 apps suitable for patients according to the 10 support aspects introduced by Havas et al; the categories were discussed with the other researchers to reach a consensus [8,21]. Each functionality category corresponded to more than 2 aspects. The quality of the information from the mobile apps was analyzed with reference to previous studies [36,49]. Each aspect was regarded as a quality indicator. When

the functionalities of an app contained one of the aspects, a score of 1 was allotted; otherwise, a score of 0 was given. The highest possible score was 10.

### Statistical Analysis

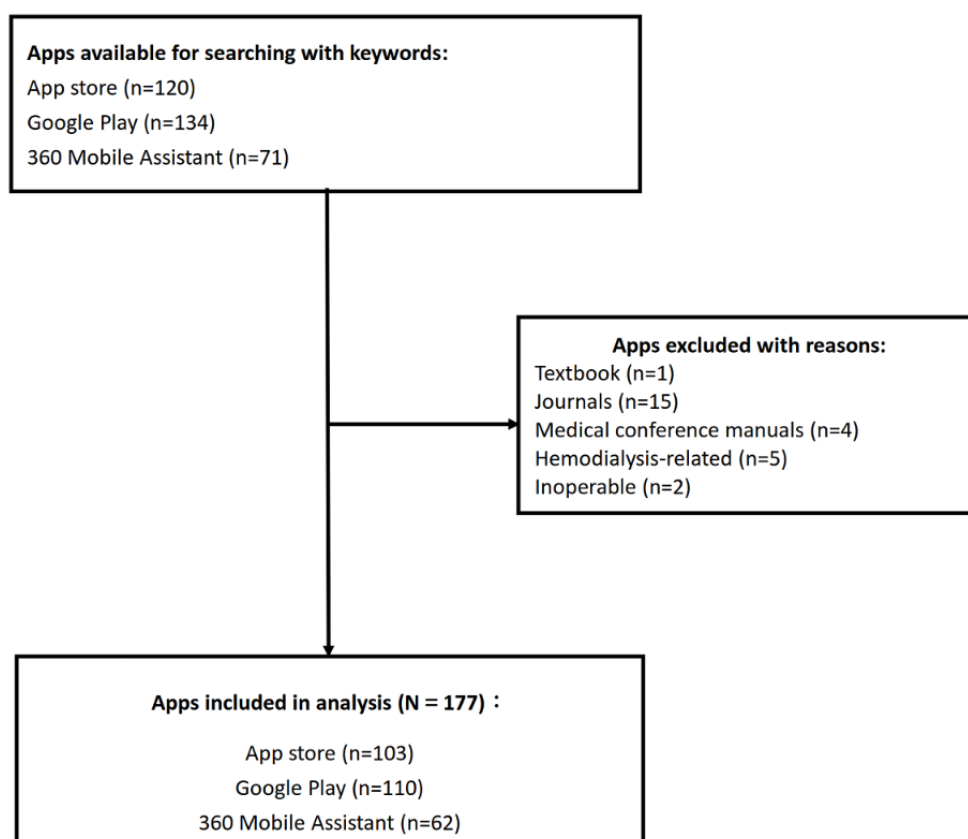
Microsoft Office Excel 2016 was used to conduct descriptive statistical analyses of the app classification properties.

## Results

### App Search Results

A total of 120 apps from the App Store, 134 apps from Google Play, and 71 apps from 360 Mobile Assistant were located. After removing duplicate apps, 204 apps remained. The default exclusion criteria were applied, after which 177 patient-centered care apps for CKD with any language were retained for analysis (Figure 1). Some apps were released on more than 1 platform simultaneously. Among these apps, 58.2% (103/177) were released on the App Store, 62.2% (110/177) on Google Play, and 35.0% (62/177) on 360 Mobile Assistant. The most common language was English (92/177, 52.0%), followed by simplified Chinese (33/177, 18.6%) and multiple languages (16/177, 9.0%). The majority of the apps (123/177, 69.5%) were free and 40.7% (72/177) required registration. A total of 148 apps were developed by non-HCP organizations. In addition, 80.2% (142/177) apps had content that referenced medical literature, and most apps included estimated glomerular filtration rate (eGFR), creatinine clearance rate (CCR), and other calculation formulas; 35 apps referenced no literature. These apps mostly provided CKD information, CKD nutrition education, self-management advice, and other functionalities. None of them were developed by HCP organizations.

Different app platforms provide users with different information regarding hosted apps. The relevant analysis is presented in Multimedia Appendix 1. On the App Store, 62 apps were free (62/103, 60.2%), and the content ratings of 47 apps were “4+.” Most apps did not have user ratings, and no installation times and privacy policies were declared on this platform. Most apps were free on Google Play (81/110, 73.6%). The content ratings for 38 apps were “high maturity” (38/110, 34.6%) and the remaining apps were rated as “3+.”

**Figure 1.** Apps exclusion chart.

Nearly half of the apps were not rated and only 4 of the apps were rated with scores of less than 3. Only 14 apps had more than 10,000 downloads, and 19 had privacy policies. All apps on 360 Mobile Assistant were free to download. A total of 35% of the apps were in simplified Chinese. The percentage of simplified Chinese apps on 360 Mobile Assistant was higher than those of App Store (25/103, 24.3%) and Google Play (1/110, 0.9%). Total downloads for most apps did not exceed 10,000. Most apps had no current rating, content rating, or privacy policy. All apps examined in this study had no descriptions of medical grade app certification issued by any government agency. A total of 7 pairs of apps suites (14 apps) had patient and HCP interoperability.

### App Content Analysis

We coded each app based on its content and functionalities and analyzed its recommended users and functionalities (Table 2). Of 177 apps, 67 apps were suitable for patients (patient apps). The most common functionalities of the patient apps were CKD information, CKD self-management, e-counseling, CKD nutrition education, and eGFR calculation. A total of 67 apps were more suitable for HCPs (HCP apps). The most common functionalities of the HCP apps were a comprehensive clinical calculation (including eGFR), provision of CKD medical professional information, stand-alone eGFR calculation, and clinical decision support for CKD. However, the designs of the decision support functionalities were mostly basic. Among the HCP apps, 7 apps contained management consultation functionality, 5 contained patient management functionality,

and only 1 contained teleconsultation functionality. A further 43 apps had main functionalities including simple eGFR calculation, CCR calculation, and CKD staging, which were suitable for both HCPs and patients.

We categorized and scored 110 patient apps based on the 10 support aspects of patient self-management for CKD (Figure 2) [21]. The highest score received was 8 (the app met 8 aspects of CKD self-management), and the lowest score was 1. Among these apps, 62 received scores ranging from 1 to 3 (56.4%), 39 apps ranged from 4 to 6 (35.5%), 8 apps scored 7 (7.3%), and only 1 app received a score of 8 (2.0%). The most common functionalities were supporting patients actively participating in health care (92/110, 83.6%), recognizing and effectively responding to symptoms (56/110, 50.9%), and disease-specific knowledge (53/110, 48.2%). Other apps were designed for managing medications (13/110, 11.8%) and engaging and sustaining social support (7/110, 6.4%). None of the apps met the maintaining social and occupational roles aspects. The detailed features of each app are listed in Multimedia Appendix 2.

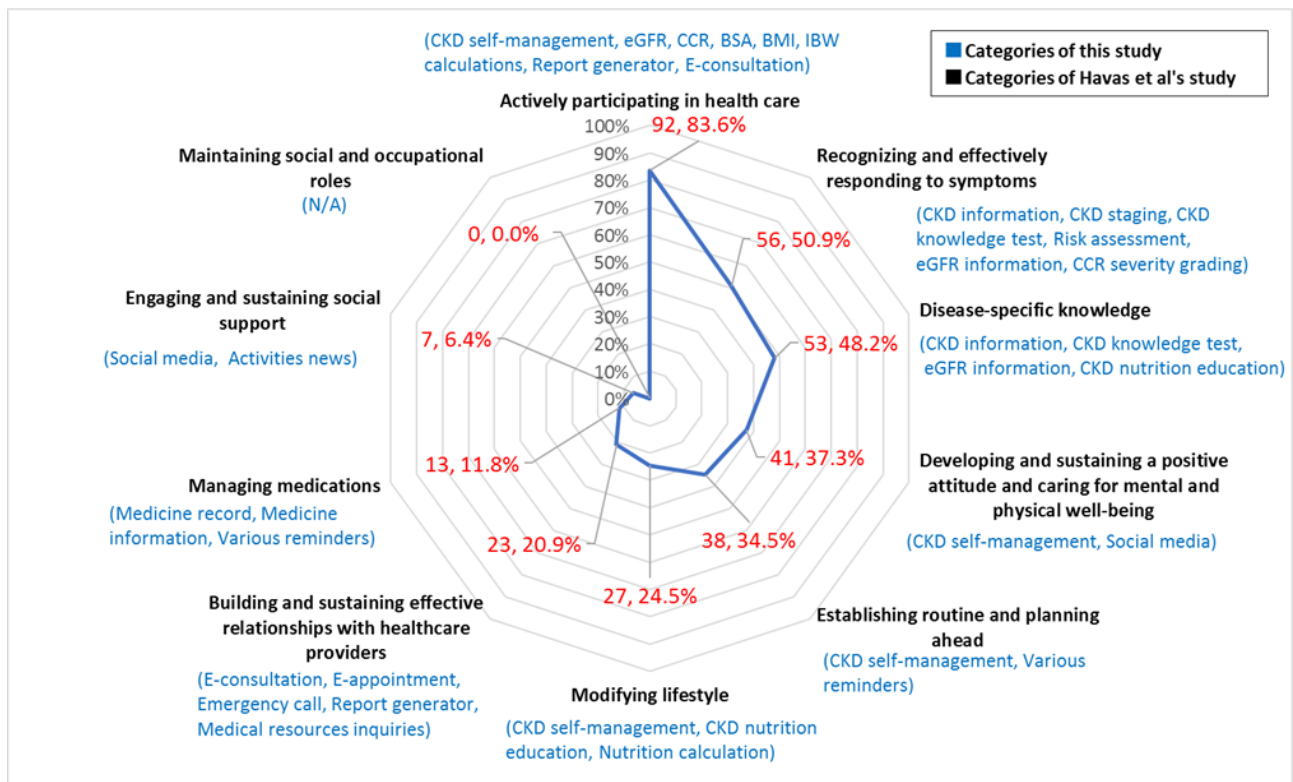
We determined that 38 patient apps provided continual recording of various data for self-management purposes. Only 7 pairs were simplified Chinese app suites (14 apps) developed by Chinese developers for both patients and HCPs that provided patient and HCP interoperability. One of the apps could be linked with wearable devices for instant monitoring of the patient's important health information such as heart rate and blood pressure for transmission back to the physician's app.

**Table 2.** Overview of the recommended users and functionalities of apps (N=177). CCR: creatinine clearance rate; CKD: chronic kidney disease; eGFR: estimated glomerular filtration rate; HCP: health care professionals.

Functionalities	Patients (N=67), n (%)	HCPs (N=67), n (%)	Both (N=43), n (%)
CKD information	38 (57)	3 (4)	1 (2)
CKD self-management	38 (57)	0 (0)	0 (0)
E-consultation	17 (25)	0 (0)	0 (0)
CKD nutrition education	16 (24)	0 (0)	1 (2)
eGFR calculation	13 (19)	14 (21)	33 (77)
E-appointment	8 (12)	0 (0)	0 (0)
Various reminders	7 (10)	0 (0)	0 (0)
Social media	6 (9)	1 (1)	0 (0)
CKD staging	5 (7)	6 (9)	10 (23)
Medicine information	3 (4)	0 (0)	0 (0)
Nutrition calculation	2 (3)	0 (0)	2 (5)
Medical resources inquiries	2 (3)	0 (0)	0 (0)
CCR calculation	1 (1)	1 (1)	11 (26)
CKD knowledge test	1 (1)	0 (0)	0 (0)
Report generator	1 (1)	0 (0)	1 (2)
Activities news	1 (1)	0 (0)	0 (0)
Risk assessment	1 (1)	3 (4)	0 (0)
Emergency call	1 (1)	0 (0)	0 (0)
Privacy management	1 (1)	0 (0)	0 (0)
Comprehensive clinical calculation (including eGFR)	0 (0)	30 (45)	0 (0)
Provision of CKD medical professional information	0 (0)	16 (24)	0 (0)
Clinical decision support for CKD	0 (0)	14 (21)	0 (0)
Consultation management	0 (0)	7 (10)	0 (0)
Patient management	0 (0)	5 (7)	0 (0)
Body surface area calculation	0 (0)	3 (4)	4 (9)
Body mass index calculation	0 (0)	2 (3)	3 (7)
Other clinical decision support	0 (0)	2 (3)	0 (0)
Appointment reminder	0 (0)	2 (3)	0 (0)
CKD evaluation	0 (0)	1 (1)	0 (0)
Provision of CKD nutritional care professional information	0 (0)	1 (1)	0 (0)
eGFR information	0 (0)	1 (1)	4 (9)
Ideal body weight calculation	0 (0)	1 (1)	4 (9)
Appointment management	0 (0)	1 (1)	0 (0)
Teleconsultation	0 (0)	1 (1)	0 (0)
CCR severity grading	0 (0)	0 (0)	1 (2)



**Figure 2.** Patient apps categories based on the 10 support aspects of chronic kidney disease (CKD) patient self-management (N=110). BMI: body mass index; BSA: body surface area; CCR: creatinine clearance rate; eGFR: estimated glomerular filtration rate; IBW: ideal body weight; N/A: not applicable.



According to the Mobile Medical Applications Guidance of the FDA [46] and the MEDDEV 2.1/6 guideline [47], this app could be governed by the FDA regulations for mobile medical apps or the regulations of the Medical Device Directive 93/42/EEC. However, the developer made no mention in the app of whether the app requires relevant certification.

### Longitudinal Analysis

After completing the baseline survey in June 2016, we conducted 3 follow-up surveys of the 177 apps to understand the loss and update frequency of such apps. We also simultaneously searched for new apps with the same keywords and analyzed the results. In December 2016, 170 apps were determined with 9 removed and 2 new released. In March 2017, 161 apps were determined with 11 removed and 2 new released. In June 2017, we reviewed the status of 165 apps updates on each platform since March 2017 and determined that 4 apps had been removed, 8 apps had been released, and 11.8% (19/161) of apps had been updated, of which 17% (14/84) of apps had been updated on the App Store and 10% (5/50) on 360 Mobile Assistant. The lowest update rate was 8.93% (10/112) on Google Play.

## Discussion

### Principal Findings

In this study, we investigated 3 mobile app platforms, the App Store, Google Play, and 360 Mobile Assistant, and found 177 patient-centered care mobile apps for CKD. Most of the apps were free and did not require registration, which can increase the willingness of users to download the apps and helps to

promote usage of patient-centered care apps for CKD. Among the platforms, Google Play provided the most categories of app information. The App Store did not provide total downloads. No content rating and little current rating information were provided on 360 Mobile Assistant. Although most apps did not require registration, many apps did, and they asked patients to provide self-management information without an adequate user privacy protection policy. Studies have demonstrated that many mobile medical apps are insufficiently safe [50,51]. Therefore, providing an adequate privacy protection policy and app security measures is critical for safeguarding users. However, neither the App Store nor 360 Mobile Assistant provided privacy announcements, and although Google Play provided this information, only 19 apps included privacy policies. Overall, the integrity of the information provided by patients to these patient-centered care apps was inadequate on each platform.

The App Store and Google Play provided content ratings, but we found that content ratings for apps with the same content on these 2 platforms were inconsistent. Some apps are released on more than 1 platform, which can increase app accessibility; however, app versions differ between platforms, providing inconsistent experiences. Zaidan and Roehrer noted that some app developers release apps on Google Play under different names but with the same content. Consequently, when users search for an app using a specific keyword, the returned apps may not meet their requirements [39]. These phenomena were revealed in this study. The gathered data indicated that app developers must enhance management of version updates, content ratings, and app naming consistency between different platforms.

Google Play was the only platform on which 14 apps were installed over 10,000 times. These apps were all related to clinical calculators (eg, eGFR, CCR, and BMI) and contained numerous medical terminologies that are usually suitable for HCPs. With training, patients can also use these apps for self-management; however, apps on all platforms usually fail to tailor themselves to the average user. According to our study, the app functionalities that apply to patients and HCPs are different. Among the 10 support aspects required for self-management of CKD [8,21], current CKD-related apps lacked not only functionalities in “modifying lifestyle,” “building and sustaining effective relationships with health care providers,” “managing medications,” and “engaging and sustaining social support” but also any functionality that met the “maintaining social and occupational roles” aspect. Maintaining social and occupational roles includes continuing to work, sustaining hobbies, maintaining relationships, and home roles. Maintaining social and occupational roles has a marked impact on health and well-being [52]. Under the pressure of a long-term battle with CKD, middle-aged patients require more support to maintain social and occupational roles. For the future development of patient self-management apps for CKD, we recommend strengthening the functionality of these aspects to meet patients’ needs and achieve patient-centered CKD care. Some studies have noted that HCPs believe the most vital aspect of patient management for CKD is to improve the coordination and referral between primary and tertiary HCPs and use a multidisciplinary team approach to improve care quality [22,23,27,31]. However, in this study, only 7 HCP apps provided consultation management functions and only 1 contained a teleconsultation function. Therefore, current HCP apps are insufficient for supporting coordination and referral between HCPs.

The core value of patient-centered continual care is the continual provision of care that meets the needs of patients. In these terms, 38 apps provided daily patient records with informational continuity. Only 5 apps were able to deliver the information directly to HCPs to provide patients with management continuity. Moreover, 2 apps could only generate reports for delivery by email or other methods. Most of the apps were based on one-way patient education. Some apps had social media features, which can provide educational, social, and emotional support through interaction between HCPs and patients. This connectivity can be crucial for maintaining relationship continuity for people with chronic diseases. No app was found to provide any shared decision-making aid, the primary feature of patient-centered care, or to support engagement for multidisciplinary HCPs and primary caregivers. These findings reveal that current apps are not designed to support continuity of patient-centered care for CKD. The relational continuity of multidisciplinary HCPs is important in patient care for CKD. Patients have different expectations of continual care depending on the type and setting of care [3]. Before designing mobile apps, designers should consider the theoretical framework, clinical situation, and expectations of different users.

Apps on 360 Mobile Assistant were all free for download, and the most common languages were English and simplified Chinese. However, these apps were not suitable for traditional

Chinese speakers. Since April 2016, many new and entirely different to former CKD-related apps have been released in China. All of these apps were developed by a hospital in collaboration with a medical device or app developer, were released with corresponding patient and HCP apps, required registration, included iOS and Android versions, and were simultaneously released on the App Store and 360 Mobile Assistant. This reveals China has attached increasing importance to the development of CKD-related apps. However, we found that some apps developed in China provided comprehensive CKD knowledge without describing the reference resources. Other researchers have also raised similar observations in mobile apps for cardiovascular disease in China [49,53]. Although some of these apps seem to provide information or advice regarding diagnosis, prognosis, monitoring, and treatment for HCPs and patients, none of the apps state in their introduction whether their function meets the definition of a medical device. We recommend that once the functionality and usage of an app fell into the scope of medical devices or in vitro diagnostic devices [46], it should be developed in accordance with the MEDDEV 2.1/6 guidelines and adhered to the requirements of EU Directive 93/42/EEC on medical devices [47]. Apps should have clear explanations regarding their medical device status in introductions on app platforms.

Larsen et al conducted a longitudinal study of mental health apps; they noted that 50% of apps change after 4 months and 1 app is removed every 2.9 days [44]. In this study’s follow-up analysis conducted in June 2017, the update rate of all apps was 11.8% (19/161) over 4 months. Moreover, 4 apps were removed from listings and 8 new apps were added. The frequency of change was much lower than that found by Larson et al for mental health apps. We also noted that 26 patient apps (23.64%) were single-function designs with high homogeneity, especially those apps that supported calculations such as eGFR and CCR. These apps usually refer to fixed formulas (eg, Cockcroft-Gault and Modification of Diet in Renal Disease) and simply alter the user interface. Because the functionality is simple and fixed, the frequency of updates is low. Apps with higher update frequency are mostly associated with CKD information for HCPs. Due to the frequency with which medical evidence is updated, updates occurred more often. In addition, apps related to self-management of CKD patients, such as CKD information, CKD nutrition education, and CKD self-management, were mostly developed by non-HCP organizations without statements of evidence-based references. This suggests that, although current apps related to self-management of CKD patients may have some self-managing functionalities, helping patient self-management without applying evidence-based medicine is prevalent. In the future, developers should apply evidence-based medicine when designing a patient-centered holistic solution for CKD.

## Limitations

This research was based on the public information provided by each platform. Therefore, we were unable to directly connect to users’ data to further understand their specific situations. We searched the 3 app platforms as thoroughly as possible to complete the baseline survey; however, due to rapid changes in the app platforms, we were unable to guarantee that no app

was missed in the baseline survey. In addition, we only investigated and analyzed apps released on the App Store, Google Play, and 360 Mobile Assistant. We did not explore apps released on other channels, such as websites. We were also unable to determine how many apps released on other channels. Because comparing the quality of apps with different functionalities is complicated, we focused on exploring the functionalities of apps without judging the mobile app quality.

## Conclusions

In this study, we determined that the majority of patient-centered care mobile apps for CKD on popular app platforms contain calculation functions with one or more indicators. These popular

app platforms do not provide sufficient information or medical evidence to help users choose apps. Currently, CKD-related mobile health apps have insufficient functionalities for both patient self-management and HCP management of patient care. A holistic solution is required that considers disease characteristics based on theoretical frameworks, clinical situations, and the needs of different users to enhance the continuity of patient-centered care. Furthermore, developers should follow uniform policies or regulatory standards from various internationally recognized organizations to ensure that apps meet the criteria of a medical device or in vitro diagnostic equipment; moreover, detailed descriptions should be provided for all apps.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Overview of mobile chronic kidney disease (CKD) patient-centered care related apps (N=177).

[[PDF File \(Adobe PDF File\), 171KB - mhealth\\_v6i4e10173\\_app1.pdf](#)]

## Multimedia Appendix 2

List of detailed features for each app.

[[PDF File \(Adobe PDF File\), 449KB - mhealth\\_v6i4e10173\\_app2.pdf](#)]

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## Abbreviations

- BMI:** creatinine clearance rate
- BSA:** body surface area
- CCR:** creatinine clearance rate
- CKD:** chronic kidney disease
- eGFR:** estimated glomerular filtration rate
- FDA:** US Food and Drug Administration
- HCP:** health care professional
- IBW:** ideal body weight

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Original Paper

# Relevance of Trust Marks and CE Labels in German-Language Store Descriptions of Health Apps: Analysis

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## Abstract

**Background:** In addition to mandatory CE marking (“CE” representing *Conformité Européenne*, with the CE marking being a symbol of free marketability in the European Economic Area) for medical devices, there are various seals, initiatives, action groups, etc, in the health app context. However, whether manufacturers use them to distinguish their apps and attach relevance to them is unclear.

**Objective:** The objective was to take a snapshot of quality seals, regulatory marks, and other orientation aids available on the German app market and to determine whether manufacturers deem such labels relevant enough to apply them to their apps, namely as reflected by mentions in app description texts in a typical app store (ie, Apple’s App Store).

**Methods:** A full survey of the metadata of 103,046 apps from Apple’s German App Store in the Medicine and Health & Fitness categories was carried out. For apps with German-language store descriptions (N=8767), these were automatically searched for the occurrence of relevant keywords and validated manually (N=41). In addition, the websites of various app seal providers were checked for assigned seals.

**Results:** Few manufacturers referenced seals in the descriptions (5/41), although this would have been expected more often based on the seals we were able to identify from the seal providers’ Web pages, and there were 34 of 41 that mentioned CE status in the descriptions. Two apps referenced an app directory curated by experts; however, this is not an alternative to CE marks and seals of approval.

**Conclusions:** Currently, quality seals seem to be irrelevant for manufacturers. In line with regulatory requirements, mentions of medical device status are more frequent; however, neither characteristic is effective for identifying high-quality apps. To improve this situation, a possibly legally obligatory, standardized reporting system should be implemented.

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## KEYWORDS

mobile phone; mobile health app; quality assessment; quality seals; medical device regulation

## Introduction

Calls for clear labels reflecting “quality” aspects of health-related apps are becoming ever louder in the medical community [1]. Such labels are intended to provide interested laypersons as well as professionals with a quick and easy way to identify apps with an adequate level of quality for use on their mobile phones or tablets, which is not an easy task considering the highly dynamic, borderless, and largely

unregulated nature of the app market [2-4]. The demand is justified; often, it is a challenge for users to make a decision to use an app or to refrain from doing so because provided information is limited in many cases. Although it is already difficult to identify an app having the desired features among the often large variety of those available, assessing whether an app is a high-quality product poses an even greater challenge. For health experts, content-related assessments are often unproblematic, but when technical aspects, data protection, and data security come into play, they are often out of their depth

as well. Carrying out such assessments in an adequate manner requires not only knowledge and experience, but is often time consuming and technically demanding. If reliable, seals of approval and other marks of quality have the potential to simplify the situation for users because they hold the promise of an in-depth (quality-related) inspection by independent third parties that users can base their decisions on. Driven by these demands, quality seals are increasingly being offered and a new business field appears to be establishing itself. Various commercial and institutional initiatives are trying to meet the demand.

This paper is dedicated to the question of whether quality seals, regulatory marks, and other orientation aids are available on the market and, if so, which ones are available and do they (and how often) appear in the app context and to what extent are they being used in the app description texts of a typical app store (ie, Apple's App Store). Subsequently, the relevance of quality seals and CE markings ("CE" representing *Conformité Européenne*, with the CE marking being a symbol of free marketability in the European Economic Area) will be discussed on the basis of the results. For the initial assessment of the situation, we focused on apps listed in Apple's German storefront as well as quality seals relevant to the German or European market.

## Methods

### Overview

To answer the aforementioned questions, a two-stage process was used. First, relevant quality seals and corresponding keywords were identified. These were then applied to the metadata of the full set of apps listed within the Health & Fitness as well as Medicine categories of Apple's App Store on a specific date to determine whether and how often manufacturers reference quality labels within the information they provide. The composition and frequency of the quality labeling of apps is then described to what degree they are actually used.

### Search Strategy for Identifying App Seals

Official test institutions specializing in health-related apps and their specific requirements, standardized and (universally) accepted testing procedures, or registers that list various approaches applicable in a health context are rare. Ultimately, this is not surprising because regulations—and, therefore, obligatory testing of quality- and transparency-related aspects—only apply to a limited subset of apps on the market. For unregulated apps, a number of private institutions and initiatives try to step in by providing various quality marks and orientation guidelines, but similar to the seemingly chaotic manner in which apps are presented in the stores, potential approaches—and the quality of their evaluation processes—are equally confusing for end users.

Our assessment of seals, orientation guidelines, or similar approaches mentioned by manufacturers was based on relevant key terms we found based on searches within the literature (PubMed, IEEE, and Scopus) as well as other online media (internet). In addition, we also included our own previous work to identify relevant key terms [5,6].

### Acquisition of Apps Listed Within the Health & Fitness and Medicine Categories

In the first step, an initial list of apps—or, to be more precise, their names and numeric IDs—listed in two categories, namely Medicine and Health & Fitness of the German Apple App Store, was acquired using R-based scripts [7] by parsing the Web pages for both categories. Using these scripts, on February 5, 2018, it was possible to read information (app names and unique identifiers) for 103,046 apps listed in the two categories. The readout of the corresponding meta-information was done in a second step and took place between February 5, 2018 and February 6, 2018. Again, R-based scripts, this time using the iTunes search application programming interface provided by the App Store provider were used to retrieve the meta-information for the initially acquired app list based on the previously acquired unique identifiers. The acquired data were stored in an SQLite-based database for further analysis.

### Semiautomatic Retrospective App Store Analysis

For analyzing the data acquired for the apps of the two target categories, a newly developed method for semiautomatic retrospective App Store analysis ("SARASA" for future reference) was used (details are to be published soon). The method provides a step-by-step filtering of apps by formal criteria. In addition to keyword searches (with the use of Boolean operators where desired), it also allows for differentiation by factors deduced from the original information (eg, automatically determined language and text complexity of app store descriptions, topic analyses). Using the semiautomatic retrospective App Store analysis, the intermediate and final results of the filter process can be presented in descriptive form and, if desired, in a graphical manner as well. At the end of an analysis according to the semiautomatic retrospective App Store analysis filter scheme, there is a selection of apps that can then be manually validated. For data used in this case, this evaluation was performed by the authors based on further formal criteria. There was only a single initial disagreement relating to one app that ambiguously stated conformity to medical device regulation in its store description. This app was finally found not to be a medical device itself, but rather to have the sole purpose of providing information about a medical device to be used in the context of fertility tracking. The problem was easily resolved based on the facts determined using additional Web-based searches (Google) and the app was excluded from further analysis.

### Formal Inclusion Criteria

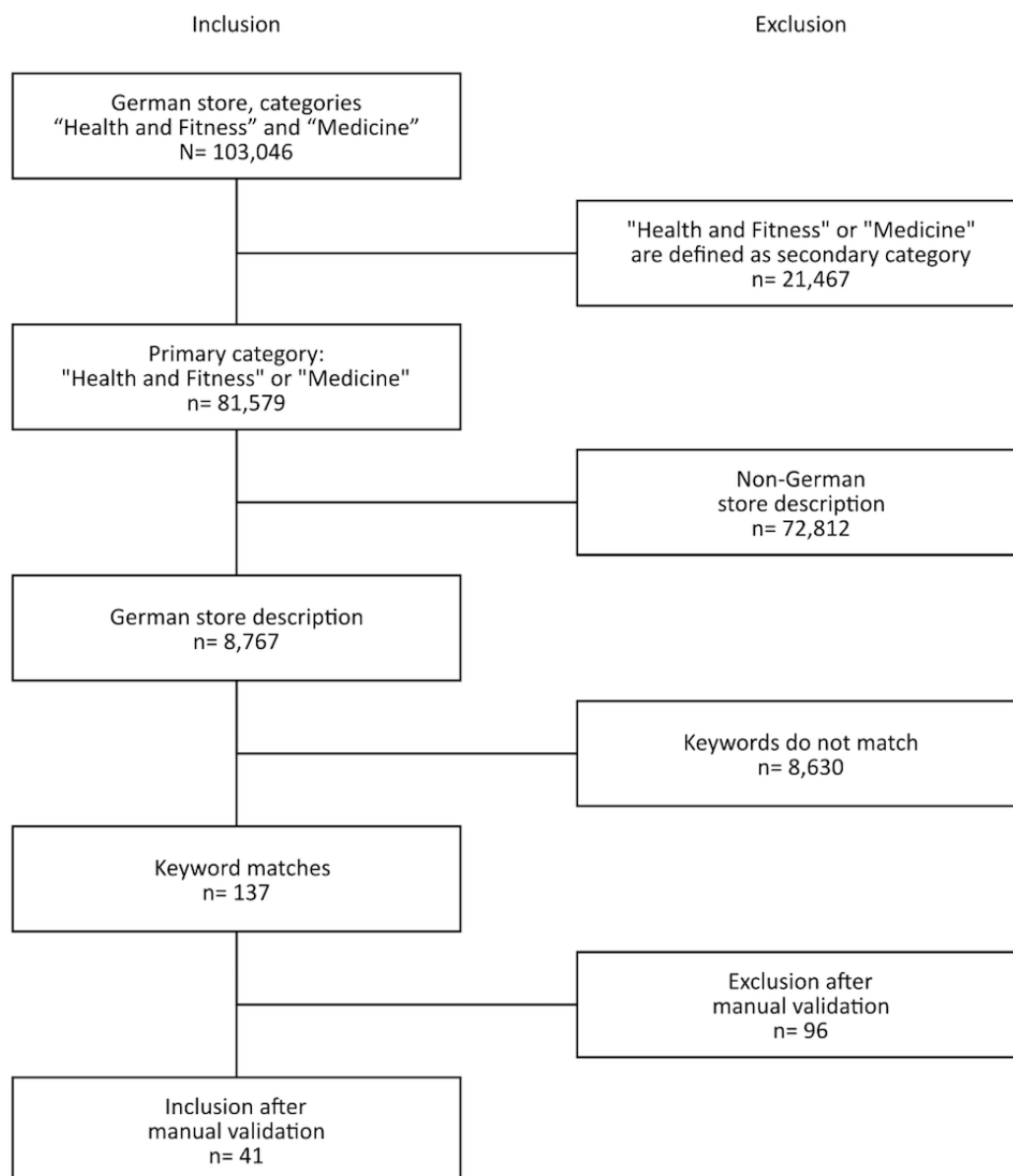
Only the apps from Apple's German App Store, whose primary category was Medicine or Health & Fitness, and whose descriptions were written in German and contained predefined keywords (see [Textbox 1](#)) were included in the study; apps with store descriptions in languages other than German were not included. This may have caused exclusion of some multilingual apps with a German interface that were missing a translation in the store description. Apps that were only assigned to the two categories via their secondary category were not included in this analysis ([Figure 1](#)).



**Textbox 1.** Keywords used to identify matching apps via their store descriptions, stratified by “labeled medical device,” “seal of approval / quality seal,” and “other.”

<p><b>Labeled medical device</b></p> <p>Keywords: Medizinprodukt; medical device; CE-; CE mark; CE label; 93/42/; 2017/745; Medical device directive; MDD; Medical Device Regulation; MDR</p> <p><b>Seal of approval / quality seal</b></p> <p>Keywords: Siegel; Prüfzeichen; Ehrenkodex; Trusted App; AppCheck; Qualitätsprodukt Internetmedizin; Qualität durch Transparenz; Geprüfte App; EuroPrisSe; Privacy Seal; mWellth-Certificate; SocialWellth; eprivacy; Health On the Net; HealthOn; mediatest digital; TÜV; DiaDigital; Diabetes-App-Siegel; Zentrum für Telematik und Telemedizin GmbH; ZTG; Stiftung Warentest; Bundesverband Internetmedizin; BIM; aktionsforum gesundheitsinformationssystem; afgis; Happtique; tekit Consult Bonn; mWellth; app-quality.com; Appquality-Alliance</p> <p><b>Other</b></p> <p>Keywords: Kodex; Privacy Code of Conduct; HONcode; HON-code; Quality Alliance; AQUA; Medical App Journal; JMIR mHealth peer review; Journal of Medical Internet Research; JMIR; JMU; iMedicalApps.com; MyHealthApps; European Directory of Health Apps; App Script; NHS Health Apps Library; Myhealthapps.net; App Chronic Disease Checklist; ACDC; Mobile Application Rating Scale; MARS; User Version of Mobile Application Rating Scale; uMARS; ClassifyDroid; Mobile Apps Assessment and Analysis System; MARS; interactive Mobile App Review Toolkit; IMART; App-Synops; Zertifikat; BfDI</p>
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**Figure 1.** Flowchart of the inclusion and exclusion of apps acquired on February 5, 2018. N=41 apps were finally available.



## Search Strategy for Identifying Matches Within the Store Descriptions

Of the 103,046 apps with German-language description texts (N=8767, with the language used within the texts automatically identified using the `clld2` package in R, which provides an interface to Google's C++-based "Compact Language Detector 2" library), the keywords listed in [Textbox 1](#) were used to identify potentially relevant apps. To not miss out on any

possible matches, a case-insensitive search process was applied for defined terms or spelled-out names of initiatives, seals, orientation guidelines, checklists, or similar. However, case sensitivity was required for matching acronyms. The description texts of the apps identified in this manner were then manually checked for plausibility. For example, apps that explicitly stated that they are "not a medical device" or used any other phrasing within their descriptions precluding use as a medical device were marked separately.

**Table 1.** Types and numbers of seals identified from the Web search (stratified by primary category).

Seal of approval / quality seal	Provider	Labels/seals assigned to health-related apps as specified on the providers' Web pages (N=100)	Corresponding apps found within the store (N=52)	App category		
				H&F <sup>a</sup> (n=10)	Medicine (n=31)	H&F and Medicine (n=41)
AppCheck [8]	Zentrum für Telematik und Telemedizin GmbH; ZTG	36	15	0	0	0
CE-Kennzeichnung / CE-mark (various databases, the German DB can be found in [9])	Responsible notified body	39	20	7 <sup>b</sup>	27 <sup>c</sup>	34
CheckYourApp [10]	MIASEC GmbH	Seals not listed, but can be researched by app name.	N/A <sup>d</sup>	0	0	0
Diabetes-App-Siegel [11]	DiaDigital der AG Diabetes und Technologie der Deutschen Diabetes Gesellschaft e.V.	5	5	0	0	0
eprivacyseal; ePrivacyApp [12]	ePrivacy GmbH	5	4	1	0	1
EuroPriSe European Privacy Seal [13]	EuroPriSe GmbH	Apps not listed separately	N/A	0	0	0
HealthOn-Siegel [14]	HealthOn	11	6	0	2	2
HONcode [15]	Health On the Net Foundation	Unpublished	N/A	0	0	0
Test [16]	Stiftung Warentest	Apps not listed separately but as parts of various test reports	N/A	1	0	1
Trusted App [17]	mediaTestdigital GmbH	4	2	1	0	1
TÜV SÜD Software-Prüfzeichen [18]	TÜV Süd Produkt Service GmbH	Unpublished	N/A	0	0	0
Qualität durch Transparenz; afgis-Qualitätslogo [19]	aktionsforum gesundheitsinformationssystem afgis e.V.	Unpublished	N/A	0	0	0
Qualitätsprodukt Internetmedizin [20]	Bundesverband Internetmedizin BIM e.V.	Unpublished	N/A	0	0	0
Other	Other	Unclear	N/A	0	2	2

<sup>a</sup>Health and Fitness.

<sup>b</sup>For 6 of 7 CE-marked Health & Fitness apps, we were able to confirm class I either from statements by the manufacturers themselves or from information listed in the DIMDI (Deutsches Institut für Medizinische Dokumentation und Information [German Institute of Medical Documentation and Information]) database. For the remaining app, we were unable to determine its class, but suspect it to belong to class I as well (due to its functionality).

<sup>c</sup>Of the 27 CE-marked apps listed in the Medicine category, 17 apps were specified as class I, 1 app as class Im, 6 apps as class IIa, 2 apps as class IIb, and for one app, we were unable to determine its class, but again suspect it to be of class I due to its functionality.

<sup>d</sup>Not available or not applicable.

## Identification of Apps With Definite Seal Assignments

As an additional validation step, we also checked for a relationship between the seals actually awarded by various initiatives active in this business and their actual mention by manufacturers within the App Store descriptions. This was intended to counteract a potential bias caused by apps that are mentioned by the initiatives, but are either not (or no longer) listed in the App Store or simply fail to mention the respective seal within their descriptions. For this purpose, the publicly available app information provided by the initiatives/providers (namely app and manufacturer names as listed on the initiatives' Web pages on February 7, 2018) was used and apps identified in this manner were deemed as having their "seal status" validated (Table 1). The acquired information included names, providers, and URLs of the labels or seals, as well as the number of apps listed. Based on the store descriptions, the number of apps that stated to be using the respective seal or label were recorded as well.

## Results

There were a number of quality marks and initiatives that deal with the testing and evaluation of apps and general health information. We counted 13 individual seals in our search, and the organizational character (eg, public or private sector, corporate form) of those providing these seals varied greatly (Table 1). There were also various differences in the objectives and methods of the offers, which have been described in detail elsewhere [6,21] and are therefore not the subject of this work. These mostly related to what the evaluation process focused on (eg, content validation, technical aspects, and information security/data protection as well as usability or any combinations thereof), but differences were also attributable to how those initiating the evaluation were organized or financed (eg, private initiatives, patient organizations, commercial offers) and who was recruited for performing the evaluation (eg, patients/laypersons, medical or technical experts).

There was little evidence that the manufacturers and vendors made use of references to any seals or quality-related marks and reported on them in the descriptions they provided for their apps. In total, only for 41 of 8767 apps (all German-language apps with their primary category being either Health & Fitness or Medicine; Figure 1) were there any mentions of any type of quality label (0.47%). The largest proportion of these (34/41) were apps with medical device status (CE mark). Of these 34, seven were in the Health & Fitness category and 27 in the Medicine category. Only five of 41 had been awarded nongovernmental quality seals or labels, three in the Health & Fitness category and two in the Medicine category. For two of 41 apps, there was a reference to an app directory curated by experts. We found no apps that were labeled as medical devices and also carried a seal of approval. For four apps found in the Medicine category as well as four additional apps in the Health & Fitness category, medical device status was expressly excluded.

With respect to app demographics (Table 2), the 41 apps significantly differed from the total group of apps with German descriptions with respect to the time that had passed since the last update (Wilcoxon rank sum test for unpaired samples, two-sided, confidence level 95%,  $U=237,440$ ,  $P<.001$ ) and in the length of their store descriptions ( $U=84,360$ ,  $P<.001$ ). However, for overall age, app size, price, and star ratings, differences were insignificant. A more in-depth analysis of other app characteristics associated with assigning a quality label will be part of further work and will be discussed in detail then. To ascertain that we did not inadvertently miss any apps by restricting our app selection to apps listed with primary categories of either Health & Fitness or Medicine, the keyword-based search was also applied to the other apps with a German description. However, there was only one Health & Fitness app (primary category "Sport") that mentioned a medical device certification and another one that explicitly excluded medical device status. There were no additional mentions of relevant seals or similar markings.

The surprisingly low number of seals mentioned in our data led us to consider checking the relationship between seals officially awarded by the initiatives (as designated by information on the websites of the respective seal providers) and their actual mention by manufactures in the App Store descriptions. This was done to rule out that our keywords were insufficient to find seals that were assigned. However, this concern was unfounded, as out of 100 apps we identified as being officially allowed to use a seal based on the information published by the seal providers, there were still only 41 matches also found on the App Store, even when allowing for slightly different spellings (eg, missing whitespaces, differing capitalization) of the names of the manufacturer and apps (41%, 41/100; Table 1). In addition to apps sometimes being withdrawn from the App Store for no obvious reasons, this may also be due to apps being renamed, takeovers of manufacturers by other companies and subsequent retraction of the apps from the store, etc. Evidently, such events are either not appropriately communicated to the initiatives that assigned a specific seal to the respective app or the initiatives themselves fail to update their register of apps carrying that specific seal on a regular basis (eg, every half year or annually), resulting in apps that are no longer available on the market still being included.

In our evaluation, we made sure that the apps we identified on the Web pages of the initiatives were listed on Apple's App Store or additionally on Google's Play Store. Only slightly more than one-third of the "seal carrying apps" identified from the Web pages of the seal providing initiatives could be found on Apple's App Store. The identified apps were accepted as a sample of apps "assuredly carrying a seal or other quality mark," which is by no means reflected in the app descriptions. As mentioned previously, only for 41 of 8767 (0.47%) apps were there any references to one of the previously identified seals within the app descriptions listed on Apple's App Store.

**Table 2.** App demographics for apps with a primary category of either Medicine or Health & Fitness and German-language store descriptions (N=8767) as well as for the manually validated (N=41) apps.

App demographic	All apps with German-language store descriptions and primary category Medicine or Health & Fitness (N=8768), median (IQR)	Manually validated apps (N=41), median (IQR)	U value <sup>a</sup>	P value
Overall age (months)	30.74 (33.21)	28.14 (32.84)	N/A <sup>b</sup>	N/A
Time since last update (months)	9.48 (20.68)	3.62 (12.92)	237,440	<.001
Size (MB)	28.08 (37.57)	30.29 (46.22)	N/A	N/A
Price (€; paid apps only)	2.29 (2.5) <sup>c</sup> for n=1706 paid apps	3 paid apps (5.99, 43.99, and 69.99)	N/A	N/A
Length of description (characters)	922 (1419.5)	2352 (1610)	84,360	<.001
Average rating (current version; stars)	4.5 (2) for n=2841 rated apps	4 (1.75) for n=26 rated apps	N/A	N/A
Average rating (all versions; stars)	4 (2) for n=3287 rated apps	4 (1) for n=27 rated apps	N/A	N/A

<sup>a</sup>Wilcoxon rank sum test where applicable.

<sup>b</sup>N/A: not applicable. Differences between both groups were descriptively too small to warrant testing.

<sup>c</sup>Price range: €0.49 to €99.99.

Surprisingly, it was not the quality seals but the CE marking that was most often mentioned within the app descriptions (Table 1); for a total number of 34 apps, manufacturers declared their app to be a medical device. Based on a previously performed search in the databases of the German DIMDI (Deutsches Institut für Medizinische Dokumentation und Information [German Institute of Medical Documentation and Information], responsible for the official German register of medical products), we initially expected to find just 20 German-language apps with CE markings on the store. However, we found that the 14 additional apps we had identified via the information contained in the store descriptions were registered in other European countries and were therefore not part of the DIMDI dataset.

Our investigation also showed that the number of apps that were explicitly mentioned as not being a medical device exceeded the number of apps for which there was a reference to quality-related seals or labels. Medical device status was explicitly excluded eight times in total (which we believe to be valid based on the information given in the respective store descriptions), and there were only five references to seals or labels (Table 1). Two apps only referred to being listed on a website curated by experts, which although possibly being an alternative, may or may not provide users with the same level of confidence about quality as CE markings or established quality seals.

## Discussion

### Principal Findings

The aim of this study was to provide an up-to-date overview of how official regulatory markings for medical devices, namely the CE marking applicable in Europe, and marks supposedly designating quality (eg, quality seals) are used in apps found on the market. For this, we determined how often these are mentioned in German-language store descriptions of individual apps in the German storefront of Apple's App Store, with primary categories being specified as either Health & Fitness

or Medicine. This was done to investigate whether manufacturers prefer to publish apps that are subject to official regulation (due to their functionality) or whether they would rather limit themselves to apps that do not contain functions requiring adherence to medical device regulations and for which quality seals would therefore be sufficient. App characteristics were also factored in to narrow down potential reasons for either alternative being preferred.

The small number of health-related labels or seals being mentioned (5 of 8767 apps with a German description and primary category of Medicine or Health & Fitness, 0.06%) is somewhat astonishing because, apart from the mandatory CE marking for medical devices, which is required by regulation, these are low-threshold and relatively easy to apply options that may especially be relevant for nonmedical products and can be used for advertising purposes. However, manufacturers and providers seem to attach little importance to them. Reasons may be similar to those often given with respect to quality seals for websites, which are also used less frequently than expected. Here too, seals of approval are fairly unknown, although there are many different seals that are potentially applicable in this context. Wetter [22] suspects that it is this considerable number of seals (and the different approaches they stand for) as well as the resulting competition among seal-awarding authorities that confuses those who have to decide which seal to apply for. The decision whether to apply for a seal or certification or to pursue another strategy to convince users of a product's quality remains open [22]. Whether quality seals assigned to websites actually give an indication of quality is also controversial. As was already shown by Keselman et al in 2008 [23], there is not always a connection between defined quality criteria being fulfilled and websites providing accurate content, and the same probably holds true in an app context. Therefore, it would be understandable if, especially for apps that are deemed medical devices, manufacturers and providers were to concentrate on advertising CE markings rather than quality seals, presumably also because this is already deemed sufficient with respect to marketing considerations in this context.

In addition, for health apps, the concept of “quality” still needs to be discussed and there are several dimensions to consider. Beyond the perception of quality by users and how this perceived quality influences decisions to purchase and install apps within the secondary health care market, manufacturers are aware that obtaining a CE marking significantly increases (or is presumed to increase) chances of entering the primary (and insurer-paid) health care market. However, although CE markings are often regarded as a quality feature, one needs to remember that they are representations of manufacturers following regulatory requirements, which is the basis for being allowed to market medical products (market harmonization), rather than labels representing a product’s actual quality [24,25]. As a rule, a detailed quality check, which many users may expect, does not take place in this context. However, it can be stated that the conformity assessment procedure is at least transparent in its requirements and thus provides more information about what is to be expected than is the case with some providers of quality seals.

It may also be possible that the financial and time expenditure involved in obtaining a seal or other quality approval is an obstacle [26,27]. For apps for which this is a requirement, following regulation is just as time consuming and costly, and obtaining a seal is voluntary and may thus be foregone if manufacturers perceive no obvious benefit. Possibly, the fees (usually in the range of several hundred to several thousand Euros) often required for developers to be able to obtain these seals or approvals for their apps may be a deterrent as well; some are available for free, but others require either a one-time, monthly, or yearly fee or (paid) membership in an organization, which may be perceived as a continuing burden especially for apps with limited potential for commercial success. However, there are some measures that may hold much lower thresholds for manufacturers while aiding potential users in their decisions. To provide future users with low-threshold, cost-neutral support, it would be conceivable to produce meaningful descriptions following a standardized structure that covers relevant information (eg, about sources used for implementing the app, qualifications of those involved) rather than only providing marketing phrases. We already previously published drafts for such standardized app reporting [28,29], which would also cover CE markings, quality seals, or results of any other tests and/or studies possibly performed. This approach would provide users with relevant information they need to make purchase decisions and it would not be an undue burden—sometimes mentioned in the literature [30]—on developers because they should have the corresponding information at their fingertips. Making such standardized reporting obligatory (albeit without regularly performed mandatory checks by official bodies), similar to what is currently required with respect to an imprint [21,31-33], should certainly be discussed by all stakeholders. This would ensure that users are provided with relevant information before downloading. Even if some items were only listed as “information unavailable,” users would benefit from not having to invest too much effort to determine this.

### Limitations

Our study was subject to the following limitations. Our focus was specifically on the German-speaking region, reflected by

the evaluation of apps for which German-language store descriptions had been provided. We also considered only quality initiatives and regulatory approaches relevant in the German-speaking regions, and we had to limit ourselves to app registrations found in the DIMDI database due to the fees required for searching in other regulatory databases. For the future, with the introduction and adoption of unique device identifiers and the European Database on Medical devices, as required under medical device regulation, it will henceforth become easier to assess all medical devices, including apps, placed on the European market. Ongoing work, to be published later, also considers regulatory requirements (eg, US Food and Drug Administration approval) as well as seals found internationally to determine whether there are significant differences between geographic regions. Also, there is currently no legal obligation to publish information about following regulation (eg, medical device related) within the store descriptions and because our evaluation was solely based on the information provided here, we may have missed some apps only mentioning adherence to regulation within the apps themselves and/or on related Web pages and manuals, which we did not evaluate.

Even though considerable effort was made to identify existing quality-related seals with a special focus on applicability in a health context, it cannot be ruled out that there are possible, probably recently established, initiatives we did not find. Also, the seal providers’ Web pages are often not conducive for identifying seals that have been assigned to apps. Of course, seal providers are also called on to not only publish information about what they offer but also to ensure that this information can be found using relevant search engines. They should also take care to keep their information about validated apps up to date.

In addition, we only used the description texts of the apps for our keyword-based searches. No statements can be made on the basis of this information about whether this actually reflects the information provided within the apps themselves or elsewhere. Another limitation of the work is its limitation to one single app store. Therefore, it remains to be seen whether our result can also be reproduced for other app stores (eg, Google’s Play Store).

### Conclusions

The prevalence of labels in App Store descriptions is negligible. Therefore, it is reasonable to assume that these are not of any noteworthy relevance for manufacturers when it comes to providing information and promoting their products. Only medical device designations are communicated regularly and in full, which does take account of the regulatory necessity, but also helps with differentiating them from other nonregulated and labeled products in terms of advertising effectiveness. To improve the quality-related information provided in the stores, a standardized reporting process used for compiling the app description text is recommended. A legal obligation to do so would contribute to the effective enforcement of appropriate information.

## Conflicts of Interest

None declared.

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## Abbreviations

**CE:** Conformité Européenne

**DIMDI:** Deutsches Institut für Medizinische Dokumentation und Information [German Institute of Medical Documentation and Information]

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Original Paper

# Interactive Two-Way mHealth Interventions for Improving Medication Adherence: An Evaluation Using The Behaviour Change Wheel Framework

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## Abstract

**Background:** Medication adherence is an important but highly complex set of behaviors, which for life-threatening and infectious diseases such as HIV carry critical consequences for individual and public health. There is growing evidence that mobile phone text messaging interventions (mHealth) connecting providers with patients positively impact medication adherence, particularly *two-way* engagement platforms that require bidirectional communication versus *one-way* in which responses are not mandatory. However, mechanisms of action have not been well defined. The Behavior Change Wheel is a comprehensive framework for behavior change that includes an all-encompassing model of behavior known as Capability Opportunity Motivation-Behavior and is complemented by a taxonomy of behavior change techniques. Evaluating mHealth interventions for medication adherence using these tools could provide useful insights that may contribute to optimizing their integration into the healthcare system and successful scaling-up.

**Objective:** This study aimed to help address the current knowledge gap regarding how two-way mHealth interventions for medication adherence may work by applying the Behavior Change Wheel to characterize WelTel: an interactive digital health outreach platform with robust evidence for improving adherence to antiretroviral therapy.

**Methods:** To characterize how WelTel may promote medication adherence, we applied the Behavior Change Wheel to systematically (1) generate a *behavioral diagnosis* through mapping known antiretroviral therapy adherence barriers onto the Capability Opportunity Motivation-Behavior model of behavior, (2) specify the behavior change techniques that WelTel delivers, (3) link identified behavior change techniques to corresponding intervention functions of the Behavior Change Wheel, and (4) connect these behavior change techniques and intervention functions to respective Capability Opportunity Motivation-Behavior influences on behavior to determine potential mechanisms of action.

**Results:** Our evaluation of WelTel using the Behavior Change Wheel suggests that most of its impact is delivered primarily through its personalized communication component, in which 8 different behavior change techniques were identified and linked with 5 intervention functions (environmental restructuring, enablement, education, persuasion, and training). Its mechanisms of action in promoting antiretroviral therapy adherence may involve addressing all Capability Opportunity Motivation-Behavior influences on behavior (physical and psychological capability, physical and social opportunity, reflective and automatic motivation).

**Conclusions:** Systematically unpacking the potential active ingredients of effective interventions facilitates the creation and implementation of more parsimonious, tailored, and targeted approaches. Evaluating WelTel using the Behavior Change Wheel



has provided valuable insights into how and why such interactive two-way mHealth interventions may produce greater impact than one-way in addressing both nonintentional and intentional forms of nonadherence. The application of the Behavior Change Wheel for evidence synthesis across mHealth interventions targeting various conditions would contribute to strengthening the knowledge base regarding how they may work to impact medication adherence behavior.

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## KEYWORDS

mHealth; chronic disease; medication adherence; primary health care; disease management

## Introduction

### Medication Adherence Is a Significant Global Challenge

In chronic disease management worldwide, only 50% of patients on average adhere to their prescribed long-term therapies [1]. Medication adherence is an important, but highly complex set of behaviors, which for life-threatening and infectious diseases such as HIV carry critical consequences for individual and public health. Adherence to antiretroviral therapy (ART) for people living with HIV combats chronic infection through viral suppression, optimizes an individual's immune recovery, mitigates drug resistance, and reduces odds of viral transmission [2-4]. Viral suppression achieved through adherence is essential for achieving global "90-90-90" targets declared by the Joint United Nations Programme on HIV/AIDS: by 2020, 90% of all people living with HIV will know their status, 90% of all people diagnosed as HIV-positive will receive uninterrupted ART, and 90% of all people taking ART will achieve viral suppression [5]. However, suboptimal ART adherence is not uncommon, and realizing the full benefits of ART requires considerable effort for many [6]. Concerted efforts over the past two decades have been geared toward specifying effective interventions for ART adherence globally [6,7]; however, efforts to distill active intervention ingredients remain largely absent. Given that medication adherence is often subject to multilevel influences beyond the individual, investigating mechanisms of action through which interventions may promote this behavior facilitates the delivery of systematically created and targeted approaches. Understanding and specifying the potential underlying mechanisms behind effective interventions is critical for design improvement and successful wide-scale implementation.

### Certain mHealth Interventions may Offer a Solution

Mobile phone interventions for promoting health (mHealth) are becoming increasingly available, and several interventions aim to improve medication adherence across various disease states [8,9]. Among people living with HIV, the World Health Organization recognizes text messaging in their current guidelines as an evidence-based intervention for encouraging ART adherence [10]. However, no distinction has been made between the various types of applications that exist. In particular, *two-way* versus *one-way* engagement platforms are significantly different from each other; the former implies an expectation of patient-provider communication, whereas the latter simply prompts reminders and instructions without mandatory patient

feedback. Two-way text messaging is thought to be more effective compared with one-way for inducing ART adherence, and this distinction has important implications on the usage of text messaging for chronic disease management [9,11]. Policy makers in control of health care expenditure may attempt to promote cost saving through spacing clinic visits further apart; therefore, interactive mHealth interventions potentially offer cost-effective and essential touch points between these visits to keep patients engaged in care [12]. In addition, they may prompt the self-management of issues as they occur in a timely manner. Furthermore, such interventions can benefit both patients and health care providers in more resource-limited contexts through addressing demand-side and supply-side challenges that exist in service delivery. Interactive two-way mHealth engagement can help alleviate such health care system strain and improve its efficiency through focusing on patients who are in the most need of care at any given time, while promoting the individualized downstream care pathway that may include tailored patient-provider communication beyond text messaging.

### Ambiguity Exists Today Regarding how mHealth Interventions for Medication Adherence Work

Although there is growing quantitative evidence that two-way text messaging is superior to one-way for improving medication adherence, there remains a significant knowledge gap as to why. Mechanisms of action behind these interventions are currently unspecified. Consequently, this lack of insight may contribute to future challenges with regard to integrating such interventions into health services, and ultimately scaling them up. Attaining strong foundational knowledge of *how* the intervention influences adherence behavior may contribute to maximizing implementation success. In the context of HIV, similar sentiments have been shared in a systematic review focused on unpacking group-based ART adherence interventions to describe how they may work [13].

WelTel is an example of an interactive two-way mHealth intervention that has been shown to improve self-reported 95% ART adherence and viral load suppression rates, as demonstrated by a multisite randomized clinical trial conducted in Kenya [14] and further validated in Canada [15]. Delivery of the digital health outreach platform included a weekly automated text message saying "How are you?" ("Mambo?" in Kiswahili), and the patient was obliged to respond accordingly. If the patient replied "problem" ("Shida" in Kiswahili) or was unresponsive, a care provider initiated a follow-up and personalized care was given.

Figure 1. Behavior Change Wheel (image spelling has been modified, based on Michie S et al [18]).

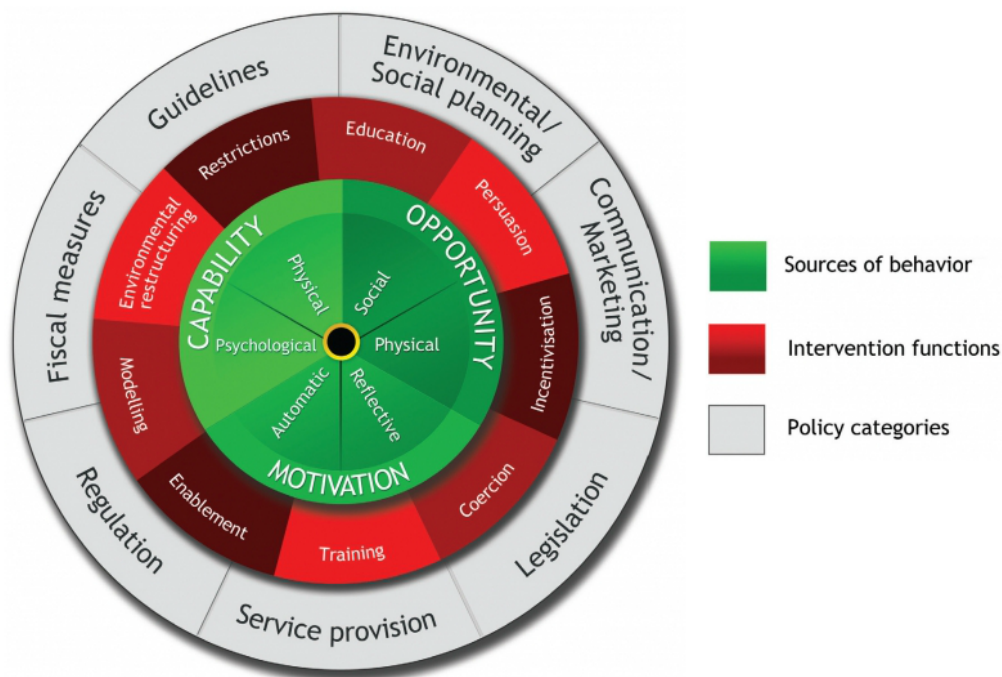
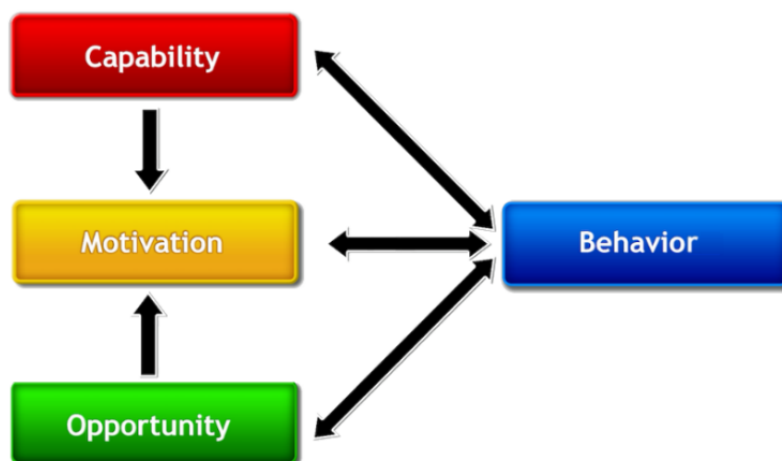


Figure 2. Capability Opportunity Motivation - Behavior (COM-B) model of behavior (image spelling has been modified, based on Michie S et al [18]).



**Objective**

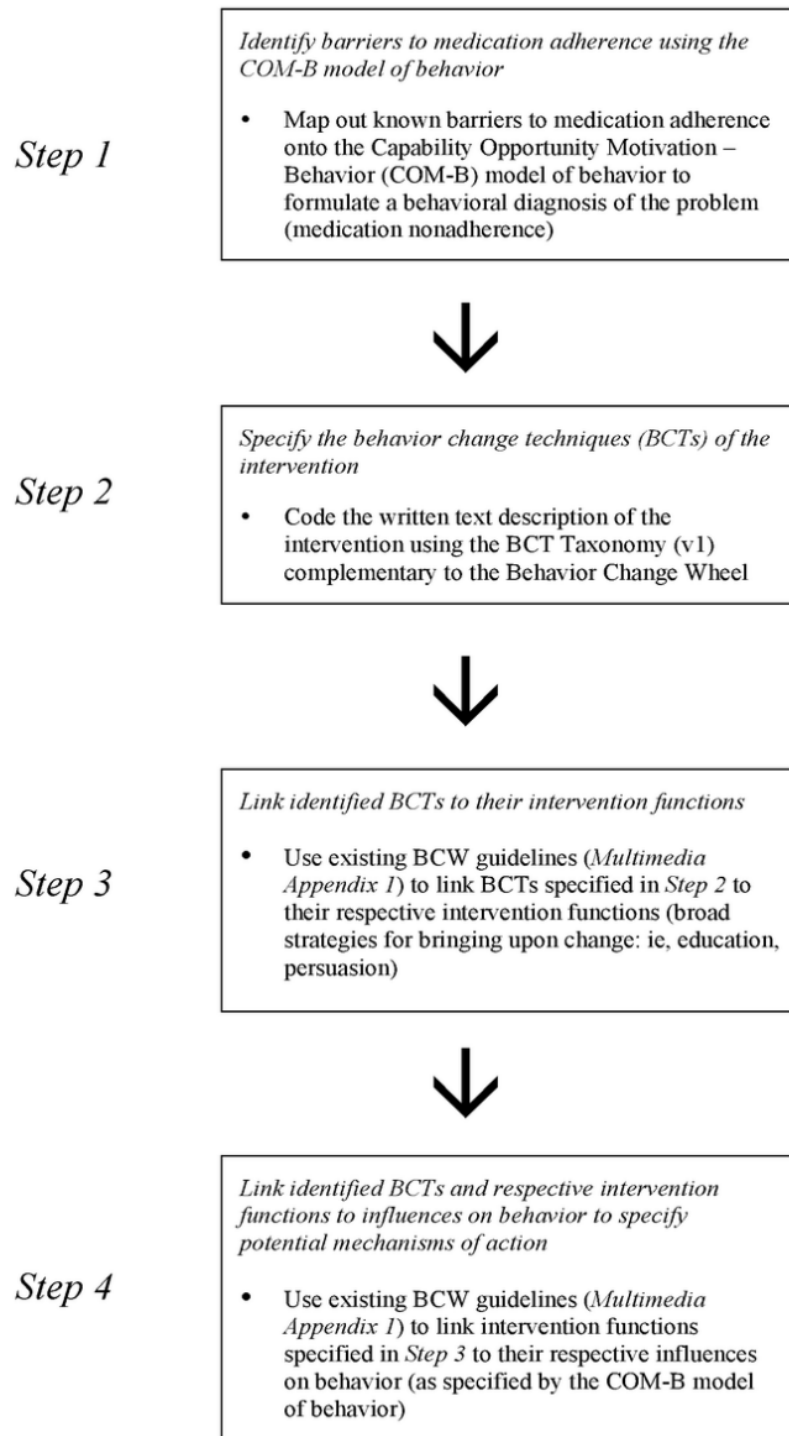
The primary objective of this study was to investigate and specify WelTel’s potential mechanisms of action using a comprehensive and evidence-based theory of behavior change framework. The Behavior Change Wheel (BCW) (Figure 1) provides a systematic approach to designing and evaluating interventions, and has been developed through the synthesis of 19 existing behavior change frameworks [16]. It characterizes an array of intervention functions (broad strategies for inducing the target behavior) and policy functions (ways to support and implement these strategies) that can be used within a wide range of contexts. Specifying linkages between intervention functions and influences on the target behavior reveals appropriate strategies for potentially bringing upon change [16]. A complementary behavior change taxonomy further elaborates upon these intervention functions in terms of many specific

behavior change techniques (BCTs) [17]. Moreover, the BCW highlights the importance of taking into account multilevel influences on behavior through incorporation of the Capability Opportunity Motivation-Behavior (COM-B) model of behavior (Figure 2).

Using WelTel as a case study, our goal was to help address the current research gap regarding the qualitative evidence of two-way mHealth interventions for improving medication adherence.

**Methods**

In our evaluation of WelTel using the BCW and its complementary taxonomy of BCTs, 4 steps were required to systematically determine the intervention’s potential mechanisms of action for improving medication adherence (Figure 3).

**Figure 3.** Determining potential mechanisms of action of an intervention using the Behavior Change Wheel (BCW).

### Step 1: Identify Barriers to Medication Adherence Using the Capability Opportunity Motivation-Behavior (COM-B) Model of Behavior

A *behavioral diagnosis* of ART nonadherence was formulated through the application of the COM-B model of behavior. Known barriers to ART adherence that exist within various countries have been specified in a systematic review [2]. Nine of them considered to be globally relevant were chosen and mapped onto COM-B to reveal influences on behavior that are potentially associated with nonadherence. This process enabled

us to gain insight into what needs to change for the target behavior of adherence to occur.

The COM-B model of behavior comprises the core of the BCW, encompassing *capability*, *opportunity*, and *motivation* as the influences on behavior, illustrating the potential interactions between them and the resultant behavior [16]. According to this theory, capability, opportunity, and motivation all need to be present for any behavior to occur, and each component can influence it independently of one another as well as synergistically [18]. Capability is related to one having the psychological (required knowledge and skills) and physical

capacity to engage in the behavior. Opportunity is divided into physical (associated with the external environment) and social (ie, cultural norms and interpersonal influences) factors that promote or impede behavior within the individual [16]. Motivation encompasses all brain activity that provokes behavior, including automatic (ie, emotions, wants and needs, and habits) and reflective (ie, belief systems, plans, and evaluations) processes [16].

### Step 2: Specify the Behavior Change Techniques of the Intervention

BCTs delivered by WelTel were characterized using the BCT taxonomy version 1 (BCTTv1). A BCT has been defined as an “observable, replicable, and irreducible component of an intervention designed to change behaviour and a postulated active ingredient within the intervention” [18]. An intervention protocol or manual is typically reviewed to provide the most elaborate description of what it entails. In our evaluation, the WelTel system’s user manual was chosen for analysis, as it provides the most detailed information about the intervention. Furthermore, BCT identification occurred through semistructured discussions within a study team including key stakeholders who have previously collected user feedback from the WelTel platform. During the process of specifying BCTs, all discrepancies were resolved by consensus.

The BCTTv1 serves to characterize an array of behavior change interventions using a standardized language [17]. In the evaluation of established interventions, their delivered content can be specified, synthesized, and linked to the BCW to reveal their intervention functions in order to provide insight into possible active ingredients and mechanisms of action [17]. Upon application, the relationships between the specified BCTs and intervention effectiveness can be investigated; the BCTs that may or may not be effective at changing behavior in addition to other ones not currently being delivered by the intervention have the potential to become identified.

### Step 3: Link Identified Behavior Change Techniques to Their Intervention Functions

Identified BCTs were connected with their respective intervention functions, or broad strategies for bringing upon behavior change, as characterized by the BCW. This process was directed by guidelines provided by the creators of the BCW (Multimedia Appendix 1) that list the BCTs associated with each of the 9 intervention functions.

### Step 4: Link Identified Behavior Change Techniques and Respective Intervention Functions to Influences on Behavior to Specify Potential Mechanisms of Action

To specify potential mechanisms of action, identified BCTs and respective intervention functions were connected to influences on behavior according to the COM-B model (capability, opportunity, and motivation). We followed guidelines provided by the creators of the BCW (Multimedia Appendix 1) that link intervention functions to COM-B influences on behavior; only those thought to be relevant to our study context were included.

## Results

### Step 1: Identify Barriers to Medication Adherence Using the Capability Opportunity Motivation-Behavior (COM-B) Model of Behavior

Formulating a behavioral diagnosis (Multimedia Appendix 2) by mapping out 9 known globally relevant ART adherence barriers onto the COM-B model has revealed that all influences on behavior (physical and psychological capability, physical and social opportunity, and automatic and reflective motivation) may be associated with ART nonadherence, validating the notion that bringing upon this change in behavior is highly complex. The majority of these barriers were linked to more than one COM-B influence on behavior, with reflective motivation and automatic motivation being the most recurring. This implies that both intentional and unintentional forms of nonadherence commonly co-exist within the general adult population. Furthermore, barriers related to a lack of social opportunity (ie, fear of revealing HIV status to family/friends because of stigma and competing priorities) may be appropriately mapped out onto both reflective and automatic motivation. This suggests that facilitating social opportunity could also promote the latter COM-B influences on behavior simultaneously, and this association could even contribute to inducing ART adherence synergistically.

### Step 2: Specify the Behavior Change Techniques of the Intervention

Upon coding the WelTel manual using the BCTTv1 (Multimedia Appendix 3), one BCT was identified for the intervention’s automated text message component and specified as a *prompt/cue*. In contrast, 8 different BCTs were identified for its personalized communication component delivered in response to receiving patient feedback of a problem. These were specified as follows: (1) *prompt/cue*, (2) *unspecified social support*, (3) *reduce negative emotions*, (4) *credible source*, (5) *natural consequences*, (6) *emotional social support*, (7) *practical social support*, and (8) *instruction on how to perform a behavior*.

### Step 3: Link Identified Behavior Change Techniques to Their Intervention Functions

The one BCT identified for WelTel’s automated text message component was linked to one intervention function (*environmental restructuring*; Multimedia Appendix 3). In contrast, the 8 BCTs identified for its personalized communication component were linked to 5 intervention functions (*environmental restructuring*, *enablement*, *education*, *persuasion*, and *training*; Multimedia Appendix 3).

Although the latter component of the intervention appears to be more comprehensive, each of its intervention functions (broad strategies for bringing upon behavior change) can be elaborated upon in terms of several other different BCTs that were not identified in our evaluation (Multimedia Appendix 1). Furthermore, no BCTs were linked to other intervention functions characterized by the BCW (specifically *incentivization*, *coercion*, and *modeling*). These types of strategies may also be ones to consider given the complexity of ART adherence, as demonstrated by the behavioral diagnosis generated in this study

([Multimedia Appendix 2](#)). This suggests that the design of the current intervention could be modified accordingly to potentially have a greater impact on ART adherence.

#### **Step 4: Link Identified Behavior Change Techniques and Respective Intervention Functions to Influences on Behavior to Specify Potential Mechanisms of Action**

On the basis of our evaluation, WelTel's potential mechanisms of action in promoting ART adherence have been specified as the intervention's ability to: (1) influence one's opportunity (both physical and social) and automatic motivation through environmental restructuring and enablement: the delivery of an external trigger, as well as social support, to facilitate adherence behavior; and (2) influence one's capability (both physical and psychological), opportunity (both physical and social), and motivation (both automatic and reflective) through education, persuasion, training, and enablement: the delivery of health-related information and social support to facilitate adherence behavior.

## **Discussion**

### **Contribution to Behavioral Science Research**

In the light of the current literature, this is the first paper to demonstrate how a comprehensive and evidence-based behavior change framework can be applied to an existing two-way mHealth intervention. WelTel has robust evidence for improving ART adherence [19]; therefore, it serves as an optimal means for evaluation using the BCW, an all-encompassing theory that can be appropriately applied worldwide [18]. Our evaluation has systematically revealed its potential mechanisms of action in addressing all influences on behavior regarding ART adherence. This has been specified by the COM-B model of behavior that encourages the critical multilayer examination of the behavior at the individual, interpersonal, and system levels, whereas other established behavioral theories may potentially miss important drivers as not all of these levels of influence are considered.

### **One-Way Versus Two-Way mHealth Intervention Strategies: Distinguishing Between Them With Regard to Targeting Nonintentional Nonadherence and Intentional Nonadherence**

The application of COM-B highlights the important differences between unintentional and intentional medication nonadherence with regard to their influences on behavior [20,21]. In the context of taking ART daily, unintentional medication nonadherence is often considered simply forgetting to perform the behavior. This factor is related to one's automatic motivation, described as "processes involving emotional responses, desires (wants and needs), impulses and reflex responses" [18]. In contrast, intentional nonadherence is related to purposeful deviation of the behavior that is associated with reflective motivation, defined as "involving self-conscious planning and evaluations (beliefs about what is good or bad)" [18]. Although they stem from different sources of motivation, both forms of nonadherence are not mutually exclusive from each other, and thus often exist in any one individual prescribed chronic disease treatment (such as ART) over the course of

treatment [22,23]. This reality emphasizes the need for adherence-promoting strategies that are multifaceted and target different COM-B influences of behavior.

The distinction between nonintentional and intentional medication adherence behavior is important to consider designing and evaluating interventions. It can provide an explanation as to why interventions solely focused on self-prompting and one-way medication reminders often have failed to show significant impact in clinical trials. This lack of effect has been shown in a randomized control trial using an alarm device for promoting ART adherence [24], in addition to a systematic review evaluating technology-based self-care strategies for improving ART adherence [25]. Moreover, in a systematic review of various mobile technology-based interventions across chronic disease states beyond HIV (ie, diabetes and hypertension), it has been implied that simple text message reminders on their own have modest benefits for influencing adherence [26]. The application of the BCTTv1 for the purpose of evaluating such interventions would likely reveal that the primary BCT being delivered by them is a *prompt/cue* linked appropriately with the intervention function *environmental restructuring*. Connecting this specification with COM-B would indicate that this particular function likely has the potential to only influence one's physical opportunity (providing a trigger to perform the behavior) and automatic motivation (habit formation through reflex response). Limited effects on other influences on behavior relating to adherence would be expected, including the intervention's ability to impact one's reflective motivation, psychological capability, and social opportunity. Therefore, one-way reminder-based interventions may bring upon behavior change with regard to nonintentional nonadherence, but they are unlikely to influence intentional nonadherence. This has been echoed in a meta-analysis comparing one-way versus two-way text message interventions for medication adherence across disease states [9].

Furthermore, it is useful to distinguish between simple two-way text messaging and more complex interactive two-way communication that provides open-ended, enhanced follow-up support tailored to patients' needs [27]. The former is only one component of the WelTel intervention; however, a recent network meta-analysis that evaluated all types of interventions for HIV adherence globally has classified WelTel as a short messaging service (text message) intervention only [6]. An in-depth analysis of WelTel has revealed a comprehensive blend of mechanisms behind its digital health outreach platform for promoting ART adherence, thus differentiating itself from other mHealth applications considered one-way in nature and other forms of two-way communication that provide a relatively low degree of social support and personalized care. Through consistent weekly automated text messaging and subsequent provider follow-up by phone if patients report a problem or are nonresponsive, WelTel is postulated to deliver a variety of BCTs that comprehensively induces ART adherence. The automated text message component of the intervention is hypothesized to primarily influence one's physical opportunity and automatic motivation. More importantly, the personalized, interactive patient-provider communication component may have the potential to impact all influences on behavior (physical and

psychological capability, social and physical opportunity, and reflective and automatic motivation). Through application of the science of behavior change, we have been able to strengthen the qualitative evidence base for how interactive two-way mHealth interventions may impact both nonintentional and intentional nonadherence.

### Limitations of Our Evaluation Using the Behavior Change Wheel

There were several limitations in using the BCW to evaluate the mHealth intervention. First, coding of an intervention is limited by its documented description (ie, an intervention protocol or manual). Although this method promotes transparency and data validation by external reviewers, information about what the intervention delivers in terms of BCTs may not be captured to its entirety. For example, encouraging *self-monitoring* and *goal setting* could potentially be BCTs delivered independently by the provider upon patient follow-up using the WelTel platform. Evaluating a detailed provider-patient communication log could help determine the presence of such BCTs, and thus contribute to further specifying WelTel's behavior change mechanisms.

Second, using the BCTTv1 to characterize the mHealth intervention resulted in some ambiguity because of its varied interpretation. In our evaluation, we were uncertain whether or not to code its automated text message component ("Mambo?" or "How are you?") as a *prompt/cue* and *unspecified social support*, or solely the former. Given WelTel's personalized communication component for delivering tailored individual care, we decided whatever social support that may be conveyed in the automated text message component would be relatively insignificant. Authors of an mHealth intervention evaluation for smoking cessation have expressed similar sentiments, given the brevity of its text message content and consequently less meaning to draw upon [28]. To address limitations of the taxonomy, one suggestion has been to modify the BCTTv1 for mobile technology-based interventions as opposed to using a generalized classification system for all types of behavioral interventions [26].

Third, behavior change outcomes depend heavily on the patient-provider relationship, which the BCW is unable to account for. Interventions (for medication adherence and retention in care) that prioritize patient confidentiality of HIV status and promote the development of trusting relationships would reduce barriers to their implementation [29,30]. The benefits of personalized care have been echoed in [31] and highlighted in a meta-analysis examining one-way and two-way mHealth interventions for promoting ART adherence [11]. Regular two-way interaction allows for more opportunity to build rapport; therefore, the presence of relatively strong social support (greater enablement) through patient-provider communication by phone would be postulated to enhance the delivery of the BCTs specified in our evaluation.

Overall, the BCW can help to specify what the intervention delivers in terms of content; however, more research is needed to gain a better understanding of other intervention dimensions that play a role in influencing medication adherence (ie, who delivers it, messaging frequency), and how respective processes

of change may occur. Another consideration is the behavioral facilitators and barriers that may exist with regard to using the intervention itself. Identifying influences on user engagement with WelTel may elucidate facilitators and barriers at the patient and provider levels, such as comfort level with using the technology and the provider's style of communication, in addition to knowledge base. It would be wise to identify significant user facilitators and barriers before scaling up the intervention to further optimize its integration into the health care system. The importance of describing user feedback has been emphasized in the mHealth evidence reporting and assessment (mERA) checklist: recent guidelines that have been created to improve the quality of evidence for mHealth through providing a comprehensive and standardized way to report these interventions [32].

### Generalizability of Our Findings

Although WelTel's digital outreach strategy is thought to address ART adherence more comprehensively than one-way text message engagement platforms, it cannot be assumed that its proposed mechanisms of action would translate across all HIV-positive populations worldwide. A systematic review examining various ART adherence interventions have concluded that behavioral interventions producing a positive impact in one setting may not translate to other populations because of differences in economic, social, and behavioral barriers to adherence [33]. Such barriers including poverty and mental health comorbidities commonly co-exist in various contexts, and addressing these issues through respective integrative services alongside public health HIV interventions may increase implementation success of the latter [34].

Furthermore, it is uncertain if WelTel's proposed mechanisms of action are generalizable across other chronic disease states. Beyond aiming to promote ART adherence globally and within different populations [13,14,35], WelTel is currently being tested and evaluated for impact on HIV retention in care [36-38], in addition to medication adherence behaviors across other health conditions such as tuberculosis and asthma [39-41]. Arguably, interventions based on a thorough understanding of its target behavior in context will have greater potential for impact. Upon specifying the underlying mechanisms of medication adherence and nonadherence in a given environment, it may be possible to map out the potential value of a WelTel approach. In addition, the mechanisms of action of the intervention may vary by context, and thus the expansion of WelTel to other chronic conditions (as well as target behaviors beyond medication adherence) will require future validation work.

### Implications for Future Research: Our Call to Action

It has been emphasized that replication, implementation, and evidence synthesis are required to gain a more in-depth understanding of behavior change mechanisms and to establish a growing qualitative knowledge base for informing the development of interventions that have greater impact [17]. We hope that our evaluation of the WelTel mHealth service using the BCW is repeated in a similar manner by other researchers involved with mHealth interventions for promoting medication adherence across various disease states and populations. Given

the BCW's established common language of behavior change across interventions, such widespread application of the framework would serve to identify the commonalities and differences between their postulated effects, or lack of. Repeated application would eventually serve to synthesize the current evidence in a systematic manner, and help build a stronger foundation as it relates to specifying how and which combination of BCTs likely have a positive impact, and which ones have minimal influence on medication adherence. With this collective insight, the design of mHealth interventions could be modified accordingly to improve population health outcomes.

### Conclusions

Imposing the BCW onto WelTel has systematically revealed its potential mechanisms of action for improving ART adherence, while deepening our understanding that it may

address all influences of this behavior: capability (physical and psychological), opportunity (physical and social), and motivation (reflective and automatic). Our evaluation has revealed that interactive, two-way mHealth interventions may deliver a combination of BCTs that are more likely to capture this to its entirety compared with one-way mHealth interventions, which may only affect automatic motivation and physical opportunity. This has strengthened the evidence base for how and why a two-way design may be more effective than a one-way design at addressing both nonintentional and intentional forms of nonadherence. The application of the BCW for evidence synthesis across mHealth interventions targeting various chronic diseases would contribute to strengthening the knowledge base regarding how they may work to impact medication adherence behavior.

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### Conflicts of Interest

RTL has founded WelTel International mHealth Society (a nonprofit organization) and WelTel Inc (a company) to help develop and scale the technologies to deliver the research-based services and has an interest in both organizations.

### Multimedia Appendix 1

Intervention functions: linkages with BCTs and COM-B.

[PDF File (Adobe PDF File), 30KB - [mhealth\\_v6i4e87\\_app1.pdf](#) ]

### Multimedia Appendix 2

Behavioral diagnosis of ART nonadherence.

[PDF File (Adobe PDF File), 97KB - [mhealth\\_v6i4e87\\_app2.pdf](#) ]

### Multimedia Appendix 3

Evaluating WelTel: characterizing its delivered BCTs, linking them to their intervention functions and COM-B.

[PDF File (Adobe PDF File), 108KB - [mhealth\\_v6i4e87\\_app3.pdf](#) ]

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## Abbreviations

- ART:** antiretroviral therapy
- BCW:** Behavior Change Wheel
- BCT:** behavior change technique
- BCTTv1:** behavior change technique taxonomy (version 1)
- COM-B:** Capability Opportunity Motivation-Behavior

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Original Paper

# Prevalence, Demographic Correlates, and Perceived Impacts of Mobile Health App Use Amongst Chinese Adults: Cross-Sectional Survey Study

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## Abstract

**Background:** Mobile health apps have changed the way people obtain health information and services and advance their understanding and management of their health. Although many health apps are available, little is known about the prevalence of their use for different purposes, whether such use is associated with demographic characteristics, and the impacts of their use on health knowledge and management.

**Objective:** The main objectives of this study were to examine the prevalence, extent, and demographic correlates of health app use and the perceived impacts of health app use on increased health knowledge and improved health condition management.

**Methods:** We conducted a cross-sectional questionnaire survey of 633 Chinese adults randomly drawn from the general population in Hong Kong.

**Results:** Of the 633 participants, 612 (96.7%) reported using mobile devices. Of them, 235 (38.4%) reported using multiple types of health apps. The most-used type of health app was about healthy living information (197/612, 32.2%), followed by measuring/recording vital signs (80/612, 13.1%), health and medical reminders (64/612, 10.5%), recovery and rehabilitation information (42/612, 6.9%), diagnosis assistance (28/612, 4.6%), emergency services (16/612, 2.6%), telehealth (11/612, 1.8%), and “other” (19/612, 3.1%). Multivariate logistic regression analysis found that health app users were more likely to be women (odds ratio [OR] 1.68, 95% CI 1.14-2.48,  $P=0.01$ ) of a higher self-rated social class (OR 3.66, 95% CI 1.11-12.11,  $P=0.03$ ). Participants who worked in education/culture/academia (OR 2.31, 95% CI 1.16-4.59,  $P=0.02$ ) or disciplinary forces (OR 5.07, 95% CI 1.25-20.62,  $P=0.02$ ) were more likely to believe that using health apps could increase their health knowledge; participants working in education/culture/academia were also more likely to believe that using health apps could improve the effectiveness of health condition management (OR 2.18, 95% CI 1.10-4.34,  $P=0.03$ ).

**Conclusions:** Effort should be made to promote health app use, especially to demographic groups that are currently less likely to use health apps (eg, males, individuals from lower social classes). From the public health perspective, guidelines could be developed to help individuals identify quality health apps that meet their needs. Moreover, app developers could improve the usability of health apps to promote health app use.

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**KEYWORDS**

mHealth; mobile health apps; prevalence; demographic correlates; health behavior

## Introduction

The rapid development of mobile devices, particularly mobile phones, and internet technology has led to a surge of interest in using mobile apps to implement mHealth [1-3]. There are more than 325,000 health apps available, covering various health topics such as disease management, healthy lifestyles, self-diagnosis, and emergency services [4-6]. The number of health app downloads is high, with more than 3 billion in 2015, and it is growing at a rate of more than 7% each year [4].

Several studies have examined the prevalence of health app use and the association between demographics and health app use. For instance, Krebs and Duncan [7] found that 58.2% of US mobile phone users had downloaded a health app and that health app users tended to be younger, were of Latino/Hispanic ethnicity, had higher income, were more educated, and had higher body mass index. Based on a US survey, Carroll et al [8] found that health app users tended to be younger, female, more educated, high income earners, and individuals in excellent health. Ernsting et al's [9] German survey results revealed that 20.5% of mobile phone users used health apps and that health app use was related to age, first language, internet use, chronic conditions, health behaviors, and health literacy. The demographics associated with health app use can vary greatly across different app types (eg, healthy living information, diagnosis assistance, health and medical reminders), but previous studies have focused on general health app use overall and have not examined the demographic correlates of each type of health app separately.

Moreover, although health apps aim to offer their users health benefits, such as increased health knowledge and improved health management [10-13], relatively little is known about whether users find or perceive that health apps confer such benefits. Although studies have examined the perceived impacts of using health apps, they focused on only one or two types of health apps for a specific population (eg, young adults, sports dietitians) [14,15]. The demographic correlates of the perceived impacts of health app use have also been little studied.

In this study, we set out to first explore the prevalence and extent of mobile device use and mobile internet access. We then examined the prevalence, extent, and demographic correlates of health app use in general and by app type, along with individuals' perceived impacts of health app use on increased health knowledge and improved health condition management, and the demographic correlates of these perceptions.

## Methods

### Design

The study used a cross-sectional questionnaire survey design. [Multimedia Appendix 1](#) presents the questionnaire we used. The survey collected demographic data (age, gender, self-rated social class, education, and occupation), mobile device use, mobile internet access, health app use, and perceived impacts of health app use on increased health knowledge and improved health condition management. No compensation was given for participation in the study. The study was approved by the ethics

committee of the University of Hong Kong, and informed consent was obtained from all participants.

### Participants

The sample consisted of 633 adults who were selected using convenience sampling and stratified by age group (18-29, 30-44, 45-59, and  $\geq 60$  years) and gender. Individuals who met the following criteria were eligible for the study: aged 18 years or older, able to understand written and spoken Chinese, and able to understand the questionnaire.

### Procedure

Research assistants randomly approached individuals in public areas (eg, shopping malls, subway stations, residential neighborhoods, and parks), introduced the study to them, asked them if they would be willing to participate in the study, and confirmed their eligibility. Those who agreed and were eligible were asked to complete the questionnaire. The research assistants read the questions aloud and recorded the responses for individuals who asked them to administer the questionnaire. The data were collected between April 2016 and March 2017.

### Data Analysis

Two research assistants independently entered the data and crosschecked them for accuracy. Some participants did not respond to some questions. Responses that contained errors, such as reporting desktop computer use as mobile device use or social media app use as health app use, were excluded from the data analysis. Participants' self-ratings of social class, which were obtained on a 9-point scale anchored at the extremes by poor (1) and rich (9) were collapsed into three categories: lower (1-3), middle (4-6), and upper (7-9). Descriptive statistics were computed for demographic variables, mobile device use, mobile internet access, health app use, and perceived impacts of health app use. Multivariate logistic regressions were conducted to assess the demographic correlates of health app use and perceived impacts of health app use. The odds ratios and 95% confidence intervals were calculated. All the analyses were performed using STATA 14.

## Results

### Sample Characteristics

[Table 1](#) shows the demographic characteristics of the sample (N=633). The mean age of the sample was 45.25 years (SD 17.44). Of all the participants, only 2.2% (14/633) reported that they were from an upper social class, with 63.5% (402/633) from a middle social class, and 33.2% (210/633) from a lower social class.

### Prevalence and Extent of Mobile Device Use and Mobile Internet Access

The prevalence and extent of the participants' mobile device usage are presented in [Table 2](#). Overall, 96.7% (612/633) of the participants reported using mobile devices, and 90.5% (573/633) reported using mobile phones. Of the mobile device users, 90.8% (556/612) reported having internet access on their devices, and only 7.2% (44/612) reported not having mobile internet access (2% did not respond to this question).

**Table 1.** Demographic characteristics of the sample (N=633).

Characteristic	n (%)
<b>Gender</b>	
Male	325 (51.3)
Female	307 (48.5)
No response	1 (0.2)
<b>Age (years)</b>	
18-29	156 (24.6)
30-44	158 (25.0)
45-59	156 (24.6)
≥60	158 (25.0)
No response or erroneous data	5 (0.8)
<b>Self-rated social class</b>	
Lower	210 (33.2)
Middle	402 (63.5)
Upper	14 (2.2)
No response	7 (1.1)
<b>Education level</b>	
No schooling completed	8 (1.3)
Some primary school	18 (2.8)
Completed primary school	37 (5.8)
Some secondary school	54 (8.5)
Completed secondary school	175 (27.7)
Diploma, advanced diploma, associate degree or equivalent	90 (14.2)
Bachelor's degree	154 (24.3)
Master's degree	77 (12.2)
Doctoral degree	19 (3.0)
Other	1 (0.2)
<b>Occupation</b>	
Service	83 (13.1)
Sales	24 (3.8)
Catering	13 (2.1)
Finance	41 (6.5)
Engineering	49 (7.7)
Art	4 (0.6)
Education/culture/academia	64 (10.1)
Administration/professional	35 (5.5)
Office/white-collar worker	35 (5.5)
Disciplinary forces	7 (1.1)
Student	65 (10.3)
Housewife/househusband	45 (7.1)
Unemployed/awaiting job assignment	16 (2.5)
Retiree	122 (19.3)
Other	24 (3.8)

Characteristic	n (%)
No response	6 (1.0)

### Prevalence, Extent, and Demographic Correlates of Health App Use

**Table 3** presents the prevalence and demographic correlates of health app use in general. Overall, 38.4% (235/612) of the mobile device users reported using health apps, and 60.3% (369/612) reported not using any health apps (1.3% did not respond to this question).

The logistic regression results showed that females (odds ratio [OR] 1.68, 95% CI 1.14–2.48,  $P=.01$ ) and participants in higher self-rated social classes (middle: OR 1.43, 95% CI 0.94–2.16,  $P=.09$ ; upper: OR 3.66, 95% CI 1.11–12.11,  $P=.03$ ) were more likely to use health apps.

**Multimedia Appendix 2** presents the prevalence, extent (the mean length of time spent on each occasion of use, in minutes), and demographic correlates of health app use by type. The most prevalent health app type was healthy living information, which 32.2% (197/612) of the mobile device users reported using, followed by measuring/recording vital signs (80/612, 13.1%), health and medical reminders (10.5%, 64/612), recovery and rehabilitation information (6.9%, 42/612), diagnosis assistance (28/612, 4.6%), emergency services (16/612, 2.6%), telehealth (11/612, 1.8%), and “other” (19/612, 3.1%).

Users of health and medical reminder apps were more likely to be female (OR 2.44, 95% CI 1.31–4.52,  $P=.01$ ) and less likely to be housewives/househusbands (OR 0.16, 95% CI 0.03–0.82,  $P=.03$ ) or retirees (OR 0.23, 95% CI 0.06–0.88,  $P=.03$ ). Participants who had retired were also less likely to use diagnosis assistance apps (OR 0.06, 95% CI 0.01–0.43,  $P=.01$ ). Participants who had completed secondary school (OR 35.68, 95% CI 2.85–447.02,  $P=.01$ ), or a diploma, advanced diploma, associate degree or equivalent (OR 15.55, 95% CI 1.07–225.77,  $P=.04$ ) were more likely to use diagnosis assistance apps. Participants in higher self-rated social classes (middle: OR 2.74, 95% CI 0.88–8.51,  $P=.08$ ; upper: OR 111.09, 95% CI 4.31–2828.89,  $P=.004$ ) were also more likely to use diagnosis assistance apps. In addition, participants in higher self-rated social classes were more likely to use apps for healthy living

information (middle class: OR 1.55, 95% CI 1.01–2.40,  $P=.046$ ; upper class: OR 2.84, 95% CI 0.88–9.08,  $P=.08$ ), recovery and rehabilitation information (middle class: OR 2.98, 95% CI 1.14–7.80,  $P=.03$ ; upper class: OR 15.01, 95% CI 2.03–110.78,  $P=.01$ ), and measuring/recording vital signs (middle class: OR 2.31, 95% CI 1.16–4.60,  $P=.02$ ; upper class: OR 8.32, 95% CI 2.16–32.05,  $P=.002$ ).

### Perceived Impacts of Health App Use on Increased Health Knowledge and Improved Health Condition Management

**Figure 1** shows the frequency distribution of the participants' perceived impacts of health app use on increased knowledge about health conditions and improved health condition management. The participants rated their agreement with the statement “using mobile health apps can increase your knowledge about and improve the effectiveness of the management of your health conditions” on a 7-point scale, with 1=very strongly disagree and 7=very strongly agree. For increase in health condition knowledge, 37.4% (237/633) of the participants gave a rating of 5 or above, and 33% (209/633) gave a rating of 3 or below. For health management improvement, 38.2% (242/633) of the participants gave a rating of 5 or above and 33.3% (211/633) gave a rating of 3 or below.

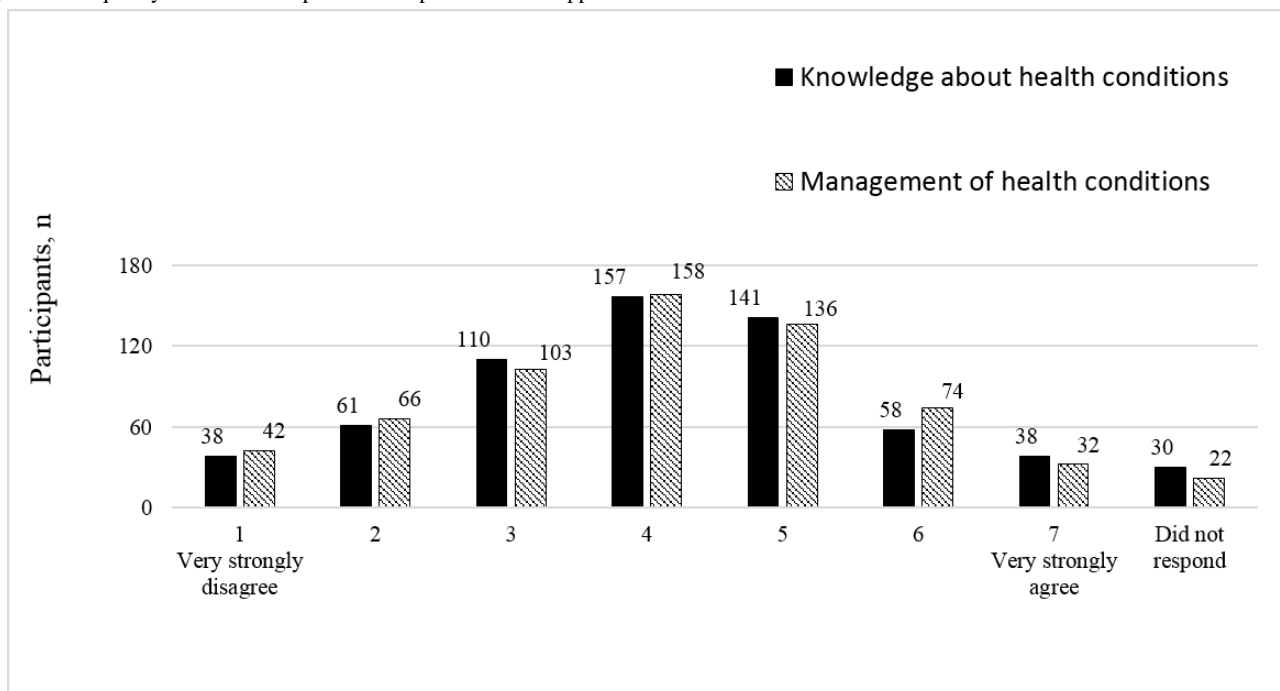
**Table 4** presents the means and standard deviations of the perceived impacts of health app use on increased health knowledge and improved health condition management by demographic characteristics and demographic correlates of perceptions. The analysis showed that participants working in education/culture/academia (OR 2.31, 95% CI 1.16–4.59,  $P=.02$ ) and disciplinary forces (OR 5.07, 95% CI 1.25–20.62,  $P=.02$ ) tended to believe that using health apps could increase their health knowledge. In addition, participants working in education/culture/academia (OR 2.18, 95% CI 1.10–4.34,  $P=.03$ ) and those who reported “other” occupations (eg, health care, sports, media, social work; OR 2.50, 95% CI 1.07–5.82,  $P=.03$ ) were more likely than other types of workers to believe that using health care apps could improve the effectiveness of their health condition management.

**Table 2.** Prevalence and extent of mobile device use (N=633).

Mobile device	n (%)	Hours spent using the device daily, mean (SD)
Mobile phone	573 (90.5)	4.0 (3.6)
Feature phone	49 (7.7)	1.5 (2.2)
Tablet computer	209 (33.0)	2.5 (2.5)
Other	23 (3.6)	4.5 (3.6)
Not using any mobile devices	18 (2.8)	—
No response or erroneous data	3 (0.5)	—

**Table 3.** Prevalence and demographic correlates of use of any type of health app (N=612). OR: odds ratio.

Demographic characteristics	n (%)	OR (95% CI)	P
Total	235 (38.4)		
<b>Gender</b>			
Male	108 (33.2)	1	
Female	126 (41)	1.68 (1.14-2.48)	.01
<b>Age (years)</b>			
18-29	61 (39.1)	1	
30-44	70 (44.3)	1.06 (0.61-1.81)	.84
45-59	59 (37.8)	0.96 (0.53-1.74)	.90
≥60	41 (25.9)	0.69 (0.31-1.51)	.35
<b>Self-rated social class</b>			
Lower	66 (31.4)	1	
Middle	156 (38.8)	1.43 (0.94-2.16)	.09
Upper	9 (64.3)	3.66 (1.11-12.11)	.03
<b>Education level</b>			
No schooling completed	0 (0)	1	
Some primary school	3 (16.7)	0.26 (0.05-1.43)	.12
Completed primary school	10 (27.0)	0.40 (0.10-1.58)	.19
Some secondary school	22 (40.7)	0.66 (0.19-2.28)	.51
Completed secondary school	55 (31.4)	0.39 (0.13-1.20)	.10
Diploma, advanced diploma, associate degree or equivalent	31 (34.4)	0.46 (0.15-1.42)	.18
Bachelor's degree	67 (43.5)	0.50 (0.17-1.44)	.20
Master's degree	37 (48.1)	0.65 (0.22-1.92)	.44
Doctoral degree	10 (52.6)	1	
Other	0 (0)	1	
<b>Occupation</b>			
Service	36 (43.4)	1	
Sales	9 (37.5)	0.70 (0.26-1.87)	.47
Catering	1 (7.7)	0.14 (0.02-1.17)	.07
Finance	19 (46.3)	0.87 (0.37-2.06)	.75
Engineering	17 (34.7)	0.59 (0.26-1.35)	.21
Art	2 (50.0)	1.01 (0.12-8.22)	>.99
Education/culture/academia	26 (40.6)	0.55 (0.25-1.22)	.14
Administration/professional	21 (60.0)	1.48 (0.60-3.64)	.40
Office/white-collar worker	15 (42.9)	0.77 (0.31-1.94)	.59
Disciplinary forces	3 (42.9)	0.80 (0.16-4.03)	.79
Student	22 (33.8)	0.46 (0.20-1.07)	.07
Housewife/househusband	14 (31.1)	0.50 (0.22-1.17)	.11
Unemployed/awaiting job assignment	5 (31.3)	0.60 (0.18-1.97)	.40
Retiree	32 (26.2)	0.63 (0.29-1.40)	.26
Other	11 (45.8)	1.09 (0.40-2.96)	.86

**Figure 1.** Frequency distribution of perceived impacts of health app use.



**Table 4.** Means and standard deviations of perceived impacts of health app use on increased health knowledge and improved health condition management, and demographic correlates (N=633). N/A: not applicable; OR: odds ratio.

Demographic characteristics	Health knowledge			Health condition management		
	Mean (SD)	OR (95% CI)	<i>P</i>	Mean (SD)	OR (95% CI)	<i>P</i>
<b>Gender</b>						
Male	4.11 (1.51)	1		4.03 (1.55)	1	
Female	3.97 (1.55)	0.81 (0.59-1.13)	.22	4.02 (1.54)	1.08 (0.78-1.49)	.64
<b>Age (years)</b>						
18-29	3.93 (1.29)	1		3.91 (1.45)	1	
30-44	4.07 (1.48)	1.07 (0.67-1.70)	.79	4.12 (1.40)	1.16 (0.73-1.84)	.53
45-59	4.03 (1.55)	1.09 (0.66-1.80)	.74	4.10 (1.57)	1.33 (0.80-2.20)	.27
≥60	4.15 (1.76)	1.51 (0.77-2.97)	.23	3.99 (1.75)	1.34 (0.69-2.60)	.39
<b>Self-rated social class</b>						
Lower	3.89 (1.56)	1		3.80 (1.57)	1	
Middle	4.10 (1.50)	1.11 (0.79-1.57)	.55	4.13 (1.51)	1.22 (0.86-1.73)	.27
Upper	4.36 (1.49)	1.62 (0.60-4.34)	.34	4.38 (1.64)	1.72 (0.60-4.94)	.32
<b>Education level</b>						
No schooling completed	4.00 (1.41)	1		4.00 (0.93)	1	
Some primary school	3.88 (1.94)	1.34 (0.21-8.62)	.76	3.47 (1.94)	0.42 (0.07-2.47)	.33
Completed primary school	4.26 (1.66)	2.99 (0.55-16.37)	.21	3.76 (1.78)	0.83 (0.17-4.17)	.82
Some secondary school	4.08 (1.62)	2.36 (0.46-12.28)	.31	4.38 (1.67)	1.86 (0.39-8.89)	.44
Completed secondary school	3.85 (1.60)	1.58 (0.32-7.80)	.57	3.89 (1.62)	0.85 (0.19-3.83)	.83
Diploma, advanced diploma, associate degree or equivalent	4.02 (1.36)	2.11 (0.41-10.82)	.37	3.86 (1.50)	0.87 (0.18-4.07)	.86
Bachelor's degree	4.12 (1.38)	2.16 (0.42-11.00)	.35	4.12 (1.24)	0.94 (0.20-4.38)	.94
Master's degree	4.29 (1.52)	2.65 (0.50-13.89)	.25	4.26 (1.68)	1.03 (0.21-5.01)	.97
Doctoral degree	3.72 (1.52)	1.09 (0.17-6.95)	.93	4.42 (1.39)	1.15 (0.20-6.66)	.88
Other	7.00 (0)	N/A	N/A	5.00 (0)	2.15 (0.08-59.35)	.65
<b>Occupation</b>						
Service	3.68 (1.43)	1		3.79 (1.53)	1	
Sales	3.21 (1.28)	0.65 (0.27-1.57)	.34	3.30 (1.45)	0.74 (0.31-1.81)	.51
Catering	4.30 (1.35)	2.31 (0.67-7.96)	.19	4.50 (1.20)	2.68 (0.79-9.09)	.11
Finance	4.30 (1.54)	1.90 (0.90-4.01)	.09	4.28 (1.28)	2.03 (0.97-4.26)	.06
Engineering	4.30 (1.24)	1.88 (0.96-3.68)	.07	4.08 (1.44)	1.38 (0.70-2.70)	.35
Art	3.75 (0.83)	0.99 (0.19-5.08)	.99	4.75 (0.83)	3.40 (0.64-18.10)	.15
Education/culture/academia	4.27 (1.53)	2.31 (1.16-4.59)	.02	4.42 (1.43)	2.18 (1.10-4.34)	.03
Administration/professional	3.71 (1.47)	1.00 (0.46-2.14)	.99	4.17 (1.48)	1.58 (0.74-3.40)	.24
Office/white-collar worker	4.12 (1.30)	1.96 (0.88-4.36)	>.99	3.89 (1.28)	1.43 (0.66-3.11)	.37
Disciplinary forces	4.86 (1.46)	5.07 (1.25-20.62)	.02	4.29 (1.48)	1.80 (0.45-7.23)	.41
Student	3.88 (1.23)	1.37 (0.68-2.72)	.38	3.98 (1.31)	1.54 (0.76-3.10)	.23
Housewife/househusband	4.12 (1.65)	1.91 (0.90-4.05)	.09	3.95 (1.84)	1.23 (0.57-2.64)	.60
Unemployed/awaiting job assignment	4.00 (1.66)	1.58 (0.60-4.21)	.36	3.56 (1.62)	0.81 (0.30-2.19)	.68
Retiree	4.11 (1.77)	1.28 (0.65-2.52)	.48	3.95 (1.77)	1.11 (0.57-2.19)	.76
Other	4.38 (1.47)	2.21 (0.94-5.17)	.07	4.46 (1.35)	2.50 (1.07-5.82)	.03

## Discussion

### Mobile Device Use

The results of this study contribute to the evidence for the high penetration of mobile devices, with almost every participant having a mobile device of some kind. Mobile phone users comprised over 90% of the participants. This is significantly higher than the mobile phone user rates reported in previous studies [8,9], which could be due to the proliferation of mobile phones in Asia in recent years [16].

### Prevalence and Demographic Correlates of Health App Use

In this study, approximately one-third of the mobile device users reported using health apps. The most prevalent types of health apps were those that can help individuals obtain more health information, track their vital signs, or receive health and medical reminders. The popularity of these apps could be related to the fact that individuals are now increasingly interested in managing their diets and lifestyles to stay healthy [17]. Moreover, we suggest that the popularity of health apps is related to their usability because apps that are easier to use might increase users' self-efficacy and willingness to use them [17].

We found that people in higher self-rated social classes were more likely to use health apps, especially apps offering healthy living information and recovery and rehabilitation information, and apps measuring/recording vital signs. One reason for this could be that individuals in higher self-rated social classes are more health conscious, as research has shown that individuals in higher social classes are more likely to think about how to stay healthy [18]. Another reason could be that individuals in higher social classes find it easier to pay for apps or mobile technology (eg, wearable devices) that is often used with health apps [9,19].

We also found that women were more likely to use health apps than men, particularly health and medical reminder apps. This might be because women care more about healthy living than men; for instance, women attach greater importance to healthy eating than men [20]. There is also evidence that women better adhere to public health recommendations for exercise, tobacco and alcohol consumption, and healthy diets [21]. In addition to the gender differences in attitudes toward healthy living, motherhood might be one reason that women used health apps more than men because women have more need for apps related to pregnancy, postnatal recovery, baby care, etc.

It was also noted that participants who had obtained medium-level education (ie, completed secondary school or obtained a diploma, advanced diploma, or equivalent degree) were more likely to use diagnosis assistance apps than participants with either lower or higher education levels. As indicated by previous research, individuals whose education levels were lower than secondary schooling tended to have lower health literacy, which may be why they were less likely to use diagnosis assistance apps [22]. Individuals who had obtained bachelor's degrees or higher might have more trust in health care professionals, and might thus tend to visit physicians

for diagnoses instead of conducting self-diagnosis using health apps [23].

Retirees and housewives/househusbands were less likely to use certain types of apps (eg, diagnosis assistance apps, and health and medical reminder apps). This could be because they live life at a slower pace and are less likely to be occupied with work, so have less need for reminder apps or apps assisting with immediate self-diagnosis. We also found that participants working in the art industry were more likely to use recovery and rehabilitation information apps, but the underlying reason for this is less clear.

### Perceived Impacts of Health App Use on Health Knowledge and Health Condition Management

Research has shown that health apps have the potential to promote healthy behaviors, facilitate health management, and improve health outcomes [10-13]. However, only slightly more than one-third of the participants in our study held positive opinions about the impacts of using health apps. The reason for this could be that most of the participants had not used any health apps before and were not aware of their potential benefits.

Participants with occupations related to health or education (eg, health care professionals, education/culture/academic professionals) or those whose occupations required a high level of physical fitness (eg, sports players, disciplinary forces) were more likely to perceive health apps as useful. This might be because the participants in these occupations had higher health literacy and better understood how to use health apps to improve their health outcomes.

### Implications for Future Research

To better understand the reasons for health app use disparities among different demographic groups, knowledge about why or why not individuals use health apps is needed. This has not been thoroughly studied. We suggest that more qualitative research should be conducted to explore the facilitators of and barriers to health app use. Moreover, most studies examining the impacts of health apps focused on their impacts on health outcomes, whereas their impacts on resource utilization were less studied. Health apps have the potential to save time and money for their users, reduce hospitalization, cut costs, and reduce necessary human resources in health care, but these effects need to be further validated. Thus, we suggest that more research be done to examine whether using health apps can improve resource utilization.

### Implications for Policy

With so many health apps now available, people might find it difficult to identify quality health apps that match their needs and are trustworthy. The European Commission and the US Food and Drug Administration have offered guidelines to regulate health apps to assure their safety and effectiveness [24,25]; however, these guidelines only apply to a small number of health apps [26]. In addition to controlling the quality of health apps, guidelines or recommendations that help people choose appropriate health apps for their needs are also important. Governmental health agencies or other influential health organizations could consider developing standardized health

app evaluation criteria and a decision-making framework to help people evaluate health apps and choose the apps they need.

### Implications for Practice

Despite the fact that health apps can be convenient and useful, we found that most people were not aware of their benefits. We suggest that effort be made to promote health apps, especially to demographic groups that are less likely to use health apps (eg, males, individuals from lower social classes), to facilitate health management and improve individual health outcomes.

Usability is a prerequisite for widespread use of health apps. However, research has found significant usability barriers for health apps that are currently available and suggested that their usability needs to be improved [27]. Moreover, we suggest that app developers consider the needs of individuals with low health and technology literacy so that even people with little knowledge

about health or mobile technology can easily learn to use health apps. This might not only promote the use of health apps, but also help ameliorate health app use disparities.

### Conclusions

Despite the prevalence of mobile devices, many people have never used any mobile health apps. In fact, many of them are unaware of the potential benefits of using health apps. Effort should be made to promote health apps, especially to demographic groups that are less likely to use health apps. Health organizations and agencies could help individuals identify quality health apps that meet their needs by developing standardized health app evaluation criteria and a decision-making framework for choosing health apps. App developers should improve the usability of health apps so that even people with little knowledge about health and mobile technology can easily learn to use them.

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### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Study questionnaire.

[PDF File (Adobe PDF File), 45KB - [mhealth\\_v6i4e103\\_app1.pdf](#)]

### Multimedia Appendix 2

Prevalence, extent, and demographic correlates of health app use (N=612).

[PDF File (Adobe PDF File), 58KB - [mhealth\\_v6i4e103\\_app2.pdf](#)]

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## Abbreviations

**OR:** odds ratio

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Original Paper

# Social Interaction Needs and Entertainment Approaches to Pregnancy Well-Being in mHealth Technology Design for Low-Income Transmigrant Women: Qualitative Codesign Study

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## Abstract

**Background:** Low-income Caribbean transmigrant women face unique health challenges during pregnancy that set forth multidimensional implications for the design of mobile health (mHealth). Acknowledgment of the unique health needs of low-income Caribbean immigrant women in the United States and what that entails regarding technology design remains rarely examined in the literature of mHealth technologies.

**Objective:** The goal of this study was to reveal the needs and gaps in mHealth interventions for pregnant immigrant women not yet realized in this field. These understandings reveal design opportunities for mHealth.

**Methods:** The use of the qualitative participatory action research approach of codesign workshops in this study resulted in design solutions by the participants after reflecting on their earlier focus group discussions. The highlights are not the resulting designs per se but rather the inferences derived from the researcher reflecting on these designs.

**Results:** The designs exposed two themes relevant to this paper. First, the participants desired the inclusion and rebuilding of social and organizational relationships in mHealth. The resulting designs formulate an understanding of the women's health-related social support needs and how technology can facilitate them. Second, the participants wanted entertainment with an element of social participation incorporated in mHealth pregnancy management interventions. This brings attention to the role entertainment can add to the impact mHealth can deliver for pregnancy well-being.

**Conclusions:** The study concluded with an examination of social and entertainment design implications that reveal pregnant immigrant women's virtual health-related sharing habits, choice of sharing interaction scenarios during pregnancy (eg, local, long distance, one-way, two-way, and many-many), and choice of sharing media (eg, text, voice, and video). Additionally, the study revealed exclusions to social sharing capabilities in health technologies for these women.

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## KEYWORDS

mHealth; mobile health; participatory design; pregnancy; Caribbean; immigrant women

## Introduction

### Transnational Social Support

What constitutes social support is the feeling of one's being cared for and assisted as part of a loving social circle [1]. Transnational social support within the context of immigrants

is about accessing social support resources in the receiving country, while also maintaining existing ties in the origin country [2]. The term *transmigrants* was coined to describe immigrants that neither limit themselves to their geographical origin nor to the limits of the new migratory space [2]. Instead, they proactively and creatively partake in new ways in developing a new sense of self and maneuvering creative routes

to resources to help the new self. The conception of the term transnational social support is accredited to technological advances in communication technologies such as the use of the Internet and cellular phone capabilities [2] and hence, the use of the term transmigrants at times throughout this research study to reference the participants.

There is literature advocating for Web-based health-related social sharing across borders [3,4], connecting people across different parts of the world. Additionally, there is other literature advocating for virtual mobilization of local communities with shared issues [5,6] in a term referred to as “community computing” [7].

### Mobile Health and Immigrant Women

Prenatal health is especially critical for low-income recent immigrants who face many health-related challenges as they adjust to their new host country. Their health is compromised as it is because of the unique challenges with this minority group of not knowing the medical resources available to them in the host country, cultural insensitivity by doctors and nurses [5], and mental health stigmas [8]. Thus, pregnancy only adds to their health vulnerability. Pregnancy is an ideal phase for intervention to achieve lifelong health changes, as many are unaware of the benefits associated with preventative care. During this critical time, women are open-minded toward health information and are more likely to follow through [9-11].

The literature on mobile health (mHealth) technologies is saturated with studies investigating contexts in developing countries. As such, the World Health Organization encourages efforts to be extended to the ignored context of minorities in developed countries [12].

### Prosocial Health Technologies

Several technologies promote health initiatives through social motivation or social pressure [3,13-16]. An example included applications that publish the user's physical activity performances to their social media profile for others to see. This exposure motivates users through online encouragement from others or fear of being portrayed as an underachiever. Other forms of virtual support include online health communities, which provide a venue for social sharing, support, and health empowerment [6]. In addressing poor mental health in victims of domestic abuse among immigrant women in the United Kingdom, Clarke et al [17] introduced the digital technology means of photo sharing and storytelling to promote coping and mental wellness through peer support. Another example was a mobile phone app facilitating social sharing of knowledge about healthy eating from personal experiences in low-income African American communities [6]. Engaging in online communities can help users feel empowered with information so that they are better prepared to make better health decisions [3].

### Aims of This Study

Due to the small number of studies exploring health-related technology tools for immigrant women in developed countries, this study aims to contribute in filling this gap. In addition, this paper pushes to the surface the consideration of issues, including emotional and social care to shed light on a new perspective for

the typical topics of diet, activity, and weight tracking in pregnancy management. Thus, social health technology research is extended through the examination of mHealth as a social technology empowering pregnant transmigrant women with safe user-generated health-promoting content.

## Methods

### A Qualitative Study

The methods used in this study were approved by Purdue University Institutional Review Board. This qualitative study adopts a participatory framework within a critical theory paradigm [18], which underpins the choice of methods used. This paradigm helps to produce data informed by two processes: analyzing the interpretation of data and then suggesting an action agenda as recommendations for reform. The participatory framework provides the researcher with the opportunity to seek immediate and valuable input from stakeholders in the design of mHealth technologies to contribute strategic design decisions with the barriers they face daily in mind [19]. The following sections cover recruitment and sampling strategies, study procedures, and data analysis methods.

### Recruitment

The study participants were recruited over the course of 6 months (April 2015-September 2015) by email and in-person recruitment and through personal connections. Information about the purpose of the study along with criteria for eligibility were distributed by email through Healthy Mothers Healthy Babies organization in West Palm Beach, Florida. Additionally, flyers were displayed in public advertisement boards at grocery stores and college campuses around South Florida. In addition, the information was pitched through face-to-face contact with potential participants in public areas. The majority of participants were enrolled in this study by snowball sampling [20], as in word of mouth through personal connections of the author.

### Sampling

The target participants were determined using criterion-sampling strategy [20]. The purpose of employing criterion-sampling strategy was to include cases that showcase predetermined criteria that exhibit the potential to be “information rich” to uncover strengths and weaknesses that can be considered “targets of opportunity” for quality improvement of programs, systems, products, and so on. To be eligible, each participant must satisfy the following criteria: (1) be a Caribbean immigrant women living in South Florida, (2) low income with an hourly minimum wage paid job, (3) had given birth to at least one child in the United States in the age range of 18 to 30 years and in the last 5 years. All other age groups were excluded because of higher risk birth complications that were outside the scope of this study, (4) be able to communicate in English, and (5) have basic knowledge of using cell phones and the Internet. However, the researcher did not directly collect characteristics information specific to each participant in order not to alienate the female participants and to make them feel protected. The study enrolled 12 participants divided into three sessions with 4 participants each.

**Procedures**

The study used focus group discussions and participatory codesign workshops. The first phase of focus group discussions took 30 min to complete. Focus groups were used as a warm up for engagement in the second phase of codesign workshops. Participants were asked to discuss their prenatal experiences as recent immigrants related to topics of pregnancy, relationships, and technology. The second phase of codesign workshops took 50 min to complete . Codesign is a collaborative activity between the researcher and the participants, with the participants taking on the expert role in ideation and conceptualization of design ideas reflecting their personal experiences [21]. The participants were divided into two groups with 2 participants each to ensure equal participation. Each group was asked to come up with design solutions reflecting themes discussed in phase 1. Then, the groups were asked to exchange designs, critique them, and revise them if they were so inclined. The researcher assured participants that no design is considered right or wrong. They were reminded that this activity is not to test their sketching skills. So, the researcher demonstrated plain and simple examples of how to sketch ideas [5]. This demonstrated what the expectations of their sketching skills were to be to encourage participation by those who might be intimidated. A script of the procedures is provided in [Multimedia Appendix 1](#).

All sessions were audiorecorded, and lasted about 2 hours. One of the sessions took place in a conference room of a public library in West Palm Beach, Florida. The two remaining sessions took place on a quiet beach in Surfside, Florida. This is an unpopulated beach for most days of the week. These locations were chosen because of the proximity to where some of the participants worked.

**Data Analysis**

Both focus group and codesign workshops were transcribed following each session. The researcher supplemented each

transcription with notes on preliminary reflection and a set of possible codes attached to pieces of text. An inductive constant comparative method was used to review and compare transcripts to come up with codes using an iterative coding process. The codes emerged from the transcripts and were not assumed beforehand. The process was iterated several times until connections were established among low-level themes and later combined into broader themes. Only after codes have emerged, the researcher consulted with past literature to make sense of the data. In the following sections, excerpts from the transcriptions are referenced using the session number 1, 2, or 3, with either group 1 or 2 within that session, and then with either 1, 2, 3, or 4 for each participant in that session. For example, [1.2.4] refers to session 1, with group 2 of the codesign segment, and participant 4.

**Results**

**Overview**

The results in the following section outline themes (Figure 1) related to social health-related stressors, social health-related behaviors, and social design interventions (Table 1) relevant to the context of transmigrant women.

**Social Health-Related Stressors**

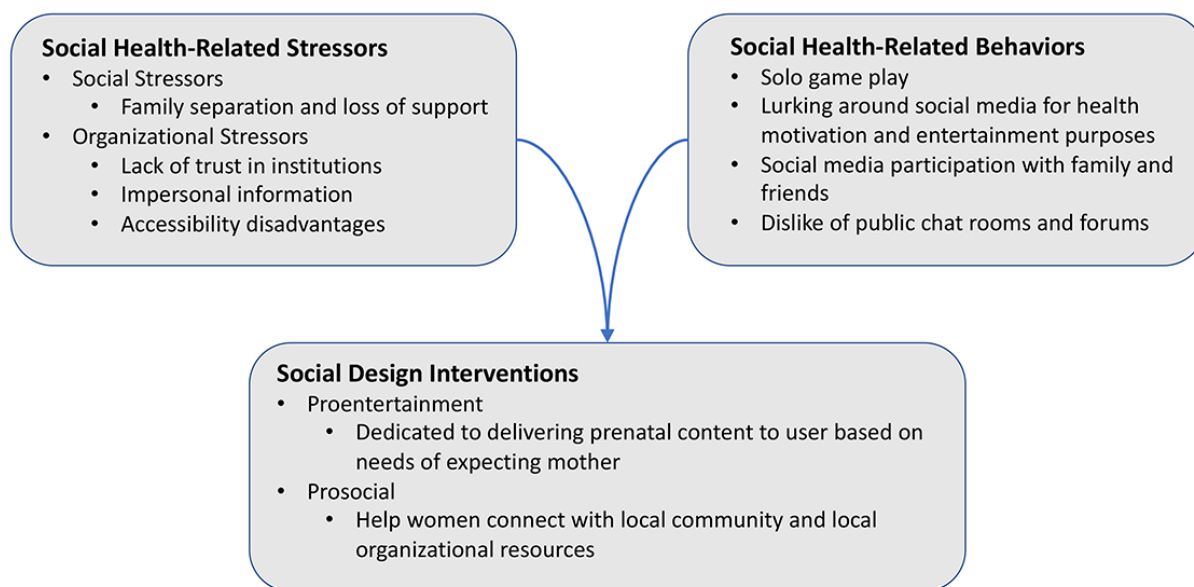
This section presents a brief summary of the social and organizational health-related stressors faced by pregnant immigrant women.

**Social Stressors**

For these Caribbean women, pregnancy is a celebrated occasion among female members of the family, such as with the mother and siblings, as illustrated in the following quote:

*...men back home not his business you are pregnant. Bring your mama over to help you. [3.1.3]*

**Figure 1.** Themes related to social health-related stressors, social health-related behaviors, and social design interventions.





**Table 1.** Social design interventions relevant to transmigrant women.

Intervention	Description
<b>Proentertainment<sup>a</sup></b>	
Unlock My Pregnancy	Customized personal pregnancy lifestyle app
Virtual Clinic	Prenatal clinic services <ul style="list-style-type: none"> <li>• “You Really Should”</li> <li>• “All-Access”</li> <li>• “Relaxation Suite”</li> </ul>
<b>Prosocial<sup>b</sup></b>	
Buddy Network	Local caregiving social support system <ul style="list-style-type: none"> <li>• Reciprocal local support</li> </ul>
Video Call	One-to-one support <ul style="list-style-type: none"> <li>• Video, text, call, local doctors, or health care professionals</li> <li>• Speak same language</li> <li>• Understand the patient’s culture</li> </ul>
Conference Call	Three-way with patient, doctor, and family

<sup>a</sup>Dedicated to delivering prenatal content to user based on needs of expecting mother.

<sup>b</sup>Help women connect with local community and local organizational resources.

During this time, they help alleviate a lot of the burdens to allow the expecting mother to pursue wellness activities. Due to family separation and the loss of support such relationships play during pregnancy, many felt homesick, as illustrated in the following quote:

*You are homesick when pregnant, or sometimes wish you have family or sisters or friends with you in appointments or when you need to make decisions or need the emotional support you know. [1.2.4]*

### Organizational Stressors

Another relationship stressor for these women is at the organizational level. Their relationship with health care professionals were strained by mistrust, as illustrated in the following quote:

*You coming here, you want to be part of the modern life. Is a hustle mama. They tell you all these things you need that you don’t need, or something wrong with you to charge you for tests you don’t need. [2.1.2]*

Their interactions and experiences were not pleasant, as illustrated in the following quote:

*I ask the nurse at the clinic and she turn her nose up at me. The doctor dun speak in a language I understand then push me out. [3.1.1]*

Furthermore, it did not help that they used outdated, crammed, and impersonal informational mediums such as brochures and pamphlets, as illustrated in the following quote:

*By the time I get home, you know, I already remove the brochure from my mind. By the time I get home, it is part of the trash if I remember that is somewhere. Mostly all wrinkled in my handbag. [1.2.1]*

Even when trust existed toward local organizations with resources catered specifically toward this population, the women could not make use of them because of fatigue and accessibility disadvantages, as illustrated in the following quote:

*You have some organizations that give free access to pregnant women to professionals like social workers or free yoga classes and pregnancy lessons for, which is great. But, you have issues of commuting time and money to get there, when you already have to commute sometimes up to one hour or more on a bus everyday, sometimes for a job or two. Or maybe you have no time with job and family. [1.2.4]*

### Social Health-Related Behaviors

Variable energy and fatigue during pregnancy led some participants to feel isolated and bored. Equally, the changing pregnant body led some participants to be antisocial during pregnancy. In response, some participants found comfort in using gaming entertainment technologies, as illustrated in the following quote:

*I play candy crush, is good when you stressed. It help your brain work again. [2.1.4]*

Additionally, some found lurking around social media sites as an entertainment strategy, as illustrated in the following quote:

*I be addicted to finding out what’s goin on! I love lookin at the pictures and tweets while I’m sittin at home fat and lazy! [3.1.3]*

Surprisingly, few participants found lurking around social media to be a motivating strategy to engage in better prenatal health and wellness behaviors, as illustrated in the following quote:

*I also sometimes go online and look for pregnant women pictures like Instagram and Pinterest, who dress up and workout, so I can be motivated. [1.1.2]*

Furthermore, some found comfort in connecting with family and friends by posting “pregnant selfies” to their mobile group messages or social media, as illustrated in the following quote:

*I think I look better in pictures. You can use filters and if you are smart with how you pose, you will look sexy. You have more curves...So, I have a chance to celebrate my pregnancy. I can also say that I like when people like my pictures or put a comment things that I am glowing or say other nice things and it makes my day better because then I feel better about myself. [1.1.2]*

However, participants disliked sharing with strangers in chat rooms and forum features, as illustrated in the following quote:

*If you have a good question, no one answer, no one care. Only if you a drama queen question, like my baby daddy drama, I don't know what...Women are drama. They judge each other and rude to each other, mean, very mean. [2.1.1]*

## Social Design Interventions

### Proentertainment Designs

Two design solutions in particular were dedicated to delivering prenatal content to the user based on the needs of the expecting mother. One is called *Unlock my Pregnancy* and another *Virtual Clinic*. Participants wanted to see content regarding prenatal diet and exercise, misconceptions, body changes, and emotional coping strategies. Participants described *Unlock my Pregnancy* as a customized personal pregnancy lifestyle app. On the other hand, *Virtual Clinic* is exactly as the name implies, a clinic. It was the participants interpretation of what prenatal clinic services should be about, all brought together virtually. The clinic is divided into three suites: *You Really Should*, *All-Access*, and the *Relaxation Suite*. The *You Really Should* suite is a lifestyle suite about healthy pregnancy diet and fitness. *All-Access* is a health suite with week by week content in relevant medical information. The *Relaxation Suite* within the *Virtual Clinic* endorses a range of relaxation strategies that participants referred to as “me time” (1.2.2), such as providing a weekly glossary on mood boosting foods, herbs, scents, beauty, and hair routines and added entertainment music, videos, and games. Additionally, the suite was equipped with support features from people in the immediate social circle and professionals as well. The goal for involving the immediate social circle was to boost the user’s mood through socializing and better communication. For example, the user may choose to display updates about their pregnancy mood by choosing from a list of mood emojis or sarcastic memes. Then, it sends push notifications to their social circle prompting them to react. They may react by initiating a Skype session, or an invitation for a joint activity, or vote from a set of system-generated relaxation tips, or send in their own recommendations. One of the participants described the value of these features by adding the following:

*A lot of women feel lonely when pregnant, you are away from family and you bored because you wonder you can't do the same things with friends like go dancing or go somewhere looking cute but you not.*

*But, you don't know how to communicate that. I think, ok, what I would do if I was back home now? You are always having family get together eat and talk hours and hours. Then I should try to do the same here because it's fun and being social make you feel better. So now this maybe can help you communicate maybe that better with your husband, your family and friends back home, and your new friends here. [1.2.2]*

Furthermore, participants suggested adding a feature where you can chat with or send questions to a medical professional or therapist within relevant cultural organizations about emotional stressors. A user can view bios of these volunteers and therefore, ease their stress regarding with whom they communicate with. Additionally, it allows the user to ask questions without having to deal with the stress of interacting with strangers in forums with too many opinions and bullying.

### Prosocial Designs

Participants offered recommendations to help women connect with local community and local organizational resources as a means of alleviating burdens and allowing more time to pursue wellness. One resulting design, the participants named *Buddy Network*, showcased a local caregiving social support system. Ultimately, the participant’s goal was building a reciprocal local support system, through which a two-way give and take platform allows people in the same community to share services and resources such as transportation, childcare, fitness companion, and so on. Here is what one participant shared about the added value to such a design:

*When you first come to this country, something like this is really good. Also, its hard when you are not with your family and need help. Even if you have a man, maybe you feel like a single mother. Its good if a group of women want to help each other walk or run, like exercise, and anything else. I don't know what I would do when I first come here, you know, if I didn't have connections like kind neighbors or kind people in the church. It makes a difference. [2.2.2]*

Participants were quick to clarify that this is not similar to applications such as *Craigslist* or *Meetup*. To them, it is safer and more intimate and is built on a system of accountability, as illustrated in the following quote:

*But, to take, you have to give back. It doesn't have to be back to the same person. But, you can't take without giving, or you can take and then it count as credit, and you can't redeem another favor until you gave something...you subscribe to a community you live in. Maybe through local organizations connecting you, you can choose your own circles. Some features like that...We are thinking this is organized by community leaders, organizations, churches. So, then this can help with safety, also now you don't have to deal with online bullying. [2.2.3]*

Another resulting concept for social support, *Video Call*, is a one-to-one support app that allows you to video, voice, or text chat with local doctors or other health professionals such as psychologists and nutritionists. After a very brief profiling step,

the user will be connected with a professional who can speak the same language and can understand their culture. Participants expressed a preference for building a trusting long-term relationship with their doctors, as illustrated in the following quote:

*What if I like them? Can I choose the same each time I use this? I think it will be nice to have the same professional every time. I will be willing to wait for them to be available if now I have a comfortable relationship with them, I feel like they know me, they actually know me! Now I don't have to be stressed.* [3.2.1]

Several resulting designs came with both local and long distance virtual social support capabilities prompting others to participate in the intervention to aid in supporting the user. For example, *Unlock My Pregnancy* allowed screen-sharing capabilities so that a parent or a spouse can view and contribute to their profile, as illustrated in the following quote:

*Maybe you have contributing days like #familysundays or #husbandsmonday. You see how I sneak that in?* [2.2.4]

Those who you allow to contribute to your profile are encouraged to participate by providing a “thumb up” if they like any content or “thumb down” if they dislike any content. One participant stated the following:

*So you know what the people who care about you think, and you don't have to ask them about every single thing when there is time difference or we busy. You know I would be curious, I would feel better too because I have companions with my decisions.* [2.2.4]

Similar to *Video Call*, *Unlock My Pregnancy* and *Virtual Clinic* also added social support features, enabling chat and question and answer sessions with volunteer local doctors, nutritionists, fitness instructors, and so on.

Another design, named *Conference Call*, is about having family accompany you virtually to all your prenatal activities so that you don't have to feel homesick or alone. The concept allows you to share precious moments during pregnancy with family and friends no matter where everyone is. One participant stated the following:

*You are homesick when pregnant, or sometimes wish you have family or sisters or friends with you in appointments or when you need to make decisions or need the emotional support you know. Even if they are in the same country or even city, sometimes you can't both be there at same time. Or, you are even busy. We were talking about beautiful memories like skyping with sisters or friends showing how we prepare for a new child.* [1.2.4]

Participants acknowledged that it is similar to apps such as Skype or Facetime in a way, and they hope for it to be added as a feature to pregnancy apps. For example, to enable a three-way or more video call with in-person doctor appointments, or with a virtual specialist, or to stream prenatal classes, or to view videos together at the same time.

## Discussion

### Principal Findings

The desire for the inclusion of social relationships, rebuilding of organizational support, and incorporation of social entertainment in design make up the themes outlined in the findings of this study. The Discussion outlines design considerations of the role of transnational relationships, including the choice of sharing interaction styles and the role of entertainment in mHealth interventions.

### Consider the Role of Transnational Relationships

Due to the absence of family and the tensions in the relationships of the women with their significant other if he fails to adapt post migration into fulfilling these missing roles during pregnancy, the participants defaulted to transnational ties for social support during pregnancy. Several of the resulting designs further emphasized how transmigrant women value the important role social support plays in coping with pregnancy stressors. Thus, this study joins previous studies [5,22] that are prosocial design in health care interventions. However, within the context of this study's transmigrant participants, the findings are rather protransnational social design in health care interventions. Incorporating the roles others play in a woman's life is suggested in the literature for human-computer interaction (HCI) and health design interventions [5,22].

The transnational relationships in a transmigrant woman's life fluctuate in influence and contribution power depending on her informational and emotional needs at a particular time throughout the course of pregnancy. Concluding from the participants' accounts during focus group and design sessions, available prenatal technologies offer no social support capabilities despite the role relationships play in a pregnant transmigrant woman's life. Social features and capabilities should enable valued transnational interactions to contribute in the women's pregnancy mHealth interventions. Here is how the study envisions interaction scenarios that facilitate local, long distance, and individual caregiving themes the pregnant transmigrants showed interest within their resulting designs.

### One-to-One Interactions

In this type of interaction scenario, mHealth allows others in the transmigrant pregnant woman's intimate social circle to participate with aiding the pregnant woman in her health journey. Due to the significance in the meaning of family during pregnancy for immigrant women, inclusion of immediate family members such as the mother, siblings, and very close mom friends (moms with children of the same age) is a key design opportunity for mHealth. Another advantage to this type of interaction capability is the facilitation of an outlet to rebuild social relationships that play a major role in a woman's pursuit of health behaviors, such as the role of the significant other.

Because the health care system and online sources fail them, the participants rely heavily on informal resources of information such as family and a close circle of mom friends. This could lead to socially and culturally influenced misconceptions that are common among pregnant women. This was evident during focus group discussions as women shared

socially and culturally troubling discourses regarding fitness practices, food consumption, weight management, birthmark, fetal development, miscarriage causes, and more. The inclusion of these intimate relationships are beneficial in the sense that mHealth can play a role in controlling and filtering the type of information usually trickled down through such sources. This is one area where mHealth can make a significant impact.

Thus, this study calls for gender-neutral designs [22] so as not to discourage others from participation. Furthermore, consider adding social support enabling features such as interactive screen sharing, saved video chat messaging, the use of prompts, and creative contribution commands.

### **One-to-Many Interactions**

A one-to-many interaction scenario provides a platform for rebuilding organizational support. The findings revealed that participants desire a caring connection with professionals whom they seek medical and wellness guidance from. This is consistent with findings in the literature regarding immigrant women's health [5]. This was highlighted by designs such as *Conference Call*, *Video*, *Virtual Clinic*, and *Unlock my Pregnancy*. Additionally, participants desired such an interaction scenario in mHealth technologies that would help local community organizations provide their services virtually. The purpose is to allow for easy access by accommodating their busy lifestyle because of commuting time and fatigue. This type of interaction could allow the inclusion of one-to-one scenarios with transnational relationships to provide support and motivation to engage with organizational health activity resources.

### **Exclusions in Interaction Scenarios**

Within previous HCI and social networking research [23-25], pregnant women are described as comfortable sharing pregnancy and motherhood information on online social settings, even with strangers. This certainly contradicts with the findings in this study and previous studies by Peyton et al [22] and Willcox et al [26]. Although the study by Peyton et al [22] does not explain this finding, Willcox et al [26] relate these findings to the women's perceived risk of online bullying. What accounts for these contradictions are examined to a greater depth in this study. Let us examine what is been concluded from the findings on the participants' social sharing habits during pregnancy and imposed impact of social sharing networks on the transmigrant's pregnancy ecology.

In sharing with family, participants mostly preferred using private group texting apps such as Whatsapp and video chats such as Skype. Participants were comfortable sharing only in intimate social circles such as with parents, siblings, and few very close friends. The findings revealed that the women's sharing habits in their personal social media profiles were conservative and cautious during pregnancy, with the exception of a few. Cultural beliefs, shaming, distrust over what people share on social media, and fatigue were some of the reasons for such conservative practices.

In the context of pregnancy, some transmigrants took on the role of viewers rather than sharers in interactions with strangers on social networking tools. Being a viewer allowed these participants to seek motivation and inspiration to engage in

healthier activities. Others used it as an entertainment tool to feed curiosity and deal with boredom. Very few transmigrant participants did engage in online social media sharing during pregnancy in which their content was viewed by family members, coworkers, and acquaintances. There might be slight variations in sharing habits among transmigrants depending on factors such as age, exposure to pop culture, and the desire for a socializing support outlet while pregnant in a new country.

However, all participants seemed to have no desire for engaging with complete strangers online. All participants disliked chat rooms and forums in any Web or mobile pregnancy tool, which sometimes grouped strangers together who share the same birth month. They cited reasons of disapproval such as bullying, conflicting information, and responses that often go out on irrelevant tangents. As a result, participants did not feel comfortable engaging and sharing with strangers online within pregnancy tools.

### **Many-to-Many Interaction Scenarios**

The only case of sharing with strangers the study's participants felt at ease with were a community building form of social sharing. This theme was present in the resulting design *Buddy Network* that facilitated the concept of local caregiving. For immigrants, new ties in the host country contribute for an easy transition by providing help in guidance with navigating the new country, help with transportation, child care, and socializing [14]. What eases such interaction is that those who feel marginalized or excluded by the health care system and existing technologies come together because of shared circumstances to engage in a reciprocal relationship for the purpose of community building and organizational support. Such interventions can create opportunities for guided interaction within these groups to support and facilitate community sharing. The study suggests that such interventions be directed by local community organizations to ensure safety and accountability.

### **No Role Interactions**

Not every design needs to include social support capabilities. Discussions during focus groups and one design by the study's transmigrants, *Pregnancy Siri*, revealed that in certain instances participants preferred managing pregnancy independently and in others discretely. Therefore, designs that require no role from others are intended for the pregnant woman's individual self-support use or individual private use. This conclusion is consistent with online information-seeking behaviors of Caribbean immigrant women [5]. In such cases, the built-in support capabilities of the technology itself are sufficient for achieving their needs. This presents an opportunity for future mHealth to examine in depth what entails designing for technologies that supports pursuing well-being discretely for transmigrant pregnant women. This certainly does not fit well with social networking technologies that publish to others [13,16], for example, the user's fitness activities and progressions.

### **Consider the Role of Entertainment**

The female participants came up with designs to manage emotions and mental pregnancy stressors. They believed in the healing influence relaxation and entertainment activities provide

in managing pregnancy health. Being healthy during pregnancy for these women goes beyond what has been predominately covered in prenatal health and HCI work that is been oriented toward topics such as dietary needs and weight management [9,22]. This is especially significant because of the emotional challenges reported by the participants and the likelihood of Caribbean women not receiving treatment for mental health issues [27] such as perinatal depression [28] and domestic abuse [17], which puts them at higher risk for prolonged mental distress than white American women.

Although this often ignored component was introduced in a previous study on immigrant women's health by Brown et al [5], this study joins by endorsing the value of entertainment but in the context of pregnancy for transmigrants' mHealth design. This means not only being proentertainment by advocating for relaxation activities as part of mHealth interventions [5] but also in adding a support aspect to it. This comes in a form where a technology prompts the important transnational ties in a pregnant woman's life to contribute with recommended or joint entertainment activities.

### Limitations

The small sample size of participants may pose limitations with regard to the generalizability of the findings. The limitation of small sample size in this study was in part because of the extensive amount of time and work it took to engage and recruit these participants and schedule sessions with them. Additionally, the researcher was focused heavily on achieving depth to the emerging data and did not want to compromise the integrity of the data by focusing on a larger sample within the time

constraints of this research. Small sample sizes are appropriate in certain research instances. Inductive exploratory research concerned with generating rich and multidimensional concepts from the data itself rather than being implied beforehand may benefit from small sample sizes [29,30]. In such cases, small samples can enhance the researcher's role in recruitment and engagement with participants [29,30]. Furthermore, it allows for repeated access to participants, which strengthens the validity and reliability of the data [29,30].

### Conclusions

This paper focused on presenting two approaches to design imagined by the transmigrant participants of prenatal mHealth technologies. The first approach is for mHealth to facilitate the transnational social and organizational support and resources necessary for better pregnancy health management. The women formulating and then revising the resulting designs exposed attention to the role transnational relationships play in health and well-being and how technology can facilitate them. The second approach is employing entertainment and relaxation while accounting for social and cultural dimensions to bring pregnancy health into full circle for these women. Future work should examine transnationalism as a methodology for mHealth design to examine whether the country of origin for these immigrant women has the infrastructure to facilitate mHealth social interactions with the new host country. Finally, the value of transnational interactions in mHealth for potentially improving healthy behavior and technology use adoption may extend to other immigrant populations as well and prove beneficial beyond the period of pregnancy.

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### Conflicts of Interest

None declared.

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### Multimedia Appendix 1

A script of the procedures used.

[[PDF File \(Adobe PDF File\), 29KB - mhealth\\_v6i4e61\\_app1.pdf](#)]

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## Abbreviations

**HCI:** human-computer interaction

**mHealth:** mobile health

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Original Paper

# Management of the General Process of Parenteral Nutrition Using mHealth Technologies: Evaluation and Validation Study

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## Abstract

**Background:** Any system applied to the control of parenteral nutrition (PN) ought to prove that the process meets the established requirements and include a repository of records to allow evaluation of the information about PN processes at any time.

**Objective:** The goal of the research was to evaluate the mobile health (mHealth) app and validate its effectiveness in monitoring the management of the PN process.

**Methods:** We studied the evaluation and validation of the general process of PN using an mHealth app. The units of analysis were the PN bags prepared and administered at the Son Espases University Hospital, Palma, Spain, from June 1 to September 6, 2016. For the evaluation of the app, we used the Poststudy System Usability Questionnaire and subsequent analysis with the Cronbach alpha coefficient. Validation was performed by checking the compliance of control for all operations on each of the stages (validation and transcription of the prescription, preparation, conservation, and administration) and by monitoring the operative control points and critical control points.

**Results:** The results obtained from 387 bags were analyzed, with 30 interruptions of administration. The fulfillment of stages was 100%, including noncritical nonconformities in the storage control. The average deviation in the weight of the bags was less than 5%, and the infusion time did not present deviations greater than 1 hour.

**Conclusions:** The developed app successfully passed the evaluation and validation tests and was implemented to perform the monitoring procedures for the overall PN process. A new mobile solution to manage the quality and traceability of sensitive medicines such as blood-derivative drugs and hazardous drugs derived from this project is currently being deployed.

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## KEYWORDS

parenteral nutrition; mobile apps; quality control; validation software

## Introduction

The use of information and communication technologies (ICTs) in the health field opens a long list of possibilities aimed at achieving benefits at many levels in the health environment. A

wide spectrum of research trends emerges. The use of ICTs plays a paramount role in the development of innovative clinical nutrition projects, especially in collaborative environments that go far beyond Web apps. A new area emerges, eHealth, in which great advances, new benefits, and possibilities arise when



applying ICT to the health care domain, especially with the use of mobile apps, mHealth.

Systems supported by telematic apps enable registries that allow linking and evaluation of information on parenteral nutrition (PN) processes at any time [1]. The activity of verification of a system developed for PN control allows determining if it meets the requirements and conditions imposed in the design phase [2] and allows defining the tasks the telematic app is expected to perform. Verification should confirm that the system correctly implements its specification. Control operations must validate that hazards are monitored and ensure that the system works as planned. Likewise, the developed system must document the registries of the controls established to demonstrate that the entire PN process is under control and corrective actions have been taken in the event of any deviation from the critical points [3].

The good practices guide for the preparation of medicines in hospital pharmacy services establishes that all procedures related to the preparation of medicines, including PN, should be approved and reviewed. This guide establishes the need to evaluate and verify all procedures related to the preparation of medicines under the premise of “applying the principles of risk management for quality and quality by design” [4]. The European Commission, in its guide on principles and guidelines for good manufacturing practices for medicines [5], pointed out the need for qualification and validation of facilities, equipment, services, processes, protocols, etc. The quality by design implied systematized and continuous validation of the processes in order to improve them based on the scientific evidence, always taking into account quality, efficiency, and safety [4].

The Spanish Society of Hospital Pharmacy (Sociedad Española de Farmacia Hospitalaria), in its standards of practice for specialized nutritional support established by its Nutrition Working Group [6], recommended “defining the tools of the management process aimed at achieving an efficient nutritional support, which allow obtaining the best results with a reasonable cost.” One of the standards that helped achieve this goal was developed by identifying the problems that affected quality, evaluation of the processes, and verification of the results.

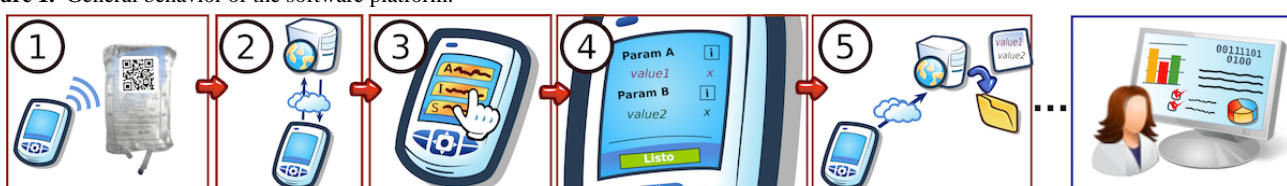
The objective of this study was to evaluate the mHealth app and validate its effectiveness in monitoring the management of the PN process.

## Methods

### Design of the Study

A follow-up study was planned to evaluate a previously developed mHealth app and validate that it covers the real needs of the general process of PN.

**Figure 1.** General behavior of the software platform.



### Unit of Analysis

The units were the PN bags prepared by the pharmacy service of the Son Espases University Hospital (HUSE) of Palma, Spain.

### Identification of the Parenteral Nutrition Bags

For the management of the stages of validation and transcription of the prescription, HospiWin 2000 version 8 (Baxter SL) software was used. This program provided the label that was attached to each PN bag. In addition, the entities to be monitored (PN bags) were identified with a unique code (a QR label was attached).

### Study Period

The tracking of the PN bags was carried out from June 1 to September 6, 2016.

### Determination of the Parenteral Nutrition Process

The flow diagram, including all the stages of traceability and management of the PN, was generated and is published elsewhere [7]. Using this flowchart as the starting point, a dashboard to monitor the involved stages was created selecting the critical control points (CCPs).

### mHealth App

Using a methodology based on hazard analysis and taking advantage of semantic technologies, a holistic service platform for traceability and process control was designed. Figure 1 summarizes the operation of the platform.

Upon the reading of a QR tag attached to an element to be monitored (in this case a PN bag), a data exchange occurs between the mobile app and the analysis server (steps 1 and 2). This server accesses its semantic knowledge base to infer the potential control operations associated with the PN bag. Using this data and other contextual information (such as the user type, location, or time), a personalized list of ranked operations is sent to the mobile app (steps 2 and 3). The user selects the most convenient operation (step 3), probably the first one on the list, and the app generates a form to capture the values required for the task under consideration (step 4). At this point, the human user completes the form and captures photos when required, and the mobile app acquires any other required pieces of data, such as GPS location or time. These data are sent to the server to update the knowledge base (step 5). Finally, analysts and auditors can use a Web dashboard to visualize the data and trace the operations. A more detailed description of the platform is published elsewhere [8,9].

The verification of this app was previously published [10]. The app was deployed in an environment of home hospitalization to test its capacity to geoposition the stages and, in particular, the medicine administration stage [3].

### Invocation of the mHealth App

Each one of the requests performed by this app was linked to a certain control operation in a particular stage. In case an operation was invoked more than once, by PN bag, the system only validated the first request, storing the remaining ones as “null requests.”

### Evaluation of the mHealth App

An assessment of the utility and ease of use was performed. For this purpose, the Poststudy System Usability Questionnaire (PSSUQ) [11] was used. This questionnaire was designed to collect the perception of the participant in this type of study. It consists of 19 items, uses a 7-point Likert scale, and allows estimating the perceived value of usability over 4 dimensions: general satisfaction (OVERALL), utility of the app (SYSUSE), quality of the information (INFOQUAL), and quality of the interface (INTERQUAL). Based on the collected data, reliability of the responses was determined. The survey was generated in electronic format and sent to 50 professionals at HUSE with no advanced knowledge in ICT. They could answer anonymously.

### Validation of the Parenteral Nutrition System

Validation was performed by checking the compliance of all the operations in each of the stages and corroborating that they were adequately monitored, particularly the operative control points (OCPs) and, more importantly, the CCPs. In order to validate the process, the results obtained from 387 PN bags at HUSE were analyzed.

In the preparation stage for the gravimetric control, according to HUSE protocol for PN bags with a volume greater than 100 mL, the real weight should not exceed a margin of  $\pm 5\%$  of its theoretical weight.

For control of the storage temperature of the PN bags according to the procedure for the preservation of thermolabile medications at HUSE [12], the operational limits were established at 2°C (lower limit) and 8°C (upper limit) and the critical limits at 0.1°C and 12°C.

In the administration stage, in the absence of preestablished limits for time and speed infusion, recommendations for each specific nutrition were observed according to the patient's clinical and social situation and the device used for its administration.

### Variables to Study

The stages of the process were prescription, preparation, preservation, and administration. All control operations at each stage of the process were recorded in a dichotomous way (yes/no), according to whether they were finished or not.

The operations characterized as CCPs were gravimetric control, temperature of the refrigerator, and volume and time of infusion (administration). These operations were recorded in a continuous and quantitative manner.

The operations characterized as OCPs were microbiological control (which is recorded a posteriori), final check of the PN (including the checking of physical parameters such as turbidity, precipitate, strange color, etc), and existence of the filter in the

infusion pump (according to the PN type). These operations were recorded by means of dichotomous observations (yes/no). In all cases, it was possible to capture an image to prove compliance with a certain operation.

### Data Analysis

The parameters monitored through the mobile device (phone or tablet) were sent to the Web server. This server processed these data and stored them in the knowledge base in the form of facts. The information model used was designed using Semantic Web-based techniques that allowed representation of concepts and relationships and offered advanced query services and analysis capabilities [9].

To access the information managed by the system, the Web service offered a dashboard accessible through a common Web browser. In this dashboard, analysts and auditors were able to study and evaluate the history of records generated in any phase of the process, filter them based on various aspects of the context (date, responsible user, etc), download the information in a standardized format (comma-separated values), and visualize usage statistics through easily interpretable graphics.

A descriptive analysis was performed on the control operations assigned to each stage. The quantitative variables were characterized by their sample mean, standard deviation, median, mode, maximum, minimum, and interquartile interval (IQI). To avoid problems caused by outliers in the mean, the robust average was also calculated. The qualitative variables were characterized by their absolute and relative frequencies. Figures and tables were used to represent the most relevant qualitative variables.

For analysis of the internal consistency of the answers obtained from the PSSUQ (study of the reliability of the measurement scale), a Cronbach alpha coefficient was used. To evaluate the significance in the difference of means for independent samples, a Student *t* test was used. The significance level used in all hypothesis tests was  $\alpha \leq 0.05$ .

Quality control of the data was performed through double tables and active search for errors. When errors were found, they were corrected by consulting the original source. SPSS Statistics version 22.0 (IBM Corp) was used for the analysis.

### Ethical Requirements

This work is part of the PI13/00464 project and was approved by the project evaluation body of the Miguel Hernández University with registration number 2013.95.E.OEP.

## Results

During the implementation of the mHealth system for the traceability and management of PN at HUSE, 50 professionals took part and a total of 387 PN bags were managed.

### Evaluation of the mHealth App

The usability test was performed at HUSE, with a total of 21 hospital professionals collaborating (42% of the staff was invited to participate).

**Table 1.** Results according to the dimensions of the Poststudy System Usability Questionnaire [11].

Usability dimensions	Description	Mean (SD)	Median <sup>a</sup>	Cronbach alpha <sup>b</sup>
OVERALL	Overall satisfaction	5.1 (1.9)	6	.98
SYSUSE	System usefulness	5.2 (1.8)	6	.94
INFOQUAL	Information quality	5.8 (1.9)	6	.96
INTERQUAL	Interface quality	4.8 (2.0)	5	.98

<sup>a</sup>Maximum value: 7.

<sup>b</sup>Maximum value: 1.

**Table 2.** Control operations for each stage of the parenteral nutrition management system at Son Espases University Hospital.

Stage	System control operation	Adult (n=353), n	Pediatric (n=34), n
Validation of the prescription	Validate prescription	353	34
Transcription of the prescription	Transcribe prescription	353	34
Preparation	<ol style="list-style-type: none"> <li>1. Initial check of trays/materials</li> <li>2. Control of PN<sup>a</sup> preparation</li> <li>3. Final check of trays/materials</li> <li>4. Gravimetric control (CCP<sup>b</sup>)</li> <li>5. Adequacy of physical parameters (OCP<sup>c</sup>)</li> <li>6. Final check of PN (OCP)</li> <li>7. Microbiological record of PN (OCP)</li> </ol>	353 <sup>d</sup>	34 <sup>d</sup>
Conservation	Temperature control of the refrigerator (CCP)	353	34
Interruption/suspension of administration	Cause of interruption/suspension of the administration <sup>e</sup>	26	4
Administration	<ol style="list-style-type: none"> <li>1. Start time</li> <li>2. Infusion time (CCP)</li> <li>3. Volume to be administered (CCP)</li> <li>4. Identification of the pump</li> <li>5. Existence of the filter (OCP)</li> </ol>	327	30

<sup>a</sup>PN: parenteral nutrition.

<sup>b</sup>CCP: critical control point.

<sup>c</sup>OCP: operative control point.

<sup>d</sup>The records regarding the microbiological analysis of the PN and, where appropriate, the counter sample were generated a posteriori once the results were known.

<sup>e</sup>Suspension: complications due to underlying disease or complications related to PN (mechanical, infectious, metabolic). Interruption: improvement (oral/enteral), transfer to another center or exitus.

The overall result of the responses to the questionnaire presented the following values: mean 96.0 (SD 6.6), median 102, minimum 29, maximum 133, and IQI 72.5 to 118.5 (maximum score 133 = 19 items × 7 maximum score). The statistics obtained according to the different usability dimensions and study of the reliability of the measurement scale using the Cronbach alpha coefficient can be seen in [Table 1](#).

### Validation of the Parenteral Nutrition System

In the validation study, 387 PN bags were managed; 91.2% (353/387) of the bags were from adult patients and 8.8% (34/387) from pediatric patients, with a total of 3860 control operations (see [Table 2](#)). A total of 7.8% (30/387) of the bags were interrupted in administration, 6.7% (26/387) in adults and 1.0% (4/387) in pediatrics: 2.1% (8/387) changed to oral/enteral nutrition, 2.3% (9/387) due to the underlying disease, and 3.4% (13/387) due to complications related to PN (mechanical,

infectious, or metabolic issues). These data proved that all operations could be registered in the digital repository.

### Dichotomic Controls of the Operative Control Point

All operations related to OCP were recorded and audited in the knowledge base, including the type of operation, date, and person who carried out the operation. Compliance with these controls was 100%.

### Quantitative Controls of the Critical Control Points (Gravimetric, Infusion Time, and Volume to Be Administered)

The statistics obtained from the control of the operations labeled as CCPs for PN bags intended for adults and children can be checked in [Table 3](#). Compliance with CCP control was 100%.

As shown on [Table 3](#), the gravimetric controls allowed verification that deviation of weight of the bags was 0.5% in adult PN and 4.9% in pediatric PN (both measurements were

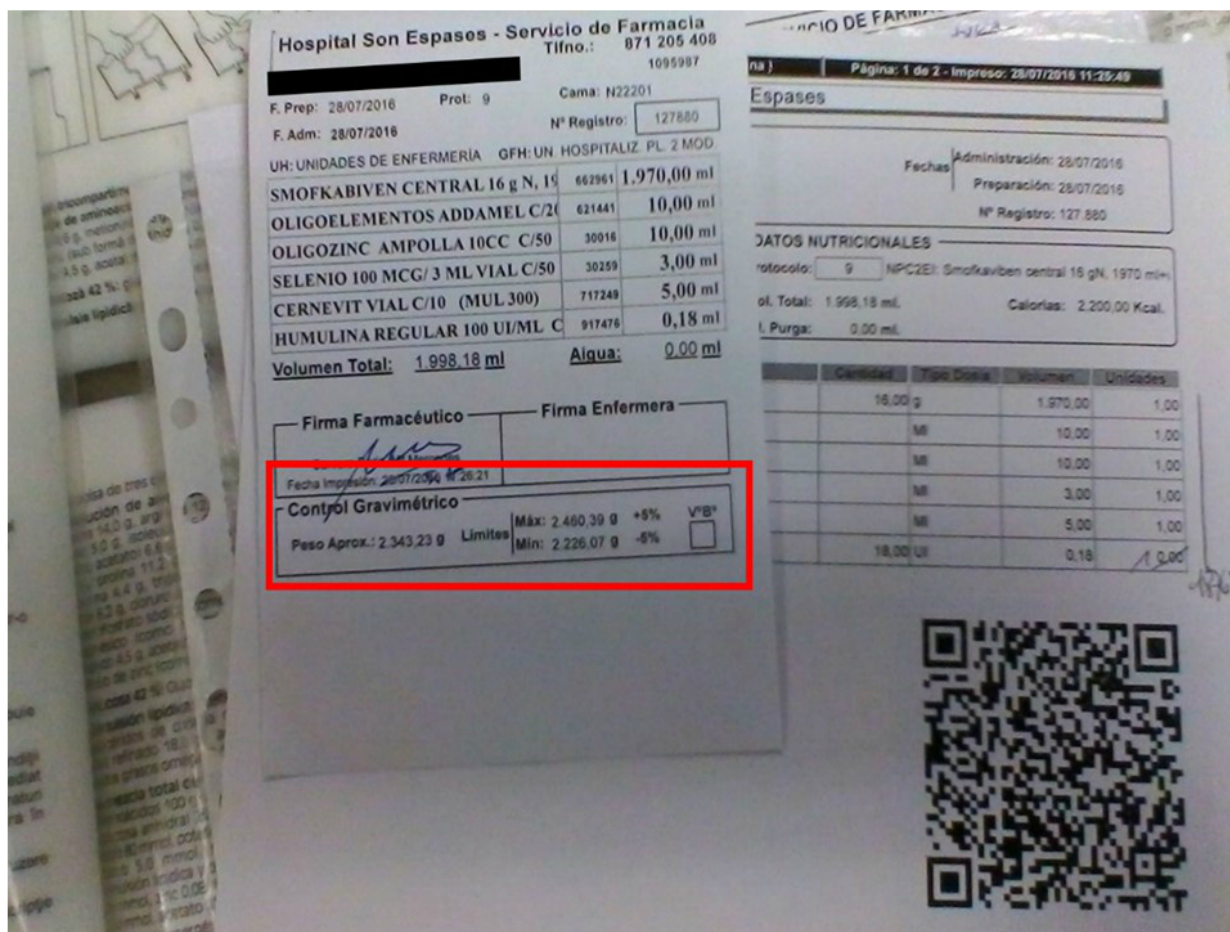
within the range of allowed deviation:  $\pm 5\%$  of the theoretical weight). In addition, the gravimetric control of each bag and its registration by image allowed verification that all were within the expected weight (see Figure 2).

In the administration stage, it was found that for infusion time (measured in hours), the deviation from the mean was 0.3 hours for adults and 0 hours for children (see Table 3).

**Table 3.** Statistics regarding the control operations identified as critical control points in the management system and the traceability control of parenteral nutrition.

Patient, stage, and control operation	Mean (SD)	Robust mean	Median	Max	Min
<b>Adult</b>					
<b>Preparation</b>					
Gravimetric control (g)	2182.0 (11.3)	2195.0	2285	2885	1730
<b>Administration</b>					
Infusion time (h)	22.2 (0.3)	21.7	24	48	11
Volume to be administered (mL)	1868.8 (10.8)	1886.5	1998	2028.4	1200
<b>Pediatric</b>					
<b>Preparation</b>					
Gravimetric control (g)	937.9 (46.8)	936.0	955	1270	640
<b>Administration</b>					
Infusion time (h)	24.0 (0)	24.0	24	24	24
Volume to be administered (mL)	736.7 (58.4)	703.5	700	2028	300

**Figure 2.** Label on a bag of parenteral nutrition, including data from the gravimetric control.



### Temperature Monitoring in the Refrigeration Chamber

The results obtained in the period under consideration from daily recording of the temperature by 2 probes in the refrigeration room (Kardex Remstar, BioCold Environmental Inc) can be seen in [Figure 3](#).

A nonconformity was detected from June 24 to July 7 that did not influence the validity of the PN bags since although the operative limit was exceeded (8°C), the critical limit was not reached (12°C). Likewise, there was a 10-day period when the temperature was lower than 2°C, although in no case was it below 1.1°C, so the temperature never fell below the critical limit (0.1°C). In both situations, measures described in the established protocol had to be adopted [12]. On July 17 and August 6, the temperature in the refrigeration room was not registered (nonconformity). All nonconformities were recorded in the digital repository.

The statistics for data collected from the temperature sensors in the refrigeration room were:

- Maximum temperature (in °C):
  - Probe 1 (P1): mean 7.2 (SD 0.1) (CI 95% 6.9-7.5); robust average 7.1; median 6.9; maximum 11.8; minimum 5.5; and IQI (6.1-7.5)

- Probe 2 (P2): mean 7.0 (SD 0.1) (CI 95% 6.7-7.3); robust average 6.9; median 6.7; maximum 11.0; minimum 5.2; and IQI (5.9-7.2)

Comparison of means between P1 and P2 was  $t_{190}=1.0$ ;  $P=.31$ . There were no statistical differences in the measure of the maximum temperature between the 2 probes.

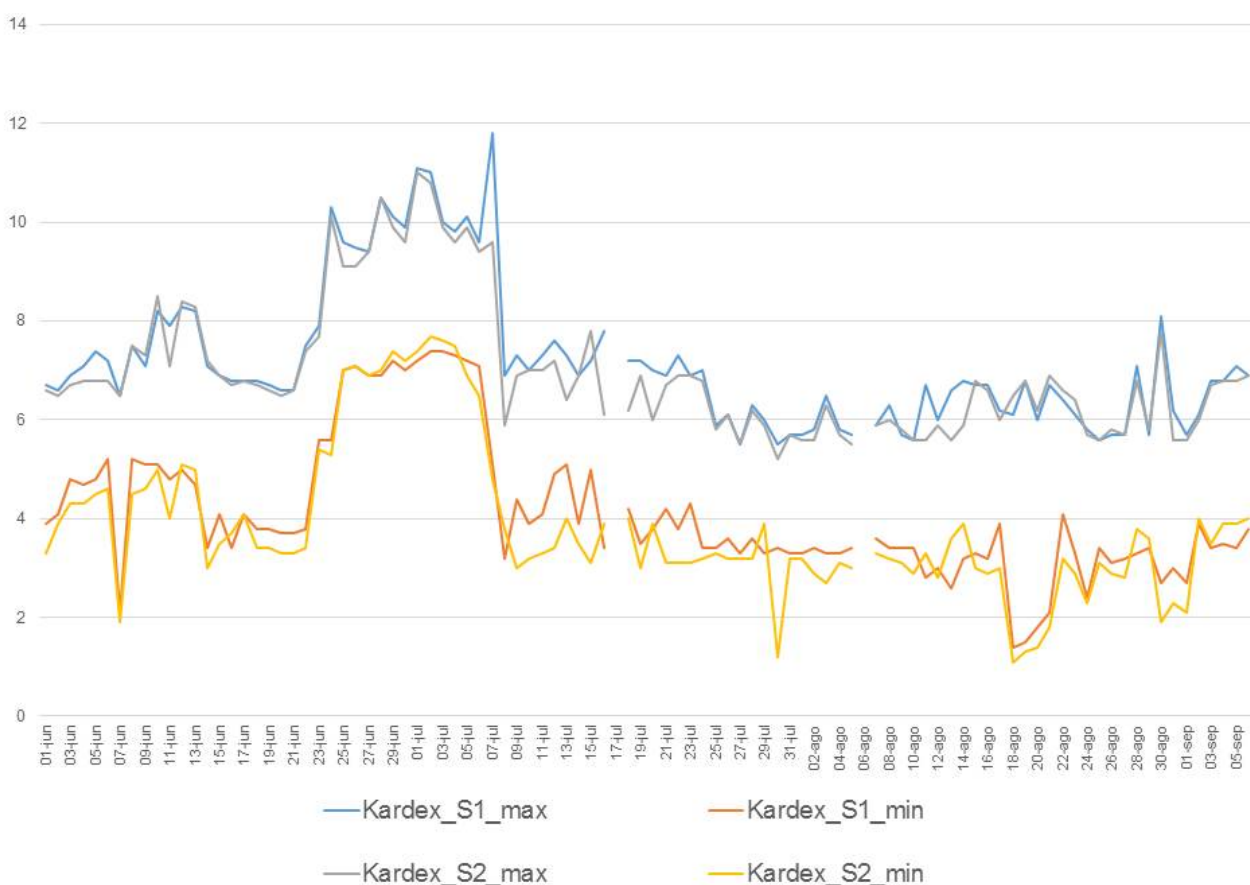
- Minimum temperature (in °C):
  - Probe 1 (P1): mean 4.1 (SD 0.1) (CI 95% 3.8-4.4); robust average 4.1; median 3.8; maximum 7.4; minimum 1.4; and IQI (3.3-4.8)
  - Probe 2 (P2): mean 3.8 (SD 0.2) (CI 95% 3.5-4.2); robust average 3.7; median 3.4; maximum 7.7; minimum 1.1, and IQI (3.0-4.6)

Comparison of means between P1 and P2 was  $t_{190}=1.3$ ;  $P=.19$ . There were no statistical differences in the measure of the minimum temperature between the 2 probes.

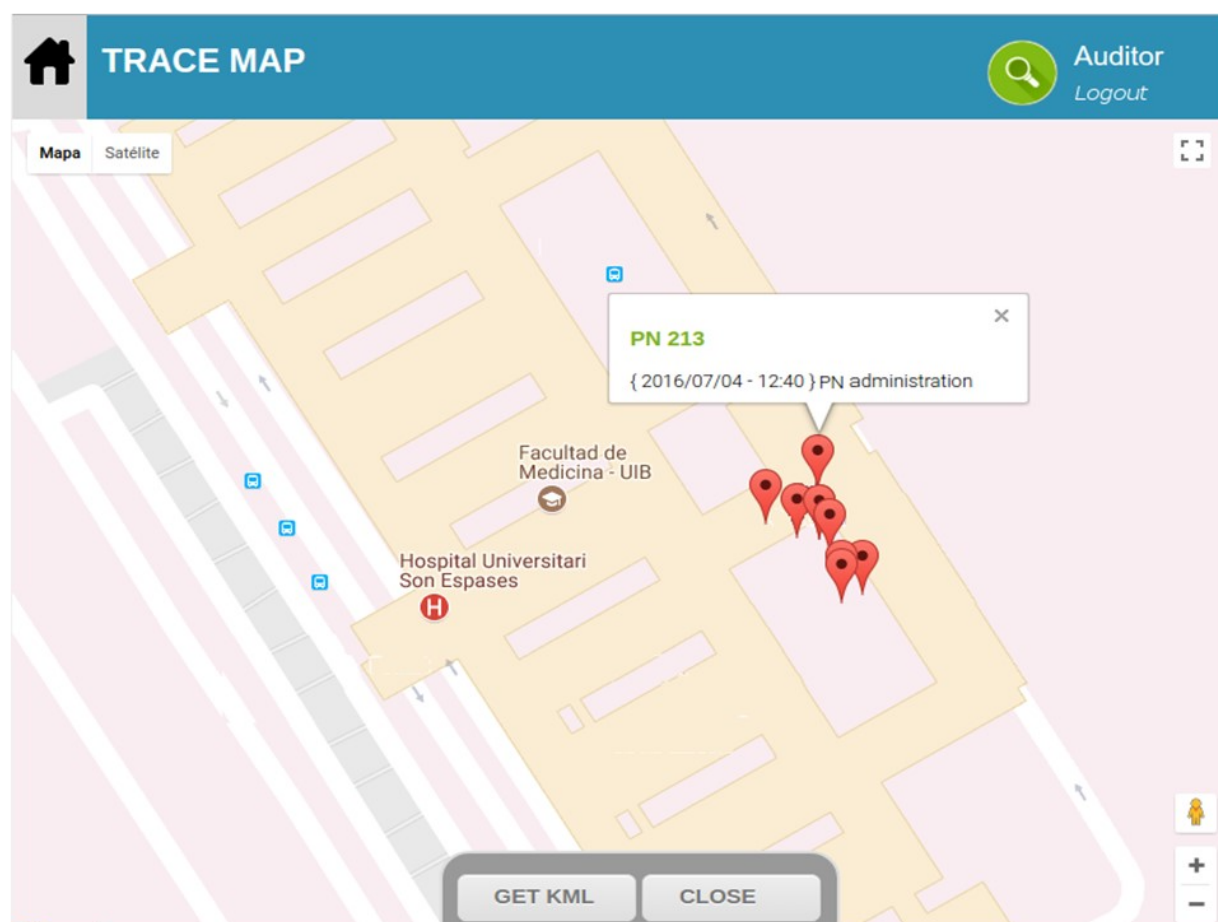
### Management Controls

The geolocation function provided by the app made it possible to know the location, day, and hour of administration of every PN bag (see [Figure 4](#)).

**Figure 3.** Maximum and minimum temperatures measured by the 2 probes in the refrigeration chamber from June 1, 2016 to September 6, 2016.



**Figure 4.** Collected data about the parenteral nutrition administration, including location, date, and time of administration. PN: parenteral nutrition.



## Discussion

### Principal Findings

The evaluation and validation performed verified the ability of the mHealth app to register all designed processes and record nonconformities that occurred. Therefore, it was found that holistic monitoring of the traceability and management system of the PN could be implemented.

The results of the evaluation of the mHealth app through a survey revealed that, in general, users assessed its usability positively. The 4 dimensions measured (general satisfaction, app utility, information quality, and interface quality), on average, tended to the highest values of the Likert scale used. This means that the professionals considered the mHealth app useful in their work, and they found it easy to manage even without technological experience. The calculated Cronbach alpha (with values close to 1) allowed us to be sure about the consistency of the evaluation test (ie, the absence of errors in the measurements made). This result showed that the positive perception of the app is common to all the users who took part in the process.

The validation of the system allowed us to observe the monitoring and registration of all stages of the PN system. As already stated in the scientific literature, compliance with protocols minimizes unjustified clinical variability, which

directly affects the reduction of risks associated with PN [13] and even facilitates the improvement of clinical skills [14]. It should be pointed out that the possibility of controlling and registering the trays with the initial and final preparation products and the postprocessing verification of the PN bags added an additional guarantee to the process. The repository of the registers in each one of the stages records the deviations (nonconformities) and, consequently, allows us to apply the necessary corrective actions to improve the whole PN process.

The characterization and quantification of CCPs was essential to know to what extent the process designed met the quality standards (scope or degree of compliance with the standards) [15]. The empirical controls complied with the recommendations of the standardized work procedures established at HUSE and the Spanish consensus on the preparation of parenteral nutrient mixtures [16]. According to Siebert et al [17], although research in this area is limited, it is important to develop and evaluate mobile apps that reduce the rate of medication errors.

All bags prepared were of volumes greater than 100 mL, so the margin of error of actual weight compared to theoretical weight should not exceed 5%. These results are in line with previous studies on gravimetric control in the PN process [17-20], which in any case met the established standards. The registration by image of each one of the PN bags allowed verification that the real weight of each was within the range of the expected weight.

In the administration stage, characterized mainly by the speed or rate of infusion of PN (volume to be infused per time), there are no specific regulations. Usually, only recommendations based on the clinical situation of the patient and device used for administration are established.

A margin of  $\pm 1$  hour of the scheduled infusion time is a sensible recommendation, and the reasons for larger deviations should be evaluated [21]. In this study, the mean deviation of the infusion time met the established margins.

Other data on administration, such as location, date, and time, made it possible to collect very important data on control of the processes and holistic traceability of the PN. A large number of errors associated with the use of PN occur at the administration stage. Therefore, every stage of the process must be properly followed and managed. It is appropriate to establish procedures, especially in home care, that provide alerts about unwanted deviations [22]. The software app allowed us to ensure the validity of the conservation temperature and avoid variations on the compatibility and stability of the PN, which contributes to patient safety, one of the relevant dimensions in the quality of health care [23]. This control allowed us to detect the exceeding of the operating limit that occurred and lack of compliance during 2 days of the temperature record of the refrigeration room. These nonconformities were collected and studied from the history of the digital repository.

The use of a geographic information system made it possible to be certain about the disposition of the PN and get additional information about administration of the PN. In home care, the app would allow us to be aware of the actual arrival date of the PN at the patient's home [3]. The benefits from the use of Web 2.0 tools, such as Mashups, as well as Web 3.0 or Semantic Web technologies have been demonstrated previously [24] and can be very useful to track the adherence to nutritional treatment.

But mobile apps not only help the adherence to treatment; the traceability also contributes to minimizing security issues related to custody of the data and controlling the integrity of the medicine itself [25].

In any case, in a context of progressive penetration of mobile apps for the management and traceability of medicines, it is desirable for health professionals to contribute by increasing health literacy (necessary to adequately recognize risks) and proper decision-making to take advantage of the opportunities inherent in Medicine 2.0 [26].

Furthermore, as has been demonstrated in previous projects, the use of mobile apps designed to guide the medication-related

processes significantly reduces, compared to conventional preparation methods, the medicine preparation time, administration time, and rate of medication errors [27].

From the point of view of the authors, it is clear that the use of mobile apps for the management of medication, including parenteral nutrition, is a hot research topic with a bright future [3,26,28].

### Limitations

To control the volume being administered, it is difficult to establish a margin. The PN has a particular volume. Therefore, the potential hazard is linked to infusions done in less time than established, which would generally be due to a failure in the infusion pump [29]. To avoid errors in the rate of infusion, MacKay et al [30] proposed the establishment of minimum and maximum limits and double verification against the electronic prescription data. These advices were implemented by the app developed.

In its recommendations [21], the American Society for Parenteral and Enteral Nutrition emphasizes safety measures that avoid potential issues related to the infusion pump. Whenever possible, the pumps must be standardized and there must be operating protocols (including rules about silencing the alarm) to reduce errors due to programming issues. Avoiding these errors and capturing the data can support quality improvement programs. Beside all these issues, it also must be noted that ad hoc training on the procedures concerning the infusion pump for patients and caregivers, especially in home care, must be provided [3,31]. All of these recommendations were taken into account when deploying the CCPs of the proposed PN process.

### Conclusion

From the results obtained, we have concluded that the developed app successfully passed the evaluation and validation tests and, more importantly, properly completed the procedures for monitoring the overall PN process. In addition, the repository of records allowed us to see the deviations at all times. Therefore, a system for the management and traceability of PN that quantifies the main control points at a low cost has been successfully implemented and verified at HUSE in Palma, Spain.

A new mobile solution to manage the quality and traceability of sensitive medicines such as blood-derivative drugs and hazardous drugs derived from this project is currently being deployed.

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### Conflicts of Interest

None declared.

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## Abbreviations

- CCP:** critical control point  
**HUSE:** Son Espases University Hospital  
**ICT:** information and communication technology  
**IQI:** interquartile interval  
**OCP:** operative control point  
**PN:** parenteral nutrition  
**PSSUQ:** Poststudy System Usability Questionnaire

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Original Paper

# Lessons From the Dot Contraceptive Efficacy Study: Analysis of the Use of Agile Development to Improve Recruitment and Enrollment for mHealth Research

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## Abstract

**Background:** Smartphone apps that provide women with information about their daily fertility status during their menstrual cycles can contribute to the contraceptive method mix. However, if these apps claim to help a user prevent pregnancy, they must undergo similar rigorous research required for other contraceptive methods. Georgetown University's Institute for Reproductive Health is conducting a prospective longitudinal efficacy trial on Dot (Dynamic Optimal Timing), an algorithm-based fertility app designed to help women prevent pregnancy.

**Objective:** The aim of this paper was to highlight decision points during the recruitment-enrollment process and the effect of modifications on enrollment numbers and demographics. Recruiting eligible research participants for a contraceptive efficacy study and enrolling an adequate number to statistically assess the effectiveness of Dot is critical. Recruiting and enrolling participants for the Dot study involved making decisions based on research and analytic data, constant process modification, and close monitoring and evaluation of the effect of these modifications.

**Methods:** Originally, the only option for women to enroll in the study was to do so over the phone with a study representative. On noticing low enrollment numbers, we examined the 7 steps from the time a woman received the recruitment message until she completed enrollment and made modifications accordingly. In modification 1, we added call-back and voicemail procedures to increase the number of completed calls. Modification 2 involved using a chat and instant message (IM) features to facilitate study enrollment. In modification 3, the process was fully automated to allow participants to enroll in the study without the aid of study representatives.

**Results:** After these modifications were implemented, 719 women were enrolled in the study over a 6-month period. The majority of participants (494/719, 68.7%) were enrolled during modification 3, in which they had the option to enroll via phone, chat, or the fully automated process. Overall, 29.2% (210/719) of the participants were enrolled via a phone call, 19.9% (143/719) via chat/IM, and 50.9% (366/719) directly through the fully automated process. With respect to the demographic profile of our study sample, we found a significant statistical difference in education level across all modifications ( $P < .05$ ) but not in age or race or ethnicity ( $P > .05$ ).

**Conclusions:** Our findings show that agile and consistent modifications to the recruitment and enrollment process were necessary to yield an appropriate sample size. An automated process resulted in significantly higher enrollment rates than one that required phone interaction with study representatives. Although there were some differences in demographic characteristics of enrollees as the process was modified, in general, our study population is diverse and reflects the overall United States population in terms of race/ethnicity, age, and education. Additional research is proposed to identify how differences in mode of enrollment and demographic characteristics may affect participants' performance in the study.

**Trial Registration:** ClinicalTrials.gov NCT02833922; <http://clinicaltrials.gov/ct2/show/NCT02833922> (Archived by WebCite at <http://www.webcitation.org/6yj5FHRBh>)

**KEYWORDS**

mobile apps; mHealth; higher mobile research; fertility tracker; contraceptive; family planning; fertility awareness method; Dot; contraceptive efficacy

## Introduction

### Background

Use of smartphone apps for tracking personal health information has grown exponentially in the last decade. Nearly 100,000 such apps are currently available, and almost 1000 enter the market every month [1]. Health care providers, researchers, and app users themselves are concerned about the accuracy of the information provided by these apps, particularly those that claim to give users information on which to base behaviors that affect health outcomes. Building the evidence about which apps provide accurate information and result in the intended behaviors and benefits requires new tech-relevant approaches. Recruiting study participants, particularly for longitudinal mHealth studies, has been challenging; several mHealth studies have adjusted their original strategies to enroll a sufficient number of participants for an appropriate sample size [1,2].

Georgetown University's Institute for Reproductive Health (IRH) is conducting an efficacy study of the Dynamic Optimal Timing (Dot) app. Dot was developed by Cycle Technologies located in the District of Columbia and is available in app stores for download to iPhones and Android devices. Dot identifies a woman's fertile window based on her menstrual cycle lengths. The woman enters the first day of her period into the app, and the app provides her with information about her risk of pregnancy each day. She can use this information to achieve or avoid pregnancy. The Dot algorithm adapts its identification of the fertile window to the individual woman as she continues to enter information about her cycle lengths over time [3]. Dot was developed to be a suitable means of pregnancy prevention for women with menstrual cycles between 20 and 40 days long and with fewer than 9 days variation in length.

The prospective, longitudinal, contraceptive efficacy study is being supported by the United States Agency for International Development. It is designed to follow the standard guidelines for establishing contraceptive efficacy [4,5], and it takes into account the recommendations for efficacy studies of fertility awareness methods suggested by Trussell and Kost [4]. We adapted the study design to the digital context and integrated participant engagement recommendations from other successful mHealth studies [6,7]. Potential participants were women who had downloaded the app on their Android phones during the recruitment period (February through July 2017) and chosen to use it for pregnancy prevention (rather than achieving pregnancy or tracking their periods). They had entered their most recent period start date at the time of download, and they had continued using the app until they entered a second period start date. There were no literacy criteria specified in the protocol, and Dot currently is only offered in English. In the United States, Android and iPhones hold similar market shares. Outside the United States, Android-based phones far outnumber iPhones. In the United States, we anticipate that a similar percentage of

women Android users will download the app as those who downloaded the iPhone app.

The mHealth research literature provided limited guidance regarding recruitment and enrollment for longitudinal studies. The only previous research on an app for pregnancy prevention was a postmarketing study in which all women who downloaded the app were automatically enrolled [8]. But this approach resulted in very high attrition rates, retaining only 3.53% of participants through 13 cycles [8]. It had significant amounts of missing data regarding sexual behavior on fertile days and cycle length. We approached recruitment and enrollment from the perspective of a standard contraceptive efficacy study, setting our goal for recruiting a minimum of 700 women to have at least 255 women complete 13 cycles of use. Thus, we needed women to recognize that they were part of a study, to provide informed consent, to meet specific criteria necessary for a contraceptive efficacy study of this type of method (eg, being sexually active with a male partner, not having used hormonal contraception in the prior 3 cycles, not already being pregnant when they enter the study, aged between 18 and 39 years, and entering their second period start date into the Dot app), and to understand what was being asked of them in terms of data entry.

### Objective

In this paper, we describe the original recruitment and enrollment strategy and the 3 subsequent modifications we made to recruit an adequate sample size. We compare the impact of each change in strategy on the percentage of eligible women who completed the recruitment and enrollment process. In addition to considering the numbers of study participants, we were also concerned about how our sample represents potential users of the Dot app (and other fertility apps). Although we did not design our strategy to ensure that our sample reflected the general US population of women aged 18 to 39 years, we expected that the advertising approach implemented by Cycle Technologies (primarily Facebook and app store advertisements) would reach a fairly representative sample. Facebook was the main advertising platform used to distribute the Dot app, with 2.07 billion active users and 1.37 billion daily users [9]. We examined whether the changes to the recruitment process resulted in shifts in the demographic characteristics of participants.

## Methods

### Dot Study Overview

For the ongoing prospective, longitudinal, nonrandomized efficacy study of Dot, we recruited and enrolled a cohort of women in the continental United States; in-depth information about the study protocol and approach is available in a previous publication [10]. The study and subsequent modifications were approved by Georgetown University's Institutional Review Board (IRB), and the study is registered with [clinicaltrials.gov](http://clinicaltrials.gov)

(NCT02833922). Participant data over 13 menstrual cycles are collected through the app by activating Proofmode (see Figure 1) at enrollment. Proofmode, developed by the IRH, is the framework for a multicomponent data collection system that overlays the Dot app. This research interface collects study data in real time and allows participants to enter data directly into their phones with or without interacting with a study representative.

Proofmode is divided into 2 components: people and software. Figure 1 is a simplified model of an intricate system that illustrates user-to-system interactions and software-to-software interactions. Data, collected through multiple channels, are stored on a secure research platform that is housed on Georgetown University’s servers [10].

To receive the recruitment message to participate in our study, there were 2 requirements. As depicted in Figure 2, the women had already downloaded the Dot app onto their Android phones, and second, they had designated their intention to prevent pregnancy [10] (rather than to get pregnant or track their cycles).

Once users in this pool entered their second period start date, a pop-up message describing the study appeared on their app asking whether they were interested in participating in the study. Sending this message immediately after a woman entered her second period start date ensured that she was not pregnant on entry to the study [10]. It also increased the likelihood that potential participants would be actual app users rather than someone who downloaded the (free) app out of curiosity and did not actually use it. Women who were interested in participating in the study received prescreening pop-up questions about their age (18-39 years), fertility intention (prevent pregnancy), and recent use of hormonal contraception [10]. Pre-eligible women were then (1) further screened for study eligibility, (2) provided with more information about the study, (3) led through an informed consent process, and (4) enrolled in the study [10]. To minimize the risk of pregnancy before enrollment, women were required to complete this process within 6 days [10] of entering their period start date. Figure 3 reflects the pop-up screen women received on their smartphone after being identified as pre-eligible for the study.

Figure 1. Proofmode’s framework for data collection adapted from Dot study protocol.

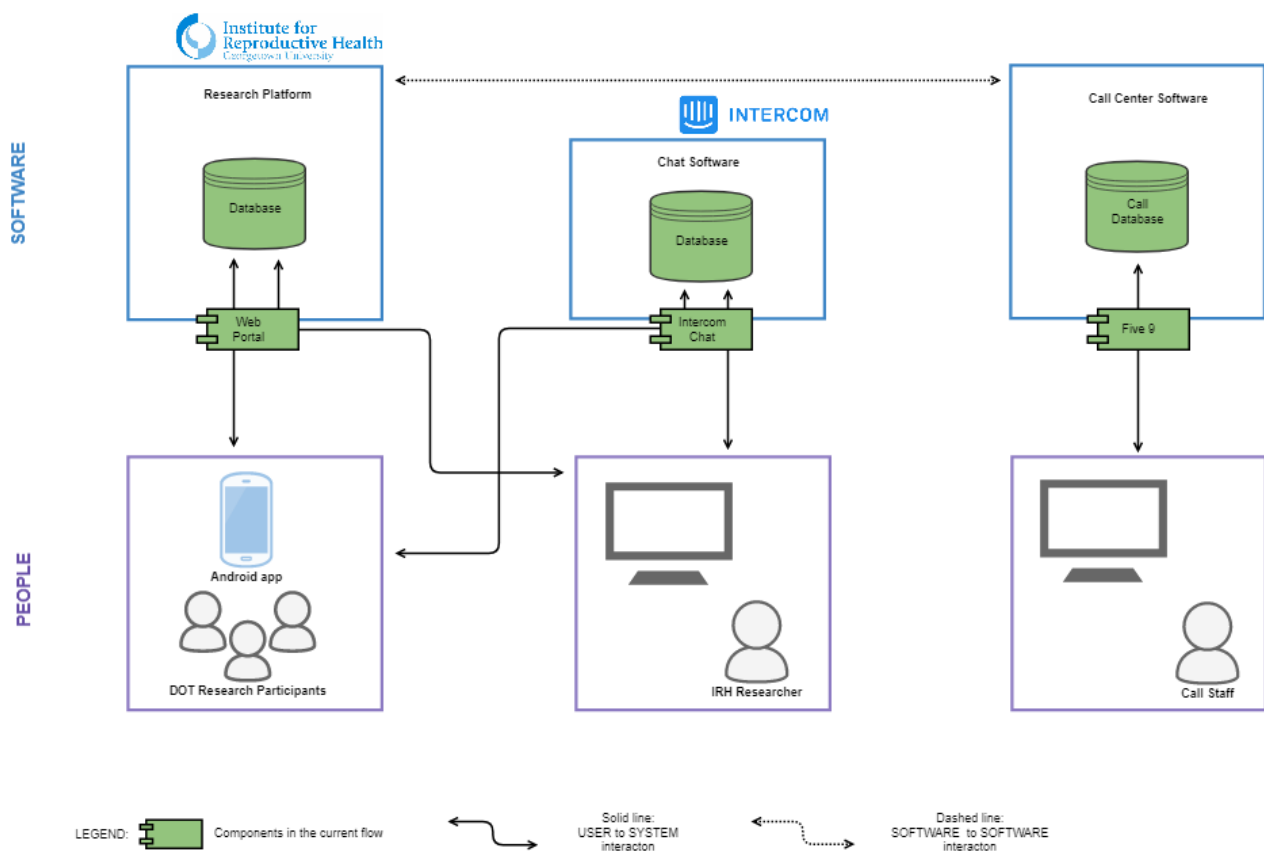
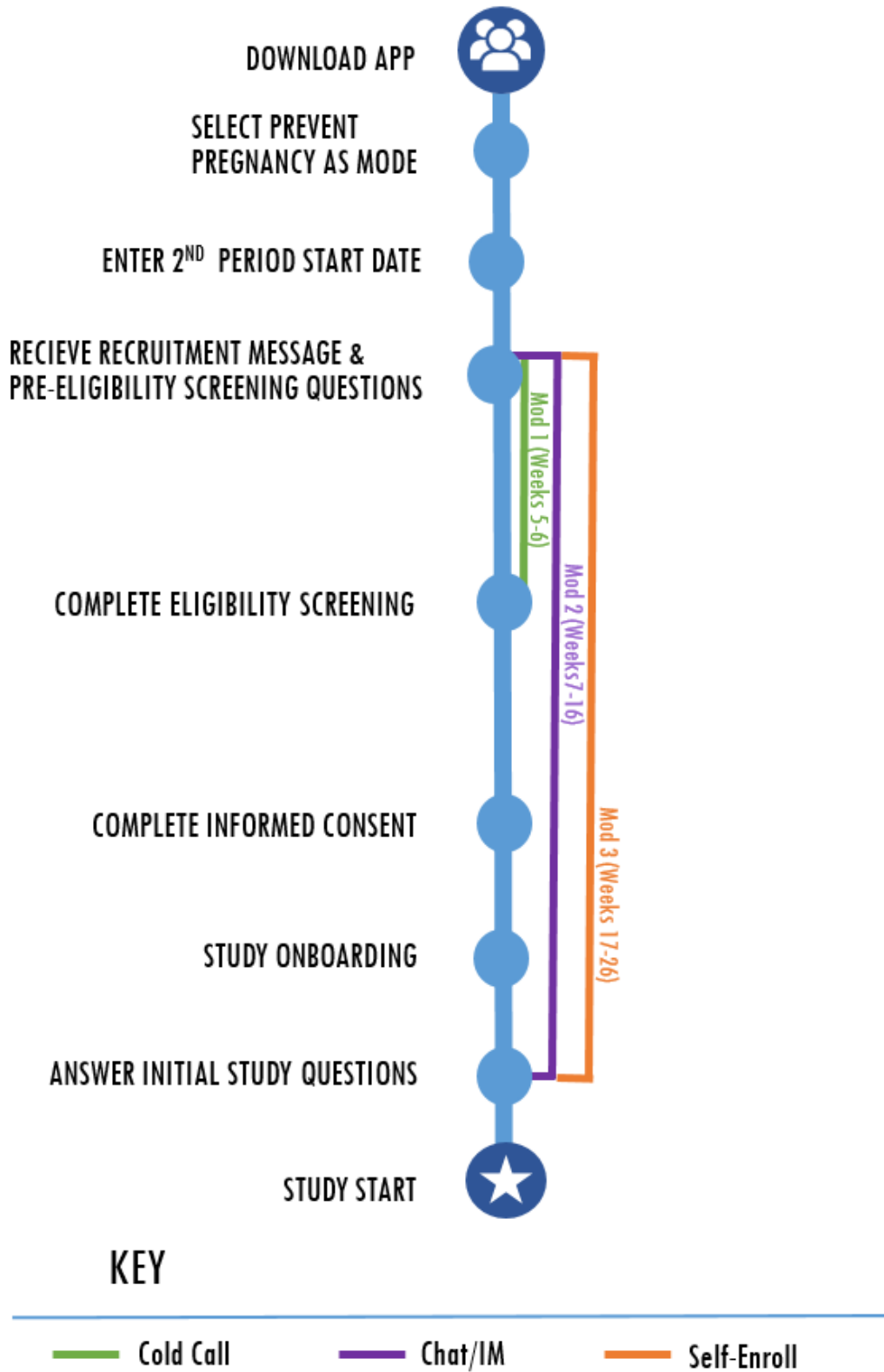
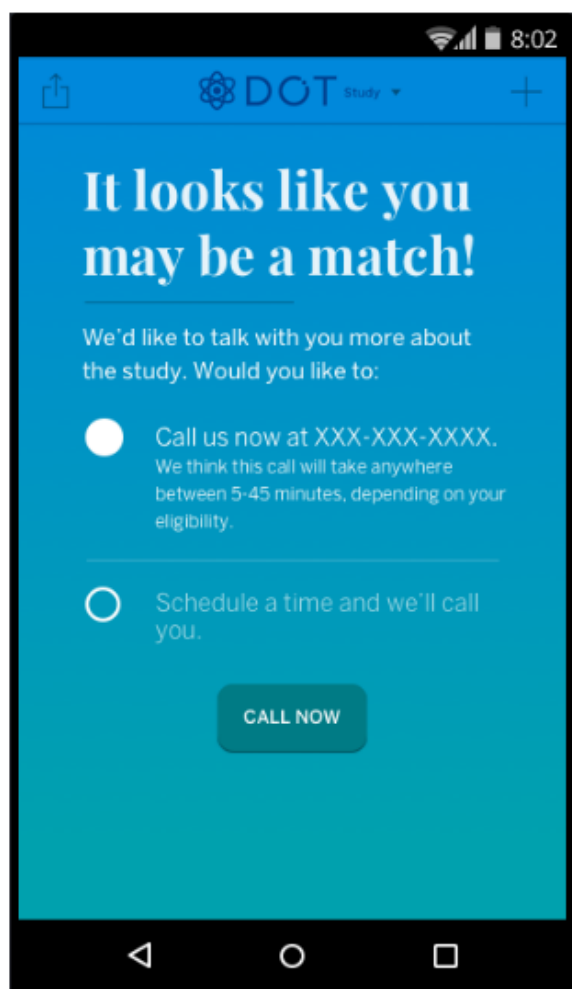


Figure 2. Recruitment process with modification impact zones.



**Figure 3.** The pop-up screen after women were determined to be pre-eligible.

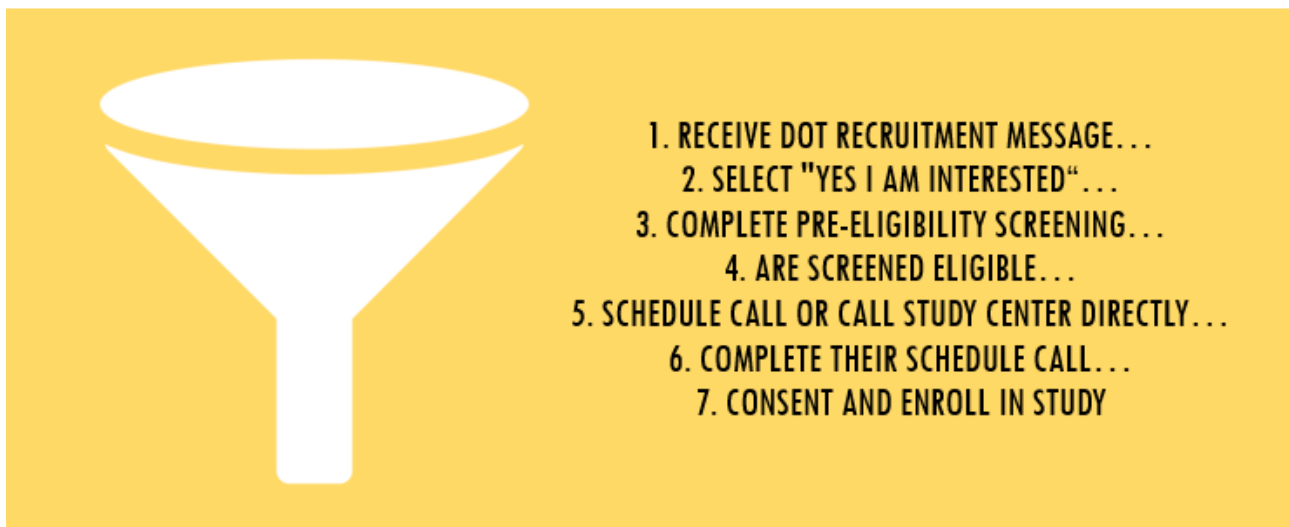


### Original Approach

In the original strategy, women who had responded appropriately to the prescreening questions spoke on the phone to study representatives who led them through the full enrollment questionnaire as well as the informed consent document. This informed consent process, which was approved by the Georgetown University's IRB, required that the participants initial the document in their app and verbally consent to a study representative that they agreed to participate. On agreement, the study representative was able to activate Proofmode on the participant's phone. Study representatives then conducted a brief onboarding process, explaining Proofmode and the data it collects to ensure that participants were familiar with and agreed to what the study was asking of them. Participants followed this process with visual onboarding screens on their phones and were given the opportunity to ask questions about the study and the features of the research interface. Once onboarding was complete, study representatives then administered a brief sociodemographic survey that included information about age, ethnicity/race, and education, among others.

Within the first month of the 6-month recruitment and enrollment period, only a small number of users who initially indicated interest in the study actually enrolled (described in detail in the following). Due to the low recruitment rates using this method, the recruitment procedures were reconsidered. Tailoring the recruitment "funnel," or the way users are guided to the goal with fewer navigation options at each step, began with an assessment of the app's user analytics data with our technology partner (EastBanc Technologies) and the app developer (Cycle Technologies) to identify "leakage" places within the recruitment funnel where potential participants do not continue to full enrollment or how we were losing potentially interested participants at each step of the process (Figure 4).

The changes described in the modifications below reflect a series of meetings and decision points that our team implemented in conjunction with EastBancTechnologies and Cycle Technologies. In collaboration, we identified problems within recruitment process and brainstormed solutions. We also developed long- and short-term contingency plans that included benchmarks for recruitment numbers. Finally, solutions were pilot-tested by the teams to ensure seamless implementation. On any new updates to the app or Proofmode, participants received push notifications from the study team.

**Figure 4.** Dot study recruitment and enrollment process funnel.

### Strategy: Establish Recruitment Leakage Points

To identify the causes of leakage and adapt the process accordingly, we used aggregate data from the Google Play store, app user analytics data using Amplitude analytic software, and data from Proofmode to review the funnel.

### Understanding the Funnel

Figure 4 describes the funnel, which comprised a series of 7 steps from the time a woman selected “Yes, I’m Interested” in response to the recruitment message to the time she was enrolled in the study.

Over the first 4 weeks, 690 users received the recruitment message, 176 were interested in participating in the study, of whom 103 (103/176, 62.1%) were eligible; but only 22 eligible participants completed enrollment in the study (22/103, 21%). This conversion rate was far lower than what we needed to achieve our enrollment goal (a minimum of 700 women) in the time available. We determined that reducing leakage at this point would require increasing the likelihood of scheduled or immediate calls.

#### Modification 1: First Point of Study Contact (Weeks 5-6)

In the original recruitment process, lack of completion of scheduled calls with study representatives appeared to be the first point of leakage. Thus, the main change in modification 1 was the integration of a call reminder. We presumed that increased awareness might decrease the likelihood of women rejecting or forgetting about the call.

The following steps were taken to reduce leakage at this point in the process:

- Increased visibility of the study center contact information, which was pinned to the app home screen for women who reported interest but did not enroll. The contact screen required the women to either exit the reminder screen or select a contact option.

- Created a protocol for identifying eligible women who scheduled a call and provided appointment reminders for those scheduled calls.
- Established a phone contact protocol to reach for eligible women who indicated interest and were considered pre-eligible after completing the pre-eligibility questions but had not yet called or scheduled a call. Study representatives called the identified women. If the woman did not answer, representatives left a voicemail explaining the limited window of time for enrollment and providing contact information.
- Integrated a call scheduling feature into the app that allowed women to schedule a call only until the last day of their enrollment window.
- Created appointment syncing functionality with Google calendars.

After modification 1, a total of 1907 users received the recruitment message, 460 identified interest in the study, and 267 were eligible. Still, only 60 of the eligible participants enrolled in the study (60/267, 22.5% success).

#### Modification 2: Enabling a Research Chat/Instant Message Feature (Weeks 7-15)

We learned from the first modification that it was acceptable to call eligible women proactively, but many women allowed these calls to go to voicemail. When contact was made, conversations reflected 2 main themes: first, women had additional questions about what was required of them in the study; second, women had assumed they were already enrolled after completing the pre-eligibility questions. In the second modification, we instituted a “Chat with us now” feature by integrating Intercom, a software that incorporated chat functionality into Proofmode (Figure 1). This facilitated multiple simultaneous chat conversations between users and study representatives, as shown in Textbox 1. This feature was widely used, and the team found that women were comfortable communicating through the chat feature.

**Textbox 1.** An example of a potential participant using the “Chat with us now” feature to ask a question.

*Hi! I'm interested in being part of the Dot study. It seems like a great technological advancement for women's health, so I don't mind contributing my data. Will my information be collected automatically just by using the app?* [Potential participant on chat]

**Textbox 2.** Reminder messages about recruitment were sent at different points through different mechanisms in Intercom.

*Hi there, this is the Dot Study team. Time's running out to enroll in our research study- we only recruit for six days after your cycle starts. If you think you might be interested, feel free to reach out to us. We're available via chat, or you can always call our study center.* [Scripted 48 hour “Reminder” Text]

*Hi there! Today is the last day for you to enroll in the Dot study via chat or call us before your time expires! We're happy to answer any questions you might have. Our hours are Monday- Friday 9am – 5pm EST. You are always welcome to contact our study center at XXX-XXX-XXXX to enroll as well. Let us know!* [Scripted 24 hour “Reminder” Text] [Dot Study Representative]

**Textbox 2** shows a series of standardized messages that were sent to participants to facilitate conversations and encourage enrollment. All participant conversations were archived for future analyses. The chat feature provided a user-friendly tool to communicate the enrollment process to participants and also was linked with the database, providing study staff with the ability to enroll participants directly. **Textbox 1** provides exemplary chat interactions with participants.

In addition, standardized messages based on user behaviors were tested by our technology partner to identify which types of communication (in-app messages, push messages, automated messages, or manual messages to specific participants) were most effective at eliciting a response. After identifying the most effective mechanism for communication, study protocols were updated. We also learned that many women were not aware that the enrollment window was limited to 6 days. Addressing this challenge, an automated enrollment message was sent through Proofmode to remind potential participants of their enrollment deadline, both at 48 and 24 hour before their enrollment window ended.

The changes integrated into this modification are summarized in the following:

- Integrated Intercom chat software into Proofmode, which enabled chat use for women who responded with interest in the study.
- Included a “Chat with us now” option within the research interface dropdown menu. Women who reported interest in the study received a message, allowing them to engage in a chat session with study staff at their convenience.
- Identified enrollment windows and implemented standardized push reminders informing women when their enrollment window was closing.

After modification 2, a total of 5089 users received the recruitment message, 1067 identified interest in the study, and 674 were eligible. However, only 143 eligible participants were converted to study enrollment (143/674, 21.2%).

### **Modification 3: Self-Enroll Mechanism (Recruitment Weeks 16-26)**

After examining the rate of enrollment after the integration of chat functionality and considering feedback from current

participants, we decided to integrate a fully automated enrollment functionality into Proofmode. On approval from the IRB, we implemented an option that enabled participants to complete both the full eligibility screening and the informed consent process solely through the app. Participants were also provided complete access to the chat or phone call options that were integrated earlier.

The major consideration for the study team was the transition from an informed consent process that was facilitated through live interaction between study representatives and potential participants to a fully automated consent process. There are numerous examples of app-based (automated) informed consent procedures in mHealth research [11,12]. In several studies, electronic signatures were identified as sufficient to validate the consent process [13,14]. Women in the Dot study had 3 choices: (1) completing the informed consent through a fully automated process, (2) having a phone call with study representatives, or (3) using chat functionality. Again, study protocols and automated response messages were generated and tested by the study team before implementation. Regardless of which option the women chose, each provided the opportunity to communicate with a live person to ask any questions or resolve any concerns before signing the informed consent document.

During the 10 weeks that modification 3 was implemented, most women used self-enroll (366/494, 74.1%), followed by chat (90/494, 18.2%), and phone (38/494, 7.7%). After modification 3, a total of 6451 users received the recruitment message, 1311 identified interest in the study, 715 were eligible, and 494 eligible participants were converted to study enrollment (494/715, 69.1%).

## **Results**

### **Recruitment and Enrollment**

Data from the Amplitude user interface portal were analyzed to show how each modification impacted the number of women actually enrolling in the study. During the enrollment period, 719 women enrolled in the study. Weekly enrollment increased after the first modification, then decreased until the final modification was implemented, at which point the overall



enrollment numbers went up significantly and conversion rates improved (Table 1).

**Table 1.** Percentage change in enrollment by modification.

Recruitment strategies and modifications	Weeks implemented (total weeks)	Number enrolled	Mean participants per week	Percentage change in weekly enrollment
Original recruitment strategy	1-4 (4)	22	5.5	— <sup>a</sup>
Modification 1	5-6 (2)	60	30	500
Modification 2	7-15 (8)	143	17.9	40.3
Modification 3	16-26 (10)	494	49.4	176
Total		719		

<sup>a</sup>There was no change in recruitment during the first phase as this was the original recruitment strategy.

**Table 2.** Recruitment and enrollment funnel results during each modification strategy. N/A: not applicable.

Key funnel indicators	Original strategy	Modification 1	Modification 2	Modification 3
Time frame	Weeks 1-4	Weeks 5-6	Weeks 7-15	Weeks 16-26
Number of downloads	27,364	19,801	28,478	54,018
Estimated women preventing pregnancy with Dot <sup>a</sup>	9030	6534	9398	17,826
Received recruitment message	690	1907	5089	6451
Indicated interest in the study, n (%)	176 (25.5)	460 (24.12)	1067 (20.97)	1311 (20.32)
Completed pre-eligibility screening questions, n (%)	166 (94.3)	448 (97.4)	1038 (97.28)	1280 (97.64)
Eligible for the study and given enrollment options, n (%)	103 (62.1)	267 (59.6)	674 (64.93)	715 (55.86)
Scheduled call confirmation screen, n (%)	62 (60.2)	149 (55.8)	29 (9.8)	8 (1.1)
Called immediately, n (%)	4 (4)	14 (5.2)	4 (0.5)	25 (3.5)
Enrolled total	22	60	143	494
Conversion rate (%) <sup>b</sup>	21.4	22.5	21.2	69.1
Enrolled via chat, n (%)	N/A	N/A	53 (37.4)	90 (18.2)
Enrolled via self-enroll, n (%)	N/A	N/A	N/A	366 (74.1)

<sup>a</sup>Information on the proportion of users using Dot to prevent pregnancy obtained from Cycle Technology suggests that 33% of Dot users are preventing pregnancy.

<sup>b</sup>Conversion rate calculated by dividing the number of enrolled women by the number of women identified as eligible for the study and given enrollment options.

Through all of these changes, there were certain steps in the recruitment funnel that remained constant. The percentage of women who declined the recruitment message or chose “Ask me later” did not change significantly. This is also true of the percentage of women who answered the pre-eligibility questions and were screened ineligible.

Table 2 shows the flow of participants through the recruitment and enrollment process from the original strategy through modification 3.

### Demographics

Chi-square comparisons of participant demographics are presented in Table 3. We found that as we implemented the modification, the percentage of women in each age category shifted slightly and not significantly across the modifications ( $\chi^2_9=16.3$ ,  $P=.06$ ). Individuals aged 18 to 29 years comprised

about two-thirds (440/719, 1.2%) of participants throughout enrollment process, whereas 30- to 34-year-olds made up a little more than one-fifth of the participant base (158/719, 22.0%).

Participants' race or ethnicity changed descriptively across the modification as well, but with limited impact ( $\chi^2_{21}=30.5$ ,  $P=.08$ ) on the generalizability of study findings. The percentage of white participants remained relatively high (391/719, 54.4%) throughout recruitment, whereas black and Hispanic enrollment shifted with each change in process and comprised 18.3% (132/719) and 15.7% (113/719) of our overall participant base, respectively. We found the highest percentage of black and Hispanic participants enrolling after modifications 3 and 4.

Comparisons of participants' education level across each enrollment modification reflected significant differences ( $\chi^2_{15}=36.5$ ,  $P<.001$ ). Of note, a higher percentage of enrolled

women reported their education as “some college” after each modification, whereas the inverse was true for women reporting that they completed their “bachelor’s degree” (Table 3).

**Table 3.** Demographic distribution of participants during the enrollment modification.

Demographic characteristics	Original (N=22) n (%)	Modification 1 (N=60) n (%)	Modification 2 (N=143) n (%)	Modification 3 (N=494) n (%)
<b>Age<sup>a</sup></b>				
Verified 18-39	0 (0)	5 (8)	7 (4.9)	3 (0.6)
18-24	2 (9)	20 (33)	45 (31.5)	147 (29.8)
25-29	9 (41)	17 (28)	50 (35.0)	150 (30.4)
30-34	9 (41)	13 (22)	28 (19.6)	108 (21.9)
35-39	2 (9)	5 (8)	13 (9.1)	86 (17.4)
<b>Race/ethnicity<sup>b</sup></b>				
No response	1 (5)	6 (10)	8 (5.6)	20 (4.0)
Black/African American	6 (27)	8 (13)	31 (21.7)	87 (17.6)
Hispanic or Latino	2 (9)	9 (15)	15 (10.5)	87 (17.6)
White	12 (55)	31 (52)	79 (55.2)	269 (54.5)
Other	1 (5)	6 (10)	10 (7.0)	31 (6.3)
<b>Education level<sup>c</sup></b>				
No response	0 (0)	4 (7)	11 (7.7)	20 (4.0)
High school/ GED	3 (14)	14 (23)	16 (11.2)	83 (16.8)
Trade/vocational school	1 (5)	1 (2)	3 (2.1)	41 (8.3)
Some college	8 (36)	20 (33)	64 (44.8)	226 (45.7)
Bachelor's degree	9 (41)	16 (27)	30 (21.0)	86 (17.4)
Postgraduate degree	1 (5)	4 (7)	19 (13.3)	38 (8.0)

<sup>a</sup>Note that participants are not required to give exact age but simply confirm to be between 18 and 39 years old.

<sup>b</sup>Note that responses to race/ethnicity and education level are not mandatory.

<sup>c</sup> $P < .05$ .

The percentage of participants who reported completing some college increased across the modifications, whereas those reporting a bachelor’s degree decreased over time (Table 3). The percentage of participants with a high school diploma or General Equivalency Development was highest after modification 1 but dropped under 20% in subsequent modifications. Also, with each modification, the percentage of participants with a college degree decreased.

## Discussion

### Principal Findings

Our intention was to recruit into the Dot study women who understood that they were participating in a study and what study participation involved, recognized the importance of consistent data entry, and had the potential to complete up to 13 cycles of use. At the same time, we wanted to minimize participants’ interaction with study staff because this might have an effect on study results. In addition, we wanted our study population to reflect the general population of the United States to maximize generalizability of results. Our experience suggests that it is possible to achieve this balance, but that app-based

research requires agile and creative approaches that increase clarity and communication with potential participants during the recruitment-to-enrollment process. Findings reveal that a more automated and self-guided enrollment process was preferred by many of the Dot study participants. The percentage of women who converted to participant status after modification 3 was 69.1% (494/715) versus a conversion rate of approximately 21% for the original and 2 earlier modifications.

Each modification reflected varying levels of contact and interaction with women through the enrollment process and required different behaviors on the part of potential study participants. Modification 1 targeted women who were eligible for the study, whether they did or did not schedule a call, by having study representatives remind them of their possible eligibility and/or scheduling phone calls. This tripled our enrollment, yet the trajectory for achieving enrollment requirements was still not within the requisite enrollment time frame. This led us to implement modification 2, which gave women the alternative of interacting with study staff, asking questions, and enrolling in the study via chat. The value of the chat functionality was apparent quickly. As a result, we maintained this feature throughout enrollment and the study to

provide women with the opportunity to continue asking questions through the study. Chat engagement was managed by the study team and used a series of prewritten responses and protocols. The implementation of modification 3 resulted in a 176% increase in weekly enrollment. Although almost 75% of the participants self-enrolled during this modification, it was beneficial to maintain phone calls and chat functionality throughout the process. We received positive feedback from participants about the chat feature in particular; although many chose to self-enroll, participants liked the fact that they could easily ask questions through chat about the study and the enrollment process.

### Key Learnings and Participant Characteristics

Studies have investigated the role of the recruitment process as it pertains to “contact timing, content of the subject line, and incentives” [15-17], but we were unable to find an example that recruited in a similar manner as in this study. A systematic review of studies using Facebook for recruitment found that participants were often compared with a control arm or another study arm using traditional methods [18]. They also found that the demographics of participants recruited through Facebook were “relatively representative,” but the authors cited several exceptions often based on study criteria [18]. Although Facebook advertisement was used to promote the Dot app, participants were recruited through the existing pool of Dot users who entered their second period start date. Anecdotally, participants reported seeing ads for Dot on a range of sources that included news articles, Instagram, and the Google Play Store, but more than two-thirds traced back to Facebook advertisements. Thus, our sample predominantly reflects women who are both Facebook users and women who were interested in downloading the Dot app. Unfortunately, systems do not facilitate comparing the demographics of women who downloaded Dot and chose not to enroll with those who did.

In this study, advertisement through Facebook and the enrollment processes resulted in a diverse sample, but variation in participant demographics was descriptively different across the modifications in the enrollment process. This variation may merit further investigation on the influence of internet/app-based enrollment procedures on participant inclusion. Such analyses are beyond the scope of these data and would require more intentional variation in enrollment procedures. For the purposes of this study, poststudy analyses will describe retention of participants across a number of variables, including enrollment procedure to provide guidance for future studies.

Comfort and familiarity with mobile technologies and digital apps may vary across the participant pool. As presented previously, self-enrollment was consistently near or above 50% among all age groups, whereas one-fourth to about one-fifth used the chat feature. The decrease in call frequency during modifications 2 and 3 may have been due to participants' ease and familiarity with IM/chat and self-enroll procedures for other purposes. Given that a significantly higher proportion of women were enrolled through the self-enrollment mechanism, it can be assumed that participants preferred to engage with the study without the aid of study representatives, regardless of age category. Although there were some differences in demographic

characteristics of women enrolling across the 3 modifications, the diversity of the study population is reassuring and suggests that study results will be generalizable in the United States and potentially in other settings as well.

### Conclusions

Studies have shown that mHealth apps have the potential to address a number of needs across several health areas [19,20], but recruiting and enrolling participants into prospective mHealth studies to understand apps' effectiveness is challenging. The Dot efficacy study represents an attempt to apply criteria for high-quality research, in this case, a contraceptive efficacy study, to a technology that is largely unstudied.

Each step in the study process thus presents unknown challenges with few guidelines for establishing best practices for success. With the rapid expansion of the availability and use of personal information apps, it is critical that we understand their implications for health outcomes. Rigorous studies, similar to those focused on more traditional approaches to providing information, are needed. Our experience provides several suggestions for recruiting and enrolling adequate number of participants to app-based studies. Broadly, we encourage future app researchers to be agile in their approach to recruitment, reviewing, and responding quickly to issues as they arise, while maintaining both ethical standards and rigorous research. Recommendations based on our experiences include the following:

1. Establish an ongoing relationship with developers and technology partners to quickly identify and resolve issues as they arise.
2. Before recruitment launch establish minimum recruitment numbers by certain dates and identify potential pivot strategies based on various outcome scenarios, as well as their potential budget impacts.
3. Invest in and use analytic and monitoring data to provide real-time insights to successes and challenges to use true data to decision making.
4. Foster a “fail fast fail forward” mindset among all partners from the beginning, so that everyone will be on board with implementing strategic shifts in a timely manner.
5. Budget for likely changes to strategy and approach.

With this picture of the Dot efficacy study population, we now intend to continue monitoring participants through Proofmode and Amplitude to observe whether women who enrolled through different approaches and with different sociodemographic characteristics perform differently vis-à-vis their daily sexual behavior data (ie, whether they enter data as frequently; whether during the days Dot identifies as “risk” days for pregnancy, they have unprotected intercourse or use condoms, withdrawal, and/or emergency contraception as frequently). We will also analyze quantitative and qualitative data on partner communication and supportiveness, app perception, and fertility awareness knowledge collected through periodic surveys.

Implementing changes in the recruitment-to-enrollment process required both technical adjustments to Proofmode and protocol amendments to our IRB and thus took time. Future studies that wish to implement agile recruitment strategies should include

contingency recruitment strategies that factor in the time for changes to occur. In addition, recruitment planning should predesignate benchmarks to assess recruitment and enrollment success and ensure that ineffective processes are quickly identified and addressed.

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## Conflicts of Interest

DS and LH are employed by the Institute for Reproductive Health (IRH), Georgetown University, which is recipient of a grant from the United States Agency for International Development that supports this study. The research tests an app for which a patent application has been filed by Cycle Technologies. Neither DS nor LH, or any other employee of Georgetown University, have any financial relationship to or receive any income or royalties from Cycle Technologies, a company that is owned by a family member of the director of the institute. Cycle Technologies is solely responsible for the app that is the subject of this research. All data from this research will be made available through the Open Data Act, as required by US law. RS, a former employee of IRH, also does not have any conflict of interest to declare.

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## Abbreviations

- Dot:** Dynamic Optimal Timing  
**IRB:** Institutional Review Board  
**IRH:** Institute for Reproductive Health  
**IM:** instant message

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Original Paper

# Counting Steps in Activities of Daily Living in People With a Chronic Disease Using Nine Commercially Available Fitness Trackers: Cross-Sectional Validity Study

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## Abstract

**Background:** Measuring physical activity with commercially available activity trackers is gaining popularity. People with a chronic disease can especially benefit from knowledge about their physical activity pattern in everyday life since sufficient physical activity can contribute to wellbeing and quality of life. However, no validity data are available for this population during activities of daily living.

**Objective:** The aim of this study was to investigate the validity of 9 commercially available activity trackers for measuring step count during activities of daily living in people with a chronic disease receiving physiotherapy.

**Methods:** The selected activity trackers were Accupedo (Corusen LLC), Activ8 (Remedy Distribution Ltd), Digi-Walker CW-700 (Yamax), Fitbit Flex (Fitbit inc), Lumoback (Lumo Bodytech), Moves (ProtoGeo Oy), Fitbit One (Fitbit inc), UP24 (Jawbone), and Walking Style X (Omron Healthcare Europe BV). In total, 130 persons with chronic diseases performed standardized activity protocols based on activities of daily living that were recorded on video camera and analyzed for step count (gold standard). The validity of the trackers' step count was assessed by correlation coefficients, t tests, scatterplots, and Bland-Altman plots.

**Results:** The correlations between the number of steps counted by the activity trackers and the gold standard were low (range: -.02 to .33). For all activity trackers except for Fitbit One, a significant systematic difference with the gold standard was found for step count. Plots showed a wide range in scores for all activity trackers; Activ8 showed an average overestimation and the other 8 trackers showed underestimations.

**Conclusions:** This study showed that the validity of 9 commercially available activity trackers is low measuring steps while individuals with chronic diseases receiving physiotherapy engage in activities of daily living.

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**KEYWORDS**

activity tracker; accelerometer; wearable; chronic disease; validity; physical therapy; physical activity

## Introduction

The use of activity tracking to self-monitor physical activity is gaining popularity. In 2015, 1 out of 3 Dutch inhabitants was using apps, wearables, or activity trackers [1]. Physical activity is the most popular variable measured with these devices followed by nutrition, weight, and body functions (eg, blood pressure) [1]. Initially, these activity trackers were developed for athletes and the healthy population, but they could potentially also be useful in treating people with medical conditions (eg, physiotherapy treatments). The Royal Dutch Society for Physical Therapy composed physical activity intervention guidelines for the most common chronic diseases seen by a physiotherapist [2]: cardiovascular disease [3], diabetes mellitus [4], chronic obstructive pulmonary disease (COPD) [5], chronic pain [6], cancer [7], and osteoarthritis [8]. In all these guidelines, it is recommended to objectively measure the physical activity level of a patient outside of guided therapy [2]. Frequently used measurement tools by physiotherapists are questionnaires or diaries, but they have limited reliability and validity, tend to overestimate most activities while underestimating low intensity activities, and are time consuming to fill out [9,10]. For patients and physiotherapists, more objective and feasible measurement tools are useful, and activity trackers seem to be a good alternative [11].

To provide guidance in choosing an appropriate activity tracker for people with a chronic disease, we performed a literature search on the validity of activity trackers, preferably commercially available ones. The following criteria were taken into account. First, step count was considered to be the most important outcome, since it is specific to ambulation and easily interpreted by patients and physiotherapists [11]. Second, people with a chronic disease should be the target population of the study, as they often have impaired ambulatory abilities (eg, shuffling) [12], and activity trackers may measure incorrectly due to these altered walking patterns [13-15]. Third, activities of daily living should be assessed (no laboratory settings), as insight into these specific activities (eg, vacuum cleaning, walking stairs) is needed to monitor and coach participants in daily life, and activity trackers are not able to measure validly during low walk speeds (<0.8 m/s) [16], which is often the case in activities of daily living. Last, published articles were screened on standardization of the performed activities of daily living by means of an activity protocol.

Although the literature on clinometric quality of commercially available activity trackers is growing [17-19], only a few recent studies were found in which almost all criteria were met (validity of step count of commercially available activity trackers during free living conditions) [19,20]. However, the target population in those studies consisted of healthy participants.

Remoortel et al [18] recently published a literature review regarding validity and reliability of activity trackers in people with a chronic disease. It was confirmed that most commercially available activity trackers have been studied in healthy populations [17,19-21], and little is known about which types of activity trackers provide valid results in people with chronic diseases. In their review, they found that only 12 of the 134

studies on validity of activity trackers included people with a chronic disease [18]. Of the 12 identified studies, only 3 evaluated activities of daily living (free living or an activity protocol) in people with a chronic disease [22-24]; however, these studies only tested noncommercially available activity trackers and mainly evaluated energy expenditure instead of step count. Results from other studies with participants with chronic diseases are not generalizable to daily practice because they did not have step count as the primary outcome (eg, mostly energy expenditure) [25-31], involved only walking and no other activities of daily living [32-35], or free living conditions were not protocolled (eg, cardiac patients [36] and patients with COPD [37] or cancer [38]).

As stated before, for both people with a chronic disease and their therapists, insight into physical activity level and patterns outside of therapy are very relevant. Since no article was found that matched our criteria, we decided to validate 9 potential trackers ourselves in people with a chronic disease.

The main aim of this study was to investigate the validity of 9 selected commercially available activity trackers for measuring step count in people with a chronic disease receiving physiotherapy during a selected set of activities of daily living. Results from this study should provide guidance in choosing the right activity tracker for people with a chronic disease.

## Methods

### Study Design

A cross-sectional validity study with 9 activity trackers was performed in patients with chronic diseases. The data collection took place over a 1-year period. All participants provided written informed consent. This study was approved by the local ethics boards (Atrium-Orbis-Zuyd Medical Ethical Committee, 15-N-48; Adelante Medical Ethical Committee, MEC-15-07).

### Participants

Participants were recruited from 2 physiotherapy practices (Fysiotherapie Schaesberg and ParaMedisch Centrum Zuid) and a rehabilitation center (Adelante Zorggroep) in the Netherlands. Patients were included if they were aged 18 years and older and diagnosed with at least 1 of the following chronic diseases: cardiovascular disease, COPD, diabetes mellitus, chronic pain, cancer, or osteoarthritis. Exclusion criteria were insufficient understanding of the Dutch language, use of a walking aid, and asymmetrical gait (eg, stroke). A power calculation was conducted, and a minimum of 57 participants with an equal spread among the 6 chronic subpopulations was considered to be sufficient for a validity study [39].

### Activity Trackers

Researchers and physiotherapists agreed to the following selection criteria for commercially available activity trackers: costs less than €150 (US \$185), no monthly costs for a subscription, real-time feedback on the tracker to the user, measures number of steps, and no chest strap to perform heart rate measurements. To ensure that the scope of different system requirements was covered, trackers were randomly selected in a second round based on the following criteria: a variety of

wearing places (eg, belt, wrist) and types of activity trackers (eg, pedometers, accelerometers). Hence, 9 activity trackers were selected: Accupedo (Corusen LLC), Activ8 (Remedy Distribution Ltd), Digi-Walker CW-700 (Yamax), Fitbit Flex (Fitbit Inc), Lumoback (Lumo Bodytech), Moves (ProtoGeo Oy), Fitbit One (Fitbit Inc), UP24 (Jawbone), and the Walking Style X (Omron Healthcare Europe BV) (Table 1).

### Data Collection and Procedure

Participants were measured in either of the physiotherapy practices or the rehabilitation center. Baseline characteristics were reported (gender, age, body weight, height, diagnosed chronic disease) by 1 of the 10 participating physiotherapists or a psychologist. For participants with COPD, the Global Initiative for Chronic Obstructive Lung Disease stage [40] was specified. For participants with osteoarthritis, a differentiation was given for lower extremity (toe, ankle, knee, hip), upper extremity (finger, wrist, elbow, shoulder), and cervical and lower spine. In participants with cancer, curative and palliative treatments were distinguished. Two questionnaires were completed with the participant. The Cumulative Illness Rating Scale (CIRS) was used to indicate the number and severity of comorbidities [41,42]. For an impression of the participant's physical activity level, a brief physical activity assessment tool was used to determine whether the participant was sufficiently active [43]. After completing the questionnaires a 10-meter walk test (10MWT) was performed 3 times to determine the average comfortable walk speed of the participant [44]. Thereafter, participants were fitted with 3 or 4 activity trackers, chosen at random, and asked to perform the activity protocol.

### Activity Protocol

Tasks representing activities of daily living from protocols in previous validation studies [24,29,45,46] were used to create the protocol for this study (Table 2). In order to match the participants' physical activity capacity, 2 versions of the protocol were developed, assuming that the length of the protocol had no influence on the validity of the trackers. The short version

of the protocol did not include lying on a bed, vacuum cleaning on the spot, and 3 additional periods of standing, shortening the execution time of the protocol by 9 minutes. Activity trackers not able to classify different postures were used in the short protocol. Participants were given extra resting periods during the protocol if they needed them.

Step count was collected from the activity trackers before and directly after the protocol. The entire activity protocol was recorded on video camera, focusing only on the lower extremity for privacy reasons. The video recordings were used to determine the number of steps taken by each participant. Step count was manually counted using a digital step counter (gold standard). A person was considered to make a step when the entire foot was lifted from the floor and was placed back on the floor again (detailed information is published elsewhere [39]). The 7 raters involved used a standardized written assessment protocol and were trained by 1 researcher beforehand. The first 2 video recording assessments per rater were checked by the researcher (DU) to secure standardization of the measurement method.

### Data Analysis

Data analysis was performed using the SPSS Statistics version 23.0 (IBM Corp). Descriptive statistics of the participant characteristics were presented as raw data and percentages for the categorical variables gender, diagnosed disease, and physical activity (sufficient/insufficient) [43] and as means and standard deviations for the continuous variables age, CIRS score, and average walk speed.

The video recordings of the activity protocols were analyzed by at least 1 researcher. One-tenth randomly chosen video recordings were analyzed by a second researcher to assess intra observer reliability of our gold standard. This was assessed by intraclass correlation coefficients (ICCs; 2-way random, absolute agreement) and Bland-Altman plots including limits of agreement [47]. It was hypothesized that there would be a strong correlation ( $r > .90$ ) [48].

**Table 1.** Selected commercially available activity trackers used in this validity study.

Activity tracker	Manufacturer	Type	Wearing position	Outcome variables
Accupedo	Corusen LLC	App	Belt	Number of steps
Activ8	Remedy Distribution Ltd	Accelerometer	Trouser pocket	Number of steps; time spent lying, sitting, standing, walking, running, and cycling; active minutes
Digi-Walker CW-700	Yamax Corp	Pedometer	Wrist	Number of steps, active minutes
Flex	Fitbit Inc	Accelerometer	Wrist	Number of steps, active minutes
Lumoback	Lumo Bodytech	Accelerometer	Lower back	Number of steps; time spent lying, sitting, standing, walking, running, and cycling; active minutes; number of sit-to-stand transitions
Moves	ProtoGeo Oy	App	Trouser pocket	Number of steps, active minutes
One	Fitbit Inc	Accelerometer	Belt	Number of steps, active minutes
UP24	Jawbone	Accelerometer	Wrist	Number of steps, active minutes
Walking Style X	Omron Healthcare Europe BV	Pedometer	Belt	Number of steps, active minutes



**Table 2.** The developed activity protocol based on principles and free living tasks from other protocols.

Activity type	Duration of activity, repetitions, or walking distance	Included in short version
Standing	1 minute	Yes
Simulated cleaning of windows	1 minute	Yes
Walking weaving around cones	7 meters	Yes
Sitting in a chair	2 minutes	Yes
Standing	1 minute	No
Vacuum cleaning on the spot	1 minute	No
Vacuum cleaning while walking	1 minute	Yes
Walking weaving around cones	7 meters	Yes
Walking up and down stairs (3 or 4 steps)	3 times	Yes
Lifting a 1-kg object and placing it on a table	1 minute	Yes
Walking in a straight line	7 meters	Yes
Lying in a bed	6 minutes	No
Sitting in a chair	5 minutes	Yes
Standing	1 minute	No
Walking in a straight line while carrying a shopping bag (2.5 kg)	7 meters 2 times	Yes
Walking sideways along a 2-meter kitchen counter	2 ways 3 times	Yes
Standing	30 seconds	No
Walking in a straight line	7 meters	Yes
Cycling (50 to 60 rpms <sup>a</sup> at 30 watts)	3 minutes	Yes
Total time	28 to 33 minutes	19 to 24 minutes

<sup>a</sup>Revolutions per minute.

The validity of the activity trackers was assessed in multiple ways. To gain insight into step count distribution, descriptive statistics and scatterplots were used for all trackers. To gain insight into the strength of the relation between measured steps by the activity trackers and the gold standard, Pearson correlation coefficients were calculated. It was hypothesized that there would be at least a moderate correlation ( $r > .40$ ) [48]. To assess systematic differences between the activity trackers and the gold standard, paired samples *t* tests were used. With a power of 80%, a *P* value below .05 was considered to be of statistical significance. To examine the level of agreement between the activity trackers and the gold standard, Bland-Altman plots were constructed with their associated 95% limits of agreement [49].

To assess if there were difference between the chronic diseases, visual inspection of the scatterplots were performed. To assess if there were systematic differences between the average mean differences of the short and long protocols, independent *t* tests were used. To test if there was a systematic difference in the mean difference between the gold standard and the activity tracker between the short and long protocols, a paired sample *t* test was used in the case of normally distributed data. In the case of missing data, pairwise deleting was applied.

## Results

### Participant Characteristics

A total of 130 participants with chronic diseases participated in this validation study (Table 3). Cardiovascular disease, chronic pain, and osteoarthritis were the most prevalent single conditions, and 26.4% (34/130) of the population had multimorbidity. The combinations occurring most often were osteoarthritis with chronic pain (6/34, 17.6%), osteoarthritis and diabetes (4/34, 11.7%), and COPD and diabetes (3/34, 8.8%). Approximately 60% (75/130) of the participants were sufficiently physically active in their daily life according to the physical activity assessment tool. Of the included COPD patients, 7.7% (1/14) were diagnosed with stage 1 COPD, 35.7% (5/14) with stage 2, 42.9% (6/14) with stage 3, and 14.3% (2/14) with stage 4. Of the cancer patients, 82.6% (19/23) had a curative treatment and 17.4% (4/23) a palliative treatment. The affected joints in osteoarthritis were almost equally spread in upper extremity (22/33, 66.7%), spine (24/33, 72.7%), and lower extremity (23/33, 69.7%). There were 2 missing values for gender, diagnosed disease, resting heart rate and body mass index (BMI) (2/130, 2.6%), and 3 missing values for age (3/130, 3.9%). There was 1 missing value for the number of steps from the Lumoback (1/51, 5.1%) and 1 from the Accupedo (1/50 5%).

**Table 3.** Characteristics of the included population.

Characteristics	Participants (n=130)
Gender, male, n (%)	55 (43.6)
Age, years, mean (SD)	61.5 (11.1)
Body mass index, kg/m <sup>2</sup> , mean (SD)	27.7 (5.2)
<b>Blood pressure, mm Hg, mean (SD)</b>	
Systolic	136.2 (20.3)
Diastolic	80.3 (9.7)
Resting heart beat, beats per minute, mean (SD)	74.0 (12.2)
Transcutaneous oxygen saturation, %, mean (SD)	96.4 (2.3)
<b>Diagnosed disease, n (%)</b>	
Cardiovascular disease	20 (15.2)
Chronic obstructive pulmonary disease	15 (11.4)
Diabetes mellitus	8 (6.1)
Cancer	15 (11.4)
Osteoarthritis	18 (14.4)
Chronic pain	19 (14.4)
Combination	34 (27.3)
Comorbidity, CIRS <sup>a</sup> 0 to 52, mean (SD)	6.2 (3.9)
Average walk speed <sup>b</sup> (m/s) mean (SD)	1.3 (0.3)
<b>Sufficient total activity, n (%)<sup>c</sup></b>	74 (56.4)
Physical activity level (0 to 8), mean (SD)	3.8 (2.4)
Physical activity with moderate intensity (0 to 4), mean (SD)	1.6 (1.6)
Physical activity with vigorous intensity (0 to 4), mean (SD)	2.2 (1.5)

<sup>a</sup>CIRS: Cumulative Illness Rating Score.

<sup>b</sup>Based on the 10-meter walk test [44].

<sup>c</sup>Based on the brief physical activity assessment tool and its accompanying cut-off value [43].

### Interobserver Reliability

The interobserver reliability of the gold standard, calculated in the random sample, was high (ICC<sub>agreement</sub> 0.98,  $P < .001$ , 95% CI 0.96 to 0.99). There was no substantial offset (SEM<sub>agreement</sub> = 81.6) and the Bland-Altman plots showed no systematic differences between the observers (with narrow limits of agreement: -35.3 to 30.8 steps).

### Step Count

Step count for the gold standard and each tracker are shown in Table 4. The average total number of steps during the short and long activity protocols counted by the gold standard was 405.4 (SD 84.7). The average total number of steps for the short protocol was 327.7 (SD 54.3) and the average total number of steps for the long protocol was 446.6 (SD 58.6). There was no significant difference between the mean difference (gold standard versus activity tracker) in the short and long protocols. For all activity trackers except for the Activ8, the mean

difference with the gold standard was lower than zero, which indicated an underestimation of the total number of steps. The mean difference between the tracker and gold standard varied from -29.7 (SD 155.10) for the Fitbit One to 252.4 (SD 129.0) for the Digi-Walker CW-700. Overall, data distribution showed a wide range of observations for all activity trackers. There were no differences found per chronic disease compared to the whole population. Scatter plots of the Fitbit One, Digi-Walker CW-700, and Activ8 are presented in Figures 1-3 to give examples of data distribution.

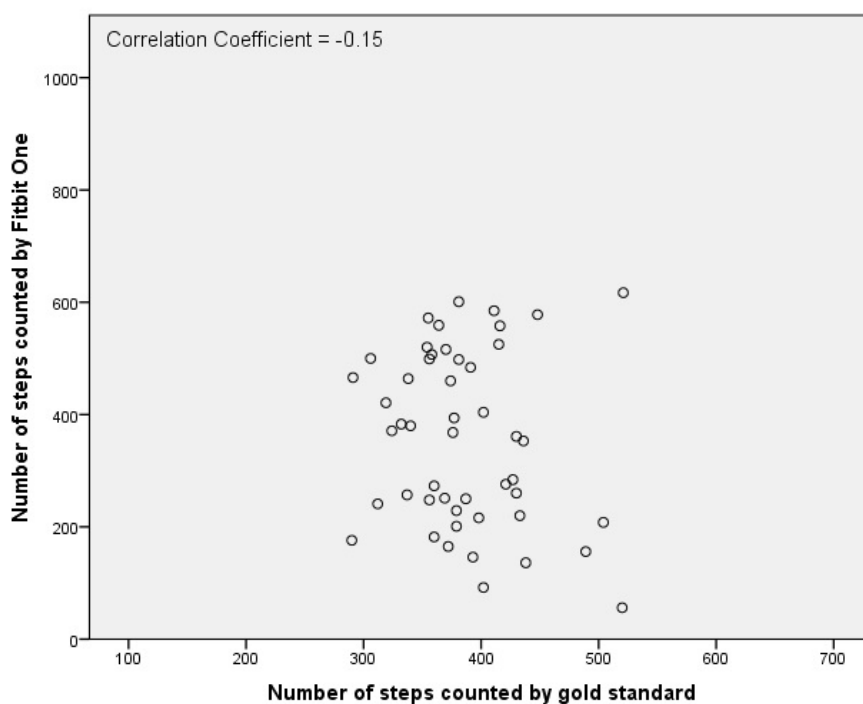
### Strength of the Relation and Systematic Difference

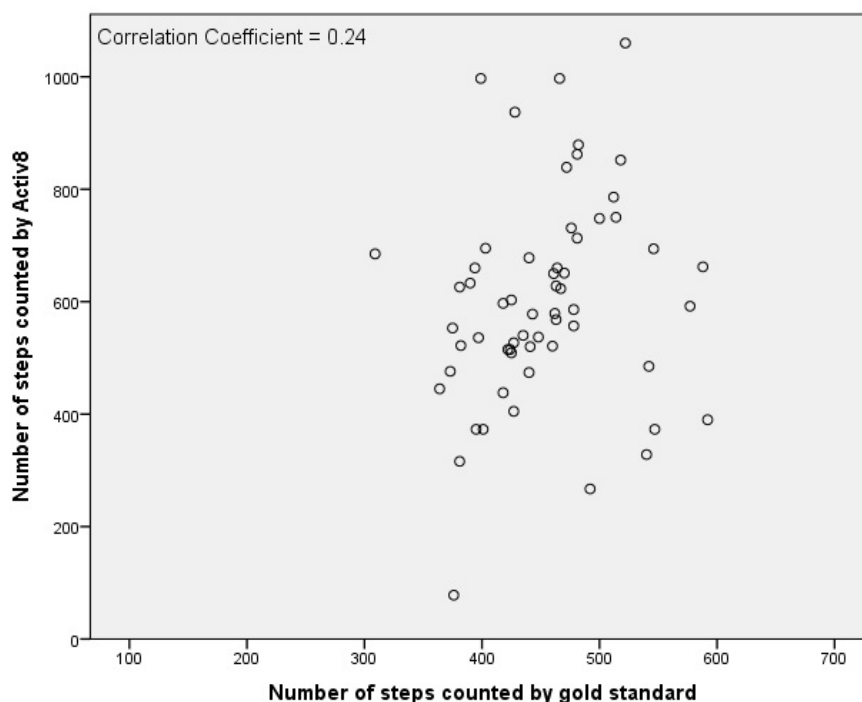
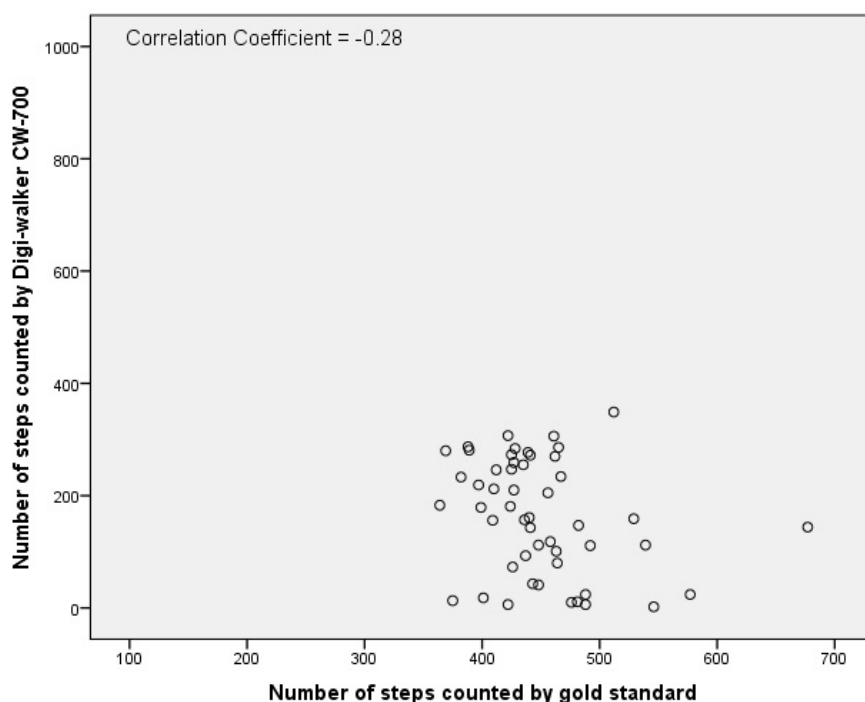
The correlation between the number of steps measured by the activity trackers and the gold standard was weak for all activity trackers ranging from  $r = -.02$  for the Moves to  $r = -.33$  for the Digi-Walker CW-700 (Table 5). The average underestimation of all trackers and the average overestimation of the Activ8 revealed a significant systematic difference with the gold standard for step count, except for the Fitbit One ( $P = .35$ ).

**Table 4.** Descriptive statistics of step count by activity tracker compared to the gold standard.

Activity tracker	Number of participants	Average mean difference in step count (SD) <sup>a</sup>	Average median difference in step count (25 to 75 percentile) <sup>a</sup>	Limits of agreement (lower bound–upper bound)
Accupedo	50	-176.3 (132.1)	-174.5 (-251.0 to -102.5)	-435.2 to 82.7
Activ8	62	107.3 (251.9)	126.0 (30.5 to 243.5)	-471.3 to 721.0
Digi-Walker CW-700	52	-284.5 (129.0)	-253.0 (-383.0 to -169.0)	-537.4 to -31.7
Fitbit Flex	47	-93.5 (126.7)	-111.0 (-167.0 to 3.0)	-326.9 to 123.7
Lumoback	51	-178.5 (96.0)	-168.0 (-205.5 to -117.0)	-366.9 to 9.3
Moves	48	-146.6 (216.3)	-215.0 (-279.5 to -89.3)	-570.5 to 277.4
Fitbit One	49	-29.7 (155.1)	-8.0 (-160.0 to 128.0)	-367.8 to 308.6
UP24	49	-252.4 (104.7)	-266.0 (-327.0 to -176.5)	-457.7 to -47.2
Walking Style X	50	-204.4 (117.7)	-206.5 (-256.0 to -105.0)	-438.0 to 27.2

<sup>a</sup>Activity tracker minus gold standard.

**Figure 1.** Scatterplot of the number of steps counted by Fitbit One and the gold standard.

**Figure 2.** Scatterplot of the number of steps counted by Activ8 and the gold standard.**Figure 3.** Scatterplot of the number of steps counted by Digi-walker CW-700 and the gold standard.

### Level of Agreement

In all plots the limits of agreement are high, with the highest limits of agreement (-471.3 to 721.0) for the Activ8 (Table 4). In the plots, 2 trends are visible: either an over- and underestimation of the number of steps during the activity protocols as shown in Figures 4 and 5 (eg, Fitbit One and Activ8) or an underestimation of the number of steps only, as shown in Figure 6 (eg, Digi-Walker CW-700). Depending on the height of step count, overestimation or underestimation was

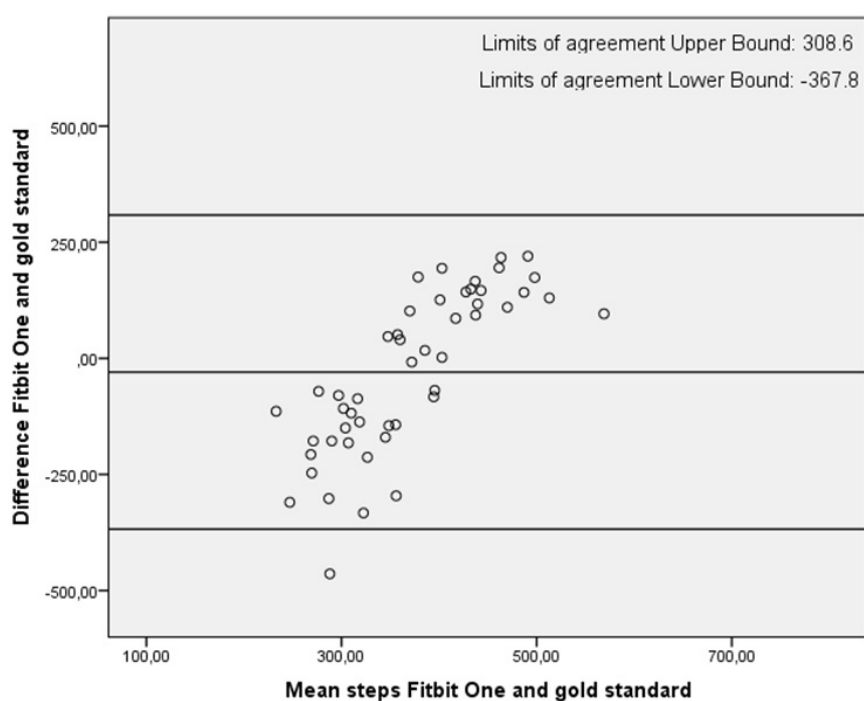
shown. Overestimation became more pronounced when participant took more steps and vice versa.

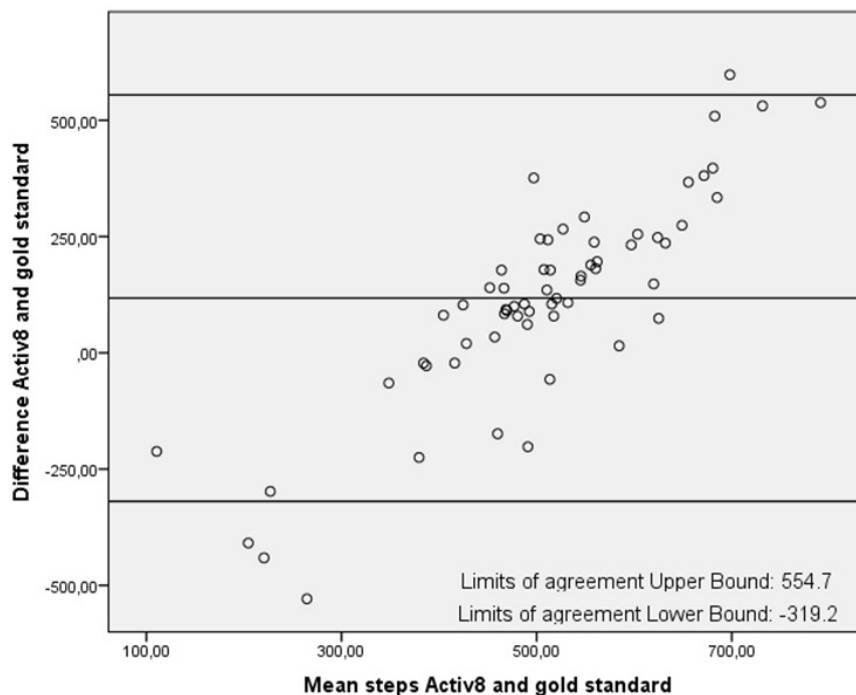
### Systematic Difference Between Short and Long Protocols

Only the Walking Style X, Accupedo, and Fitbit Flex were used in both protocols. For all trackers, there were no systematic differences found for the average mean difference in step count between the short and long protocols.

**Table 5.** Correlation coefficient of the activity trackers and the gold standard for step count.

Activity tracker	Correlation coefficient ( <i>P</i> value)	t value ( <i>P</i> value)
Accupedo	.32 (.02)	-9.4 (<.001)
Activ8	.24 (.06)	-3.9 (.001)
Digi-Walker CW-700	-.33 (.02)	-6.2 (<.001)
Flex	.31 (.04)	-5.1 (<.001)
Lumoback	.19 (.20)	-6.2 (<.001)
Moves	-.02 (.88)	-3.4 (.001)
One	-.15 (.30)	-0.9 (.35)
UP24	.09 (.52)	-6.9 (<.001)
Walking Style X	.25 (.08)	-12.3 (<.001)

**Figure 4.** Bland-Altman plot of Fitbit One and the gold standard.

**Figure 5.** Bland-Altman plot of the Activ8 and the gold standard.**Figure 6.** Bland-Altman plot of Digi-Walker CW-700 and the gold standard.

## Discussion

### Principal Findings

The results of this study showed that none of 9 selected commercially available activity trackers was valid for measuring steps while individuals engage in activities of daily living among a diverse group of patients with various chronic diseases receiving physiotherapy in the Netherlands.

All activity trackers in this study had an average underestimation in step count except the Activ8, which overestimated step count. The Digi-Walker CW-700 and Lumoback consistently underestimated step count in every participant, while the other activity trackers had a combination of under- and overestimation. For all trackers, the correlations between step count measured by the activity trackers and the observed steps were low. On group level, the Fitbit One seemed to be the best activity tracker due to its low mean difference; however, on individual basis

the scatter and Bland-Altman plots showed a large under- and overestimation in step count.

Several studies have shown that a low walking speed decreases the validity of activity trackers [12,16,50,51]. For an activity tracker to measure the number of steps correct, a walking speed of 0.8 m/s is required. All of our participants walked faster than 0.8 m/s during the 10MWT; therefore, their walking speed should have been sufficient for an accurate measurement by the activity tracker. However, the activity protocol consisted of different household tasks such as vacuum cleaning and washing windows, resulting in a walking speed below 0.8 m/s. Recently, Nelson et al [52] published the results of a validation study in which the Fitbit Flex and Fitbit One were assessed during activities of daily living in a healthy population. They concluded that these activity trackers underestimate step count by 60% during household activities, but during walking activities the percentage error was within 4%. Nelson et al concluded that this difference might come from slow ambulation speed and shuffling during these household activities. Although the populations differ, these results confirm the findings in our study. Our standardized activity protocol was based on earlier protocols with activities of daily living in COPD patients [24,29,45] and is therefore comparable to real-life performance of people with a chronic disease. Our protocol consisted of various activities of short duration, since this is more comparable to the performance of the activities in the daily life of people with a chronic disease. Since the study population had a limited physical activity capacity and more fatigue, pain, and possibly dyspnea, the requirements of the longer protocol might not have matched their physical possibilities and might not represent the daily life of people with a chronic disease. During the execution of the study, all patients were able to perform the entire protocol, and no patients had to be excluded due to the effort required by the protocol. However, the results of our study contradict studies performed in healthy populations in which the 9 tested activity trackers showed good validity in free-living situations [19,20]. An explanation could be that the walking speed is faster during free-living situations because patients perform more walking activities in comparison to an activity protocol with activities of daily living. To the authors knowledge, only 1 validation study was performed in people with a chronic disease (cardiac patients) using one of the assessed activity trackers (Fitbit Flex [36]). This study concluded that there was a high correlation between the Fitbit Flex and the Actigraph for step count ( $r=.95$ ).

### Limitations and Strengths

The chosen activity trackers were the most up-to-date activity trackers at the time. During this study, several updates were released for the chosen activity trackers (mostly the exterior instead of the algorithm), and several new activity trackers were brought to the market. But the chosen activity trackers are still the most popular and most used activity trackers currently available [53-55].

In this study design, 2 activity protocols were used. It was assumed that the length of the protocol had no influence on the trackers' validity because the removed activities were activities that didn't require walking. There were no systematic differences

in average mean difference in step count between the short and long protocols.

For determining the validity of the step count, the definition of a step is very important. In this study, a step was defined as when the entire foot was lifted from the floor and placed back on the floor again. However, shuffling is frequently seen in elderly populations and in people with a chronic disease [12]. If shuffling steps were included in our analysis (thus more steps during the protocol), more underestimation of the activity trackers would be likely, implying an even lower validity.

In this study, it wasn't possible to report validity of the activity trackers per activity. All selected activity trackers were commercially available trackers, and thus their algorithms and time slots were not available on request. Without specific information regarding (at least) the timeslots, it was not possible to disentangle time per activity.

In this study, we used different methods for evaluation of the validity. By using these different methods, insight was gained on validity on both group and individual levels. Validity on individual level is important for daily practice for patients and therapists. We included the *P* value for the correlation coefficient; however, this is a measurement on group level and not on individual level. Therefore, the significant correlations are not clinically relevant. Moreover, the 3 significant correlations (Accupedo, Digi-Walker CW-700, and the Flex) are still considered weak correlations [48].

A strength of this study is the use of observed steps as gold standard. The high reliability of this gold standard assures very little systematic bias in the analysis method. The chronic diseases included in this study are those most frequently seen by physiotherapists in the Netherlands [2], implying that the study results might be generalizable to a broad population. However, this should be confirmed by including a broader range of patients with chronic diseases not limited to primary care physical therapy practices.

### Clinical Relevance

Guidelines recommend objectively measuring the physical activity level of a patient outside of guided therapy [2]. However, underestimation or overestimation of physical activity by an activity tracker is not desirable. Not only might it demotivate people to engage in physical activity, it may also influence the advice and intervention of physiotherapists. This study showed that the trackers are not valid for activities of daily living performed in this study. Considering this limitation, the trackers should only be used to measure steps during free living situations in which patients perform more walking activities.

### Conclusion

This study showed that the validity of 9 commercially available activity trackers is low measuring steps while individuals engage in activities of daily living among a diverse group of patients with various chronic diseases receiving physiotherapy. Frequent underestimation and a wide range of measurements were seen for step count during a protocol with activities of daily living compared to observed steps as gold standard.

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## Authors' Contributions

EB, SB and AB created the design of this study. DU and EB collected the data in one physiotherapy practice together with other physiotherapists. DU, EB and KT analyzed the data. DU, EB, KT, SB and AB made interpretations of the data. DU, EB, KT, SB and AB drafted the manuscript. EB, SB and AB revised the manuscript regularly.

## Conflicts of Interest

None declared.

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## Abbreviations

- 10MWT:** 10-meter walk test
- CIRS:** Cumulative Illness Rating Scale
- COPD:** chronic obstructive pulmonary disease
- ICC:** intraclass correlation coefficient

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Original Paper

# Wearable Activity Tracker Use Among Australian Adolescents: Usability and Acceptability Study

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## Abstract

**Background:** Wearable activity trackers have the potential to be integrated into physical activity interventions, yet little is known about how adolescents use these devices or perceive their acceptability.

**Objective:** The aim of this study was to examine the usability and acceptability of a wearable activity tracker among adolescents. A secondary aim was to determine adolescents' awareness and use of the different functions and features in the wearable activity tracker and accompanying app.

**Methods:** Sixty adolescents (aged 13-14 years) in year 8 from 3 secondary schools in Melbourne, Australia, were provided with a wrist-worn Fitbit Flex and accompanying app, and were asked to use it for 6 weeks. Demographic data (age, sex) were collected via a Web-based survey completed during week 1 of the study. At the conclusion of the 6-week period, all adolescents participated in focus groups that explored their perceptions of the usability and acceptability of the Fitbit Flex, accompanying app, and Web-based Fitbit profile. Qualitative data were analyzed using pen profiles, which were constructed from verbatim transcripts.

**Results:** Adolescents typically found the Fitbit Flex easy to use for activity tracking, though greater difficulties were reported for monitoring sleep. The Fitbit Flex was perceived to be useful for tracking daily activities, and adolescents used a range of features and functions available through the device and the app. Barriers to use included the comfort and design of the Fitbit Flex, a lack of specific feedback about activity levels, and the inability to wear the wearable activity tracker for water-based sports.

**Conclusions:** Adolescents reported that the Fitbit Flex was easy to use and that it was a useful tool for tracking daily activities. A number of functions and features were used, including the device's visual display to track and self-monitor activity, goal-setting in the accompanying app, and undertaking challenges against friends. However, several barriers to use were identified, which may impact on sustained use over time. Overall, wearable activity trackers have the potential to be integrated into physical activity interventions targeted at adolescents, but both the functionality and wearability of the monitor should be considered.

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**KEYWORDS**

qualitative research; fitness trackers; physical activity

## Introduction

In recent years, there has been a proliferation of commercially available wearable activity trackers (eg, Fitbit, Misfit, Garmin, Apple Watch) on the market. The popularity and appeal of these devices, combined with decreasing costs, have resulted in a significant uptake by individuals to self-monitor physical activity levels, such as how many steps they take [1,2]. However, empirical research supporting the use and benefits of such devices is still emerging. To date, researchers have tended to focus on the validity and/or reliability of such wearable devices for measuring a range of outcomes in laboratory and free-living settings, including steps, distance traveled, energy expenditure, and sleep [3,4]. Research conducted with adults suggests that wearable devices have good validity for measuring steps in both settings, but lower validity for active minutes and generally poor validity for sleep outcomes [5-7]. Although comparatively little research has been conducted among youth, similar validity findings have been reported [8,9].

More recently, researchers have begun integrating wearable devices into physical activity promotion interventions in a range of populations [10-13] and tracking patients' habitual activity and/or sleep over longer periods of time [14]. Most of the research has been conducted in adult populations, with few using these devices in interventions targeted at youth [15]. Fundamental to these interventions is an expectation that individuals know how to use the technology [16] in order to engage with and sustain their use of the device and accompanying app over a period of time (eg, weeks, months [10,11]). In the context of interventions, studies typically report an individual's engagement with the device over time (eg, how many days of data were recorded [11,17]), and examine whether the wearable activity tracker had an impact on behavioral outcomes [15,18]. However, little research has focused on the acceptability of using these devices, particularly among youth who are active users of a range of digital devices and have had greater exposure to technology from a younger age [15,19]. Moreover, few have examined how the individual perceived and used the wearable activity tracker [20]. This is important to establish in adolescents, who are unlikely to be motivated by long-term health concerns as compared with adults [21], and perceptions of such technology may differ.

One of the biggest concerns associated with wearable activity trackers is whether individuals continue to engage with the technology over longer periods of time [22]. For example, Hermsen and colleagues found across their study that 2% of participants per week stopped using the wearable tracker entirely after being provided with the device, and 50% no longer used the technology after approximately 6 months [23]. Interestingly, increasing age was related to sustained use [23]. In contrast, despite their high use of technology generally, some studies conducted with adolescents suggest that wearable activity tracker usage reduces after approximately 2 weeks [19,24]. There is clearly a need to further examine perceptions and engagement of youth with wearable devices. Such information would provide critical insights into potential facilitators and barriers to ongoing use [24], which, in turn, has the potential to inform the

development of future interventions and integration of these technologies into broader health promotion programs.

An integral component of wearable activity trackers is the automation of physical activity tracking in real time [2,15]. This allows the user to self-monitor their physical activity against public health recommendations or their own goals [2,25], receive feedback via a visual display (device and/or an accompanying app), and receive prompts or cues to be active (eg, via notifications sent through the app). These are examples of behavior-change techniques that are known to change behavior [26]. Notably, several reviews have found that up to 30 well-established behavior change techniques are present across a number of wearable devices (eg, Fitbit Flex, Garmin Vivofit, Jawbone UP, Polar Loop [2,27]) and their range of different features or functions. Such features include social support and social comparison, which may motivate adolescents to be active, given that peer influence is associated with health behaviors such as physical activity [28,29]. However, little research has examined users' awareness and use of the different features or functions of such devices or apps with youth [1,30]. Ascertaining how to change behavior through targeting specific aspects of the device and/or app, for example, would help to inform the development of future interventions.

Therefore, the aim of this study was to examine the usability and acceptability of a wearable activity tracker among adolescents. A secondary aim was to determine adolescents' awareness and use of the different functions and features incorporated into the wearable activity tracker and accompanying app.

## Methods

### Overview

This study drew on data collected via focus group discussions conducted with adolescents aged 13-14 years after they were given a Fitbit for a 6-week period. Participants had not previously owned or used a Fitbit. The project received ethics approval from Deakin University Human Ethics Advisory Group (Health) and the Victorian Department of Education and Training.

### Participants and Settings

Secondary schools located within an approximate 40 km radius of Deakin University Burwood Campus were identified using the publicly available My Schools website and stratified into tertiles of area-level socioeconomic status (SES) using the Socio-Economic Index for Areas [31]. A stepwise approach to recruitment was undertaken. Specifically, within each tertile, a random number generator identified the order in which schools were invited to participate in the study. In the event that the first school contacted declined the invitation, the next school on this list was contacted. This approach was continued until one school in each tertile agreed to participate in the study. Three schools (one low, one medium, and one high SES) returned informed written Principal consent (total response rate: 38%, 3/8).

Adolescents in year 8 (aged 13-14 years) were randomly selected by a school liaison teacher and invited to participate in the project. The research team was not involved in the participant

selection process. A minimum age of 13 was used due to the terms and conditions stipulated by Fitbit concerning the age of use. As this was a formative evaluation study, we aimed to recruit approximately 20 adolescents (10 boys, 10 girls) per school. To be eligible to participate in the project, students could not currently own or have previously used a Fitbit monitor. Sixty adolescents from 3 schools were invited, and all provided written parental consent and student assent to take part (60/60 or 100% response rate). The participants were evenly split across school and sex.

### Wearable Activity Tracker

This study investigated the acceptability and usability of the Fitbit Flex (San Francisco, California, United States). Acceptability was defined as the perceived usefulness of the Fitbit Flex for tracking activity behaviors, while usability was defined as the perceived ease of use of the device. The Fitbit Flex is a small, wrist-worn monitor that collects minute-by-minute real-time information on steps taken, estimated energy expenditure, physical activity intensities, and sleep. Twenty behavior change techniques are integrated into the Fitbit and accompanying app [2]. Feedback is provided to the wearer through a visual display that consists of 5 light emitting diodes (LEDs) that light up as the user progresses toward their preset daily goal (1 light equates to 20% of daily goal). The Fitbit Flex wirelessly syncs data to a Web-based account (typically through a smartphone or Fitbit connect), which is only accessible via a personal log-in and password. The account can be created to enable the wearer to view and track their own personal statistics using the Web-based portal (free to access and download from Fitbit webpage) or the mobile phone app (free to download from the App Store or Google Play Store). The Fitbit Flex requires charging approximately every 5 days and can store data for up to 7 days without being synced to the user's account. This device was chosen for four reasons: (1) Fitbit had the greatest market share of wearable activity trackers at the time of the study [32], (2) the relatively low cost (approximately Aus \$100 dollars/device), (3) the inability to store personal data on the device or provide location details (ie, no global positioning system tracker), which was considered important for adolescent populations, and (4) the excellent reliability and acceptable validity of the Fitbit Flex in adults [5].

### Protocol

#### *Six-Week Experimental Period*

Each participant was provided with a Fitbit Flex (San Francisco, California, United States) and asked to wear it for 6 weeks (September 2015–November 2015). As participants had not previously owned or used a Fitbit device, the research team helped them to set up their Fitbit Flex. This setup process included creating a personal Fitbit account and familiarizing them with the basic functions and features of the device, including charging, syncing, and using the Web-based portal or mobile phone app for viewing their data. Such information is also provided within the packaging of the device. In an attempt to mirror experiences of consumers using the device following purchase, no other information was provided to the

participants about the use of the monitor (eg, how frequently to wear it, how often to access their data, goal-setting).

### Focus Group Discussions

Demographic data (age, sex) were collected via a Web-based survey completed during week 1 of the study. At the conclusion of the 6-week period, all adolescents participated in focus groups (up to 10 adolescents per group) that explored their perceptions of the acceptability and usability of the Fitbit Flex, accompanying app, and Web-based Fitbit profile. Adolescents' awareness and use of the different functions and features were also discussed. A qualitative approach was used to respect the expert knowledge of the participants and to enable them to provide insights into their experiences [33]. The focus groups followed a semistructured format and were designed to address the adolescents' perceptions and experiences of using the Fitbit Flex, views on the acceptability and usability of the different features and functions, potential facilitators or barriers to ongoing use, and describe their thoughts on the impact of the Fitbit (if any) on their overall activity levels. In total, 6 mixed sex focus groups were conducted (2 per school). All focus groups were conducted in a quiet area at each school by two of the authors (SKL, KR) and digitally recorded. Focus groups (mean duration 41.1 min, SD 6.7 min) were then transcribed verbatim, producing 198 pages (Times New Roman, size 12) of raw transcription data for further analysis.

### Data Analyses

Pen profiles, an increasingly utilized technique, were constructed from verbatim transcripts using a manual protocol [33,34]. Such a technique, which presents analysis outcomes via diagrams of composite key emergent themes, is considered appropriate and accessible to researchers with an affinity for both qualitative and quantitative backgrounds]. Example verbatim quotations were then extracted directly from the transcripts to further contextualize the theme. To provide an indication of the prevalence of the themes, the number of times a specific theme was mentioned across all focus group data is also presented [33].

Consistent with recommended approaches [35], one researcher (MF) independent to the project delivery team, initially read and analyzed the transcripts. These findings were then presented to another independent researcher (KAM) with expertise in qualitative analyses (eg, [34]), by means of cooperative triangulation. Having independently analyzed the transcripts, KAM then critically questioned the presented thematic analyses and challenged differing interpretations. A third independent researcher (MAM) subsequently analyzed the data in reverse from the pen profiles back to the transcripts. This process assured the reliability of the data obtained [33]. Finally, the pen profiles were presented to the lead author, who further critically challenged the data. This process allowed authors to offer alternative interpretations and interrogate the data until a consensus was reached. Overall, methodological rigor (ie, credibility and transferability) was demonstrated through verbatim transcription of data and triangular consensus procedures. Moreover, dependability was demonstrated through the comparison of pen profiles with verbatim citations and the triangular consensus processes.

## Results

### Findings

As no thematic differences between participants attending schools in high-, mid-, and low-SES areas emerged, data are presented collectively in 3 pen profiles. Two pen profiles broadly focus on facilitators and barriers to Fitbit use, whereas the third pen profile focuses on specific features and functions of the Fitbit Flex, which have been linked to particular behavior change techniques [2,26].

### Facilitators

The facilitators of Fitbit Flex use are presented in Figure 1. Participants reported that the key enablers were the wrist-worn location, their enjoyment of tracking their physical activity levels, and ease of use as well as accessibility of data through the app. While some adolescents were content with the feedback provided through the visual display on the device (5 LED lights), others found the lack of specific feedback to be a limitation. A common theme was the desire to gain further information about their physical activity levels, such as current progress: “You can’t tell how many steps you’ve already done.” Adolescents highlighted that the ability to perform maintenance tasks (eg, clean the device, which is important for charging it), as well as the ability to easily access and interpret data through the app were key facilitators. In addition, there was a general consensus that the Fitbit facilitated awareness of and an improvement in their physical activity levels. Adolescents also felt that the

vibrating function (ie, feedback that they had reached their daily step goal) reinforced positive physically active behaviors.

### Fitbit Features, Functions, and Associated Behavior Change Techniques

Adolescents described a number of Fitbit features and functions that they either used or were aware of that reflected 7 specific behavior change techniques: social support, self-monitoring or tracking, social comparison, prompts or cues, feedback, rewards, and goal setting (Figure 2). Adolescents commonly reported that they enjoyed using the features that enabled them to self-monitor and obtain feedback on their steps, distance covered, calories burnt, as well as their sleep time. This was facilitated by both the visual display and the app. It was also evident that the adolescents capitalized on the opportunity afforded by the monitors to not only reflect on their daily goals but also to challenge themselves to increase them by setting new goals. Adolescents also frequently cited their enjoyment of engaging with their peers through the app, including the option to undertake challenges with their friends (eg, daily showdown). There were mixed opinions as to the motivational impact of the achievement badges (rewards) awarded via the Fitbit app for walking a set distance on a particular day (eg, 10,000 steps). Some felt motivated by these rewards to maintain their activity levels, whereas others did not feel they were a “huge achievement” and, therefore, they were not considered as an incentive as they did not value this feature. However, for one adolescent, simply wearing the monitor itself acted as cue: “Just knowing it’s on your wrist, it makes me want to be more active.”

**Figure 1.** Facilitators of Fitbit use in young adolescents (n’s in brackets refer to the number of times a theme was mentioned during the focus groups). The dashed line indicates link made between different themes was noted by the researchers from the points discussed, rather than directly mentioned by the adolescents.

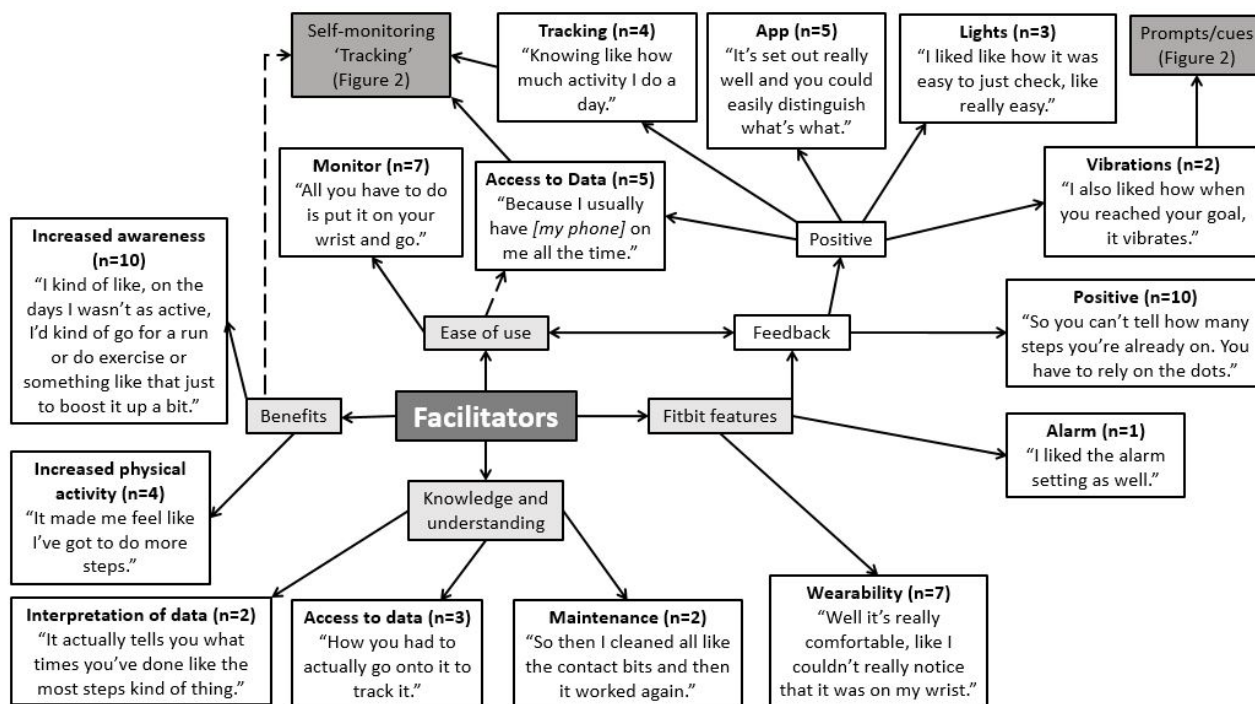


Figure 2. Features and functions of the Fitbit used by the adolescents.

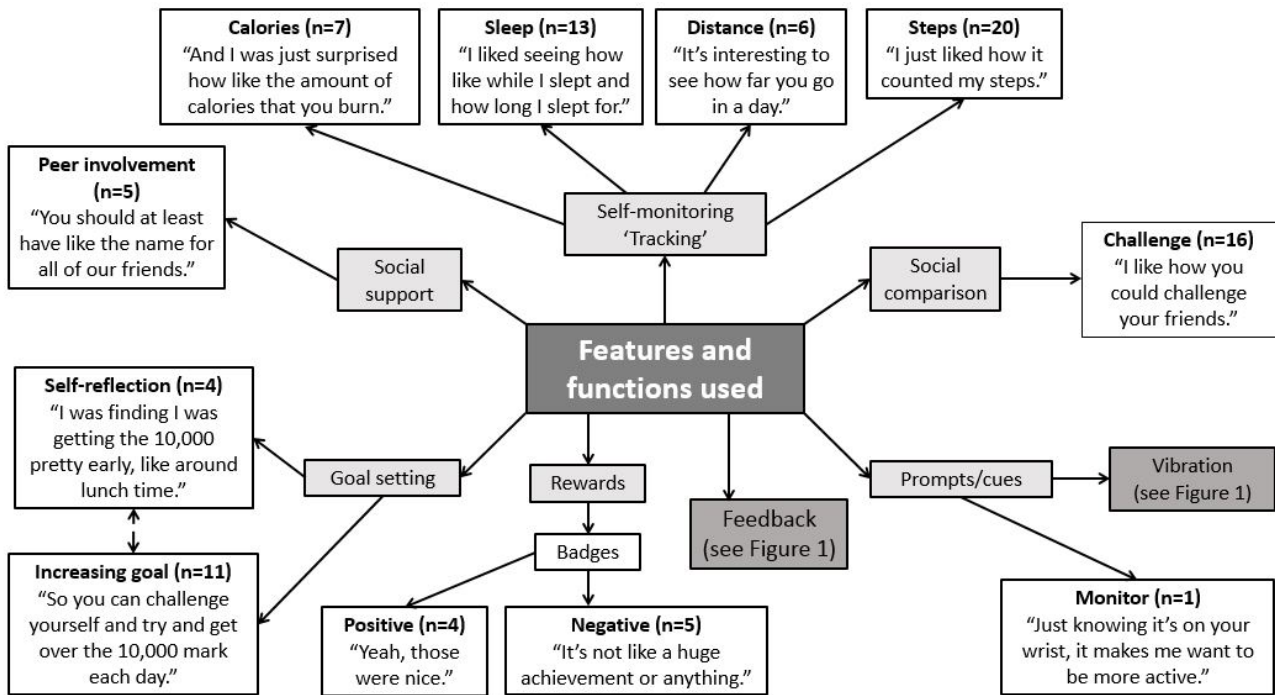
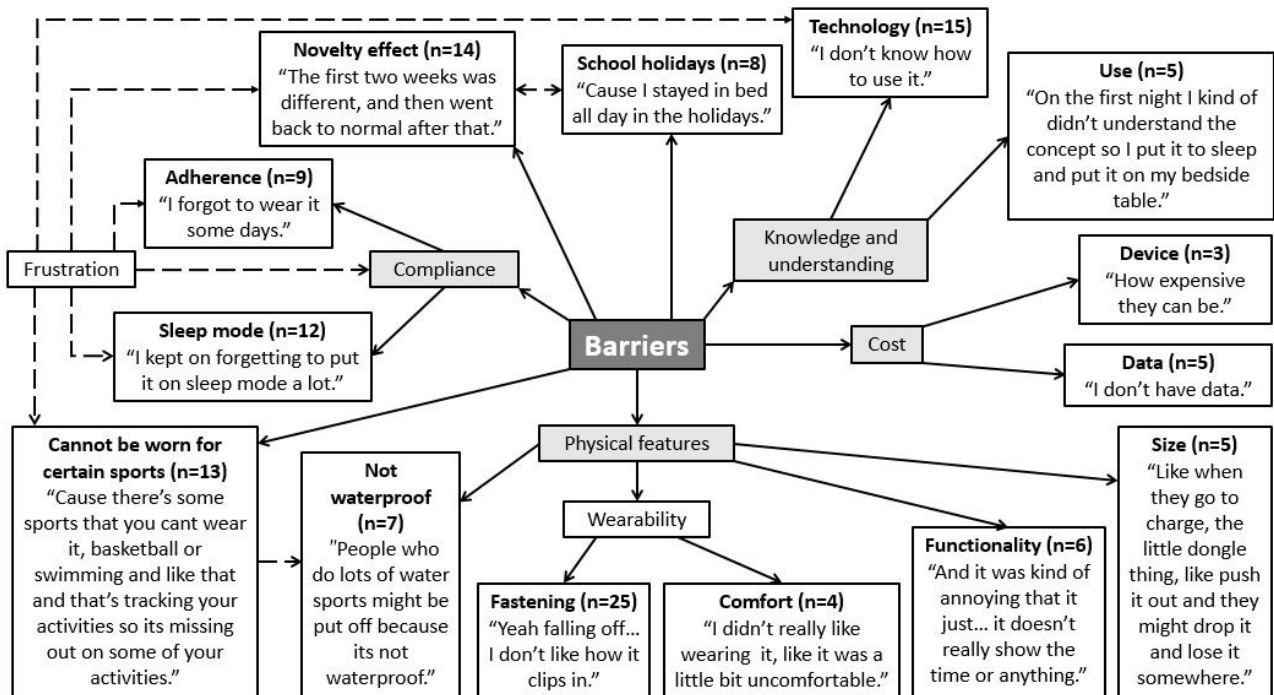


Figure 3. Adolescent’s barriers to Fitbit use. The dashed line indicates link made between different themes was noted by the researchers from the points discussed, rather than directly mentioned by the adolescents.



**Barriers**

A number of barriers to use were raised by participants (Figure 3). These related to the design of the monitor, a lack of knowledge and understanding about how to use the device, and costs associated with using the Fitbit. Adolescents expressed frustration that the monitors were not waterproof and also could not be worn for certain sports, particularly sports such as soccer and basketball. Moreover, the fastener (ie, not secure), comfort and lack of functionality of the device per se (ie, no digital time

display) were frequently cited as barriers to wearability. Furthermore, long-term compliance issues were highlighted due to problems associated with the sleep mode, which in turn was linked to frustration with the monitor (eg, not knowing how to use it), as well as a potential novelty effect after receiving the Fitbit. Adolescents reported that they had trouble either setting the monitor to record sleep or forgot to enable this feature. In addition, some adolescents identified that there was a novelty effect in terms of using the monitor to track activity,



which returned back to normal after a period of time (approximately 2 weeks). However, this coincided with school holidays, which adolescents reported as a separate barrier that they thought affected their activity levels and how much they wore the Fitbit.

While Fitbits were provided to the adolescents participating in the study, in order to access their physical activity data via the app, they often had to use the data allowance that was associated with their mobile phone at a cost to the participants. This emerged as a barrier to use across all focus groups, regardless of SES. Finally, some adolescents demonstrated a lack of understanding regarding how to use various app components, such as personalizing their daily step goal (ie, increasing/decreasing goal), suggesting that participants neither used the monitor as the manufacturer intended nor accessed the various features available to them, particularly in the app.

## Discussion

### Principal Findings

The main aim of this study was to examine adolescents' perceptions concerning the usability and acceptability of the Fitbit Flex when provided with the device to wear for 6 weeks. Adolescents generally found the Fitbit Flex easy to use and reported that it was a useful device for self-monitoring their day-to-day activity. They noted that this ability to self-monitor their activity increased their awareness and knowledge of their activity levels. However, a number of potential barriers were also identified, which may impact on whether they would sustain their use of the Fitbit over time. A secondary aim of the study was to examine adolescents' awareness and use of the different functions and features incorporated into the Fitbit Flex and accompanying app. The adolescents utilized a range of functions and features of the device and app, which corresponded to 7 behavior change techniques. Together, these findings provide insights into how adolescents engaged with the Fitbit Flex, which in turn may help to identify how to integrate it into physical activity interventions for adolescents and what factors may need to be addressed to try to facilitate long-term use.

### Comparisons With Prior Work

There is currently a dearth of research that has examined the acceptability and usability of wearable devices by youth [15]. Results generally indicate that wearable devices are viewed favorably by youth, with factors such as ease of use, aesthetics, and comfort important facilitators for ongoing use [10,16,17,22,36,37]. Similar findings were observed in this study. Specifically, ease of use was an important facilitator of monitor use, with adolescents noting that the app was easy to navigate and the Fitbit Flex visual display straightforward to check. However, a number of adolescents expressed difficulties with the sleep mode in particular, which led to frustration with the device and, in some cases, the adolescents reported that this impacted on wearing the device (eg, removed overnight and forgot to put it back on the following day). This suggests that the user may need assistance with using features or functions of wearable devices. However, the assistance required may differ for different age groups. For example, previous research has indicated that adolescents may need support in personalizing

the device in relation to daily goals [28]. On the other hand, research with adults and older adults indicates that training on how to use the device and the app more generally may be required [38,39]. Researchers and practitioners should consider including information as part of an intervention to ensure the device is used as intended.

There were contrasting findings in relation to comfort and wearability, with some adolescents noting that they found it comfortable to wear on the wrist (7 mentions) while others found this was a barrier to wearing the device (4 mentions). The biggest issue noted by the adolescents was the manner in which the device fastened around the wrist (25 mentions), with concerns being raised that this was not secure. Previous research has noted that loss of a device (or fear of losing the device) is a major barrier to an individual's experience and engagement [16]. Interestingly, a study conducted with older adults also found the Fitbit Flex locking mechanism to be problematic. This was due to fastening the clasp itself, but once closed, the older adults did not report concerns about losing the device [39]. Overall, this suggests that researchers should consider not only the function of the wearable device for use in an intervention (eg, feedback on steps, sleep) but the wearability of the device in different age groups to enhance the individual's experience and promote compliance with the monitoring protocols.

In general, adolescents noted that they did use the Fitbit Flex to track a range of data, including steps taken, distance traveled, and sleep. This appeared to increase their awareness of their activity levels, with several adolescents noting that they used this feedback to increase their overall activity levels. Others have noted similar findings, suggesting that the use of a wearable device can trigger short-term increases in physical activity levels [24], particularly when the step target had not been achieved [19]. This is a positive finding in the context of using the devices within an intervention, as without knowledge of their current activity levels, youth are unlikely to change their behaviors as they may see no need to do so [40]. It is important to note that feedback is also an important component for increasing awareness [40], yet several issues were raised relating to the feedback provided by the Fitbit Flex. Some adolescents reported that the visual display on the device provided sufficient feedback against their day goal, yet others found that this was inadequate and, in some cases, this was identified as a barrier to use. In particular, adolescents expressed interest in knowing their actual steps rather than relying on the lights for information. This might be explained, in part, by the current adolescents participating in a step challenge within the app to compete against their peers, for which knowing how your daily step score compared with others may have been critical to success (or not). While detailed step feedback is available through the Fitbit app, some adolescents noted that accessing this information came at a cost as they had to use their mobile phone data allowance. As previous research has found that youth tend to prioritize use of their data for entertainment purposes [41], it is possible that these adolescents did not access the app frequently [if at all] to view their data and did not receive specific feedback on their daily steps. Overall, researchers may need to consider using devices that provide specific feedback on the display (eg, steps), particularly in this population, to address these issues.

A positive finding was that adolescents reported using a range of features and functions of the Fitbit and the accompanying app, which are based on behavior change techniques that are known to influence behavior [22,26]. In addition to self-monitoring, goal setting, and feedback, peer involvement (either as support or comparisons) was frequently cited as an element of the app (in particular) that the adolescents liked and used. This supports previous research that noted that competition with peers and peer-surveillance promoted social connections [19]. Future interventions using wearable devices should consider how to capitalize on these features that promote peer involvement (eg, daily challenges), particularly given the influence of peers on adolescents' physical activity [42]. However, this must be balanced with promoting self-comparisons and autonomy and ensuring that activity engagement is self-determined. Indeed, some have suggested that competition can increase negative feelings of self, and adolescents have reported engaging in activity due to peer pressure [19]. As a consequence, adolescents may remove themselves from engaging in peer-surveillance (eg, sharing activity levels with others) altogether [19,28].

Interestingly, other features of the app that are considered to reward physical activity behavior (eg, step badges) were not particularly valued by most and, in general, were not seen as a significant achievement. This is in contrast to previous studies in adolescents that combined a Fitbit Flex with a Facebook group, where the badges were seen as a reward for effort, reinforced activity behaviors, and also provided opportunities for social comparison and support within the group [12,37]. Those results may be due to adolescents being able to see other group members' achievements, which introduced an element of social comparison, competition, or support (ie, achieving badges as a group; [12]). It is possible that factors such as motivation regulation or stages of change may moderate the acceptability and usability of specific features of the Fitbit [24,28]. As an example, the Fitbit app awards badges to reward individuals, and those with higher autonomous motivation or readiness to change their physical activity behavior may perceive these badges differently to those with lower autonomous motivation. Examining how individuals perceive such features that are designed to reward daily and sustained effort (eg, distance badges) may be warranted to identify how (if at all) they can be utilized within wider programs using wearable technology. Overall, the findings of this study provide insights into potential features embedded into the device and/or app, which are based on behavior change techniques that could be targeted within an intervention to increase activity levels. However, it is important to note that these are likely to be device-specific and may not apply to other wearable activity trackers, and the usability of the linked features may dictate whether or not these features should form a specific component of an intervention [2].

One of the concerns of wearable technology is whether an individual sustains their use of the device over the longer term [22]. It has been reported that use of wearable devices declines over time, with approximately 25% to 50% of adults ceasing to use the technology within the first 6 months of ownership [22,23]. This is consistent with previous studies that have

utilized self-monitoring of behaviors [43]. Despite the adolescents in this study using the Fitbit Flex for 6 weeks, it was noted by participants that there was a novelty effect of using the device, which started to wear off after the first couple of weeks of use. This finding supports previous studies conducted with adolescents, where interest waned after 2 to 4 weeks of use [19,24,28]. This may suggest that the devices could be a useful first step in helping to establish an individual's awareness of activity levels but other techniques may need to be targeted (eg, via the app or additional resources) to facilitate sustained use over longer periods of time. Alternatively, this may indicate that during this initial period when motivation and interest are likely to be high [24], researchers can capitalize on this window of opportunity within an intervention to try to integrate the device into a feature of daily living. Addressing factors that lead to sources of frustration, such as knowledge of the technology, how to use the device, and how to access and interpret data may be critical during this time to try to encourage the wearer to continue to use the technology. Previous studies have reported helping participants to know how to use the device and understand the collected data when the device is distributed [10,11,38], though additional information may need to be provided during an intervention to manage issues such as expectation mismatch (eg, technology is not doing what the user expected), which are a common reason for ceasing to use wearable devices [44].

The strengths of this study include the assessment of the feasibility of a wrist-worn wearable device in young adolescents in free-living settings, the inclusion of adolescents from low-, medium-, and high- SES backgrounds, and the use of qualitative methods to explore adolescents' thoughts and experiences in depth. However, there are several limitations that should also be noted. First, the liaison teacher at participating schools was asked to randomly select adolescents to receive an invitation to participate. The only selection criterion that we stipulated was no previous use or ownership of a Fitbit device. However, as we were not involved in the random selection of students, it is possible that students may have been specifically invited based on characteristics unknown to the research team to participate by their teacher. Second, the Fitbit used during the study has since been superseded by a newer model, which has addressed issues relating to waterproofness and automatic sleep tracking. These were 2 barriers identified by the adolescents in this study. Third this study assessed the adolescents' experiences after a 6-week period. While this study provides insights into their initial experiences of using the device, it is not known how this may have influenced long-term use, if at all. Longer-term studies are needed to establish how use of the device changes over time. Finally, no information was collected from the adolescents concerning their experience of using other wearable devices. It is possible that they had previously used other devices (eg, Garmin, Jawbone), which may have influenced their perceptions of the Fitbit Flex. However, it should be acknowledged that none of the adolescents in the focus groups compared their experiences of the Fitbit Flex with other wearable devices that were commercially available at the time of the study.

## Conclusions

Wearable devices provide an opportunity to promote physical activity to adolescents, yet little is known about how youth engage with and use such technology. Overall, this study found that a wearable device (Fitbit Flex) was highly acceptable to adolescents, and the device was used to self-monitor activity levels (and other behaviors). Adolescents reported using a range of functions and features that could be integrated into comprehensive physical activity interventions, reinforcing the

potential of these technologies for promoting activity levels in this population. Potential issues were also noted, which may decrease the feasibility of using such technology within an intervention or health promotion program, though barriers related to knowledge of using the different functions and interpreting data can be addressed using supporting techniques. Other barriers related to the specific device used, highlighting that these must also be considered during intervention development.

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## Conflicts of Interest

None declared.

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## Abbreviations

**LED:** light emitting diode

**NHMRC:** National Health and Medical Research Council

**SES:** socioeconomic status

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Original Paper

# Evaluating the Validity of Current Mainstream Wearable Devices in Fitness Tracking Under Various Physical Activities: Comparative Study

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## Abstract

**Background:** Wearable devices have attracted much attention from the market in recent years for their fitness monitoring and other health-related metrics; however, the accuracy of fitness tracking results still plays a major role in health promotion.

**Objective:** The aim of this study was to evaluate the accuracy of a host of latest wearable devices in measuring fitness-related indicators under various seminatural activities.

**Methods:** A total of 44 healthy subjects were recruited, and each subject was asked to simultaneously wear 6 devices (Apple Watch 2, Samsung Gear S3, Jawbone Up3, Fitbit Surge, Huawei Talk Band B3, and Xiaomi Mi Band 2) and 2 smartphone apps (Dongdong and Ledongli) to measure five major health indicators (heart rate, number of steps, distance, energy consumption, and sleep duration) under various activity states (resting, walking, running, cycling, and sleeping), which were then compared with the gold standard (manual measurements of the heart rate, number of steps, distance, and sleep, and energy consumption through oxygen consumption) and calculated to determine their respective mean absolute percentage errors (MAPEs).

**Results:** Wearable devices had a rather high measurement accuracy with respect to heart rate, number of steps, distance, and sleep duration, with a MAPE of approximately 0.10, whereas poor measurement accuracy was observed for energy consumption (calories), indicated by a MAPE of up to 0.44. The measurements varied for the same indicator measured by different fitness trackers. The variation in measurement of the number of steps was the highest (Apple Watch 2: 0.42; Dongdong: 0.01), whereas it was the lowest for heart rate (Samsung Gear S3: 0.34; Xiaomi Mi Band 2: 0.12). Measurements differed insignificantly for the same indicator measured under different states of activity; the MAPE of distance and energy measurements were in the range of 0.08 to 0.17 and 0.41 to 0.48, respectively. Overall, the Samsung Gear S3 performed the best for the measurement of heart rate under the resting state (MAPE of 0.04), whereas Dongdong performed the best for the measurement of the number of steps under the walking state (MAPE of 0.01). Fitbit Surge performed the best for distance measurement under the cycling state (MAPE of 0.04), and Huawei Talk Band B3 performed the best for energy consumption measurement under the walking state (MAPE of 0.17).

**Conclusions:** At present, mainstream devices are able to reliably measure heart rate, number of steps, distance, and sleep duration, which can be used as effective health evaluation indicators, but the measurement accuracy of energy consumption is still inadequate. Fitness trackers of different brands vary with regard to measurement of indicators and are all affected by the activity state, which indicates that manufacturers of fitness trackers need to improve their algorithms for different activity states.

**KEYWORDS**

wearable electronic devices; fitness trackers; data accuracy; physical activity

## *Introduction*

Level of physical activity (PA) is an important health factor; monitoring and promoting the level of PA can therefore improve people's health outcomes [1,2]. According to the 2010 World Health Organization (WHO) guideline [3], under normal circumstances, adults aged 18 to 64 years need to engage in at least 150 min of moderate-intensity PA or 75 min of high-intensity PA per week. In addition, to derive more health benefits, 300 min of moderate-intensity PA or 150 min of high-intensity PA per week is required. Currently, large populations in both developed and developing countries have not achieved the recommended levels of PA [2]. For example, 80% of adults in the United States have not reached the recommended level of activity, and around US \$117 billion in health care costs are associated with inadequate PA [4]. According to the data released by the WHO in 2014 [5], lack of PA has become the world's fourth greatest mortality risk factor, leading to 3.2 million deaths and 69.3 million lost disability-adjusted life years. The risk of all-cause mortality of adults with low levels of PA is 0.20 to 0.30 higher than that of adults with moderate or high levels of PA. In contrast, increased PA can not only reduce the risk of death of the whole population but also help lower the risk of chronic diseases such as ischemic heart disease, stroke, diabetes, and breast and colon cancers.

Recent years have seen a rapid development of wearable devices such as fitness trackers, which track PA in real time. They are able to enhance users' PA levels and cultivate healthy living habits because of their superior portability and user-friendly interface and are being accepted by more and more people [6,7]. Compared with the traditional pedometer, fitness trackers are equipped with more accurate sensors and more comprehensive software systems, which not only greatly reduce the discomfort of the wearer but also promote the development of the wearers' health habits with a friendly interface. Through a systematic review, Bravata et al [8] revealed that fitness tracker use not only increases PA levels but also lowers the user's body mass index and blood pressure. Poirier et al [9] conducted a randomized controlled trial on 265 individuals, and after 6 weeks of follow-up, they found that in both the mild activity group and the moderate activity group, the number of daily walking steps in the fitness tracker intervention group was significantly higher than that in the control group. Gualtieri et al [10] followed up 10 patients with chronic diseases on fitness tracker use for 3 months and found that the average body weight of the subjects decreased, whereas their PA levels and healthy behaviors improved. After a systematic review, Abedtash et al [11] argued that the combination of fitness tracker and other information technology (IT) measures were more conducive to improving health behaviors. Sullivan et al [12] noted that fitness tracker-based health intervention strategies such as target reminders, progress feedback, healthy behavior

recommendations, social encouragement, and other strategies can lead to greater health promotion in the future.

With the development of various miniature sensors, in addition to pedometer functions, wearable device providers are continuously providing new features such as energy consumption measurement, sleep measurement, body temperature measurement, and other feedback. Wen et al [13] surveyed 200 subjects via questionnaire and found that in addition to the aforementioned daily functions, the respondents were more interested in functions more significant to health, such as heart rate monitoring, electrocardiography monitoring, and oxygen saturation monitoring using wearable devices. Therefore, the acquisition of more health-related data through wearable devices will be the focus of future development. Although wearable devices are generally considered as having great potential in health monitoring, the accuracy and reliability of fitness trackers' monitoring data are the basis and premise on which fitness trackers play their role in health promotion [6,13]. With fitness trackers' enormous practical value, major technology companies have launched a variety of fitness tracker products, but there's still a lack of extensive and scientific validation with respect to their accuracy and reliability in health monitoring. Through a systematic review, Evenson et al [14] showed that except for the fact that the measurement of the number of steps is fairly accurate, the measurement of distance overestimates or underestimates with changes in the speed of the activity, and the measurements of energy consumption and sleep duration are usually overestimated relative to the actual values, and the measurements of activity duration varied among different studies; in addition, under different measurement modes, fitness tracker measurements varied significantly. Desilets et al [15] asked 20 subjects to simultaneously wear a fitness tracker and three research-grade heart rate measurement devices and compared the measurement results. They found that when sitting still, the heart rate measurement by the fitness tracker was lower compared with the other devices; under the activity state, the measurements by the fitness tracker and the other devices were also inconsistent, with correlation coefficients ( $r$ ) of .63 to .78. By comparing the accuracies of heart rate and energy consumption measured on 65 subjects under different levels of activity intensity by three types of fitness tracker devices, Dooley et al [16] showed that the measurement accuracies of heart rate measured under all activity states by the Apple Watch 2 and the Garmin Forerunner 225 were high, with the mean absolute percentage error (MAPE) ranging from 0.01 to 0.06, but the measurements of energy consumption were too high, with a MAPE of 0.16 to 0.84. Bai et al [17] asked 52 subjects to complete activities under four intensity levels and compared the measurement accuracies of energy consumption measured by five types of fitness tracker devices and found that the overall error rates of all of the devices ranged from 0.15 to 0.30, which can be even higher in actual use. The results of these studies on the accuracies of wearable

devices indicate that various monitoring measurements acquired by wearable devices should be treated precociously.

Given the importance of the accuracy of measurements given by fitness tracker products, the rapid development of the fitness tracker market and the rapid evolution of various brand products, it is necessary to continuously conduct verifications and evaluations of the accuracy of the latest features of the latest products. In this regard, this study has the following characteristics. First, six types of the latest and most representative fitness tracker products, including smart watches, internationally renowned smart bracelets, and smart bracelets popular in China, were included. Second, 2 smartphone apps both having over 50 million users in the Chinese market were included for the first time and compared with fitness tracker devices. Third, the accuracies of the most common and most popular major indicators, including heart rate, number of steps, distance, and energy consumption, under different activity states were simultaneously verified. Fourth, the influences of various activity states were taken into account, and the measurement accuracies of fitness tracker devices under different activity states such as walking, running, and cycling were compared. Fifth, for the first time, the Chinese population was used as the research subject to fill the gap on the Chinese population in such investigations to provide data support for the development of fitness tracker products and a theoretical basis for consumers in choosing products.

## Methods

### Research Equipment and Subject Recruitment

From three types of wearable devices—smart watch, smart bracelet, and smartphone app—8 representative products were chosen. First, when selecting smart watches based on the sales data of Taobao [18] and Jingdong [19], China's two major electronic commerce platforms, the Apple Watch 2 (Apple Inc, Cupertino, CA, United States) and the Samsung Gear S3 (Samsung Inc, Korea), two top sellers, were chosen as representatives. Second, in selecting smart bracelets, according to the market research data of Canalsys and NPD [14-16], Fitbit had the largest market share, and Jawbone had a good market performance and appeared in most of studies. Therefore, the Fitbit Surge (Fitbit Inc, San Francisco, CA, United States) and the Jawbone Up3 (Jawbone Inc, San Francisco, CA, United States) were chosen as representatives of smart bracelets of foreign brands (unfortunately Jawbone was out of business and was no longer producing smart bracelets at the end of this study). In choosing smart bracelets of Chinese brands, the sales of the Xiaomi Mi Band 2 were second only to Fitbit in the health tracking device market, whereas the Huawei Talk Band B2 showed the highest attention among bracelet series products on Zhongguancun Online [20], China's IT professional website. Therefore, the Xiaomi Mi Band 2 (Mi, China) and the Huawei Talk Band B3 (HUAWEI, China) were chosen as the representatives of smart bracelet of domestic brands. Third, when choosing smartphone apps, according to App Store rankings in the health and fitness category, 2 apps, Dongdong [21] (Dongdong, China) and Ledongli [22] (Ledongli, China) were chosen. The 6 devices and 2 apps were anonymously

labeled as FT1-6 and APP1-2 during data analysis so that investigator bias was avoided using a single-blind method.

A total of 44 healthy university students were recruited from Beijing City through open recruitment. The recruitment news was posted in university bulletin boards or forums. The inclusion criteria included 18 years of age, without major illnesses, no allergies to rubber bands, and willing to participate in this study. According to a preset procedure and the product specification, each subject was asked to wear six types of wearable devices to be tested and a standard energy metabolism analyzer to perform the five most common activities. The researchers recorded the corresponding measurements before, during, and after each of the activities. This study was granted permission from the Biomedical Ethics Committee of Peking University, and the subjects were informed on the research objectives and procedures.

### Measurement Indicators and Gold Standard

The five major health indicators—heart rate, number of steps, distance, energy consumption, and sleep duration—which are currently the most common indicators used in fitness tracker monitoring, were used to respectively measure values and gold standards in the states of resting, walking, running, cycling, and sleeping. Manual measurements of heart rate, number of steps, distance, and sleep were used as the gold standards. In measuring energy consumption, a Cosmed K4b2 cardio-pulmonary function tester was used to calculate respiratory quotient and then the energy consumption per unit time [23]. The measurement of sleep duration with the Apple Watch 2 was set as the gold standard because the device requires manual initiation and termination of the sleep mode, and this was the most commonly used method in previous literature.

### Experimental Procedure

Under the resting state, only the indicator of heart rate was measured. First, the subject's heart rate was measured manually, and then the measurement was repeated using the Apple Watch 2, the Samsung Gear S3, the Fitbit Surge, and the Xiaomi Mi Band 2.

Under the walking state, the subjects were asked to walk on a 400 m standard track for two laps, and the number of steps, distance, and energy consumption were measured. The subjects were asked to wear the Fitbit, the Xiaomi Band 2, and the Apple Watch 2 sequentially from the elbow to the hand on the left wrist and the Samsung, Huawei, and Jawbone bracelets on the right wrist from the elbow to the hand, with the smartphones in the subject's pocket, while correctly wearing a gas collection device for detecting energy consumption. A researcher followed the subject and recorded the number of steps using a video camera.

Under the state of running, the procedure was identical to that in the case of walking, except that the distance was one lap, and two indicators (distance and energy consumption) were measured.

Under the state of cycling, the subject was asked to ride three trips back and forth in a predetermined route, and the actual cycling distance was recorded with a pedometer (KINGSIR,



China) that had been mounted on the bike, while the method of wearing the wearable devices was identical to that in the case of walking. Two indicators (distance and energy consumption) were measured.

Under the state of sleep, the subject was asked to record their going-to-bed and wake-up times with the Apple Watch 2. Duration of sleep was measured.

### Data Management and Analysis

The data acquired by the wearable devices were exported to Excel (Microsoft), saved, and again verified. Heart rate and sleep duration were exported directly, whereas the number of steps, distance, and energy consumption were obtained by extracting the preactivity value from the postactivity value. Outliers derived from the subject's improper operation were discarded.

Regarding descriptive statistical analysis, the basic information of the subjects, including gender, age, height, weight, and self-stated weekly PA level, was described. MAPE was calculated to reflect the degree of error between the measured value and the true value for each indicator by first dividing the absolute value of the difference between the measured value and the true value with the true value for each sample and then multiplying by 100 and, finally, calculating the mean of all of the samples.

In terms of inferential statistical analysis, Spearman correlation coefficient was employed to evaluate the correlation between the measured value and the true value of each indicator, and the pair-wise *t* test was used to determine whether the difference between the measured value and the true value was statistically significant.

## Results

A total of 44 subjects were enrolled in this study; men and women each accounting for approximately 0.50 of the total.

**Table 1.** Basic information about the subjects.

Item	Males (n=23)		Females (n=21)	
	Mean (SD)	Range	Mean (SD)	Range
Age (years)	22.2 (2.2)	19.0-27.0	22.5 (2.1)	19.0-27.0
Height (cm)	173.4 (5.8)	162.0-188.0	161.5 (4.1)	155.0-169.0
Weight (kg)	65.7 (8.9)	51.0-85.0	55.7 (5.0)	47.5-68.0
Weekly physical activity (min)	195.5 (117.7)	60.0-600.0	110 (97.2)	0-360.0

**Table 2.** The correlation coefficients (*r*) and pair-wise *t* test between the measured and the true values of different indicators

Measures	Spearman correlation		Paired sample <i>t</i> test
	<i>r</i>	<i>P</i> value	<i>P</i> value
Heart rate	.667	<.001	.045
Step	.342	<.001	<.001
Distance	.728	<.001	<.001
Calorie	.492	<.001	.19
Sleep time	.683	<.001	.007

The subjects were aged 19 to 27 years, and the height, weight, and weekly activity levels of the men were significantly higher than those of the women. The basic information of the subjects is shown in [Table 1](#).

Upon comparing the correlation coefficients between the measured and the true values of different indicators, we found that the correlation coefficients between the indicators were statistically significant, indicating that the measured values and the real values were consistent to a certain degree. Among these values, the correlation coefficient of distance was the highest ( $r=.728$ ), whereas that of the number of steps was the lowest ( $r=.342$ ). The pair-wise *t* test result showed that except for the energy consumption measurement ( $P=.19$ ), the differences between the measured and actual values of other indicators were statistically significant ( $P<.05$ ). Details are shown in [Table 2](#).

### Overall Accuracy of the Indicators (After Summarizing the Results of Various Wearable Devices)

Regarding the measurements of heart rate, number of steps, distance, and sleep duration, the accuracies of the wearable devices were fairly high, with a MAPE of approximately 0.10, but the accuracy of the wearable devices for energy consumption (calories) was rather low, with a MAPE of up to 0.44. The differences between the MAPE and SDs of the measurements of different indicators were large, ranging from 0.10 to 0.50. Among the indicators, the measurement of heart rate performed the best, with a MAPE of 0.08 and an SD of error of 0.10, whereas that of energy consumption performed the poorest, with a MAPE of 0.44 and an SD of error of 0.50. Although the measurement accuracies of the number of steps and sleep duration were similar, the measurement of sleep duration was more stable, with an SD of error of 0.17. The MAPE of each indicator is shown in [Table 3](#).

**Table 3.** Overall accuracies of different measures

Measures	Mean (SD)	Minimum	Maximum	Number
Heart rate	0.08 (0.10)	0.00	0.73	168
Steps	0.09 (0.22)	0.00	0.98	331
Distance	0.13 (0.15)	0.00	0.98	933
Calorie	0.44 (0.50)	0.00	5.79	916
Sleep time	0.11 (0.17)	0.00	1.00	172

### Accuracy of the Same Indicators by Different Wearable Devices

The radar map of [Figure 1](#) reflects the comprehensive accuracy and stability of the measurement of each indicator by each of the wearable devices, and the results showed that the comprehensive measurement accuracies of different wearable devices differed significantly. Apple Watch 2 and Samsung Gear S3 had a large radar map area and an irregular shape, indicating that their measurement accuracies on different indicators were low and that the stabilities on different indicators were rather poor. Samsung Gear S3 and Jawbone Up3 had a moderate radar map area and a regular shape, indicating that their measurement accuracies on different indicators were appropriate and that the stabilities on different indicators were rather balanced. Fitbit Surge, Huawei Talk Band B3, Xiaomi Mi Band 2, Ledongli, and APP-2 had a small radar map area and a very irregular shape, indicating that their measurement accuracies on energy consumption were low and that their SDs were also rather high; however, their measurement accuracies on distance and the number of steps were high and stable.

Next, we will present the accuracies of each indicator by different wearable devices (see [Table 4](#)).

#### Heart Rate Accuracy for Different Devices

As shown in [Table 4](#), the subgroup analysis showed that the heart rate measurements recorded with various wearable devices were accurate and stable, whereas the Xiaomi Mi Band 2 performed relatively poorly, with a MAPE of 0.12 and an SD of error of 0.13.

#### Step Accuracy for Different Devices

As shown in [Table 4](#), the subgroup analysis showed that the accuracies and stabilities of the wearable devices on the measurement of the number of steps varied significantly, with a lowest MAPE of 0.01 (Dongdong) and a highest MAPE of 0.42 (Apple Watch 2) and with a lowest SD of error of 0.03 (Dongdong and Ledongli) and a highest SD of error of 0.37 (Apple Watch 2). Overall, in terms of the accuracy and stability of the measurement of the number of steps, the Ledongli and the Dongdong gave the best performance, followed by the Huawei Talk Band B3, whereas the Samsung Gear S3 and the Apple Watch 2 performed rather poorly.

#### Distance Accuracy for Different Devices

As shown in [Table 4](#), the subgroup analysis showed that except for the Apple Watch 2, the accuracies and stabilities of the various wearable devices on the measurement of distance were similar, with a MAPE of 0.08 to 0.15 and SDs of error of 0.08

to 0.18. The Fitbit Surge had the highest accuracy, whereas the Jawbone Up3 had the highest stability. The MAPE and SD of error of the Apple Watch 2 were 0.20 and 0.25, respectively, having the poorest accuracy and stability.

#### Calorie Accuracy for Different Devices

As shown in [Table 4](#), the subgroup analysis on the energy consumption measured by different wearable devices showed that the measurement accuracies and stabilities of all the wearable devices were poor, with a MAPE of 0.28 to 0.67 and SDs of error of 0.27 to 0.80. Of these devices, the Jawbone Up3 gave the best performance, with a MAPE of 0.28 and an SD of error of 0.27, whereas the Fitbit Surge had the worst performance, with a MAPE of 0.67 and an SD of error of 0.80. The other devices performed similarly, with an average MAPE of approximately 0.40 and an SD of approximately 0.40.

#### Sleep Time Accuracy for Different Devices

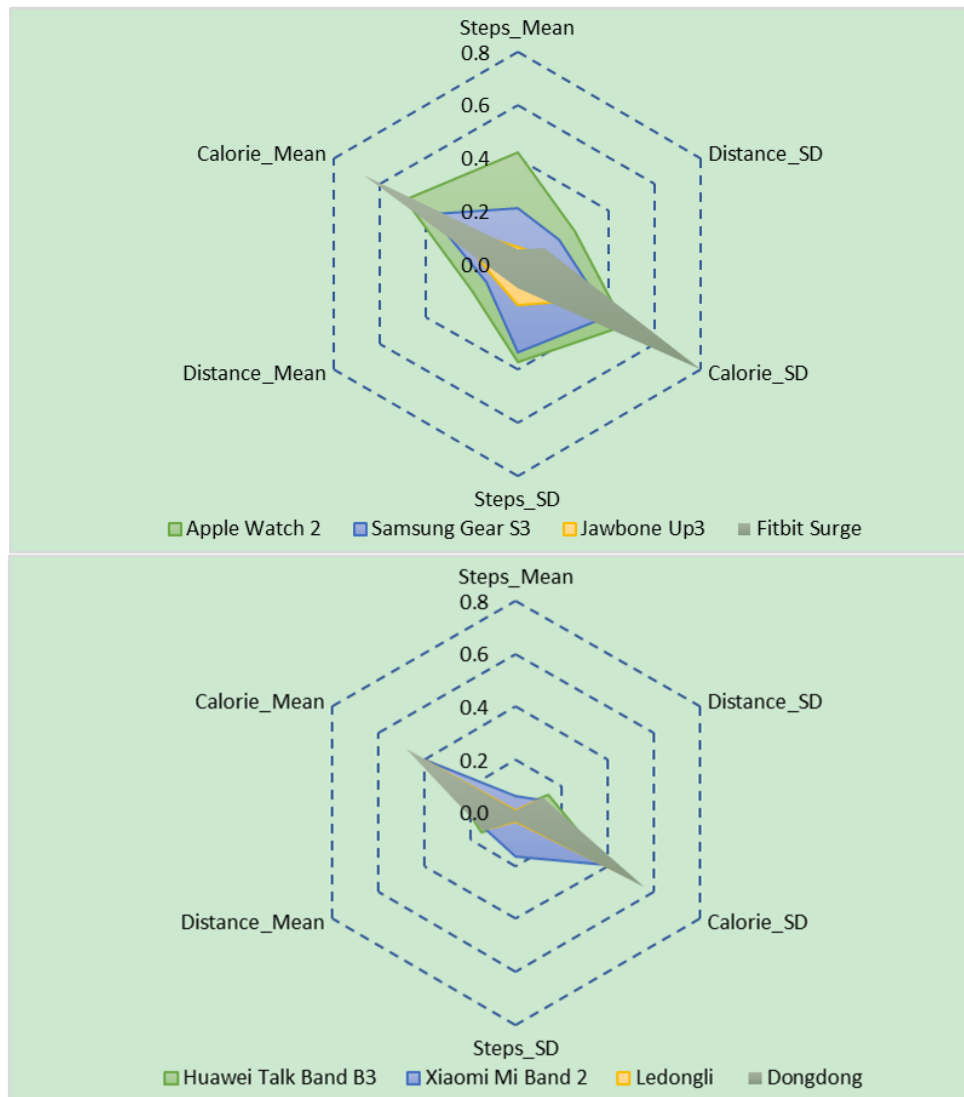
As shown in [Table 4](#), the subgroup analysis on sleep duration measured by the different wearable devices showed that the measurement accuracies and stabilities of all of the wearable devices on sleep duration were good, with a MAPE of 0.06 to 0.17 and SDs of error of 0.10 to 0.21. Of these devices, the Samsung Gear S3 performed the best, and the Huawei Talk Band B3 performed the poorest, whereas the rest performed similarly.

#### Accuracy of the Same Indicators Under Different States of Activity

As shown in [Table 5](#), the subgroup analysis on distance measured by different wearable devices under different states of activity showed that under the state of running, the measurements of the wearable devices were both most accurate and most stable, with a MAPE of 0.08 and an SD of error of 0.07. Under the states of walking and cycling, the measurement accuracies of the devices were similar, with a MAPE of 0.16 and 0.17, but the SD of error under the state of walking was far higher than that under the state of cycling, indicating that the measurement of distance in the case of walking was less stable than that in the case of cycling.

As shown in [Table 6](#), the subgroup analysis on energy consumption measured by different wearable devices under different states of activity showed that under different states of activity, the measurement accuracies of the various devices were similar, with a rather high MAPE of over 0.40, whereas the stabilities of the SEs under different states of activity were low and varied remarkably; the SD of error under the state of running was twice as high as that under the state of cycling, being as high as 0.65.

Figure 1. Comprehensive accuracies of indicators by different wearable devices. S=steps, D=distance, and C=calorie.



**Table 4.** Accuracies of all indicators by all devices.

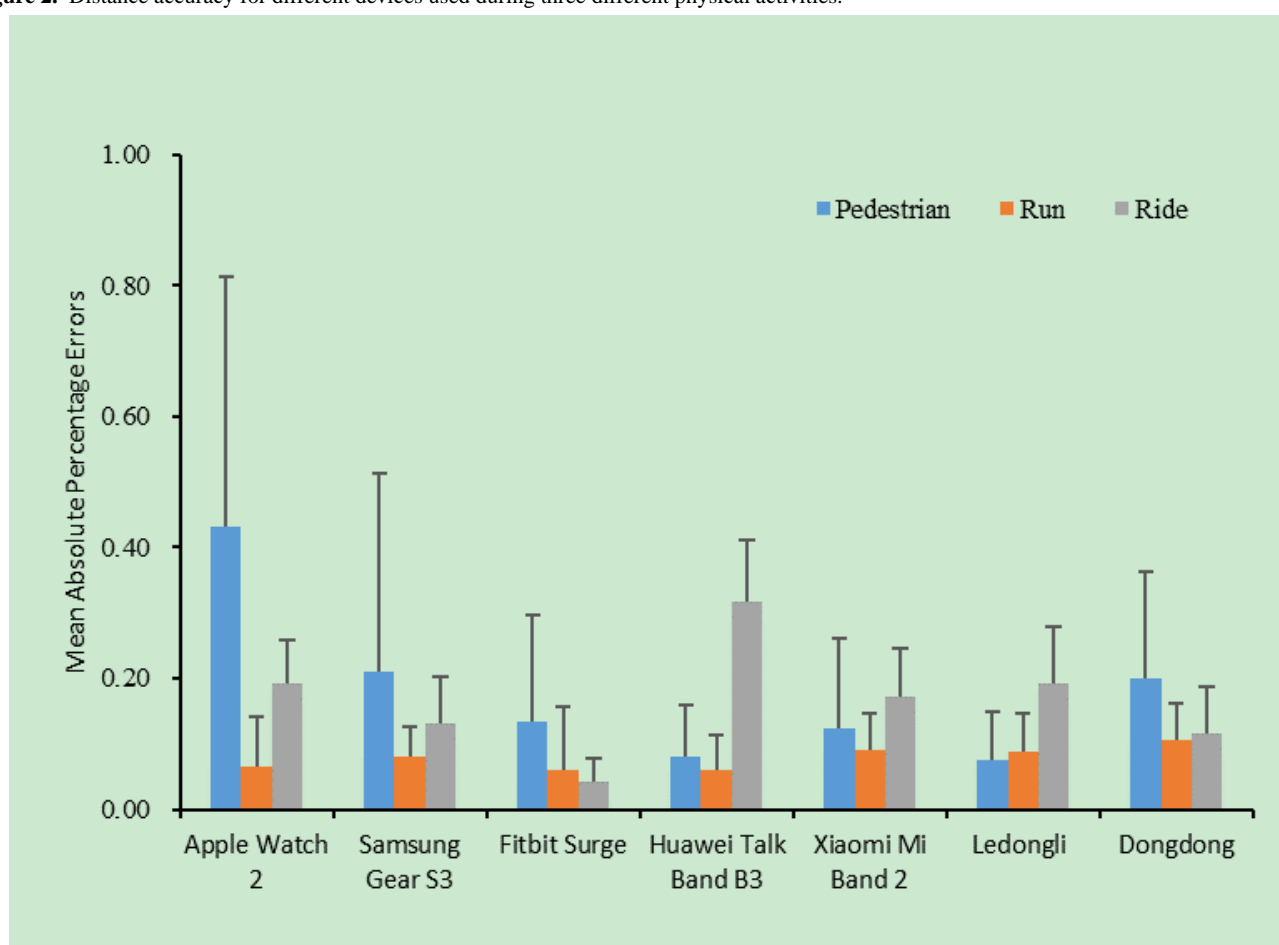
Measures/ Device	Mean (SD)	Minimum	Maximum	Number
<b>Heart rate</b>				
Samsung Gear S3	0.04 (0.03)	0.00	0.14	42
Apple Watch 2	0.07 (0.08)	0.00	0.32	42
Fitbit Surge	0.08 (0.12)	0.00	0.73	42
Xiaomi Mi Band 2	0.12 (0.13)	0.00	0.42	42
<b>Step</b>				
Dongdong	0.01 (0.03)	0.00	0.15	44
Ledongli	0.02 (0.03)	0.00	0.20	44
Huawei Talk Band B3	0.02 (0.04)	0.00	0.16	44
Fitbit Surge	0.06 (0.09)	0.00	0.45	44
Jawbone Up3	0.06 (0.16)	0.00	0.99	44
Xiaomi Mi Band 2	0.06 (0.17)	0.00	0.96	44
Samsung Gear S3	0.21 (0.33)	0.00	0.98	39
Apple Watch 2	0.42 (0.37)	0.00	0.98	29
<b>Distance</b>				
Fitbit Surge	0.08 (0.12)	0.00	0.60	130
Jawbone Up3	0.10 (0.08)	0.00	0.25	42
Ledongli	0.12 (0.09)	0.00	0.35	131
Xiaomi Mi Band 2	0.13 (0.10)	0.00	0.63	131
Dongdong	0.14 (0.11)	0.00	0.88	130
Samsung Gear S3	0.14 (0.18)	0.00	0.99	125
Huawei Talk Band B3	0.15 (0.14)	0.00	0.49	129
Apple Watch 2	0.20 (0.25)	0.00	0.98	115
<b>Calorie</b>				
Jawbone Up3	0.28 (0.27)	0.00	1.24	43
Huawei Talk Band B3	0.32 (0.39)	0.00	3.83	128
Samsung Gear S3	0.38 (0.40)	0.00	4.00	124
Ledongli	0.39 (0.43)	0.00	3.50	129
Xiaomi Mi Band 2	0.40 (0.40)	0.00	3.50	128
Dongdong	0.48 (0.56)	0.00	4.83	128
Apple Watch 2	0.49 (0.47)	0.00	3.67	125
Fitbit Surge	0.67 (0.80)	0.00	5.79	111
<b>Sleep</b>				
Samsung Gear S3	0.06 (0.10)	0.00	0.49	43
Jawbone Up3	0.09 (0.16)	0.00	0.83	43
Xiaomi Mi Band 2	0.12 (0.19)	0.00	0.87	43
Huawei Talk Band B3	0.17 (0.21)	0.00	1.00	43

**Table 5.** Distance accuracy for different statuses.

Activity	Mean (SD)	Minimum	Maximum	Number
Walking	0.16 (0.21)	0.00	0.98	323
Running	0.08 (0.07)	0.00	0.55	308
Cycling	0.17 (0.11)	0.00	0.49	302

**Table 6.** Calorie accuracy for different statuses.

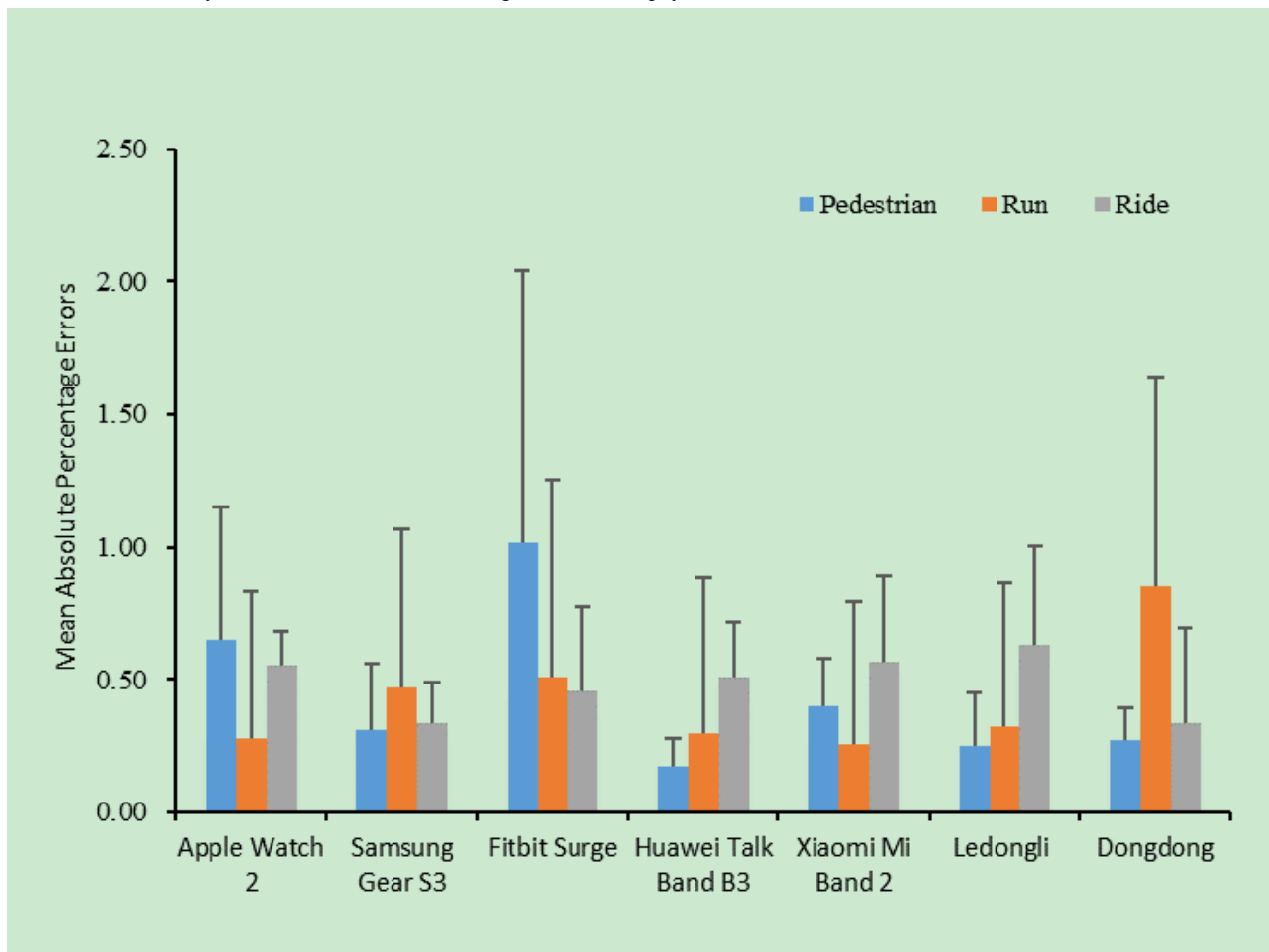
Activity	Mean (SD)	Minimum	Maximum	Number
Walking	0.41 (0.50)	0.00	5.79	335
Running	0.42 (0.65)	0.00	4.83	297
Cycling	0.48 (0.30)	0.00	2.20	284

**Figure 2.** Distance accuracy for different devices used during three different physical activities.

### Accuracy of the Same Indicator by Different Wearable Devices Under Different States of Activity

As shown in Figure 2, the subgroup analysis on distance measured by the different wearable devices under different states of activity showed that except for the Apple Watch 2 and the Huawei Talk Band B3, the measurement accuracies and stabilities of distance under different states of activity varied little. In the case of walking, the MAPE of the Apple Watch 2 was as high as 0.43, whereas in the case of running, it was as low as 0.06.

As shown in Figure 3, the subgroup analysis on distance and energy consumption measured by the different wearable devices under different states of activity showed that the measurement accuracies and stabilities of energy consumption differed significantly. The Fitbit Surge performed the poorest on the measurement of the number of steps but best when used during cycling. The Huawei Talk Band B3 and the Ledongli performed the best on the measurement of the number of steps but poorest when used during cycling. The Apple Watch 2 and the Xiaomi Mi Band 2 performed the best when used while running, whereas the Samsung Gear S3 and the Dongdong performed the poorest when used while running.

**Figure 3.** Calorie accuracy for different devices used during three different physical activities.

## Discussion

### Principal Findings

In this study, we examined the accuracy of the measurements on various data by mainstream wearable devices and mobile apps on the market under seminatural states, and the results showed that in measuring heart rate, number of steps, distance, and sleep duration, the mainstream wearable devices and mobile apps on the market all achieved a rather high accuracy, with MAPE maintained at approximately 0.10. However, in measuring energy consumption, the accuracy was not ideal, and the MAPE was as high as 0.44. In addition, the accuracy on each indicator varied among the individual subjects to varying degrees, with SDs of MAPE ranging from 0.10 to 0.50.

For the measurement of heart rate, Stahl et al [24] examined the measurement accuracies of six types of wearable devices on 50 subjects walking or running on a treadmill and showed that the wearable devices were very accurate in measuring heart rate; the TomTom Runner Cardio performed the best, with a MAPE of only 0.03, whereas the Fitbit Charge HR performed the poorest, with a MAPE of 0.06. Jo et al [25] found that the measurement accuracy of heart rate was significantly affected by activity status; under the state of high PA, the accuracy was significantly reduced. Parak et al [26] found that the accuracies of heart rates measured by different types of wearable devices varied and that the type of sensor and the position in which the

device was worn were important factors affecting the accuracy. In this study, we found that the MAPE of a wearable device in measuring heart rate under resting state was approximately 0.08; however, the accuracies of the different wearable devices varied.

For measuring the number of steps, Jones et al [27] evaluated the accuracies of the measurements by 10 types of wearable devices simultaneously worn by 35 subjects under three activity states and found that the measurements were most accurate on the treadmill, with a MAPE of 0.08, followed by that under the state of normal walking, with a MAPE of 0.09, whereas that under the natural state of life was the poorest, with a MAPE of 0.18. Nelson et al [28] found that regardless of the activity state (performing household chores or exercising), the Fitbit models One, Zip, and Flex and the Jawbone UP24 were very accurate in measuring the number of steps, with a MAPE of lower than 0.10. By examining the correlation between the numbers of steps measured by the Fitbit Zip, the ActiGraph GT3X, and the Yamax CW700 pedometers, Mark et al [29] found that the Fitbit Zip was an effective tool for measuring the number of steps taken. Takacs et al [30] examined Fitbit One measurements on 30 adult subjects running on a treadmill at five different speeds and found that the measurement accuracy was affected by the wearer's running speed. Adam Noah et al [31] showed that under the states of walking and jogging, the Fitbit and the Fitbit Ultra had the highest accuracies in measuring the number of steps. In this study, we found that the devices all had high accuracies in measuring the number of steps, with a MAPE of

approximately 0.10, but the MAPE of the Apple Watch 2 was as high as 0.42, likely because of improper operation by the subjects when collecting the data. The Apple Watch 2 requires the watch screen to be awakened so that the data can be correctly synchronized, but in the experiment, the subjects failed in operating it as required, and some of the data were not properly synchronized.

For distance measurements, Takacs et al [30] reported the accuracy of the Fitbit One in measuring distance on a treadmill and that the device had a poor accuracy in measuring distance, with a MAPE of 0.39. In this study, we found that the latest wearable devices have substantially improved the measurement of number of steps, with an average MAPE of 0.14. The subgroup analysis showed that the accuracies of different wearable devices on the measurement of distance were similar, with the best performance when used while running.

For the measurement of energy consumption, John et al [32] evaluated the accuracies of the Sense Wear Armband monitor and the BodyMedia Mini in measuring the energy consumption in the natural state of life over 14 consecutive days and showed that the accuracies of the latest devices were significantly improved compared with those of older models, with the MAPE being reduced to 0.10 and 0.11, respectively. Calabro et al [33] examined the accuracies of three types of wearable devices—the Movband, the Sqord, and the Zamzee—in measuring energy consumption and found that the accuracy was acceptable even for children. Lee et al [34] asked 60 subjects to simultaneously wear eight types of wearable devices in a natural state of life for 69 min and used the Oxycon mobile 5.0 as the gold standard of energy consumption measurement and found that, except for the Basis Band (MAPE=0.23), the majority of the devices had good accuracy, maintaining a MAPE at approximately 0.12. Bonomi et al [35] predicted total energy consumption and energy consumption during activity using the output results of wearable devices and found that the output value of the device and the energy consumption value were clearly correlated. Dannecker et al [36] found that in measuring energy consumption, the accuracy of wearable devices was affected by the activity status; the simpler the activity status, the higher the accuracy. Drenowatz et al [37] subjected 20 subjects to high-intensity PA and found that the accuracy of the Sense Wear Armband monitor in measuring energy consumption under high-intensity PA was much lower than that under low-intensity PA. The results of this study were largely different from those of previous studies, and the MAPE of the Jawbone Up3, which performed the best in measuring energy consumption, was as high as 0.28, and that of the Fitbit Surge, which performed the poorest, was 0.67, far below the acceptable standard.

For the measurement of sleep duration, Montgomery et al [38] found that neither the Fitbit nor the Actigraph was able to accurately identify whether a subject was asleep and often overestimated sleep duration and quality. Lisa et al [39] evaluated the accuracies of the Fitbit Ultra on monitoring sleep with 63 subjects under experimental conditions and showed that the measured value obtained by the Fitbit Ultra and the true value differed significantly. In this study, we found that the wearable devices' accuracies of sleep duration measurement

were rather high, with a MAPE of 0.11, exhibiting little variation among different types of devices.

### Strengths and Limitations of This Study

Compared with previous studies, this study has the following strengths. First, this study simultaneously evaluated multiple latest and most representative wearable devices and mobile phone apps on the market, including internationally renowned smart watches and smart bracelets and smart bracelets of Chinese brands, along with smartphone health apps. Specifically, Dongdong and Ledongli, as the most popular fitness smartphone apps in China, were first studied in our research. These devices are equipped with the latest indicator estimation algorithms, representing the highest level of commercially available wearable devices. Second, the accuracy of the same indicator was examined under different states of activity (resting, walking, running, cycling, and sleeping) so that the measurements were more reasonable and reliable. Third, the evaluation indicators were comprehensive, not only measuring common indicators such as heart rate, number of steps, and distance but also measuring energy consumption and sleep, which essentially cover the most common health monitoring functions of wearable devices. Fourth, this study included 44 subjects who are all college students with high education and little individual variations, had undergone rigorous instruction and training, and were therefore familiar with the operation of various types of devices, thus effectively avoiding the bias derived from improper wearing of the devices. All subjects simultaneously wore different types of fitness trackers so that the selection bias derived from the differences among the individual wearers when comparing different fitness trackers could be avoided. Fifth, the choice of gold standard was reasonable; manual measurements of heart rate, number of steps, distance, and sleep duration were used as the gold standards, which effectively avoided the system error derived from using instrument measurements as gold standards. The calculation of energy consumption through oxygen consumption is currently recognized as the most objective estimation method for energy consumption.

However, the study also has some limitations. First, the monitoring data were acquired from subjects under seminatural circumstances, so the results might not fully reflect those under natural living conditions. For example, in measuring distance while walking, the subjects were asked to walk the preset 800 m, therefore, the accuracy measured under this distance condition may not represent the accuracy under other distance conditions. However, exerting certain restrictions on the subject's activity conditions can effectively reduce the amount of random and accidental error derived from measurements taken in the natural state of life. Second, although this study included 44 subjects, each indicator under various states of activity was only performed with one cross-section measurement, whereas multiple longitudinal measurements were not conducted, resulting in the reduced size of valid samples. However, the simultaneous measurements on each indicator using a variety of wearable devices compensated for the inadequacy of the sample size to a certain extent. Finally, because of the test conditions and the limitations of the functions of the wearable devices, we did not evaluate the accuracies of

various wearable devices in measuring the indicators when the subjects were climbing stairs.

### Conclusions

At present, mainstream devices are able to reliably measure heart rate, number of steps, distance, and sleep duration, which can be used as effective health evaluation indicators, but the measurement accuracy of energy consumption is still inadequate.

Fitness trackers of different brands vary with respect to the measurement of indicators and are affected by the activity state. Compared with watch and bracelet, the performance of smartphone apps is better. Future research should further explore why differences among devices exist and how the activity states affect accuracy, thus helping fitness tracker manufacturers improve their algorithms.

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### Authors' Contributions

JL developed the conceptual framework and research protocol for the study. WD and JX conducted the recruitment, field experiments, data collection, and data analysis. WD conducted the experiments. LG, LL, and YJ interpreted the data, and JX drafted the manuscript. JL made major revisions. All authors approved the final version of the manuscript.

### Conflicts of Interest

None declared.

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## Abbreviations

- IT:** information technology
- MAPE:** mean absolute percentage error
- PA:** physical activity

**WHO:** World Health Organization

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Original Paper

# A Novel Algorithm for Determining the Contextual Characteristics of Movement Behaviors by Combining Accelerometer Features and Wireless Beacons: Development and Implementation

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## Abstract

**Background:** Unfortunately, global efforts to promote “how much” physical activity people should be undertaking have been largely unsuccessful. Given the difficulty of achieving a sustained lifestyle behavior change, many scientists are reexamining their approaches. One such approach is to focus on understanding the context of the lifestyle behavior (ie, where, when, and with whom) with a view to identifying promising intervention targets.

**Objective:** The aim of this study was to develop and implement an innovative algorithm to determine “where” physical activity occurs using proximity sensors coupled with a widely used physical activity monitor.

**Methods:** A total of 19 Bluetooth beacons were placed in fixed locations within a multilevel, mixed-use building. In addition, 4 receiver-mode sensors were fitted to the wrists of a roving technician who moved throughout the building. The experiment was divided into 4 trials with different walking speeds and dwelling times. The data were analyzed using an original and innovative algorithm based on graph generation and Bayesian filters.

**Results:** Linear regression models revealed significant correlations between beacon-derived location and ground-truth tracking time, with intraclass correlations suggesting a high goodness of fit ( $R^2=.9780$ ). The algorithm reliably predicted indoor location, and the robustness of the algorithm improved with a longer dwelling time ( $>100$  s; error  $<10\%$ ,  $R^2=.9775$ ). Increased error was observed for transitions between areas due to the device sampling rate, currently limited to 0.1 Hz by the manufacturer.

**Conclusions:** This study shows that our algorithm can accurately predict the location of an individual within an indoor environment. This novel implementation of “context sensing” will facilitate a wealth of new research questions on promoting healthy behavior change, the optimization of patient care, and efficient health care planning (eg, patient-clinician flow, patient-clinician interaction).

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**KEYWORDS**

context; indoor location; activity monitor; behavior; wearable sensor; beacons/proximity; algorithm; physical activity; sedentary behavior

## Introduction

### Background

Contextual characteristics of the physical and built environment are known to affect health, both directly and indirectly, through the influence on individual activities and health-related behaviors [1-5]. Indeed, individual choices can be determined by social and physical environmental context [6], which may also affect the intervention strategies needed to influence and change behavior. Therefore, it is crucial to measure the time (the “when”), the place (the “where”), and the potential social settings where human movement behaviors (physical activity and sedentary time) occur. Recent methodological advances have emphasized the need for more holistic approaches, which can allow for greater specificity and flexibility in exploring and understanding the relationships between behavior and place [7,8]. Tracking and determining where specific movement behaviors are performed could provide valuable information and could greatly enhance research determining the correlates of physical activity and sedentary behaviors. Most commonly, movement behaviors (the “what”) are objectively measured using wearable devices such as accelerometers, which can record motion and postural changes over time [9]. However, there are limitations to accelerometry—most notably, their inability to accurately assess lifting and carrying, cycling, and water-based activities, and the general lack of contextual information relating to activity mode and/or location and domain [10,11]. Indeed, current methods of objectively assessing behavior do not provide information on the situational context of where behavior is conducted within free-living enclosed environments. Therefore, more appropriate technologies have been sought to measure the behavioral context. Improved measures would be of use in etiological studies in tracking trends in movement behavior within populations, making objective comparisons between populations, and monitoring the effect of interventions [12].

Global positioning systems (GPS) have been used to identify activities in outdoor locations [13,14]; however, a GPS cannot receive signals in the majority of indoor environments or provide room-level location [15]. This is problematic as most people spend the majority of their time in an indoor environment. Indoor tracking systems are a potential alternative solution [8], and according to the review of Loveday et al [16], several technological tools are available which are able to measure indoor location, for instance, Bluetooth low energy (BLE) beacons, radio-frequency identification, and real-time locating systems. These technologies have primarily been used to track activities in warehousing environments [17] or identify when a patient is in or out of their hospital bed [18]. Despite this, the technologies offer a great opportunity to be applied to the measurement of movement behaviors. BLE beacon functionality has also been incorporated within physical activity monitors, which provides the opportunity to assess duration, intensity, and context of movement behaviors only using one monitor. However, beacon functionality and support are limited, and there is currently a lack of validated algorithms that are using off-the-shelf activity monitoring products to aid behavioral scientists to determine location from the data. Validated and simple-to-implement algorithms for off-the-shelf activity

monitors would increase the ability of behavioral scientists to utilize this innovative technology in their own research.

Furthermore, algorithms available in the literature use BLE and accelerometry for precise localization inside a specific room rather than multiple rooms or larger environments [14,19]. More accurate assessments of free-living behavior would help to (1) characterize the relationship between movement behaviors, (2) context and disease prevention (ie, the dose-response relationship), (3) assess the efficacy of intervention strategies, and (4) monitor the behavior and activity patterns of various populations [20].

### Objectives

The primary aim of this study was to conceive, create, and test a novel algorithm using accelerometry-based, proximity-enabled sensors to detect location for a more sensitive and accurate understanding of where specific movement behaviors are occurring in an indoor context. The secondary aim of this study was to provide a working example of how location and accelerometer data can be combined. By assessing these data together, a novel measurement and consequently a novel line of research can be created that is focused on the interactions of context and information about movement behaviors.

## Methods

### Experimental Protocol and Equipment

The algorithm was developed using data collected within a typical indoor workplace location at Loughborough University. The building comprised a multifloor, multiroom setting with a mixture of open-plan and partitioned office spaces.

As a location prediction may be influenced by individual factors such as walking speed and dwelling time in a given location, 4 trials were developed to model the potential effect upon indoor location acquisition:

- Trial 1: normal walking speed (self-paced at approximately 1.4 m/s), stopping for at least 3 min in each area (rooms and social areas) on a specified route.
- Trial 2: slow walking speed (self-paced relative to the normal speed walk at approximately 0.9 m/s or slower), stopping for at least 2 min in each selected area (rooms and social areas) on a specified route.
- Trial 3: fast walking speed (self-paced at approximately 2.0 m/s), stopping for at least 1 min in each area (rooms and social areas) on a specified route.
- Trial 4: the walking speed, dwelling time, and route were not prescribed (ie, not previously decided).

Each trial started and finished in the same location, and all trials were also video-recorded using a wearable camera (HD-1080p, 60 fps) which served as criterion validity. A second technician recorded the sequence of the areas and the total time for each trial. [Figure 1](#) represents the walking speed and dwelling time for each trial. [Multimedia Appendix 1](#) represents the speed and dwelling time of each trial, and [Multimedia Appendix 2](#) shows the path of trials 1 to 3.

ActiGraph accelerometers (GT9X Link, ActiGraph, Pensacola, United States) were used to provide time-stamped acceleration

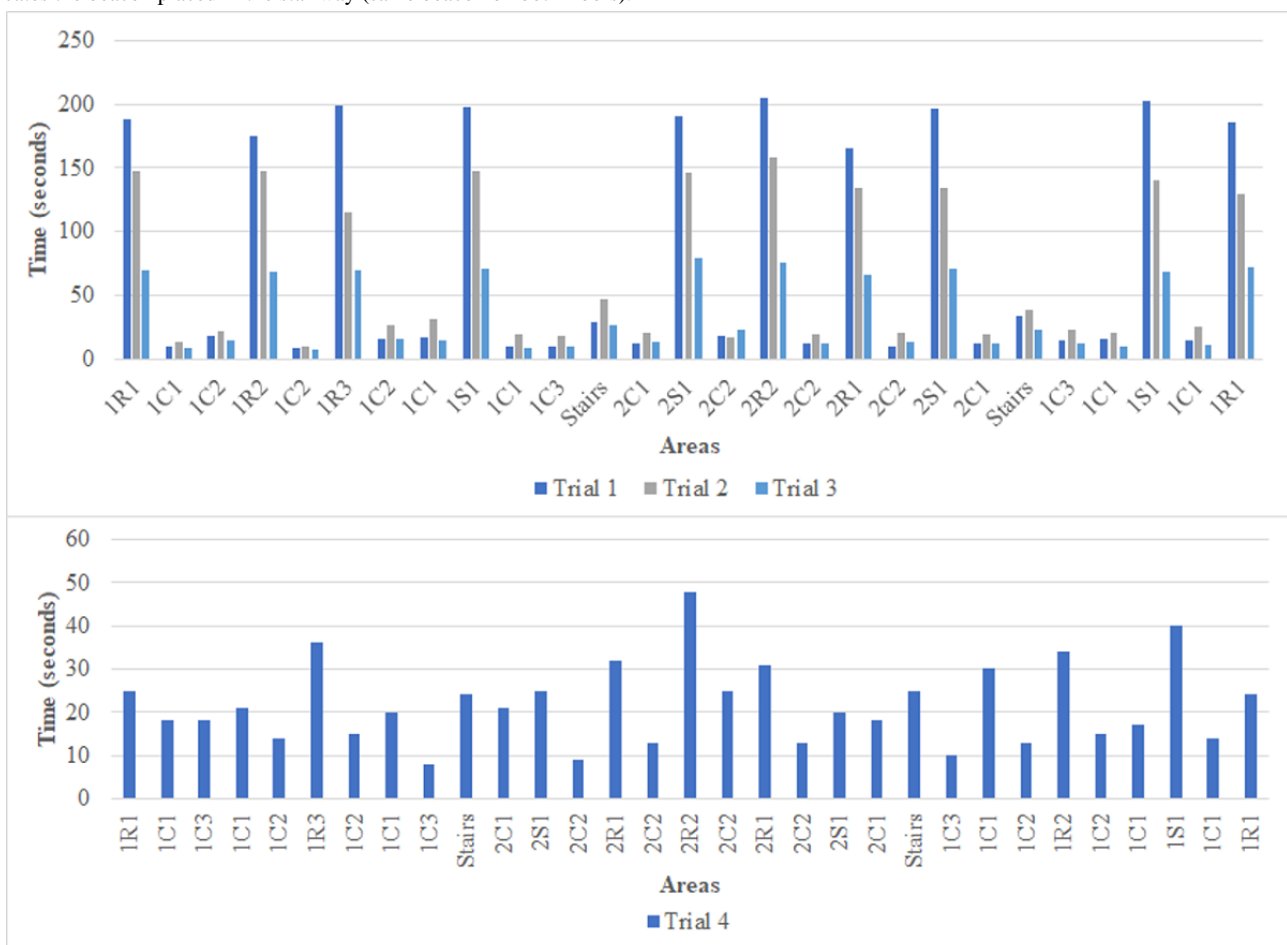
and indoor location. ActiGraph provides the most widely used accelerometers to measure physical activity and sedentary behavior. ActiGraphs are used within several national surveillance programs, including the US National Health and Nutrition Examination Survey. Researchers using ActiGraph in their own studies are therefore able to compare their own data with nationally representative samples. Equipped with BLE functionality, the devices can utilize proximity tagging, which allows for identification of other nearby devices. To enable location to be assessed, the devices are either initialized as a beacon or a receiver.

Beacons should be placed around the environment in a high and unobstructed placement, if possible. Certain rooms were relatively small; therefore, one beacon was sufficient to cover the whole room and provide a discreet room occupancy measure (in line with ActiGraph recommendations). In these areas, the beacon was placed on the wall, 20 cm above the room's door. To ensure sufficient social area coverage, more than one beacon was required. These were placed on 2 opposing walls of the area at 20 cm above the area's door. Corridor beacons were placed in such a way that one beacon was used to cover a

straight passage of a corridor (1 corridor required 2 beacons due to the length of the corridor), with a second beacon then placed when the corridor changed direction (always at 20 cm above the corridor's door). The beacons were placed in this way to ensure reproducibility of the experimental situation in different built environments. To evaluate the performance of the proposed algorithm, 17 beacons were used in total, with 4 beacons used in 2 social areas (2 beacons in each), 1 beacon each in 5 rooms, 6 in corridors, and 1 in stairway (1 beacon). For a visual representation of the beacon locations, see Figure 2.

To track location, a receiver device is worn on the wrist, which records received signal strength indication (RSSI) readings from the beacons within the environment. In total, 4 ActiGraph devices were used as receivers, and 1 individual wore all devices, with 2 devices on each wrist. Receivers were initialized to record proximity at the highest sample rate possible (10-s intervals, 0.1Hz). Accelerometers were initialized and downloaded using ActiLife Version 6.13.3 (ActiGraph, Pensacola, United States).

**Figure 1.** A visual representation, based on the areas order, of the dwelling time for each trial. Trial 1 at normal walking speed (self-paced at approximately 1.4 m/s); Trial 2 at slow walking speed (self-paced at approximately 0.9 m/s or slower); Trial 3 at fast walking speed (self-paced at approximately 2.0 m/s); Trial 4, the walking speed, dwelling time and route were not prescribed (ie, not previously decided). The locations are named as follows: First number indicates the floor: "1" indicates the first floor and "2" indicates the second floor; Uppercase letter indicates the type of room where the beacon was installed: "S" indicates a social area, "R" indicates a standard room, "C" indicates a corridor; Second number is a counter for the same type of room on the same floor; Lowercase letter is used only for long corridors or a large social area to indicate when multiple beacons were used; The label "Stairs" indicates the beacon placed in the stairway (same beacon on both floors).



**Figure 2.** Building floorplan and beacon positions: Top: First floor; Bottom: Ground floor. Each beacon is shown in red with an accompanying Bluetooth symbol showing its direction.



In this study, accelerometers were initialized to collect acceleration data at a sample rate of 100 Hz. Accelerometer data were then processed to obtain a measure of activity every 10 s [21]. The metric selected is based on jerk (derivative of the acceleration) and consists of the following steps: (1) Module of acceleration:



(2) moving SD of the module of the acceleration with window size 5 samples; and (3) average of the SD of the acceleration calculated in step 2 with nonoverlapping windows (window size 1000 samples, ie, 10 s at 100 Hz).

The first 2 steps aim to cancel the gravitational effect on the accelerometer data independently from the orientation of the sensor, while the third step defines the metric, which is proportional to the jerk level in the last 10 s. A k-mean classifier was then used to classify activity levels into low, middle, or high by using the previous metric from each test.

**Localization Algorithm**

To produce the algorithm, a 4-step process is conducted that derives indoor location from receiver RSSI data: “graph generation,” “Bayesian filtering,” a priori motion model

generation and state update, and “exception management.” This process is summarized in Figure 3.

**Graph Generation**

The position of the beacons on the floorplan is first represented as a graph, where each state represents the proximity to a specific beacon and the arrows indicate the possible paths among the beacons. Figure 4 shows the first and second floor graph used within the experiment; the first floor is connected to the second floor by the beacon “Stairs.” We grouped the beacons inside the same social area or corridor and named them excluding the lowercase letter.

The sparse transition matrix *A* represents the graph of the beacons:



This matrix contains elements  $a_{i,j}$  that will assume the value:

- 1: if the beacons *i* and *j* are connected with a walking pathway,
- 0: if the beacons *i* and *j* are not connected with a walking pathway, and

*N*: number of beacons in the map.

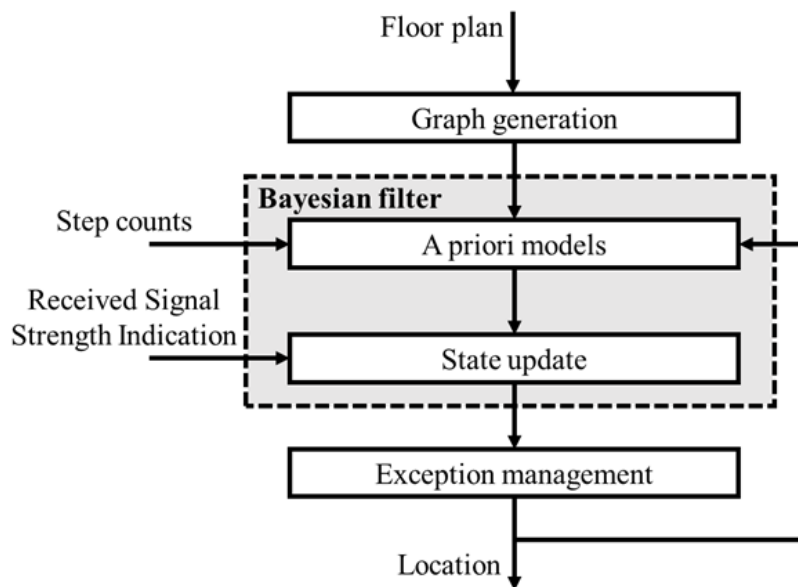
$$i, j = 1 \dots N$$

**Bayesian Filtering**

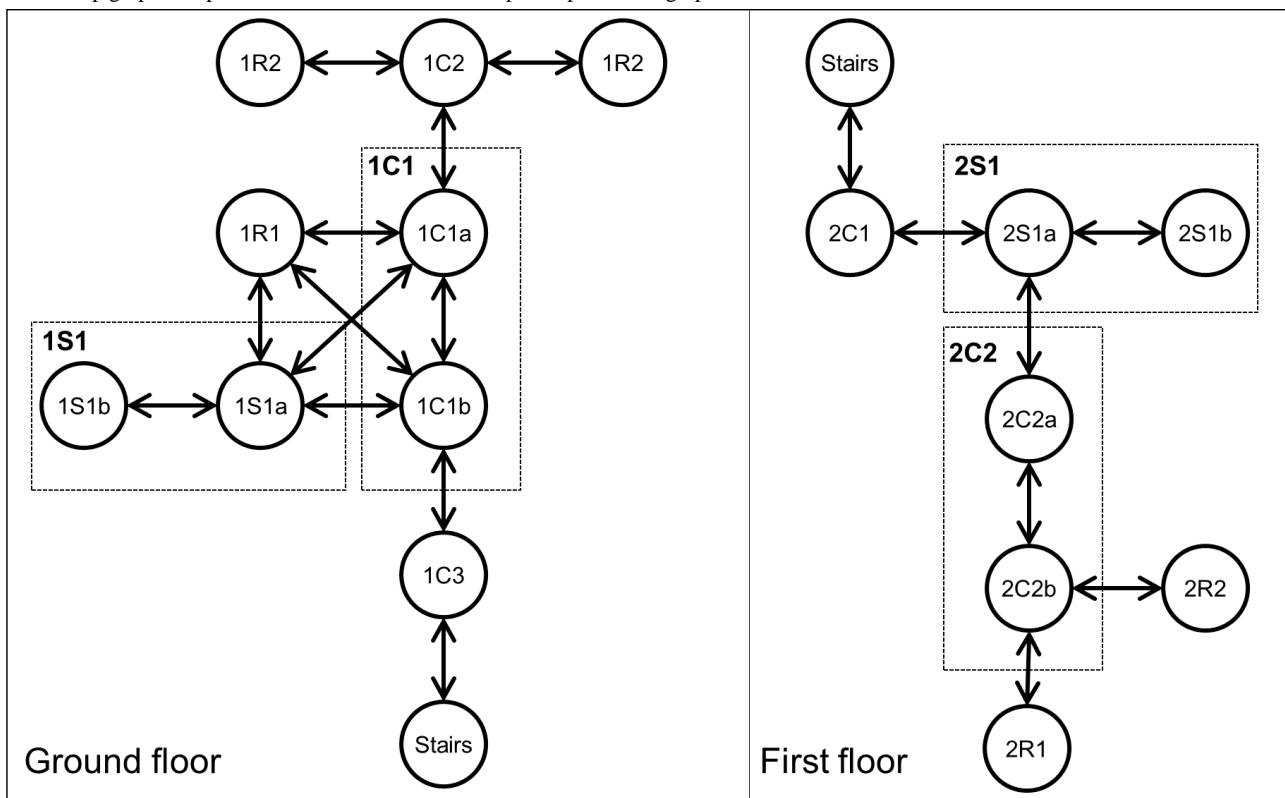
Bayesian filtering aims to apply Bayesian statistics and Bayes rule to probabilistic inference problems [22]. It describes the probability of an event, in this case, the proximity to a beacon, based on prior knowledge of conditions that might be related to the event, such as the step counts and the proximity to a beacon in the previous sample. The criterion of optimality used for Bayesian filtering is the Bayes risk of minimum mean-square

error [23]. Bayesian filtering is optimal because it searches for the posterior distribution, which integrates and uses all available information, in this case the RSSI measurement, expressed by probabilities [22]. Bayesian filtering works in 2 stages: (1) “a priori motion models” based where only the generated graph or step count measurements are used to estimate the probability of being in a specific room and (2) “state update” then corrects the estimation based on RSSI measurements.

**Figure 3.** A schematic representation of how the localization algorithm was derived.



**Figure 4.** Map graph: the position of the beacons in the map transposed as a graph.



### A Priori Motion Models

In total, 3 a priori motion models were tested based on heuristic hypothesis on the movement of the participant.

#### Model 1

The connection weight among the beacons is constant, meaning that the technician can move to another room or stay in the same one with the same probability. This model can be described using a transition matrix model  $M=A$ .

#### Model 2

The connection weight among the beacons changes accordingly to the step count measurements. We can describe this model using a transition matrix model in which the elements  $m_{i,j}$  of the transition matrix model  $M$  are built as follows:

$m_{i,j} = a_{i,j}$  if  $i \neq j$ ;

$m_{i,j} = 0.5$  if  $i = j$  and the step counts estimates more than 2 steps in the last 10 s (a higher number of steps indicates a lower probability of remaining in the same room); and

$m_{i,j} = 2.0$  if  $i = j$  and the step counts estimates 2 or less steps in the last 10 s (a lower number of steps indicates a higher probability of changing room).

#### Model 3

The connection weight among the beacons changes according to the step counts measurements but not for the corridors. This hypothesis is reasonable because the likelihood of a transition does not depend so strongly from the step counts measurements due to the length of a corridor. This model can be described using a transition matrix model in which the elements  $m_{i,j}$  of the transition matrix model  $M$  are built as follows:

$m_{i,j} = a_{i,j}$  if  $i \neq j$ ;

If  $i$  is a beacon in a standard room or social area:

$m_{i,j} = 0.5$  if  $i = j$  and the step counts estimates more than 2 steps in the last 10 s;

$m_{i,j} = 2.0$  if  $i = j$  and the step counts estimates 2 or less steps in the last 10 s;

else

$m_{i,j} = w$

The value of  $w$  was manipulated in increments of 0.25 from 0.25 to 1.25. A lower value of  $w$  would indicate a higher likelihood to move into another room while in a corridor; in contrast, a higher value of  $w$  would indicate a lower likelihood to move in another room while in a corridor. If  $w=1.0$ , then the corridor was treated neutrally with respect to other transitions.

The position of the receiver can be defined as a state vector that contains the probability to be closer to a specific beacon. The position was estimated at the time  $k$ , based on the current state vector at the time  $k$  and the probability transition matrix as:

$$X_{k+1} \sim \text{norm}(X_k M)$$

where

$X_k$   $1 \times N$  state vector of the  $N$  probabilities (1 for each beacon) at the sample  $k$ ;

$X_{k+1}$   $1 \times N$  estimation of the  $N$  probabilities (1 for each beacon) at the sample  $k+1$ ; and

the state vector  $X_0$  is initialized with equal probability for all the beacons.

### State Update

The probability of being in proximity to a beacon  $i$  at the sample time was heuristically estimated  $k$ , indicated as  $y_i(k)$ , based on the Bluetooth RSSI strength  $RSSI_i$ :



The rationale for these selections was:

1. The distance is inversely proportional to the RSSI in case of free air, although there are limitations on the estimation of distance indoor because of reflection and scattering [24].
2. The value of the RSSI does not exceed  $-45\text{dB}$  when the receiver is less than 1 m away from the beacon.
3. The communication is interrupted when the RSSI is less than  $-90\text{dB}$ .

The measurement vector was normalized at each sample time  $Y_k$  with respect to the sum of the probabilities of all the beacons:



It is possible to measure the posterior probability  $X_{k+1}$  based on  $Y_{k+1}$  measurements and the estimation from the a priori model using the Bayes equation:

$$X_{k+1} = \text{norm}(X_{k+1} Y_{k+1})$$

where  $X_{k+1}$  is the state vector of the  $N$  probabilities (one for each beacon) at the sample  $k+1$  and  $\cdot$  indicates a point-wise vector multiplication.

The most probable position is the beacon  $i$ :



### Exception Management

A block for exception management was implemented to make the algorithm more robust with respect to the following 3 failures:

1. This exception manages cases in which the estimated position based on the model is not in accordance with the RSSI measurements. Indeed, the measurement could not fit the estimated probability when there is at least one RSSI measurement ( $c \neq 0$ ) but the previous estimation is not fitting the a priori motion model ( $X_{k+1} = 0$  for all the beacons). This exception was managed by imposing a uniform probability for all the areas (resampling) and setting the updated state as the previous one because the RSSI measurement might have been corrupted by a glitch due to reflection or scattering.
2. There are no RSSI measurements ( $c=0$ ), and therefore no update was performed in that step.



- Due to reflection and scattering, the RSSI measurement could create hopping effects between 2 contiguous rooms. To improve the characteristic of stability in these cases, it was imposed that hopping from a room A to a room B and then back to the room A can happen only if the transition is stable for at least 2 samples (20 s). In this case, the updated probability of the room was left unchanged, and the most probable room before the hopping event was selected.

**Statistical Analysis**

For the analyses, each transition period was defined as when the receiver moved from one room to the next. The total transition period for the trial *l* was indicated as  $T_{t,l}$ . The total nontransition period for the trial *l* was defined as the remaining period and was indicated as  $T_{nt,l}$

The total time of the trial  $T_l$  was:

$$T_l = T_{t,l} + T_{nt,l}$$

We considered the errors on the transitions ( $\hat{e}_{t,l}$ ) and the errors on the nontransition ( $\hat{e}_{nt,l}$ ) for trial *l*, and we calculated the relative transition errors for trial *l*:

$$e_{t,l} = 100 \times \hat{e}_{t,l} / T_{t,l}$$

The relative nontransition errors for trial *l* was:

$$e_{nt,l} = 100 \times \hat{e}_{nt,l} / T_{nt,l}$$

The error caused by tracking problems on the transitions for trial *l* was:

$$\bar{e}_{nt,l} = 100 \times \hat{e}_{nt,l} / T_l$$

The relative error in trial *l* was:



The average error on transitions was:



The average error on nontransitions was:



The average error caused by tracking problems on the transitions was:



The average error was:



Furthermore, the total dwelling time within each room was evaluated for each trial to quantify the consistency of the location and videotaped tracking time. A two-way mixed intraclass correlation coefficients with absolute agreement was performed. Differences between estimates are reported as mean differences (95% CI). The regression model between the location tracking time and the videotaped tracking time was analyzed. The goodness of fit between the measured values and the expected value (videotaped tracking time) was tested by the following: sum of squares due to error (SSE), which is a measure of the discrepancy between the data and the model estimated  $R^2$ , between 0 and 1, with a value closer to 1 indicating that a higher proportion of variance is accounted for by the model; adjusted  $R^2$ , (ie,  $R^2$  adjusted for the residual degrees of freedom); and finally, root mean square error (RMSE, ie, the sample SD between predicted and observed values).

Accelerometry step counts were synchronized with the criterion video using timestamps from an exported .csv file, and the error was evaluated by measuring the time for which the estimated room position and the criterion were different. The validity of the algorithm was determined using the absolute percentage error scores calculated for each trial.

**Results**

**Algorithm Performance**

In general, all algorithm models calculated an average percentage error ranging from 14% to 17%. The two main sources of error within these models were (1) transition state, that is, moving from a room to a corridor or vice versa in the transition period and (2) nontransition state, defined as the dwelling time longer than 20 s (equal to two recorded samples of RSSI). Transition estimates improved when the algorithm used model 3 and the corridor was treated neutrally with respect to other transitions, where the connection weight among the beacons changed according to the step count measurements but not for the corridors (in which the weight was constant). The results for each model and trial are outlined in [Table 1](#).

All algorithm models calculated low average error in the nontransition state with a decrease in error from 3% in the model 1 to between 0.31% and 0.47% in model 3 variations. In the transition state, an average error of between 31% and 34% was exhibited across all algorithm models. Generally, the relative error is affected more by transition errors if there is a higher transition rate.

The tracking quality is represented by [Figure 5](#) for all trials. The red line represents the criterion location obtained from the video, and the blue line represents the locations obtained from the 4 receivers. From these graphs, it is evident that the quality of tracking is better for trials with lower transition rates.

**Table 1.** Percentage error of transition and nontransition states for each trial and algorithm model. Italics is used to reflect the model that showed the best results. The letter *w* is the weight.

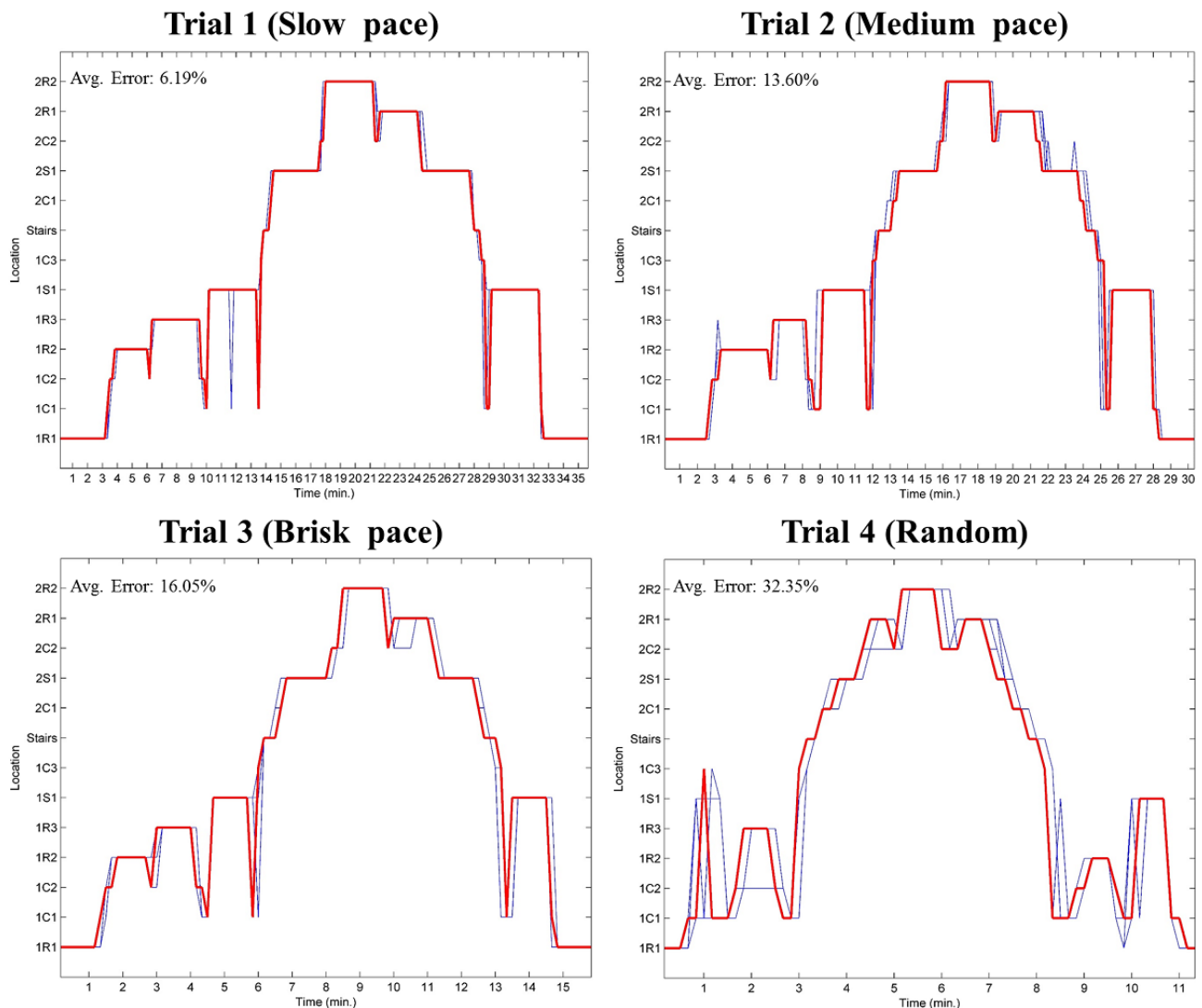
Algorithm model	Trial 1 (slow pace)	Trial 2 (medium pace)	Trial 3 (brisk pace)	Trial 4 (random)	Average error
<b>Model 1<sup>a</sup>, %</b>					
Error on nontransitions $e_{nt,l}$	3	8	6	8	6
Error on transitions $e_{t,l}$	27	40	25	3	32
Error caused by tracking problems on the transitions $\bar{e}_{nt,l}$	7	14	14	34	4
Error $e_1$	9	20	16	35	17
<b>Model 2<sup>b</sup>, %</b>					
Error on nontransitions $e_{nt,l}$	3	7		8	5
Error on transitions $e_{t,l}$	25	3	29	38	31
Error caused by tracking problems on the transitions $\bar{e}_{nt,l}$	6	13	16	35	14
Error $e_1$	8	17	17	35	16
<b>Model 3<sup>c</sup> (<math>w=1.25</math>), %</b>					
Error on nontransitions $e_{nt,l}$	0.31	4	2	8	3
Error on transitions $e_{t,l}$	23	39	31	38	31
Error caused by tracking problems on the transitions $\bar{e}_{nt,l}$	6	14	17	35	14
Error $e_1$	6	16	18	35	15
<b>Model 3 (<math>w=1.00</math>), %</b>					
Error on nontransitions $e_{nt,l}$	<i>0.31</i>	<i>1</i>	<i>2</i>	<i>4</i>	<i>1</i>
Error on transitions $e_{t,l}$	25	39	30	35	31
Error caused by tracking problems on the transitions $\bar{e}_{nt,l}$	6	14	16	32	13
Error $e_1$	6	15	17	33	14
<b>Model 3 (<math>w=0.75</math>), %</b>					
Error on nontransitions $e_{nt,l}$	0.31	1	2	4	1
Error on transitions $e_{t,l}$	25	39	31	34	32
Error caused by tracking problems on the transitions $\bar{e}_{nt,l}$	6	14	17	31	13
Error $e_1$	7	15	17	32	14
<b>Model 3 (<math>w=0.50</math>), %</b>					
Error on nontransitions $e_{nt,l}$	0.47	1	0	4	1
Error on transitions $e_{t,l}$	26	39	31	35	30
Error caused by tracking problems on the transitions $\bar{e}_{nt,l}$	7	14	17	32	14
Error $e_1$	7	15	17	32	14
<b>Model 3 (<math>w=0.25</math>), %</b>					
Error on nontransitions $e_{nt,l}$	0.31	1	0	4	1
Error on transitions $e_{t,l}$	27	41	34	36	34
Error caused by tracking problems on the transitions $\bar{e}_{nt,l}$	7	14	18	33	14
Error $e_1$	7	15	18	33	15

<sup>a</sup>Model 1: The connection weight among the beacons is constant.

<sup>b</sup>Model 2: The connection weight among the beacons changes according to the step count measurements.

Model 3: The connection weight among the beacons changes according to the step counts measurements but not for the corridors.

**Figure 5.** Tracking quality graphs for trials 1-4 (model 3;  $w=1.0$ ). The red line represents location derived from the criterion measurement (camera), and the blue lines represent the locations obtained from the algorithm.



Linear regression models  $y = p_1x + p_2$  showed coefficients with 95% CI of  $p_1=1.069$  (1.046-1.061) and  $p_2=-7.098$  (-10.27 to -3.925) between algorithm and criterion time in seconds (Figure 6). Moreover, the intraclass correlation highlighted a very high goodness of fit of the model  $R^2=.9780$  (Table 2).

Greater location prediction robustness was obtained when the receivers spent over 100 s within a specific area, which is equivalent to more than 10 samples (quantization error less than 10%), for which we obtained an  $R^2=.9775$  (Table 2). Conversely, the algorithm poorly estimates dwelling time ( $R^2=.4719$ ) when the time spent in an area is under 100 s (Table 2).

RMSE is between 15.28 s and 15.62 s (see Table 2) independent from the time spent in a specific area. For this reason, the main source of error can be attributed to the transitioning of the receiver from one area to another because:

1. the highest amount of error is observed during transitions (3%-34%; Table 1); and

2. the sampling rate of the sensor is 10 s. The sampling effect is evident in the gaps between the estimations in Figure 5.

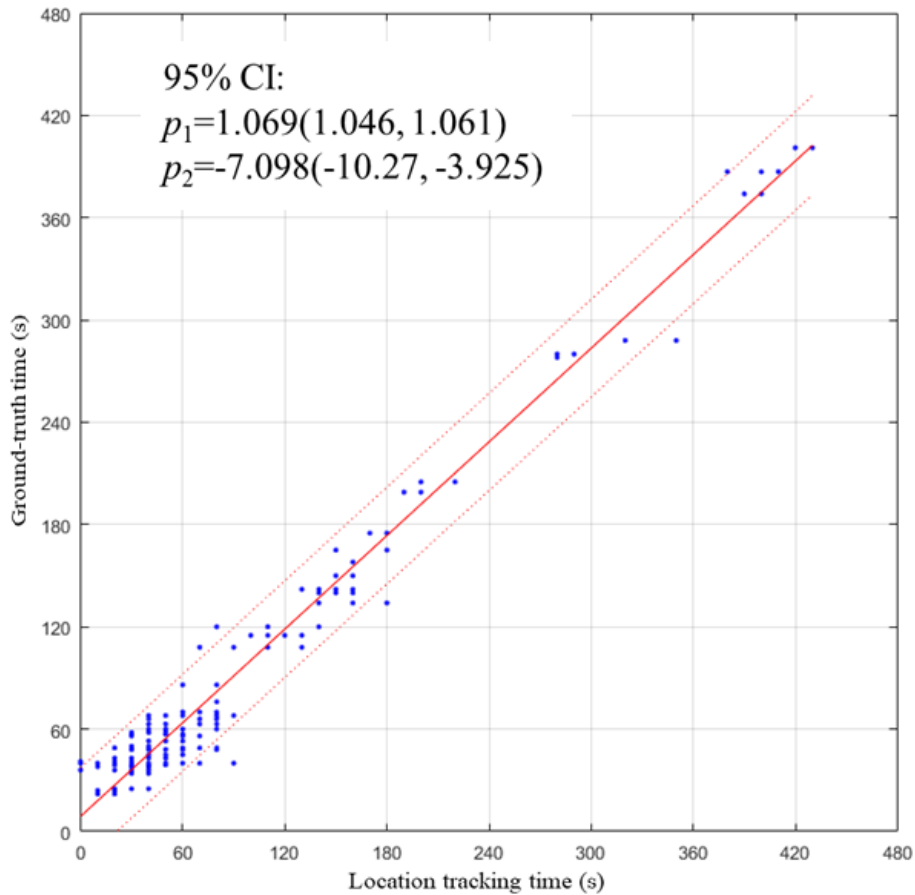
Column A of Figure 7 displays the confusion matrices of model 3 ( $w=1.0$ ) for all trials. A darker diagonal line represents a better prediction from the algorithm. From the graphs, it is evident that errors often occur between adjacent beacons. For trial 1 (column A), the algorithm confused 1C1 with 1S1 because beacon 1C1b is close to 1S1a. Likewise, for trial 3 (column A), the algorithm confused 1C1 with 1C3 because beacon 1C1b is close to 1C3. The close proximity of certain beacons increases the possibility that refraction effects lead to a misclassification of the room that the receiver is located within. However, this effect is only evident in the case of transitions, and it never happens for beacons placed on different floors even though the distance between the beacons is relatively small, such as in the case of the beacons 2C1 and 1C3.

Column B displays the confusion matrices of model 3 ( $w=1.0$ ) for all trials but only in nontransition states. Location prediction was high (values higher than 0.99) within nontransition states

such as the standard rooms (R), the social areas (S), and the stairs. However, within trial 2, the algorithm confused the standard room 1R3 and the corridor 1C2 in 10% of the cases

because of the proximity between the beacons. Therefore, precautions must be taken in the placement of the sensors to avoid such ambiguities.

**Figure 6.** Linear regression model between accelerometry and criterion measure (video) tracking time in seconds.



**Table 2.** The goodness of fit between the measured and the expected values of model 3 ( $w=1.0$ ). SSE: sum of squares due to error, which is a measure of the discrepancy between the data and the model estimated; RMSE: root mean square error that is the standard error of a measurement, the standard error of the regression.

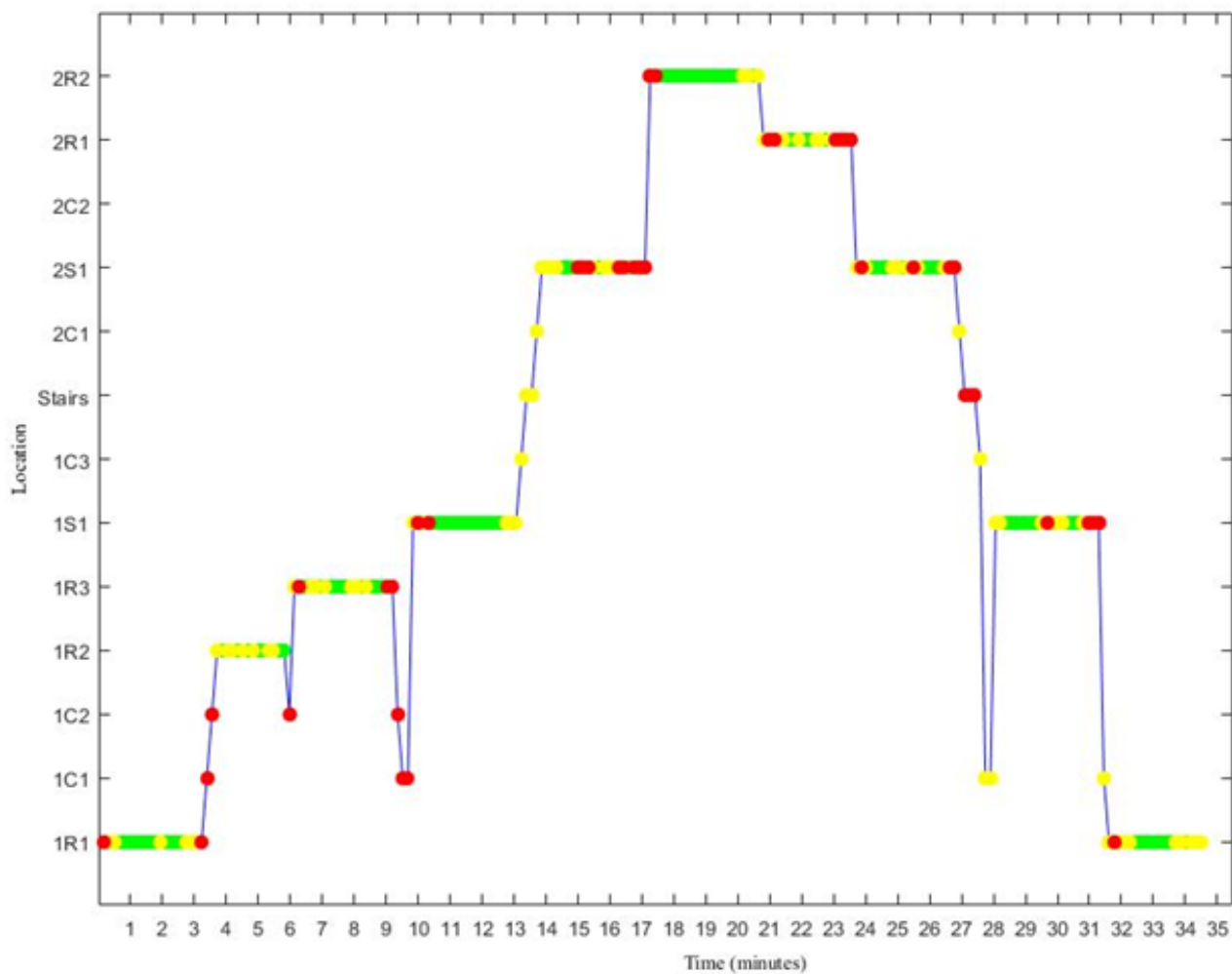
Measurements	SSE (s <sup>2</sup> )	R-squared <sup>a</sup>	Adjusted R-squared <sup>b</sup>	RMSE (s)
Measurements under 100 s (130 points)	31,700	.4759	.4719	15.62
Measurements over 100 s (73 points)	17,290	.9775	.9772	15.28
All measurements (203 points)	49,543	.9780	.9779	15.51

<sup>a</sup> $R^2$ , between 0 and 1, with a value closer to 1 indicating that a higher proportion of variance is accounted for by the model.

<sup>b</sup>Adjusted  $R^2$  that adjusts  $R^2$  for the residual degrees of freedom.

**Figure 7.** Confusion matrices of model 3 ( $w=1.0$ ) for trials 1-4. Column A represents all the transition and nontransition states, and B only nontransition states.

**Figure 8.** The combination of localization tracking and activity data of trial 1. The green, yellow, and red color indicate low, middle, and high level of activity, respectively.



### Behavioral Analysis

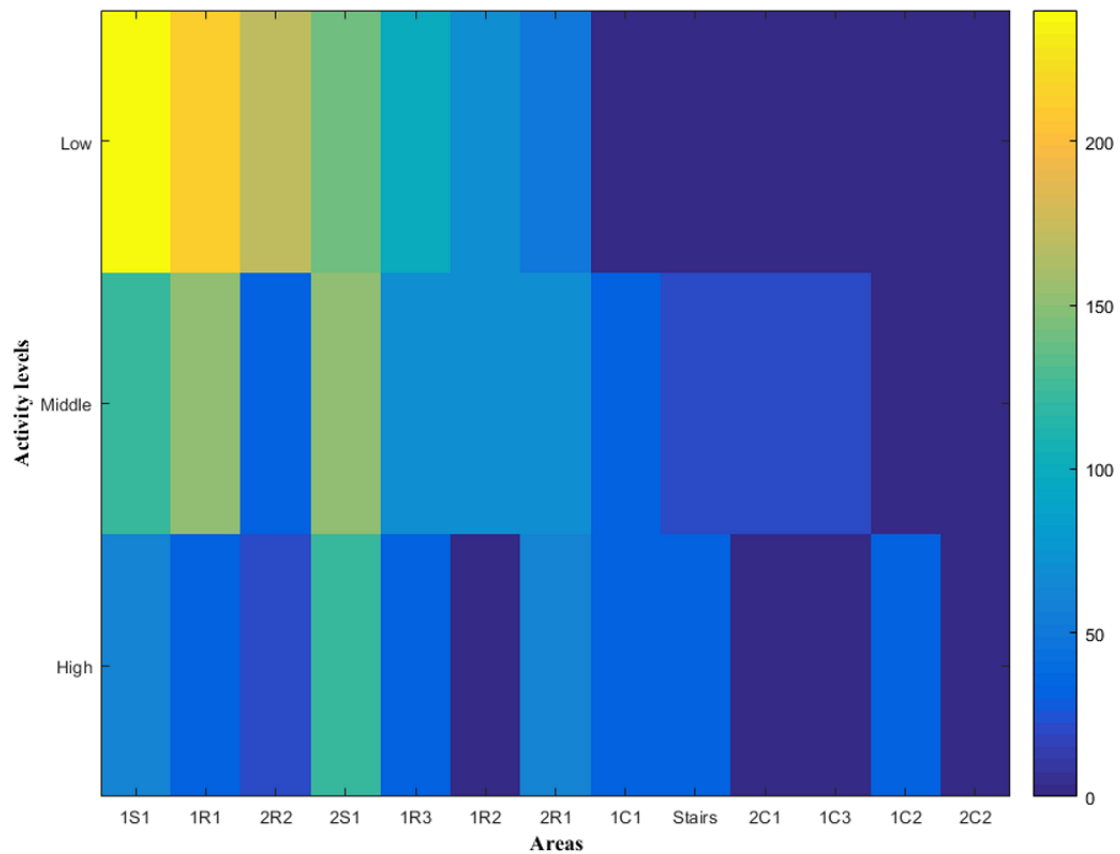
Given that the proposed algorithm is able to accurately determine indoor location, it is worth considering the utility this offers researchers in assessing where behavior occurs indoors. Figure 8 shows the combination of localization tracking and activity data in the case of trial 1. It is evident that the highest levels of activities are conducted between rooms, in corridors and stairs, just before and after transition. Conversely, activities of a low or moderate nature were most commonly conducted within rooms.

The combination of localization tracking and activity levels can be used to create a Lasagna plot. The absolute time associated to each room and activity level is represented by a color gradient from blue (time equal to 0) to yellow (time equal to 230 s). The graphs were initially produced without sorting the data by absolute time, and this made it difficult to extract useful information. Therefore, for Figure 9 (trial 1), locations were

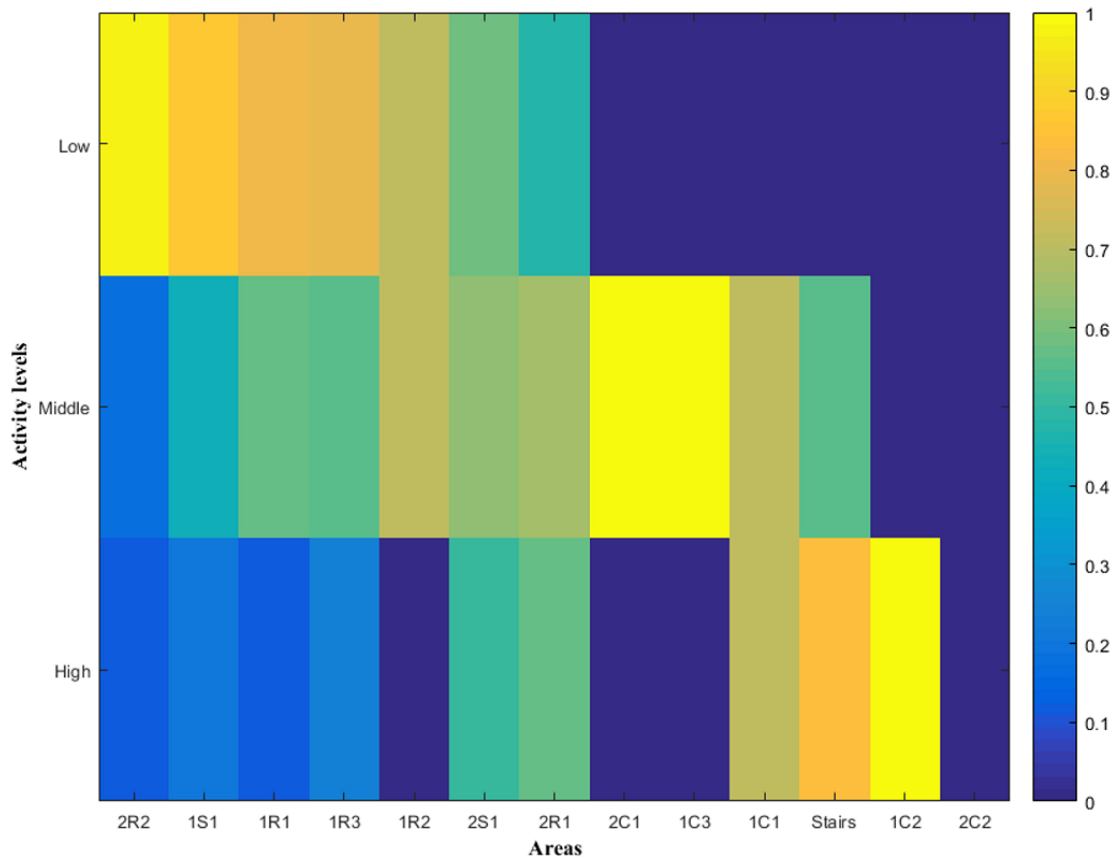
sorted in descending order based upon absolute time. It is clear that there are areas where the receiver spent longer periods of time such as within rooms and social areas and areas where the time spent was minimal such as within corridors and stairs. Multimedia Appendix 3 represents the combination of localization tracking and activity levels with the area sorted based on the route of trial 1.

We also considered the relative time to compare the activity levels in each room regardless of the time the participant stays in a specific area. Figure 10 represents sorted location data based upon the relative time at low-level activity. The rooms and social areas are mainly represented on the left side of the plot (indicating predominantly low activity in these areas), while the corridors and stairs on the right-hand side (indicating predominantly high activity in these areas). Multimedia Appendix 4 represents the combination of localization tracking and activity levels with the area sorted based on the route of trial 1.

**Figure 9.** Lasagna plots representing the combination of localization tracking and activity levels. Areas are sorted in descending order depending on the absolute time. The color between blue (time equal to zero) and yellow (time equal to 230 s) represents the activity level spent-time.



**Figure 10.** Lasagna plots representing the combination of localization tracking and activity levels. Areas are sorted in descending order depending on the relative time. The color between blue (time equal to zero) and yellow (time equal to 230 s) represents the activity level spent-time.



## Discussion

Understanding the contribution of context to the health-behavior relationship first requires the accurate measurement of location, which is often overlooked when quantifying movement behaviors. In this study, an algorithm was presented that integrated indoor location and accelerometer measured step counts to create a better representation of the human-environment interactions. This approach to indoor location facilitates the assessment of 3 main elements: (1) time, (2) location, and (3) activity level. This is advantageous over deriving time and activity levels alone, as discerning the contribution of context to movement behaviors will allow researchers to create location-specific interventions that may act as more potent “levers” for sustained lifestyle behavior change.

### Algorithm Performance

Generally, the algorithm models calculated lower error during nontransition states, which could be explained by the fact that the time of each transition was always faster than the sampling rate of the sensors (see [Table 2](#)). Consequently, the transition state error is always higher, where the location time was shorter. This is not related to the time per se but the RSSI recording as the signal may be collected in the previous or next location during the sample interval of 10 s. Transitional error is high probably using the current methodology and contributes approximately 30% of error within the models. Sampling rate is currently manufacturer limited; however, an investigation into higher sampling rates should be explored to ascertain if error associated with transitional states can be reduced, or if specific guidance can be provided to account for the RSSI transition. Moreover, a potential way to improve the performance of the algorithm could be by modeling the RSSI distribution [14,19], but this kind of static model is not practically applicable in realistic environments due to dynamic changes in RSSI brought about by refraction and scattering. In this study, we endeavored to test the algorithm in a realistic environment, where it is more likely there will be a nontransitional situation (ie, dwelling in 1 location) than transitional (ie, not making frequent transitions between areas).

### Context and Activity

Considering the combination of accelerometric and location data within specific built environments makes it possible to objectively assess the contribution of different environments to overall levels of behavior [7]. This type of data can answer questions about environmental exposure and behaviors that are specific in particular locations or at certain times of day. Typically, accelerometers provide objective information on physical activity intensity and duration. While the intensity of the activity may be an important concept for health, it lacks specificity to recognize specific activities [10]. The addition of context to accelerometer data provides an opportunity to develop a novel line of research focused on the interactions of environment and movement behaviors in a temporal, spatial, and behavioral way [7]. Moreover, intervention studies that measure changes in locations and behavior will provide more

robust evidence of the effects of the interventions and their causality [25].

Typically, to record and analyze location and accelerometer data, different devices are used, which requires the synchronization of multiple data sources. This can be challenging; in fact, poor synchronization could directly impact the proper processing and interpretation of the data. In this study, only one sensor was used to record both measures. This is an important and, to our knowledge, novel step in indoor location research. The timestamped data from the ActiGraph receivers can give a rich and detailed sequence of the types of activities people are engaging in (intensity, duration, etc), what spaces are used, and at what time in the day. In fact, as time-based analysis is further integrated into behavioral studies, more complex space-time modeling analysis and strategies can be applied to model the possible range of activities that an individual can engage in, and to determine if events and exposures during one day could influence activities during the next day [7]. A prerequisite for this level of space-time modeling is an accurate measure of time spent in a given location. Additionally, location data could help researchers better understand if spending more time in one environment influences certain behaviors, if there is a specific number of times a person must be in an environment to exhibit certain behaviors, or if there are specific times of the day to observe certain behaviors. Subsequently, the introduction of the additional time and behavioral variables could offer a novel insight into locations that are promoting or inhibiting of a behavior.

The combination of location data with behavior is a starting point for researchers to understand the determinants of different behaviors in indoor environments. For example, the illustrative combination of accelerometer and location data from this study showed that more activity was performed during the transitions from one area to another than within certain rooms or social areas. Furthermore, it was possible to identify a third cluster of areas (2S1-IC3) in which the participant performs mostly middle-level activities. From this, behavior could be classified as mainly low, middle, or high, potentially giving insight on where the participant mainly performs their daily activities.

To the best of the authors' knowledge, the approach implemented herein is novel. In particular, being able to provide objectively measured data regarding changes in location and activities, rather than self-reported information, may provide greater utility and relevance to researchers and stakeholders. Simple epidemiological measures of behavior and activity, such as questionnaires, have performed adequately to demonstrate associations with a number of chronic disease outcomes; however, they rarely separate activity into its different dimensions, nor have they facilitated an estimation of dose-response effects [12]. Therefore, improved measurement methods, such as indoor location tracking, would be of use in epidemiological studies to record trends in behavior and activity within populations, making objective comparisons between populations, and in monitoring the effect of interventions and programs [12]. Nevertheless, due to the lack of research within the contextual domain, it is still unclear what additional benefit will be added to our current understanding. It is therefore essential that algorithms such as the one presented within this



paper be refined and used in practice before the quantification of context is advocated as a necessary measurement within behavioral research.

### Limitations

Some technical and practical difficulties associated with the approach reported within this paper must be highlighted. First, one issue relates to difficulties in establishing a valid protocol that can ensure consistent performance in different environments, without the need for ad hoc testing and calibration. In fact, some aspects are likely to deviate to some degree, such as the possible variation in performance coming from differences in building materials and morphology.

Quantifying contextual movement behaviors using the presented technologies could be considered costly due to the number of devices required to accurately capture location over multiple domains. These limitations equally apply to existing measurement practices such as the combination of accelerometry and GPS [7]; however, these practices do not appear to have been decisively held back by these limitations. This is, presumably, due to the idea that the value added by the combination of activity data and GPS outweighs these limitations [7]. Future iterations of contextual technologies will hopefully alleviate these concerns.

A final limitation is related to the contextual tracking system that was used. The ActiGraph model does not allow the user to adjust the strength of the BLE signal or the sampling rate for data collection. In our opinion, the possibility to adapt the signal of the beacons to the size of the different areas could improve the performance of the tracking location algorithm. Indeed, this could avoid situations where signals from beacons in multiple rooms are recorded simultaneously. Additionally, the maximum sampling rate for the BLE signal is 10 s. There are situations where transitioning between 2 or more adjacent areas could take place between samples and consequently, the algorithm would not be able to accurately track location. A higher sample rate of the BLE signal, for example, 5 s or even every second, would make it possible to have a more precise indoor tracking output.

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### Authors' Contributions

DM, SS, AS, MZ and DEW conceived and designed the experiments. DM and AL performed the experiments. DM and SS analyzed the data. MZ and DEW contributed reagents/materials/analysis tools. MZ and DEW supervised the experiments and the analysis. DM, SS, and APK wrote the paper. DM, SS, APK, AL, AS, MZ, and DEW reviewed and edited the paper.

### Conflicts of Interest

None declared.

### Conclusions

The aim of this study was to create and test a novel algorithm, using accelerometry-based proximity-enabled sensors, to combine the “where,” the “when,” and the “what” of movement behaviors by the novel exploitation of existing technologies (conventionally used only to understand the “what”). Compared with a criterion measure, it has been demonstrated that the new approach can reliably predict location within rooms and social areas; however, there is increased error for transition between areas. This combination allows us to objectively and reliably determine the individual characteristics of contextual behavior. This new information can be used to better inform evidence-based practice and research interventions. The results have shown that it is possible to capture location information in indoor environments and that this can be combined with activity monitoring data to create variables previously unavailable for research.

It is clear that many behaviors and health issues are directly related to the context; thus, this novel approach is a powerful tool for researchers to monitor the “where,” “when,” and “what” of daily activities. As a first step into utilizing both context and behavior from one device, there is a need to conduct more research to refine the algorithm and bring about more technological advancement to reduce the current limitations, before indoor location can be utilized within intervention and epidemiological research.

Our study shows that a novel implementation of “context sensing” will facilitate a wealth of new research questions on promoting healthy behavior change, the optimization of patient care, and efficient health care planning (eg, patient-clinician flow; patient-clinician interaction). This fresh perspective will help both researchers to develop new strategies to study human behavior, and policy makers to design new public health initiatives aimed at improving positive and functional behavior within the population.

## Multimedia Appendix 1

A visual representation of the speed and dwelling time of each trial.

[[PNG File, 11KB - mhealth\\_v6i4e100\\_app1.png](#)]

## Multimedia Appendix 2

A two-dimensional floorplan representing the beacon locations and path of trials 1-3.

[[PNG File, 369KB - mhealth\\_v6i4e100\\_app2.png](#)]

## Multimedia Appendix 3

Lasagna plots representing the combination of localization tracking and activity levels. Areas are not sorted by absolute time. The color between blue (time equal to zero) and yellow (time equal to 230 s) represents the time being active.

[[PNG File, 47KB - mhealth\\_v6i4e100\\_app3.png](#)]

## Multimedia Appendix 4

Lasagna plots representing the combination of localization tracking and activity levels. Areas are not sorted in descending order by relative time. The color between blue (time equal to zero) and yellow (time equal to 230 s) represents the activity level spent-time.

[[PNG File, 53KB - mhealth\\_v6i4e100\\_app4.png](#)]

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## Abbreviations

- BLE:** Bluetooth low energy
- GPS:** global positioning system
- RMSE:** root mean square error
- RSSI:** records received signal strength indication
- SSE:** sum of squares due to error

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Corrigenda and Addenda

# Metadata Correction: Mobile Phone Ownership Is Not a Serious Barrier to Participation in Studies: Descriptive Study

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In the metadata for “Mobile Phone Ownership Is Not a Serious Barrier to Participation in Studies: Descriptive Study” (*JMIR Mhealth Uhealth* 2018;6(2):e21), the degrees for Sabrina L Smiley were listed in an incorrect order as “MCHES, MPH, PhD”. The degrees should have been ordered “PhD, MPH, MCHES”.

The corrected article will appear in the online version of the paper on the JMIR website on April 25, 2018, together with the publication of this correction notice. Because this was made after submission to PubMed or Pubmed Central and other full-text repositories, the corrected article also has been re-submitted to those repositories.

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Corrigenda and Addenda

# Metadata Correction: Direct Adherence Measurement Using an Ingestible Sensor Compared With Self-Reporting in High-Risk Cardiovascular Disease Patients Who Knew They Were Being Measured: Prospective Intervention

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In the paper by David Thompson et al, "Direct Adherence Measurement Using an Ingestible Sensor Compared With Self-Reporting in High-Risk Cardiovascular Disease Patients Who Knew They Were Being Measured: A Prospective Intervention" (*JMIR Mhealth Uhealth* 2017;5(6):e76), author Nicholas S Peters's middle name initial was omitted.

The author's name has been corrected and the corrected article will appear in the online version of the paper on the JMIR website on April 27, 2018, together with the publication of this correction notice. Because this was made after submission to PubMed, Pubmed Central, and other full-text repositories, the corrected article also has been re-submitted to those repositories.

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