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Original Paper

Effect of Using an Indoor Air Quality Sensor on Perceptions of and Behaviors Toward Air Pollution (Pittsburgh Empowerment Library Study): Online Survey and Interviews

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Abstract

Background: Air quality affects us all and is a rapidly growing concern in the 21st century. We spend the majority of our lives indoors and can be exposed to a number of pollutants smaller than 2.5 microns (particulate matter, $PM_{2.5}$) resulting in detrimental health effects. Indoor air quality sensors have the potential to provide people with the information they need to understand their risk and take steps to reduce their exposure. One such sensor is the Speck sensor developed at the Community Robotics, Education and Technology Empowerment Lab at Carnegie Mellon University. This sensor provides users with continuous real-time and historical $PM_{2.5}$ information, a Web-based platform where people can track their $PM_{2.5}$ levels over time and learn about ways to reduce their exposure, and a venue (blog post) for the user community to exchange information. Little is known about how the use of such monitors affects people's knowledge, attitudes, and behaviors with respect to indoor air pollution.

Objective: The aim of this study was to assess whether using the sensor changes what people know and do about indoor air pollution.

Methods: We conducted 2 studies. In the first study, we recruited 276 Pittsburgh residents online and through local branches of the Carnegie Library of Pittsburgh, where the Speck sensor was made available by the researchers in the library catalog. Participants completed a 10- to 15-min survey on air pollution knowledge (its health impact, sources, and mitigation options), perceptions of indoor air quality, confidence in mitigation, current behaviors toward air quality, and personal empowerment and creativity in the spring and summer of 2016. In our second study, we surveyed 26 Pittsburgh residents in summer 2016 who checked out the Speck sensor for 3 weeks on the same measures assessed in the first study, with additional questions about the perception and use of the sensor. Follow-up interviews were conducted with a subset of those who used the Speck sensor.

Results: A series of paired t tests found participants were significantly more knowledgeable (t_{25}=−2.61, P=.02), reported having significantly better indoor air quality (t_{25}=−5.20, P<.001), and felt more confident about knowing how to mitigate their risk (t_{25}=−1.87, P=.07) after using the Speck sensor than before. McNemar test showed participants tended to take more action to reduce indoor air pollution after using the sensor (χ^2_{25}=2.7, P=.10). Qualitative analysis suggested possible ripple effects of use, including encouraging family and friends to learn about indoor air pollution.

Conclusions: Providing people with low- or no-cost portable indoor air quality monitors, with a supporting Web-based platform that offers information about how to reduce risk, can help people better express perceptions and adopt behaviors commensurate with the risks they face. Thus, thoughtfully designed and deployed personal sensing devices can help empower people to take steps to reduce their risk.

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KEYWORDS

indoor air pollution; particulate matter; inhalation; decision aids

Introduction

Air quality affects all of us and is a rapidly growing concern in the 21st century [1]. According to results of a recent study, environmental exposures such as air pollution may even be linked to autism spectrum disorder rates among children [2]. Furthermore, airborne particulates smaller than 2.5 microns (particulate matter, $PM_{2.5}$) can cause significant harm to human health because they not only lodge deep in the lungs but also cross the air-blood barrier into the human bloodstream and endocrine systems. Exposure to $PM_{2.5}$ has been associated with asthma attacks, respiratory disease, arrhythmia, and cardiovascular disease [2].

Air Pollution

Pittsburgh, in particular, has a long history of pollution stemming from coal mining and other industrial activities [3]. Although the city is now notably cleaner, there are still many invisible and visible pollutants contaminating the air we breathe [4,5]. According to a 2012 report from the Pennsylvania Department of Health, among Pennsylvania's 67 counties, Pittsburgh's Allegheny County had the 6th highest number of emergency room visits caused by asthma (21 visits per 10,000 residents) [5,6]. Moreover, during the 2008-2009 school year, 12.1% of Allegheny County students were reportedly diagnosed with asthma. These rates are alarming and also have significant economic impact for the community, with each asthma-related hospital stay (from 2008-2010) costing over US $20,000 on average [6]. Conversely, improving air quality in Pittsburgh could yield substantial economic benefits. In a 2013 report, RAND Corporation estimated that reducing the city's 2012 levels of $PM_{2.5}$ to meet National Ambient Air Quality Standards yields approximately US $488 in economic value [7]. These findings were driven primarily by reductions in premature mortality among residents and provide evidence that there may be considerable economic benefits associated with reducing residents' exposure to $PM_{2.5}$.

Although outdoor air pollution is widely accepted as a problem, indoor air quality can often be overlooked because the level of visible pollution indoors is relatively low. Indoor air pollution can be caused by outdoor contaminants seeping in through windows or poor air filtration systems, or generated from indoor sources such as smoking, cooking, and vacuuming. Many of these sources can produce $PM_{2.5}$ inside our homes, schools, and offices, but because these particles are so small (about a 30th of the diameter of a human hair or less), they would be invisible to us, except in very high concentrations. We spend the majority of our lifetime in indoor spaces, so our level of exposure to these indoor pollutants can be very high. However, unlike outdoor air pollution, which is a significant challenge to mitigate and requires years to enact necessary air quality regulations, indoor air quality can be managed by anyone.

Risk Perceptions and Behaviors

Although individuals are better able to control their air quality indoors, whether or not individuals or families take action to reduce their risk of exposure to pollution indoors is largely dependent on how they perceive this risk [8,9]. One key requisite for this risk perception is the awareness that there is a risk [10]. Moreover, providing people with personalized information about their risk influences attitudes and behaviors more powerfully than simply informing them about the risk in general [11-13]. Furthermore, research in the domain of risk perceptions has found that people use experiential/affective processes to understand risk [14] and that helping people experience that risk may help them better learn about it [15].

By contrast, studies in other domains, notably health, have often found that fear and worry can undermine individuals' resolve to act, unless they see opportunities for effective action [16]. An illustrative early study by Leventhal et al found that arousing concern about tetanus increased more favorable attitudes and intentions to get a vaccination, but people rarely followed through and actually received one [17]. However, when the researchers augmented their fear appeal with a specific plan, a map with instructions on how to get to the clinic, they found people actually followed through on their intent to get vaccinated. Indeed, the most effective fear appeals are those coupled with high-efficacy messages showing effective measures that people can take to reduce their risk [18]. One way to help people make the connection between their activities and lifestyle choices, subsequent changes in $PM_{2.5}$ concentration levels, and ways they can mitigate their risk is through the introduction of indoor air quality monitors.

Personal Sensor Technologies for Indoor Air Pollution

There are a growing number of personal sensor technologies, including those that detect ambient $PM_{2.5}$ levels, available in the market [19]. A few of these technologies are portable, allowing people to place the monitor in different places in their home and conduct a variety of activities such as cooking and vacuuming to see how their indoor air quality is affected by reading directly off the monitor. Some also offer a companion mobile phone app, which may provide continuous real-time and historical $PM_{2.5}$ information. Other sensors, such as the Speck (Figure 1 [20]), developed at the Community Robotics, Education and Technology Empowerment Lab at Carnegie Mellon University, also have a Web-based platform where people can track their $PM_{2.5}$ levels over time and learn about ways to reduce their exposure; these sensors also provide a venue (blog post) for the user community to exchange information.

Figure 1. Image of the Speck monitor home screen displaying air quality reading.

Little research has been conducted to evaluate the effect of these types of monitors on people's knowledge, attitudes, and behaviors; however, one study investigating the use of air quality visualizations over a 4-week period with 14 participants did find changes in attitudes and an increase in prohealth behaviors [21,22]. Research findings in the area of personal wearable fitness devices on physical activities are mixed, with some studies finding an increase in activity [23,24] and others finding no change [25]. Therefore, whether and how indoor air quality monitors influence people's behavior to improve indoor air quality remains an empirical question.

Our research objective was to assess whether and how the use of a Speck sensor to monitor indoor air quality empowers people to reduce their risk of exposure to indoor pollutants. To that end, we conducted 2 studies. Our first exploratory study gathers baseline information about what Pittsburgh residents, recruited online or from their local library, generally know and do about indoor air pollution; how confident they are that those actions are effective; and how they would want to learn about it (eg, are indoor air quality sensors appropriate?). Our second study evaluates the effect of using a sensor to monitor indoor air pollution on what people know and do about indoor air pollution among those library patrons from our exploratory first study. These patrons were invited to use the monitor for a period of up to 3 weeks, with their views and behaviors being surveyed after using the monitor. To better explicate our findings, we also interviewed a select subset of those who checked out the monitor from their public library.

Methods

Study 1: Baseline Views and Behaviors of the General Public

Survey Protocol

After a brief introduction to the study, eligible participants (18 years or older, and living in Pittsburgh) took a 10- to 15-min survey to assess their views and behaviors related to indoor air pollution, and basic demographics.

Variables

Knowledge

Knowledge of air pollution was assessed by asking, "How much do you know about air quality?" where 1=none and 5=everything.

Health

The seriousness of perceived health consequences was assessed by asking, "Do you think air quality can cause or make worse the following issues?" Participants were encouraged to check all of the potential issues from a list of 8 items, which included asthma and other respiratory illnesses, heart disease, diabetes, lung cancer, stroke, epilepsy, allergic responses, and others they think may apply. For our analyses, we summed the number of perceived consequences where higher counts indicated greater severity of perceived health consequences (range of 0-8).

Source

Perceived sources of indoor air pollution risks were assessed by asking, "What do you think are some of the sources of pollution inside your home?" Participants were encouraged to check all of the potential sources from a list of 11 items, which included cooking, vacuuming, smoking, microwave oven, gas heating, fireplace, open windows, insulation, pets, refrigerator, or other. For our analyses, we summed the number of perceived sources where a higher count indicates greater severity of perceived risk (range of 0-11).

Mitigation

Perceptions about the number of possible avenues to mitigate risk were assessed by asking, "What do you think are effective ways to reduce your exposure to indoor air pollution?" Participants were encouraged to check all effective ways from a list of 10 items, which included installing a range hood, opening windows, closing windows, installing an air purifier, changing air filters, cleaning the house, smoking outside instead of inside, installing an air quality monitor, cleaning air filters, and others that they think may apply. For our analyses, we summed the number of perceived mitigation strategies where a higher count indicates a greater number of perceived avenues for reducing risk (range of 0-10).

Air Quality

Perceptions of indoor air quality was assessed by asking participants, "On average, how would you rate the air quality in your home?" where 1=very poor and 5=very good.

Confidence

Confidence in knowing what to do to mitigate risk was assessed by asking, "How confident are you that you will know what actions to take if you learned that your indoor air quality was poor?" where 1=not at all confident and 5=extremely confident.

Behavior

Behaviors related to improve indoor air quality was assessed by asking participants, "In the past 3 months, have you made any changes in your home to improve the air quality?" where 1=yes, I have; 2=not yet, but I plan to; and 3=no, I have not and do not plan to. For our analyses, we recoded affirmative responses ("yes, I have or not yet, but I plan to") as 1, and unenthusiastic responses ("no, I have not and don't plant to") as 0.

Empowerment

We used Rogers et al's [26] empowerment scale that includes five constructs: self-esteem and self-efficacy, power and powerlessness, community activism and autonomy, optimism and control over the future, and righteous anger. Participants indicated their agreement level (1=strongly disagree and 5=strongly agree) on:

- nine statements related to self-esteem and self-efficacy (eg, "I generally accomplish what I set out to do")
- seven statements related to power and powerlessness (eg, "I feel powerless most of the time")
- six statements related to community activism and autonomy (eg, "People have a right to make their own decisions, even if they are bad ones")
- four statements related to optimism and control over the future (eg, "People are limited only by what they think is possible")
- four statements related to righteous anger (eg, "Getting angry about something is often the first step toward changing it")

We created an overall measure of empowerment by taking the average of all 27 items (Cronbach alpha=.86).

Creativity

Previous research suggests creativity is inextricably linked to learning and experimentation [27,28]. Hence, we wanted to be able to control for creativity in our analyses to gain a more accurate measure of the sensor's influence on learning, perceptions, and actions. We used Kirton's short [29] Adaptation-Innovation Inventory where people rated their agreement (1=strongly disagree; 5=strongly agree) with statements describing themselves, such as "When involved in a project, I forget that other people are involved and should be consulted." We created an overall measure of innovativeness by taking the mean of all 9 items (Cronbach alpha=.60).

Recruitment

Participants from the Pittsburgh area were recruited using Amazon's Mechanical Turk, a Web-based survey platform [30-32], in spring and summer 2016. Participants (n=214) were invited to take a Web-based survey on air quality and were compensated US $1 for the 10- to 15-min survey. Participants (n=62) were also recruited from the local branches of the Carnegie Library of Pittsburgh that had Speck sensor indoor air monitors in their catalogs, made available courtesy of Carnegie Mellon University's Community Robotics, Education and Technology Empowerment Lab. These participants were entered into a lottery for the chance to win 1 of 5 Speck sensors in exchange for their participation, and they completed the presurvey at one of the computer stations located in the library. At the time of recruitment, they were also informed of a follow-up survey that they would be invited to take after returning the Speck sensor (see study 2 for more details).

Participants

Participants reported being on average 36.2 years old (SD 12.26), with 55.6% (149/268) being female, 78.0% (206/264) having at least a college degree, and 44.7% (118/264) with a household income of US $51,000 or greater per year. Most identified as Democrats (119/264, 45.1%), followed by Independents (70/264, 26.5%), Republicans (46/264, 17.4%), Other (14/264, 5.3%), or Prefer Not to Answer (15/264, 5.7%). Most households had at least one child under the age of 18 years living at home (230/267, 86.1%), and of those, 9.0% (24/267) had at least one child under the age of 5 years. Most households also had at least one adult over the age of 65 years living at home (212/264, 80.3%), suggesting that many households were multigenerational. About 21.3% (56/263) of our participants reported that they or someone in their household suffered from a respiratory illness. Overall, the average long-term outdoor $PM_{2.5}$ levels experienced by our participants were good (mean 10.48, median 9.97, SD 1.85). Of note, the Environmental Protection Agency's federal long-term (annual average) standard is 15 $\mu g/m^3$ and short-term (24-hour average) standard is 35 $\mu g/m^3$ [33].

Data Analytic Plan

Statistical analyses were conducted using Stata version 14 (Stata Corp, College Station, TX, USA). One-sample *t* tests were used to assess whether self-reported knowledge, views on indoor air quality, and confidence in ability to improve air quality was different than average (midpoint test value of 3). Descriptive statistics were used to characterize views on health impacts, sources and mitigation options related to indoor air pollution, as well as for views on learning about indoor air quality. Logistic regressions were used to assess the following: (1) the consistency in people's responses between sources of pollution and mitigation options, (2) the degree to which perceived home air quality and confidence in ability to improve poor quality predicted mitigation behavior, and (3) the extent to which intent to take action predicted interest in learning about air quality. All analyses controlled for empowerment and creativity where appropriate.

Study 2: Views and Behaviors After Using Sensor

Survey and Interview Protocol

Survey

Participants checking out the sensor completed the first survey following the same protocol described in study 1. Upon returning the sensor to the library, participants were asked whether they would like to take a 10- to 15-min follow-up survey. They answered the same set of questions as before, with the addition of a few questions regarding their opinions. No compensation was offered for the follow-up survey.

Interview

Participants were asked about their views on indoor air pollution, managing indoor air pollution and the Speck sensor, as well as basic demographic questions.

Variables

The variables for study 2 were exactly the same as for study 1, with Cronbach alpha for empowerment being .89 and for creativity being .72.

Recruitment

Survey

Of the 62 participants who checked out the sensor and completed study 1, 26 agreed to participate in study 2 (attrition rate of 58.1%). Those who agreed to participate in study 2 did not meaningfully differ from those who elected not to participate, based on demographics, baseline knowledge, perceived home air quality, and confidence in ability to mitigate risk. Please refer to Multimedia Appendices 1 and 2 for more details.

Interview

Of the 62 participants who checked out the sensor and completed study 1, 4 agreed to be interviewed. The interviews lasted approximately 1 hour, were audio-recorded, and were transcribed for later analysis.

Participants

Participants reported being on average 44.5 years old (SD 12.6), with 61% (14/23) being female, 87% (20/23) having at least a college degree, and 57% (13/23) with a household income of US $51,000 or greater per year. Most identified as Democrats (11/23, 48%), followed by Independents (9/23, 39%), Republicans (1/23, 4%), or other (2/23, 9%). Many households had at least one child under the age of 18 years living at home (9/22, 41%), and of those, all (9/9, 100%) had at least one child under the age of 5 years. Few households also had at least one adult over the age of 65 years living at home (1/23, 4%). About 17% (4/23) of our participants reported that they or someone in their household suffered from a respiratory illness. Overall, the average long-term outdoor $PM_{2.5}$ levels experienced by our participants were good (mean 10.56, median 10.36, SD 1.17).

Data Analytic Plan

One-sample *t* tests were used to assess whether participants saw the sensors as easy-to-use, accurate, or helpful for them to learn and if they would recommend or had recommended it to others. Paired-sample *t* tests were conducted to assess the impact of the sensor on self-reported air quality knowledge, perception of indoor air quality and confidence in ability to improve air quality, understanding of health impacts and sources of pollution, and knowledge of possible mitigation solutions. McNemar test was conducted to assess whether using the sensor resulted in people reporting having taken or intending to take mitigation measures to reduce risk, with a follow-up logistic regression to assess the association between, before, and after sensor mitigation behavior. Interview transcripts were coded for understanding of indoor air pollution, as well as beliefs and behaviors before and after using the sensor. Illustrative quotes and themes, including the percentage of the participants interviewed who mentioned them, are presented in the Results section. All analyses controlled for empowerment and creativity where appropriate.

Results

Study 1: Baseline Views and Behaviors of the General Public

What Do People Know and Do About Indoor Air Pollution?

In general, Pittsburgh residents reported knowing less than the average citizen (mean 2.62, SD 0.75) about indoor air quality (t_{273}=−8.35, $P \leq .001$) (Table 1). Residents reported a median of 4 health consequences arising from indoor air pollution, with the most cited being asthma, allergic responses, lung cancer, and heart disease (Table 2). They also reported a median of 4 main sources contributing to indoor pollution, including pets, cooking, open windows, and gas heating. Residents saw a median of 6 actions as being most effective at reducing pollution, such as installing an air purifier, changing the air filter, cleaning the air filter, cleaning the house, and installing an air quality monitor. Logistic regressions found high internal consistency in reported sources and actions to mitigate risk. For example, those who reported that open windows contribute to air pollution were 8 times more likely to report closing windows mitigate risks (odds ratio [OR] 8.03, $P<.001$) and significantly less likely to report opening windows mitigate risks (OR 0.34, $P<.001$). However, there was one exception. Those who reported that vacuuming contributes to air pollution were 2 times more likely to report that cleaning is a way to reduce exposure (OR 2.12, $P=.02$). See Multimedia Appendices 3-5 for more details on internal consistency.

On balance, most people thought that their indoor air quality is relatively good (mean 3.31, SD 0.72, t_{273}=18.69, $P<.001$) and were ambivalent about their confidence in knowing what to do should they learn their air quality was bad (mean 2.42, SD 0.96, t_{275}=−1.44, $P=.16$) (Table 1). Despite this, most people reported that they had (56/276, 20.3%) or were intending to (122/276, 44.2%) take action to improve their indoor air quality. Moreover, a logistic regression found that those reporting better indoor air quality were significantly less likely to report having taken or intending to take future action (OR 0.65, $P=.03$), whereas those expressing greater confidence they would know how to mitigate being significantly more likely to have or to intend to take action (OR 1.69, $P<.001$). Whether those individuals actually have good air quality and if the actions taken effectively reduce the risk is unknown.

Table 1. One-sample *t* tests of knowledge, air quality, and confidence (midpoint of 3).

Variables	Mean (SD)	N	*t* statistic (degrees of freedom)	*P* value
Knowledge	2.62 (0.75)	274	−8.35 (273)	<.001
Air quality	3.31 (0.72)	274	7.15 (273)	<.001
Confidence	2.42 (0.96)	276	−10.1 (275)	<.001

Table 2. Percent of participants indicating possible health consequences, sources, and mitigation solutions related to indoor air pollution among the general public.

Survey prompts relating to indoor air quality knowledge	Participants who agreed, n (%)
Consequences	
Asthma	271 (100.0)
Allergic responses	263 (97.0)
Lung cancer	246 (90.8)
Heart disease	130 (48.0)
Stroke	68 (25.1)
Epilepsy	45 (16.6)
Diabetes	24 (8.9)
Other	19 (7.0)
Sources	
Pets	163 (60.1)
Cooking	160 (59.0)
Open windows	147 (54.2)
Gas heating	140 (51.7)
Vacuuming	127 (46.9)
Insulation	111 (41.0)
Fireplace	73 (26.9)
Refrigerator	67 (24.7)
Smoking	66 (24.4)
Microwave oven	48 (17.7)
Other	39 (14.4)
Mitigation	
Installing air purifier	239 (88.2)
Changing air filter	238 (87.8)
Cleaning air filter	231 (85.2)
Cleaning the house	217 (80.1)
Installing air quality monitor	201 (74.2)
Smoking outside instead of inside	151 (57.9)
Installing range hood	131 (48.3)
Opening windows	120 (44.3)
Closing windows	75 (27.7)
Other	14 (5.2)

Do People Want to Know More About Indoor Air Pollution?

Among those who are not already interested (checked the sensor out of the library), most people report wanting to know whether their indoor air quality is good or bad (146/195, 74.9%), with those claiming that they would indeed take action being those expressing the most interest in knowing about it (beta=.76, $P<.001$). These residents overwhelmingly preferred to learn about their indoor air quality through the use of an indoor monitor (152/195, 77.9%), followed by a local expert (101/195, 51.7%), social media (84/195, 43.1%), friends/family (67/195, 34.5%), flyers (60/195, 30.8%), community meetings (45/195, 23.1%), librarian (17/195, 8.7%), or other ways (15/195, 7.7%). People were even willing to pay for such a device, although at a price point (mean US $63.59, SD US $44.17) much lower than currently available monitors, which typically start at US $135 [34]. Residents were also interested in renting out a Speck monitor for free for a short period of time, with the two most convenient locations being work (119/195, 61.0%) and the public library (105/195, 53.8%).

Study 2: Views and Behaviors After Using Sensor

How Do People View the Sensor?

On balance, interviewed participants reported being interested in using the sensor because of health concerns (4/4, 100%), curiosity (3/4, 75%), and its free availability at the library (1/4, 25%). In general, survey participants viewed the sensor quite favorably. Participants thought that the sensor was more easy to use (mean 4.24, SD 0.97, $t_{24}=6.39$, $P<.001$) and accurate than average (mean 4.21, SD 0.72, $t_{23}=8.21$, $P<.001$) (Table 3). They also reported that they felt like they learned from using the sensor (mean 4.12, SD 1.01, $t_{24}=5.53$, $P<.001$) and would recommend or had recommended the sensor to others (mean 3.80, SD 1.15, $t_{24}=3.46$, $P=.01$).

Does Using a Sensor Change What People Know and Do About Indoor Air Pollution?

A paired *t* test found that participants reported being more knowledgeable about indoor air pollution after using the sensor than they were before, (after: mean 2.77, SD 0.71; before: mean 2.38, SD 0.75; $t_{25}=-2.61$, $P=.02$) (Table 4). Participants (3/4, 75%) we interviewed described having "a-ha moment[s]" (Participant K) when using the sensor where they felt like they learned something new about sources of indoor pollution:

> *...like, running the vacuum and cooking, and you know, things like that.* [Participant G]

After using the sensor, participants attributed indoor air pollution to biological (3/4, 75%), chemical (3/4, 75%), combustion (4/4, 100%), and dust/dander (3/4, 75%) sources and saw it as being much worse in the spring/summer (1/4, 25%) than at other times of the year.

Although we did not observe a significant difference in reported action, our findings suggest a trend toward taking or intending to take action to reduce indoor air pollution after using the sensor (McNemar $\chi^2_1=2.7$ $P=.10$) (Figure 2). We also found those who reported having taken or intending to take action to mitigate their risk were significantly more likely to do so in the future (OR 17.6, $P=.02$). Indeed people reported that they had significantly better indoor air quality after using the sensor than before (after: mean 3.65, SD 0.75; before: mean 2.96, SD 0.77; $t_{25}=-5.20$, $P<.001$), possibly as a result of what they did in response to what they learned. Participants we interviewed reported experimenting with the sensor (4/4, 100%), saying that they:

> *...moved [the sensor] around and tested various behaviors to see if it had any impact [on PMreadings].* [Participant J]

It was through this experimentation that participants discovered the impact of cooking (4/4, 100%), movement (2/4, 50%), and vacuuming (3/4, 75%) on indoor air pollution. They also used the sensor to monitor particulate levels in spaces such as their child's room (Participant G) (3/4, 75%), where vulnerable people spend a lot of time, to make sure that air quality remained good.

We found that people felt more confident about knowing what to do to mitigate their risk after using the sensor (after: mean 2.62, SD 0.94; before: mean 2.31, SD 1.01; $t_{25}=-1.87$, $P=.07$).

We observed no difference in mean number of reported sources of indoor air pollution and ways to mitigate risk. However, participants we interviewed reported taking new measures they had not tried before to reduce their exposure to indoor air pollution. These included improved pet care and maintenance (1/4, 25%) to reduce dander, a new furnace (1/4, 25%), cleaning more frequently and thoroughly (1/4, 25%), opening windows when cooking (1/4, 25%), and running ventilation systems when necessary (3/4, 75%). Our participants also expressed more concern about the consequences of indoor air pollution after using the sensor than before (after: mean 4.64, SD 1.66; before: mean 3.88, SD 1.56; $t_{24}=-2.10$, $P=.05$) and seemed especially concerned about allergic responses, lung cancer, heart disease, and stroke (Table 5) with people wondering:

> *I have asthma...how can I improve my own air quality to avoid having an asthma attack?* [Participant K]

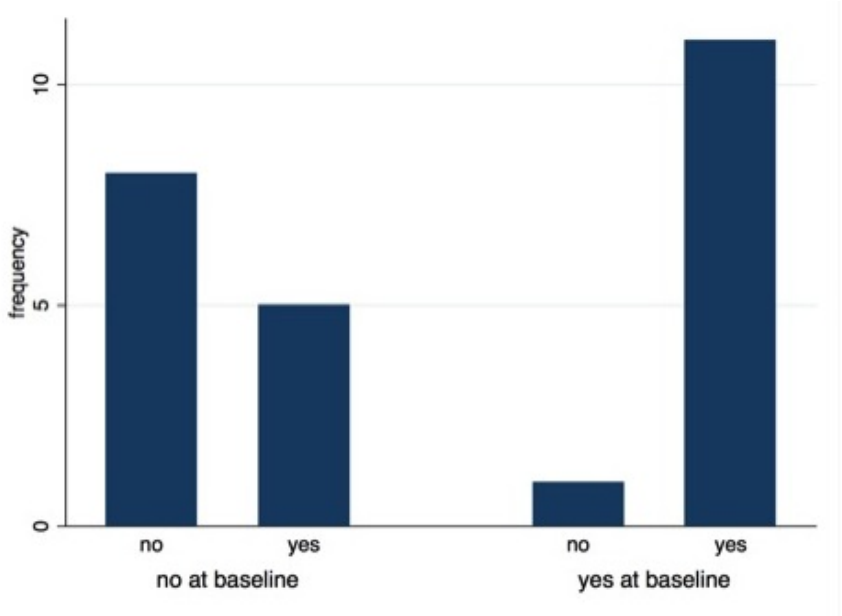
Table 3. One-sample *t* tests of views of the sensor (midpoint of 3).

Variables	Mean (SD)	N	*t* statistic (degrees of freedom)	*P* value
Easy	4.24 (0.97)	25	6.39 (24)	<.001
Accurate	4.21 (0.72)	24	8.21 (23)	<.001
Learn	4.12 (1.01)	25	5.53 (24)	<.001
Mitigation	3.2 (1.15)	25	.87 (24)	.40
Recommendation	3.8 (1.15)	25	3.46 (24)	.01

Table 4. Paired-sample *t* tests of knowledge, air quality, and confidence.

Variables	Before, mean (SD)	After, mean (SD)	N	*t* statistic (degrees of freedom)	*P* value
Knowledge	2.38 (0.75)	2.77 (0.71)	26	−2.61 (25)	.02
Air quality	2.96 (0.77)	3.65 (0.75)	26	−5.2 (25)	<.001
Confidence	2.31 (1.01)	2.62 (0.94)	26	−1.87 (25)	.07

Figure 2. Reported or intended mitigation action after using the sensor for those who did not take or intend to take previous action before using the sensor (no at baseline) and those who did (yes at baseline).



However, not everyone made a change since they found they did not really need to do anything because their indoor air quality was not bad. As a result, they would not adopt any new measures (2/4, 50%) and moreover, one participant said:

> *I had no idea what I would do if it said it was bad [laughs].* [Participant L]

Participants also mentioned a number of barriers to reducing exposure, should the air quality be bad, such as lack of equipment (2/4, 50%), nearby polluters they have no control over (2/4, 50%), and pollution naturally being worse at certain times of year (2/4, 50%). For example:

> *We don't have central air...if it's hot, we need to have the window open.* [Participant L]

The sensor was also used outside of the home to help participants learn about their indoor air pollution in other settings (2/4, 25%):

> *I took it into work so it's there.* [Participant G]

Indeed, one participant was able to use the output from the sensor to pressure building owners to make changes to improve the indoor air quality at work:

> *The office is right beside a nail salon and they were getting some really powerful smells and so they're getting on the landlord about "something's got to give, you know?" My folks can't suffer like that, so I mean one of the things I've been—to be honest with you—one of the bargaining chips was, "well, listen we're bringing this air monitor up so you'd better get your shit together...," so they did, and we took the readings up there and they were generally pretty good.* [Participant G]

Not only did participants bring the sensor to places outside of the home, they also talked to other people about the sensor, encouraging them to use it (3/4, 75%):

I did tell my parents who live near me that they should check it out and see what their quality looks like. [Participant K]

They also showed other people how to use it (1/4, 25%) and shared what they had learned about air pollution with others (1/4, 25%):

Some of the things we have learned just by seeing them...[I] would like to try to pass it on. [Participant G]

Table 5. Percent of participants indicating possible health consequences, sources, and mitigation solutions related to indoor air pollution among the sensor users.

Survey prompts relating to indoor air quality knowledge	Participants who agreed, n (%)
Allergic responses	26 (100)
Lung cancer	25 (96)
Heart disease	17 (65)
Stroke	10 (39)
Epilepsy	8 (31)
Diabetes	4 (15)
Other	4 (15)
Asthma	1 (4)
Sources	
Cooking	21 (81)
Vacuuming	18 (69)
Open windows	15 (58)
Pets	14 (54)
Gas heating	14 (54)
Refrigerator	5 (19)
Microwave oven	5 (19)
Other	5 (19)
Smoking	4 (15)
Insulation	3 (12)
Fireplace	2 (8)
Mitigation	
Cleaning the house	24 (92)
Changing air filter	23 (89)
Installing air purifier	22 (85)
Cleaning air filter	20 (77)
Installing range hood	18 (69)
Installing air quality monitor	13 (50)
Opening windows	12 (44)
Smoking outside instead of inside	11 (42)
Closing windows	8 (31)
Other	2 (8)

Discussion

Principal Findings

In general, most people see themselves as knowledgeable about indoor air pollution, the sources of the pollution, and ways to mitigate their risk should they learn that their indoor air quality is poor. Although people report that they believe they have fairly good indoor air quality, they are not completely certain and are generally open to learning about it through the use of a portable indoor air quality monitor. People are willing to pay for such a monitor providing them with information about indoor air

quality; however, the amount they are willing to spend is considerably less than that of those currently available. Therefore, making these monitors freely available to the public at a place that is convenient for them, such as at their local public library, is a way to help people access needed tools for informed decision making about indoor air quality.

We found that after using the sensor people reported higher levels of knowledge about indoor air pollution, confidence in their ability to improve indoor air, and improved indoor air quality (possibly as a result of taking mitigation actions). Moreover, we found a significant increase in the number of perceived health impacts after using the sensor, suggesting enhanced perceptions of risk. We also found a positive trend in action-taking among those who already took action before using the sensor *and* those who did not take action (and did not intend to do so in the future), suggesting the potential for this type of personalized risk information as an important motivating factor in prohealth behavior change.

Our findings also suggest that using the sensor was an interactive experience, where participants learned about the link between what they do in their home and what their exposure levels are. There is evidence that this type of experiential learning may be a more powerful way of helping people master new information and suggests a way to enhance motivation to make positive behavior changes [14,15]. These changes seemingly may have both a direct (people making changes in their own homes) and an indirect impact (people talking to others about it or making changes at their place of work [35,36]) on exposure levels, suggesting the potential for a positive ripple effect from using such a personalized device. Research looking at these direct and indirect impacts could be instructive to learn about the true potential and limitations of such monitors on reducing exposure to indoor air pollutants.

Limitations

Although our study has very strong external validity, it is not without its limitations. First, we did not recruit a representative sample of Pittsburgh residents to participate in either study 1 or study 2, and therefore we cannot generalize our findings. However, we were mostly interested in evaluating those individuals most likely to use an indoor air quality monitor when made freely available. Future studies could be conducted to more rigorously evaluate the effect of using such monitors through a randomized controlled trial, allowing for more generalizable findings and a more thorough examination of underlying predictive factors.

Second, we were not able to collect actual exposure data since it was logistically difficult to offload data in real time from every single Speck checked out from a library branch and because of data privacy concerns. However, in this study we were less interested in actual exposure level and more interested in how the information induced changes in perceptions and self-reported behavior. A future study could look at actual $PM_{2.5}$ levels along with knowledge and behaviors as predictors or covariates to better understand the relationship between these factors and outcomes.

Third, we did not ask our participants in study 2 what actions they took to improve their indoor air quality, nor did we ask them or evaluate which features of the sensor they found to be most persuasive in pursuing the given actions. Due to the design of our study, responses would likely have been subject to recall bias; thus, we did not pursue these lines of questions. However, a future study could ask participants to keep a running log of their activities and changes in behavior (with rationale) related to engagement with the sensor.

Fourth, given our design, we do not know whether learning one time from using the sensor is enough to influence actions over the long term. A future longitudinal study could help determine whether this type of short-term learning can lead to long-term impacts.

Finally, only a small subset of individuals who checked out the sensor from the library agreed to participate in a phone interview for our study. One possible reason is that email-based recruitment from a small sample for a time-consuming activity—with interviews lasting approximately 1 hour in length—is challenging and usually does not yield large numbers. Nonetheless, the researchers believe that the information gathered from the interviews that were conducted does yield insights into people's perceptions and behaviors. Future studies should collect this valuable qualitative data that allow for deeper understanding of people's views and actions.

Conclusions

There is much to be hopeful about in these findings. Providing people with low- or no-cost portable indoor air quality monitors with a supporting Web-based platform that offers information about how to reduce risk can help people better express perceptions and adopt behaviors commensurate with the risks they face. Moreover, there appear to be other benefits from engaging in information about indoor air pollution through this experiential means, such as talking to others about the potential risks they may face and using the technology to make positive changes in indoor spaces other than the home. The emerging picture is that thoughtfully and well-designed personal sensor technologies can empower people to take control of the risks that they face and affect positive outcomes in their lives.

Acknowledgments

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Conflicts of Interest

MT and MBD are consultants with Airviz, Inc, which manufactures Speck air quality monitors. They do not directly benefit from any Speck sales but have a very small share of nonqualified stock options with the company.

Multimedia Appendix 1

Comparison of the demographics of library patron participants who elected to participate in study 2 versus those who did not.

[PDF File (Adobe PDF File), 21KB - mhealth_v6i3e48_app1.pdf]

Multimedia Appendix 2

Comparison of knowledge, air quality, and confidence of library patron participants who elected to participate in study 2 versus those who did not.

[PDF File (Adobe PDF File), 19KB - mhealth_v6i3e48_app2.pdf]

Multimedia Appendix 3

Logistic regression evaluating whether opening or closing windows as a solution to poor indoor air quality predicts open windows as a source of pollution.

[PDF File (Adobe PDF File), 16KB - mhealth_v6i3e48_app3.pdf]

Multimedia Appendix 4

Logistic regression evaluating whether installing a range hood as a solution to poor indoor air quality predicts cooking as a source of pollution.

[PDF File (Adobe PDF File), 16KB - mhealth_v6i3e48_app4.pdf]

Multimedia Appendix 5

Logistic regression evaluating whether smoking outside as a solution to poor indoor air quality predicts smoking indoors as a source of pollution.

[PDF File (Adobe PDF File), 16KB - mhealth_v6i3e48_app5.pdf]

Multimedia Appendix 6

Logistic regression evaluating whether cleaning as a solution to poor indoor air quality predicts vacuuming as a source of pollution.

[PDF File (Adobe PDF File), 15KB - mhealth_v6i3e48_app6.pdf]

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Abbreviations

OR: odds ratio
PM $_{2.5}$: particulate matter smaller than 2.5 microns

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Original Paper

Patient and Family Engagement in the Design of a Mobile Health Solution for Pediatric Asthma: Development and Feasibility Study

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Abstract

Background: Asthma is a highly prevalent, chronic disease with significant morbidity, cost, and disparities in health outcomes. While adherence to asthma treatment guidelines can improve symptoms and decrease exacerbations, most patients receive care that is not guideline-based. New approaches that incorporate shared decision-making (SDM) and health information technology (IT) are needed to positively impact asthma management. Despite the promise of health IT to improve efficiency and outcomes in health care, new IT solutions frequently suffer from a lack of widespread adoption and do not achieve desired results, as a consequence of not involving end-users in design.

Objective: To describe a case study of a pediatric asthma SDM health IT solution's development and demonstrate a methodology for engaging actual patients and families in IT development. Perspectives are shared from the vantage point of the research team and a parent of a child with asthma, who participated on the development team.

Methods: We adapted user-centric design principles to engage actual users across three main development phases: project initiation, ideation, and usability testing. To facilitate the necessary level of user engagement, our approach included: (1) a Development Workgroup consisting of patients, caregivers, and providers who met regularly with the research team; and (2) "real-world users" consisting of patients, caregivers, and providers recruited from a variety of care locations, including safety-net clinics.

Results: Using this methodology, we successful partnered with asthma patients and families to create an interactive, digital solution called Carolinas Asthma Coach. Carolinas Asthma Coach incorporates SDM principles to elicit patient information, including goals and preferences, and provides health-literate, tailored education with specific guideline-based recommendations for patients and their providers. Of the patients, caregivers, and providers surveyed, 100% (n=60) said they would recommend Carolinas Asthma Coach to a friend or colleague. Qualitative feedback from users provided support for the usability and engaging nature of the app.

Conclusions: This project demonstrates the feasibility and benefits of deploying user-centric design methods that engage real patients and caregivers throughout the health IT design process.

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KEYWORDS

engagement; pediatric asthma; shared decision-making; health information technology

Introduction

Asthma is a highly prevalent, chronic disease with significant morbidity, cost, and disparities in outcomes [1-5]. Despite the availability of effective treatment options, many patients with asthma lack adequate symptom control and almost 50% have symptoms more than once per week [6,7]. Improving patient engagement, self-management, and provider adherence to guideline-based therapy may help improve asthma symptoms [8-10]. One modality associated with improved patient engagement and asthma outcomes is shared decision-making (SDM), which is a process whereby patients and clinicians work together to incorporate evidence, preferences, and values into treatment decisions. Widespread adoption of SDM into practices is challenged by staffing shortages (eg, limited personnel who can assume a health coaching role), staff turnover, and provider time constraints in volume-based reimbursement models [11-13]. These challenges of integrating SDM into everyday practice, as well as personalizing complex asthma guidelines, can both be addressed by leveraging health information technology (IT) applications [14].

A health IT app that enables SDM for pediatric asthma must uniquely deliver an experience that is useful to all end-users: caregivers, patients, and providers. Furthermore, to ensure that an app addresses asthma disparities, it must be designed to be accessible and understandable by populations who have limited health literacy [15,16]. Unfortunately, health IT apps frequently do not achieve desired results as a consequence of inadequately involving this full spectrum of end-users in their designs [16-18]. This absence of end-user involvement is particularly prevalent for those patients with additional barriers to accessing quality medical care, such as the underserved and chronically ill; however, these groups may stand to gain the most from health improvements offered by emerging health IT solutions [19]. Indeed, for health IT to be successful, end-user alignment must begin at project inception by first understanding who the users are, then asking them what they want and need, followed by ongoing testing of a solution's usability and responsiveness to addressing identified needs [20-22].

While there is growing recognition of the need for this level of user engagement in design, there are limited studies demonstrating methods of how to achieve this in health care settings. Moreover, despite the opportunity for health IT to alter the trajectory of health disparities, there is a paucity of research on understanding best practices for engaging underserved patients in the design and implementation of health IT interventions [23].

As we set out to create a digital app for pediatric asthma SDM, we aimed to develop a design process that truly engaged the diverse cast of users involved in caring for a pediatric asthma patient. The interactive digital solution, called Carolinas Asthma Coach, incorporates SDM principles to elicit patient information (including goals and preferences) and provides health-literate, tailored education with specific guideline-based recommendations for patients and their providers. Here we describe the approach used to engage pediatric patients, their caregivers, and their providers, while providing additional perspectives from Beth, a parent who participated on the development team.

Methods

User-Centric Design Approach

We created a process that partnered researchers, IT experts, patients, caregivers, and providers to develop patient- and provider-centered health IT solutions. This approach incorporates user-centric design principles to collaborate with end-users throughout a health IT project's ideation, design, pilot testing, implementation, and evaluation phases (Figure 1). To facilitate this level of engagement and ensure broad representation, we created a Development Workgroup that met regularly with the research team and consisted of seven representative patients, caregivers, and providers who were involved in pediatric asthma care (and who were recruited through existing contacts with the research team). Whenever substantive changes were made to the solution, the research team solicited feedback and approval from this Development Workgroup. Further testing was then performed with "real-world users" consisting of pediatric asthma patients aged 7 to 17 years, their caregivers, and their providers, who were recruited from the health care system's primary care clinics, the Children's Emergency Department, and a Children's Hospital located in Charlotte, North Carolina. A research coordinator located in these various clinical settings used convenience sampling to recruit pediatric patients and their caregivers as they presented for visits related to asthma. To ensure that we adequately addressed health literacy, technical literacy, and social contexts, we intentionally performed preliminary testing work within safety-net clinics.

When developing the Carolinas Asthma Coach, our approach to user-centric design included three phases: *Initiation*, *Ideation*, and *Usability*. First, in the *Initiation Phase*, we gathered information to help understand potential users' needs and barriers using: (1) key informant interviews with providers and caregivers selected by convenience sampling, and (2) reviewed focus group results from previous asthma research conducted in local clinics [24]. This phase was followed by the *Ideation Phase*, in which we engaged the Development Workgroup to conceptualize a virtual tool and possible workflows for asthma SDM [25]. Finally, the project entered the *Usability Phase*, in which we conducted real-world user testing. To allow for iterative development, we solicited this real-world feedback at three distinct time points. First, at the paper prototype stage of the solution, we vetted the script content for tone and meaning with a health literacy consultant, patients, caregivers, and providers. With each iteration, we revised the scripting based on feedback. Second, in the preliminary production stage, we solicited feedback on all critical segments, which included rough cuts combining scripts, illustrations, and animations.

Figure 1. User-centric design process to engage the Development Workgroup and real-world end-users.

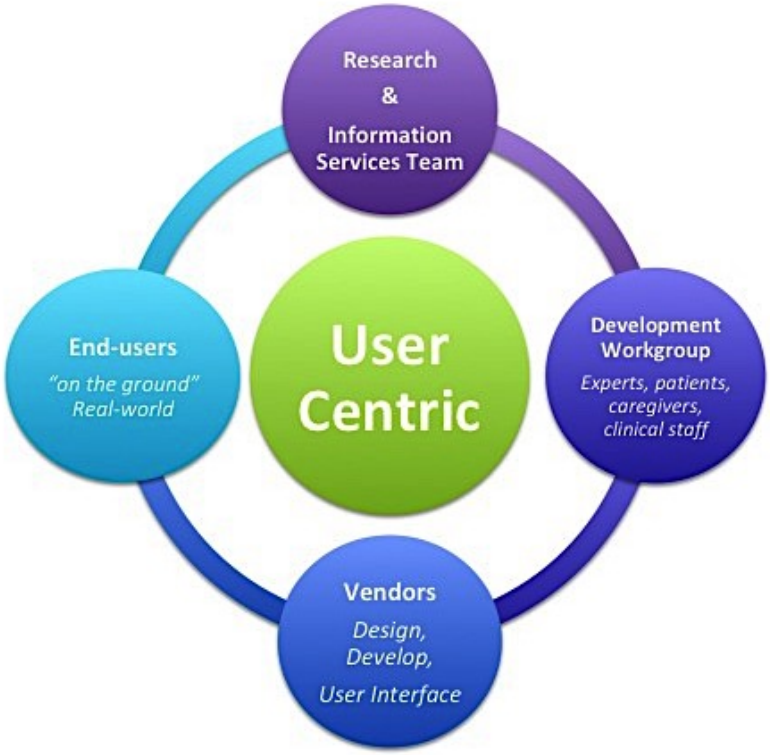
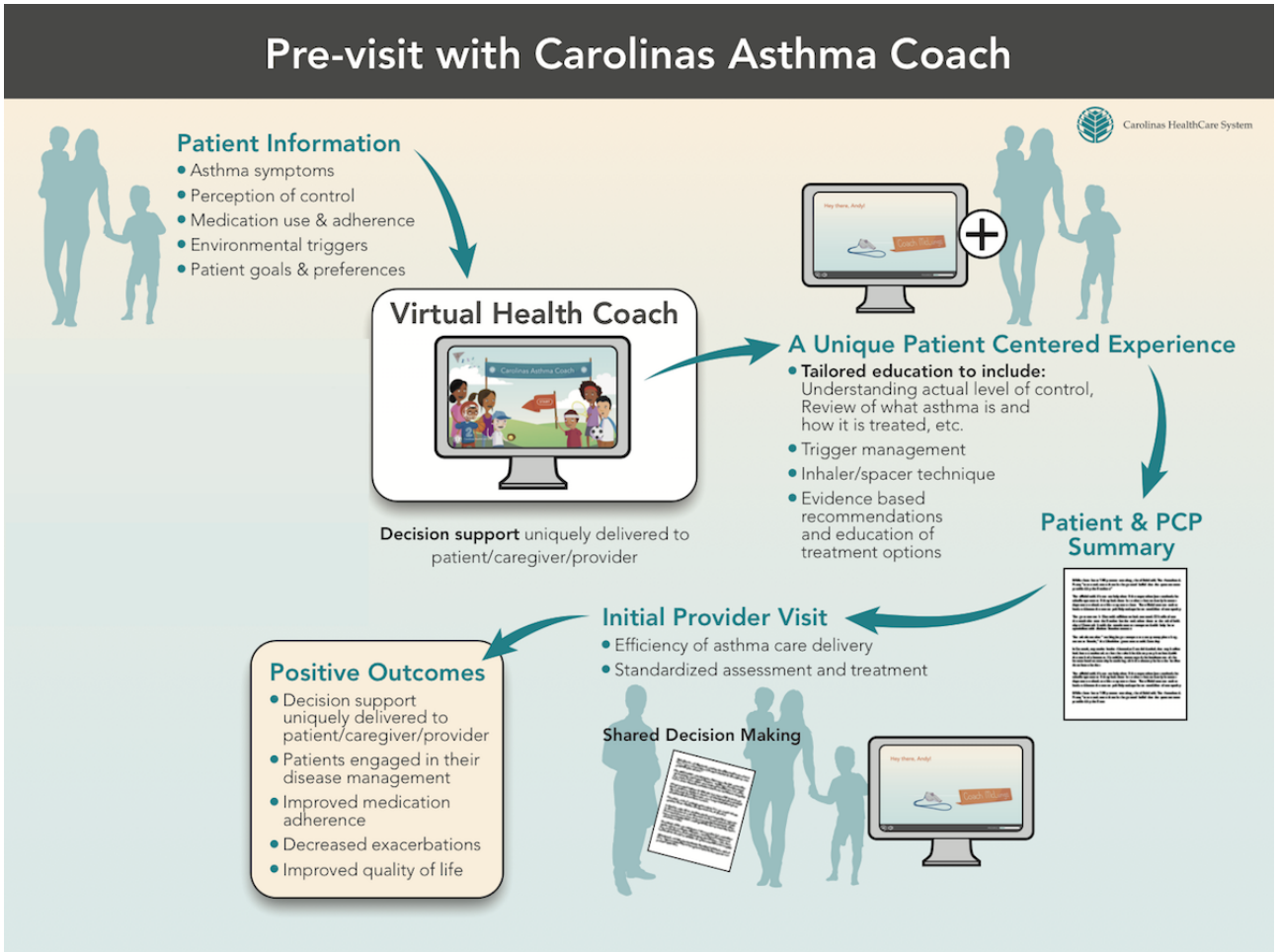


Figure 2. Process diagram for use of Carolinas Asthma Coach in a Primary Care Provider (PCP) visit setting.



Third, with the fully-produced version of the product, we conducted quality assurance testing, while soliciting feedback on both the overall experience and the solutions' summary pages. Furthermore, at this stage we observed patients and caregivers as they interacted with the Asthma Coach prior to an asthma visit with a primary care provider. Following the visit, we conducted in-depth interviews regarding the experience and asked structured questions about satisfaction and likelihood of recommending the intervention.

Intervention Description

Carolinas Asthma Coach is an interactive health IT-enabled solution designed to facilitate SDM, encourage self-management, and drive standardized, evidence-based care. The Asthma Coach is a Web-based app built on a platform that incorporates branching technology to navigate through the HTML5 multi-media experience, which emulates the key humanistic components of in-person health coaching (see Multimedia Appendix 1 for additional information and screenshots). The app incorporates elements of SDM by using a conversational style to: (1) elicit patient information (symptoms, perception of asthma severity or control, medication adherence, triggers, and goals); (2) provide tailored education (asthma background basics, inhaler technique, trigger avoidance); and (3) incorporate motivational interviewing techniques. Additionally, clinical decision support is woven into the conversation through background analytics and logic that allow the Asthma Coach to determine asthma disease severity or control and recommend treatment options, which are individually filtered from up-to-date evidence. Designed to be completed prior to an asthma-specific provider visit, the Asthma Coach sets the stage for SDM, where patients and caregivers are better informed, resulting in a more meaningful and efficient visit with their providers (Figure 2).

Results

Reflection From a Workgroup Participant

The following is a reflection from a parent, Beth, who was a participant in the development workgroup:

> *I am a busy working mother of four children ages 7-23, three of whom have asthma. The three that have asthma are not at all the same. Each child is developmentally different; they are on different medicines, and the things that trigger their asthma are unique. It is difficult to keep all their medications straight and monitor their asthma, but I know each of them, and I know what works well, at least most of the time. I worry about each of them as any mother worries. As they grow and develop, my hope and goal is for them to be able to manage their asthma independently, as they are able. How do I teach them to be advocates for their health? I feel that I can recognize a good pediatrician when he or she walks into the exam room. A good pediatrician talks with my child and me and does not talk at us. When pediatricians ask our opinions, our beliefs, our concerns, and our goals, I know they are going to work with me. I believe that this shared team approach is critical to deciding on the best treatment plan. When I was approached about working on Carolinas Asthma Coach, I was excited about the opportunity to partner and help create a tool that might benefit all children with asthma and will assist parents to become active partners in our children's care.*
>
> *As a parent stakeholder in the design of Carolinas Asthma Coach, I met with the research team often to give my opinions on content, flow, and the approach of the app. I was not only listened to, but my feedback was also incorporated into future iterations of the Asthma Coach. My 16-year-old daughter was asked to test the app. She had been self-sufficient in taking her medication and independently monitoring her asthma. As I watched her answer the questions, I was startled by some of her responses. I thought her asthma was doing well, but as it turns out she had actually been struggling… unable to sleep well or participate fully on her swim team! Her asthma was not well controlled, as I had assumed! Carolinas Asthma Coach's results prompted me to make an appointment with the doctor. She shared with her doctor her challenges and her goal of doing better on the team. We decided together to change her medication. This improved her control and ultimately her endurance on the swim team.*

Example Feedback From Real-World End-Users in the Usability Phase

In the preliminary production stage, examples of user feedback on animations included: (1) the animation of the airways during an exacerbation did not convey the intended depiction of inflammation; (2) animations of children should be doing physical activity, rather than using electronics; (3) an initial theme of mountain climbing did not resonate well with children, who instead suggested a sports theme; and (4) an animated character demonstrating an exacerbation appeared to be in too much distress, invoking a feeling of fear in the user. With each of these examples, improvements were made based on feedback and then tested again with users and the Development Workgroup.

An example of user feedback and resultant changes during the piloting of the fully-produced version of the Carolinas Asthma Coach was that both providers and caregivers reflected that the summary pages were too long and critical information needed more emphasis. Based on this feedback, the summary content was shortened to a concise single page and yellow highlighting was added for critical elements.

When patients, caregivers, and providers were surveyed while testing the fully-produced version, 100% (n=60) said they would recommend Carolinas Asthma Coach to a friend or colleague. Additional comments from patients, caregivers, and providers about their experiences using Carolinas Asthma Coach in the clinic prior to an asthma visit included:

I didn't understand what asthma was before… this (Carolinas Asthma Coach) made it easy to understand. [Parent]

I need to get a spacer because the Asthma Coach said it was important. [Parent]

It (Carolinas Asthma Coach) is friendly and funny. [Pediatric patient]

It helped me to know what questions to ask the doctor. [Pediatric patient]

When we can do this (implement the standardization and efficiency of Carolinas Asthma Coach) it is going to be really big for asthma care. [Provider]

Discussion

Prinicipal Findings

By leveraging the combination of a Development Workgroup and frequent usability testing in real-world clinics, we successfully engaged end-users in the development of a health IT app for pediatric asthma SDM. The approach presented here offers an example of how to incorporate user-centric design methods with an intentional focus on inclusion of vulnerable populations. Regardless of the approach used, these results highlight that it is critical to specifically engage with and address the needs of patients, caregivers, and providers throughout the health IT design process.

While our approach to end-user engagement helped to ensure that we produced a useful product, it was not without challenges. Perhaps the biggest challenge was that this level of engagement and iteration slowed our development down by approximately six months. Efficiency might be improved if more resources were applied to the project; for example, to allow simultaneous patient recruitment at multiple sites.

Second, recruitment of patients and caregivers within real-world clinic settings proved difficult. Issues included: the time commitment involved in usability testing for participants, not disrupting workflows in busy clinical environments, space limitations for testing, and patients who were prescreened but did not show up for appointments. Despite these challenges, the pay-off in terms of the improved usability from this level of engagement was well worth the additional effort and expense.

The following is Beth's thoughts on her role in the development of Carolinas Asthma Coach:

As health care evolves, health IT solutions can help patients and doctors better connect. My role in the development of Carolinas Asthma Coach, I think, helps to demonstrate how these tools can be that much more helpful, when a parent and patient have a hand in creating the solution they will use. My recommendation for health IT is to ensure that the voice of the user is included every step of the way.

Conclusion

This project demonstrates the feasibility and benefits of deploying user-centric design methods that engage real patients and caregivers throughout the health IT design process. Furthermore, Carolinas Asthma Coach provides an example of how this approach can produce a solution that is acceptable and useful for patients, caregivers, and providers.

Acknowledgments

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Authors' Contributions

AM conceptualized the methods and content for this project and drafted the initial manuscript. KR coordinated the project, led all patient and caregiver engagement activities, and reviewed and revised the manuscript. LS assisted with the methodological design, led content development, and reviewed and revised the manuscript. EB provided feedback in product design and content, and reviewed and revised the manuscript. HT, CC, AG, and MFD provided feedback on product design and content, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Shared decision making intervention description: Carolinas Asthma Coach.

[PDF File (Adobe PDF File), 874KB - mhealth_v6i3e68_app1.pdf]

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Abbreviations

IT: information technology
SDM: shared decision-making

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Original Paper

Satisfying Product Features of a Fall Prevention Smartphone App and Potential Users' Willingness to Pay: Web-Based Survey Among Older Adults

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Abstract

Background: Prohibiting falls and fall-related injuries is a major challenge for health care systems worldwide, as a substantial proportion of falls occur in older adults who are previously known to be either frail or at high risk for falls. Hence, preventive measures are needed to educate and minimize the risk for falls rather than just minimize older adults' fall risk. Health apps have the potential to address this problem, as they enable users to self-assess their individual fall risk.

Objective: The objective of this study was to identify product features of a fall prevention smartphone app, which increase or decrease users' satisfaction. In addition, willingness to pay (WTP) was assessed to explore how much revenue such an app could generate.

Methods: A total of 96 participants completed an open self-selected Web-based survey. Participants answered various questions regarding health status, subjective and objective fall risk, and technical readiness. Seventeen predefined product features of a fall prevention smartphone app were evaluated twice: first, according to a functional (product feature is implemented in the app), and subsequently by a dysfunctional (product feature is not implemented in the app) question. On the basis of the combination of answers from these 2 questions, the product feature was assigned to a certain category (must-be, attractive, one-dimensional, indifferent, or questionable product feature). This method is widely used in user-oriented product development and captures users' expectations of a product and how their satisfaction is influenced by the availability of individual product features.

Results: Five product features were identified to increase users' acceptance, including (1) a checklist of typical tripping hazards, (2) an emergency guideline in case of a fall, (3) description of exercises and integrated workout plans that decrease the risk of falling, (4) inclusion of a continuous workout program, and (5) cost coverage by health insurer. Participants' WTP was assessed after all 17 product features were rated and revealed a median monthly payment WTP rate of €5.00 (interquartile range 10.00).

Conclusions: The results show various motivating product features that should be incorporated into a fall prevention smartphone app. Results reveal aspects that fall prevention and intervention designers should keep in mind to encourage individuals to start joining their program and facilitate long-term user engagement, resulting in a greater interest in fall risk prevention.

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KEYWORDS

prevention; cell phone; accidents

Introduction

Background

Falls and fall-related injuries pose a major threat to older adults' health and are associated with increased morbidity and mortality [1-3]. Indication from the literature [4,5] suggests that older adults tend not to be sufficiently aware of their potential for falls or their fall risk. In addition, the literature [6-9] suggests that client outcomes vary with the type of treatment prescribed, the equipment of the clinic, and the health professional's abilities. Hence, preventive measures are important for fall prevention and reduction of associated injuries over time.

One method is enabling older adults to self-assess their possible fall risk and thereby enable them to become aware of their potential fall risk [4,10,11]. A promising attempt is to incorporate health apps in this context, given that the use of health apps is rising among older adults [12-18]. A health app is an unobtrusive way to offer potential support in terms of prevention activities [19-21]. The sensor technology built into smartphones is precise enough to allow extensive data collection to record the user's state of health [14,22,23]. Different research projects have already addressed the topic of fall prevention using varied approaches [14,24]. The FARSEEING project, funded by the European Union (EU), developed a smartphone app to measure users' fall risk based on daily activities as it incorporated an adapted version of the Timed-Up and Go test [14,25]. Users of this product were able to get real-time feedback regarding their individual fall risk. An intervention or decision about treatment was not included in this app. The question on how to decide about the right treatment was investigated by the ProFouND project, also funded by the EU [26]. Within this project, an app for health care professionals was developed, which can help the decision process regarding a certain patient [27]. A different approach was undertaken by the FallCheck project at Coventry University [28]. They developed an app that helps older adults identify typical tripping hazards within their home [24]. The question on how to motivate and instruct physical exercises for older adults in their home was investigated by the iStoppFalls project [29]. This project showed that a continuous exercise plan could decrease older adults' fall risk. Within this project, older adults performed physical exercises on their own. They were instructed and motivated by exergames on a television. The correct performance of the exercises was supervised using information and communication technology such as activity tracker [29].

However, there has been no app that combines these approaches into a single product. To design such a fall app, it is necessary to determine potential users' expectations regarding such a fall prevention smartphone app.

Aim of This Study

This study investigates which product features potential users expect of a fall prevention app and how these features would contribute to users' satisfaction with such an app. A Web-based survey was performed questioning older adults who were not participants in a prior fall prevention–related study conducted by the authors [21,30].

Research Questions

In summary, the main research questions of this study were as follows:

1. Which product features should a fall prevention app have, to increase the likelihood of acceptance by the elderly and consequently reduce the risk of falls in the elderly population?
2. Which product features increase or decrease use of such an app?

This study aims to provide guidance on how to design a user-friendly and acceptable fall prevention app for older adults.

Methods

Design

An open, self-selected, Web-based survey was designed to investigate the research questions. The survey was designed in German and provided for German-speaking Internet users. A Web-based survey was used, given it is a suitable method to reach individuals with particular characteristics or interests in a short period without any limitations on physical space [31,32].

On the basis of research questions, the aim of this survey was to collect data regarding expected product features of a fall prevention app. Expectation was measured using the Kano technique [33]. This is a preference classification technique to identify user requirement and expectation during the early product development stage [34]. Within the health care sector, this technique is not a well studied and less used approach but potentially a suitable one to design health care interventions and services according to users' needs [35-37].

Investigated Product Features of a Fall Prevention App

For this study, features were identified based on literature of former fall prevention projects and expert interviews. These product features are related to 6 different topics, including detection of a fall risk, decision making about a treatment or intervention, comfort functions, advice and support functions, physical exercise advice, and cost coverage by health insurance companies (refer to Table 1).

Detection

Related to the topic detection, 2 product features were identified to be relevant: (1) the automatic detection of the risk of falling through the app during general everyday activities and (2) the detection during the execution of standardized tests. Both product features have already been implemented in the "FARSEEING" project [14,25]. However, it remains to be seen whether potential users prefer continuous data collection in everyday life, based on which a fall risk is determined or whether they prefer to carry out explicit test procedures for detection.

Table 1. Investigated product features of a fall prevention app. C: criteria.

Topic	Description
Detection	
C1	The app recognizes your fall risk based on a standardized test.
C2	The app automatically detects your risk of falling if you carry your smartphone with you.
Decision making	
C3	The app leaves the decision to treat your fall risk to your health care professional.
C4	The app itself decides about the treatment of your fall risk.
Comfort	
C5	In addition to the risk of falling, other health data such as medication can be stored in the app.
C6	You can share the results of your fall evaluation with your health care professional or friends and family by email.
C7	The following treatment appointments can be stored in the app.
Advice and support	
C8	The app contains a checklist of typical tripping hazards.
C9	The app contains a guideline on how to react in the case of a fall for the falling person and the person who is helping.
Physical exercise	
C10	The app includes physical exercises to reduce your risk of falling.
C11	The app includes an ongoing workout program to reduce the risk of falling.
C12	The training integrated into the app is supervised by a therapist.
C13	The training integrated in the app can be adapted to your personal needs (scope of training, exercises, time expenditure, and so on).
C14	Within the integrated training, individual goals can be defined.
C15	New social contacts can be made while using the app.
C16	The training within the app includes playful elements such as awards, rankings, and so on.
Cost coverage	
C17	The costs of the app are covered by the health insurance company.

Decision Making

After the detection of a certain fall risk, the second question is how to manage this risk and which interventions or treatments could be applied [26,27]. Two potential product features were included in the study: (1) a health professional decides on the possible treatment measures based on data collected by the app and (2) the app itself makes a recommendation for the treatment of a possible fall risk. Here too, the question arose as to what would be preferred by potential users.

Comfort

Several product features related to certain comfort of an app were derived from literature. Product features include additional data storage, sharing data, and setting reminder for medical appointments. Mendiola et al identified these features to be valuable features of health apps [19]. Other health apps included such functions to increase users' adherence to the app [38,39].

Advice and Support

Another question within this study was whether potential users would appreciate a checklist of typical tripping hazards as what the FallCHeck website offers [24]. Furthermore, the option of an emergency guideline to guide users' actions after a fall incident was included in this investigation [38].

Physical Exercise

Physical exercise is known to reduce a potential fall risk [4,40-43]. Hence, the integration of physical exercises in the fall prevention app seemed to be an important aspect. In this context, 7 different product features were investigated. First, including physical exercises itself was questioned. Second, participants were asked whether they prefer a continuous exercise plan or not. Third, participants were asked whether they want to have a therapist to oversee their training such as what the Otago program includes [42,43]. It was further questioned whether the training should be adaptable to personal needs as, for example, types of exercise or time spent on training. Whether potential users want to set individual training goals was asked as fifth product feature. This was included as a study by Schlomann et al implicates older adults to exceed their abilities in physical training by missing individual training goals and exercises [44]. Lastly, 2 product features, one regarding making new social contacts and another regarding gamification were included in this investigation as both features were recommended by Mendiola et al to be valued ones in health apps [19].

Cost Coverage

The last product feature investigated was cost coverage by a health insurance company. With this characteristic, it should

be examined whether the general customary assumption of costs by the health insurance company is desired or presupposed in the case of a fall prevention app [45].

Kano Technique

Each of the 17 predefined product features was evaluated twice: first, according to a functional (product feature is implemented in the app), and subsequently by a dysfunctional (product feature is not implemented in the app) question. This technique is based on the Kano model, widely used in the user-oriented product development realm [35-37].

Both types of questions were asked in succession. Five possible answers were available for both questions:

- I would be very happy
- I take that for granted
- I don't care
- I barely accept this
- That would annoy me

Through the combination of answers of functional and dysfunctional questions, the classification of a product feature was derived, as defined earlier in the section [29]. This technique differentiates 7 categories.

- Must-be (M): These product features are taken for granted when fulfilled but result in dissatisfaction if they are not fulfilled.
- One-dimensional (O): These product features result in satisfaction when fulfilled and dissatisfaction when not fulfilled. These are product features that are spoken and the ones in which companies compete.
- Attractive (A): These product features provide satisfaction when achieved fully but do not cause dissatisfaction when not fulfilled. These product features are not expected by a normal customer and thereby have the potential to please the customer.
- Indifferent (I): These product features refer to aspects that are neither good nor bad, and they do not result in either customer satisfaction or customer dissatisfaction.
- Reverse (R): These product features refer to a high degree of achievement, resulting in dissatisfaction and to the fact that not all customers are alike. For example, some customers prefer high-tech products, whereas others prefer the basic model of a product and will be dissatisfied if a product has too many extra features.
- Questionable (Q): Product features in this category should be reviewed. It is most likely that the questions for this product feature were not appropriate for the app of the Kano technique.

Generally, a product feature is assigned to the category most frequently rated [33]. To verify the results of the encoding by the Kano technique, 2 different decision rules are available: (1) category and total strength [46] and (2) the Fong test, if category and total strength led to no clear categorization [47].

Furthermore, customer satisfaction (CS) coefficients were calculated for all investigated products. This coefficient is a measure of whether a product feature can explicitly increase the satisfaction of the potential user or whether the existing product characteristic can only prevent the potential user from being dissatisfied with the overall product [48,49]. According to this definition, the CS coefficient is divided into 2 components. One component has a positive sign and describes whether the satisfaction of the potential user can be increased beyond an expected level by fulfilling the product characteristic (CS+). The second component of the CS coefficient has a negative sign and thus indicates to what extent the satisfaction of the potential user would fall below an expected level if this product characteristic is not taken into account in the overall product (CS−). If the individual component of the CS coefficient (CS+ or CS−) has an absolute value greater than .5, this component and thus the CS coefficient of the associated product characteristic is assumed to be significant [48,49].

Willingness to Pay for a Fall Prevention App

Willingness to pay (WTP) was assessed as monthly payment [50,51]. A potential fall prevention app should be available in the common app stores for users to explore use without having to purchase it (Freemium Business model) [13,50]. Hence, necessary revenues to develop and maintain the app need to be generated afterward, meaning monthly payments by a subscription model or in-app purchases. WTP was studied to explore how much money potential users would spend on in-app purchases so that developers could estimate potential revenues [50]. This topic was addressed after participants rated the 17 product features. Participants were able to enter an amount between 0 and several hundred euros, including 2 decimals.

Characterizing Participants of This Survey

Measuring Health Status

Participants self-reported known medical conditions and chronic diseases. Health competency of participants was measured using an adapted version of the European Health Literacy Scale with 16 items [52]. Corresponding statements were evaluated on a 4-point Likert scale (1=not correct and 4=fully correct). Subsequently, final score was calculated according to Röthlin et al [53]. Final score ranges between 0 points and 16 points, with a high score indicating a high health competency [52].

Quality of life was assessed with the EuroQol Questionnaire (EQ5D-3L) [54], which is a validated tool for measuring general health-related quality of life. It consists of 5 items (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression), each of which is rated as causing "no problems," "some problems," or "extreme problems." The EQ5D-3L thus distinguishes 243 unique health states. Each unique health state has a utility score which lies within a range between 0 (poor health) and 1 (perfect health). This single EQ5D-3L summary index score was used in this study [54].

Measuring Fall Risk

Given that purpose of this study was to investigate the desired functions of a fall prevention app, measurements to access participants' objective and subjective risk of falling were included as measured by the individual's history of falls in the past year [55], the Aachen Falls Prevention Scale (AFPS) [10] and the short Falls Efficacy Scale-International (FES-I) [56].

Objective fall risk was determined retrospectively based on the individual's history of falls in the past year [55]. Using fall risk screening criteria, participants reporting ≥2 noninjury falls in the past year or ≥1 injury fall were categorized as "fallers"; participants reporting no falls were categorized as "nonfallers"; the remaining subjects were defined as indifferent [55,57]. On the basis of the answer whether participants have fallen or not, detailed questions about the falls and their circumstances were asked.

Subjective fall risk was accessed by 2 aspects: the AFPS and the FES-I. The AFPS is a self-assessment test containing 3 steps participants had to perform in this survey [10]. First, participants answered a self-test containing 10 standardized yes or no questions (positive criterion≥5 "Yes"). Questions addressed relevant risk factors derived from several fall risk assessment tools [10]. Second, participants performed a balance test on their own. During this test, participants had to position their feet next to each other and hold this position for at least 10 s without compensatory movement (positive criterion: compensatory movement). In the third and final step, participants rated their "subjective risk of falling" on a 10-point Likert scale based on the results of the first 2 steps. A score of more than 5 points on this scale indicates a certain fall risk (cutoff score >5 points).

The short FES-I questionnaire was used to assess participants' Fear of Falling (FOF) [56,58] to investigate whether certain product features are related to this psychological aspect of patients' fall risk. This questionnaire contains 7 items rated on a 4-point Likert scale (1=not at all concerned to 4=very concerned). The results of all 7 items are added into a final score, ranging from 7 (no concern about falling) to 28 (severe concern about falling) [56].

Measuring Technology Readiness

Technology readiness was included as it might influence the use of modern information and communication technology as well as the engagement with these products [59]. It is calculated based on 12 standardized items which are rated on a 5-point Likert scale (1=not correct and 5=fully correct). For negatively formulated items, the scale is converted so that a high point value corresponds to high technology readiness. Subsequently, final score is calculated by mean value over all 12 items; thus, the score ranges between 1 and 5 points [59].

Measuring Attitude Toward a Fall-Related Intervention

Participants' attitude toward the fictive fall prevention app was accessed using the Attitudes Falls Related Intervention Scale (AFRIS) [60,61]. Hence, it was possible to evaluate whether a participant is generally interested in a fall intervention program or not. The questionnaire consists of 6 items rated on a 7-point Likert scale (1=I totally disagree to 7=I totally agree). The results of all 6 items are summed up to a final score, ranging from 6 points (no intention) to 42points (absolute intention) [60,61].

Questionnaire

The questionnaire started by presenting a short description of the context, followed by demographic questions regarding participants' age, educational level, and health status. Next, the participants performed a self-assessment of their subjective fall risk and their FOF. In addition, participants fulfilled a standardized questionnaire regarding their technological readiness. Then participants evaluated the 17 product features regarding described measurements and entered an amount of money they would spend to use such an app. Finally, participants fulfilled the AFRIS questionnaire measuring whether participant would engage with a prevention program or not.

Data Collection

Data were collected between September 1 and October 31, 2017. The questionnaire was programmed and made available on a website hosted using the Unipark software (QuestBack GmbH, Cologne, Germany) [62]. The survey was introduced as a study examining the desired functions of a fall prevention smartphone app (see Multimedia Appendix 1).

All participants were informed about the duration of the survey, data storage, and the leading investigator. Each participant decided to take part in this survey voluntarily by following the designated link to the survey. A monetary incentive of €3 per participant was offered for participation.

The survey was tested properly by 2 independent examiners with regard to wording and technical functionality. The survey included 63 items, distributed over 16 different pages. Participants were able to review their entries per page before moving on.

Recruitment

Different channels of recruitment were applied to reach a broad range of potential participants in this open survey. It was avoided to address existing users of the Aachen Fall Prevention App or participants of a different fall prevention−related study of the authors as these participants might have a different opinion about the design and necessity of features of a fall prevention smartphone app [21,30]. Further exclusion criteria or screening questionnaires were not applied. The sampling procedure was nonprobabilistic, and respondents were selected based on their voluntary willingness to participate [31].

The Web-based survey was promoted by a Clickworker advertisement, targeting persons aged older than 60 years [63]. This method of recruitment was chosen because this platform offers the possibility of providing monetary incentives. Finally, the link to the open Web-based survey was distributed in a mailing list for elderly who are regularly taking part in studies at the Institute of Industrial Engineering and Ergonomics of RWTH Aachen University, Germany. In all cases, the recruitment was based on the same text as shown in Multimedia Appendix 1.

In total, 157 unique individuals visited the website of the Web-based survey. The identification of different individuals was performed using the Unipark software based on Internet Protocol address and cookie function. Of 157, 49 visitors never started the survey. Nine discontinued completing the survey. In total, 99 visitors finally participated in the survey and completed the whole questionnaire. Three of these were excluded for analysis as attention checkmarks within the questionnaire showed inappropriate data quality. The

participation rate was thus 68.8% (108/157), and the completion rate was 63.1% (99/157). The average duration of completing the survey was 17 min and 12 s, with a median of 15 min and 13 s.

Statistical Analysis

Data were analyzed with SPSS 22 (IBM, USA) and MatlabR2017b (The MathWorks, USA). Investigated product features were assigned to the corresponding category according to the Kano technique. Furthermore, the category strength and total strength of each product feature are provided. In case that applying category and total strength rule resulted in an indifferent categorization, Fong test was performed . In addition, CS coefficients were calculated to analyze and prioritize investigated product features in terms of their contribution to users' satisfaction with a fall prevention app.

Ethics Statement

The Ethics Committee at RWTH Aachen Faculty of Medicine authorized this study and its ethical and legal implications in its statement EK236/16.

Results

Participants

In total, 96 participants took part in this study. The mean age was 63.8 years (SD 7.02), and 51% (49/96) were female. All participants lived autonomously in a flat or house. In all, 29% (19/96) lived together with their family, 56% (54/96) with their marriage partner or companion, and 29% (28/96) lived alone. The level of education varied from minor educational degree to postsecondary degree.

About 78% (75/96) of all participants stated to use a smartphone; however, none of the participants had any experience at all with a smartphone app aiming to prevent falls, and 19% (19/96) stated to already use health apps.

Health Status

About 64% (62/96) of all participants suffered from a chronic disease such as high blood pressure (37%, 36/96), back pain (20%, 20/96), cardiovascular disease (16%, 16/96), or diabetes (12%, 12/96).

Health literacy varied a median score of 15.00 points (interquartile range, IQR 4) on a range from 0 to 16 points, indicating a high qualification and interest in managing personal health.

Median score of quality of life as measured by the EQ5D-3L was 0.716 (IQR 0.365) ranging from 0 to 1 and thereby indicating a good quality of life within the sample.

Fall Risk

Fifty-eight (60%, 58/96) participants stated that they had fallen within the last year. Furthermore, 31 (32%, 31/96) reported to have fallen at least once within the last year, and finally, 7 participants (7%, 7/96) indicated to have fallen between 2 and 3 times within the last year. Seven of these 38 participants, who had fallen, needed to visit the hospital for medical care as a direct result of their fall. Hence, 84 participants (87%, 84/96) were classified as "nonfallers," and 12 participants (12%, 12/96) were classified as "fallers." Fallers are defined as participants reporting ≥2 noninjury falls in the past year or ≥1 injury fall. Main reasons for falling were tripping (26%, 25/96), dizziness (4%, 4/96), and physical weakness (4%, 4/96), whereas combination of reasons are possible as multiple answers were allowed.

For 8 participants (8%, 8/96), the self-test (step 1 of the AFPS: 10 standardized questions, positive criterion ≥5 points) was positive. In contrast, 6 (6%, 6/96) participants did not pass the balance test (step 2 of the AFPS: balance test, positive criterion: compensatory movement). After steps 1 and 2 of the AFPS had been completed, 88 (91%, 88/96) participants estimated their "subjective risk of falling" to be low (≤5 points), and 8 (8%, 8/96) participants rated their "subjective risk of falling" as high (>5 points). The overall median value was 2.0 points (IQR 2.0) on a 10-point Likert scale ranging from 0 to 10 points.

The median FOF was 8.0 points (IQR 2.5) on a scale ranging from 7 to 28 points, suggesting a low FOF.

Technology Readiness

The median technology readiness was 4.0 points (IQR 0.917) on a scale ranging from 1 to 5 points, indicating a high technology readiness.

Attitude Toward a Fall-Related Intervention

Median score for the attitude toward a fall-related intervention was 24.0 points (IQR 9.5) ranging from 6 points (no intention) to 42points (absolute intention), indicating moderate intention to attend a fall intervention program.

Classified Product Features According to Kano Technique

Table 2 presents the investigated product features assigned to the corresponding category according to the Kano technique. Furthermore, the category strength and total strength of each product feature are provided. The Fong test was performed in case that category and total strength rule did not lead to a clear categorization. According to these rules, all product features were valid categorized.

Figure 1 provides CS coefficients for each product feature. Both components of the CS coefficient (CS+) and (CS−) are shown as one bar, whereas darker color indicates (CS+) values.

Willingness to Pay for a Fall Prevention App

One of the last questions asked was how much money participants would spend per month to use a fall prevention smartphone app. Results showed a wide variety ranging from €0 to €80 per month with a median amount to spend €5 per month (IQR 10; see Figure 2).

Table 2. Investigates functions of a fall prevention app and their results. C: criteria. N/A: not applicable. Sig: significant categorization according to Fong test.

Topic	Product feature	Category	Category strength (%)	Total strength (%)	Fong test
Detection					
C1	Fall risk identification by standardized test	Must-be	60.42	95.80	N/A
C2	Automatically identification of fall risk	Must-be	17.71	94.80	
Decision					
C3	Decision about treatment by health care professional	Must-be	82.29	99.00	
C4	Decision about treatment by app	Must-be	50.00	91.70	
Comfort					
C5	Additional data storage	Must-be	46.88	99.00	
C6	Data sharing via email	Must-be	41.67	97.90	
C7	Appointment reminder	Must-be	25.00	97.90	
Advice and support					
C8	Checklist of typical stumbling blocks	Attractive	11.46	99.00	Sig
C9	Guideline in case of a fall incident	Attractive	6.25	97.90	Sig
Physical exercise					
C10	Description of physical exercises to reduce fall risk	Attractive	14.58	100.00	
C11	Continuous workout program	Attractive	18.75	100.00	
C12	Training integrated is supervised by a therapist	Must-be	8.33	100.00	Sig
C13	Individualization of training within app	Must-be	10.42	97.90	Sig
C14	Define individual training goals	Must-be	0.00	97.90	Sig
C15	Make new social contacts	Must-be	33.33	100.00	
C16	Serious gaming elements	Must-be	60.42	97.90	
Cost coverage					
C17	Cost coverage by health insurer	Attractive	33.33	97.90	

Figure 1. Customer satisfaction (CS) coefficients of investigated product features.

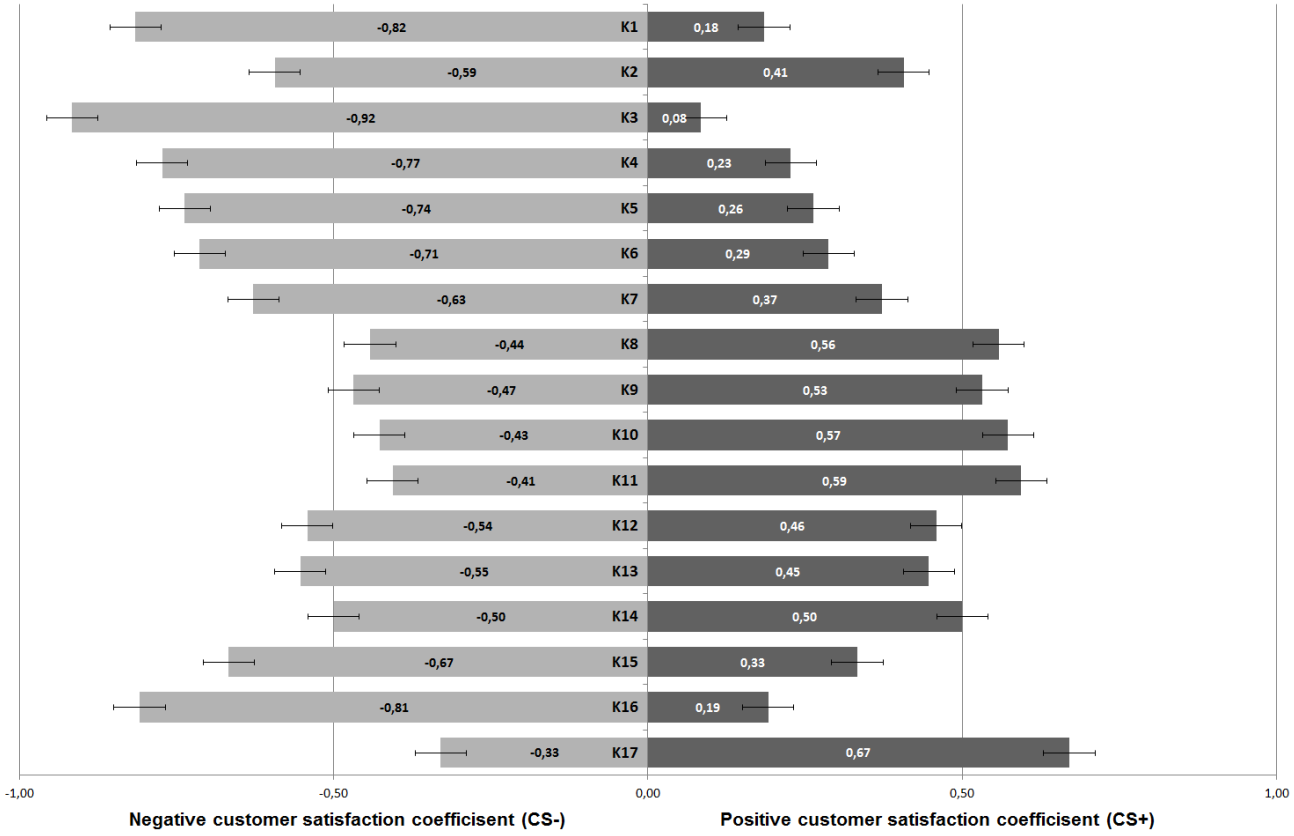
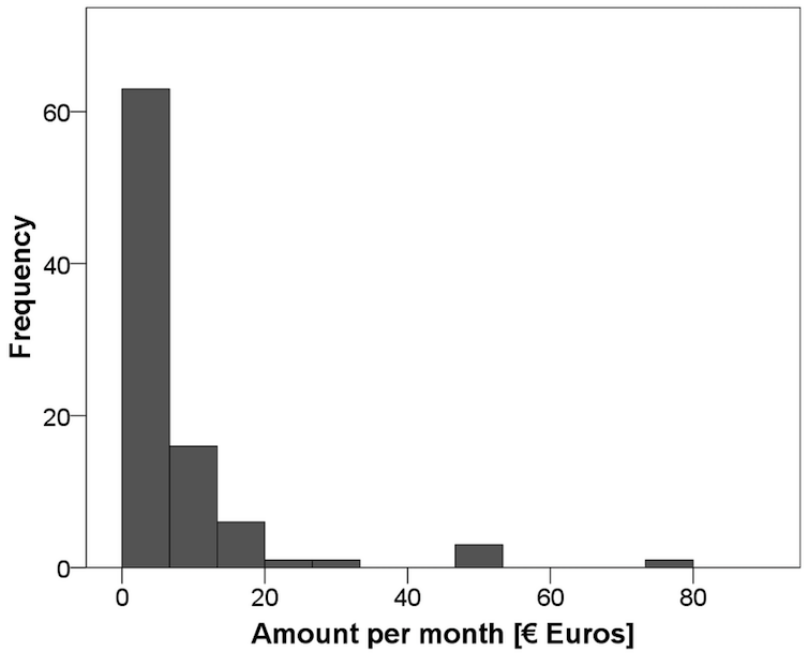


Figure 2. Histogram for the willingness to pay.



Separate univariate one-way analyses of variance (ANOVA) revealed no significant effects of the between-subject factors “age,” “gender,” “education,” “Health Literacy Scale,” “number of chronic diseases,” “faller or nonfaller,” “FES-I,” “technology readiness,” or “attitude toward a fall-related intervention” for the WTP. Separate univariate ANOVAs revealed significant effects for the WTP if the categorization of the product features is treated as between-subject factor. Regarding 4 product features, significant effects were revealed (decision about treatment by app, $F_{2,68}$=3.593, P<.05; description of physical exercises to reduce fall risk, $F_{1,68}$=8.964, P<.05; continuous workout program, $F_{1,68}$=4.87, P<.05; and make new social contacts, $F_{1,68}$=1.124, P<.05). Regarding the feature “decision of treatment by app,” 8 participants categorized this feature as

questionable. Within these 8% (8/96), mean amount spent per month was higher than within the group of participants who categorized this feature as attractive or must-be one. In case of the other 3 features, participants who rated these as attractive ones were also willing to spend a higher median amount of money to use such an app.

Discussion

Principal Findings

In an exploratory approach, requirements were ascertained which may influence users' acceptance of a fall prevention smartphone app. Seventeen product features were rated according to the Kano technique. According to the calculated category and total strengths as well as the Fong tests, all product features have been validly categorized by the Kano technique. In total, 12 must-be product features were identified ranging from "automated detection of a fall risk," over "storing additional medical data" within the app up to "letting a health care professional and the app make decisions about the type of intervention treatment." Five remaining product features were identified as so-called attractive ones. These are features participants do not expect a fall prevention app to have but would be attracted to the app if it would have this function. Product features within this group were mainly related to offering a physical training program via the app, including a personalized workout plan and individual goal setting. In addition, a checklist of typical tripping hazards and an action guide in case a fall occurs were identified as attractive product features.

Detailed analysis using CS coefficient calculations revealed that all except one product feature significantly increased or prevented loss of users' satisfaction. The exception was the product feature "define individual training goals," as this feature showed no significant contribution regarding an extent of satisfaction or dissatisfaction.

Missing fall risk detection, missing consultation of a health care professional regarding the treatment, and missing serious gaming aspects within the app were rated highest among negative CS coefficients and therefore would greatly reduce users' acceptance ($CS_{decision\ by\ health\ care\ professional}=-0.92$, $CS_{detection}=-0.82$, and $CS_{serious\ gaming}=-0.81$). Product features, for example, cost coverage by health insurance companies, a continuous workout plan, and instructions for home-based physical exercises, both aiming to decrease a fall risk, would significantly increase users' acceptance and attraction to a fall prevention smartphone app ($CS_{cost\ coverage}=0.67$, $CS_{workout\ plan}=0.59$, and $CS_{exercise\ instructions}=0.57$).

These results impressively show how difficult it is to design a user-accepted fall prevention app as all suggested product features of a possible app were evaluated as "must-be" or "attractive" product features. Hence, a fall prevention app would need numerous features to be developed and implemented. One reason for the categorization might be that participants had not ever used a fall prevention smartphone app and thereby desired as many features as possible. After their first experience, they might have a more concrete idea of the features they might need. Nevertheless, CS coefficients indicate a clear priority order among investigated must-be and attractive product features. Developers should address the topic of decision making and fall risk detection as well as serious gaming aspects in their potential app. In addition, clear instructions for exercises and workouts that would decrease a fall risk, as well as cost coverage by health insurance companies would increase users' acceptance as well as their attraction to use such an app.

Investigated WTP revealed a median amount of €5 per month (IQR 10) participants would invest to use a smartphone app, incorporating the 17 products features as they rated them. This amount is similar to the average price of paid apps within the Apple App Store and Google Play as measured in 2017 [64].

Different independent ANOVA indicate that participants who rated the features "description of physical exercises to reduce fall risk," "continuous workout program," and "make new social contacts" as attractive ones were willing to pay a higher amount of money to use such an app as participants who did not. Only for the fourth significant product feature (decision about treatment by app) was a reverse correlation identified. Participants who did not rate this feature as an attractive one were willing to pay a higher amount of money. This might be because of the 8% (8/96) of participants who categorized this feature (decision about treatment by app) as questionable. Results show that attractive product features result in a higher WTP. Features such as "description of physical exercises to reduce fall risk," "continuous workout program," and "make new social contacts" would motivate potential users to spend significantly more money for the ability to use a fall prevention app as the other investigated ones.

Comparison With Prior Work

Product Features

The FARSEEING demonstrated the technical possibility of measuring users' fall risk during daily activities by a special device [14,25]. This study could extend this knowledge as it shows that potential users would appreciate an automated fall risk assessment and detection as this would be done by a fall prevention smartphone app. The survey revealed detection of users' potential fall risk to be a must-be product feature, whereas automated detection without performing standardized test as a Timed-Up and Go test would be preferred (product features: criteria (C)1; C2).

An intervention or decision about treatment was not included in the app of the FARSEEING project. Nevertheless, this was considered to be the next mandatory step to design an innovative fall prevention app. Therefore, the product features "decision of treatment by health care professional" (product feature: C3) and "decision of treatment by app" (product feature: C4) were investigated in this survey. Related results show that the decision about a necessary intervention is a must-be product feature, whereas "decision of treatment by health care professional" even reached the highest negative CS coefficient, indicating that missing this feature would reduce potential users' satisfaction significantly. Hence, future research should try to include such options into a fall prevention app. A recent attempt was made by the ProFouND project [26]. Within this project,

an app for health care professionals was developed, which should support them during the decision process about the treatment of a certain patient [27].

Mendiola et al identified in their content analysis 12 features a health app might profit from [19]. In this study, 3 of these 12 features were investigated regarding their relevance for a fall prevention app. In this survey, participants classified product features as additional data storage, data sharing via email, and appointment reminder as must-be features of a fall prevention app. Hence, this survey supports the content analysis of Mendiola et al by empirical data.

Physical exercise is known to be an important factor to reduce a person's fall risk [4,29,40-43]. Therefore, it was part of this study to investigate how a physical exercise program should be designed according to potential users' expectations. The results indicate that participants are aware of the positive effect physical exercise has on a potential fall risk, as all related product features were at least rated as must-be features. Interestingly, a continuous workout program such as the Otago program and the instruction of physical exercises within the app were even classified as attractive features. On the basis of the results from this study, physical exercise interventions within a fall prevention app should be designed as continuous workout programs, which are supervised by a health professional or clinician. Nevertheless, instructions for the exercises themselves should be available within the app; so potential users are able to exercise on their own. Such an exercise program is also expected to support social contact and add an element of fun or be more satisfying as serious gaming elements were classified as must-be features.

These results are similar to the findings of Danbjørg et al [65]. Their study revealed that older adults appreciate a personal therapist as the therapist could motivate them through comments and personal social contact. Furthermore, they did identify "motivation by competition" to be a highly relevant factor to motivate older adults to perform physical activities [65]. The feature of defining individual training goals was rated ambivalent. This result is quite reasonable as a study by Schlomann et al identified diverse acceptance of fixed training goals within fitness apps among older adults [44]. Their study revealed that the elderly try to achieve a socially accepted goal, as it is suggested by a fitness app, even if this is exceeding their physical abilities [44].

Willingness to Pay

Participants' WTP was quite small compared with the expected product features of a fall prevention smartphone app. Cost coverage of a fall prevention app was classified as an attractive feature according to the Kano technique. Comparing measured WTP for fall risk prevention to Alzheimer prevention shows how small the amount of money is that potential patients would invest in a fall prevention service. WTP for an Alzheimer prevention was about $155 per month, whereas a median amount around €5 per month was revealed for a fall risk prevention [66]. Nevertheless, to the best of the authors' knowledge, this is the first survey being able to price a fall prevention smartphone app and therefore is able to support developers in designing an app satisfying users' expectations. Prior studies primarily investigated the clinical costs of fall patients as well as the amount of money saved by different intervention programs [67,68]. On the basis of the results of this survey, researchers, as well as practitioners, can better understand which product features are necessary to design a smartphone app that will be acceptable to potential users and also be cost-effective.

Limitations

This study has several limitations related to its methodological design as well as the reported results. The open Web-based study was not representative because of regional recruiting in Germany via Clickworker. A bias in recruitment might lead to differences in the groups in the accessed fall risk or desired product features of a fall prevention app.

Furthermore, participants' health status and quality of life were good within the sample. Therefore, results might differ with a sample of participants suffering from worse health status or who have poorer quality of life. Just a small portion had already experienced a fall incidence; therefore, rating of product features might change with a sample including individuals with a higher number of experienced fall incidents. Future research might address this topic by in-depth focus groups to design a fall prevention app, especially for already fallen older adults.

Conclusions

Fall incidents are severe problems among the elderly [2]. A major problem in this context is that older adults are unaware of their potential fall risk as it rises slowly [4,5]. It is, therefore, necessary to offer older adults a low-threshold service to assess their own risk of falling. In view of the increasing use of health apps in society and especially in the group of elderly individuals, an app appears to be a useful long-term approach to helping older people to prevent falls [12-16].

The aim of this study was to determine potential product features of a fall prevention app adults aged older than 60 years would appreciate irrespective of whether they already experienced a fall or not.

In an exploratory approach, product features were ascertained that potential users would expect from a fall prevention smartphone app. To the best of the authors' knowledge, this is the first study explicitly investigating this aspect. In total, 17 product features were investigated, which were derived from different recent research projects about fall prevention. Twelve aspects were determined to be "must-be" product features, including unobtrusive fall risk detection, decision making about necessary treatment, and offering physical exercises to reduce the risk of falling. Attractive features of a fall prevention app would include educational features such as a checklist for typical tripping hazards and a guide of action in case of a fall. Hence, the authors are of the opinion that such an app could be successfully adapted within a common app store. This may enable interested older adults to identify, monitor, and treat under the supervision of a health professional their risk of falls, albeit the effectiveness of such an app would need to be evaluated in follow-up research studies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Introduction text of survey (German/English).

[PDF File (Adobe PDF File), 20KB - mhealth_v6i3e75_app1.pdf]

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Abbreviations

AFPS: Aachen Falls Prevention Scale
AFRIS: Attitudes Falls Related Intervention Scale
ANOVA: one-way analyses of variance
EQ5D-3L: EuroQol Questionnaire 3 Level
C: criteria
CS: customer satisfaction coefficient
EU: European Union
FES-I: short Falls Efficacy Scale-International
FOF: fear of falling
IQR: interquartile range
WTP: willingness to pay

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Original Paper

A Mobile App (BEDSide Mobility) to Support Nurses' Tasks at the Patient's Bedside: Usability Study

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Abstract

Background: The introduction of clinical information systems has increased the amount of clinical documentation. Although this documentation generally improves patient safety, it has become a time-consuming task for nurses, which limits their time with the patient. On the basis of a user-centered methodology, we have developed a mobile app named BEDSide Mobility to support nurses in their daily workflow and to facilitate documentation at the bedside.

Objective: The aim of the study was to assess the usability of the BEDSide Mobility app in terms of the navigation and interaction design through usability testing.

Methods: Nurses were asked to complete a scenario reflecting their daily work with patients. Their interactions with the app were captured with eye-tracking glasses and by using the think aloud protocol. After completing the tasks, participants filled out the system usability scale questionnaire. Descriptive statistics were used to summarize task completion rates and the users' performance.

Results: A total of 10 nurses (aged 21-50) participated in the study. Overall, they were satisfied with the navigation, layout, and interaction design of the app, with the exception of one user who was unfamiliar with smartphones. The problems identified were related to the ambiguity of some icons, the navigation logic, and design inconsistency.

Conclusions: Besides the usability issues identified in the app, the participants' results do indicate good usability, high acceptance, and high satisfaction with the developed app. However, the results must be taken with caution because of the poor ecological validity of the experimental setting.

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KEYWORDS

clinical information system; mobile health; usability testing

Introduction

Background

The introduction of clinical information system in hospitals has impacted the workflow of nurses in several ways. Despite positive consequences in terms of patient safety and quality of care [1-3], the use of such systems has also resulted in an increase in the documentation workload with a subsequent shift of nursing activity from the patient bedside to the computer [3-5]. Studies have reported that up to 30% of daily workload was spent on documentation [6]. Until recently, all this clinical documentation was performed on desktop computers, which keeps nurses away from the patient bedside [7], induces

transcription errors [8], and creates a delay in the availability of collected data within the electronic health record (EHR). To some extent, this problem has been addressed with the use of wireless networks and computers on wheels (COWs) [9], but mobility can be further increased by the use of smartphones and mobile apps [10,11].

The transition from a system designed for desktop computer to a small smartphone screen is a complex task. Careful attention must be given to choosing the most useful functionalities of such systems and for the design of the user interface [12]. Otherwise, this transition can easily lead to unexpected failures such as an increased number of input errors [13], loss of data, or decreased efficiency, as well as user frustration, and discontent [14-16].

In this paper, we have presented the usability testing of a mobile app named BEDSide Mobility, which was developed to support nursing workflow at the patient bedside.

The Current Intervention Process

The University Hospitals of Geneva is a consortium of public hospitals in Geneva, Switzerland. It provides primary, secondary, tertiary, and outpatient care for the whole region with 50,000 inpatients and 950,000 outpatient visits a year.

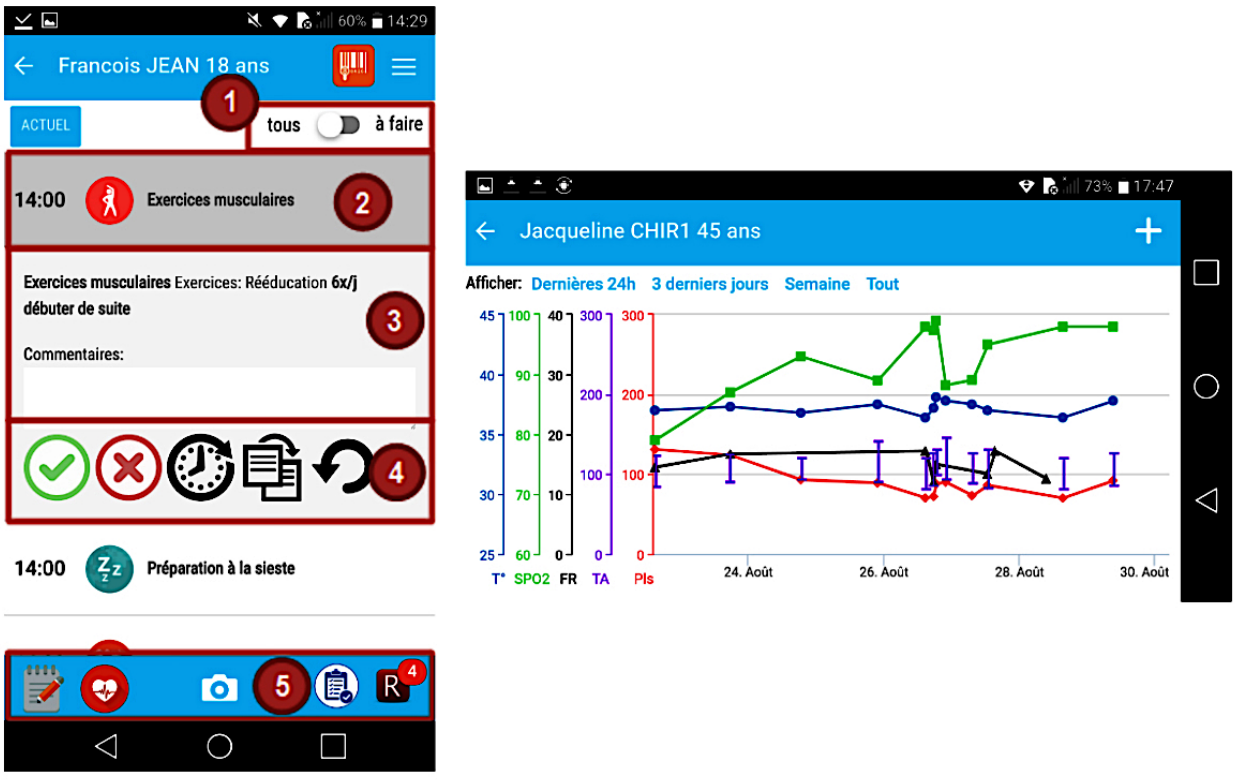
Patient data are managed by a clinical information system (CIS) that possesses most features of modern CIS such as computerized physician order entry, clinical pathways, care management, laboratory, imaging, etc. One of its modules supports the work of nurses by providing a list of their daily tasks. These tasks cover a large range of interventions such as assistance for bathing, drug administration, or wound care. Interventions are planned by nurses, either as a nursing-based task or in response to a physician's prescription. They are defined by several parameters such as their type, date and time of planning, and the start and end dates. The task list module of the CIS allows visualization of a patient's intervention list in several ways such as by shift, by type of task, by room, and by nurse, etc.

There is no clear guidance regarding the way nurses have to manage their list of interventions. However, most of the time, they take a printout of the list of interventions they have to perform during the day at the beginning of their shift. Then, they perform their care following the instructions that are given on the list. Every time nurses perform one of these interventions, they tick the intervention on their printouts, indicating that the task has been completed. At a later time of day, they enter these validations and other gathered information into the CIS. This process has only partly changed even with the implementation of COWs in the wards. Indeed, the COW trolley is not always adapted to the room setting, preventing access to the CIS at the bedside.

The BEDSide Mobility App

The introduction of the BEDSide Mobility app aims at suppressing media disruptions and at enabling the management and documentation of interventions at the patients' bedside [17]. The app was developed based on a user-centered design approach [18]. The iterative development included focus group sessions and informal usability evaluations at different times in the agile development cycle as well as a heuristic evaluation of an advanced version of the prototype. This allowed a continuous improvement of the app.

Figure 1. Main screen and vital sign screen of the BEDSide Mobility app.



The tool supports the entire nurse workflow [19,20]. Nurses start by selecting the rooms and patients under their responsibility during their shift and access their patient's charts either by selecting a ward with a patient list or by scanning a quick response (QR) code on the patient's hospital bracelets with the smartphone camera [21]. In the patient charts, the nurses have access to all the planned interventions (Figure 1). These interventions are presented in chronological order, starting at the current time of app use (Figure 1, point 2). Interventions of similar nature (different types of medication, for example) are grouped together for easier readability. Interventions can be validated with rapid swipe motions but can also be modified, delayed, or repeated (Figure 1, point 4). These functions are often used when documenting in the EHR. Each patient chart also includes administrative patient information (identity, age, length of hospital stay) and clinical data on the current hospitalization such as comorbidities and daily nursing objectives. These components were included to provide support for the handoff process [22-24]. Vital signs and clinical scores can be entered and visualized easily in the app as data entry is directly available from the task list to facilitate usability. Users can also add vital signs and clinical score results through the data visualization screen, even when they are not planned tasks (Figure 1, point 5). The vital signs graph is similar to the EHR graphs for familiarity and easier readability [25,26]. The "pro re nata" (PRN) use medication (or medication "as needed") is available in another part of the app, with indications of prescribed doses and frequencies [27]. It also records when these PRN medications have been administered during the past 24 hours.

Before the usability study, a heuristic evaluation was performed on the app using Neilsen's usability heuristics [28]. The heuristic review identified usability issues such as problems with confusing and unclear labels as well as icons, unexpected behavior, confusing navigation, and consistency issues. Users were not sure where an icon or label would take them and were frustrated by iconography or patterns that did not generate the same behavior in the app. Alternatively, similar tasks required the user to have different input or actions to accomplish them. Remedies addressing these identified usability issues were implemented before the lab tests reported in this paper.

Methods

Study Design

The usability test consisted of a human-computer interaction evaluation, which focused on an outcome quality, user perception, and user performance in the laboratory setting. It consisted of the completion of 10 goal-oriented tasks by targeted end users [29].

The tests were carried out between August 8, 2016 and August 12, 2016 in the Evalab, a medical informatics lab room, which was arranged to simulate a hospital room. It contained a bed with a mannequin that had a patient identification bracelet with a QR code. The tests were run on a Samsung Galaxy Xcover 3 with a 4.5-inch screen size and a resolution of 480 x 800 pixels and an Android OS V4.4.4 (KitKat).

To record the participants' interactions, participants wore eye-tracking glasses (ETG by SMI, sampling rate 30 Hz). Although the glasses are less discreet than peripheral cameras, they have the advantage of allowing us to also see the smartphone screens clearly, rather than just the users' actions. Participants were asked to perform the scenario and tasks, which are described below. To gain a deeper insight into the behavior and the considerations of the users, participants were asked to describe their actions by using the "think aloud" protocol [30].

Scenarios

Two scenarios, a surgical and a medical one, were created and validated by a surgical head nurse, a medical head nurse, and a physician. Both scenarios intended to recreate a realistic situation where nurses would have to use the app to interact with the clinical information system. During these scenarios, the participants had to interact with the app to complete 10 typical tasks reflecting the most frequent actions in the nurses' daily work. This allowed us to validate most of the functionalities of the tool. It is important to highlight that the actions requested by the nurses were strictly limited to the interaction with the app and therefore their completion of a task only required the app. To have a high level of realism and to reflect the actual workflow in the different wards, drug names, dosages, etc, were adapted for surgical and medical unit settings. Although the details of the tasks differed between the scenarios, performing these tasks required the use of the same app functionalities, enabling us to combine the results of the scenarios.

The following list provides an overview of the requested interactions according to the tasks of the surgical and medical scenario:

1. Identification of the patient by scanning the QR code on his bracelet
2. Review of the interventions performed during the night
3. Stating the necessary interventions for the medication rounds (3a); validating the administration of drugs (3b); removing the validation for breakfast (3c)
4. Postponing (4a) and duplication (4b) of an intervention
5. Validating the start of an intravenous (IV) drug (5a), checking the PRN painkillers, administration of a dose of painkiller, and validation of this action in the app (5b)
6. Indication of the elapsed volume for the intravenous drug (6a), documentation of the patient's pain level (6b)
7. Documentation that the patient refused to eat his dinner
8. Completing a Braden scale (8a) and taking a photo (8b)
9. Listing of remaining interventions to be completed before the end of the working shift
10. Validation of all open interventions and log out

Participants

The study participants were recruited in several medical and surgical wards of our hospital. The only inclusion criterion was to have more than 6 months experience (clinical experience and experience with our EHR).

Procedure

The participants were invited to an individual session. After signing the consent form, the participants filled out a short questionnaire about demographics, satisfaction with the CIS, and their familiarity with smartphones and mobile apps. Subsequently, the test manager presented the main functionalities of the tool to the participants in 5 to 10 min. After setting up and calibrating the eye-tracking system, participants began the evaluation. The test manager gave the participants a printout of the scenario with the list of 10 goal-oriented corresponding tasks. The participants were asked to complete the tasks by themselves and to think aloud if possible. The test manager did not offer any help during the task execution. This aimed at minimizing any disruptions of the spontaneous thoughts of the participants as well as to avoid bias on the results.

After completing the goal-oriented tasks, the participants filled out a paper version of the system usability scale questionnaire (SUS). SUS is a standardized and simple tool to get a global view of the participants' subjective assessment of usability based on 10 questions [31]. For this study, a French translation of the original items was used.

Data Analysis

The videos from the test sessions that were created with the ETG were imported into Techsmith Morae. We used mixed methods for the analysis with quantitative analyses of the success rates and task duration and a qualitative analysis of the problems the nurses encountered.

Two independent evaluators analyzed the video recordings for the duration of the tasks. The timer began after the participant read the task instructions and ended when the participant performed the correct action or gave the proper answer to the final task. The reported time was computed as the mean between the two calculations. In case of a disagreement larger than 10%, a third evaluator helped to reach a consensus.

The analysis of the SUS score was conducted according to the scoring strategy of Brooke [31]. The score for each item ranges from 0 to 4. With regard to the positively worded items (1, 3, 5, 7, 9) the score contribution is computed as the scale position minus 1. For the negatively worded items (2, 4, 6, 8, 10), the contribution is computed as 5 minus the scale position. Afterwards, the sum of the scores is multiplied by 2.5 to get the overall value of SUS ranging from 0 to 100 [6].

Results

Participants

In total, 10 nurses participated in the study. Sixty percent (6/10) of the nurses had more than 5 years of professional experience, with the rest (4/10) having between 1 to 5 years of experience. This duration corresponded with their experience with the use of the institutional CIS since it has existed for more than 10 years. Overall, the nurses were satisfied with the CIS. Sixty percent (6/10) indicated that they were very satisfied (20%) or satisfied with the CIS (40%). The remaining 40% (4/10) were rather satisfied with the system. Table 1 provides more detailed descriptions of the participants.

Visual and Interaction Design

The test session for P1 did not record properly and was not included in the video analyses. Therefore, only the data of 9 participants could be analyzed for the goal-oriented tasks. For the analyses, the results of both scenarios were summarized. They are presented in the sequence of the surgical scenario. Figure 2 gives an overview of the success rates for all tasks of the evaluation.

Task 1—Patient Identification

The first task, which was to select the patient by scanning the QR code, was completed successfully by all participants. Two nurses had problems while scanning the code due to the orientation of the camera during the scan. Since this is more a camera usability issue rather than an app issue, we did not code this as a usability issue. Another participant misunderstood the instructions. He initially attempted to select the patient through the manual selection (unit—room—patient) and not with the QR code. After the test manager advised him to reread the task description, he scanned the code without problems. However, before scanning the QR code, he returned to the home screen of the app, even though that function was available on the screen he was on.

Task 2—Interventions Completion Control

The second task was to verify the correct completion of interventions performed during the previous shift. Although all participants managed this task, 3 participants had problems with the use of the "back button" (see Figure 3). Indeed, clicking an intervention opens an accordion that displays advanced interaction options. The participants attempted to close this accordion using the back button, which led them back to the previous screen. Participants then had to rescan the bracelet and therefore took longer to complete the task.

Task 3—Medication Round

The third task consisted of three actions. First, the participants had to identify the interventions associated with the medication round (Task 3a). Then, they had to validate the administration of the drugs in the app (Task 3b). Finally, they had to cancel the validation of a meal intervention that had been previously validated by mistake (Task 3c).

The first subtask (Task 3a) was completed by all nurses without any problems. Two nurses chose a suboptimal approach for the second subtask (Task 3b): although the swiping validation is quicker, a task can also be validated via an icon that appears when clicking on the intervention. The two oldest participants, who also have the least experience with smartphones and mobile apps did not recognize this possibility, yet had no trouble validating via the icon. Three other participants had difficulties with the third subtask (Task 3c). They mixed up the icons for validating an uncompleted task and for undoing the validation of an intervention (see Figure 4). Initially, they clicked on the red icon with the cross, but this validates that the intervention was not completed rather than undoing the validation. One nurse recognized this mistake herself. The other 2 participants only

corrected this error after the test manager asked them whether they were sure about their correct completion of this task. One participant was not able to solve the last subtask at all. First, he unintentionally pressed the home button of the smartphone and closed the app. After opening it again, he could not find an option to remove the validation of the intervention.

Table 1. Demographics of the study participants (n=10).

Characteristics	n (%)
Age	
21-30 years	3 (30)
31-40 years	5 (50)
41-50 years	2 (20)
Gender	
Female	6 (60)
Male	4 (40)
Professional experience	
< than 1 year	0
1-5 years	4 (40)
>than 5 years	6 (60)
Experience with the CIS[a]	
< than 1 year	
1-2 years	3 (30)
>than 2 years	7 (70)
Type of personal smartphone	
iOS	5 (50)
Android	4 (50)
Nokia	1 (10)
Frequency of mobile apps use	
Often (daily)	8 (80)
Regularly (several times per week)	
Sometimes (1 to several times per month)	1 (10)
Rarely (1 to several times per year)	
Never	1 (10)

[a]CIS: clinical information system.

Figure 2. Success rates for task completion (n=9).

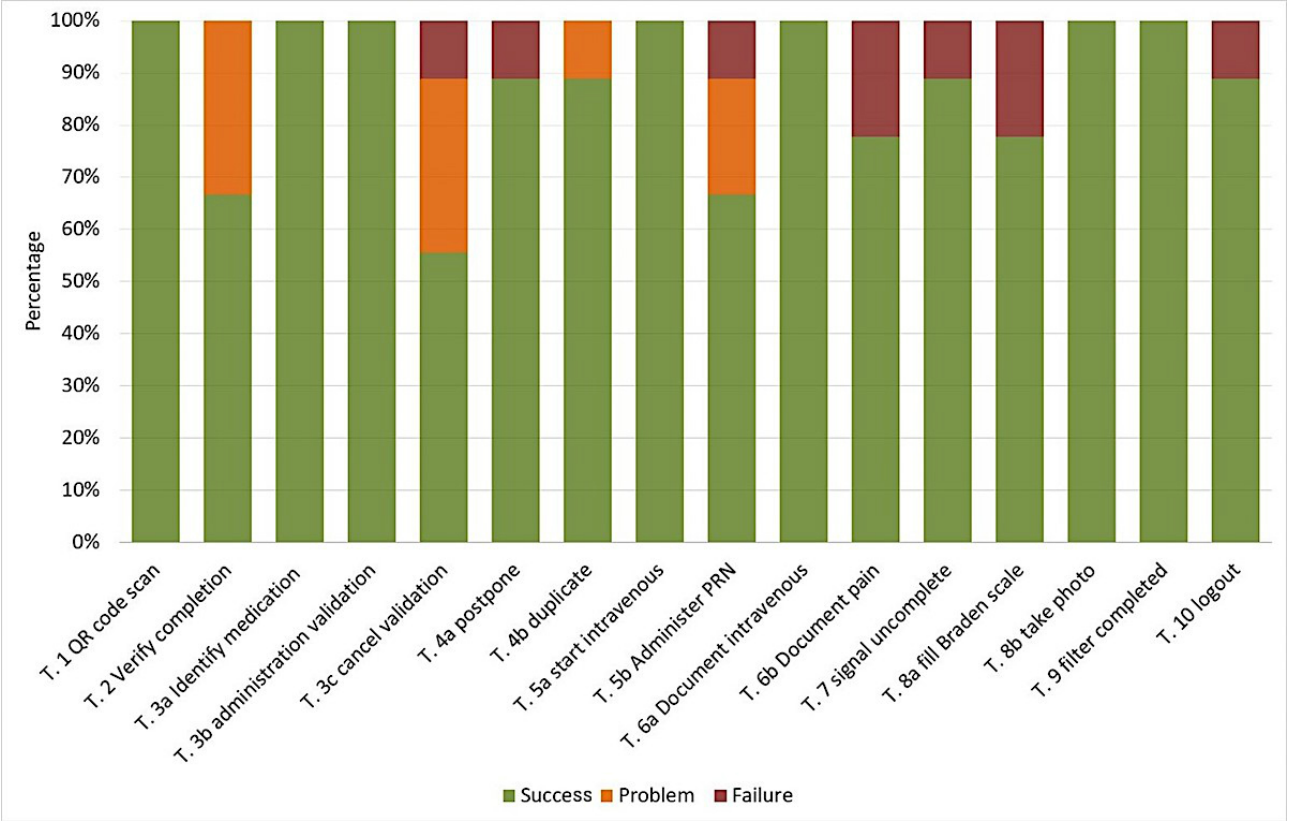


Figure 3. Problem related to use of back button. Whereas an opened intervention is closed by clicking on it again, many users used the back button and returned on the previous screen (patient selection screen).

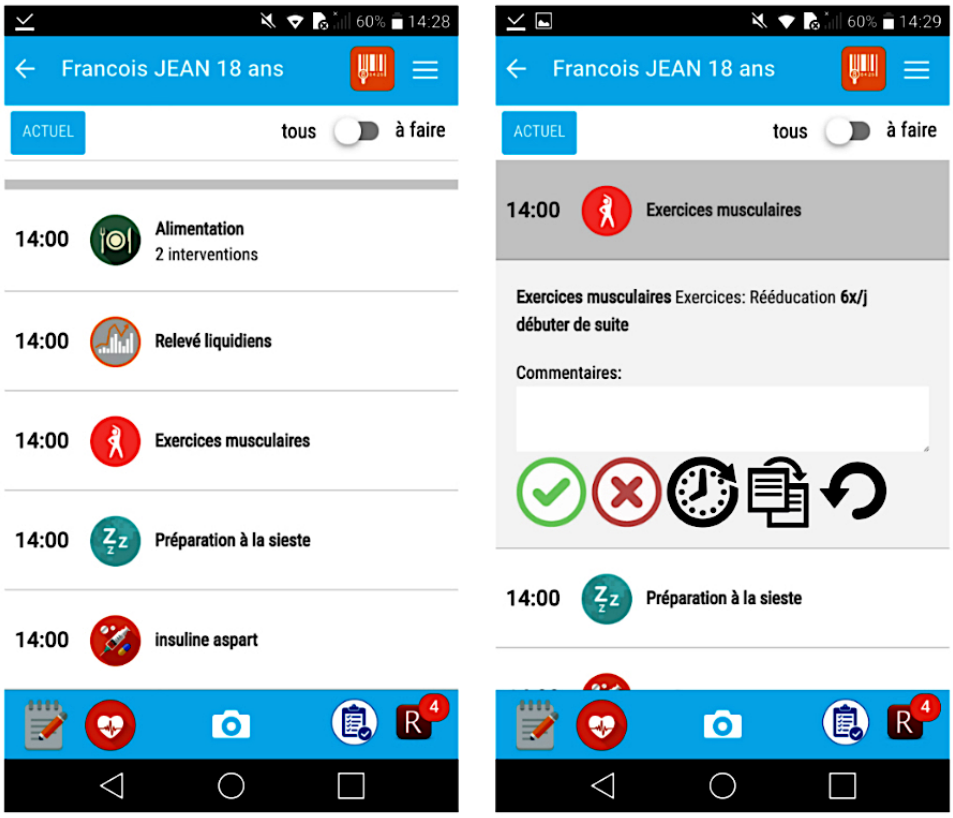


Figure 4. Problem with distinction of icons. The red "X" button is used to document an incomplete intervention and the "rounded arrow" button is used to undo the validation of a task.

Task 4—Postponing and Duplication

All nurses except one managed to postpone (Task 4a) and to duplicate (Task 4b) an intervention requested in Task 4. Instead of postponing the intervention, the nurse made a copy of the intervention. Another user navigated out of the patient chart after clicking on the wrong button (see descriptions of results for Task 1). But after reopening the patient data, he performed all subtasks without problems.

Task 5—PRN Medication

To complete Task 5, nurses had to begin an intravenous medication for the patient and document in the app (Task 5a). Furthermore, as described in the scenario, the patient complained of pain during the administration. The nurse was then supposed to look up which PRN painkiller the patient had before administering a dose of that drug and validating this action (Task 5b). Three participants had problems with the completion of this task. Contrary to the interventions that had to be validated in Task 3, the administration of a PRN medication can only be validated via the swipe gesture (clicking on an entry opens the history of administration; see Figure 5). One nurse was not able to validate the drug administration at all. The other 2 participants needed more time to find this solution. However, the participants facing difficulties with this task were the same as those who did not use the swiping validation for the completion of Task 3.

Task 6—Documentation of Pain Level

Task 6 was related to the previous one. After documenting the PRN painkiller (Task 6a), the participant was asked to document the pain level in the app (Task 6b). Two participants were not able to complete the second subtask. This action is accessible via an icon ("clinical scale") in the footer bar of the app. However, those nurses were not able to link this icon with the associated functionality (see Figure 4, second icon from right).

Task 7—Documentation of Uncompleted Intervention

Task 7 was performed successfully by all nurses except for one. He did not understand that intervention could be flagged as incomplete. Instead, he validated the intervention as done and entered a free-text comment indicating that intervention was incomplete because the patient refused to eat.

Task 8—Braden Scale and Photo

For Task 8, participants were asked to take a photo of a red lesion on the patient's elbow (Task 8a) and to fill out a Braden scale (Task 8b) to report the risk of pressure ulcers. This scale was accessible through the same icon used for the documentation of the pain level for Task 6. All participants were able to take the photo without difficulties. However, the 2 users who did not manage to document the pain level did not succeed to document the Braden scale either.

Figure 5. Problem with administration/validation of drugs from reserve.

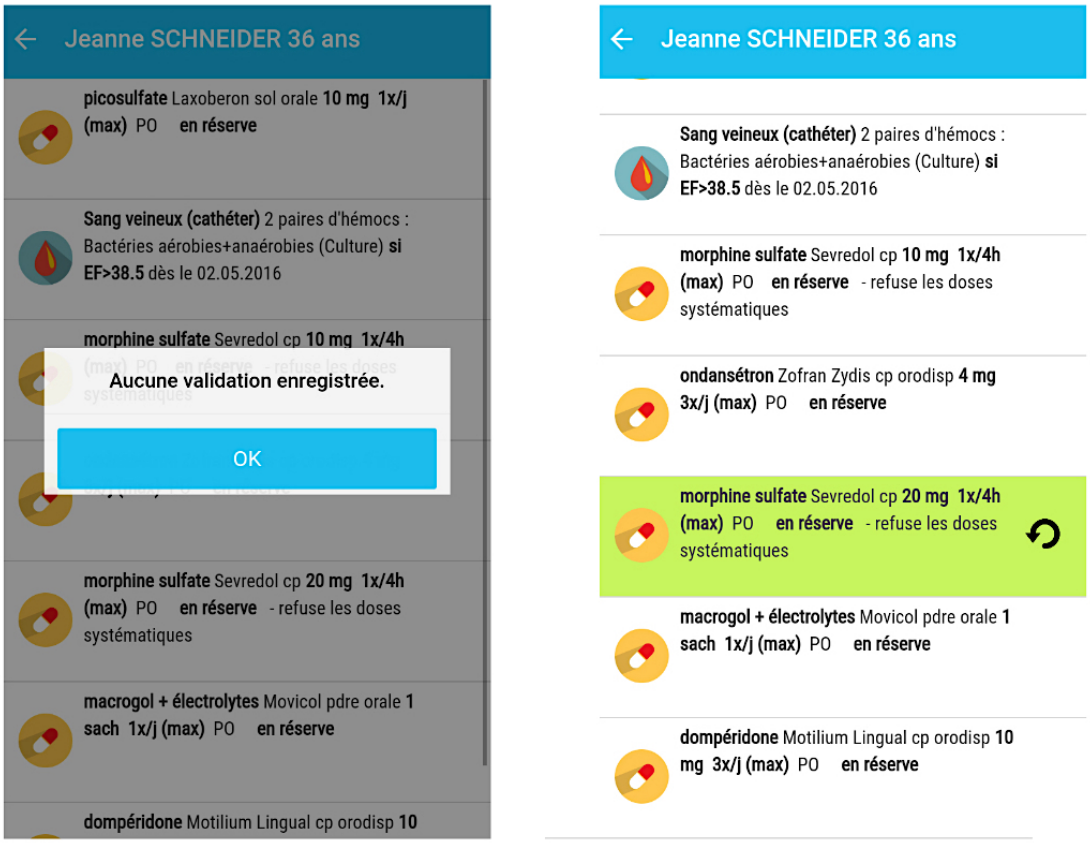


Table 2. Task completion by participants (S=Success, P=Problem, F=Failure).

Tasks	P2	P3	P4	P5	P6	P7	P8	P9	P10	%S	Nb P	Nb F
1. Patient Identification	S	S	S	S	S	S	S	S	S	100	0	0
2. Reading interventions	P	S	P	S	P	S	S	S	S	67	3	0
3A. List drug interventions	S	S	S	S	S	S	S	S	S	100	0	0
3B. Validate drug interventions	S	S	S	S	S	S	S	S	S	100	0	0
3C. Cancel intervention	S	S	S	P	P	P	F	S	S	56	3	1
4A. Postponing	S	S	S	S	S	S	F	S	S	89	0	1
4B. duplication	S	S	P	S	S	S	S	S	S	89	0	0
5A. Starting infusion intervention	S	S	S	S	S	S	S	S	S	100	0	0
5B. Reserve administration	P	S	S	F	S	S	F	S	S	67	2	1
6A. Ending infusion intervention	S	S	S	S	S	S	S	S	S	100	0	0
6B. Documentation of pain level	S	F	S	S	S	S	F	S	S	78	0	2
7. Signal incomplete	S	S	S	S	S	S	F	S	S	89	0	1
8A. Fill Braden scale	S	F	S	S	S	S	F	S	S	78	0	2
8B. Take a photo	S	S	S	S	S	S	S	S	S	100	0	0
9. Filtering interventions	S	S	S	S	S	S	S	S	S	100	0	0
10. Log out	S	S	S	S	S	S	F	S	S	89	0	1
Task success rate (%S)	88	88	88	88	88	94	56	100	100			
Total problem (Nb P)	2	0	2	1	2	2	0	0	0			
Total failure (Nb F)	0	2	0	1	0	0	7	0	0			
IOS (I), Android (A), Nokia (N)	I	I	A	I	A	I	A	A	N			

Task 9—Filtering Interventions

Task 9 was to filter the completed interventions, keeping only the pending tasks visible during their work shift. This task was completed successfully by all participants.

Task 10—Validation of Open Interventions and Logout

The last task of the test was to perform a logout. All except one participant managed through this task. He unintentionally clicked on the "back" icon and was dropped out of the patient screen. He did not try to disconnect after that. Instead, he gave feedback about the design of several icons, which were not clear for him.

Table 2 provides an overview of the success rates of the individual participants for the different tasks. "S" (success) means that the user solved the task easily. "P" (problem) indicates that the user had a problem but finally managed to complete the task. "F" (failure) indicates uncompleted tasks.

Time on Task

The 2 evaluators differed on their measurement of duration for more than 10% on 25.7% (37/144) of the observations. The inter-rater agreement was high with a score of 0.976 obtained using the Krippendorff alpha test.

Regarding the time spent on the different task, we observed (Figure 6) that Task 2, which was requesting to review the completion of previous interventions, took the longest time with a mean of 94.4 s. Task 8a, which consisted of completing the Braden scale, also took a long time, with an average of 72.1s. Finally, Task 4b regarding duplication took a very long time for participant 4 because he first postponed the task instead of duplicating it.

Perceived Usability and Satisfaction

The results of the SUS score are displayed in Table 3.

As visible in Table 3, the app was rated with a mean average score of 76.3 (SD 16.75). According to Bangor et al (2009), a mean SUS score of 71.4 or higher can be interpreted as good [32]. Sixty percent (6/10) of our participants rated the BEDSide Mobility app as good, 20% (2/10) assessed it as excellent, and only 20% (2/10) rated it as okay (10%, 1/10) or poor (10%, 1/10). The adjective rating of the app is shown in Figure 7.

Forty percent of the participants completed all tasks without any problem. Thirty percent of participants had difficulties with one subtask but were finally able to accomplish all tasks. Only 2 users (P3 and P8) had problems with more than one task. In the SUS score, participants rated the app as good usability overall. It is not surprising that the participants who gave the lowest SUS ratings (P8 and P10) also had the most difficulties during the goal-oriented tasks.

Tasks 6b and 8a (Braden scale and pain level scale) both required accessing the clinical scale screen via an icon on the foot menu of the app and was not completed by P3 and P8. Either the icon used to represent this function was not comprehensible for some participants, such as P3, or the participants' mental models for documentation did not correlate well with the design of the app.

The most difficult tasks for the participants were Tasks 2 (review interventions), 3c (cancel intervention) and 5b (validate PRN medications). The issue with Task 2 was related to the navigation in the app—clicking on the intervention opens an accordion to see advanced functions and details. Users tended to click the back button to close the accordion, but it actually led them back to the previous page.

Figure 6. Boxplot of time spent on each tasks.

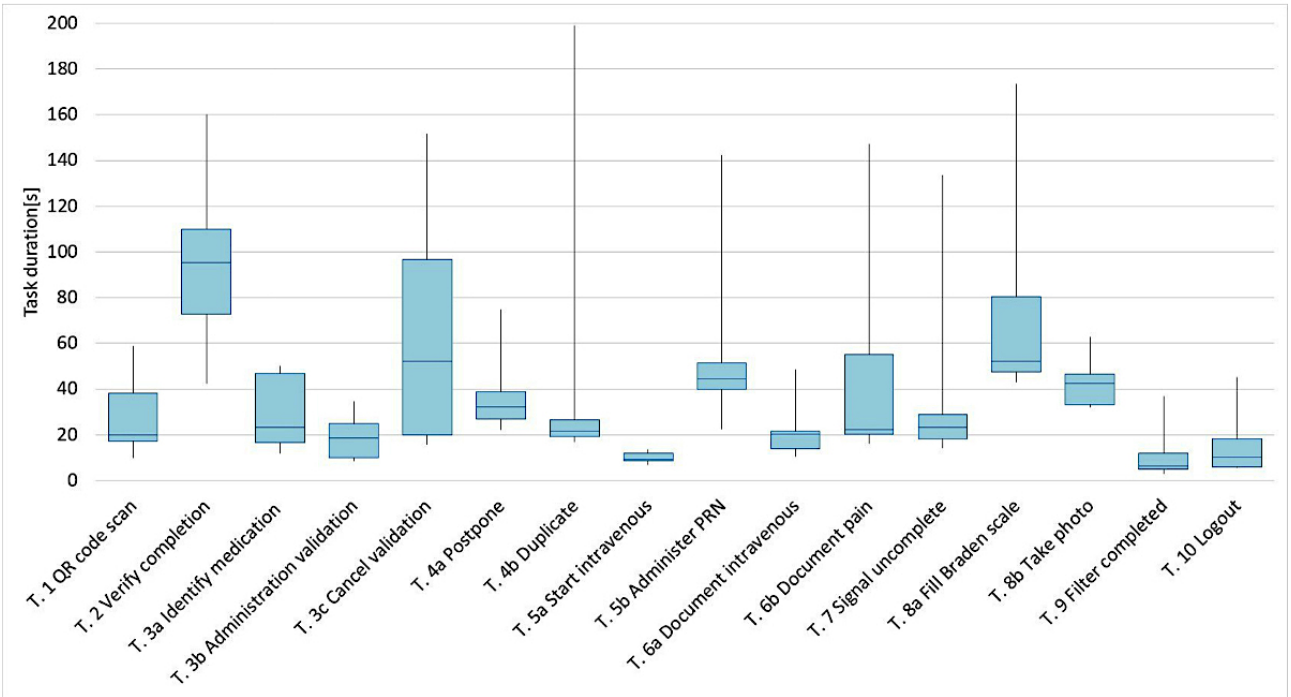


Table 3. Results of System Usability Scale (SUS).

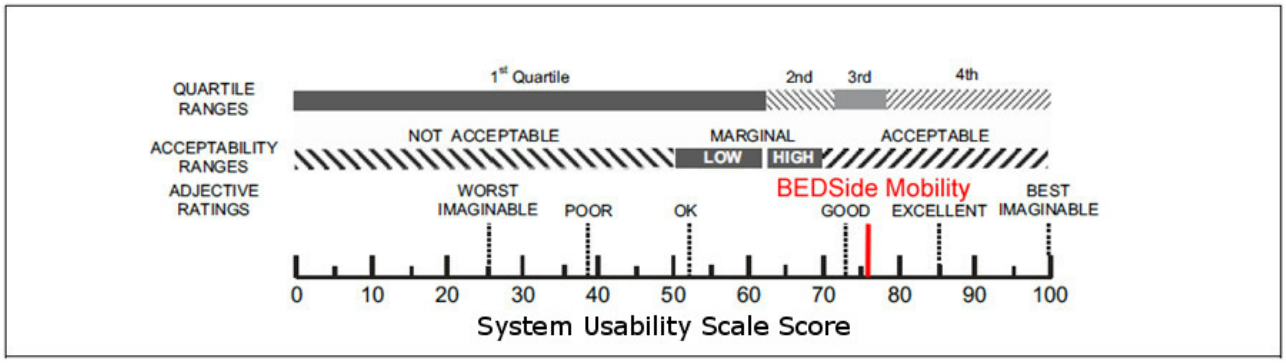
Questions	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	Average	Mean
1. I think that I would like to use this system frequently	3	4	3	3	4	1	2	2	4	2	2.8	3.0
2. I found the system unnecessarily complex	4	4	4	2	4	4	2	2	4	3	3.3	4.0
3. I thought the system was easy to use	4	4	3	3	4	3	4	2	4	2	3.3	3.5
4. I think that I would need the support of a technical person to be able to use this system	4	1	3	3	4	4	4	1	4	3	3.1	3.5
5. I found the various functions in this system were well integrated	3	2	3	3	3	4	1	1	4	2	2.6	3.0
6. I thought there was too much inconsistency in this system	3	4	4	3	4	4	2	1	4	4	3.3	4.0
7. I would imagine that most nurses would learn to use this system very quickly	2	3	2	4	2	0	4	1	3	3	2.4	2.5
8. I found the system very cumbersome to use	3	4	4	3	4	4	4	0	4	3	3.3	4.0
9. I felt very confident using the system	4	3	2	3	4	2	2	2	3	2	2.7	2.5
10. I needed to learn a lot of things before I could get going with this system	4	4	3	3	4	4	4	2	4	3	3.5	4.0
SUS-score (sum × 2.5) [maximum 100]	85.0	82.5	77.5	75.0	92.5	75.0	72.5	35.0	95.0	67.5	75.8	76.3

Table 4. Identified shortcomings and correction measures.

Identified shortcomings	Correction measures
Miscomprehension of the clinical scale icon	Identification with the users of a more appropriate icon to represent clinical scale
Unexpected navigation of the back button when an intervention is open	Modification of the navigation mechanism by closing the intervention when opened rather than returning to the previous page
Canceling the validation of an intervention	Improved explanations before app use can help avoid this confusion
Inconsistent implementation of the functional design validating the administration of a PRN[a] drug	Integration of similar validation mechanism to administer PRN drug using consistent icons

[a]PRN: pro re nata.

Figure 7. Adjective rating of BEDSide Mobility app.



One participant remarked:

> *In fact, the mistake is that I clicked there to go back [the user points to the arrow icon (back button)]. You just have to click above.* [P4]

Overall, the evaluation results and SUS scores show that the tested prototype of the app already has a good usability. Correction measures were identified to address the shortcomings (Table 4). These correction measures did not only involve modifying the interface but also have implications for the deployment and user training at that time.

Discussion

Principal Findings

The purpose of this study was to assess the usability of the BEDSide Mobility app, which can inform the development of similar tools in other settings. A previous study utilized a

heuristic review to identify usability issues before this user study, which were then subsequently fixed. This study is aimed at identifying further issues, as users may have unexpected issues or problems that were not anticipated by the designers of the app.

While participants rated the app as having good usability overall, there are some issues that can be fixed to improve the experience for users and hopefully help a greater number of users complete their specified tasks smoothly. The participant who gave the lowest SUS score had the most difficulty completing the tasks and also happened to be the oldest participant in the study (P8). This participant also reported a low use of mobile apps outside the study, suggesting that it was probable that the failure of task completion was partly due to a lack of familiarity with mobile apps, complaining that:

It's the app that is not logical. It is not logical.

This participant also gave a much lower rating of the app with SUS than all others (see Table 3).

Such reactions suggest that designers should take into consideration the wide variance of people who could be using the app, from people who have a high familiarity with mobile app conventions and use to those who have very little familiarity with technology and mobile app conventions. These two populations are often correlated, with older adults showing lower mobile adoption than younger adults. This observed resistance is also in line with previous findings in the literature, which show that low familiarity with computer and older age are barriers to the adoption of new technologies [33]. As such, if the said population constitutes a sizable amount of the users that may use any future apps, extra care should go into education and easy learnability of the app by both tutorials and best practices, depending on the makeup of the potential users.

Some participants had issues linking functionality to certain iconography within the app. For example, one-third of the (n=3) participants had problems with distinguishing the icons related to tagging an intervention as incomplete versus undoing a validation of an intervention. Also, a number of associated participants had trouble identifying the icon that would allow data collection via a clinical scale. If designers wish to maximize the number of users who can easily pick up the app and use, iconography should be tested with the target population. However, some more complex workflows may not be able to work only with icons, and text labels could greatly improve the ease of use of the app. Alternative methods could include education or a quick tutorial to see whether the icon makes sense after pointing out the functionality behind it.

Having an easy undo to actions could also encourage users to explore the interface more since they know there would be a quick way to undo any action if they take the wrong action. We recommend implementing such functionality so that users are encouraged to use the app with minimal chance for permanent errors.

The consistency of actions design is also an important way to keep users happy with the workflow. For example, issues with Task 5b were caused by an inconsistent implementation of the functional design. In general, all interventions in the app can either be validated by using a specific icon or by a swiping gesture. However, validating the administration of a PRN drug is only possible by swiping since there is no icon in that dialog. By changing the actions available, participants had issues completing the task. Future designers should clearly identify what functionality and interface actions they wish to support and keep it consistent throughout the whole app to facilitate ease of task completion.

Our findings are consistent with existing guidelines, previous studies, and recommendations. For example, previous guidelines recommend allowing user control and freedom with easy undo, to have consistency and standards, and have users use recognition rather than recall in the interface to minimize memory load. While these guidelines are a great place to start, for maximum use and usability, extensive user testing should take place throughout the design process to make sure that the app will match user's mental model and to have them use an easy, intuitive app that meets their needs.

Limitations

With regard to the results of the study, two main limitations have to be noted. On the one hand, a sample of 10 nurses may be insufficient to reveal all usability issues. However, previous works with 9 to 10 participants have shown good cost efficiency and should allow most of the usability problems to be identified [7,8,34]. On the other hand, we used an artificial lab environment, which has a low degree of fidelity. We simulated the patient with a static mannequin, and the environmental influences such as noise, interruptions from patients or other colleagues, etc, have been eliminated. Therefore, the generalizability and transferability of the results may be limited in a real setting.

Conclusions

This study aimed to assess the usability and the suitability of the BEDSide Mobility app to facilitate the caregivers' workflow at the patient's bedside. Our study identified several usability flaws. Among them, the navigation incoherence, in particular, was cumbersome during use and should be corrected in priority. Some inconsistencies in the design were barriers to the successful completion of some tasks. Other problems were linked to the lack of clarity of some icons and their associated functionalities. This can be improved by choosing better signalization. If the interface can be improved to mitigate some issues, appropriate training, and deployment measures should also be implemented to avoid misuse of the app. It was reassuring that no data entry problems occurred during our study, as this can be an important source of errors.

Besides the problems identified, the results indicate a good usability, a satisfactory acceptance, and satisfaction of the participants with the developed app. This tends to demonstrate the relevance of our end user-centered approach in the development of tools dedicated for care providers. Indeed, end users were involved in formative evaluation rounds throughout the specification and development phase to minimize the gap between their requirements and the actual realization.

Finally, it is important to recognize that the ecological validity of the experimental setting was quite low. Therefore, additional

usability flaws may occur when the tool is used in the real setting. This study is a part of a more global assessment of the efficiency of the app that will be tested in a real setting.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CIS: clinical information system
COWs: computers on wheels
EHR: electronic health record
F: failure
P: problem
PRN: pro re nata
QR: quick response
S: success
SUS: System Usability Scale

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Original Paper

An mHealth Pain Coping Skills Training Intervention for Hematopoietic Stem Cell Transplantation Patients: Development and Pilot Randomized Controlled Trial

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Abstract

Background: Pain is a challenge for patients following hematopoietic stem cell transplantation (HCT).

Objective: This study aimed to develop and test the feasibility, acceptability, and initial efficacy of a Web-based mobile pain coping skills training (mPCST) protocol designed to address the needs of HCT patients.

Methods: Participants had undergone HCT and reported pain following transplant (N=68). To guide intervention development, qualitative data were collected from focus group participants (n=25) and participants who completed user testing (n=7). After their input was integrated into the mPCST intervention, a pilot randomized controlled trial (RCT, n=36) was conducted to examine the feasibility, acceptability, and initial efficacy of the intervention. Measures of acceptability, pain severity, pain disability, pain self-efficacy, fatigue, and physical disability (self-report and 2-min walk test [2MWT]) were collected.

Results: Participants in the focus groups and user testing provided qualitative data that were used to iteratively refine the mPCST protocol. Focus group qualitative data included participants' experiences with pain following transplant, perspectives on ways to cope with pain, and suggestions for pain management for other HCT patients. User testing participants provided feedback on the HCT protocol and information on the use of videoconferencing. The final version of the mPCST intervention was designed to bridge the intensive outpatient (1 in-person session) and home settings (5 videoconferencing sessions). A key component of the intervention was a website that provided personalized messages based on daily assessments of pain and activity. The website also provided intervention materials (ie, electronic handouts, short videos, and audio files). The intervention content included pain coping advice from other transplant patients and instructions on how to apply pain coping skills while engaging in meaningful and leisure activities. In the RCT phase of this research, HCT patients (n=36) were randomized to receive the mPCST intervention or to proceed with the treatment as usual. Results revealed that the mPCST participants completed an average of 5 out of 6 sessions. The participants reported that the intervention was highly acceptable (mean 3/4), and they found the sessions to be helpful (mean 8/10) and easy to understand (mean 7/7). The mPCST participants demonstrated significant improvements in pre- to post-treatment pain, self-efficacy (P=.03, d=0.61), and on the 2MWT (P=.03, d=0.66), whereas the patients in the treatment-as-usual group did not report any such improvements. Significant changes in pain disability and fatigue were found in

both groups (multiple $P<.02$); the magnitudes of the effect sizes were larger for the mPCST group than for the control group (pain disability: $d=0.79$ vs 0.69; fatigue: $d=0.94$ vs 0.81). There were no significant changes in pain severity in either group.

Conclusions: Using focus groups and user testing, we developed an mPCST protocol that was feasible, acceptable, and beneficial for HCT patients with pain.

Trial Registration: ClinicalTrials.gov NCT01984671; https://clinicaltrials.gov/ct2/show/NCT01984671 (Archived by WebCite at http://www.webcitation.org/6xbpx3clZ)

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KEYWORDS

stem cell transplantation; hematopoietic stem cell; cancer-related pain; coping skills

Introduction

Background

Persistent pain is a major challenge for patients following hematopoietic stem cell transplantation (HCT) [1-5]. This pain can be related to diverse sources including patients' disease, treatment regimens, medications, or pre-existing conditions [1]. HCT patients may experience multiple sources of pain including joint, bone, headache, mouth, gastro-intestinal, neuropathic, and thoracic pain [1,6]. Moderate to severe pain has been reported by 30-58% of HCT patients [4,5,7,8]. Pain occurs before, acutely following, and in the months and years following the transplant [4-6]. Persistent pain in patients with HCT is related to lower levels of physical functioning, less energy, and more psychosocial problems [4,7,9,10]. There are limitations of analgesic regimens in HCT patients (eg, side effects and limited relief); there is a clear need for adjuvant strategies to manage pain in these patients [11].

Psychosocial Pain Interventions

Psychosocial interventions that teach patients with chronic diseases skills to manage their pain can improve their abilities to cope with and reduce the pain [9,10]. Addressing psychosocial, cognitive, and behavioral factors related to persistent pain may be especially important for HCT patients [12-14] who face unique challenges and may have particularly low levels of confidence in their abilities to control their pain (ie, self-efficacy for pain control) [15,16]. HCT patients with low self-efficacy for pain control are more likely to report high levels of pain disability and other bothersome symptoms [17,18]. As such, a psychosocial pain intervention designed to help HCT patients manage their pain in the context of their unique pain-related challenges may prove to be particularly beneficial.

Psychosocial pain protocols are typically delivered in-person, require patients to travel to a medical center setting, and/or are not tailored to the unique challenges faced by HCT patients [19-21]. Patients undergoing HCT face substantial burden resulting from the life-threatening, chronic illness that has led to HCT, invasive treatment regimens (including HCT), and interruptions to their normal routines and functioning. When undergoing HCT, patients are required to spend several days pre- and post-transplant in an inpatient or intensive outpatient setting. Then, patients and their caregivers transition to temporary housing that is in close proximity to the medical center to receive several weeks of daily outpatient care. Finally, after weeks of intense care in the medical center setting, they are discharged home as they continue to recover, often many miles from the clinic. These unique challenges can increase pain and make pain management particularly difficult. Using mobile health (mHealth) technologies to deliver psychosocial pain interventions may increase the feasibility, acceptability, and efficacy of these interventions for HCT patients.

Study Objectives

The objective of this line of research was to develop a mobile health pain coping skills training (mPCST) protocol, designed to address the specific pain and psychosocial challenges of HCT patients. We used an iterative development model to design the protocol; methods from grounded theory were followed [22]. First, we developed an initial mPCST intervention for HCT patients using our study team's expertise and experience in PCST, cognitive-behavioral pain interventions, mobile health technology, and the treatment of HCT. We then conducted focus groups with both HCT patients and providers to refine and adapt the intervention. Following this, the enhanced intervention was delivered to a separate small group of patients who completed user testing. Qualitative data gathered from each stage of development were used to inform the subsequent modification of the intervention.

A pilot randomized controlled trial (RCT) was conducted to examine the feasibility, acceptability, and initial efficacy of the final mPCST protocol. The first aim of the pilot RCT was to show that the mPCST protocol would be feasible (ie, accrual, attrition, and adherence) and acceptable. The second aim was to examine the initial efficacy of the mPCST protocol (compared with a treatment as usual condition) on pain severity, pain disability, pain self-efficacy, fatigue, and physical disability (ie, self-report and 2-min walk test [2MWT]).

Methods

Participants

All participants were recruited from the adult bone marrow transplant clinic (ABMT) at a major academic medical center. Eligible patients were >21 years old, had cancer that led to transplant, and had at least one clinical post-transplant pain score of ≥3/10. Exclusion criteria included cognitive impairment (eg, dementia, psychosis) and inability to converse in English. Eligible health care providers were recruited through ABMT administrators and included nurse practitioners, physician's assistants, and registered nurses.

Development of the Mobile Pain Coping Skills Training Protocol

An initial mPCST protocol was developed that was informed by the investigators' expertise in several areas including PCST protocol development [9,23-31], mHealth applications [32-34], and observational studies of pain and other symptoms in HCT patients [8,35]. Traditional PCST protocols have been delivered over several weekly sessions (eg, 6-12), conducted face-to-face at a major medical center or sometimes by telephone, and are often about an hour long [36-39].

Most PCST protocols include some combination of the following content and skills training. A rationale is provided [40,41] to help patients understand that pain is a complex experience influenced by thoughts, feelings, and behaviors. Patients are taught several skills (eg, relaxation training, cognitive-restructuring, activity pacing, pleasant activity planning, imagery, problem solving, and goal setting) [21,23,31,42] to enhance their ability to cope with their pain by changing their thoughts, feelings, and behaviors. Sessions focus on reviewing content and skills practice from the previous session, learning a new skill, skill rehearsal, and home skills practice planning for the upcoming week.

The initial mPCST protocol we proposed included 6, 50-min sessions delivered over a period of 6-10 weeks. This protocol included several innovative features designed to address the unique challenges faced by HCT patients: it was brief, bridged the intensive outpatient (1 session) and home (5 sessions) settings, and used videoconferencing via an iPad for delivery in patients' homes. The initial mPCST session was designed to occur in-person in the medical center setting before discharge home to allow facilitation of a relationship between the therapist and patient, and to establish care that bridges intensive outpatient and home care. The subsequent 5 sessions were to be delivered to the patients in their home environment through the use of videoconferencing (iPad and Skype). Videoconferencing (vs in-person and/or telephone delivery) provided the following important advantages: (1) it allowed patients who lived far from the medical center to engage in the intervention, (2) there is evidence that educational and psychosocial content is better communicated through videoconferencing than through telephone [43], and (3) social cognitive theory suggests videoconferencing could lead to improvements in pain self-efficacy by having patients practice and receive feedback on skills in their home environment (ie, where they need to implement skills daily) [44].

The initial intervention included didactic and experiential components, which were summarized in handouts and on the study website. Homework on how to incorporate material from the session into daily life was also given to facilitate skill acquisition and generalization of skills use into their normal routine [45,46]. Adherence was promoted by reviewing homework at the beginning of each session, developing action plans for skills use, and providing positive reinforcement. The study website provided patients with a place to have a daily connection with the mPCST intervention by recording their symptoms and skills use, accessing study materials, and receiving tailored feedback based on their daily assessment of skills practice.

Figure 1 displays mPCST for the HCT focus groups, user testing, and RCT development process.

Focus Groups

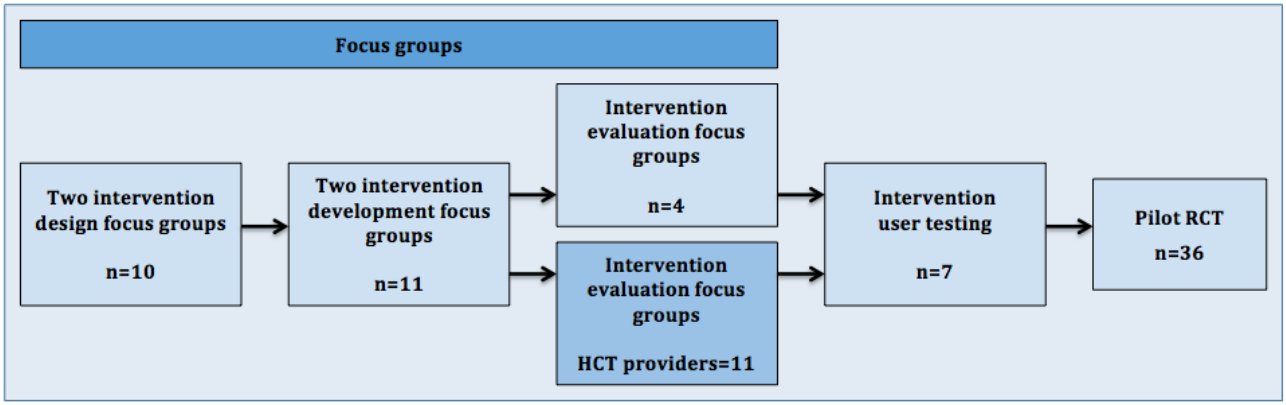
Intervention Design Focus Groups

Two participatory design focus groups (n=10) were conducted to guide investigators in tailoring the mPCST protocol to meet the unique needs of HCT patients with pain. Focus group guides were developed based on the investigators' experience, past work, and the larger empirical literature. Group discussions focused on the patient's experiences and challenges of HCT pain, intervention content, and intervention characteristics (eg, material types, topics).

Intervention Development Focus Groups

Two intervention development focus groups allowed participants (n=11) to evaluate the tailored mPCST protocol materials developed in the intervention design focus groups. These groups were conducted using both in-person examples and a visual demonstration of the iPad and Skype system; patients were asked to provide the research team with objective information on challenges in using and preferences for delivery using this modality.

Figure 1. Mobile pain coping skills training (mPCST) for hematopoietic stem cell transplantation (HCT) focus groups, user testing, and randomized controlled trial (RCT) development process.



Intervention Evaluation Focus Groups

The final two focus groups comprised HCT patients (n=4) and providers (n=10). Providers recruited for the focus groups were clinical providers in the ABMT clinic and had no other role in this study. Using the feedback from the intervention design and development focus groups, the evaluation focus group was geared toward the final refinement of the mPCST protocol and technology. Participants were provided with a description of the intervention protocol, were asked detailed questions about specific components of the protocol (eg, daily measures, iPad technology, and use of pedometer), and were provided with an example of the materials that would be given to the potential participants (eg, iPad, patient manual, and handouts). Providers were asked to review and provide feedback on the patient manual and session handouts, and to use the study website on the iPad.

User Testing

User testing of the developed mPCST protocol was conducted with 7 participants who reported HCT-related pain. Participants completed the 6-session mPCST protocol and were asked to provide feedback following each session. The information collected was used to further refine the intervention protocol.

Pilot Randomized Controlled Trial

A separate group of participants (n=36) were randomized to either the mPCST or treatment-as-usual, control group. Pre- (before randomization) and postintervention assessments included measuring pain severity, pain disability, pain self-efficacy, fatigue, and physical disability (ie, self-report, 2MWT). Self-report assessments were completed via the study website; the 2MWT was conducted at the medical center.

Participants randomized to mPCST completed the first session following their baseline study assessment and before discharge home. The time between the baseline assessment and first session was on average 4.5 days (SD 9) and from the first session in the hospital to the first session at home was on average 10.5 days (SD 10). Participants who did not have Internet access to participate in videoconferencing and Web-based assessments from home or who desired to have study-provided hardware were loaned a tablet computer (ie, iPad) equipped with 3G Internet access; most participants elected to use the study-provided iPad to complete the intervention. Participants randomized to treatment as usual were also loaned a tablet computer as needed to complete assessments.

Measures

Pilot RCT participants completed self-reported measures of acceptability, pain severity, pain disability, pain self-efficacy, fatigue, and physical disability. Demographic and medical variables were also collected.

Feasibility

Feasibility was assessed by examining overall accrual, attrition, and adherence.

Acceptability

Acceptability was assessed with the client satisfaction questionnaire (CSQ), 10-item version [47]. CSQ was completed by participants in the mPCST intervention group at the post-treatment assessment. The measure was shown to have good reliability (Cronbach alpha=.96).

Pain Severity

Pain severity was assessed with the 4-item brief pain inventory [48]. Patients rated their pain from 0=no pain to 10=worst pain imaginable in response to average pain, worst pain, least pain, and pain right now over the past 7 days. An average of the 4 items was used to create a single pain severity score. Internal consistency at pretreatment was found to be Cronbach alpha=.90.

Pain Disability

Pain disability was measured with the pain disability index [49]. This 7-item scale measures the degree of a patient's disability within 7 life domains and has demonstrated good reliability and validity [49]. Internal consistency at pretreatment was Cronbach alpha=.91.

Pain Self-Efficacy

Self-efficacy for pain control was measured using the 5-item self-efficacy for pain subscale of the chronic pain self-efficacy scale measure (pretreatment Cronbach alpha=.86) [50].

Fatigue

Fatigue was measured with the patient-reported outcomes measurement information system adult fatigue profile short form (6 items) [51,52]. This scale has good precision across different levels of fatigue and has demonstrated good reliability (>.90) [52]. Internal consistency in this sample at pretreatment was Cronbach alpha=.95.

Physical Disability

Self-reported physical disability was measured with the functional assessment of cancer therapy well-being scale (FACT; 7-items). FACT has demonstrated good internal consistency, criterion validity, and sensitivity to change [53]. Internal consistency at pretreatment in this sample was Cronbach alpha=.84. Physical disability was also assessed using an objective measure, the 2MWT. The 2MWT is a laboratory-based assessment of patients' physical disability that measures the functional capacity for physical lifestyle activity. The 2MWT provides a self-paced, timed test of the total distance in meters that a patient is able to walk over a 2-min period, and it has been shown to be sensitive to change following medical treatments. The 2MWT has shown moderate correlations with physical disability [54].

Analytic Strategy

Focus groups were audio-recorded and 2 group leaders took field notes. Audio files were transcribed by a member of the research study team; a second team member performed a quality check by replaying the audio file and editing the transcript as needed. Grounded theory methods were used to evaluate the data gathered from the focus groups. Audio recordings were reviewed using open coding (ie, in vivo) and memoing by 3

members of the study team to generate repeated concepts. These results were categorized into 5 major themes through selective coding methods.

For the RCT, descriptive statistics were calculated for demographic, medical, feasibility, study self-report variables (ie, acceptability, pain severity, pain disability, pain self-efficacy, fatigue, and physical disability), and 2MWT. Analysis of variance (ANOVA), chi-square, or Fisher exact tests were used, as appropriate, to examine baseline differences between groups on medical and demographic variables. Outcome analyses were conducted using both an intent-to-treat approach (last value carried forward) and complete case analysis. The results of both the analytic strategies were comparable. Results using the complete case analysis approach are presented below. Paired *t* tests were used to examine within group differences from baseline to follow-up on study outcome variables (ie, pain severity, pain disability, self-efficacy for pain management, fatigue, and physical disability). The magnitudes of the effect sizes were defined according to standard convention for Cohen *d* (small=0.2, medium=0.5, large=0.8) [55].

Results

Focus Groups and User Testing

Participants included 32 individuals with HCT pain who had undergone autologous (87%, 28/32) or allogeneic (13%, 4/32) stem cell transplant and reported having post-transplant pain. Participants were 50% female (16/32), 72% Caucasian (23/32), and were aged between 43 and 76 years (mean 61). Majority of the participants were married (84%, 27/32) and 53% (17/32) had a college degree or higher. Participants were on average 20 (SD 14) months post-transplant. The provider intervention evaluation focus group consisted of 10 providers, all of whom were females and held a position within nursing care for HCT patients (5 nurse practitioners, 2 clinical nurse specialists, 1 registered nurse, 1 outpatient clinic nurse manager, and 1 clinical research nurse).

Focus Group Results

Review of focus group recordings and field notes revealed 5 overall themes. Each theme is presented and described below; theme order is reflective of the order of content presented to the focus group and not related to rank or importance. A description of how the intervention protocol was modified based on each theme is provided. Textbox 1 provides representative patient quotes related to each theme.

Theme 1: Pain Experiences Pre- and Post-Transplant and Strategies Used to Cope With Pain

Participants reported experiencing post-transplant pain. The majority also reported having pain before transplant, with some reporting increased pain following the transplant. Patients reported that reasons for pain were neuropathy, graft versus host disease symptoms, joint inflammation, and pre-existing osteoarthritis. Neuropathy was frequently reported in hands and feet, whereas osteoarthritis pain was most commonly described in the hips, knees, hands, and feet. Participants in focus groups reported that pain was worse when they were sedentary and improved when they were busy and moving. Notably, many participants also endorsed significant sleep or fatigue problems following transplant.

Participants reported using the following measures to manage their pain: taking pain medications, wearing supportive shoes, receiving gentle massages, participating in regular exercise (eg, physical therapy, chair yoga, stationary biking, walking, and elliptical training), relying on their faith (eg, attending church, prayer, and scripture reading), being active in volunteer work (eg, cancer groups), and participating in hobbies (eg, cooking or baking, gardening, reading, and playing a musical instrument). Participants acknowledged that participating in these activities helped to distract them from their pain. On the basis of this theme, information was added to the protocol that describes the pain experiences of other transplant patients and suggestions from other patients about helpful pain coping strategies.

Theme 2: Post-Transplant Activities and Limitations in Activities

Participants in the intervention development focus groups were asked to brainstorm pleasant activities that they could begin again or start anew post-transplant. Participants listed playing a musical instrument, watching grandchildren, visiting friends and children, traveling, gardening, getting a pet, planning dinner parties, baking and cooking, getting manicures or pedicures, being more involved in their church, and volunteering. Interestingly, many participants also mentioned an increased post-transplant desire to participate in activities they find meaningful. Figure 2 displays patient intervention materials showing how this information was integrated into the study protocol.

Participants also stated that their pain limited their abilities to engage in leisure or recreational activities. In particular, several participants noted that their abilities to engage in daily exercises (eg, biking, running) had decreased or diminished. Participants also reported overdoing activities related to their work, family, and leisure time. Focus group participants recommended extending and expanding the information provided to participants on pleasant, meaningful, and leisure or recreational activities. This information was added to both the therapist protocol and patient handouts.

Textbox 1. Representative quotes from focus group participants related to each theme.

Theme 1: Pain experiences and pain coping strategies

- It's a hard balance [getting off pain meds] because you can't just stop. When you scale back, we're trying to work it out, so I'm gradually dosing down.
- Always wind up with my hips hurting the most [post-transplant].
- Honestly I can say I went from horrendous pain and can say I'm in no pain sitting here. It felt like a huge rubber band around my chest. And it was just as tight as it could possibly be. I couldn't lie down; I would sit up and rock, just rock and pray, until I finally fell asleep.
- I wonder if my chemo and the whole situation didn't just age my whole body, and the pains that I feel now might have been pains I wouldn't feel, 5, 6, 17 years from now but that I think I'm feeling now.
- I have a lot of bone pain, but I had it before the transplant because the chemo was eating away at the bones in my back, so I've had some surgery on my back to help with that. The pain in my back got better during the transplant because I was in so much pain everywhere else.
- I've had some trouble with neuropathy. I still feel it, but I'm not taking anything for it.
- I'm feeling more pain now post-transplant. After the transplant was when I really started having the pain.
- Foot and leg cream—it has done wonders.
- Walking is the best thing for me when I have pain.
- I find that at night, even putting socks on makes a difference [in regards to the pain].
- I need to sit properly; if I didn't have support in my lower back the pain is immediate. Breathing helps, in through the nose out through the mouth.

Theme 2: Activities and limitations in activities

- I was a very athletic person, and still am, I try to keep up with my kids. I had my walking stick, I had to stop and rest for a bit.
- I take breaks. I love baking Christmas cookies, but I can't stand that long anymore. I'll do a little bit; then take a break. Funny ways to do it and still get something accomplished.
- My husband bought me a piano for Christmas because I've always wanted to play it. I just forget everything. It is really a good relaxer.
- I love to garden, even on my worst days, I take a bucket and sit out there. Not only did I get something accomplished, but I did something I really enjoy.
- You're finally home and you're like I can do something, but you're not allowed to.
- Right now I'm just getting out of seclusion so I'm not able to do much, but we're planning to take trips.
- Now I have a totally different perspective on life, and it's nice to get out and do something.

Theme 3: Pain-related cognitions

- I just try to deal with it.
- Sometimes I just live with it because I don't want to take the pain meds.
- I feel better when I do anything.
- I made it through the first time, if I have to go it through again, I know what to expect and I can do it again.
- My cancer is back [in reference to thinking about the pain].
- How long is this [pain] going to last?
- It's been 2 years, and if something strange happens [related to pain], I still worry.
- When you don't really have any symptoms, it's scary.

Theme 4: Advice for other transplant patients

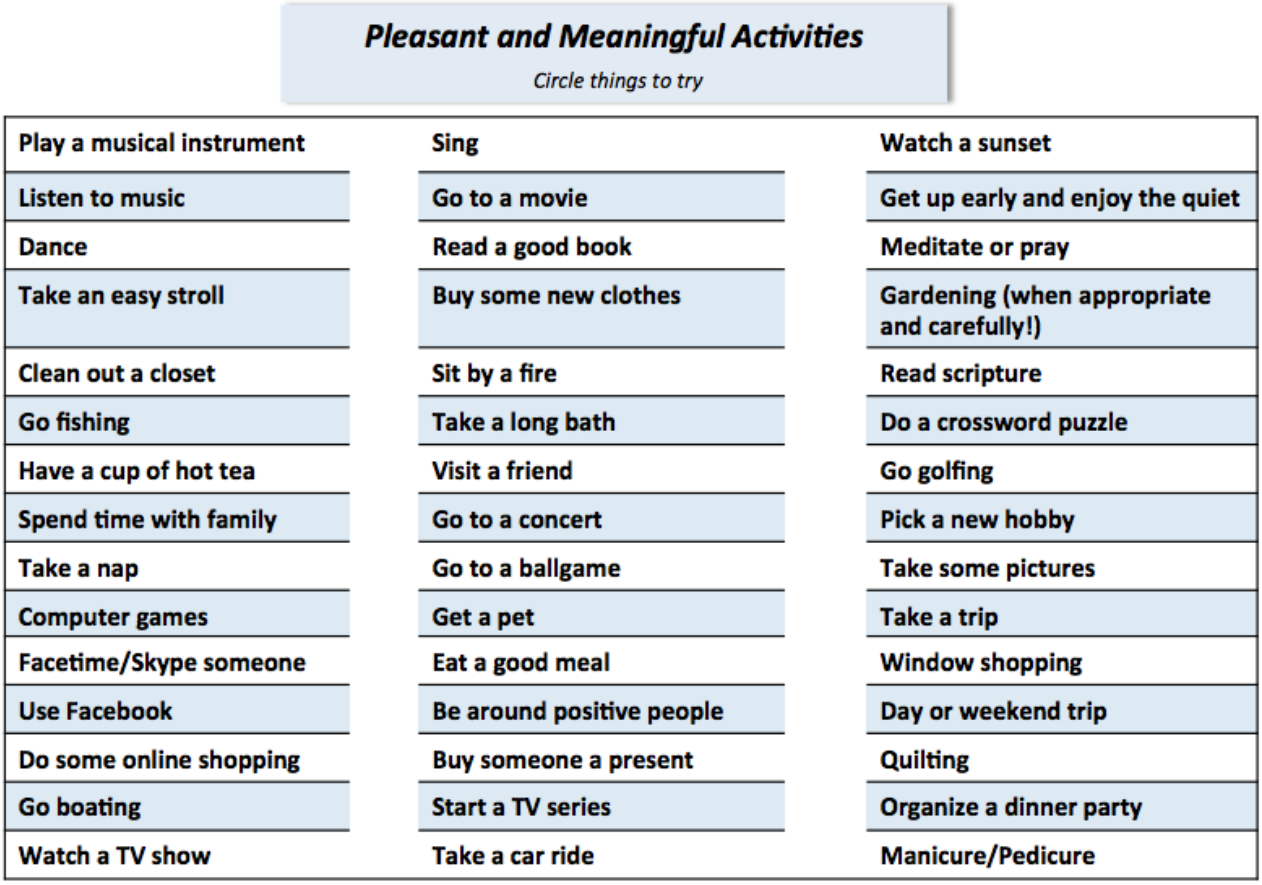
- Don't try to fight it [the pain]. Let the doctors know. It's not their first rodeo.
- We're not supposed to be proud at a time like this; we're supposed to be honest.
- Would have been helpful to have spoken to some who had been through transplant beforehand.
- It does make you have to learn how to do things, such as learning how to take medication. And washing my hands, I'm good at that now.

Theme 5: Feedback on the mobile pain coping skills training (mPCST) protocol

- I'd call my daughter for help [with the iPad]. [I] wouldn't try if she wasn't there, she is a real techie. It could be managed with her.
- I can barely turn a computer on.

- I've been wearing a pedometer for about 3 years, so I wouldn't have a problem. I do it already.
- I'd be willing to give this [the iPad and videoconferencing] a try with help.

Figure 2. Intervention handout for pleasant and meaningful activities for hematopoietic stem cell transplantation (HCT) patients.



Pleasant and Meaningful Activities

Circle things to try

Play a musical instrument	Sing	Watch a sunset
Listen to music	Go to a movie	Get up early and enjoy the quiet
Dance	Read a good book	Meditate or pray
Take an easy stroll	Buy some new clothes	Gardening (when appropriate and carefully!)
Clean out a closet	Sit by a fire	Read scripture
Go fishing	Take a long bath	Do a crossword puzzle
Have a cup of hot tea	Visit a friend	Go golfing
Spend time with family	Go to a concert	Pick a new hobby
Take a nap	Go to a ballgame	Take some pictures
Computer games	Get a pet	Take a trip
Facetime/Skype someone	Eat a good meal	Window shopping
Use Facebook	Be around positive people	Day or weekend trip
Do some online shopping	Buy someone a present	Quilting
Go boating	Start a TV series	Organize a dinner party
Watch a TV show	Take a car ride	Manicure/Pedicure

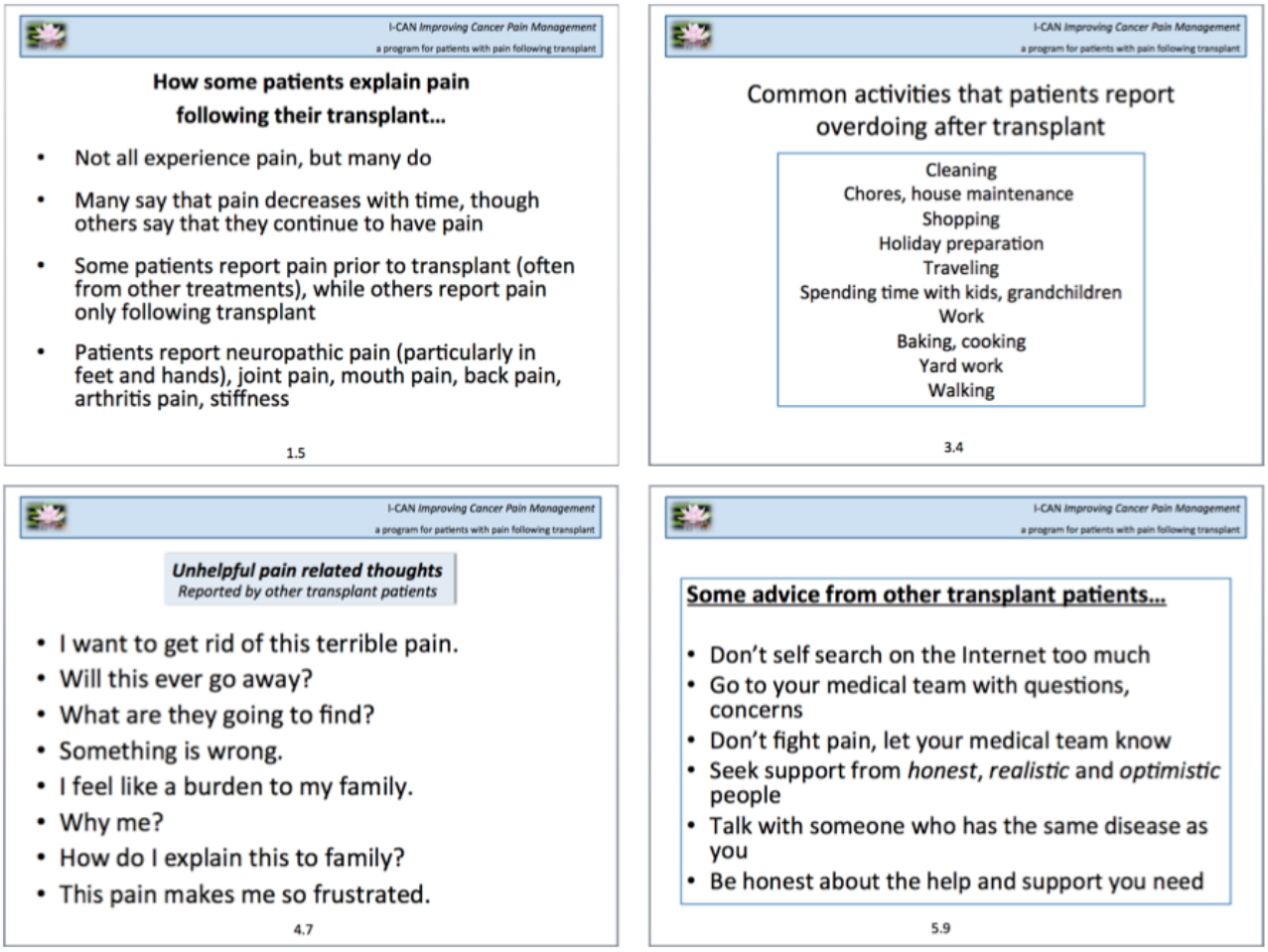
Theme 3: Pain-Related Cognitions

Focus group participants were asked about their thoughts (negative and positive) surrounding their pain experience pre- and post-transplant. Many patients worried that their pain might indicate disease recurrence or progression. For example, participants endorsed the following cognitions: "What are they going to find at my next check-up appointment?," "My cancer is back," and "Something is wrong." For others, thoughts were associated with perceptions of their pain and their abilities to reduce their pain. Negative thoughts included the following: "I want to get rid of this," "How long will this pain last?," "Will this ever go away?," and "Why me?." Overall, participants said that staying positive yet realistic was the best way for them to cope with these negative cognitions related to post-transplant pain. Positive thoughts that helped patients cope with pain and combat the aforementioned negative cognitions included the following: "This too shall pass," "I am blessed," and "This is my life right now." Common negative and positive cognitions about pain provided by focus group participants were used as examples in the protocol during sessions with the therapist and in patient handouts.

Theme 4: Advice for Other Transplant Patients

We asked participants what pain-related information they wish they had known before their own transplant. Group members acknowledged that it would have been helpful to receive more information on neuropathy and the different types of pain that might be experienced post-transplant. More broadly, participants expressed a desire for communication with prior transplant patients regarding the pain experience and general transplant-related information. Most of the participants agreed that having someone who had gone through a similar situation to talk to about their pain was helpful and comforting, and that such an outlet should be made available to HCT patients approaching transplant. On the basis of this consistent observation acknowledged across the focus groups, patient materials were updated to reflect advice from other transplant patients. The most common suggestion among HCT patients was to communicate any pain, discomfort, or other concerns to the medical team and caregivers rather than holding back. Group members advised future patients to be honest about their pain and about what physical and emotional help they needed. Figure 3 shows how the theme of advice for other transplant patients was incorporated into the patient handouts. Throughout the protocol, we used language that indicated that the information had come directly from other HCT patients.

Figure 3. Intervention handout examples using advice from other transplant patients.



Theme 5: Feedback on the Mobile Pain Coping Skills Training Protocol

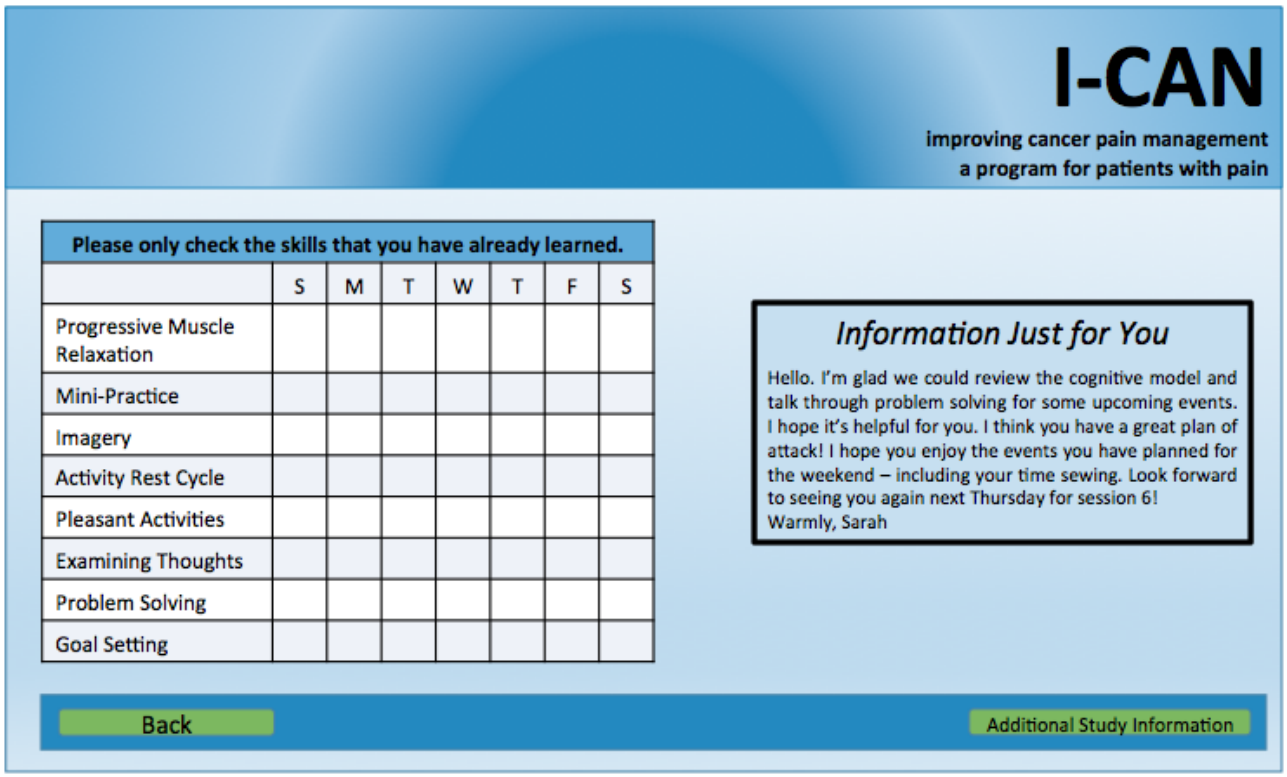
Focus group participants provided feedback on the mPCST protocol and technology. The majority of participants agreed that they would be willing to use the iPad, Skype, and website technology with adequate instruction. Many of the participants reported that it would be helpful to have a connection with their medical team and a therapist during the transition to post-transplant life, as they often missed the daily contact with their medical team once discharged from daily care. This feedback reinforced our position that the most appropriate timing of this protocol was once the patient returned home. Participants' responses also led to the inclusion of detailed instruction in the use of the technology (eg, iPad, Skype) for this study in the patient handouts.

Provider Results

Providers recommended that the study team collect daily fatigue levels in addition to daily pain scores and daily steps due to their strong observed relationship between pain and fatigue. Providers also expressed that it would be worthwhile to have participants wear a pedometer to track activity. One aspect of the website that was particularly popular with the providers was the *Just for You* feedback box designated for individualized therapist feedback for participants (See Figure 4). Providers also made suggestions about the appearance of the website (ie, use an easy to read font and color scheme).

Providers were asked how they currently help patients who experience post-transplant pain. The most common methods recommended by providers to deal with pain were medication and/or distraction. When providers recommended exercise, they frequently advised patients to use a recumbent bike, exercise bands for muscle strengthening, and yoga or chair yoga. Providers were asked to outline the most commonly reported challenges that patients face 5 to 10 weeks post-transplant besides pain. Fatigue, nutrition, and depression were listed as frequently encountered problems, and it was recommended that information be included in our protocol to help patients deal with such issues. For fatigue, providers underscored that patients should avoid going back to bed if tired; rather, they should take brief cat naps throughout the day. They also recommended establishing a routine to keep busy and making a point to get dressed every morning as well as pacing and prioritizing activities. Finally, when patients have pain, psychological issues such as depression are prevalent post-transplant, and providers recommended that study therapists be aware of this and encourage patients to seek help when needed.

Figure 4. Intervention website page providing patient with tailored feedback.



User Testing Results

User testing (completed with separate participants than from the focus group) was designed to identify problems with the mPCST protocol and videoconferencing technology. Overall, participants reported enjoying the relationship they fostered with their therapist first in-person and then by videoconferencing. Participants noted that they looked forward to sessions and appreciated having someone to talk to about their pain and progress each week. Progressive muscle relaxation and goal-setting skills were reported to be especially helpful. Although participants acknowledged that some skills presented were new, they described that it was helpful to receive a refresher course for previously learned skills (eg, problem solving, goal setting) to remind them of the importance of the skill and how the skill applied to pain management.

Overall, positive feedback was common, yet 2 noteworthy criticisms were reported. One participant believed the 6-session protocol felt too condensed for the amount of information delivered. Another participant recommended we tailor the sessions to suit the individual needs of different patients, for example, spending more or less time on certain sessions depending on the patient's specific needs and preferences. Three testers reported difficulties in using the iPad and connecting with their therapist via videoconferencing; these difficulties were resolved and all participants were able to finish the protocol. We added visual information to the directions for the protocol based on these technical difficulties. All participants reported videoconferencing to be more convenient than in-person pain coping skills training sessions. Two of the 7 user-testers indicated it would be beneficial to also include the caregiver in these sessions due to the stress experienced by caregivers of HCT patients. Along these lines, 1 patient indicated the title of the protocol could be changed to "Pain and Stress Coping Skills Training" due to the relevance of the coping skills introduced in the intervention for both pain and stress management. Table 1 provides an overview of the mPCST content and how the mPCST content was adapted for HCT patients.

Pilot Randomized Controlled Trial Results

The pilot RCT participants (n=36; different than all previous participants) were on average 56 (SD 12) years old and 50% female (18/36). Most participants were white (83%, 30/36) and 17% were black (6/36). The majority of participants were married (81%, 29/36) and just over half (56%, 20/36) had a college and/or professional degree. Most participants received an autologous HCT (83%, 30/36); 61% (22/36) had been diagnosed with multiple myeloma, 19% with lymphoma (7/36), and the remaining with various other hematological diseases. The average time since cancer diagnosis was 22 months (SD 30). Participants reported 1 other medical comorbidity, on average, with hypertension (28%, 10/36), osteoarthritis (14%, 5/36), diabetes (11%, 4/36), and sciatica (11%, 4/36) being the most common. There were no significant differences in medical or sociodemographic variables by the treatment group.

Table 1. Mobile pain coping skills training (mPCST) protocol adaptations made for hematopoietic stem cell transplantation (HCT) patients.

Session	Pain coping skills content	Adaptations for mPCST[a] for HCT[b] patients
1	• Psychoeducation on pain • Gate-control theory • Progressive muscle relaxation	• HCT patients pain experiences • Audio of relaxation • Relaxation video didactic • Track daily pain
2	• Mini-relaxation practice • Imagery for relaxation	• Procedure-related mini-relaxation • Mini-practices in routine returning home • Pair mini-practices with lifestyle recommendations (eg, walking) to increase use of both
3	• Activity rest cycle • Pleasant and meaningful activity planning	• Activities that HCT patients report overdoing • Conceptual addition of meaningful activities • Activities suggested by HCT patients • Volunteer activity ideas • Physical activity for HCT patients
4	• Examining unhelpful thoughts	• Pain related thoughts reported by other HCT patients
5	• Problem solving	• Theme of life after transplant • Pain related challenges for HCT patients • Pain management suggestions from other HCT patients • Training in asking for support from family and friends • General advice from other HCT patients
6	• Moving forward	• Life priorities • New life goals reported by HCT patients • Training in shifting goals in response to physical health

[a]mPCST: mobile pain coping skills training.

[b]HCT: hematopoietic stem cell transplantation.

The consort diagram for the RCT is presented in Figure 5. Ninety percent (36/40) of the intended participants were recruited during the proposed study timeframe. Of the 36 participants recruited, 92% completed the study (n=33). Of the 3 non completers, 2 were randomized to the intervention group and 1 was randomized to the control group. Reasons for noncompletion included patient illness and loss to follow-up. The Mann-Whitney *U*-test or Fisher exact test, whichever was appropriate, was used to determine if the baseline characteristics of noncompleters systematically differed from participants completing the study. There were no significant differences in the baseline sociodemographic characteristics between individuals who completed the study and those who did not. However, noncompleters reported significantly greater pain severity at baseline when compared with completers (mean 6.17 vs 3.14; Mann-Whitney U=13.50, P=.03).

Out of all the patients accrued, 50% (18/36) were randomized to the intervention group. Patients in the intervention group completed an average of 5 of the 6 sessions offered to them. A total of 14 participants completed all 6 sessions (1 in-person and 5 via videoconferencing); on average, these participants completed the intervention in 34 days (SD 5). Following the final session, 85% of participants reported using the skills they had learned on several days of the week. Participants reported the sessions to be helpful (mean 8/10), easy to understand (mean 7/7), and highly acceptable (mean 4/4). Overall, 75% participants rated the intervention as excellent and 25% rated it as good.

At baseline, there were no significant differences in outcome variables (ie, pain severity, pain disability, pain self-efficacy, fatigue, and physical disability [ie, self-report, 2MWT]) between randomization groups. Within-group comparisons from baseline to postintervention are presented in Table 2. Individuals in the intervention group saw improvements in all variables of interest. The pattern of effect sizes suggests that individuals in the intervention group showed greater improvements in pain disability (d=0.79 vs 0.69), pain self-efficacy (d=0.61 vs 0.10), fatigue (d=0.94 vs 0.81), and on the 2MWT (d=0.66 vs 0.41), an objective assessment of physical disability. Although differences between the outcomes are fairly subtle, the largest relative difference between the intervention and control groups appears to be for pain self-efficacy, which is a natural intermediate outcome that the intervention was designed to address directly. The magnitude of the effect sizes was greater for the control group with regard to self-reported physical disability and pain severity; however, both groups evidenced large and small-to-medium effect sizes, respectively, on these variables.

Figure 5. Pilot randomized controlled trial consort diagram.

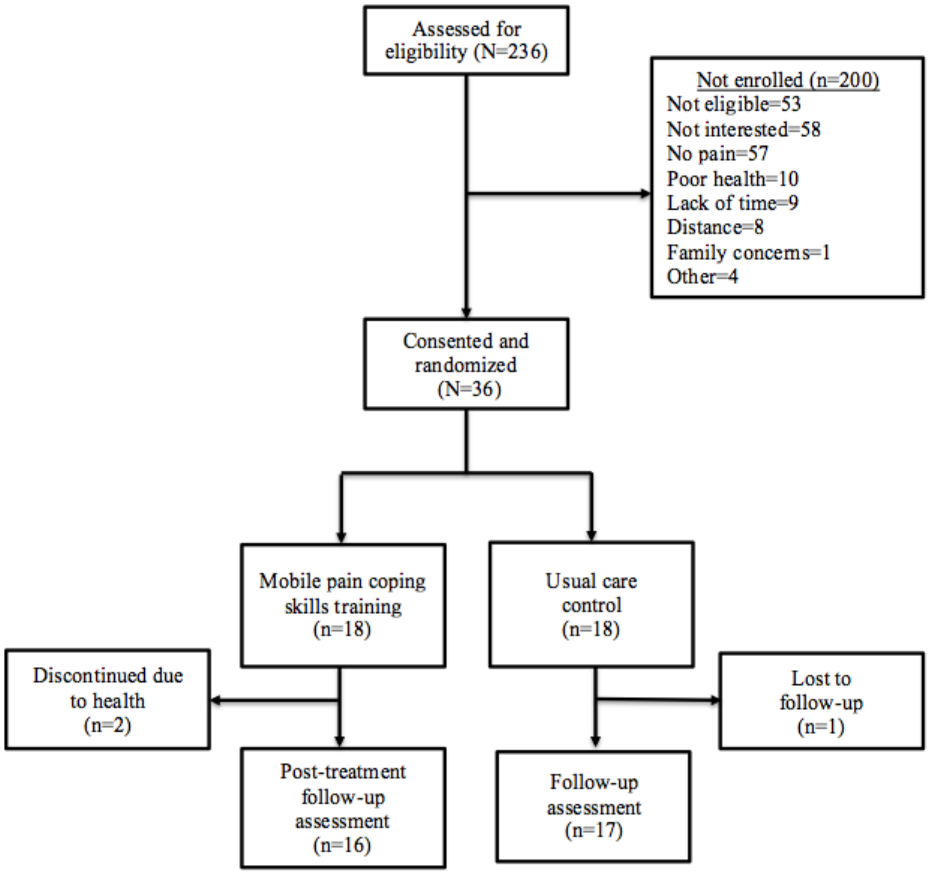


Table 2. Comparative pre- and postintervention data.

Outcome variables	Pretreatment, mean (SD)	Post-treatment, mean (SD)	Mean difference (SD)	95% CI	*P* value	*d*
Intervention (n=16)						
Pain severity	3.00 (2.09)	2.69 (1.89)	0.31 (1.20)	−0.33 to 0.95	.32	0.26
Pain disability	30.26 (13.97)	19.22 (12.59)	11.04 (13.92)	3.48 to 3.63	.006[a]	0.79
Pain self-efficacy	60.50 (23.39)	77.13 (19.39)	−16.63 (27.42)	−31.24 to −2.01	.03[b]	0.61
Fatigue	18.60 (5.75)	13.27 (4.89)	5.33 (5.68)	2.19 to 8.48	.003[a]	0.94
Physical disability	12.36 (4.11)	16.11 (4.14)	−3.76 (4.56)	−6.19 to −1.32	.005[b]	0.82
2-min walk test	125.88 (19.69)	134.94 (19.05)	−9.06 (13.75)	−17.00 to −1.12	.03[a]	0.66
Treatment as usual (n=17)						
Pain severity	3.28 (2.40)	2.50 (1.87)	0.78 (1.67)	−0.08 to 1.64	.07	0.47
Pain disability	23.84 (20.11)	18.00 (15.84)	5.84 (8.50)	1.31 to 10.38	.02[b]	0.69
Pain self-efficacy	61.53 (25.52)	63.76 (24.52)	−2.24 (21.72)	−13.40 to 8.93	.68	0.10
Fatigue	19.29 (4.83)	15.35 (5.41)	3.94 (4.88)	1.43 to 6.45	.004[a]	0.81
Physical disability	11.72 (5.76)	16.61 (3.85)	−4.89 (3.80)	−6.84 to −2.93	<.001[a]	1.29
2-min walk test	121.12 (19.24)	126.99 (21.71)	−5.87 (14.19)	−15.40 to 3.67	.20	0.41

[a]*P*<.01.

[b]*P*<.05.

Discussion

Primary Outcomes

The goal of this study was to develop a PCST intervention that could be used to enhance the ability of HCT patients to manage their pain following transplant. HCT patients face many pain-related challenges and challenges accessing behavioral interventions post-transplant. We used both patient and provider focus groups to adapt the effective components of existing PCST protocols to meet the unique needs of patients following transplant. After developing the HCT-focused protocol, we conducted a small RCT to examine feasibility, acceptability, and initial efficacy of the developed mPCST protocol.

The developed mPCST protocol included 1 in-person session at the medical center between the patient and study therapist, which led to the development of a successful working relationship and the integration of mPCST with the patient's medical care. Then, once the patient returned home following intensive outpatient care, 5 more sessions were conducted using videoconferencing. This bridge between hospitalization and home maintained the continuity of care as patients moved away from the medical center. This mixed delivery modality fostered a strong patient-therapist relationship that likely increased the feasibility, acceptability, and efficacy of the intervention. To our knowledge, this is one of the first studies that has examined the use of videoconferencing to provide patients with PCST upon their return home from inpatient or intensive outpatient care.

Patient focus groups highlighted several areas of consideration in the development of the intervention content including the importance of strategies for coping with pain that was unique to HCT patients, enjoyable activities following transplant, pain-related thoughts following HCT, and connecting with other HCT patients for support. Accordingly, we addressed many of these areas in the developed mPCST protocol. For example, we highlighted advice from other patients throughout the sessions and in patient materials. Although we were unable to include all patient suggestions (eg, incorporate a caregiver as an active member of the intervention, tailoring the protocol to meet the specific needs of each patient) into the protocol, we will consider these suggestions in our future work.

Provider focus group information was used as one of the last steps in refining the intervention protocol and website. Providers emphasized the importance of helping participants track and manage not only their pain but also their fatigue. They also suggested that participants wear pedometers to track daily steps. We incorporated these suggestions into this study by modifying the study website to collect daily pain, fatigue, and steps; we used the data clinically to help patients increase their activity by providing feedback in the *Just for You* portion of the website (see Figure 4). In our planned future work, we will incorporate daily reports of pain, fatigue, and steps to tailor the intervention content to meet patients' specific needs. As technology use has advanced from primarily Web-based platforms to mobile phone-based platforms, it will be important to consider data entry (eg, through apps) on hand-held devices and the provision of immediate feedback through programming (eg, push notifications) in future work. In the time since provider focus groups and the end of this study, there has been evidence that providers find the mPCST protocol to be feasible and acceptable to patients. First, HCT providers have continued to refer HCT patients for pain coping skills to our clinical practice. Second, the larger transplant program is working with our pain program to incorporate videoconferencing pain coping skills and other psychosocial services for HCT patients in both their clinical practice and their research protocols.

The pilot RCT was designed to put us in a good position to perform a more definitive RCT in a subsequent follow-up study. Apart from assessing the feasibility of the study methods, we asked the following 2 questions: (1) would the intervention group improve and, if so, how much, and also which outcomes would show the greatest improvement, and (2) how much improvement would we see in the control group? This latter question is critical for the design of the more definitive RCT. We used a small pilot RCT to examine the pattern of effects for those who received mPCST and those who did not. We found that participants who received the intervention experienced greater improvements in pain disability, pain self-efficacy, fatigue, and the 2MWT, with the largest relative difference between the intervention and control groups being for pain self-efficacy and the 2MWT. The finding that HCT patients completed the mPCST intervention at the intended pace of about 1 session per week adds support for past work suggesting that videoconferencing intervention protocols compared with in-person protocols can be completed at the pace of 1 session per week, whereas in-person protocols can take twice as long [56].

These outcomes suggest that mPCST is particularly likely to help patients manage their pain in a way that might lead to decreases in the impact of pain on their day-to-day activities (ie, pain disability). In line with social cognitive theory, teaching and receiving feedback on pain coping skills practice in their own home (vs a medical center setting) may have been particularly helpful for increasing participants' self-efficacy for pain management. Furthermore, the finding that an objective measure of the physical ability (ie, the two-min walk test) appears to have been positively impacted by mPCST has important implications for improving patients' physical functioning in their daily activities. It may also be said that helping patients control their pain and other symptoms can lead to increased physical activity.

Both the groups evidenced small-moderate effect sizes for pain severity. The majority of individuals participating in the RCT had been diagnosed with multiple myeloma (62%) for which autologous transplantation is most commonly recommended [56]. Complete remission is achieved in only about half of all cases following autologous transplantation [56]. Persistent pain (ie, in bone) is common among these patients, and may result from the disease, therapeutic interventions, or indicate disease progression [56-60]. Typically, pain is associated with functional limitations [57] as well as increased mood disturbance [61]. Although large changes in ratings of pain severity were not found, participants receiving the intervention experienced greater improvements in self-efficacy for pain control and pain disability when compared with participants in the control group. Given

the chronic nature of multiple myeloma and persistence of pain in this population, an intervention that improves the patients' confidence in their ability to manage their pain and decrease pain disability early in their disease trajectory may be critical for helping them better manage long-term complications.

The small effect sizes for pain severity ratings may indicate that it is necessary to target patients with higher baseline pain levels to find a change in pain severity. The average pain severity of patients recruited in this study was 3 on a 10-point scale; this relatively low pain level may not have been high enough to demonstrate significant change from pre- to postintervention. Another important consideration is that patients with higher pain were less likely to complete the study and may have been less likely to enroll; future work may want to consider recruitment and retention strategies to provide treatment to individuals with the highest pain levels who may need it the most. Finally, there is evidence that changes in self-efficacy for pain control and pain disability are critical for overall functioning and as such, investigators may want to consider using these variables as primary outcome variables with actual pain severity being a secondary outcome.

Limitations

This study has several limitations. First, this work was completed through the use of iPads, which require either a data plan or Internet connection to be able to videoconference with the therapist. The intervention itself is scalable for use on either a personal computer or mobile phone; the number of individual's access to a personal computer, tablet, or mobile phone is greater than 50%, and future work should be designed to be inclusive of all possible technology devices. Second, the RCT was relatively small (N=36), conducted in a single medical center, and had a short follow-up period; future work should expand the study size, consider using multiple sites, and examine longer term outcomes.

Conclusions

In summary, this study relied on past work and the expertise of the large study team to develop a mobile pain coping skills training intervention that was efficacious and could be delivered to patients following HCT. The developed intervention was also informed by patient and provider focus groups and included a 6-session, hybrid protocol (ie, in-person and videoconferencing). Our pilot RCT found that the developed intervention was highly feasible and acceptable to HCT patients with pain. Preliminary data suggest that the developed mPCST intervention likely improves patients' abilities to manage their pain (ie, pain self-efficacy), decrease pain-related disability, and decrease symptoms of fatigue.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 634KB - mhealth_v6i3e66_app1.pdf]

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Abbreviations

ABMT: adult bone marrow transplant clinic
CSQ: Client Satisfaction Questionnaire
FACT: Functional Assessment of Cancer Therapy well-being
HCT: hematopoietic stem cell transplantation
mHealth: mobile health
mPCST: mobile pain coping skills training
PCST: pain coping skills training
RCT: randomized controlled trial
2MWT: 2-min walk test

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Original Paper

Comparing the Efficacy of a Mobile Phone-Based Blood Glucose Management System With Standard Clinic Care in Women With Gestational Diabetes: Randomized Controlled Trial

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Abstract

Background: Treatment of hyperglycemia in women with gestational diabetes mellitus (GDM) is associated with improved maternal and neonatal outcomes and requires intensive clinical input. This is currently achieved by hospital clinic attendance every 2 to 4 weeks with limited opportunity for intervention between these visits.

Objective: We conducted a randomized controlled trial to determine whether the use of a mobile phone-based real-time blood glucose management system to manage women with GDM remotely was as effective in controlling blood glucose as standard care through clinic attendance.

Methods: Women with an abnormal oral glucose tolerance test before 34 completed weeks of gestation were individually randomized to a mobile phone-based blood glucose management solution (GDm-health, the intervention) or routine clinic care. The primary outcome was change in mean blood glucose in each group from recruitment to delivery, calculated with adjustments made for number of blood glucose measurements, proportion of preprandial and postprandial readings, baseline characteristics, and length of time in the study.

Results: A total of 203 women were randomized. Blood glucose data were available for 98 intervention and 85 control women. There was no significant difference in rate of change of blood glucose (–0.16 mmol/L in the intervention and –0.14 mmol/L in the control group per 28 days, *P*=.78). Women using the intervention had higher satisfaction with care (*P*=.049). Preterm birth was less common in the intervention group (5/101, 5.0% vs 13/102, 12.7%; OR 0.36, 95% CI 0.12-1.01). There were fewer cesarean deliveries compared with vaginal deliveries in the intervention group (27/101, 26.7% vs 47/102, 46.1%, *P*=.005). Other glycemic, maternal, and neonatal outcomes were similar in both groups. The median time from recruitment to delivery was similar (intervention: 54 days; control: 49 days; *P*=.23). However, there were significantly more blood glucose readings in the intervention group (mean 3.80 [SD 1.80] and mean 2.63 [SD 1.71] readings per day in the intervention and control groups, respectively;

P<.001). There was no significant difference in direct health care costs between the two groups, with a mean cost difference of the intervention group compared to control of –£1044 (95% CI –£2186 to £99). There were no unexpected adverse outcomes.

Conclusions: Remote blood glucocse monitoring in women with GDM is safe. We demonstrated superior data capture using GDm-health. Although glycemic control and maternal and neonatal outcomes were similar, women preferred this model of care. Further studies are required to explore whether digital health solutions can promote desired self-management lifestyle behaviors and dietetic adherence, and influence maternal and neonatal outcomes. Digital blood glucose monitoring may provide a scalable, practical method to address the growing burden of GDM around the world.

Trial Registration: ClinicalTrials.gov NCT01916694; https://clinicaltrials.gov/ct2/show/NCT01916694 (Archived by WebCite at http://www.webcitation.org/6y3lh2BOQ)

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KEYWORDS

gestational diabetes; pregnancy; digital health; blood glucose monitoring; app; GDM

Introduction

The prevalence of gestational diabetes mellitus (GDM) is increasing, creating demand for sustainable, cost-effective, and innovative approaches to care. There is enthusiasm for integration of digital technologies into health systems [1]. Although there is some evidence of clinical benefit with the use of digital health technologies in type 1 and 2 diabetes [2-4], large studies are lacking in the GDM population. There is potential for an integrated digital health solution for GDM: the condition requires frequent self-monitoring of blood glucose over a short time frame (typically 3 months), pregnant women are a motivated group willing to engage with health monitoring and advice, and women of reproductive age usually have an excellent grasp of digital technologies. Combining a digital blood glucose diary with real-time clinician review and feedback may improve glycemic control, reduce diabetes-associated complications, and mean potentially fewer outpatient contacts with the diabetes care team with cost savings to the health system, and it is likely to be more acceptable to women.

Several groups have developed remote blood glucose monitoring systems for women with GDM; however, trials have been small in size with potentially significant sources of methodological bias [5]. In the context of these limitations, telehealth monitoring systems have not been demonstrated to be superior to standard care for glycemic control and clinical outcomes [6-9]. Limited evidence supports that digital solutions are acceptable to pregnant women and possibly reduce the number of clinic visits [7,9,10]. No trial to date has assessed the associated health care costs.

We developed a digital blood glucose management system, GDm-health, to facilitate remote blood glucose self-monitoring and bidirectional communication between the clinical team and pregnant women. The system, described in detail elsewhere [11], was developed by patients, midwives, obstetricians, physicians, and biomedical engineers, and showed high levels of user satisfaction in a small service evaluation project [12]. We hypothesized that the real-time feedback and support offered by the system would improve glycemic control in women with GDM. To test this hypothesis, we conducted a randomized trial to assess whether digital remote management of GDM improved glycemic control compared to standard paper-based blood glucose monitoring, with secondary outcomes of maternal and neonatal outcomes, cost of care, and patient satisfaction.

Methods

Study Design and Participants

This was a single-center, balanced randomization 1:1, open-label, parallel-group, individually randomized controlled trial, conducted in a large UK tertiary referral hospital between September 2013 and June 2015 [13].

Sample Size

There were no published data on precise estimates of the likely standard deviation in mean blood glucose, making sample size calculation challenging. Therefore, we pragmatically decided to assume a standard deviation of 0.8 mmol/L for the mean blood glucose level at the end point. Thus, with 100 patients in each arm, we would be able to detect a difference between the arms of 0.32 mmol/L, with power of 80% and a significance level of .05.

Allocation

Participants were randomly allocated to two groups: intervention (the GDm-health management system; Multimedia Appendix 1) or control (usual care). Randomization used a partial minimization procedure to balance important covariates including gestational age, weight, and ethnic group using the Oxford University Primary Care Clinical Trials Unit computer-generated randomization system Sortition [14].

This trial received ethical approval from National Research Ethics Service Committee South Central-Berkshire B (reference number 13/SC/0176). Written informed consent was obtained for each participant. The trial was registered at ClinicalTrials.gov (ref: NCT01916694).

Participants

Screening for GDM was based on risk factors as per UK clinical guidelines [15] and GDM was defined using the International Association of Diabetes and Pregnancy Study Group [16] criteria.

Eligible women were aged between 18 and 45 years with a viable singleton pregnancy of less than 35 weeks and 0 days,

and had GDM diagnosed by 75 g oral glucose tolerance test [13].

Following diagnosis of GDM, women were instructed to perform preprandial and 1-hour postprandial blood glucose monitoring and were given information about the trial. If after this initial week they did not require immediate treatment with insulin, they were eligible for inclusion.

All women were asked to test their blood glucose six times a day on at least 3 days of the week, as per the local guideline. This consisted of a fasting sample, 1-hour postbreakfast, prelunch, 1-hour postlunch, predinner, and 1-hour postdinner. The target blood glucose range was fasting readings ≥3.5 and ≤5.8 mmol/L and 1-hour postprandial readings less than 7.8 mmol/L. Thresholds for further dietetic support were the same in both groups. A decision to start pharmacological treatment was made by a number of doctors unblinded to treatment allocation, but following the same local treatment guidelines for participants in both the intervention and the control arms.

Intervention and Control

Standard Clinic Care Group (Control Group)

Participants in the control group were instructed to record their blood glucose values in a paper diary. Every 2 to 4 weeks they attended the outpatient clinic for review. Women were instructed to contact the diabetes midwife if their blood glucose breached predefined thresholds [13].

Remote Glucose Monitoring Group (Intervention Group)

Participants in the intervention group were loaned a mobile phone with the preinstalled GDm-health app and taught how to record, tag, and review blood glucose readings by a research midwife. Every 4 to 8 weeks they attended the outpatient clinic (ie, half as many clinic visits as the standard clinic care group).

A diabetes midwife reviewed the blood glucose readings on a secure website at least three times a week. The system generated an alert if the same predefined thresholds as for the control group were breached [13]. An automatic alert was also generated if the participant was not recording a predefined number of blood glucose readings per week or more glucose testing strips were needed. A short message service (SMS) text message containing advice about diet, dose adjustments of hypoglycemic medications, and messages of encouragement were sent to the participant by the diabetes midwife between clinic visits via the website.

Analysis of Blood Glucose Data

Primary Outcome

The predefined primary end point was the rate of change in glycemia, measured as a function of blood glucose measurements (mmol/L/28 days), compared between the two groups. Change over time in glycemia in both groups was compared from recruitment until delivery.

Timed and tagged blood glucose data were extracted from the GDm-health management system to determine glycemia for the intervention group. Blood glucose data for the control group were extracted from the paper diaries completed by the women at each clinic visit. Paper diary data were entered into an electronic file, with a subset double-entered to check accuracy.

Paper diaries were used in preference to glucose meter downloads because the meters employed (LifeScan OneTouch Ultra Mini) did not allow mealtime tagging. Meter-generated time stamps were found to be inadequate surrogates.

Secondary Outcomes

Other predefined markers of glycemia were rate of change of glycated hemoglobin A_{1c} (HbA_{1c}); overall mean blood glucose and mean fasting, preprandial, and postprandial blood glucose; and time to treatment from recruitment in weeks. Maternal outcomes known to be associated with diabetic control were compared between the groups: weight was recorded at each visit and body mass index (BMI) was calculated, pregnancy-induced hypertension or preeclampsia, gestational age at delivery, birthweight and proportion of large for gestational age babies (>90th percentile for gestation and gender), mode of birth, and perineal severe trauma. Neonatal outcomes were shoulder dystocia or birth injury, neonatal hypoglycemia, neonatal hyperbilirubinemia, or admission to neonatal intensive care.

Participant attitudes were assessed using the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire [12]. This 12-item questionnaire has previously been validated for this population and was given to all women who participated in the trial within 6 weeks of the birth of the baby. Questions 1 to 9 asked women about their satisfaction with their care, their relationship with their diabetes team, and the reliability and convenience of the system, and were scored on a 7-point Likert scale (0=not satisfied to 6=very satisfied). Question 10 asked women about whether they felt the number of visits was too few, just right, or too many; question 11 asked whether they would be interested in using a mobile phone app to help with blood glucose monitoring; and question 12 asked whether they would recommend the app to a family member or friend with GDM. Scores for the first nine questions were summed with a maximum score of 54.

Direct health care costs, within the UK National Health Service (NHS) were compared between the two groups from the time of recruitment until hospital discharge after birth of the mother and baby. The complete list of services included in the cost analysis is reported in Table A in Multimedia Appendix 2 [17-19]. It was assumed that for some clinical outcomes (eg, shoulder dystocia, birth trauma, or neonatal hypoglycemia), and to avoid double counting, the costs associated with these outcomes were captured by the hospital length of stay. The cost analysis aimed to identify the additional costs of one group versus the other; therefore, the costs of the glucose meter and strips were excluded from the analysis because these were recommended for identical use by women in both groups. As GDm-health is free to install on a participant's mobile phone, no specific intervention costs were included in this analysis. We present unit costs, resource use, and costs separately between treatment arms [20]. Costs were expressed in 2014-2015 UK sterling pounds (£) and no discounting was employed given the short time horizon of the analysis [21].

Statistical Analysis

The analyses were based on the intention-to-treat population, which included all patients randomized. The primary analysis of blood glucose was repeated for the per-protocol population. The inclusion criteria for the per-protocol analysis were the population with more than 67% of expected numbers of blood glucose measurements (at least 28 of 42 readings for weeks when on pharmacological treatment and at least 12 of 18 readings for weeks not on pharmacological treatment).

Primary Analysis

The primary objectives were to compare rate of change in glycemia in the intervention arm with that in the control arm. Glycemia was assessed as a function of blood glucose measurements. The dependent variable, the blood glucose measurement, was recorded by each patient up to six times per day between recruitment and delivery. The change in blood glucose over gestation was modeled using a linear regression equation. A random coefficient model was fitted that allowed for differences between patients in the rate of change of blood glucose. Factors included in the model as fixed effects were (1) a two-level factor indicating the treatment group; (2) a factor with three levels indicating the time of day of the blood glucose measurement, breakfast, lunch, or dinner; (c) a two-level factor indicating whether the measurement was premeal or postmeal; and (d) baseline characteristics.

Secondary Analyses

The methods of linear mixed models were used to analyze the HbA_{1c} data. The rate of change of HbA_{1c} over gestation was modeled using a first-order regression equation. A random coefficient model was fitted that allowed for differences between patients in the rate of change, as performed for the primary outcome.

To compare maternal and neonatal outcomes in the treatment groups, continuous normally distributed variables were analyzed using analysis of covariance, including baseline characteristics as covariates, and binary outcomes using logistic regression. Results are reported as a treatment effect or odds ratio with 95% confidence limits. For continuous variables that were not normally distributed, the median and interquartile ranges (IQRs) are reported and a nonparametric test was used to compare treatment groups. For binary variables with zero or very small number of events, exact logistic regression was used.

Costs were estimated by multiplying quantities of health care resource use by the corresponding unit costs (Multimedia Appendix 2, Table A). Descriptive statistics were employed to summarize health care resource use and costs between the two treatment arms. A complete-case analysis was carried out given the small number of missing data present in the dataset. Parametric mean cost differences and associated 95% confidence intervals for each category of resource use were calculated to identify potential cost differences [21]. In addition, a summary mean total cost per delivery over the trial period was computed adding the costs of antenatal care and intrapartum and postnatal care before discharge together.

All analyses were carried out using SAS version 9 (SAS Institute Inc, Cary, NC, USA) and Stata MP14 (StataCorp LP, College Station, TX, USA,).

Results

Participant Characteristics and Data Capture

Of 301 women with GDM approached to participate in the study, 62 did not meet the inclusion criteria (6 outside age range, 22 had insulin prescribed after first week of monitoring, 11 were more than 34 weeks gestation, 6 had other medical conditions, 4 could not understand spoken English, and 13 other reasons) and 33 declined. Of the 206 women who met the inclusion criteria and provided written informed consent, 103 were randomized to the intervention group and 103 to the control. Two women in the intervention group and one in the control group chose to withdraw from the study before delivery, thus results from 101 women in the intervention and 102 in the control group are included in the intention-to-treat analysis (see Figure 1).

Baseline characteristics of the intervention and control groups were similar at recruitment (Table 1). At time of recruitment, 17 women in the intervention group and 13 women in the control group were taking hypoglycemic medication.

The number of hospital doctor visits were mean 4.65 (SD 2.89) and mean 5.06 (SD 2.86) in the intervention and control groups, respectively. The difference did not reach statistical significance.

Blood glucose data were obtained from 98 women (21,494 readings) for the intervention group; 85 patients (14,472 readings) in the control group used paper records. The median times from recruitment to delivery in the intervention and control groups were 54 (IQR 40 to 64) and 49 (IQR 41 to 60), respectively. Data capture was significantly greater in the intervention group with a mean 3.80 (SD 1.80) readings per day in the intervention group and mean 2.63 (SD 1.71) readings per day in the control group ($P<.001$).

Missing data in the intervention group were due to noncompliance with the protocol or technical failure. The possible reasons for missing data in the control group included noncompliance, missing blood glucose readings recorded by participants, or lost paper diaries.

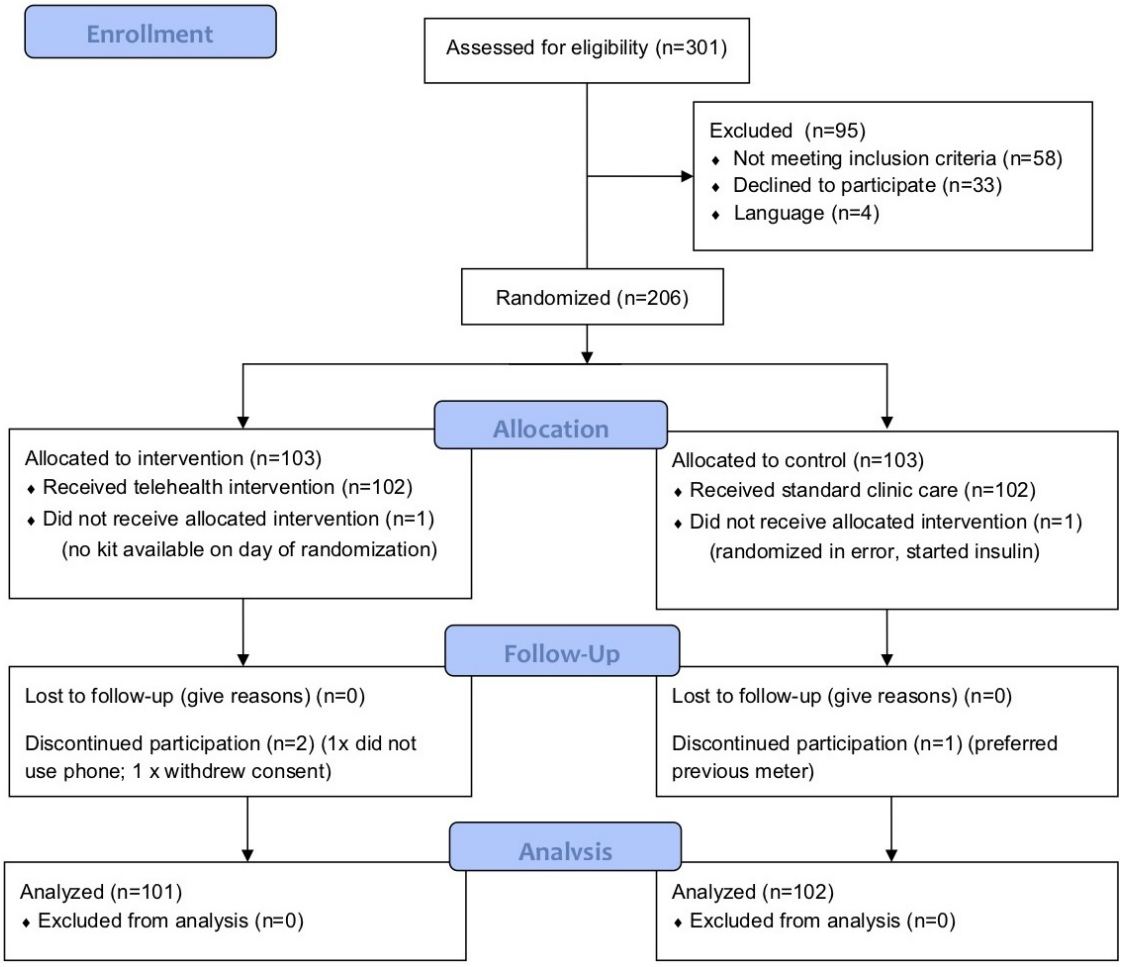
In total, 78 women in the intervention group and 52 women in the control group were included in the per-protocol analysis.

Primary Outcome

From study recruitment until delivery, the mean blood glucose fell in both groups. On average, blood glucose declined by 0.16 mmol/L/28 days in the intervention group and 0.14 mmol/L/28 days in the control group; the difference was not statistically significant (difference –0.01 mmol/L, 95% CI –0.10 to 0.08). Figure 2 shows change in mean blood glucose.

In the per-protocol analysis, the mean blood glucose decline was 0.17 mmol/L/28 days (95% CI –0.24 to –0.11) in the intervention group and 0.10 mmol/L/28 days (95% CI –0.19 to –0.01) in the control group. The difference between the two groups was not statistically significant.

Figure 1. CONSORT Flow Diagram for TREAT GDM.



Secondary Outcomes

Glycemic Control

Data for HbA_{1c} levels were obtained from 100 women (320 HbA_{1c} values; mean 3.2 values per woman) in the intervention group and from 101 women (338 HbA_{1c} values; mean 3.4 values per woman) in the control group.

Despite an overall decrease in mean blood glucose, a marginal increase in HbA_{1c} was observed in both groups from recruitment until delivery, with a mean 0.02% rise per 28 days in the intervention group and a 0.03% rise per 28 days in the control group. There was no statistically significant difference (intervention vs control: –0.01%, 95% CI –0.05 to 0.03).

At delivery, 45 of 101 (44.6%) women in the intervention group and 57 of 102 (55.9%) women in the control group were on metformin (OR 0.63, 95% CI 0.36-1.10).

Mean blood glucose and range and percentage of “on target” readings over four weekly time points as a function of meal tags are presented in Tables B and C in Multimedia Appendix 2. Mixed model analysis showing the effect of BMI and smoking is presented in Table D in Multimedia Appendix 2.

Other predefined secondary outcomes, specifically, number of dose adjustments of hypoglycemic medications and maximum dose of insulin or metformin, were inconsistently recorded in the clinical record and have therefore not been included in the results.

Maternal and Neonatal Outcomes

Maternal and neonatal clinical outcomes are reported in Multimedia Appendix 3. Women in the intervention group had a median gestational age at delivery 3 days greater than those in the control group, but the difference was not statistically significant (log-rank test: χ^2_1=14.5, *P*=.22). Preterm birth was less common in the intervention group (5/101, 5.0%) versus in the control group (13/102, 12.7%; OR 0.36, 95% CI 0.12-1.01). The cesarean delivery rate compared with other modes of delivery was lower in the intervention group compared to the control group (27/101, 26.7% vs 47/102, 46.1%, *P*=.005), with notably fewer emergency cesarean deliveries in the intervention group. Rates of other maternal complications, including hypertensive disorders of pregnancy, perineal trauma, and maternal admission to a higher level of care, were low across both groups, with no significant differences demonstrated. Weight gain from recruitment to delivery did not differ between the groups.

Table 1. Baseline characteristics of participants (N=203). BMI: body mass index; GCSE: General Certificate of Secondary Education; GDM: gestational diabetes mellitus.

Characteristic	Intervention			Control		
	N[a]	Mean (SD)	n (%)	N[a]	Mean (SD)	n (%)
Maternal age (years)	101	33.9 (5.5)		102	33.0 (5.6)	
Parity	101			102		
0			36 (35.6)			42 (41.2)
1			33 (32.7)			40 (39.2)
≥2			32 (31.7)			20 (19.6)
Height (m)	101	1.63 (0.08)		102	1.63 (0.07)	
Weight at booking (kg)	100	82.9 (18.2)		102	84.7 (21.5)	
BMI at booking (m/kg^2)	100	31.1 (6.7)		102	31.6 (7.3)	
Smoking in pregnancy	101		3 (3.0)	102		5 (4.9)
Essential hypertension	101		2 (2.0)	101		6 (5.9)
First-degree relative with diabetes	99		39 (39.4)	100		43 (43.0)
Previous GDM[b]	65		10 (13.8)	60		7 (11.7)
Previous baby weighing >4.5 kg[b]	64		5 (7.8)	60		5 (8.3)
Previous cesarean delivery[b]	65		22 (33.8)	60		24 (40.0)
Highest educational attainment	101			99		
GCSE or less			27 (26.7)			24 (24.2)
A Level			22 (21.8)			30 (30.3)
University			52 (51.5)			45 (45.5)
Ethnic group	100			102		
White			77 (77.0)			80 (78.4)
South Asian			10 (10.0)			13 (12.7)
African/Caribbean			6 (6.0)			4 (3.9)
East Asian			3 (3.0)			1 (1.0)
Other			4 (4.0)			4 (3.9)
Gestational age at recruitment (weeks)	101	30.9 (3.6)		102	31.0 (3.4)	
Oral glucose tolerance test (mmol/L)						
Fasting	98		5.2 (0.9)	96		5.2 (0.9)
1 hour	79		9.9 (1.7)	87		10.4 (1.7)
2 hour	99		7.4 (2.2)	97		7.0 (1.9)
Patients on metformin at recruitment	101		17 (16.8)	102		13 (12.7)
HbA_{1c}[c] at recruitment[d] (%)	42	5.42 (0.34)		46	5.39 (0.35)	

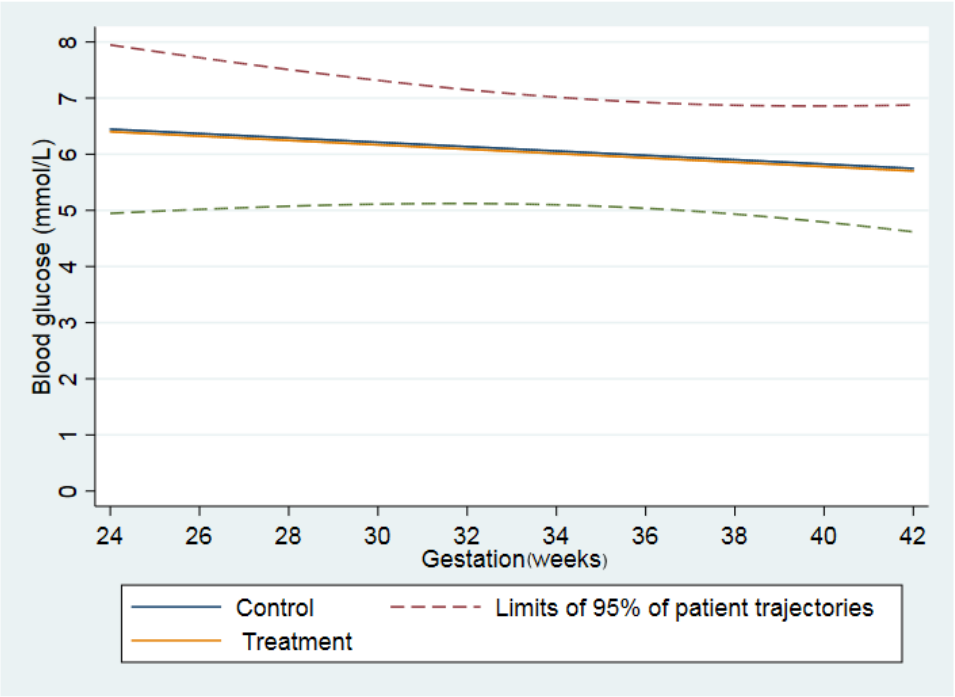
[a]N refers to the total number of participants for whom data for each variable available.

[b]Multiparous women only.

[c]HbA_{1c}: glycated hemoglobin A1c.

[d]HbA_{1c} at recruitment was measured between 18 and 35 weeks gestation.

Figure 2. Change in mean blood glucose.



Neonatal outcomes were similar between the groups. There was no significant difference observed between the groups with respect to mean birthweight, proportion of large for gestational age babies, neonatal sex, shoulder dystocia, neonatal hypoglycemia, neonatal jaundice, or admission to the neonatal intensive care unit.

Satisfaction with Care

In all, 60 of 102 patients in the control group and 60 of 101 patients in the intervention group returned the completed Oxford Maternity Diabetes Treatment Satisfaction Questionnaire. One question was misunderstood by approximately half of the patients and was omitted from the total score. Both groups reported high levels of satisfaction with the care they received (intervention: median 43, IQR 39-46; control: median 44.5, IQR 41-46; Kruskal-Wallis χ^2_1=3.9, *P*=.049). In the control group, 48 of 60 (80%), and 53 of 60 (88%) in the intervention group, felt that the number of visits was just right (*P*=.22) compared with too few or too many. In the intervention group, 57 of 60 women who used the app stated they would use it again and 51 of 60 in the control group said they would consider using a mobile phone app. In the intervention group, 59 of 60 women replied that they would recommend the app to friends or family with the same condition. Free-text comments emphasized the convenience of GDm-health, the additional support out of hospital, and the benefits of avoiding the hospital for appointments.

Cost Analysis

No statistically significant cost differences were observed between the two groups over the trial period (Multimedia Appendix 4). Estimated mean cost per delivery was £5697 (SD £3068) and £6741 (SD £4640) in the intervention and control groups, respectively, with a mean cost difference of –£1044 (95% CI –£2186 to £99).

Compliance With the Protocol

Compliance with blood glucose readings was significantly better in the intervention group. In all, 78 of 98 women in the intervention group and 52 of 85 women in the control group recorded at least 67% of the expected number of readings (OR 2.44, 95% CI 1.29-4.61).

Discussion

Principal Findings

In this randomized trial, digital remote management of blood glucose in women with GDM was associated with similar blood glucose control compared to usual care, as assessed by mean change in blood glucose. We demonstrated that women using the GDm-health system had significantly more blood glucose readings, higher satisfaction scores and fewer cesarean deliveries compared to women in the control group, and these reached statistical significance. There were longer gestations and fewer preterm births in the intervention group compared to the control group which did not reach statistical significance. Other maternal and neonatal outcomes were similar in both groups. We were not able to demonstrate a significant cost savings.

This digital health solution has proven popular with women who commented that they appreciated the additional support and monitoring it provided, as well as the perceived time and cost savings of avoiding hospital appointments. The UK strategy for improving health care is to give individuals shared access to their own health records and for them to be at the center of all decision making [1]. By directly allowing women to contribute to and access their blood glucose monitoring data, we believe GDm-health is a good example of a system moving toward this goal.

This is the largest randomized controlled trial to date of a digital health solution for the management of women with GDM. Our

findings are in keeping with our published systematic review [5], which concluded there was no evidence of superior glycemic control using digital monitoring. As with other trials, patient satisfaction was higher in the intervention group. We did not show a significant effect on secondary clinical outcomes. It is of note that interventional trials in women with GDM that are powered to show significant effects on clinical endpoints are usually much larger than our trial (typically in excess of 500 women in each arm). These trials also compare any treatment against no treatment for GDM; therefore, they are likely to have a bigger effect on outcome [22].

Fewer women in the intervention group transitioned to hypoglycemic medication during the study, which may have been related to better dietetic adherence, although we did not collect data on diet and exercise in this study. Although not statistically significant, there was an average 3-day prolongation of pregnancy and fewer preterm births in the intervention group compared to the control group, which may have influenced the significantly fewer emergency cesarean deliveries. The clinical benefit of influencing self-managed lifestyle behaviors and dietetic adherence in this population using digital technologies warrants further study.

Determining the adequacy of blood glucose control during pregnancy is challenging. Although we report no difference in HbA_{1c}, it is a poor measure of glucose control in the context of rapid changes in glycemia over a short period of time [23]. Likewise, we did not have access to continuous glucose monitoring, thus the overall linear rate of change of blood glucose we present was reliant on the woman's capillary testing and may have missed differences in fetal glucose exposure during the trial. Assessing end organ effects such as fetal growth has been suggested as an indicator of blood glucose control [24]; however, by its nature this measure is retrospective indicating past rather than current glycemic status. Trends in fasting and preprandial and postprandial capillary blood glucose monitoring, therefore, remain the mainstay of glycemic assessment in women with GDM.

Capturing the data in the paper diaries presented several challenges in this trial, with incomplete, untagged, inaccurate, and missing records. Poor compliance has been associated with poor concordance between paper diaries and meter readings and poorer glycemic control [25]. Digital blood glucose recording with automated delivery of blood glucose data provides a reliable and secure source of data for clinical interpretation. Beyond fidelity in data capture, digital data linked to mealtimes and other clinical parameters (eg, fetal growth) could be used in dynamic analyses, giving feedback to patients and clinicians about overall trends in blood glucose control. In our service development cohort, we demonstrated that 2-week moving-average blood glucose values were significantly higher in women with GDM who delivered large for gestational age infants compared to those with normal infants [26]. For this trial, we did not incorporate any predictive algorithms into the system, other than a graphical display of blood glucose trends, as algorithms have yet to be validated for clinical practice. However, digital technologies incorporating artificial intelligence or clinician based feedback as well as optimized reporting and alerting visuals could have the potential to promote desired self-managed lifestyle behaviors and dietetic adherence.

Current thresholds for treatment targets in GDM are based on consensus, historical practice, and targets selected for use in clinical trials. The ability to accurately correlate dynamic data with clinical endpoints will be an important development for future research in GDM, eventually enabling individualized glycemic management plans. As technologies for continuous glucose monitoring become more reliable and affordable, a natural progression would be to incorporate their output into a digital health system such as GDm-health [27].

Strengths and Limitations

The strengths of this study are the rigorous design and attention to randomization, which ensured similar groups at study entry and the high levels of follow-up until delivery in both groups. The trial was conducted under "real life" conditions in a busy maternity diabetes service. We considered a range of clinical and nonclinical outcomes, important for comprehensive evaluation of the potential benefits and harms of a new technology. We also present the first randomized comparison of direct costs of maternity-associated care.

The trial also has limitations. We were unable to demonstrate a difference in the number of clinic attendances between the groups, despite this being specified in the protocol. Booking follow-up appointments based on study allocation proved challenging, as routine 2-week, rather than modified 4-week follow-up appointments for participants assigned to receive the GDm-health intervention were often made by clerical staff, most of whom were unaware of the study. Therefore, it is not possible for us to determine whether this technology can safely replace clinic visits and this clearly impacted on direct health care costs.

A full economic assessment was not performed, with costs of implementation, medications, and indirect costs not included. The trial was conducted in a single referral center, where the technology was also developed and, as such, uptake and effectiveness may differ in other settings. We are currently evaluating a pilot scale-up program in three other public hospitals. At the time of writing, more than 250 women each month are using GDm-health, with similar satisfaction scores and sustained use over 2 years [28]. A further limitation is that the trial was limited to women who could understand written and spoken English to be able to provide valid consent without the need for an interpreter. In populations with large non-English speaking populations provision would need to be made to ensure equity of access to the system.

Conclusion

There is a national drive to incorporate digital health solutions into routine UK health care delivered through the NHS; however, the evidence for their efficacy and clinical and cost-effectiveness is lacking. This pilot study describes the largest randomized evaluation to date of a system to monitor and manage GDM remotely. The system appears safe with comparable glycemic control, maternal, and newborn outcomes between allocated groups, with improved patient satisfaction and superior data capture in the intervention group. Further

large, detailed health economic evaluation of these systems at scale is required to understand their potential impact on health care systems. Likewise, studies to understand whether such real-time digital monitoring systems incorporating continuous glucose monitoring technologies can provide new insights into predictive and bespoke individualized management plans are also required. Finally, studies to evaluate whether these digital systems have the potential to promote desired self-management behaviors and better dietetic adherence which could also influence clinical outcome, are required.

Acknowledgments

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Authors' Contributions

LM, JEH, KB, JB, AJF, OJF, YK, JCL, LL, ORA, CV, and LT were directly involved in the trial design and/or execution. JCL, LC, and WKM provided further statistical support. LM drafted the manuscript. All authors commented and/or drafted sections of the final manuscript. All authors have read and confirmed that they meet ICMJE criteria for authorship.

Conflicts of Interest

LM, CV, and LT reports consultancy fees from Drayson Technologies who have, subsequent to this study, become the sole licensee of the GDm-health management system. LT is also on the advisory board for Drayson Technologies. LL was funded by the RCUK Digital Economy Programme and the Clarendon, Scatcherd European, and New College Graduate Scholarship schemes. ORA reports grants from Medical Research Council, grants from NIHR-HTA, grants from NIHR-HS&DR, grants from EuroQol Research Foundation, personal fees from EuroQol Research Foundation, personal fees from Oxford Pharmagenesis, outside the submitted work. JEH, KB, JB, LC, AJF, OJF, YK, JCL, and WKM have no declarations of conflicts of interest.

Multimedia Appendix 1

GDm-health app screenshots.

[PPTX File, 5MB - mhealth_v6i3e71_app1.pptx]

Multimedia Appendix 2

Supplementary Information.

[PDF File (Adobe PDF File), 54KB - mhealth_v6i3e71_app2.pdf]

Multimedia Appendix 3

Maternal and neonatal outcomes.

[PDF File (Adobe PDF File), 35KB - mhealth_v6i3e71_app3.pdf]

Multimedia Appendix 4

Breakdown of healthcare resource use and associated cost of intervention and control groups.

[PDF File (Adobe PDF File), 40KB - mhealth_v6i3e71_app4.pdf]

Multimedia Appendix 5

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 494KB - mhealth_v6i3e71_app5.pdf]

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Abbreviations

BMI: body mass index
GDM: gestational diabetes mellitus
HbA $_{1c}$: hemoglobin A1c
IQR: interquartile range
NHS: National Health Service
NIHR: National Institute for Health Research

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Original Paper

Adolescents' Perspectives on a Mobile App for Relationships: Cross-Sectional Survey

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Abstract

Background: Adolescence can be a fertile time for relationship issues, with interpersonal conflict being a risk factor for poor mental health. Mobile app interventions may have a significant appeal to young people in assisting with relationship distress. However, currently available apps have not been formally evaluated. Youths' perspectives on engaging with mobile technology to assist with relationships are also unknown.

Objective: This study aimed to examine adolescents' attitudes toward the concept of a mobile phone app for relationship help and support, and whether they would be likely to use such an intervention.

Methods: A cross-sectional Web survey consisting of 42 questions, including 13 free responses, was delivered. The proposed app, including character vignettes, was presented, and participants were asked to indicate whether they had experienced the same relationship issues, whether their peers would relate to the issues, and how helpful they found the proposed advice. Participants were also asked to provide their own suggestions for help, which were analyzed using thematic analyses.

Results: A total of 150 adolescents (aged 15 to 18) participated. Overall, 60.7% (91/150) were likely to use an app for relationship problems, and this was not associated with demographics or social support (all *P* values >.05). Likelihood of app usage was found to be influenced by perceived need for help, personal beliefs about app effectiveness, and whether the app is engaging and easy to use. Overall, adolescents were receptive of the proposed content with an average of 99.3% (149/150), rating the strategies provided as somewhat to very helpful.

Conclusions: Adolescents were likely to use a mobile phone app for relationship support, and use was not influenced by gender, age, social support, or any other background characteristic. Instead, likely use was influenced by need, personal beliefs, usability, and the appropriateness of app content. App developers must address these factors if the app is to have a wide-scale uptake.

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KEYWORDS

family relations; peer group; help-seeking behavior; mobile apps; adolescence

Introduction

Across the lifespan, relationships are important to well-being [1]. Relationships generate social support that helps individuals to buffer psychological distress and prevents maladaptive coping [2,3]. Positive relationships are highly protective against a range of poor health outcomes [4], including mental illness [5]. Adolescence is an active phase of relationship development [6-8]. During this time, young people manage the desire for peer interaction and approval, with an increasing independence from the family. Young people begin to establish relationships on shared values, ideas, and intimacy rather than the

convenience and common interests, which characterize childhood friendships [9]. Adolescence can be a fertile time for relationship problems, and although expected, some can be disruptive and distressing. One in 5 youths is concerned about the level of interpersonal conflict in their life [10]. Up to 25% have reported experiencing recent psychological distress because of a family or interpersonal issue, and rates were higher among females [11]. Relationship problems can elevate the risk of suicide [12,13], depression [14], anxiety [15], school disengagement [16], substance misuse [17], and poor physical health [18]. Given these negative consequences, it is important to ensure young people are adequately supported when faced with relationship distress.

Help-Seeking for Relationships

In general, little is known about adolescents' help-seeking specifically for relationships. Much more is known about adolescents' help-seeking for mental health issues, which has been found to be inhibited by stigma, accessibility, and self-reliance [19]. Conversely, positive past experiences, social support, and encouragement from others is found to aid help-seeking. Although mental health issues are more complex, similar factors may affect help-seeking for relationships. Many adolescents report feeling embarrassed and ashamed of personal issues [20], believing relationship problems to be significantly more intimate than other types of problems, such as physical health, education, finance, or legal issues [21]. Help-seeking for relationships may be complicated by young people's preferences for turning to friends and family [22,23]. If these sources have been compromised because of conflict, the capacity of the support network may be diminished, and help-seeking may be inhibited. In a study by Boldero and Fallon [11], interpersonal problems were found to be associated with greater help-seeking when compared with family problems, despite family problems being more frequently reported [11]. Young people perceived interpersonal problems to be more serious than those with family, and that their locus of control over interpersonal problems was greater. Help-seeking was predicted by gender, and problem type, with females more likely to report problems with families and interpersonal relationships, whereas males were more likely to report problems with education [11]. Combined, past studies depict a complex picture of the factors influencing help-seeking among youths.

Mobile Apps for Relationships

There are evidence-based therapies (eg, cognitive behavioral therapy [CBT] and interpersonal therapy [IPT]) that have been found to be effective for relationships [24-26]. These types of interventions are delivered by trained professionals and are typically conducted over a series of weekly sessions. Despite the effectiveness, uptake among youths is likely to be low because of limited financial capacity and a reluctance of formal help [20,22,23]. CBT has been adapted for Internet delivery in the form of self-directed programs, overcoming many of the access barriers. However, these programs are designed to treat symptoms of depression and anxiety rather than prevent relationship distress. Consequently, these programs may not appeal to youths who are seeking help specifically for relationships. A recent systematic review found that mobile health interventions are a viable health behavior change modality for youths [27]. A benefit of mobile help-seeking interventions is that they can deliver brief and engaging content that has the potential to prevent mental health issues, without pathologizing normal relationship patterns. Although there are some mobile apps currently available for relationships, they predominately focus on relationship separation and neglect the range of other relationship issues young people face, for example, family conflict and psychosocial experiences [28,29]. These apps also primarily use one type of therapeutic intervention, behavioral activation, in which the user is encouraged to schedule pleasurable activities with others [30]. Few of these apps have been formally evaluated. Therefore, there is limited evidence to support the use of currently available interventions.

Our Study

Given the emotional impact of relationship conflict, the lack of help being sought for these issues, and the preference for digital health solutions, there is a clear need for an evidence-based mobile app that has universal appeal, covers a range of relationship types (eg, friendships, family relationships, romantic relationships) and psychosocial issues (eg, anxiety, body image, negative thinking, help-seeking), and is easily accessible to youths. Researchers at the Black Dog Institute have developed the content for such an app. However, to ensure that the proposed app has uptake, acceptability needs to be assessed. In the context of health care, acceptability is defined as a multifaceted construct that reflects the extent to which people delivering or receiving an intervention consider it to be appropriate, and suited to their needs, based on anticipated or experimental responses [13]. As outlined by their review, Sekhon et al [31] argue that acceptability should be assessed before individuals engage in an intervention and should measure how a person feels about an intervention, the extent to which the participant understands the intervention content, the extent to which the intervention is perceived as likely to achieve its purpose, and the participants' confidence in using the intervention. Guided by this framework, this study aimed to examine young people's attitudes toward the concept of a mobile phone app for relationship help and support, and whether they would be likely to use such an intervention. Using a series of vignettes designed to be incorporated into the app's content, this study aimed to examine the following: (1) whether young people had experienced the types of relationship issues presented; (2) the extent to which young people felt their peers would relate to the proposed content; and (3) the level of acceptability of the relationship strategies offered by the app. The study also examined whether acceptability was influenced by demographic factors or social support levels. Results will help to highlight which aspects of the proposed content could be modified to increase acceptability, and thus participation. This study presents a systematic approach to understanding end users' needs [32,33], which will support the future development of engaging and effective mobile help-seeking interventions.

Methods

Design

A cross-sectional Web survey was delivered. This study was approved by the University of New South Wales Human Research Ethics Committee (#HC15583).

Participants and Procedure

Australian adolescents aged 15 to 18 years were invited to participate in the study by responding to an online advertisement, which included a link to the online survey published on Facebook as well as the Black Dog Institute's website, Facebook, Twitter, and Instagram platforms. The online survey was delivered by the Key Survey software, hosted by the University of New South Wales. The survey included the participant information sheet and consent form in which participants were asked to provide consent online. Parental consent was not required, as young people aged 15 years and over were deemed to be mature minors capable of consenting to their own participation in this low-risk research. Once consent was given, the survey questions appeared. After completion of the survey, participants were redirected to a separate webpage on which they were asked to enter their name and email address to be reimbursed with an Aus $20 online gift voucher. Personal details were not linked to survey responses.

Survey

The survey consisted of 42 questions, including 13 free-response questions.

Demographics

A total of 7 questions were asked, assessing age, gender (male, female, or other), country of birth (Australia or other), language spoken at home (English or other), living situation (with both parents together or all other), work and study status (high school, working, university, apprenticeship, or none of the above), and whether they identified as lesbian, gay, bisexual, trans, intersex (LGBTI; answered yes, no, or rather not say) or Aboriginal and, or, Torres Strait Islander (ATSI; answered yes, no, or rather not say). Participants were also asked whether they owned a smartphone (yes or no) or mobile tablet (yes or no) and the primary device used to access the Internet.

Social Support

To determine whether the acceptability of the app was associated with current social support levels, the Schuster Social Support Scale [34] was used to measure the extent of positive and negative social interactions in 3 domains: peers, family, and partner. The scale consists of a total of 15 items: 5 items related to participants' peers (2 positive and 3 negative), 5 items (2 positive and 3 negative) to participants' family, and 10 items (5 positive and 5 negative) to participants' partner, where applicable. Participants responded using a Likert scale with 4 possible degrees of agreement, ranging from 1 to 4 (*How often…* questions answered never, rarely, sometimes, often and *How much…* questions answered not at all, a little, some, or a lot). Positive and negative subscale scores for each source of support were calculated by adding each item score and then dividing by the total number of items. Higher scores reflect higher levels of positive or negative support.

Likelihood of App Usage

Participants were asked how likely they were to use a mobile phone app for relationships (answered likely, neutral, or unlikely). Using free response, they were also asked to provide reasons why or why not, which were to be analyzed qualitatively.

Acceptability of App Content

The survey included 4 nonstandardized character vignettes that each described relationship issues experienced by 4 young people named Abigail, Jasper, Emily, and Angus. Outlined in Table 1, these vignettes were created specifically for this study by mental health researchers and clinicians and were designed as potential characters to be included in the app for the purposes of social learning. Each vignette was approximately 250 words in length and had a Flesch-Kincaid Grade Level score of 6, indicating a Grade 6 reading level. Vignettes are provided in Multimedia Appendix 1.

Participants were asked to read the vignettes and report whether they or a friend had experienced this situation (experience answered yes, no, or not sure). They were then asked to rate how much they felt their peers would relate to the character (relatedness answered not at all, a little, moderately or a lot). Given that the aim was to design a universal app with broad appeal, the relatedness variable was collapsed (a lot, moderately, a little vs not at all) to better capture what types of youths did not at all relate to the content. Using free response, participants were asked to report what they would do if faced with the character's issue, and what they would suggest a friend do in a similar situation. Finally, evidence-based coping strategies were presented. Participants were then asked to rate the helpfulness of these using a 5-point scale of not at all helpful (1) to extremely helpful (5).

Table 1. Relationship issues and coping strategies outlined in the character vignettes.

Character	Issues explored	Coping strategies
Abigail	Peer conflict, intimate relationship problems, eating disorders, negative thinking, and low self-esteem	Coping with distress, help-seeking, and relaxation and meditation
Jasper	Relationship breakdown, social anxiety, bullying, online relationships, and low self-esteem	Problem solving, sleep strategies, anxiety desensitization, and help-seeking
Emily	Academic pressure, parental conflict, peer conflict, drug use, sexuality, and negative thinking	Help-seeking, relaxation, cognitive restructuring, and social mapping
Angus	Family conflict, parent separation, intimate relationship problems, anger management, substance use, and change	Help-seeking, relaxation, conflict resolution, and cognitive restructuring

There were no minimum levels of experience, relatedness, or helpfulness expected. Instead, the study aimed to identify the aspects of the app content that may influence acceptability.

Analysis

The data were exported from Key Survey, and statistical analyses were conducted in SPSS v22 (Chicago, IL, USA). Descriptives were conducted and reported. Correlational and chi-square tests were used to examine whether background factors were associated with having experienced a character's issues, peer relatedness, and helpfulness ratings. This would help to determine whether the app content was more likely to be acceptable among certain youths. Due to the low cell counts, participants who reported that their gender was other (n=5) or that they would rather not report their LGBTI status (n=3) were excluded. Furthermore, this sample was inappropriate for examining ATSI effects because of low numbers (2.0%; 3/150), and the saturation of technology ownership (98.0%; 147/150) meant that these variables were inappropriate for inclusion in the variance analyses. For the analyses including the experience variable, participants who reported that they were unsure were excluded. This was done to ensure integrity of the data. Free-response data were analyzed using Braun and Clarke's thematic analysis guidelines [35]. The analysis involved manually coding the 13 free-response questions. Using an inductive approach, patterns and themes were identified. Two researchers (BOD and MA) refined the initial codes for cohesiveness, sorted to combine related concepts into encompassing main themes, and reached an agreement on the final themes. Using the predetermined framework, the data were then reviewed by a third researcher (YP). The mean intercoder reliability between the 2 coders (YP and MA) was 77% (range: 70%-83%). Inconsistencies were identified and resolved using consensus. In accordance with recommendations [36,37], frequency counts and percentages were reported to highlight the representativeness of themes and clarify meaning inferred from the dataset.

Results

Participants

A total of 150 adolescents completed the survey (age range: 15-18 years, mean 16.8 years [SD 1.1]). Table 2 outlines participant characteristics.

Table 3 presents the reported levels of social support. Overall, participants had higher positive support than negative support in each domain. Results show that family members and partners provided slightly higher positive support compared with participants' peers. Family members also provided the highest level of negative support across the domains.

Table 2. Participant characteristics (N=150).

Demographic	n (%)
Female	104 (69.3)
Born in Australia	130 (86.7)
English is main language	138 (92.0)
LGBTI[a]	38 (25.3)
ATSI[b]	3 (2.0)
At high school	98 (65.3)
At university	39 (26.0)
Working full-time	6 (4.0)
Living with both parents together	95 (63.3)
In a relationship	44 (29.3)
Owned a smartphone	147 (98.0)
Owned a tablet	92 (61.3)
Owned both	90 (60.0)
Did not own either	1 (0.7)
Device mainly used to access Internet	
Personal laptop or desktop computer	77 (51.3)
Smartphone	69 (46.0)
Tablet	4 (2.7)

[a]LGBTI: lesbian, gay, bisexual, trans, intersex.

[b]ATSI: Aboriginal and/or Torres Strait Islander.

Table 3. Social support levels within the sample.

Support source and nature of support	n	Mean (SD)	Range
Peer			
Positive	147	3.22 (0.63)	1.5-4
Negative	145	2.42 (0.65)	1-4
Family			
Positive	149	3.31 (0.74)	1-4
Negative	148	2.96 (0.70)	1-4
Partner			
Positive	44	3.34 (0.77)	1.4-4
Negative	44	2.03(0.72)	1-3.4

Likelihood of App Usage

A total of 60.7% (91/150) of participants reported that they were likely to seek help from a mobile app for relationship issues, 26.7% (40/150) had a neutral response, and 12.7% (19/150) were unlikely. Likelihood of app use was not significantly associated with any participant characteristics or social support (all *P* values >.06). Thematic analysis (Table 4) found that 3 key themes influenced participants' likelihood of use: (1) perceived need, (2) beliefs, and (3) engagement and accessibility.

Acceptability of App Content

Overall, only 10.6% (16/150) of participants reported that they had not experienced any of the issues presented; that is, most participants (134/150, 89.4%) had experienced 1 or more of the issues presented. All participants reported that their peers would relate to at least one of the characters, with 94.0% (141/150) reporting that their peers would relate moderately or a lot to 1 or more of the characters, and 56.0% (84/150) reporting that their peers would relate a lot to 1 or more of the characters. Table 5 outlines participant responses to the vignettes.

Participants with higher negative family support were more likely to experience Abigail's issues (r_s=−.25, n=69, *P*=.03), whereas females were more likely than males to report experience of Emily's issues (χ^2_1=6.1; OR 5.8, 95% CI 1.50-22.09; *P*=.01). Participants with lower positive family support (r_s=.25, n=69, *P*=.04) and higher negative family support (r_s=−.28, n=69, *P*= . 02) were more likely to report experiencing Angus' issues. No other significant associations were found (all *P* values >.07). On average, 99.3% (149/150) of the sample reported that the proposed suggestions were helpful to some extent. Participants were more likely to rate the advice given for Abigail as helpful if they had some experience of her issues (r_s=.239, n=70, *P*=.05). For Emily, participants were more likely to rate suggestions for her as helpful if they reported higher peer relatedness (r_s=.255, n=70, *P*=.03). Younger participants were more likely to rate suggestions for Jasper as helpful (r_s=−.412, n=70, *P*<.001) as well as Emily's suggestions (r_s=−.265, n=70, *P*=.03). No other significant associations were found (all *P* values >.43).

Table 4. Themes influencing the likelihood of app usage (N=150). R: respondent.

Theme	Definition	n (%)	Example
Perceived need	The degree to which the young person has identified a need for relationship help and support	74 (49.3)	• "...I would be able to have a better relationship with my potential girlfriend." [R132] • "I don't feel I need it at this current stage." [R2]
Beliefs	The degree to which the young person believed in the effectiveness of mobile apps for providing genuine relationship support	74 (49.3)	• "…if it does no harm then it is worth a shot." [R26] • "I'm open to the advice and possibly using such an app, but it also seems a bit silly to use an app for relationship advice." [R102]
Engagement and accessibility	The degree to which the young person valued the user experience aspects of the app, such as being easy to use, as well as engagement aspects such as being interesting and different	50 (33.3)	• "If had useful things and was easily accessible, I would use it. If it was outdated, not useful, hard to interact with etc, I wouldn't." [R90] • "...if it contains constructive advice and is designed in a way that targets my age group in a positive and welcoming way." [R64]

Table 5. Participant responses to the vignettes (N=150).

Responses	Abigail, n (%)	Jasper, n (%)	Emily, n (%)	Angus, n (%)
Experience				
Yes	79 (52.7)	49 (32.7)	53 (35.3)	27 (18.0)
No	51 (34.0)	68 (45.3)	65 (43.3)	96 (64.0)
Unsure	20 (13.3)	33 (22.0)	32 (21.3)	27 (18.0)
Peer relatedness				
A lot	51 (34.0)	23 (15.3)	32 (21.3)	15 (10.0)
Moderately	68 (45.3)	58 (38.7)	70 (46.7)	53 (35.3)
A little	27 (18.0)	63 (42.0)	42 (28.0)	76 (50.7)
Not at all	4 (2.7)	6 (4.0)	6 (4.0)	6 (4.0)
Helpfulness, mean (SD)	4.03 (0.81)	4.12 (0.88)	3.84 (0.89)	3.95 (0.87)

Table 6. Themes influencing the acceptability of the proposed relationship-coping strategies (N=150). R: respondent.

Theme	Definition	n (%)	Example
Nature	The degree to which a young person viewed the advice as appropriate, effective, feasible, or credible	127 (84.7)	• "It's very helpful useful information." [R11] • "The advice is theoretically perfect but in reality is very difficult to implement for someone in Emily's shoes." [R12]
Scope	The degree to which a young person felt that the advice adequately addressed the full range of issues being faced	38 (25.3)	• "There were many elements that I did not imagine, and the points were very comprehensive." [R68] • "You did not address the issue of Emily pressuring her to try marijuana." [R116]
Approach	The degree to which a young person felt that the advice was nonjudgmental, collaborative, empowering, or condescending	11 (7.3)	• "I like that this suggestion understands his reluctance to talk to his parents, or anybody in general, but tries to find ways around that." [R69] • "I think it's pretty good advice because it doesn't place any blame on the person receiving it." [R99]
Personal experience	The degree to which a young person identified personal experience using the advice in the past	10 (6.7)	• "I have been in a similar situation and those were pretty close to the steps I took." [R98] • "When I stopped going to school due to my anxiety I did try seeing the school counsellor and they did nothing." [R10]

Outlined in Table 6, thematic analysis identified 4 key themes that influenced participants' acceptability of proposed relationship-coping strategies: (1) nature, (2) scope, (3) approach, and (4) personal experience.

When asked what participants would do themselves and recommend to a friend, 8 themes were identified. Outlined in Table 7, 3 themes (seek help, active coping, and perceived coping efficacy) captured participants' recommendations for what they would do themselves, and 5 themes (general emotional support, informational support, encourage help-seeking, shared activities, and practical support) captured recommendations to a friend facing a relationship issue.

Table 7. Participants' recommendations for what they would do themselves and recommend to a friend when faced with a relationship issue (N=150). R: respondent.

Recommendation type and theme	Definition	n (%)	Example
What young people would do themselves			
Seek help	The degree to which a young person expressed that they would ask for help if faced with a similar issue	64 (42.7)	• "Talk to my support teacher to help advise me in the situation." [R43] • "Gain help and advice from trusted friends." [R66]
Active coping	The degree to which a young person reported an action-orientated attempt to solve or cope with the problem if faced with a similar issue	50 (33.3)	• "Ditch the smoking friend and find better friends." [R37] • "Just try to relax and make myself feel better by doing things I loved." [R81]
Perceived coping efficacy	The degree to which a young person felt that they would have the ability to cope if faced with a similar problem	50 (33.3)	• "I would tell myself that things get better and try and focus on the positives in life." [R141] • "Not sure, probably withdraw." [R120]
What to do to help a friend			
General emotional support	This involved acting in a supportive, reassuring, comforting, empathetic, caring, nonjudgmental, and encouraging manner	90 (60.0)	• "I would comfort them and make sure they feel loved." [R117] • "I would be there for them in the difficult time that they are going through." [R110]
Informational support	This involved providing advice, suggestions, or useful information	61 (40.7)	• "Warn her about the effects of marijuana." [R129] • "Convince her to move on and that there are other guys better than Brendan." [R150]
Encourage help-seeking	This involved encouraging help-seeking from both formal and informal sources	41 (27.3)	• "Encourage them to talk to as professional." [R1] • "I would urge them to see a therapist." [R80]
Shared activities	This involved spending time together and engaging in shared activities	22 (14.7)	• "Get out and do some sport or hang out." [R34] • "Organize to do things with them to distract them." [R145]
Practical support	This involved providing doing something helpful for the friend	19 (12.7)	• "I would offer to help her with homework." [R13]

Discussion

Principal Findings

This study aimed to examine young people's attitudes toward using a mobile phone app for relationship problems and to determine the acceptability of the proposed content. In the current sample, technology ownership was high, with only 1 participant not owning a smartphone or tablet. Almost half of the sample accessed the Internet from their mobile phone. Importantly, two-thirds of the sample indicated that they would be open to using a mobile help-seeking intervention for relationships, irrespective of background factors or levels of social support. These findings suggest that delivering relationship support via a mobile phone app is likely to be accessible to a general youth population and confirms a degree of acceptability for a mobile help-seeking intervention. In terms of future development, several key factors were found to influence the likely use of a mobile app for relationships including perceived need, personal beliefs, engagement, and accessibility. The acceptability of the help-seeking information was influenced by the nature, scope, and approach of the content as well as users' personal experience of the suggestions. These aspects are likely to be relevant to a range of other youth help-seeking interventions and must be systematically addressed if a mobile intervention is to have broad uptake and appeal.

Notably, likelihood of seeking help from an app was influenced by whether a young person identified a need for relationship support and whether they believed an app would be beneficial. In this study, when asked what they would do when faced with relationship issues, only one-third of the participants reported that they would seek help. Fewer suggested seeking help from a friend. The low level of help-seeking reported by participants aligns with past research on mental health issues, in which youths prefer self-management [19]. These findings are also consistent with depression and suicide, in which individuals reported perceived need as a key driver of help-seeking, alongside personal help-seeking thresholds, beliefs about the usefulness of help-seeking, and trouble identifying symptoms

[19,38]. This finding may pose a potential challenge to app developers. For an app to have wide uptake, developers of mobile help-seeking interventions must carefully consider how to address issues of need and usefulness. In the context of the proposed app, a strategy to help users identify areas of need could be the inclusion of screening, in which a user conducts a self-assessment of their relationships to help establish need. However, screening may not always be effective for changing help-seeking behavior [39]. Therefore, it is important that future evaluations of help-seeking apps assess the effectiveness of any functionality aimed at increasing need. In terms of usefulness, positioning an app as a resource that could be used to also help a friend may broaden its appeal because of the importance young people place on relationships. Integration with other youth activities, such as school curriculum or sport, may significantly enhance young people's knowledge and awareness of mobile help-seeking interventions [40].

Unsurprisingly, young people identified that accessibility and engagement issues, including user experience, influenced their likelihood of using a mobile help-seeking intervention. This is consistent with mobile health app ratings in which users report to value apps that are easy to use, deliver a clear outline of the steps involved to reach a desired goal, and provide personalized information and education tailored to a user's needs [41]. This can be difficult to achieve in universal programs, and it highlights the importance of considering users' preferences and contexts early in the design process. Developers must consider content and interface to avoid users' feeling as though their needs have been disregarded [42,43]. In relation to the proposed app content, all participants reported peer relatedness to at least one of the characters, even though many were uncertain of their own experience of the issues presented. This suggests that the character-driven content has appeal, and as social learning still occurs regardless of similarities [44], the use of character vignettes is likely to be an effective model for changing help-seeking behavior. Furthermore, almost all participants rated the proposed strategies as helpful. Helpfulness was found to be influenced by the general nature of the strategies and whether they adequately addressed the breadth of issues that a young person was experiencing. Interestingly, scheduling shared activities was only suggested by 14% of the sample as a useful strategy, and this may explain why previous apps that focus on behavioral activation may not be effective in this population [30]. A strength of this study is that it enabled end-user assessment of content developed by clinicians and researchers, which Grist and Porter [45] suggest enhances the quality and efficacy of mobile health apps. In addition to an evaluation of effectiveness, next steps will include assessing young people's views of the proposed app design, including the user interface and app structure, to ensure that the functionality and user experience within the app is positive and engaging.

Limitations

The current findings must be considered within the study's limitations. First, this study examined young people's help-seeking intentions, rather than actual behavior, and may therefore not be a true indication of how young people respond when faced with a relationship problem. Although this is appropriate for acceptability research, future trials would benefit from assessing other objective measures of acceptability, including app usage. Second, the use of an online survey restricted participation only to those who had access to the Internet, and the sample may not have been representative across a range of characteristics. In addition, the sample was recruited primarily from Facebook and Black Dog Institute social media sites. Future studies would benefit from targeting a more diverse sample as this study may have reached a more mental health literate subgroup of youths and those with an interest in mobile apps. Third, it is possible that the suggestions provided in the survey influenced participants' free responses, thereby creating a learning effect. However, visual inspection of the qualitative data did not indicate participants' reported help-seeking, coping strategies, or suggestions differed across characters. Finally, a strength of this study is the representativeness of youths who identified as LGBTI, being twice as many than the general population, which is approximately 10% to 11% [46]. It is unclear why this survey achieved such a high level of participation from the LGBTI youth.

Conclusions

Existing evidence has outlined that young people frequently experience relationship problems and associated distress. The findings of this study substantiate the need for additional relationship support and echo previous research that highlighted young people's reluctance to seek help from formal services [20,22,23]. This study confirms that youths are likely to use a mobile app that attempts to address these issues. Adolescents in this study were likely to use a mobile phone app for relationship support, and this was not influenced by gender, age, or other background factors. The development of such an app may provide a valuable help-seeking resource for young people. However, acceptability of an app may be increased by addressing the factors of need, personal beliefs, usability, and appropriateness of content. These findings will help to ensure that evidence-based apps have a broad appeal and uptake.

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Conflicts of Interest

BOD and PJB are on the editorial boards for *Journal of Medical Internet Research* (JMIR) journals.

Multimedia Appendix 1

Online survey including the questionnaire, character vignettes, and the app suggestions.

[PDF File (Adobe PDF File), 258KB - mhealth_v6i3e56_app1.pdf]

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Abbreviations

ATSI: Aboriginal and/or Torres Strait Islander
CBT: cognitive behavioral therapy
IPT: Interpersonal therapy
LGBTI: lesbian, gay, bisexual, trans, intersex

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Original Paper

A Skin Cancer Prevention Facial-Aging Mobile App for Secondary Schools in Brazil: Appearance-Focused Interventional Study

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Abstract

Background: The incidence of melanoma is increasing faster than any other major cancer both in Brazil and worldwide. Southeast Brazil has especially high incidences of melanoma, and early detection is low. Exposure to ultraviolet (UV) radiation is a primary risk factor for developing melanoma. Increasing attractiveness is a major motivation among adolescents for tanning. A medical student-delivered intervention that takes advantage of the broad availability of mobile phones and adolescents' interest in their appearance indicated effectiveness in a recent study from Germany. However, the effect in a high-UV index country with a high melanoma prevalence and the capability of medical students to implement such an intervention remain unknown.

Objective: In this pilot study, our objective was to investigate the preliminary success and implementability of a photoaging intervention to prevent skin cancer in Brazilian adolescents.

Methods: We implemented a free photoaging mobile phone app (Sunface) in 15 secondary school classes in southeast Brazil. Medical students "mirrored" the pupils' altered 3-dimensional (3D) selfies reacting to touch on tablets via a projector in front of their whole grade accompanied by a brief discussion of means of UV protection. An anonymous questionnaire capturing sociodemographic data and risk factors for melanoma measured the perceptions of the intervention on 5-point Likert scales among 356 pupils of both sexes (13-19 years old; median age 16 years) in grades 8 to 12 of 2 secondary schools in Brazil.

Results: We measured more than 90% agreement in both items that measured motivation to reduce UV exposure and only 5.6% disagreement: 322 (90.5%) agreed or strongly agreed that their 3D selfie motivated them to avoid using a tanning bed, and 321 (90.2%) that it motivated them to improve their sun protection; 20 pupils (5.6%) disagreed with both items. The perceived effect on motivation was higher in female pupils in both tanning bed avoidance (n=198, 92.6% agreement in females vs n=123, 87.2% agreement in males) and increased use of sun protection (n=197, 92.1% agreement in females vs n=123, 87.2% agreement in

males) and independent of age or skin type. All medical students involved filled in a process evaluation revealing that they all perceived the intervention as effective and unproblematic, and that all pupils tried the app in their presence.

Conclusions: The photoaging intervention was effective in changing behavioral predictors for UV protection in Brazilian adolescents. The predictors measured indicated an even higher prospective effectiveness in southeast Brazil than in Germany (>90% agreement in Brazil vs >60% agreement in Germany to both items that measured motivation to reduce UV exposure) in accordance with the theory of planned behavior. Medical students are capable of complete implementation. A randomized controlled trial measuring prospective effects in Brazil is planned as a result of this study.

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KEYWORDS

skin neoplasms; primary prevention; adolescent; schools; students, medical; mobile applications; skin aging; smartphone

Introduction

According to the World Health Organization, the incidence of melanoma is increasing more rapidly than any other major cancer both in Brazil and worldwide. Melanoma is one of the most common cancers in young adults and poses substantial health and economic burdens [1].

Approximately 90% of melanomas are associated with ultraviolet (UV) exposure, in particular with the frequency of severe sunburns, and are therefore eminently preventable [2]. Multiple studies showed that daily use of a sunscreen with a sun protection factor above 30, as recommended by international dermatology guidelines, may prevent sunburns and skin cancer, including melanoma [3-6].

Brazil has one of the highest UV indexes on earth; additionally, tanning is culturally established, and Brazilians commonly experience unprotected overexposure to the sun, especially in their childhood and teenage years [7-11]. In a 2008 population-based survey with 1604 participants in the south of Brazil, 48.7% reported at least one sunburn in the prior year [10]. In an attempt to mitigate the health damage caused by excessive UV exposure, Brazil was the first country to prohibit indoor tanning in 2009, albeit with limited success [9]. The southeast of Brazil (the location of this study) is especially populated by citizens with a European ancestry and therefore has high incidences of melanoma (up to 23.5/100,000 inhabitants) with a lack of early diagnosis and an overall survival rate below worldwide rates [12-15].

Interventions encouraging sun protection habits are important, particularly among adolescents, as increased risk of skin cancer is associated with cumulative UV exposure and sunburns early in life [16-18]. In line with this association, recent experimental studies to test these effects in young target groups aimed at promoting sunscreen use as an end point [19-22], and others used various UV protection behaviors (including avoiding sunbeds) or behavior scores [23-34]. Given the substantial amount of time that children and adolescents of all social backgrounds spend in the school environment, addressing skin cancer prevention in this setting is crucial and provides a unique opportunity to propel skin cancer prevention programs [35].

Current Knowledge on School-Based Skin Cancer Prevention

Unhealthy behavior with respect to UV exposure is mostly initiated in early adolescence [36], commonly with the belief that a tan increases attractiveness [26,37,38], and the problems related to melanoma and skin atrophy are too far in the future for them to fathom.

A recent randomized trial with Australian high school students demonstrated that appearance-based videos on UV-induced premature aging were superior in encouraging sunscreen use to videos of the same length focusing exclusively on health aspects [19]. These findings are in line with international studies demonstrating the important influence of self-perceived attractiveness on self-esteem in adolescence [39,40]. Furthermore, enhancing one's attractiveness is a primary motivation for tanning in adolescents both in Brazil and worldwide [36,37,41]. In addition, the success of appearance-based photoaging intervention mobile apps, in which an image is altered to predict future appearance, in the fields of tobacco and adiposity prevention have shown promise for these interventions in behavioral change settings [42-47].

In the setting of melanoma prevention, a quasi-experimental study by Williams et al demonstrated significantly higher scores for predictors of sun protection behavior in young women from the United Kingdom (70 participants in total) using a photoaging desktop program [48]. Furthermore, the photoaging software showed a promising reduction in young adults' tanning intentions in a study with 10 participants in total (7 female and 3 male) [49]. However, prior studies were limited by their small sample size and limitations related to expanding the target population.

Introduction to the Sunface App

We harnessed the widespread availability of mobile phones and adolescents' interest in appearance to develop the free mobile phone app Sunface, which enables the user to take a selfie and then offers a choice of 3 categories: daily sun protection, no sun protection, and weekly tanning, showing the altered face at 5 to 25 years in the future (Figures 1, 2, 3, and 4). All effects are based on the individual skin type that the user can choose at the start of the app (Figure 5). The app also shows the most common UV-induced skin cancers via extra buttons and calculates how the odds ratio is increased with different behaviors.

Figure 1. Effect view: 5 years of skin aging with sun protection.

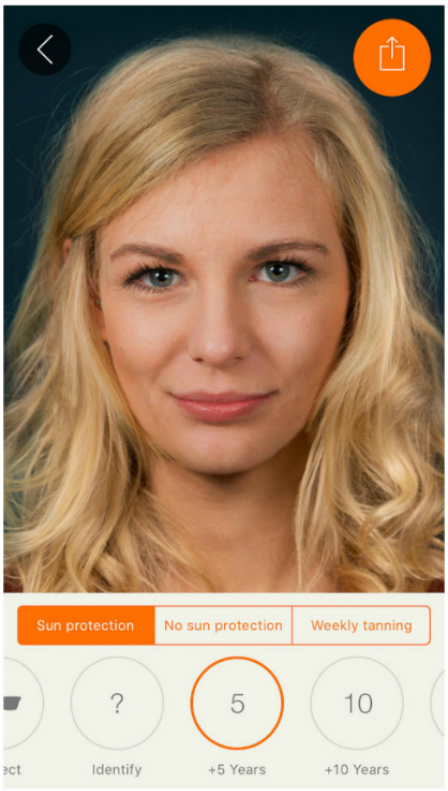


Figure 2. Effect view: 25 years of skin aging with sun protection.

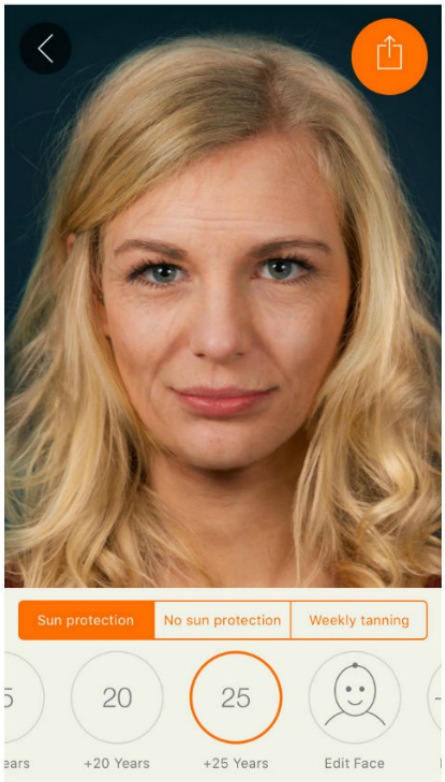
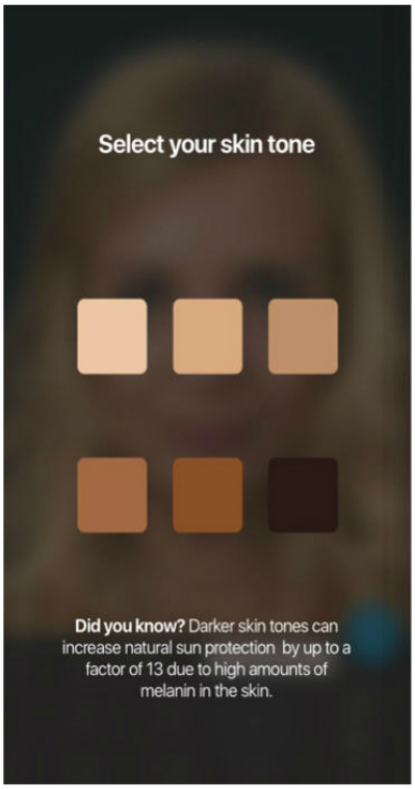


Figure 3. Effect view: 5 years of weekly tanning without sun protection.

Figure 4. Maximum effect view: 25 years of UV damage due to weekly tanning.

Figure 5. Start screen of the app prompts users to pick their skin type.



In addition, the app gives advice on sun protection, explains the facial changes, and encourages skin examinations using the ABCDE rule (asymmetry, border irregularity, color variety, diameter, and evolution [50]).

Afterward, the app offers many options for sharing (animated photo or video; see Multimedia Appendix 1) with family and friends. By this means, the social network of the user may also be informed about the various photoaging effects of excessive UV exposure and potential health consequences, as well as potentially learning about the benefits of using the app [34].

To produce realistic effects (Figure 6) and to show the user realistic odds ratios for the options they choose in the app for the three most strongly associated skin pathologies, an extensive review of the literature on UV-induced skin damage [51,52] was conducted for each specific skin type. As no trials with 25 years of follow-up were available, we had to extrapolate the evidence on UV-induced skin damage for the specific skin types. The evidence consists of more than 50 publications to create realistic effects from a clinician's standpoint (which may differ from what the average person perceives as realistic).

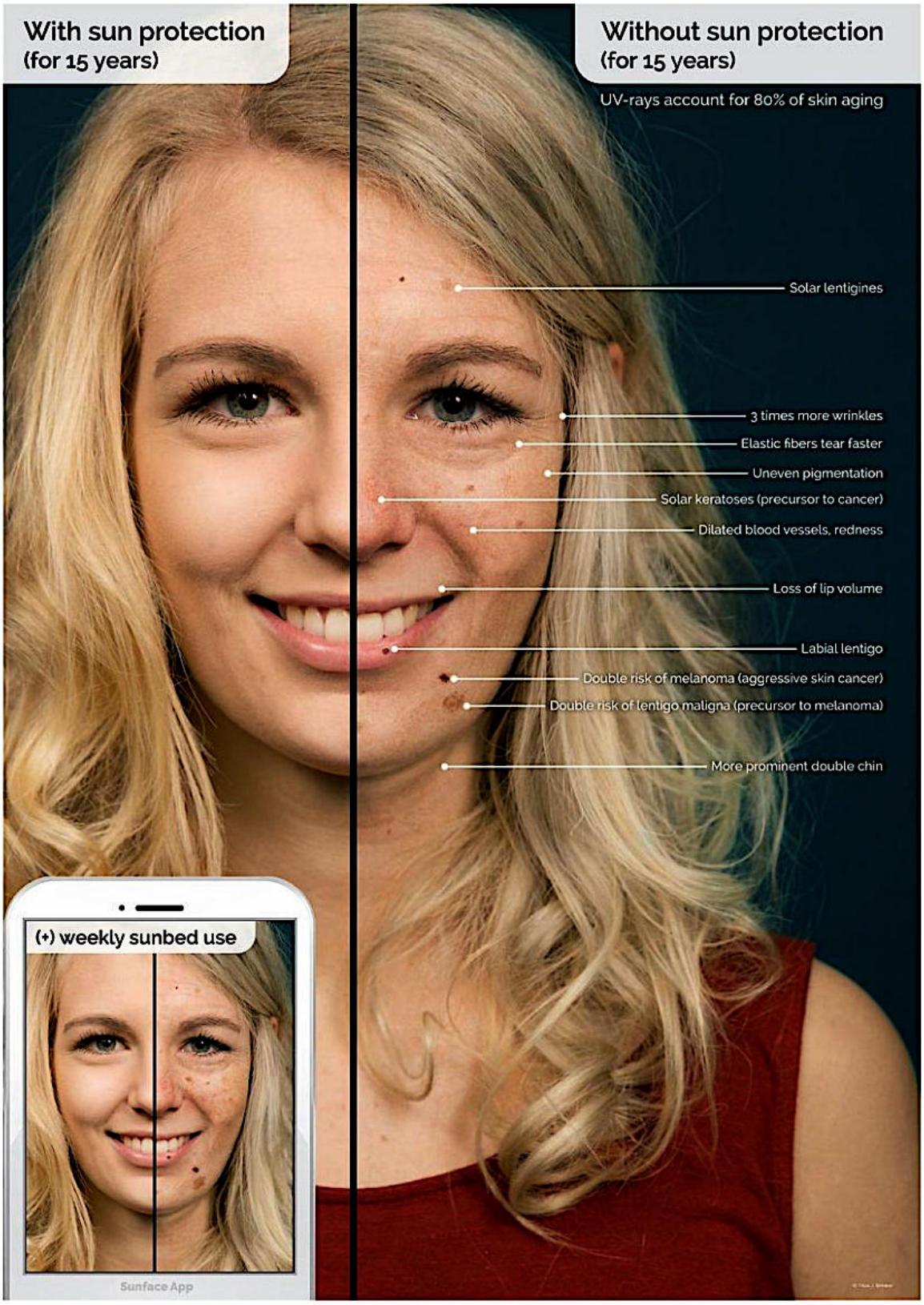
We recently implemented this app in 2 German secondary schools via a method called mirroring. Mirroring means that the student's altered 3-dimensional (3D) selfies are "mirrored" via a projector in front of the entire class. Using an anonymous questionnaire, we then measured sociodemographic data and risk factors for melanoma, as well as the perceptions of the intervention on a 5-point Likert scale among 205 students of both sexes aged 13 to 19 years (median 15 years).

In our pilot study, we found more than 60% agreement in both items measuring motivation to reduce UV exposure and only 12.5% disagreement: 126 (63.0%) agreed or strongly agreed that their 3D selfie motivated them to avoid using a tanning bed, and 124 (61.7%) agreed or strongly agreed to increase their use of sun protection; only 25 (12.5%) disagreed with both items. [33].

An explanation for these results is offered by the theory of planned behavior, according to which the subjective norm (eg, "my friends think that tanning makes you unattractive"), attitudes (consisting of beliefs, such as "tanning leads to unattractiveness"), and perceived behavioral control (eg, "I can apply sunscreen correctly") influence both the behavioral intentions of a person and his or her behavior. Photoaging interventions have the potential to affect all three of these predictors, and the mirroring intervention specifically had a strong influence on the subjective norm in the previous pilot study [33].

This study investigated whether the results of our novel photoaging intervention would be reproducible in Brazil, a country with a high UV index and, thus, higher prevalences of malignant melanoma and an even stronger need for effective skin cancer prevention programs. Also, a process evaluation investigated whether volunteering medical students would be capable of complete implementation.

Figure 6. Explanatory graphic of the effects within the app.



Methods

Setting

We conducted the study in 2 regular public secondary schools in the city of Ponte Nova, southeast Brazil. Students who were 13 to 19 years of age and attending regular secondary schools in the city of Ponte Nova were eligible.

Intervention

The mirroring approach was implemented by medical students from the Education Against Tobacco nonprofit organization who were attending the Federal University of Ouro Preto in Brazil [46,53]. To increase the pupils' familiarity with the Sunface photoaging app and their participation in the mirroring intervention, we asked them to download the app before our visit, via a letter 1 week in advance. When we visited the schools, 12.6% (45/356) had the app on their mobile phones.

The intervention consisted of a 45-minute app-based mirroring educational module in the classroom setting. It was presented by 2 medical students per classroom to approximately 24 students at a time (mean 23.7, SD 6.1 students).

In the first 10-minute phase, the displayed face of one student volunteer was used to show the app's altering features to the peer group, providing an incentive for the rest of the class to test the app. In front of their peers and teachers, students could interact with their own animated face via touch (coughing, sneezing, etc) and display their future self based on their skin type and use of sun protection or tanning beds 5, 10, 15, 20, or 25 years in the future. Multiple device displays could be projected simultaneously, which we used to consolidate the altering measures with graphics (eg, to explain skin atrophy and solar elastosis). We implemented mirroring with 10 Galaxy Tab A tablets (Samsung, Seoul, South Korea) via Apple's AirPlay interface (Apple Inc) using the app Mirroring360 (Splashtop Inc) for the Android operating system (Google Inc).

In the second 15-minute phase, students were encouraged to try the app on one of the tablet computers. We calculated the number of provided tablet computers so that this phase would take up to 12 minutes at most after factoring in a use time of approximately 4 minutes per student. By this calculation, 25 minutes of the mirroring intervention and 10 provided tablets were sufficient to have every student within a class of 40 pupils successfully photoaged at least once.

In the following 15 minutes, the medical students discussed the remaining functions of the app with the students: facial changes, the ABCDE rule, and the guidelines for sun protection were addressed in an interactive setting. In the last 5 minutes, we measured the students' perception of the intervention via an anonymous paper-and-pencil questionnaire.

Data Collection

We measured the students' sociodemographic data (sex, age, school type) and their risk profile (skin type, sex, age, sunburn in the past, sunbed use) directly after the intervention via an anonymous survey. The reactions to the intervention were captured via 6 items on 5-point Likert scales: (1) increase of UV protection intentions due to the photoaging intervention (2 items: indoor vs outdoor tanning); (2) perceived reactions of the peer group on change in attractiveness (2 items: indoor vs outdoor tanning), whether they perceived the intervention as fun (1 item), and the effects of the app as realistic (1 item).

The items used were transferred from previously published studies [33,43,54] and pretested in advance in accordance with the guidelines for good epidemiologic practice [55].

The medical students filled out a brief process evaluation consisting of 6 items capturing the complete implementation of the intervention, as well as how the medical students perceived its effectiveness when in class.

Results

Participants

We included 356 Brazilian secondary school students of both sexes in the age group of 13 to 19 years (mean 15.95, SD 1.73 years; 141/356, 39.7% male; 214/356, 60.3% female) in this cross-sectional pilot study. They were attending 2 regular public secondary schools in the city of Ponte Nova in southeast Brazil. Almost all participants (336/356, 94.4%) owned a smartphone.

From a risk profile standpoint, 43.9% (156/356) of the participants had a Fitzpatrick skin type of 1 or 2 [56]; indoor tanning bed use in the past year was reported by 2.0% (7/356) and use at least once in their life was reported by 4.5% (16/356) [57]. Most students (205/356, 57.6%) remembered at least one sunburn in the past [58], 18.3% (65/356) reported one or more sunburns in the last 12 months, and 15.8% (56/356) reported that they frequently went out in the sun to get a tan.

We analyzed and illustrated all data in regard to overall perceptions of the intervention within the whole sample (Figure 7), but also to learn about how well the app was received by students of different Fitzpatrick skin types (Figure 8), sex (Figure 9), and age groups (Figure 10).

Realism of the Created Selfies

In our sample, we measured overall agreement with the subjective realism of the created selfies (n=305, 85.9% strongly agreed or agreed on realism, while only n=8, 2.3% disagreed or strongly disagreed; Figure 7). These results did not vary notably between male (n=119, 85.0% agreement; n=3, 2.1% disagreement) and female participants (n=185, 86.5% agreement; n=5, 2.4% disagreement; Figure 9). However, the 13- to 16-year-olds (n=185, 82.6% agreement; n=7, 3.1% disagreement) and those with skin types 1 and 2 (n=133, 85.8% agreement; n=4, 2.6% disagreement) tended to perceive the selfies as less realistic, as opposed to 17- to 19-year-olds (n=120, 91.6% agreement; n=1, 0.8% disagreement) and participants with skin types 3 to 6 (n=155, 77.5% agreement; n=13, 6.5% disagreement; Figure 8 and Figure 10). The group that reported at least one sunburn in the last 12 months had a 92.3% (n=60) agreement and 1.5% (n=1) disagreement compared with 84.5% (n=245) agreement and 2.4% (n=7) disagreement among participants without sunburns in the past 12 months.

Figure 7. Overall results of the whole sample. 3D: 3-dimensional.

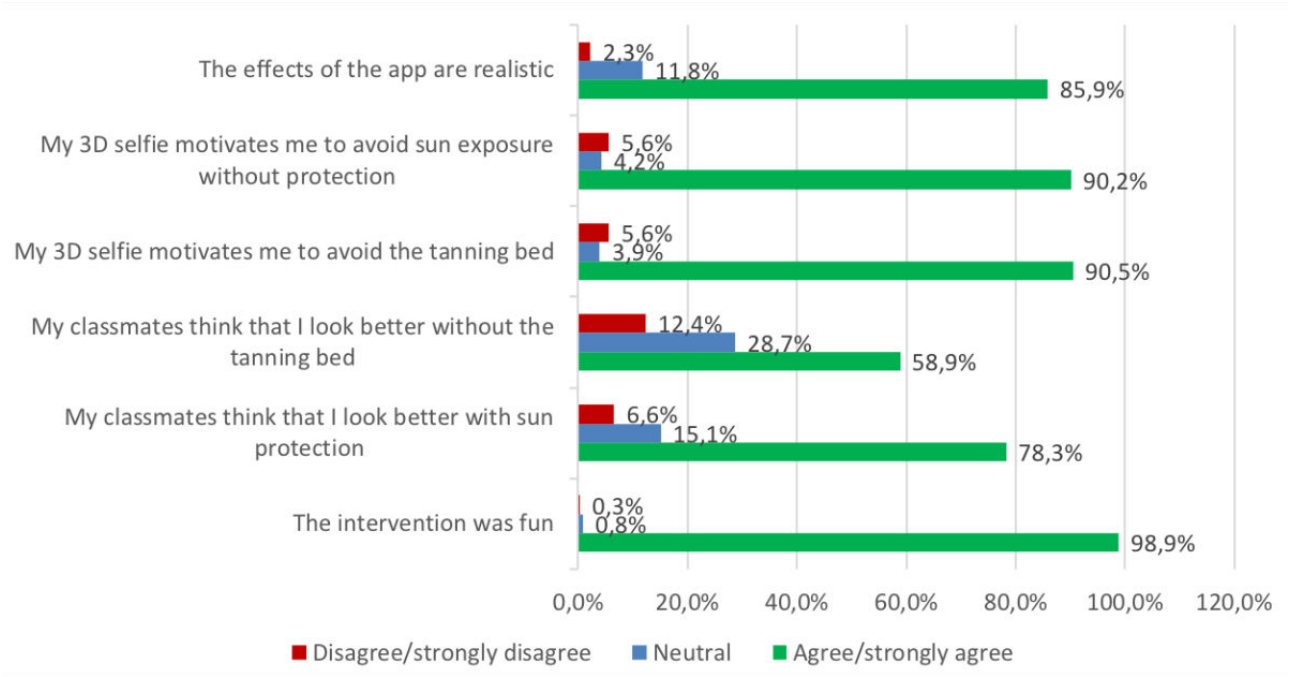


Figure 8. Results in Fitzpatrick skin types 1-2 versus 3-6. 3D: 3-dimensional.

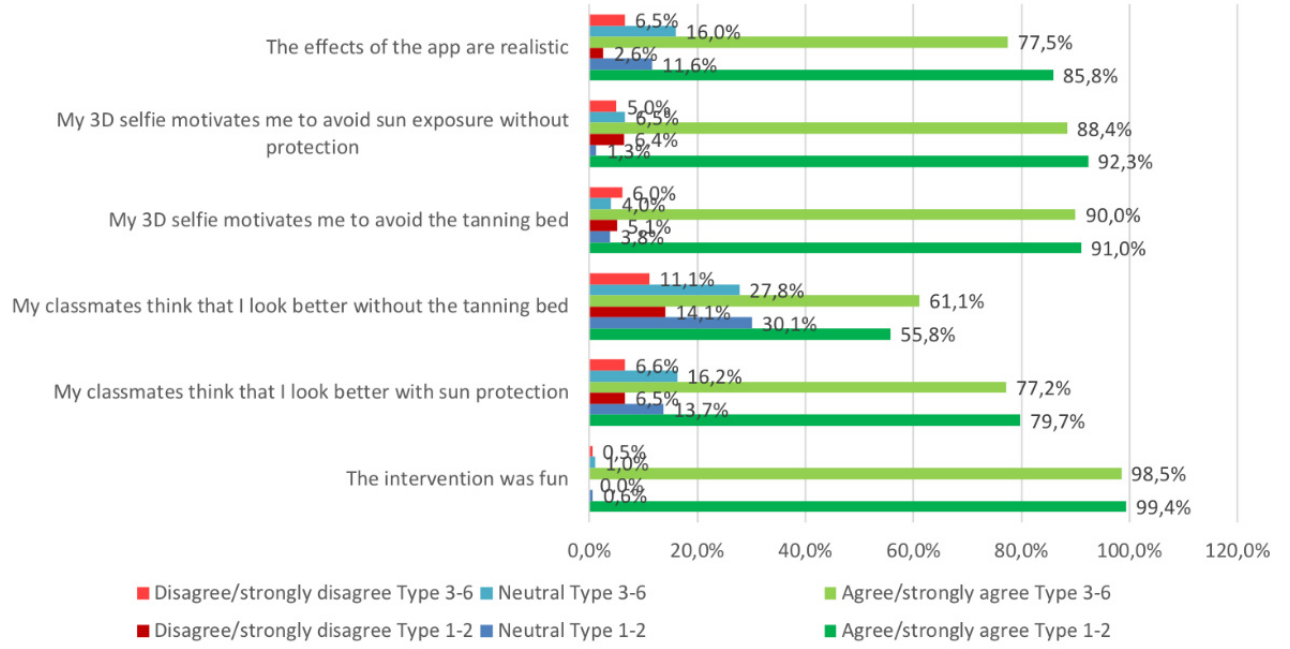


Figure 9. Results in male versus female participants. 3D: 3-dimensional.

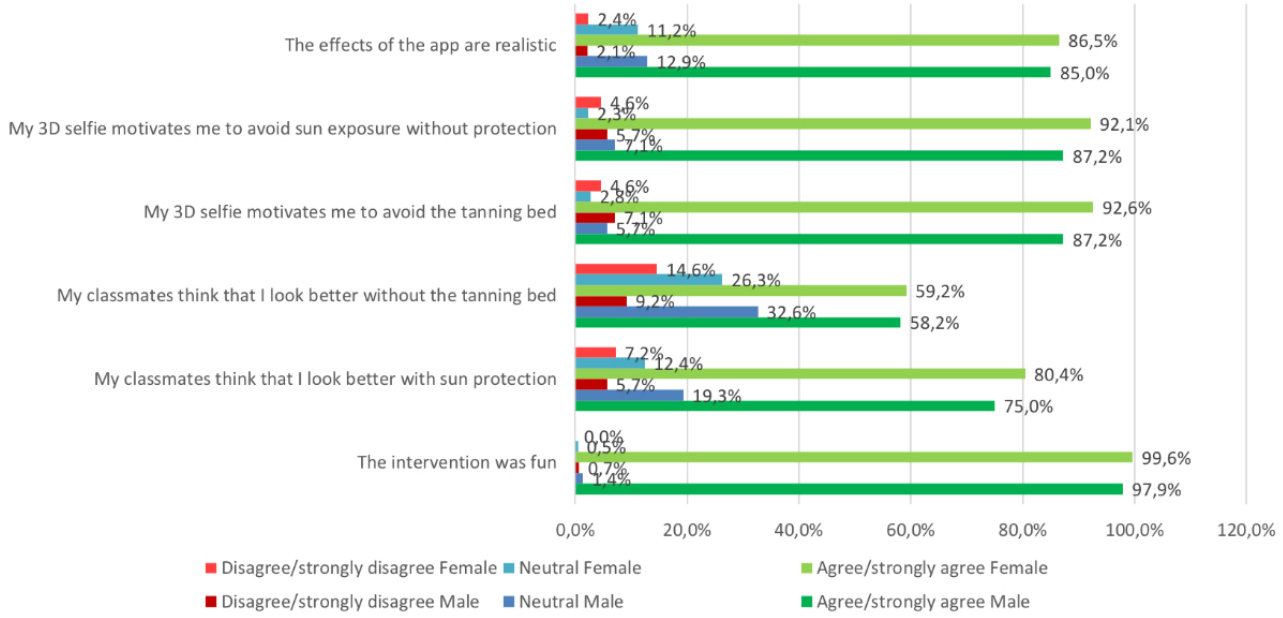
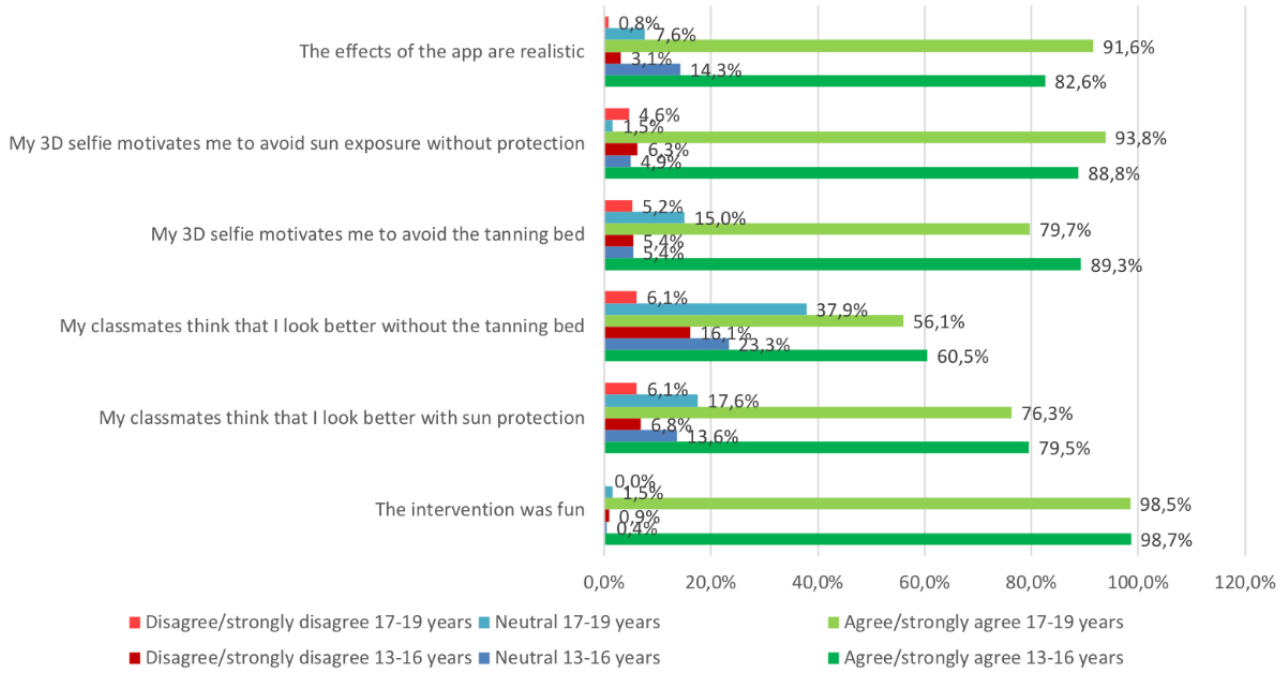


Figure 10. Results in 13- to 16-year-old versus 17- to 19-year-old participants. 3D: 3-dimensional.



Motivation to Reduce Ultraviolet Exposure

We measured more than 90% agreement in both items that measured motivation to reduce UV exposure and only 5.6% disagreement (n=322, 90.5% agreed or fully agreed that their 3D selfie would motivate them to avoid the tanning bed; n=321, 90.2% agreed or fully agreed that they would increase their use of sun protection); only 20 (5.6%) disagreed or fully disagreed with both items. The perceived effect on motivation was similar between participants with different Fitzpatrick skin types in both tanning bed avoidance (n=142, 91.0% agreement in skin types 1-2 vs n=179, 90.0% agreement in types 3-6) and increased use of sun protection (n=144, 92.3% agreement in skin types 1-2 vs n=176, 88.4% agreement in types 3-6; Figure 8), and also similar between the age groups (Figure 10). Comparing by sex, the perceived effect on motivation was higher in female pupils in both tanning bed avoidance (n=198, 92.6% agreement in female vs n=123, 87.2% agreement in male participants) and increased use of sun protection (n=197, 92.1% agreement in female vs n=123, 87.2% agreement in male participants).

Perceived Subjective Norm During the Mirroring Intervention

The 2 items measuring the perceived reactions of the peer group toward the individual selfie showed positive peer pressure in

regard to both use of sun protection (n=275, 78.3%) and tanning bed avoidance (n=209, 58.9%; Figure 7). The subjective norm on decreasing UV exposure in order to look more attractive was similarly perceived between the different age groups (Figure 10). However, female participants (n=169, 80.4% agreement; n=15, 7.2% disagreement) tended to feel a stronger urge to increase the use of sun protection due to the behavior of their classmates than did male participants (n=105, 75% agreement; n=8, 5.7% disagreement). Participants with Fitzpatrick skin types 1 and 2 (n=87, 55.8% agreement; n=22, 14.1% disagreement) tended to perceive less peer pressure for avoiding tanning beds than did skin types 3 to 6 (n=121, 61.1% agreement; n=22, 11.1% disagreement). Participants with at least one sunburn in the last 12 months had a higher agreement in the increased use of sun protection item (n=49, 75.4% agreement; n=5, 7.7% disagreement vs n=197, 67.9% agreement; n=26, 9% disagreement in participants without sunburn in the past 12 months) and in the avoidance of sunbeds item (n=55, 84.6% agreement; n=5, 7.7% disagreement vs n=220, 76.9% agreement; n=18, 6.2% disagreement, respectively).

Global Feedback

Most participants claimed that they perceived the intervention as fun (n=351, 98.9% agreement vs n=1, 0.3% disagreement), and this fraction of agreement was similar throughout all subgroups. Most participants (n=271, 77.0%) reported that they would try the app again later on, 283 (80.2%) planned to show the app to another person after school, and 352 (98.9%) agreed that they had learned new things about the advantages of sun protection.

Data Obtained From the Medical Students

Our process evaluation conducted among all of the 6 volunteering medical students via a short questionnaire after every classroom visit revealed that 100% of the secondary school students received the mirroring intervention as outlined in the methods section, and that 100% of the medical students were capable of having an empathic communication with the students and regarded the intervention as enjoyable.

Discussion

Principal Findings

Our data showed that the mirroring intervention was effective in changing the predictors of behavior in young risk groups living in Brazil, a country with a high UV index and where tanning is culturally established. The predictors measured indicated an even higher prospective effectiveness in southeast Brazil than in Germany (>90% agreement in Brazil vs >60% agreement in Germany to both items that measured motivation to reduce UV exposure [33]).

While teledermatology [59,60] and, more specifically, skin cancer diagnostic apps [61-65] are emerging, early diagnostics may only be successful if a patient is sensitized for an eventual skin cancer risk and about skin cancer in general. Photoaging smartphone apps seem capable of filling this important gap by appealing to vanity.

Interpretation

Available data on appearance-based behavioral change settings for adolescents reveal that photoaging interventions appear to be more effective for girls [46]. Also, data from our recent study in Germany indicated that the intervention was more effective in changing motivational predictors in those with Fitzpatrick skin types 1 and 2, as well as in older adolescents. In our sample, the perceived effect on motivation was higher among female pupils in both tanning bed avoidance (n=198, 92.6% agreement in female vs n=123, 87.2% agreement in male participants) and increased use of sun protection (n=197, 92.1% agreement in female vs n=123, 87.2% agreement in male participants), while it was independent of age or skin type. We hypothesize that the most likely explanation for this is that gender roles are more established in southeast Brazil than they are in Germany and that peer pressure plays a larger role, which thus flattened out the differences for age and skin type that we found in our German study [33]. Accordingly, this hypothesis is in line with the finding that an intervention like the mirroring intervention, which aims at yielding peer pressure effects and addresses social norms, had a larger impact in a country like Brazil, where social norms play a larger role than in Germany.

Limitations

As we conducted this study only in Brazil, our results might not be generalizable to other cultural or national settings. However, cosmetics are used by adolescents in most countries and appearance is a strong motivator for behavior in different cultural contexts [39,66].

In addition, our results stemmed from anonymous self-reports via paper-and-pencil questionnaires filled out after the intervention. While anonymity decreases social desirability bias in self-reports, they may not be regarded to be as objective as externally measurable markers, such as biochemical findings or clinical observation. Furthermore, handing the questionnaires out after the intervention rather than before might provoke a social desirability bias despite anonymity.

Conclusions

The photoaging intervention was effective in generating an increased intention for UV protective behavior in Brazilian adolescents. The predictors measured indicated an even higher prospective effectiveness in southeast Brazil than in Germany (>90% agreement in Brazil vs >60% agreement in Germany to both items that measured motivation to reduce UV exposure) in accordance with the theory of planned behavior. Medical students are capable of complete implementation. A randomized controlled trial measuring prospective effects in Brazil is planned as a result of this study [67].

Acknowledgments

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Authors' Contributions

TJB initiated the study; invented, designed, and organized the intervention; wrote the manuscript; drafted the design of the study; and performed the statistical analyses. BBS participated in the conception of the study. HRR, CAS, BBS, MG, SS, MVH, MCK, MH, and DS contributed to the design of the study, data collection, data analyses, and proofreading of the manuscript. BBS contributed to the logistics of the study, assisted with the translation of classroom materials, and reviewed the final version of the manuscript. All authors declare responsibility for the data and findings presented and have full access to the dataset.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Animated version of the Sunface App effect view.

[MP4 File (MP4 Video), 1MB - mhealth_v6i3e60_app1.mp4]

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Abbreviations

3D: 3-dimensional
ABCDE: asymmetry, border irregularity, color variety, diameter, and evolution
UV: ultraviolet

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Original Paper

Describing the Process of Adopting Nutrition and Fitness Apps: Behavior Stage Model Approach

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Abstract

Background: Although mobile technologies such as smartphone apps are promising means for motivating people to adopt a healthier lifestyle (mHealth apps), previous studies have shown low adoption and continued use rates. Developing the means to address this issue requires further understanding of mHealth app nonusers and adoption processes. This study utilized a stage model approach based on the Precaution Adoption Process Model (PAPM), which proposes that people pass through qualitatively different motivational stages when adopting a behavior.

Objective: To establish a better understanding of between-stage transitions during app adoption, this study aimed to investigate the adoption process of nutrition and fitness app usage, and the sociodemographic and behavioral characteristics and decision-making style preferences of people at different adoption stages.

Methods: Participants (N=1236) were recruited onsite within the cohort study Konstanz Life Study. Use of mobile devices and nutrition and fitness apps, 5 behavior adoption stages of using nutrition and fitness apps, preference for intuition and deliberation in eating decision-making (E-PID), healthy eating style, sociodemographic variables, and body mass index (BMI) were assessed.

Results: Analysis of the 5 behavior adoption stages showed that stage 1 ("unengaged") was the most prevalent motivational stage for both nutrition and fitness app use, with half of the participants stating that they had never thought about using a nutrition app (52.41%, 533/1017), whereas less than one-third stated they had never thought about using a fitness app (29.25%, 301/1029). "Unengaged" nonusers (stage 1) showed a higher preference for an intuitive decision-making style when making eating decisions, whereas those who were already "acting" (stage 4) showed a greater preference for a deliberative decision-making style ($F_{4,1012}$=21.83, P<.001). Furthermore, participants differed widely in their readiness to adopt nutrition and fitness apps, ranging from having "decided to" but not yet begun to act (stage 2; nutrition: 6.88%, 70/1017; fitness: 9.23%, 95/1029) to being "disengaged" following previous adoption (stage 5; nutrition: 13.77%, 140/1017; fitness: 15.06%, 155/1029).

Conclusions: Using a behavior stage model approach to describe the process of adopting nutrition and fitness apps revealed motivational stage differences between nonusers (being "unengaged," having "decided not to act," having "decided to act," and being "disengaged"), which might contribute to a better understanding of the process of adopting mHealth apps and thus inform the future development of digital interventions. This study highlights that new user groups might be better reached by apps designed to address a more intuitive decision-making style.

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KEYWORDS

mHealth; eating; physical activity; exercise; smartphone; mobile applications; health promotion

Introduction

In recent years, services supporting medical and public health practices via mobile technology (mHealth) [1] such as smartphone apps have become increasingly popular. More than 70,000 mHealth apps are currently available for download on Android and iOS smartphones [2], and more apps are released every year [3]. The proportion of smartphone owners currently using an mHealth app ranges between 36% [4] and 58% [5] in

the United States and between 11% [6] and 21% [7] in Germany, where this study was conducted. Although mHealth apps have the potential to deliver effective interventions [8-12] and cut health care costs [13,14], for example, because medical interventions can be delivered remotely instead of in person, a large proportion of the population does not actively use mHealth apps [15]. The European Union therefore set a goal to make Web-based health promotion, including mHealth apps, more effective, user-friendly, and widely acceptable [16,17].

A first step to attaining this goal is to identify who is currently using mHealth apps and who is not. Usually, studies divide the participants into a "user group," comprising participants who currently use an mHealth app (eg, [6]) or have one installed (eg, [4,18]), and a "nonuser group," which typically lacks further specification. Few studies have described mHealth app users and nonusers using sociodemographic and health-related characteristics or assessed further information about nonusers, such as discontinued mHealth app use (eg, [5,19]) or interest in mHealth app use (eg, [20,21]). Compared with nonusers, mHealth app users tend to have more education and are younger [18]. All genders use mHealth apps equally often [4-7,22,23]. Regarding health-related parameters, such as current health status or body mass index (BMI), research yielded mixed results. Although some suggest that mHealth app users tend to be healthier and less likely to be overweight [24,25], others report more comorbidities and a higher BMI for users [4,7].

However, more than a basic understanding of the core sociodemographic characteristics of users and nonusers is needed to increase mHealth app adoption rates. That is, we require a better understanding of the motivational processes underlying the decision making for adopting mHealth apps. In health behavior research, stage theories of behavior change [26-29] suggest that people can be differentiated according to the levels of awareness of and motivation to adopt a healthier lifestyle, such as quit smoking [30], become more physically active [31], change dietary behaviors [32-35], or to take preventive action such as increasing calcium intake to prevent osteoporosis [33]. Specifically, stage models such as the Transtheoretical Model of Health Behavior Change (TTM) [36,37], the Health Action Process Approach (HAPA) [26,38], or the Precaution Adoption Process Model (PAPM) [39-41] assume that people pass through qualitatively different motivational stages when adopting a behavior (see [27,42] for an overview). For example, the PAPM claims that people pass through 7 distinct stages of decision making for health behavior, including being "unaware," "becoming engaged," "starting to make a decision," "decided to act," "decided not to act," "acting," and finally "maintaining" (or "disengaging") from the behavior [39,43]. Importantly, the PAPM introduced differentiation between people who have "decided not to act" and people who are yet undecided. People who have already formed an opinion about an issue might be more difficult to persuade than people who did not yet form an opinion, and therefore might require different intervention approaches [40,41]. Furthermore, in the PAPM, stages are defined by psychological characteristics instead of external factors such as time, as in the TTM [28,41], which has been criticized as being a rather arbitrary criterion [44]. Using stage models to describe a person's position in the behavioral adoption process has been shown to improve recruitment, retention, and progress in the behavior change process [36,37] by providing information about barriers of change for individual stages as well as methods to facilitate stage transitions [36,40,43]. Drawing on the stage model conception from health psychology research and especially the PAPM, we used a stage model approach to assess 5 different stages in the adoption process of mHealth apps. In particular, the 5 different stages include those who have never thought about using mHealth apps ("unengaged"), intend to use mHealth apps in the future ("decided to act"), have decided against using mHealth apps ("decided not to act"), are currently using mHealth apps ("acting"), and have ceased to use mHealth apps ("disengaged"). The later stage was added based on a previous adaptation of the PAPM [45], because comparing "disengaged" nonusers to other groups, especially "acting" users, provides valuable information about when and why mHealth app use is maintained or discontinued [19]. Thus, the present stage model also includes the perspective of models of engagement with digital behavior change interventions that focus on preventing the transition from the "acting" stage to disengagement.

When stages of mHealth app adoption have been identified, a second and important step is to characterize the people at each stage to identify potential transition barriers [43]. Characterizing groups at each stage is important to both tailoring and improving the services according to users' needs and preferences and thereby enhancing user engagement and promoting the use of mHealth apps to new user groups [46-48]. The extent of mHealth app use, for example, seems to covary with health consciousness, health information orientation, and eHealth literacy [49]. These results suggest that mHealth apps are more likely to be adopted by people who are conscious about their health. Research in health screening decision-making furthermore showed that decision-making styles affect information processing. Specifically, people with a rational decision-making style engaged more with intervention materials such as leaflets than those with an intuitive decision-making style [50]. As mHealth apps that are currently available predominantly focus on self-regulatory strategies such as self-monitoring, providing instruction or feedback, and goal setting [51-53], using mHealth apps might necessitate self-regulatory competencies such as a deliberative decision-making style. Similarly, previous research suggests that self-regulatory constructs that support goal-directed, intentional behaviors (eg, self-efficacy, attitudes) may act as transition barriers in the PAPM [34]. Consequently, people who use a deliberate style when making health-related decisions, such as preferring to rely on health recommendations, may be more likely to adopt mHealth apps. A preference for deliberation might help to exert the self-control needed to perform the behavior. Conversely, people who prefer an intuitive decision-making style, that is, relying on affect and heuristics [54,55], might be less likely to adopt mHealth apps as such apps tend to stand in stark contrast to their preferred decision-making strategies. Accordingly, decision-making style preferences might systematically relate to stages in the adoption process.

Although mHealth apps have different functionalities, the majority of available apps are targeted at lifestyle and well-being, with the majority being designed to monitor eating behavior and physical activity [56,57]. Previous research, however, predominantly focused on investigating use and nonuse of mHealth apps in general, instead of investigating the use or nonuse of different categories separately (eg, [4,5,7]). However, the use of mHealth apps that target different behavioral domains, for example, eating or physical activity, might be correlated with different sociodemographic, behavioral, or psychological characteristics. For instance, women are more strongly preoccupied with eating [58]; thus, one might expect that women are more interested in nutrition apps than men. Therefore, this study focused on nutrition apps, but also included fitness apps to examine whether the results are behavior-specific or generalize across behavioral domains.

The aims of this study are twofold. First, it aimed to investigate different stages in the adoption process of nutrition and fitness apps by utilizing a newly developed stage model based on the PAPM. Second, building upon and extending previous research, the study aimed to investigate sociodemographic, behavioral, and psychological characteristics of people at the different adoption stages for nutrition apps to inform a better understanding of stage transitions. Specifically, we assumed that an intuitive decision-making style might act as a transition barrier and thus is more pronounced in participants who are not "acting."

Methods

Design and Procedure

Data were collected as part of the Konstanz Life Study, an ongoing longitudinal cohort study that was launched in spring 2012 with 1321 participants (for more details, see [59-63]). The overarching aim of the study is to investigate psychological influences on eating behavior, physical activity, and health within the general population across time [59]. The study was part of the SMARTACT research project funded by the German Federal Ministry of Education and Research. Further points of measurement, 2, 3, and 4, took place in autumn 2012, spring 2013, and spring 2016, respectively. For each point of measurement, participants were recruited via flyers, posters, and newspaper articles. Additionally, participants of the preceding points of measurement were reinvited via email and phone calls. People aged 18 years and older without acute infectious diseases were eligible for participation. The measurements included the collection of fasting blood samples, questionnaires, as well as a standardized check-up including anthropometric measures and cognitive and physical fitness tests. As compensation for participation, participants received feedback about their objective health status referenced to the current norms. This paper presents questionnaire and anthropometric data collected in the fourth point of measurement (spring 2016).

Ethics

For data processing and security, a register of processing operations was developed in cooperation with and approved by ZENDAS in 2012 and reviewed in 2016 (Zentrale Datenschutzstelle der Baden-Württembergischen Universitäten/ Center for Data Protection of the Universities in Baden-Württemberg) and reviewed by the Landesdatenschutz-Beauftragte, Baden-Württemberg (Commissioner for Data Protection in Baden-Württemberg). All participants gave written informed consent before participation. The study adhered to the guidelines of the German Psychological Society (Deutsche Gesellschaft für Psychologie) and the Declaration of Helsinki, and was conducted in compliance with relevant laws and institutional guidelines. The study protocol was approved by the University of Konstanz ethics committee.

Sample

In total, 1236 participants were recruited for the fourth wave. For 21 participants, no questionnaire data were obtained, reducing the sample analyzed to 1215 (for a detailed overview, see Figure 1). The sample had a mean age of 41.11 years (SD 17.56) and 64.44% (783/1215) were female. BMI ranged from 16.77 to 42.45 kg/m² (mean 24.21 [SD 3.63]). The majority of participants had a university entrance diploma (71.26%, 858/1204), and 53.16% (640/1204) had a university degree. Compared with the German population, the sample consisted of 13.7% more females, was 3.19 years younger, and had a lower BMI by 1.69 points [64,65]. Furthermore, the present sample was better educated than the general German population, in that 29.5% have a university entrance diploma and 16.3% have a university degree [66].

Measures

Mobile Device Ownership and Nutrition and Fitness App Use

Participants were asked to indicate whether they owned a smartphone or tablet, (1) yes; (2) no. If the participants owned a mobile device, they were subsequently asked to indicate whether they had ever installed an app to monitor their physical activity (fitness app) or their eating behavior (nutrition app) on a 4-point Likert scale ranging from (1) never to (4) currently. If they indicated that they currently had a fitness or nutrition app installed on their mobile device, they were further asked to indicate the frequency of use on a 5-point Likert scale ranging from (1) once a month or less to (5) at least once a day.

Stage Model for the Adoption Process of mHealth Apps (Nutrition and Fitness)

For this study, in accordance with the PAPM [40] and an adaptation of the PAPM by Renner and Hahn [45] (see also Multimedia Appendix 1), we defined each participant's stage in the adoption process based on their response to 5 different statements representing the different stages. Participants were asked to choose the one statement they would agree with most regarding the usage of an mHealth app for physical activity or food intake. Participants were categorized using the following 5 behavior adoption stages: (stage 1) being "unengaged" ("I have never thought about using an app for that [nutrition/fitness]"), (stage 2) "decided to act" ("I have thought about using an app for that [nutrition/fitness], but so far I did not do it"), (stage 3) "decided not to act" ("I have thought about using an app for that [nutrition/fitness], but it is not necessary for me to do it"), (stage 4) "acting" ("I am currently using an

app for that [nutrition/fitness] and intend to continue to use it"), and (stage 5) being "disengaged" ("I have used an app for that [nutrition/fitness], but I do not use it anymore"). Stages 1-3 and 5 encompass nonusers, whereas stage 4 includes current users.

Preference for Intuition and Deliberation in Eating Decision-Making

A 7-item scale was used to measure the habitual preference for intuition and deliberation in eating decision-making (E-PID; unpublished data [67]; see also Multimedia Appendix 1). The E-PID scale, consisting of 2 subscales, was developed based on the inventory for preference for intuition and deliberation by Betsch [54]. Participants answered each item on a 5-point Likert scale from (1) I do not agree to (5) I agree. A confirmatory factor analysis was conducted using a latent structural equation model in MPlus to test the hypothesized two-factor structure. The comparative fit index (CFI=.988), root mean square error of approximation (RMSEA=.048, 90% CI 0.034-0.062), and the standard root mean square residual (SRMR=.024) indicated a good model fit [68]. All items showed statistically significant factor loadings (*P* s<.001), indicating convergent validity. The first factor "preference for intuition" (E-PI) consisted of 3 items (eg, "When deciding what to eat, I rely on my gut feeling."; mean 3.34 [SD 0.83], alpha=.78) that describe decision making based on feelings or affect (cf Betsch [54]). The second factor "preference for deliberation" (E-PD) consisted of 4 items (eg, "I prefer making plans about my eating behavior instead of leaving it to chance."; mean 3.19 [SD 0.95], alpha=.84) that describe decision making based on deliberation and planning.

Healthy Eating Style

Healthy eating style was measured with 16 items assessing general food consumption patterns (eg, "I do not eat fast food," "I only eat foods containing little salt," "If I eat sweets or cakes, I only eat little," and "I eat a lot of fruit and fresh vegetables") using a 7-point Likert scale from (1) strongly disagree to (7) strongly agree (cf, Renner et al [69], Leppin [70]). To investigate the factor structure, an exploratory factor analysis was conducted using a principal component analysis and promax rotation. Global diagnostic indicators showed adequate factorability of the correlation matrix, with Kaiser-Meyer-Olkin=.81 and a significant Bartlett test of sphericity (χ^2_{120}=3106.1, *P*<.001). Both eigenvalues on the scree-plot as well as the MAP test [71] suggested a one-factor solution. A total of 4 items were excluded because they loaded less than λ=.30 on the factor, yielding a 12-item scale that accounted for 29.39% of the variance. Items were aggregated, and a higher score represents a healthier eating style (mean 4.34 [SD 0.90], alpha=.77).

Body Mass Index

BMI was calculated using the height and weight measurements taken by trained research staff following a standardized procedure. Participants wore light indoor clothing and were asked to take off their shoes. Height was measured using a wall-mounted stadiometer, and weight was measured using a digital scale (Omron Body Composition Monitor, BF511).

Sociodemographic Variables

Participants' age and gender were assessed. Additionally, participants' level of education was assessed and converted into years of education.

Means and standard deviations are listed in Table 1 for nutrition apps and in Multimedia Appendix 2 for fitness apps.

Figure 1. Flowchart of the study sample.

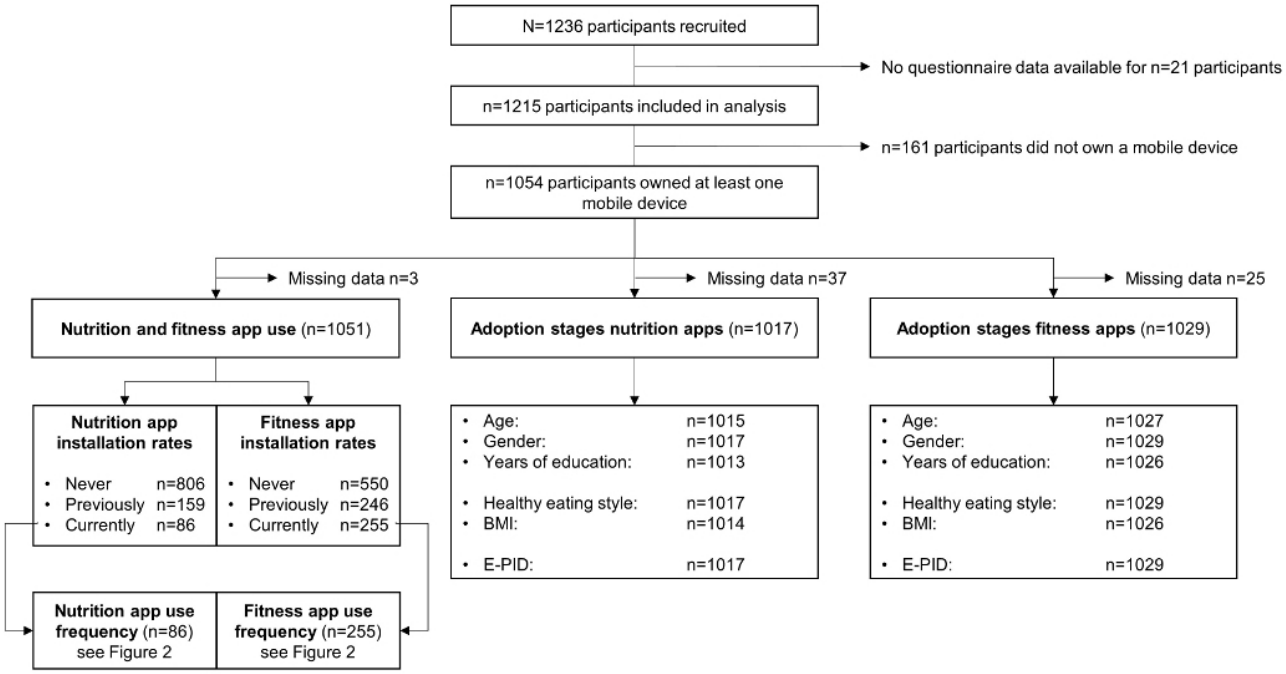


Table 1. Descriptive statistics of correlates of nutrition app adoption.

Stages of behavioral adoption	Gender[a], n (standardized adjusted residuals)			Age, mean (SD)	Years of education, mean (SD)	BMI[b], mean (SD)	Healthy eating style, mean (SD)
	Female	Male	*P* value				
Stage 1 "unengaged"	312 (−3.25)	221 (3.25)	.001	41.33 (15.88)	16.18 (2.33)	24.01 (3.24)	4.29 (0.92)
Stage 2 "decided to act"	44 (−0.07)	26 (0.07)	.94	37.33 (16.28)	15.06 (2.54)	24.86 (4.17)	4.08 (0.94)
Stage 3 "decided not to act"	126 (0.77)	66 (−0.77)	.44	35.15 (15.35)	15.89 (2.43)	23.63 (3.32)	4.26 (0.79)
Stage 4 "acting"	58 (1.47)	24 (−1.74)	.14	32.93 (14.14)	15.10 (2.44)	24.44 (3.49)	4.50 (0.84)
Stage 5 "disengaged"	103 (2.73)	37 (−2.73)	.006	32.16 (12.91)	15.69 (2.28)	24.24 (4.26)	4.29 (0.86)

[a]For gender, the number of participants in the cell and the standardized adjusted residuals (in brackets) are displayed. Due to multiple comparisons, the significance level was adjusted to alpha=.005.

[b]BMI: body mass index.

Statistical Analysis

Analyses were performed using IBM SPSS Statistics (Version 23). Missing values were 0.00% (0/1215) for gender, 0.08% (1/1215) for healthy eating style and E-PID, 0.16% (2/1215) for age, 0.25% (3/1215) for BMI, 1.4% (17/1215) for years of education and ownership of mobile devices, and 6.09% (74/1215) for fitness and 7.74% (94/1215) for nutrition app adoption stages. Participants with missing data on a variable relevant to an analysis were excluded for that specific analysis only. Descriptive statistics are reported for the full dataset (N=1215). All analyses on differences between nutrition and fitness app use stages were conducted using a subsample that had indicated owning at least one mobile device (N=1054). To investigate differences between nutrition and fitness app use stages by age, years of education, BMI, and healthy eating style, one-way analyses of variance (ANOVA) were conducted. Post hoc analyses were conducted using Bonferroni correction. Levene tests were conducted to test for the precondition of homogeneity of variances. This precondition was not met for analyzing differences in age ($F_{4,1010}$=7.84, P<.001) or BMI for nutrition app adoption stages ($F_{4,1009}$=3.27, P=.011) or for age differences between fitness app adoption stages ($F_{4,1022}$=8.00, P<.001). To analyze these relationships, Welch tests and Games-Howell post hoc tests were conducted. Gender differences were examined using chi-square tests. Post hoc tests were performed using standardized residuals and Bonferroni correction [72]. Adoption stage differences in preference for intuition and deliberation were analyzed using mixed ANOVAs, with Stages of Behavioral Adoption as a between-subjects factor and E-PID as a within-subjects factor. Significant results were followed up by simple effects (cf, Page et al [73]). For these comparisons, the alpha level was adjusted to .001 to account for multiple comparisons.

Results

Mobile Devices and Nutrition and Fitness App Use

Of the total sample, 84.95% (1010/1189) of participants indicated owning a smartphone, and 40.89% (480/1174) owned a tablet. Taken together, 1054 (87.98%) of the study population owned at least 1 mobile device that allowed them to use apps.

Installation rates of nutrition and fitness apps were further investigated in the subsample that owned at least 1 mobile device (see Figure 1). Of all the participants, 76.69% (806/1051) indicated that they never had installed a nutrition app, 15.13% (159/1051) had previously installed one, and 8.18% (86/1051) reported having one currently installed on their mobile device. For fitness apps, 52.33% (550/1051) reported never having had a fitness app installed, 23.41% (246/1051) had had one installed previously, and 24.26% (255/1051) currently had one installed on their smartphone or tablet.

In a next step, frequency of use was investigated in those participants who had indicated having a currently installed a nutrition (n=86) or fitness app (n=255) on their mobile device (for a summary, see Figure 2). For nutrition apps, most participants indicated using the app at least once a day (37.65%, 32/86), whereas for fitness apps, the largest proportion of participants indicated that they used a fitness app several times a week (36.7%, 93/255).

Stages of Behavioral Adoption

Of all the participants who owned a mobile device (see also Figure 3; means and standard deviations are listed in Table 1), 52.41% (533/1017) indicated that they had never thought about using a nutrition app and were therefore classified as "unengaged" nonusers (stage 1). Another 6.88% (70/1017) indicated that they are planning to use a nutrition app in the future and were thus categorized as "decided to act" nonusers (stage 2), and 18.88% (192/1017) were classified as "decided not to act" nonusers (stage 3) as they indicated having decided against using a nutrition app. Moreover, 8.06% (82/1017) indicated that they were currently using a nutrition app and categorized as "acting" users (stage 4), and 13.77% (140/1017) reported having previously used a nutrition app and were categorized as "disengaged" nonusers (stage 5).

In relation to the 5 stages of fitness app adoption, 29.25% (301/1029) of the participants who owned a mobile device were categorized as "unengaged" (stage 1), 9.23% (95/1029) as "decided to act" (stage 2), 20.80% (214/1029) as "decided not to act" (stage 3), 25.66% (264/1029) as "acting" (stage 4), and 15.06% (155/1029) as "disengaged" (stage 5) (see also Figure 3).

Figure 2. Frequency of use of nutrition (n=86) and fitness apps (n=255).

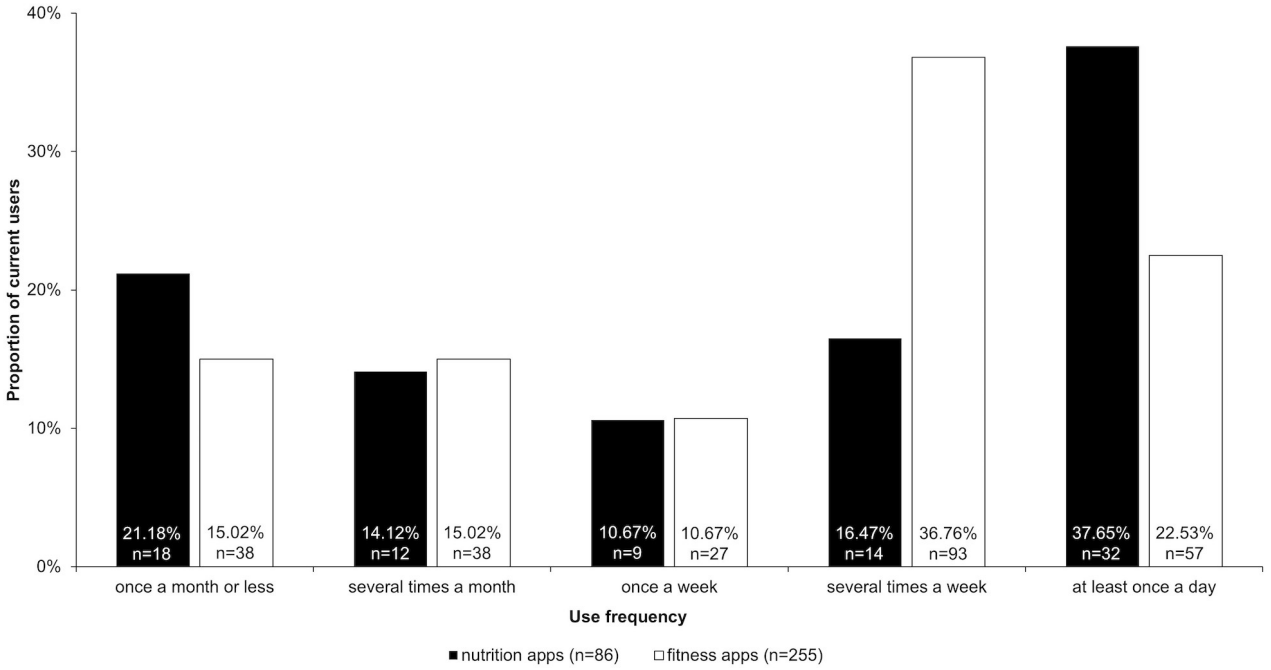


Figure 3. Stages of behavioral adoption of nutrition and fitness apps.

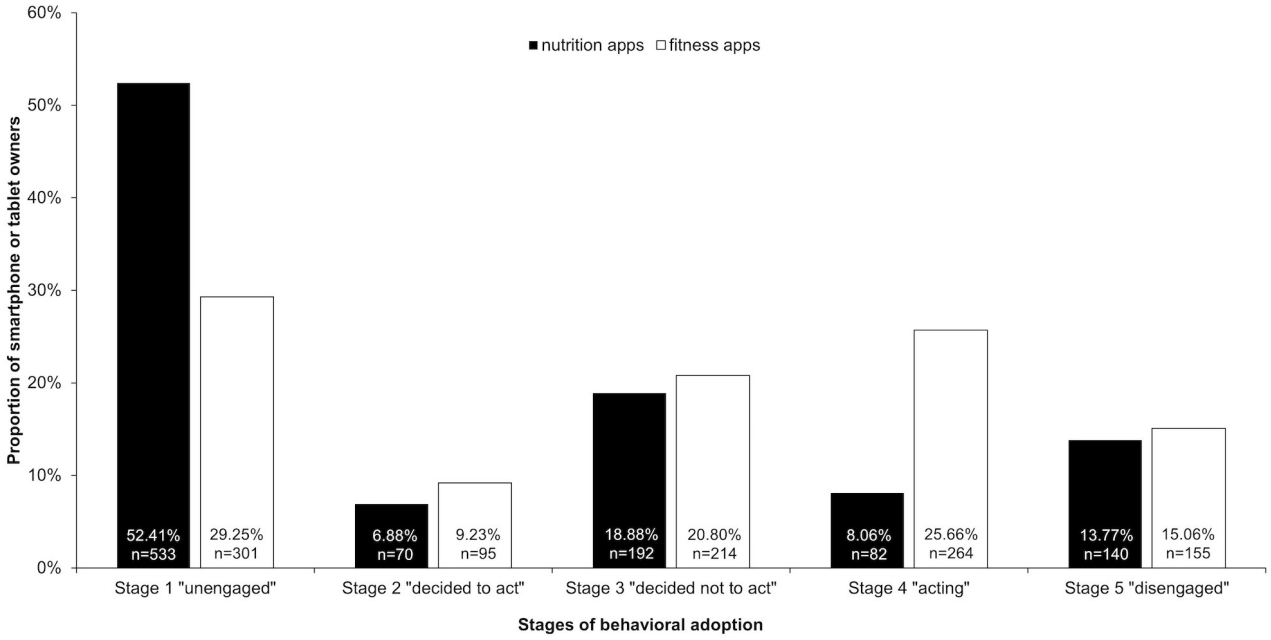
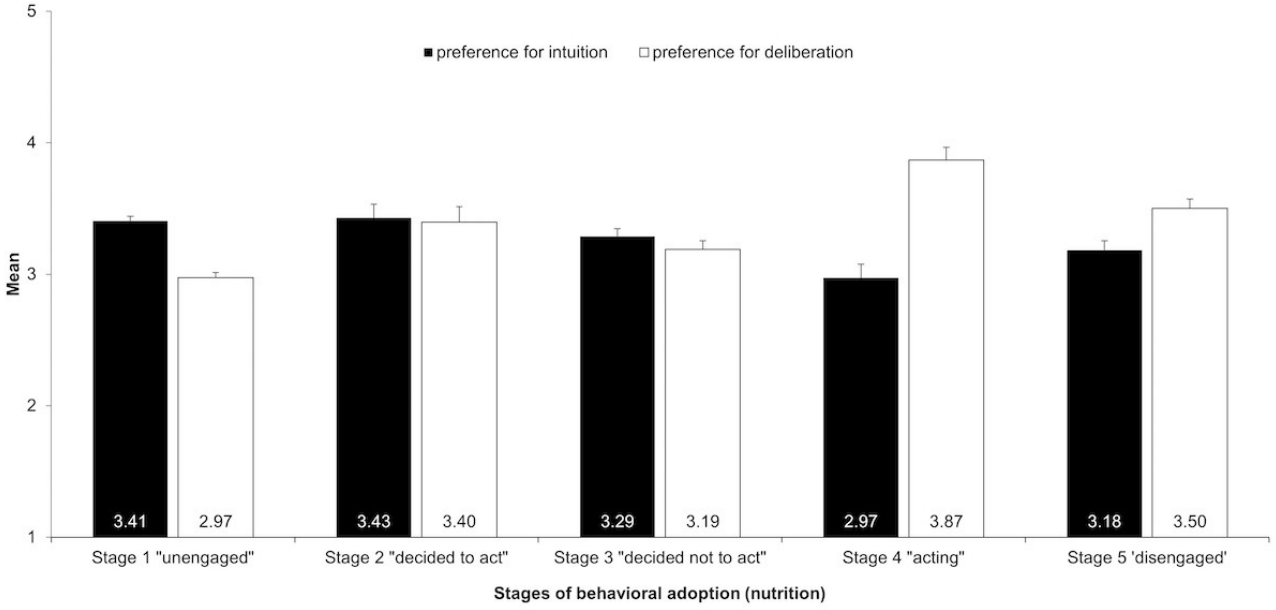


Figure 4. Differences in preference for intuition and deliberation between stages of behavioral adoption of nutrition apps.



Sociodemographic Correlates

Significant age differences between the 5 stages of behavioral adoption of nutrition apps emerged ($F_{4,252.00}$=16.85, P<.001, ω^2=.06), with the participants in stage 1 (“unengaged”) (mean 41.33 [SD 15.88]) being older than the participants in stage 2 (“decided to act”) (mean 37.33 [SD 16.28], P<.001), stage 4 (“acting”) (mean 32.93 [SD 14.14], P<.001), and stage 5 (“disengaged”) (mean 32.16 , [SD 12.91], P<.001). Furthermore, a significant association between stages of behavioral adoption of nutrition apps and gender emerged (χ^2_4=14.9, P=.007, Cramer V=.12). Men were more often in stage 1 (“being unaware”) than women. Moreover, significant stage differences were found for years of education ($F_{4,1008}$=6.65, P<.001, partial η^2=.03). Post hoc tests revealed that participants in stage 1 (“unengaged”) (mean 16.18 [SD 2.33]) were better educated than participants in stage 2 (“decided to act”) (mean 15.06 [SD 2.54], P=.002) and stage 4 (“acting”) (mean 15.10 [SD 2.44], P=.001).

Further analysis of the differences between the stages of fitness app adoption showed similar age differences as for nutrition app adoption ($F_{4,398.29}$=22.38, P<.001, ω^2=.08). Participants in stage 1 (“unengaged”) (mean 45.31, [SD 16.61]) were significantly older than participants in the remaining 4 stages (stage 2 “decided to act”: mean 37.14 [SD 15.64], P<.001; stage 3 “decided not to act”: mean 36.18 [SD 15.37], P<.001; stage 4 “acting”: mean 34.76 [SD 13.95], P<.001; and stage 5 “disengaged”: mean 33.74 [SD 13.52], P<.001). No significant differences were found both for gender (χ^2_4=8.7, P=.07) and years of education ($F_{4,1021}$=2.16, P=.07).

Behavioral Correlates

For nutrition apps, no significant differences for the 5 stages of behavioral adoption were found for both healthy eating style ($F_{4,1012}$=2.10, P=.08) and BMI ($F_{4,240.01}$=1.72, P=.15).

For fitness apps, analyzing stage differences in healthy eating style ($F_{4,1024}$=2.92, P=.02, η^2=.01) revealed a tendency for stage 1 participants (“unengaged”) to report a healthier eating style (mean 4.43 [SD 0.94]) than stage 4 participants (“acting”) (mean 4.23 [SD 0.84], P=.07). Regarding BMI, no significant stage differences were found ($F_{4,1021}$=1.71, P=.15).

Psychological Correlates: Preference for Intuition and Deliberation in Eating Decision-Making

The characteristics of the different stages of behavioral adoption of nutrition apps show that participants differed significantly in terms of their preference for a deliberative or an intuitive style when making eating-related decisions (see Figure 4; see also Table 1). Specifically, a 5 Stages of Behavioral Adoption (Nutrition) × 2 E-PID mixed ANOVA yielded significant results. Both a main effect for the between-subjects factor Stages of Behavioral Adoption ($F_{4,1012}$=6.96, P<.001, partial η^2=.03) and a main effect for the within-subjects factor E-PID ($F_{1,1012}$=5.21, P=.02, partial η^2=.01) emerged. Moreover, the interaction of the 2 factors was significant ($F_{4,1012}$=21.69, P<.001, partial η^2=.08). The interaction effect was followed up by simple effects to test differences between E-PI and E-PD at all levels of the Stages of Behavioral Adoption. Significant differences emerged between stage 1 (“unengaged”) ($F_{1,1012}$=49.55, P<.001) and stage 4 (“acting”) ($F_{1,1012}$=32.80, P<.001). Although stage 1 (“unengaged”) participants preferred on average a more intuitive eating decision-making style, stage 4 (“acting”) participants preferred on average a more deliberative eating decision-making style.

A 5 Stage of Behavioral Adoption (Fitness) × 2 E-PID mixed ANOVA was conducted to analyze stage differences in terms of the preference for a deliberative or intuitive style when making eating-related decisions to examine whether the stage characteristics are behavior specific or also generalize to the fitness app adoption process. The interaction between the between-subjects factor Stage of Behavioral Adoption (Fitness)

and the within-subjects factor E-PID reached significance ($F_{4,1024}$=6.17, P<.001, partial η^2=.02). The interaction effect was followed up by simple effects, testing differences between E-PI and E-PD at all 5 stages. A significant difference emerged only for the participants in stage 1 ("unengaged"), with a higher preference for an intuitive style when making eating decisions ($mean_{E\text{-}PI}$ 3.41 [$SD_{E\text{-}PI}$=0.84]; $mean_{E\text{-}PD}$ 3.00 [$SD_{E\text{-}PD}$ 0.98]; P<.001).

Discussion

Nutrition and Fitness App Use

In this study, the adoption process of nutrition and fitness apps and associated characteristics were investigated using a stage model approach. The present data show that there is a great potential for mHealth apps, as more than 80% of the participants owned a mobile device, whereas only 8% of them were using a nutrition app and 26% were using a fitness app. In line with other studies, the results show that fitness apps are more popular than nutrition apps, with 3 times as many fitness app than nutrition app users. For example, in a representative survey in Germany, 17% reported to use an mHealth app, of which 67% were using a fitness app and 39% a nutrition app [22]. In addition, fitness apps were mostly used several times a week, whereas nutrition apps were typically used on a daily basis. This mirrors the actual frequency of the behavior, as fitness apps are used to track specific activities such as running or working out [74], whereas nutrition apps often require that all meals are logged to provide meaningful measures and feedback. Hence, one obvious reason for the marked difference in usage of nutrition and fitness apps might be that physical activity often is tracked automatically by using smartphone sensors [75] or wearables [22,76], whereas food intake has to be tracked manually. Manual entries in food journals can be effortful and time-consuming [77,78], and therefore, fewer people might be willing to monitor their diet. Some attempts have been made to reduce effort in food journaling, for example, by including barcode scanners, digital scales [79], or reducing extensive food databases to a list of food groups [80], but these features have yet to be included in commercially available nutrition apps.

Stages of Behavioral Adoption

By using a stage model approach, this study expanded the dichotomy of mHealth app users and nonusers and shed more light on the psychological differences between nonacting participants. In the behavior adoption process, it is assumed that people move from a state of being unaware but starting to form opinions (stage 1) to a decision-making stage where they become engaged. They may decide to adopt the behavior (stage 2) or decide not to take action (stage 3). In this study, the two behavioral domains differed particularly in respect to the prevalence of stage 1 ("unengaged") as half of the participants stated that they had never thought about using a nutrition app and less than one-third stated they had never thought about using a fitness app. In comparison, similar prevalence rates for stages 2 ("decided to act") and 3 ("decided not to act") emerged for nutrition and fitness apps. Previous research has shown that people who have not yet decided often show different responses to information and are often less resistant to persuasion than people who have reached a definite position on an issue, even if they have not yet acted on their opinions [43]. Accordingly, there seems to be greater potential to increase a nutrition app uptake using tailored information to foster the transition from being "unengaged" to becoming engaged, for example, by promoting apps that target the potential user's health needs during medical counseling. These results also underline the importance of developing quality criteria and guidance for consumers and medical personnel to decide which apps to use or recommend [56].

A substantial number of participants stated that they had "decided not to act" (stage 3), which poses a qualitatively different transition barrier and therefore requires a different approach to changing beliefs and attitudes than for people in stages 1 or 2. A wealth of psychological research shows that people have a tendency to adhere to their own beliefs, which is challenging to overcome. In this case, providing information, for example, about the pros and cons of the target behavior, which has been effective for supporting people in the early stages of the behavioral adoption process [43], might be less effective. Transition might be more likely to be motivated by social influences such as significant others or social norms [34,81,82]. One might even argue that it is too costly to target this group and therefore more effective to focus on other groups of nonusers.

Although this study recorded few nonusers who had "decided to act" (stage 2), this group represents a qualitatively different and important target group for interventions. A great body of research suggests (1) that there are important gaps between intending to act and carrying out this intention, and (2) that helping people develop specific implementation plans that spell out the when, where, and how of goal striving in advance can reduce these barriers [83,84]. Such detailed implementation information is however seldom effective for people in stages 1 ("unengaged") or 3 ("decided not to act"). Likewise, perceived self-efficacy seems particularly important for the transition from "decided to act" to taking action (eg, [34,85,86]).

Participants in the "acting" stage (stage 4) showed a significant different pattern of a preference for a deliberative or an intuitive style when making eating-related decisions. As expected, the current nutrition app users showed higher preference for deliberation than intuition, whereas "unengaged" nonusers (stage 1) showed a greater preference for intuition than deliberation. Accordingly, nutrition apps seem to be especially appealing to people who tend to decide what to eat after conscious reflection. mHealth apps are targeted toward this deliberative decision-making style by helping to gain insight into and control over energy intake, for example, by allowing self-monitoring and providing instruction [52]. Interestingly, participants in stage 2 ("decided to act") expressed interest in using nutrition apps, although reporting a lower preference for deliberation and a higher preference for intuition than the current app users. This might indicate that the mismatch between the design of current available apps and preferred decision-making styles creates a significant transition barrier. Developing apps that are more tailored to an intuitive decision-making style might motivate higher stage transition rates. For example, this might be achieved by associating health behaviors with positive emotions (eg,

[87]) or including game-like features, which might also increase the likelihood of habit formation [88]. However, it has yet to be investigated which app features and behavior change techniques [89] best support an intuitive decision-making style, and whether including these features actually leads to increased mHealth app adoption. As differences in preferred decision-making style between fitness app adoption stages were similar but less pronounced than differences between nutrition app adoption stages, results highlight that psychological correlates of mHealth app use are behavior-specific and therefore need to be investigated separately for different health behaviors (cf, [90]). Moreover, it is important to note that preferred decision-making style was only assessed for eating-related decisions. Thus, future studies need to test for further differences between fitness app adoption stages and the preferred decision-making style for physical activity.

In line with previous research [5], participants in the "acting" stage (stage 4) were younger than "unengaged" nonusers (stage 1). This might be due to a general higher interest in the use of mobile technology, as indicated by a higher proportion of younger smartphone owners [91] and younger people being more convinced of the efficacy of mHealth apps [4]. Moreover, the results of this study show that current nutrition app users are less educated than "unengaged" nonusers. This is in contrast with previous studies describing mHealth app users as being more educated. One reason for this difference might be that the present sample was recruited onsite as part of a cohort study, rather than online as with most previous studies. The present sample includes a broader age range and potentially less technology savvy participants. Moreover, the continuous measure used might also have had an impact as previous studies compared participants with high school and university degrees [4,5,23]. The participants in this study were generally highly educated. Moreover, the observed differences in level of education between stages were small [92]. In contrast, no such relationships were found for fitness apps, suggesting that gender and education differences might be more pronounced for nutrition than for fitness app use.

Although no differences in psychological, behavioral, and sociodemographic variables were found between "acting" users (stage 4) and "disengaged" nonusers (stage 5), the two groups differ substantially in their mHealth app use behavior. Although one might argue that "disengaged" nonusers ceased using an app because they had reached their goal, research suggests that most "disengaged" nonusers might rather have abandoned their goal [19]. This lack of engagement could, for example, be overcome by using effective behavior change techniques that help maintain the intention or the behavior [93], for example, by boosting self-efficacy or prompting planning [38]. Moreover, users might disengage from the app because tracking is too time-consuming or not interesting enough in the long term [5]. Developments in mobile technologies such as image-based assessment methods for dietary intake [94] hold great promise for reducing user burden, which might in turn boost user motivation. Thus, when further developing and testing the stage model presented in this study, models of engagement with digital behavior change interventions can provide valuable insights as they have already identified many potential transition barriers and enablers for the transition from "acting" to "disengagement" (cf, [95]). Furthermore, engagement models might also provide further insights into transition barriers as well as enablers for the transition to the "acting" stage and re-engagement [96].

In line with previous research [4,24,25], no significant differences between stages of adopting nutrition apps were found with respect to a healthy eating style and BMI, and differences found between stages of adopting fitness apps were small [92]. This might be explained by the various reasons for using mHealth apps: Although some people use them to lose weight [19], others use them without any intention to change their behavior, for example, to maintain their weight [97] or to learn more about their physical activity or eating patterns [77]. However, to examine the effect on actual changes in dietary patterns or related outcome such as BMI, longitudinal studies such as randomized control trials are needed. Although there has been much enthusiasm for delivering interventions through mobile devices such as smartphone apps, academic research on the development and evaluation of these mobile devices is at an early stage. Most currently available devices and programs have not been empirically evaluated, and the existing studies have predominantly focused on clinical samples, including text message–based mobile interventions [98-102]. Recently, Schoeppe et al [103] identified 27 studies in 6926 publications from 2006 to 2016 that used a smartphone app to improve diet and/or physical activity as a health precaution with mixed results: only 7 of the 13 studies targeting diet and 14 of the 21 targeting physical activity reported significant improvement. As most current mHealth apps focus more on user interface aspects to keep consumers engaged than evidence-based behavior change methods [104,105], incorporating effective behavior change techniques [89,106,107] might be a promising avenue for further research.

Limitations

A strength of the study is the large sample, which represents a wide age range and was recruited onsite from the community. Although mean BMI and age were comparable to the general German population, females were overrepresented and both the university entrance diploma and the university degree rate were above the national average, potentially limiting the generalizability of the findings. Furthermore, the study was advertised as a health check; thus, the participants might have been more interested in their health than the average citizen, possibly boosting mHealth app use rates.

Conclusions

Still, the mHealth app usage rates found both in this study and in previous research (eg, [6,22]) were low, underlining the potential to engage more people in the use of mHealth apps. Using a behavior stage model approach to describe the process of adopting mHealth apps revealed motivational stage differences between nonusers, including being "unengaged," "decided not to act," "decided to act," and being "disengaged," which might contribute to a better understanding of the process of adopting behavior changes and tailoring interventions to foster transitions between stages.

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Authors' Contributions

All authors were involved in the concept and design of the study and data acquisition. LK conducted data analysis with input from BR. LK and BR drafted the manuscript with critical revisions from GS and HS. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Generation of adaptations of the PAPM (Weinstein, & Sandman, 1992) and Preference for Intuition and Deliberation (Betsch, 2004).

[PDF File (Adobe PDF File), 46KB - mhealth_v6i3e55_app1.pdf]

Multimedia Appendix 2

Descriptive statistics of sociodemographic and behavioral correlates of fitness app adoption.

[PDF File (Adobe PDF File), 33KB - mhealth_v6i3e55_app2.pdf]

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Abbreviations

BMI: body mass index
CFI: comparative fit index
E-PD: E-PID subscale preference for deliberation
E-PI: E-PID subscale preference for intuition
E-PID: Preference for Intuition and Deliberation in Eating Decision-Making
HAPA: health action process approach
PAPM: precaution adoption process model
RMSEA: root mean square error of approximation
SRMR: standard root mean square residual
TTM: transtheoretical model of health behavior change

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Original Paper

Self-Directed Engagement with a Mobile App (Sinasprite) and Its Effects on Confidence in Coping Skills, Depression, and Anxiety: Retrospective Longitudinal Study

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Abstract

Background: Inadequacies in mental health care coverage remain an enormous problem in the United States. Barriers include scarcity of accessible mental health care professionals. Use of a mental health mobile app incorporating social cognitive theory may help improve confidence in coping skills and improve anxiety and depression. Sinasprite is a mobile app that recruited users via self-referral and clinician referral. Users completed questionnaires to obtain demographic and medical histories. At baseline and 6-week follow-up, users completed the Patient Health Questionnaire 8 (PHQ-8), General Anxiety Disorder 7-Item (GAD-7), and the Coping Self-Efficacy Scale (CSE). It is unknown how self-directed use of a mobile app improves confidence in coping skills and its effects on self-reported depression and anxiety.

Objective: The objective of this study was to evaluate the Sinasprite database to assess self-directed engagement and how use of this mobile app impacted self-reported confidence in coping skills and severity of depression and anxiety.

Methods: This retrospective longitudinal study involved users recruited via clinician referral and self-referral through social media and news media. Questionnaires were used to record demographic, medical, and prescription medication histories. Mental health status was assessed via PHQ-8, GAD-7, and CSE questionnaires. A deidentified dataset reporting mobile app use data was provided to investigators. Individuals with verifiable usage data and at least one completed questionnaire at 6 weeks of use were included. Mann–Whitney *U* and Kruskal-Wallis tests were used to assess whether demographic data and psychotherapy were related to baseline questionnaire scores and usage. A Spearman rho (ρ) test was used to assess the relationship between improvement in the CSE and GAD-7 and PHQ-8 questionnaires. Changes in mental health status were assessed using Wilcoxon signed-rank test. A mixed-effects repeated-measures linear regression model assessed the main effects of time, concomitant counseling, and psychotropic prescription medication use on mental health status.

Results: Thirty-four users were eligible for inclusion in the analysis. Users were predominantly female, white, married, and college educated. At baseline, 35% (12/34) of respondents reported the use of individual/group counseling, and 38% (19/34) reported using prescription medications for their mental health. The median user completed 5.7 (interquartile range 2.7-14.1) trackable activities per week. Statistically significant improvements using a Wilcoxon signed-ranked test were observed in the PHQ-8 (P<.001), GAD-7 (P=.002), and CSE (P<.001) questionnaire scores. A strong positive correlation between improvement in the GAD-7 and CSE questionnaire scores (ρ=.572, P=.001, n=28) was observed. The mixed-effects repeated-measures regression

model revealed a statistically significant effect of time on improvements in the PHQ-8 (P<.001), GAD-7 (P=.007), and CSE (P=.001).

Conclusions: This 6-week retrospective study showed that self-directed use of the mobile app, Sinasprite, resulted in significant improvements in self-reported questionnaire scores reflecting depression, anxiety, and confidence in coping skills.

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KEYWORDS

mental health; retrospective studies; longitudinal studies; mobile apps; anxiety; depression

Introduction

Approximately 43 million adults in the United States experienced mental illness in 2015 [1]. The national cost of mental illness was $467 billion in the United States in 2012 [2]. Uncontrolled mental health conditions are associated with increased costs from medications, clinic visits, hospitalizations, incarceration, homelessness, emergency room visits, and premature mortality [3]. The financial burden, stigma, lack of perceived need for treatment, and gaps in access to health care professionals and facilities are among the barriers to attainment of mental health care in the United States [4,5]. Thus, viable alternatives are needed to address this escalating mental health care crisis.

Depression and anxiety are ranked the first and sixth global causes of disability, respectively [6]. Contemporary practice guidelines recommend initiation of antidepressant medications and/or psychotherapy such as cognitive behavioral therapy (CBT) in the treatment and management of patients' depression and anxiety [7-11]. Furthermore, one-half of all patients with anxiety [6] and one-third of those with depression [12] may benefit from early CBT interventions.

Two-thirds of the American population owns a smartphone, thereby presenting an opportunity for health care services that can overcome geographical and financial limitations [5]. This resulted in the release of 165,000 health-related mobile apps to the public in 2015 on Android and iOS platforms [5]. However, only 7% of these mobile apps provided services to track, assess, or treat mental health conditions [5].

A study by Burns et al demonstrated that a mobile app, which incorporated the use of machine learning, behavioral training, and coaching, was able to assist in the care of patients with major depressive disorder [13]. Lyet et al found the delivery of behavioral activation and mindfulness therapy through a mobile app, complemented by face-to-face therapy, to be an effective means of improving depression severity [14]. The Get Happy Program based on the principles of CBT resulted in improved self-reported Patient Health Questionnaire 9 (PHQ-9) scores up to 3 months after program completion [15]. Another study found a mobile app that incorporated CBT, behavioral activation, mindfulness, and psychoeducation in conjunction with coaching, significantly improved self-reported depression severity among users [16]. Cognitive bias modification interventions for attention via a mobile app were beneficial in the management of anxiety among patients [17]. Arean et al found that individuals with moderate levels of depression may benefit most from mobile apps [18]. Meta-analyses reported that smartphone interventions positively improved symptoms of depression and anxiety among users [19,20]. In addition, a recent systematic review also concluded that the utilization of CBT therapies via a mobile app platform might improve the management of a variety of mental health conditions [21].

Although there are significant published data on the effects of mobile health apps on depression and anxiety, little is known about the effects of these interventions on coping skills and their relationship with the management of depression and anxiety severity. Coping is defined as the behavioral and cognitive efforts individuals use when faced with psychological, emotional, and physical stressors [22,23]. Problem and/or emotional-focused coping strategies may be used to address these stressors [22,23]. Perceived self-efficacy in coping is expected to reflect one's confidence in their ability to cope with stressors, threats, and challenges [23]. Individuals with higher levels of coping self-efficacy are expected to better mediate potential stressors and challenges [24]. Previous research has highlighted the inverse relationship between coping self-efficacy with depression and anxiety [23-25]. Furthermore, the increased uses of coping strategies have been shown to reduce severity of depression and anxiety [26]. Little is known about how a mobile app designed to improve confidence in coping skills may impact depression and anxiety severity.

Sinasprite is a self-directed mobile app developed using Bandura's social cognitive theory that includes elements of CBT and mindfulness strategies to improve an individual's ability to cope with stressors and is expected to decrease the severity of an individual's anxiety and depression. Litesprite (Bellevue, WA, USA), an organization that develops mental health mobile apps, released Sinasprite in the iOS and Android app stores as a beta (Multimedia Appendix 1). To download the mobile app, users accessed the Litesprite website, completed voluntary questionnaires, and received a beta key permitting access to the mobile app. Users were recommended to use Sinasprite for 6 weeks and to complete a voluntary follow-up questionnaire afterward. The objective of this study was to conduct an assessment of the Litesprite database to evaluate engagement with the mobile app and how a self-directed mobile app can impact confidence in coping skills and depression and anxiety severity.

Methods

This retrospective longitudinal study evaluated user engagement and outcomes associated with the use of Sinasprite, a native mobile app developed by Litesprite. Investigators received a deidentified dataset from the mobile app development team

containing usage data, questionnaire responses, and demographic data. The Ohio State University Institutional Review Board deemed this study to be exempt from human subject's research.

Mobile App Design

This mobile app was developed using Bandura's social cognitive theory and included elements of CBT and mindfulness-based stress reduction [27]. The game-based modules incorporate features such as visualization, diaphragmatic breathing, meditation, anxiety journal writing, augmented reality exercise, and mindfulness. Users participate in these modules to help Socks the Fox (a digital avatar) become a Zen master. The mobile app also uses intrinsic incentives and in-game prompts and rewards to reinforce engagement and the use of multiple modules. Repeated use of the mobile app is expected to gradually improve an individual's self-efficacy, sense of self-control, reinforcements, and coping skills to ultimately improve the management of their stress, depression, and anxiety. Sinasprite is a native mobile app for iOS and Android operating systems that does not require an active internet connection. Once the mobile app is finalized and updated, prospective users would be able to access it through the iOS and Android mobile app stores.

Recruitment

The mobile app was released to the public in a live beta to allow users to use and potentially benefit from it with minimal intervention and support from health care practitioners. Anyone aged 18 years or older was invited to use the mobile app. Users were recruited via clinician referrals and self-referral through social media and news media such as Facebook advertisements and presentations and news articles published in *VentureBeat*, *Puget Sound Business Journal*, *The Northwest Guardian*, *GeekWire*, *Elevar*, *Serious Games Market*, *SVP Fast Pitch*, *The Huffington Post*, *Casual Connect*, *Seattle Met*, *Counseling Washington*, *Medgadget*, *Chase*, *425 Business*, *The Law of Startups*, *Seattle Health Innovators*, *Marketplace*, *Women 2.0*, *The Seattle Times*, *Portland Business Journal*, *International Business Times*, and *iMedicalApps*. Potential users were directed to the Litesprite website and signed up to use the mobile app. Users were then emailed a link to a secure website where they completed a voluntary questionnaire. On submission, users were sent a beta key via email within a day, providing access to the beta version of the mobile app. They subsequently downloaded the mobile app from the app store of choice and used the beta key to access the mobile app.

Questionnaires

Users were electronically sent access to a secure website where they completed a voluntary questionnaire requesting demographic information, medical history, use of psychotherapy and prescription medications, and mental health status via the Patient Health Questionnaire 8 (PHQ-8) [28,29], General Anxiety Disorder 7-Item (GAD-7) [30], and the Coping Self Efficacy Scale (CSE) questionnaires [23]. The PHQ-8 was used over the PHQ-9 to measure depression severity because the nonproctored format of the survey prevented the appropriate assessment of suicidal ideation, which is uncommon in the general population [29]. The GAD-7 and CSE questionnaires were used to assess anxiety severity and confidence in coping skills [23,30]. Users did not need to completely fill out the survey to be able to submit. After 6 weeks of using the mobile app, users were sent a link to a secure website, where they were able to complete the mental health status questionnaires (PHQ-8, GAD-7, and CSE). Questionnaires with incomplete PHQ-8 or GAD-7 questions were excluded from analysis. CSE questionnaires were included in the analysis if at least 80% (21/26) of the questions were answered [23]. Missing responses were replaced by the mean of completed items, resulting in a corrected sum [23].

Data Analysis

Data were organized and coded in IBM SPSS Statistics (v24.0; Armonk, NY, USA) and were assessed for normality using the Wilk-Shapiro test and histograms. All users were included in the initial dataset. Users who did not complete any of the surveys after 6 weeks of use or did not have verifiable usage data were excluded. Due to the low sample size and non-normal distribution of the data, Mann-Whitney *U* and Kruskal-Wallis statistics were used to assess the relationship between demographic data, psychotherapy, baseline PHQ-8, GAD-7, or CSE questionnaire scores and the usage metrics. A 2-tailed a priori alpha level of .05 was used.

Mobile App Engagement

Several indicators were used to evaluate the mobile app. Included were the average length of in-game session, completed meditation sessions, mindfulness paintings, anxiety journal entries, and self-assessment questions. Given the in-development (beta) status of the mobile app, it was not possible to collect data from some modules. These included the fishing module and an augmented reality exercise module that encouraged walking. The weekly amount of user activity was calculated by adding the number of completed activities and dividing by 6 weeks. Although the mobile app was intended to be used several times a week, users were encouraged to use the modules in the frequency they felt will be of most benefit to them. This was intended to allow users to determine their own experience and make use of the app as "nonconfrontational" as possible [31]. Thus, adherence could not be adequately assessed in the scope of this study [31]. The Sinasprite development team also provided investigators with a retention rate of users included in the analysis.

Relationships Between Outcome Measures

A Spearman rho (ρ) test was used to assess the relationship between improvement in the CSE and GAD-7 and PHQ-8 results. A preliminary analysis using a scatter plot of the results was performed to ensure the relationship between improvements in the questionnaire scores followed a monotonic relationship.

Effects of Sinasprite on Self-Reported Questionnaire Outcomes

To assess the change in self-reported questionnaire outcomes among users, a Wilcoxon signed-rank test was performed. This test was then repeated with users who reported no concomitant therapies. Cohen *d* effect size was calculated for each test [32].

Mixed-Effects Repeated-Measures Linear Regression Model

To further evaluate the effects of using the mobile app on mental health, a mixed-effects repeated-measures linear regression model using unstructured variance, restricted maximum likelihood, and intercepts was conducted. This method was chosen because of its superiority to analysis of variance in assessing correlations [13]. Q-Q plots and a Wilk-Shapiro test were used to assess the appropriateness of the model for each mental health status outcome. Transformations were used to normalize data when required. The main effects of time, receipt of prescription drug therapy, and individual or group counseling were included in the linear regression model.

Results

The sample included data from 450 users of the mobile app. However, 275 users were excluded because of lack of verifiable usage data, and an additional 141 were excluded for not completing at least one 6-week follow-up questionnaire (PHQ-8, GAD-7, or CSE). The final sample for the analysis included 34 users (Figure 1).

In this study, users included for analysis were predominantly female 77% (26/34), white 41% (14/34), married 62% (21/34), and college educated 71% (24/34) with a median age of 40 (interquartile range [IQR] 32.75-50.75) years. Moreover, 35% (12/34) of users reported receiving individual or group counseling, and 38% (13/34) reported using prescription medications for their mental health (Table 1). After 6 weeks of use, 74% (25/34) of users who were included in the analysis continued to use the mobile app. Retention of users who were excluded was unable to be assessed. Users who reported attending individual or group counseling sessions were more likely to report a higher GAD-7 (P=.04) than those who did not receive counseling. Individuals currently using prescription medications for their mental health conditions were more likely to report higher baseline GAD-7 (P=.01) and PHQ-8 (P=.03) and lower CSE (P=.01) questionnaire scores compared with their counterparts. Use of the mobile app was not significantly associated with demographic characteristics or receipt of prescriptions or counseling services for their mental health conditions.

Mobile App Engagement

Mobile app usage data are presented in Table 2. The median user averaged 6 min per session and used the mobile app once a week. The most used feature was self-assessment questions with users completing a median of 15 questions. The second most used feature was meditation; a median of 5.5 sessions was completed, and users meditated for 1 to 3 min. Completion of paintings and use of anxiety journal entries were comparable with a median of 4 and 3.5 per user, respectively. Users performed a median of 5.7 trackable activities per week. However, one user completed the pre- and postquestionnaires and yet completed no activities in the first 6 weeks, whereas the top 10 most active users completed 12 to 50 activities per week. These data highlight the large degree of interuser variability with the use of the mobile app. There was a moderate to strong, positive correlation between journal entries and self-assessment questions (ρ=.418, n=34, P=.001), meditation sessions (ρ=.631, n=34, P<.001), and paintings (ρ=.681, n=34, P<.001). A strong positive correlation between meditation sessions and paintings (ρ=.927, n=34, P<.001) also was observed. Use of the mobile app was moderately and positively correlated with the baseline self-reported GAD-7 questionnaire score (ρ=.365, n=32, P=.04).

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram illustrating exclusion criteria.

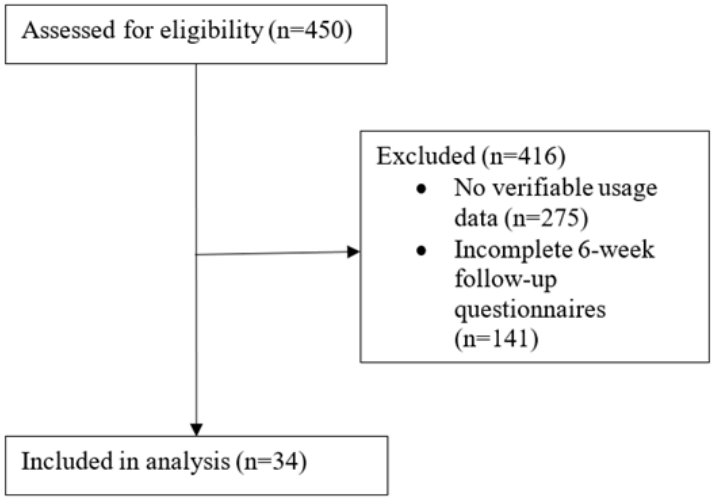


Table 1. Demographic and clinical characteristics of users of Sinasprite mobile app (N=34). Percentages may not equal to 100% because of rounding.

Characteristics	Statistics
Age in years, median (interquartile range)	40 (33-51)
Gender, n (%)	
Male	6 (18)
Female	26 (77)
Prefer not to say	2 (6)
Highest level of education, n (%)	
Did not graduate high school	1 (3)
High school diploma	9 (27)
Bachelor's degree	10 (30)
Graduate degree	14 (41)
Racial background, n (%)	
White	14 (41)
Asian	1 (3)
Prefer not to say	19 (56)
Marital status, n (%)	
Single or never married	6 (18)
Married or partnered	21 (62)
Separated	2 (6)
Divorced	3 (9)
Household income before taxes in US dollars, n (%)	
$20,000-$29,999	3 (9)
$30,000-$49,999	2 (6)
$50,000-$69,999	1 (3)
$70,000-$99,999	2 (6)
$100,000-$149,999	2 (6)
>$150,000	2 (6)
Prefer not to say	22 (65)
Received individual or group counseling, n (%)	
Yes	12 (35)
No	21 (62)
Did not say	1 (3)
Used prescription medication for behavioral health, n (%)	
Yes	13 (38)
No	19 (56)
Did not say	2 (6)

Table 2. Frequency of Sinasprite mobile app use by users.

Usage data per user	Median (interquartile range)
Self-assessment questions completed	15.0 (5.0-41.3)
Number of meditation sessions completed	5.5 (2.0-13.3)
Mindfulness paintings completed	4.0 (1.0-12.0)
Anxiety journal entries completed	3.5 (1.75-8.3)
Sinasprite activities per week	5.7 (2.7-14.1)
Sinasprite total activity	34.0 (16.0-84.5)
Total number of sessions	6.0 (3.0-13.85)
Average length of session (min)	6.0 (3.8-8.5)

Relationships Between Outcome Measures

The relationship between improvement in the CSE questionnaire and the GAD-7 and PHQ-8 questionnaire scores was assessed. Preliminary analysis indicated no violation in the assumption monotonicity. There was a strong positive correlation between improvement in the GAD-7 and CSE questionnaire scores (ρ=.572, *P*=.001, n=28). However, there was a statistically insignificant, small, positive correlation observed between improvement in the PHQ-8 and the CSE questionnaire scores (ρ=.178, *P*=.37, n=28).

Effects of Sinasprite on Self-Reported Questionnaire Outcomes

Before using the mobile app, the median user reported a PHQ-8 score of 7 (IQR=2.0-11.5, indicating mild depression) and a GAD-7 score of 5.5 (IQR=3.0-11.0, indicating mild anxiety) [29,30]. After 6 weeks of using the mobile app, the median user reported a PHQ-8 score of 3.0 (IQR=2.0-6.0, indicating none or minimal depression) and a GAD-7 score of 4.0 (IQR=1.3-7.0, indicating no or minimal anxiety symptoms) [29,30]. Figures 2-4 illustrate changes in the PHQ-8, CSE, and GAD-7 self-reported questionnaire scores. The CSE at baseline was 174.9 (IQR=128.0-210.6), which improved to 194.0 (IQR=164.3-228.5) after 6 weeks of using the mobile app. A statistically significant improvement was observed in the PHQ-8 (n=32, *z*=−3.501, *P*<.001, effect size=0.44), GAD-7 (n=31, *z*=−3.138, *P*=.002, effect size=0.40), and CSE (n=30, *z*=−3.557, *P* ≤.001, effect size=0.46) questionnaire scores after 6 weeks of engagement with the mobile app.

Before using the mobile app, the median user not currently receiving psychotropic medications or counseling services reported a PHQ-8 of 4.5 (IQR=1.3-10.5, indicating mild depression) and a GAD-7 score of 3.0 (IQR=2.0-9.0, indicating none or minimal anxiety) [29,30]. After 6 weeks of using the mobile app, the median user reported a PHQ-8 score of 2.0 (IQR=1.0-4.0, indicating none or minimal depression) and a GAD-7 score of 3.5 (IQR=0.3-4.8, indicating none or minimal anxiety) [29,30]. The CSE at baseline was 178.0 (IQR=161.0-215.5), which improved to 219.0 (IQR=189.0-230.0) after 6 weeks of using the mobile app. Significant improvements were observed in the PHQ-8 (n=16, *z*=−2.884, *P*=.004, effect size=0.51), GAD-7 (n=15, *z*=−2.282, *P*=.02, effect size=0.42), and CSE (n=15, *z*=−2.840, *P*=.005, effect size=0.52) questionnaire scores, after 6 weeks of engagement with the mobile app.

Figure 2. Changes in self-reported depression at baseline and after 6 weeks of using the Sinasprite mobile app on the Patient Health Questionnaire 8 (PHQ-8).

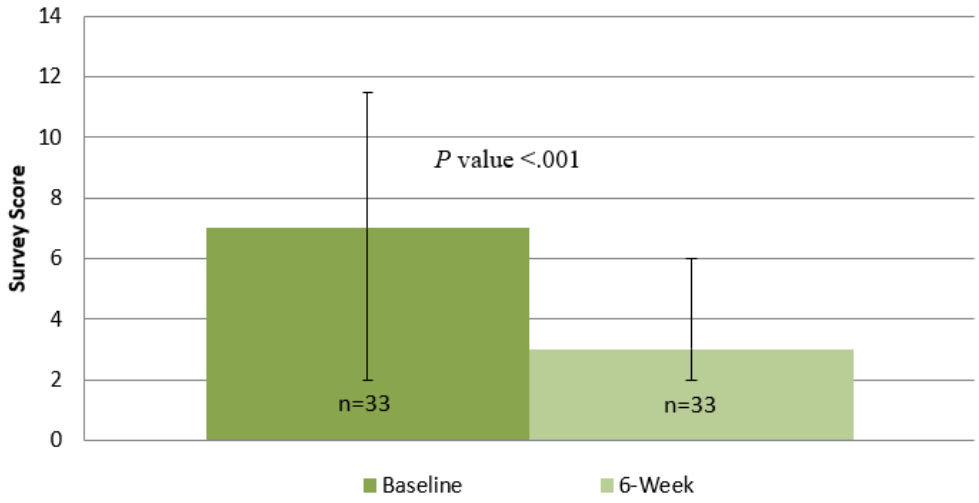


Figure 3. Changes in self-reported anxiety at baseline and after 6 weeks of using the Sinasprite mobile app on the General Anxiety Disorder 7-Item (GAD-7).

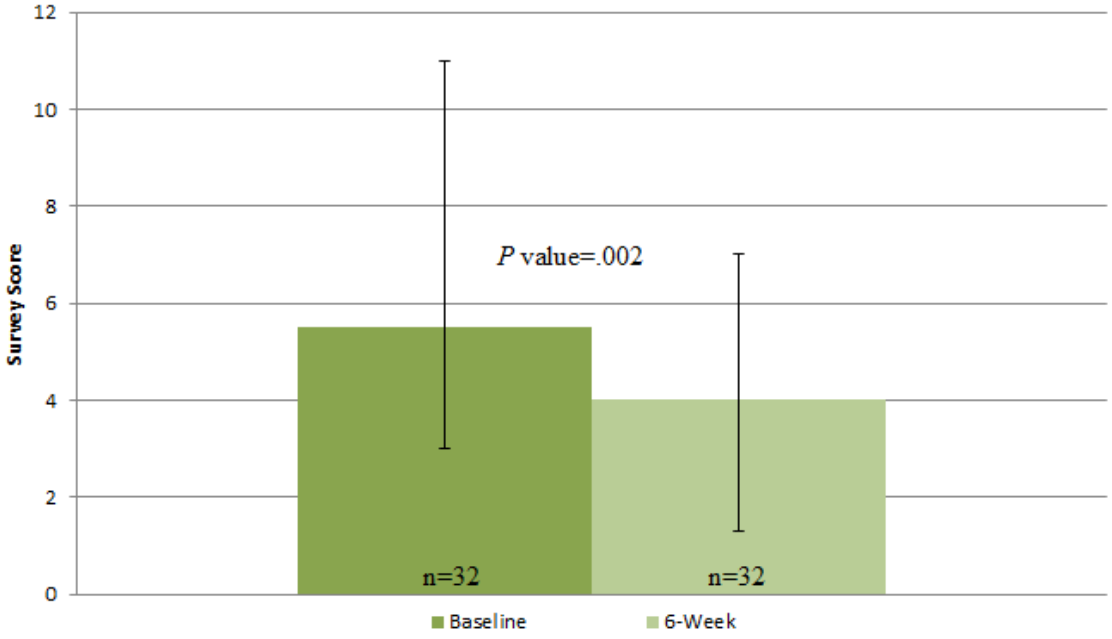
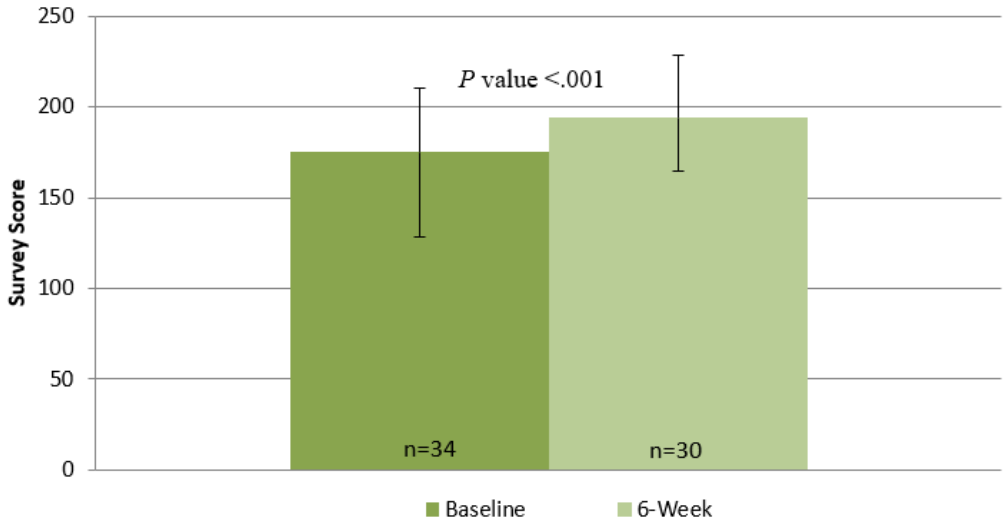


Figure 4. Changes in self-reported confidence in coping skills at baseline and after 6 weeks of using the Sinasprite mobile app on the Coping Self-Efficacy Scale (CSE).



Mixed-Effects Repeated-Measures Linear Regression Model

To assess the effects of concomitant therapies on outcomes, the changes in the self-reported questionnaire outcomes (PHQ8, GAD-7, and CSE) were modeled using a mixed-effects repeated-measures linear regression model. The variables included main effects of time, receipt of individual or group counseling, and use of prescription medications. The GAD-7 scores were transformed using square root arithmetic. Wilk-Shapiro test and Q-Q plots indicated a normal distribution, and no further transformations were necessary. This model assessed changes before and after 6 weeks of using the mobile app. The complete results can be found in Table 3. There was a significant effect of time on the PHQ-8 (P<.001), GAD-7 (P=.007), and CSE (P<.001) questionnaire scores. In addition, a significant effect of prescription medications was noted on the PHQ-8 (P=.003) and CSE (P=.009); however, statistical significance was not achieved for the GAD-7 survey. The main effect of counseling or group therapy was not statistically significant for any of the questionnaires. The main effect of time indicated that there was a statistically significant improvement between the pre- and posttests for all 3 questionnaires after controlling for concomitant therapies. Use of prescription medications was also a statistically significant variable for depression severity (PHQ-8) and confidence in coping skills (CSE).

Table 3. Results from mixed-effects repeated-measures linear regression model.

Questionnaires	F statistic (degrees of freedom)	*P* value
Patient Health Questionnaire (PHQ-8)		
Intercept	67.1 (1.0,30.0)	<.001[a]
Time	15.5 (1.0,30.0)	<.001[a]
Individual or group counseling	0.1 (1.0,30.0)	.78
Prescription medication use	10.2 (1.0,31.0)	.003[a]
General Anxiety Disorder 7-Item (GAD-7)		
Intercept	186.9 (1.0,28.0)	<.001[a]
Time	8.4 (1.0,29.0)	.007[a]
Individual or group counseling	1.7 (1.0,29.0)	.21
Prescription medication use	3.8 (1.0,29.0)	.06
Coping Skills Self-Efficacy Survey (CSE)		
Intercept	731.9 (1.0,30.0)	<.001[a]
Time	17.7 (1.0,29.0)	<.001[a]
Individual or group counseling	0.3 (1.0,28.0)	.56
Prescription medication use	7.9 (1.0,28.0)	.009[a]

[a]Significant at the .05 significance level.

Discussion

Comparison With Prior Work

Over 4800 areas around the United States reported a shortage of mental health providers in 2017 [33]. Furthermore, one-half of patients with mental illness reported not to have received any mental health care in 2014 [34]. Use of mobile apps may be able to reach individuals beyond geographical, financial, and social circumstances. The results of our study are in line with previous meta-analyses that concluded mobile app–based interventions might positively impact the severity of depression and anxiety [19,20].

The results from this study are similar to previously published studies that detailed the positive effects of different mobile app interventions on depression severity [14-16,18,35-37]. It is important to note that several of these studies included access to additional resources or health care practitioners [14,15,35,36]. Furthermore, the effect size of the present mobile app (effect size=0.44) on depression severity is comparable with other self-guided mobile apps (effect size=0.21-0.70) [35]. Regarding anxiety severity, the results from this study are similar to others that demonstrated that mobile apps may positively improve management of anxiety [17,36-39]. However, it is difficult to adequately compare the results of this study with others because of the differences in populations, methodology in assessing mental health status, execution of interventions, and follow-up period. This study also found the mobile app positively impacted self-confidence in coping skills. To our knowledge, this is the first study to assess how a mobile app may influence confidence in coping skills.

Principal Findings

Key findings from this study showed self-directed engagement of Sinasprite after 6 weeks of use was associated with statistically significant improvements in self-reported PHQ-8, GAD-7, and CSE questionnaire scores. Statistically significant improvements were seen even after controlling for concomitant prescription medication and counseling or group therapies. This study also found a strong positive correlation between improvement in the CSE and GAD-7 questionnaire scores. Unexpectedly, a statistically insignificant correlation was detected between improvement in the CSE and the PHQ-8 questionnaires.

Over the 6-week study period, the median user performed approximately 6 activities per week in the Sinasprite app. Although users were encouraged to use the mobile app to meet their needs, not all activities were tracked and assessed; thus, an underestimation of actual engagement in the mobile app may have occurred. Moreover, the beta status of the mobile app may have resulted in lower levels of user engagement; use of the mobile app may substantially increase when a fully functional version is made available to the general public. However, it is noteworthy that the degree of engagement shown from the beta version resulted in statistically significant improvements in questionnaire scores for depression and anxiety severity and coping skills. Summary data provided by the Sinasprite development team reported that 74% (25/34) of users included in the analysis continued to use the app after 6 weeks of use. This is consistent with previously reported retention rates, ranging from 10% to 70%, for internet and mobile app interventions [16]. However, it is important to note, among the entire sample, only 38.9% (175/450) of users actually presented with usage data.

Use of the Sinasprite mobile app for various features may subsequently prompt use of other features. For example, the mobile app prompted users to make a painting after completion of a meditation session to promote self-awareness from the meditation experience. Also, on completion of an anxiety journal, entry users were prompted to complete a breathing exercise although this is an untracked feature. The moderate to strong correlations detected between the trackable features suggest that users were not selectively using specific features and were likely to use multiple features that may be guided by in-game prompts. Further study is needed to assess which features are more valuable for particular populations once the mobile app is finalized and released to the public.

An underestimation of the effects of the mobile app on change in self-reported questionnaires responses may have occurred for several reasons. Users may have experienced glitches and errors in the beta version that impeded their ability to benefit from the mobile app fully. Despite this limitation, it is important to emphasize that a statistically significant change was still observed between the initial and follow-up questionnaire scores.

The CSE questionnaire measures one's confidence in their ability to carry out coping strategies when faced with external stressors and does not have thresholds to differentiate between specific levels of coping [23]. A statistically significant median improvement of 19 points on the CSE questionnaire items suggests that use of the mobile app helped users improve their confidence in the execution of coping strategies. This study also found a strong relationship between improvement in the CSE and GAD-7 scores. These results support the notion that as users improve their confidence in coping skills, they may also improve their ability to handle stressors and anxiety. This is supported by previous research that found coping strategy interventions improved depression and anxiety symptoms [26]. However, the lack of statistical significance between the CSE and PHQ-8 questionnaires conflicted with previous findings and suggested that one's confidence in their coping skills may not significantly impact depression severity among patients. This finding may have occurred because of the low sample size. It is still important to note that significant improvement in the PHQ-8 survey was observed.

Limitations

These study results are subject to several limitations. The retrospective nature of this study prevented investigators from accounting for initiation and discontinuation of mental health services during the 6 weeks of the Sinasprite mobile app use and recruitment of specific populations. The study also did not have a control group for comparison. The in-development status of the Sinasprite mobile app may have limited full user engagement. The fact that the vast majority of the original sample was excluded 92.4% (416/450) because of the lack of verifiable usage 61.1% (275/450) or completion of the postuse survey scores 31.3% (141/450) is concerning and leads to greater potential for bias (eg, nonrandom, self-selection). This, however, is expected as dropout rates among internet-based studies can fluctuate between 50% and 90% [18,40]. Comorbidities were not assessed in this study. Length of previous or current therapy was not collected. The unassisted platform of the survey may have resulted in incorrect input by users. Use of the mobile app was not supplemented by administrative or clinical assistance, which may have resulted in lower engagement [16,41,42]. The significant dropout rate in this study is concerning; however, it is important to note that the mobile app assessed is in a beta phase and is still being optimized to improve the user experience. Once a finalized product is made available via iOS and Android platforms, further study is needed to understand how the mobile app is used and how it may impact larger and more diverse populations without the use of additional health care resources.

Conclusions

This study found that individuals' scores for self-reported coping skills and depression and anxiety symptoms improved without additional investment of health care resources after 6 weeks of using the Sinasprite mobile app. Although encouraging, further study is warranted to evaluate the fully functional Sinasprite mobile app among a larger and more diverse population with mental health conditions, including anxiety and depression.

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Authors' Contributions

ASA's contributions included concept and design of the study, analysis and interpretation of the data, and writing and revision of the manuscript. DRA's contributions included concept of the study, interpretation of the data, and revision of the manuscript. SS's and DC's contributions included concept of the study, interpretation of the data, and revision of the manuscript. MN's contributions included concept and design of the study, interpretation of the data, and revision of the manuscript.

Conflicts of Interest

Ms Swatee Surve is the founder and chief executive officer of Litesprite. There are no other conflicts of interest to report.

Multimedia Appendix 1

Screenshots of the Sinasprite mobile application home screen and two modules.

[PDF File (Adobe PDF File), 269KB - mhealth_v6i3e64_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
CSE: Coping Self-Efficacy Scale
GAD-7: General Anxiety Disorder 7-Item
IQR: interquartile range
PHQ-8: Patient Health Questionnaire 8
PHQ-9: Patient Health Questionnaire 9

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Original Paper

Monitoring Energy Balance in Breast Cancer Survivors Using a Mobile App: Reliability Study

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Abstract

Background: The majority of breast cancer survivors do not meet recommendations in terms of diet and physical activity. To address this problem, we developed a mobile health (mHealth) app for assessing and monitoring healthy lifestyles in breast cancer survivors, called the Energy Balance on Cancer (BENECA) mHealth system. The BENECA mHealth system is a novel and interactive mHealth app, which allows breast cancer survivors to engage themselves in their energy balance monitoring. BENECA was designed to facilitate adherence to healthy lifestyles in an easy and intuitive way.

Objective: The objective of the study was to assess the concurrent validity and test-retest reliability between the BENECA mHealth system and the gold standard assessment methods for diet and physical activity.

Methods: A reliability study was conducted with 20 breast cancer survivors. In the study, tri-axial accelerometers (ActiGraphGT3X+) were used as gold standard for 8 consecutive days, in addition to 2, 24-hour dietary recalls, 4 dietary records, and sociodemographic questionnaires. Two-way random effect intraclass correlation coefficients, a linear regression-analysis, and a Passing-Bablok regression were calculated.

Results: The reliability estimates were very high for all variables (alpha≥.90). The lowest reliability was found in fruit and vegetable intakes (alpha=.94). The reliability between the accelerometer and the dietary assessment instruments against the BENECA system was very high (intraclass correlation coefficient=.90). We found a mean match rate of 93.51% between instruments and a mean phantom rate of 3.35%. The Passing-Bablok regression analysis did not show considerable bias in fat percentage, portions of fruits and vegetables, or minutes of moderate to vigorous physical activity.

Conclusions: The BENECA mHealth app could be a new tool to measure energy balance in breast cancer survivors in a reliable and simple way. Our results support the use of this technology to not only to encourage changes in breast cancer survivors' lifestyles, but also to remotely monitor energy balance.

Trial Registration: ClinicalTrials.gov NCT02817724; https://clinicaltrials.gov/ct2/show/NCT02817724 (Archived by WebCite at http://www.webcitation.org/6xVY1buCc)

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KEYWORDS

telemedicine; breast neoplasms; survivors; life style; exercise; diet; mhealth

Introduction

Although the relationship between diet, physical activity, and health is widely known, excess energy intakes (diet) and sedentary lifestyles are common negative habits in cancer survivors [1]. This energy imbalance may not only be highly associated with the increased risk of incidence of some of the most frequent types of cancer, but they may also be determinants in the appearance of new cancers, the increase of relapses, and even mortality due to cancer [2,3].

International guidelines for cancer survivors include maintaining a healthy weight, limiting the consumption of high-calorie foods, and engaging in physical activity [4,5], together known as energy balance. Unfortunately, only 20% to 32% of cancer survivors adhere to these standards [6,7]. Thus, the development of feasible, reliable, and accurate diet and physical activity assessment methods, as well as the promotion of cost-effective personalized behaviors are necessary to improve adherence to healthy lifestyles.

Currently, the gold standard instruments for measuring physical activity levels and diet in different populations include accelerometry and direct observation, daily records, and 24-hour dietary recall, respectively [8,9]. Despite their widespread use, new evaluation strategies are necessary to ensure that they (1) are less time consuming for patients and researchers; and (2) do not require the presence of a specialist.

Information and communication technologies are emerging as new methods to accurately and remotely evaluate different pathological processes [10-13], including oncology [14]. Literature has reported the use of electronic health (eHealth) tools that collect data on or that promote healthy lifestyles using the internet and Web-based programs [15-20]. Even though some eHealth programs were used in studies with patients with cancer [21-24], none of them quantified energy balance.

Mobile health (mHealth) apps offer many advantages over eHealth systems, including (1) instantaneous and personalized feedback; (2) self-directing data collection; (3) user-friendly interfaces; (4) evaluator bias reductions; and (5) lower costs by reducing face-to-face procedures [25]. To date, several mHealth apps have been developed to promote healthy lifestyles in the general population [26-30], and for some pathologies, such as cardiac rehabilitation [31], weigh loss interventions for endometrial carcinoma [32], and exercise and nutrition counseling for breast cancer survivors [33]. However, no mHealth app has been developed specifically for breast cancer survivors that simultaneously records energy balance (intake and physical activity), and provides immediate energy balance feedback.

The Energy Balance on Cancer (BENECA) mobile app, developed to help breast cancer survivors overcome energy balance challenges, aims to motivate and sensitize breast cancer survivors to adhere to fully personalized physical exercise programs and nutritional plans in compliance with the international guidelines for cancer survivors. Here, we describe the development of the BENECA system, its test-retest reliability, and concurrent validity against the gold standard methods to assess diet and physical activity.

Methods

Overview

A descriptive reliability study was used to test inter- and intrarater responses for a novel mhealth assessment app for energy balance in breast cancer survivors. The app, BENECA mHealth system, was developed by the CUIDATE research group.

Participants, Sample, and Procedures

Breast cancer survivors were enrolled from the Complejo Hospitalario Universitario in Granada, Spain, following their oncologist's suggestion to join the test-retest reliability study between September 2016 and December 2016. Cancer survivors were eligible if (1) they had been diagnosed with breast cancer (estrogen-receptor-positive [ER+]); (2) had a body mass index (BMI) higher than 25 kg/m^2; (3) were between 30 and 75 years old; (4) had basic abilities to use mobile apps; and (5) had completed their cancer treatment (adjuvant therapy) at least 6 months prior. The participants were excluded if they had chronic diseases or orthopedic issues that could interfere with their ability to walk. The project followed the Declaration of Helsinki guidelines and Law 14/2007 on biomedical research [34]. The study was approved by the local ethics committee of the Andalusian Health Service. All participants provided written informed consent.

A total of 20 patients was estimated to be necessary to achieve 90% power, to identify a correlation coefficient of 0.8 between the evaluation methods (gold standard versus the BENECA mHealth app), and to have an alpha error of 5%. Previous studies on the agreement between remote assessment methods had comparable sample sizes [12,14,35]. Taking into account potential study dropouts, 25 patients were invited to participate in this study. A pilot study was carried out with 10 healthy participants to develop, test, and improve the BENECA mHealth system. The data from the pilot study were not included in this study.

The participants attended the Sport and Health Center in Granada. A member of the research team downloaded the BENECA mHealth system app to the patient's mobile phone. The patients were asked to use the mHealth app at least once in the presence of a research team member to ensure the correct use of the system and ask questions if needed. Each participant was also equipped with a tri-axial accelerometer (ActiGraphGT3X+, Pensacola, FL, US). A specialized nutritionist with 3 years of experience with patients with cancer recorded the participant's sociodemographic data and their diet from the previous day using 24-hour dietary recalls. The participants also received 4 daily dietary record questionnaires, which they completed on 4 of the working days. When necessary, a member of the CUIDATE group telephoned participants if they were having difficulties with the BENECA mHealth system.

Gold Standard Methods

Physical Activity

An accelerometer was used to assess the level of physical activity of the participants following a previously published protocol [36]. The patients received a daily questionnaire and were equipped with pre-programmed accelerometers (tri-axial accelerometer, ActiGraphGT3X+, Pensacola, FL, US). They were instructed to wear the accelerometer for 24 hours for 8 consecutive days. Only records obtained from 4 or more days of use (excluding the first day) and at least 10 hours of recording (1 minute intervals) per day were analyzed. The accelerometer data were blinded to the participants.

Dietary Habits

The gold standard method for measuring diet is direct observation. However, in this study, direct observation of the participants' dietary habits was not feasible. Therefore, together with the diet information, 24-hour dietary recalls and dietary records were used as references [9]. With 4dietary records and 2, 24-hour dietary recalls, the intake of 6 days, with 5 eating occasions per day, could be collected.

Twenty Four-Hour Dietary Recalls

The 24-hour dietary recalls were obtained through interviews. The participants did not know in advance when they would be contacted. The specialized nutritionist asked, either in person or by phone [37], about their dietary intakes on the previous day. On the day of the evaluation, an interviewer (trained dietitian) systematically collected detailed information on the diet in the preceding 24 hours. The nutritional value (energy and macronutrients) was evaluated using the Alimentación y Salud software, version 2.0 (Instituto de Nutrición, Universidad de Granada, Spain).

Dietary Records

Due to their validity, dietary records are considered one of the best systems to evaluate dietary intake. These records are a kind of diary in which the patient must log all the food and beverages consumed during a full day [9]. Four dietary records were completed, coinciding with the accelerometer wearing time.

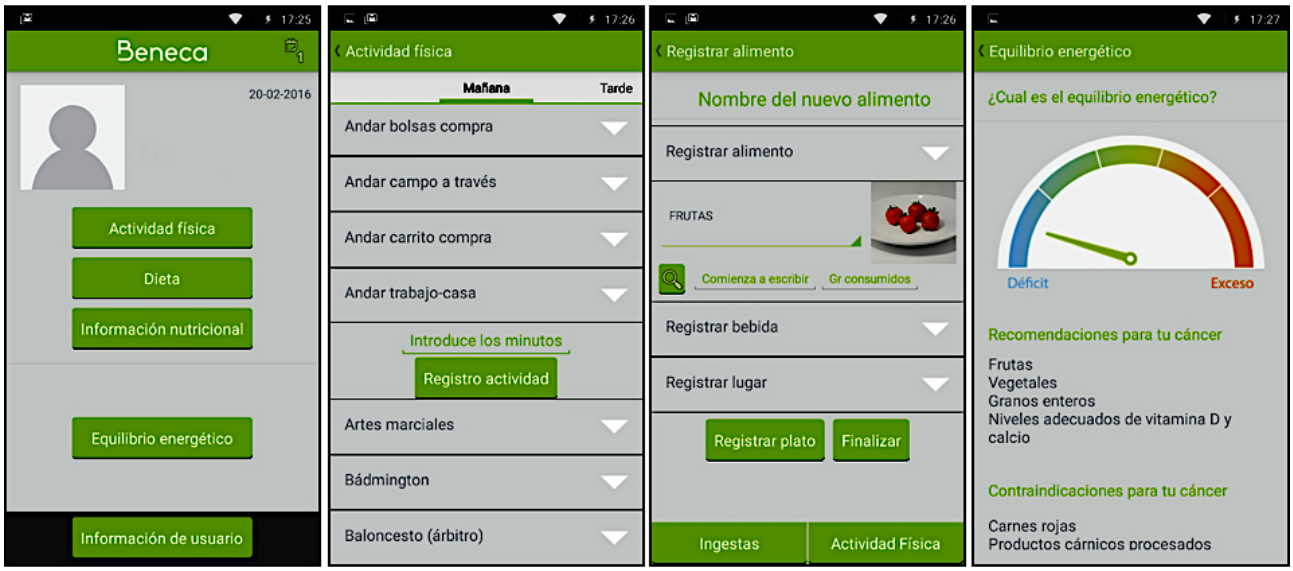
Description of the BENECA Mobile Health System

The BENECA system was developed by the CUIDATE group, which consists of physiotherapists, occupational therapists, physical activity professionals, nutritionists, and a sports physician. BENECA is a native-Android mobile app (Figure 1), with a commercial server and centralized data storage. Its internal technological development has been described previously [38].

On first use, the users of the app record their personal and anthropometric data, such as weight, height, age, and type of cancer. They are then asked to record what they ate (every item) and what they did (in terms of physical activity) the day before. Regarding intake, BENECA uses a dietary record questionnaire, structured with 6 consumption times. On each day, for each period, users report all food and beverages taken. The app limits the food and drink options that can be selected, based on an internal, predefined list adjusted from the Spanish food database (Agencia Española de Seguridad Alimentaria y Nutrición/Base de Datos Española de Composición de Alimentos v1.0; 2010). The users are asked to record the most alike possibility offered if the food or drink is not on the predefined list.

The BENECA mHealth system was created from the validated Spanish version of the Minnesota Leisure-time Physical Activity Questionnaire [39]. The patients can record the activities completed during the day (intensity and duration), from 3 possible time periods (morning, afternoon, and evening). BENECA only records those activities that have a duration of at least 10 minutes. Internally, the app assigns a metabolic equivalent value (MET) to each activity based on the Compendium of Physical Activities [40].

Figure 1. Screenshots of the Energy Balance on Cancer (BENECA) mobile health system.



Once the diet and physical activity are recorded, the users receive a daily straightforward notification about their energy balance, detecting if there has been an imbalance. Moreover, considering their individual profile and the information entered onto the BENECA mHealth app, the users can also obtain physical activity and dietary recommendations based on the guidelines of the World Cancer Research Fund International (WCRF), the strategies for physical activity and diet in patients with cancer from the American College of Sports Medicine [41], and the recommendations of the American Cancer Society [42]. A tutorial video of the BENECA mHealth app can be found in Multimedia Appendix 1.

Statistical Analysis

For each outcome measure—minutes of moderate-to-vigorous physical activity, number of portions of fruits and vegetables, and percentage of fat—the agreement between gold standard assessment methods and the mHealth system was calculated. To evaluate a systematic change in the mean (bias) from test to retest, the mean difference with 95% CI was used. Moreover, we used 2-way random effect intraclass correlation coefficients (with their CIs) to the interrater reliably trials.

The agreement between diet (foods and drinks) recorded by BENECA and those reported in gold standard diet evaluation approaches were estimated based on the analysis reported previously by Hillier et al [10,11]. Match rates (food or drink items reported in gold standard methods that had also been recorded by the BENECA mHealth system), and phantom rates (items reported in gold standard methods that had not been recorded by the BENECA mHealth system), were calculated following the formulas described by Hillier et al [10].

Mean daily values of percentage of fat, portions of fruits and vegetables, and moderate-to-vigorous physical activity reported by BENECA were calculated for a concurrent validity analysis. The accuracy of the mHealth system was calculated using a linear regression analysis, and the correlation coefficient was determined. Finally, a Passing-Bablok regression was used to control bias [10]. IBM SPSS version 20 was used for all analyses (IBM Statistical Program for Social Sciences SPSS Statistic, Corp., Armonk, NY), and XLSTAT was used for Apple computers (2016 version, Addinsoft SARL).

Results

Test-Retest Reliability

The data obtained with each assessment method (gold standard versus BENECA mHealth system), and the mean differences are shown in Table 1. The mean difference of each outcome measure (gold standard versus BENECA mHealth system) and its alpha reliability estimate are also shown in Table 1. The reliability estimates in all analyses were high (alpha≥.90); portions of fruits and vegetables achieved the lowest reliability estimate with an alpha value of .94. The interrater intraclass correlation coefficients for each gold standard method and the BENECA mHealth system showed evidence of very good interrater reliability (intraclass correlation coefficient≥.90) (Table 1).

Concurrent Validity

A total of 21 breast cancer survivor participants were recruited for this study. Of the participants, 1 (1/21, 5%) could not be included in the final sample because the Android version of her phone was not compatible with the BENECA system. Therefore, the final study sample consisted of 20 participants, with a mean age of 47.5 (SD 7.07) years.

The mean BMI of the sample was 26.51 (SD 3.06) kg/m^2. Of the participants, 12 (12/20, 60%) had higher education, of which only 2 (2/20, 10%) had sick leave. The most commonly affected side was the right breast (11/20, 55%), and both breasts were affected in only 10% (2/20) of the survivors. Most of the participants were right-handed (18/20, 90%). Of the participants, 55% (11/20) had stage II breast cancer, and 20% (4/20) had stages I and IIIA.

Table 1. Cronbach alpha reliability estimates and interrater reliability between the gold standard measurement and the Energy Balance on Cancer (BENECA) mHealth system. ICC: intraclass correlation coefficient.

Variable	Mean difference between methods in units of measurement, 95% CI	Cronbach alpha reliability estimate interrater	Interrater reliability ICC	
			ρ[a]	95% CI
Percentage of fat				
Total	0.15 (–1.44 to 1.74)	.956	.916	0.80 to 0.97
Dietary record	1.32 (0.23 to 2.4)	.957	.918	0.81 to 0.97
24-hour dietary recall	0.29 (–0.99 to 1.59)	.985	.971	0.93 to 0.99
Portions of fruits and vegetables				
Total	0.01 (–0.22 to 0.23)	.982	.964	0.91 to 0.99
Dietary record	–0.07 (–0.44 to –0.30)	.948	.901	0.77 to 0.96
24-hour dietary recall	0.26 (–0.11 to 0.63)	.970	.941	0.85 to 0.97
Minutes of moderate-to-vigorous physical activity	8.89 (6.16 to 11.64)	.991	.982	0.95 to 0.99

[a]ICC (ρ) was calculated using a 2-way mixed effect model.

A unilateral mastectomy and a lumpectomy had been performed on 40% (8/20) and 50% (10/20) of the participants, respectively. Only 2 (10%, 2/20) participants underwent a bilateral mastectomy. In addition, 75% (15/20) received postsurgical

adjuvant radio-chemotherapy, and 75% (15/20) were also receiving hormonal therapy (the estrogen receptor antagonist tamoxifen).

Compliance With Methods

Paired data for the comparison between the BENECA mHealth system and the dietary records or accelerometer were collected for all participants. The compliance rates for all assessment methods were very high. All participants completed the BENECA system on the 6 requested days. In addition, 18 participants (90%, 18/20) completed the BENECA system on more days than requested. Similarly, compliance with the gold standard assessment methods was 100%. Breast cancer survivors completed the 4 dietary records and the 2, 24-hour dietary recalls; they also wore the accelerometer for the 8 requested days. Compliance with the accelerometer was very good; there were no incomplete sets of data, and the participants did not report any problems with the device (ie, allergic skin reactions).

The BENECA mHealth system showed excellent agreement with both dietary evaluation approaches (Table 2). The dietary records and 24-hour dietary recalls showed high match rates and low phantom rates. There were 30 intake times and 1630 diet items recorded; only 106 items were not recalled in the BENECA system (omitted or forgotten). “Vegetables” was the most frequently ignored item, followed by biscuits and crisps. Of the total, there were 21 (1.29%, 21/1630) occasions in which the food was not available on the BENECA system. In most of these cases the food items were replaced by an appropriate alternative from the BENECA food option list. However, some food items, such as “couscous,” were not replaced, and the choices were entered as “matches” for replaced items. Fifty nine “phantom” items were recorded in the BENECA system without being recorded in the gold standard dietary assessment methods, with biscuits and sweets being the most common “phantom” items.

No significant differences were found between the BENECA mHealth system and the gold standard assessment methods regarding percentage of fat compared to the 24-hour dietary recall (Table 3).

Table 2. Food item agreement between the Energy Balance on Cancer (BENECA) app and the gold standard dietary instruments.

Day	Match rate	Phantom rate
Dietary record (%)		
1	94.41	5.63
2	88.87	2.53
3	89.04	2.02
4	94.01	19.10
Mean (SD)	91.58 (9.55)	7.32 (14.96)
24-hour dietary recall (%)		
1 (working day)	97.82	1.46
2 (holiday)	98.61	2.69
Mean (SD)	98.21 (2.68)	2.08 (2.88)
Global, mean (SD)	93.51 (6.36)	3.35 (4.33)

Table 3. Agreement between the Energy Balance on Cancer (BENECA) mHealth system and each gold standard assessment method.

Variable	BENECA mHealth System, mean (SD)	Gold standard method, mean (SD)	Difference of means	95% CI
Percentage of fat				
Total	38.46 (8.97)	38.61 (7.59)	–0.15	–1.74 to 1.44
Dietary record	37.44 (5.81)	38.76 (5.69)	–1.32	–2.41 to –0.23
24-hour dietary recall	38.17 (11.50)	38.47 (11.38)	–0.29	–1.59 to 0.99
Portions of fruits and vegetables				
Total	3.66 (1.91)	3.66 (1.71)	–0.01	–0.24 to 0.22
Dietary record	3.09 (1.56)	3.03 (1.96)	0.07	–0.30 to 0.44
24-hour dietary recall	3.89 (2.24)	4.15 (2.10)	–0.26	–0.63 to 0.11
Minutes of moderate-to-vigorous physical activity	85.51 (23.07)	86.91 (22.57)	–1.40	–3.34 to 0.55

Table 4. Passing-Bablok regression variables of the Energy Balance on Cancer (BENECA) mHealth system versus the 24-hour dietary recall, dietary records, and accelerometer.

Variable	Slope	95% CI	Intercept	95% CI
Percentage of fat				
Total	1.22	1.03 to 1.65	–7.85	–24.58 to –1.19
Dietary record	1.05	0.87 to 1.38	–2.84	–15.28 to 4.13
24-hour dietary recall	1.04	0.92 to 1.20	–1.17	–8.19 to 2.94
Portions of fruits and vegetables				
Total	1.11	0.98 to 1.20	–0.27	–0.58 to 0.02
Dietary record	0.84	0.70 to 1.05	0.61	–0.01 to 1.07
24-hour dietary recall	1.05	0.86 to 1.25	–0.19	–1.19 to 0.45
Minutes of moderate-to-vigorous physical activity	0.97	0.87 to 1.07	11.2	1.37 to 16.93

The linear regression analysis revealed coefficients of .93 (95% CI 0.88-1.34), .97 (95% CI 0.86-1.10), and .92 (95% CI 0.74-1.14), with respect to percentage of total fat, 24-hour dietary recalls, and dietary records, respectively. The coefficients for the portions of fruits and vegetables consumed were .97 (95% CI 0.95-1.22) for the total means, .94 (95% CI 0.82-1.19) for the 24-hour dietary recalls, and .93 (95% CI 0.59-0.86) for the dietary records. The model also showed a coefficient of .98 (95% CI 0.91-1.09) for the minutes of moderate-to-vigorous physical activity.

The Passing-Bablok regression analysis did not show considerable bias in percentage of fat (dietary record and 24-hour dietary recall), or portions of fruits and vegetables (Table 4). Only in terms of the percentage of total fat and minutes of moderate-to-vigorous physical activity did the analysis reveal a fixed bias without a substantial proportional bias. However, a substantial proportional bias, but not substantial fixed bias, was revealed when analyzing the percentage of total fat or moderate-to-vigorous physical activity in each assessment method (Table 4).

Discussion

Principal Results

The BENECA mHealth system can be used to assess the energy balance behaviors in breast cancer survivors. It is a straightforward, fast, and consistent assessment system, as shown by the results presented here. Although the BENECA mHealth system has been validated for use in breast cancer survivors, it could be used with other cancer survivors (ie, prostate or colon) because it is based on International Guidelines.

Comparison With Prior Work

The results of this study highlighted the positive agreement between the BENECA mHealth system and daily, 24-hour dietary recalls, as well as accelerometer data (high match rate, low phantom rate). Moreover, intraclass correlation coefficient data suggested satisfactory reliability, with high coefficients for the average of the measurements. To our knowledge, since this is the only strategy that has been developed to assess energy balance in cancer survivors, it is difficult to compare our results to other investigations. Hillier et al (2012) designed SNAPA, a Web-based computer platform that can evaluate the dietary and physical activity conducts in grown-ups. However, our results were not in agreement with this study, which had a match rate of over 75% and a phantom rate below 8.6%. Our results displayed greater a match rate and a lesser phantom rate than other studies, which reported match rates between 51% and 73% [10,11,15], and phantom rates between 20% and 55% [15,43]. One possibility is that these women, who felt neglected after their medical intervention, adhered better to new technologies [44,45]. Nevertheless, the protocols and evaluation were not similar.

Similar to what has been observed with the SNAPA platform, the most commonly forgotten food in the BENECA mHealth system was “healthy” food, such as vegetables or fruits. It could be that fruits and vegetables were often forgotten because of how the dietary questionnaire in BENECA system was designed. The participants had to introduce each food separately making it easy to forget about fruit and vegetable accompaniments. In contract to our observations, there is a collective perception that people tend to record more “healthy” food and tend to forget “unhealthy” food [10]. Moreover, compared with other assessment methods that use communications and information technologies in different populations, the BENECA mHealth system shows equal or higher reliability [12-14].

Strengths and Limitations

One of the advantages of the BENECA mHealth system is making the main gold standard methods to assess diet and physical activity readily available to patients. Moreover, the BENECA mHealth system is simple to install, compatible with commonly-used Android systems (in the future BENECA will be developed for IOS), and ease of access (Google Play Store in the future). Importantly, an internet connection is not required for its use. Despite these advantages, participants found it difficult to introduce the diet data into the BENECA system, where the grams of each individual food had to be entered. Other disadvantages included: (1) a requirement for basic mobile phone capabilities; and (2) it is only available in Spanish. Our

goal is to address these disadvantages and improve future versions of the app.

Given that one of the inclusion criteria to participate in the study was to be able to use mobile apps, the average age of the participants was relatively young. Technology capacity is more common in younger breast cancer survivors, so perhaps these results may not be generalizable to older breast cancer survivors. Future studies should be conducted to clarify this issue, including a population with a higher average age.

Clinical Implications

We believe it would be interesting to combine BENECA with some objective measurement instrument of physical activity, such as an automatic monitoring bracelet, in order to fully automate the recording of physical activity. BENECA is not only useful in clinical research to evaluate the instantaneous energy balance, but it could also be used as a tool to remotely evaluate the time change in this balance after different intervention procedures or surgical procedures. Moreover, BENECA could be used to facilitate the incorporation of physical exercise programs and healthy diet into the care system of cancer survivors. It is possible that the triangulation generated between the methods used in this trial to monitor physical activity and diet (BENECA, accelerometers, professionals) could have an educational and motivational impact on the patient. However, due to the simplicity of the app, not having to combine it with other components could produce even better results by decreasing the time required to monitor physical activity with accelerometers. Moreover, it could promote patients' autonomy from health care professionals, lower sanitary costs, and supply motivational support through its real-time feedback system.

Conclusions

Our preliminary results showed that the mHealth app BENECA may be a new tool to measure physical activity and intake in breast cancer survivors, in a reliable and simple way. Not only will the real-time feedback system used in BENECA enable positive changes in the lifestyles of breast cancer survivors, it can be used to motivate them to maintain these changes over time.

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Conflicts of Interest

None declared

Multimedia Appendix 1

Presentation and tutorial of Energy Balance on Cancer (BENECA) mobile health system.

[MP4 File (MP4 Video), 11MB - mhealth_v6i3e67_app1.mp4]

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Abbreviations

BENECA: Energy Balance on Cancer
BMI: body mass index
eHealth: electronic health
mHealth: mobile health

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Original Paper

Evaluating an mHealth App for Health and Well-Being at Work: Mixed-Method Qualitative Study

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Abstract

Background: To improve workers' health and well-being, workplace interventions have been developed, but utilization and reach are unsatisfactory, and effects are small. In recent years, new approaches such as mobile health (mHealth) apps are being developed, but the evidence base is poor. Research is needed to examine its potential and to assess when, where, and for whom mHealth is efficacious in the occupational setting. To develop interventions for workers that actually will be adopted, insight into user satisfaction and technology acceptance is necessary. For this purpose, various qualitative evaluation methods are available.

Objective: The objectives of this study were to gain insight into (1) the opinions and experiences of employees and experts on drivers and barriers using an mHealth app in the working context and (2) the added value of three different qualitative methods that are available to evaluate mHealth apps in a working context: interviews with employees, focus groups with employees, and a focus group with experts.

Methods: Employees of a high-tech company and experts were asked to use an mHealth app for at least 3 weeks before participating in a qualitative evaluation. Twenty-two employees participated in interviews, 15 employees participated in three focus groups, and 6 experts participated in one focus group. Two researchers independently coded, categorized, and analyzed all quotes yielded from these evaluation methods with a codebook using constructs from user satisfaction and technology acceptance theories.

Results: Interviewing employees yielded 785 quotes, focus groups with employees yielded 266 quotes, and the focus group with experts yielded 132 quotes. Overall, participants muted enthusiasm about the app. Combined results from the three evaluation methods showed drivers and barriers for technology, user characteristics, context, privacy, and autonomy. A comparison between the three qualitative methods showed that issues revealed by experts only slightly overlapped with those expressed by employees. In addition, it was seen that the type of evaluation yielded different results.

Conclusions: Findings from this study provide the following recommendations for organizations that are planning to provide mHealth apps to their workers and for developers of mHealth apps: (1) system performance influences adoption and adherence, (2) relevancy and benefits of the mHealth app should be clear to the user and should address users' characteristics, (3) app should take into account the work context, and (4) employees should be alerted to their right to privacy and use of personal data. Furthermore, a qualitative evaluation of mHealth apps in a work setting might benefit from combining more than one method. Factors to consider when selecting a qualitative research method are the design, development stage, and implementation of the app; the working context in which it is being used; employees' mental models; practicability; resources; and skills required of experts and users.

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KEYWORDS

mHealth; work; qualitative research methods; interview; focus group; technology acceptance; user satisfaction; usability; well-being; prevention

Introduction

Mobile Health Apps for Health and Well-Being at Work

Workers' health is of importance to the individual, as well as to the organization in which a person is employed. As healthy workers perform better, workplace interventions are being developed to improve performance, health, and well-being of workers [1-5]. However, research shows that interventions are often not effective, or overall effects are small [3-13]. This calls for exploring new approaches for health and well-being at work.

Mobile and wireless technology (mobile health, mHealth), defined as wireless devices and sensors, including mobile phones worn by persons during their daily activities, is a growing area in supporting health behavior change [14-20].

Various features make mHealth a good candidate for workplace interventions. For example, mobile technology offers the ability to continuously and unobtrusively monitor user's behavior. Thereby, these technologies can better assess the user's needs and preferences to deliver context-aware, personalized, adaptive, and anticipatory interventions. In addition, it offers the opportunity to bring interventions into situations where people make decisions about their health and encounter barriers to behavior change. It might also offer cheaper and more convenient interventions with a high penetration and a large reach. Finally, it can support a participative role of users, while enhancing their responsibility over their own health and performance [18-23]. On the other hand, problems have been reported as well, such as quickly declining engagement after usage onset of mHealth apps [24].

Evidence Base for Mobile Health

Studies on *Web-based interventions* show that they can have positive effects on health knowledge and behavior (eg, [25,26]). These effects also have been shown for Web-based interventions aimed at workers' health (eg, [27]). However, scientific evidence of *mobile apps* (mHealth) is still limited [28,14].

mHealth apps are being developed and evaluated in a variety of domains such as physical activity (PA) [29-33], obesity [34], and stress management [35]. A lot of these apps have poor or zero evidence base and have not been evaluated with scientific methods [24,36,37]. In recent years, mHealth apps are being developed specifically aimed at risk prevention and healthy behavior in the work setting [38,39], but despite its potential, hardly any research has been published on the content and the effectiveness. Only one study on mobile apps targeting the working population was found, which showed positive effects of a tailored mHealth intervention on PA, snacking behavior, and sleep among airline pilots [40].

Evaluation of mHealth is important, not only to estimate the magnitude of their outcomes but also to ensure they do no harm. Research is not only lacking on health outcomes but also on whether apps actually increase adherence to the behaviors they target and whether apps perform better compared with traditional interventions, either as a stand-alone strategy or integrated within a program [24]. However, technologies can only be effective when they are actually being used by end users. To advance technology design, we therefore need insight into end users' real-life experiences. Hence, evaluation must involve more than effectiveness evaluation. Testing acceptability and satisfaction of end users plays an essential role as well; this is widely recognized as critical to the success of interactive health applications [17,41]. How is the system used by participants? How well does the system fit into daily (working) lives and context? Which aspects of the system do participants find most helpful or frustrating? How do different components of the system work together? What things do participants wish the system could do? What problems do participants face? Why do participants decline to participate? Why do participants (not) remain engaged over time? [17]. To answer such questions, qualitative methods are needed.

To sum up, despite its great promise, evidence is sparse for mHealth in general [15,17,24] and specifically for risk prevention and healthy behavior at work. Insight is needed whether mobile apps are indeed a powerful medium to deliver interventions at work, a context characterized with its own specific barriers. This is a major scientific knowledge gap and might hamper the adoption of mHealth by the working population. Research is needed to examine its potential and to assess when, where, and for whom mHealth is efficacious, specifically for the working context.

Evaluating Mobile Health

To study the potential of mHealth apps, quantitative as well as qualitative studies are needed. However, mHealth interventions challenge the way we conduct research. What types of evaluations are appropriate and useful for mHealth apps?

An important challenge is to ensure that an evaluation method matches with the development cycles of technology, which is characterized by a highly iterative process. For instance, to convincingly demonstrate that mHealth apps are effective in changing behavior, often large-scale, long-term studies with control groups such as randomized controlled trials are used [15,17,42-44]. However, in mHealth research, the time it takes to perform high-quality effectiveness studies is critical because technology may be obsolete before a trial is completed. The rapidly evolving nature of both mHealth apps and their uptake means that some components are continuously improved during a trial, though changes to an intervention during an evaluation pose a threat to internal validity [15,43,44].

In addition, it is a challenge to conduct research in an occupational setting [45]. Common examples of challenges are as follows: (1) the organization wants to target all employees

with an intervention, although workers might have different needs and goals (eg, some workers suffer from sleeping problems and others need to better balance their work-private life balance); (2) organizations provide only few departments to participate in the research (which might question whether the results represent all employees); (3) the outcomes of interventions depend on the context in which they are delivered, which might be different within an organization (eg, employees performing office tasks or working at an assembly line); and (4) organizations prefer research among their employees to have minimal effect on the daily production processes [45]. The occupational context leads to additional constraints concerning the design of an mHealth intervention and additional constraints concerning the choice of methodologies.

The first step when evaluating novel technologies already starts at the earlier stages of development and consists of gaining a deep understanding of how and why a system is used (or not) [17]. Understanding how technology interacts with other important factors that affect behavior change, such as people's attitudes and preferences, their relationships, and the context in which they work and live, is critical for the development and adoption of apps [17,45-49].

The focus of this study was to gain insight in users' real-life experiences of mHealth apps in the working context and the added value of different qualitative methods that might be applied to assess this within this context.

Various qualitative evaluation methods to collect this information are available to apply in one or more stages of an iterative design process [17,46-50]. *Expert-based* methods are commonly used for reasons of practicability, because they are reported to be cheap, fast, and one does not have to recruit users [41,46,47,51]. However, results may not reflect mHealth app use in real practice, as the context in which experts use an app differs from the context of targeted workers. Commonly applied *user-based* methods to gain insight in end users' real life experiences are focus groups, interviews, surveys, and loggings [41,47,50,52,53]. Focus groups give a quick overview of users' opinions, and they give insights into the needs of the target group. Part of its value lies in the unexpected findings that can come from free-flowing discussion in the group [50,52,54]. Focus groups require less time burden for an organization than interviews, another frequently adopted method in mHealth evaluation studies [47]. Interviews can be useful to understanding perceptions, opinions, motivation, context of use, and behavior. Generally, compared with the focus group method, interviews take more time but provide deeper insight [54].

Aim

This study aims to:

- Gain insight in the opinions and experiences of employees and experts on drivers and barriers for using an mHealth app for health and well-being in the working context to develop recommendations for design and implementation
- Gain insight into the added value of different qualitative methods that might be applied within a working context through comparing three different qualitative evaluation methods and assessing whether they yield the same issues evaluating an mHealth app

For this purpose, an mHealth app specifically developed to improve health and well-being of workers at a high-tech company is used as a case study. Three different qualitative methods are used to gain insight in the opinions and experiences of employees and experts on drivers and barriers for using an mHealth app: (1) interviews with end users, (2) focus groups with end users, and (3) focus group with experts. Usability studies have shown that the types of issues revealed by end users' and experts' evaluations and by different evaluation strategies only slightly overlap [41,46,47]. Therefore, it is hypothesized that (1) issues revealed by end users' (employees) and experts' evaluations only slightly overlap and (2) issues revealed by end users' interviews and users' focus groups only slightly overlap. Issues are important topics or points, either neutral, positive, or negative, brought forward by the participants in this study on the use of the mHealth app.

Methods

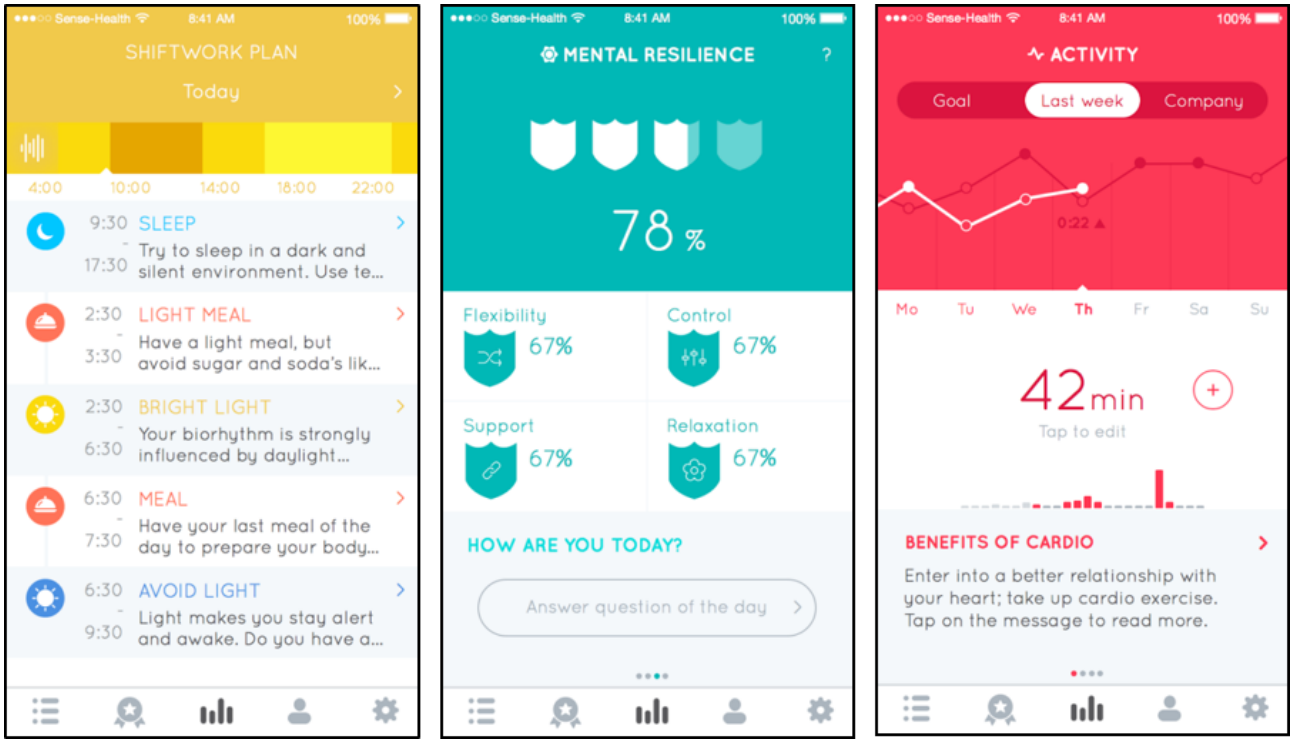
Brightr, a Mobile Health App for Health and Well-Being at Work

For this study, the Brightr app (version 1.0, Sense Health) was evaluated (Figure 1). Brightr is an mHealth app especially developed for workers at a high tech company to improve their health and well-being. Brightr continuously monitors worker's behavior, with modules for mental resilience, sleep, PA, nutrition, and shift work. Brightr aims to provide tailored and personalized feedback at the time and place when it matters the most: it offers the possibility to set personal goals that are monitored by short questionnaires (ie, in the mental resilience module) and incorporated sensor data of the mobile phone (ie, to monitor PA and sleep). The collected raw data is then being transformed into real-time human and environmental behavior measurements. On the basis of intelligent algorithms, Brightr provides tailored feedback and advice. In addition, it is possible to compare individual performance with the organization's average.

Qualitative Evaluation Methods

This study included end user as well as expert evaluation methods. To get insight in users' real-life experiences with Brightr, three qualitative methods were used: interviews with end users, focus groups with end users, and a focus group with experts. These methods were applied as is customary in practice, and group sizes of each method were based on what was found in literature. It was planned to conduct between 20 and 25 interviews. In scientific literature, the guideline for the number of interviews is not clear. Some studies show that for an assessment of needs, 10 to 15 interviews will reveal about 80% of the needs [54]. Other studies advice to conduct interviews until saturation is reached and to stop when additional interviews will not yield new information [54,55]. Researchers advice to conduct between 6 and 200 interviews; most of them lie between 5 and 35 [55]. Therefore, aiming to conduct between 20 and 25 interviews was decided to be sufficient to get good results.

Figure 1. Brightr, examples of the shiftwork, mental resilience, and physical activity modules.



Semistandardized telephone interviews were conducted by two experienced interviewers (researcher EK with a background in human factors and ergonomics and researcher NW with a background in social sciences). They worked with an interview guide that contained a list of topics that should be addressed in every interview. After an introduction to the procedures, engagement questions on personal experiences with health and well-being interventions at work were asked. Second, exploration questions were asked on personal experiences with the use of general health and well-being apps and ideas on what kind of features an ideal app for health and well-being at work should have. Then, the Brightr app was evaluated using questions on general impression (eg, “What appeals to you, what not, and why?”), goal (eg, “Could you tell in your own words what the app aims to achieve?”), target group (eg, “For whom do you think this app was developed?”), potential (eg, “What would this app change for you?”), use (eg, “Do you (still) use the app and why (not)?”), outcome expectations (eg, “To what extent does this app fit your needs as a user?”), and information quality (eg, “What do you think about the amount of information to the users?”). The interview ended with general closing questions (eg, “Is there anything else you would like to say about Brightr?”). Before the start of the interview, participants signed an informed consent form. Interviews lasted up to 60 min. The interviews were transcribed verbatim and audiorecorded to fix incomplete data during transcription.

The aim was to plan focus groups with a recommended size of 6 to 8 participants [54]. Three focus groups were conducted with end users (duration 90 min) at their company and one with experts (duration 120 min, at the research institute of EK and NW) by two experienced focus group facilitators: researchers EK and NW. Both researchers facilitated two focus groups and transcribed verbatim two times during the group discussions. The facilitator used a focus group guide that covered the same topics as the interview guide. Before the start of the focus group, participants signed an informed consent form. The focus group discussions were also audiorecorded to fix incomplete data during transcription.

Participants

Brightr was offered to all employees of a high tech company, and they were able to download the app on a voluntary basis. Before recruitment for the evaluation study started, employees had the opportunity to use the app for at least 3 weeks. Employees were recruited for this study by a message on the company website and by messages on the information screens in the hallways that contained a link to the message on the company website. The message contained information on the aim, the setup, and data privacy of the study. To get insight in reasons for declining to use Brightr, employees were asked to follow a link in case they stopped using Brightr. This link directed to a questionnaire (Survalyzer) with two questions on the reasons for not using Brightr and on conditions or situations under which they would like to use an app such as Brightr. Employees using Brightr who were interested to participate in the study were asked to follow a link to another questionnaire (Survalyzer). It contained questions on gender, age, function group (operations and order fulfillment, sales and customer support, development and engineering, or support staff), hours working per week (flexible contract, 24 hours or less, 24-32 hours, or more than 32 hours), work experience at the company, and email address. This information was used to plan homogenous interview groups and focus groups. The email addresses were used to contact the participants to plan interviews and focus groups. Participants who declined an invitation for a focus group, for example, because the focus group was planned on an unfavorable timeslot for them, were asked to participate in an interview.

The experts were recruited by sending them an email with an invitation to participate in the study along with information about the aim and the setup of the study. They were asked to use the Brightr app for 3 weeks before they participated in a focus group. A total of 15 experts were recruited among the personal networks of two researchers (EK and NW) and consisted of behavioral scientists, psychologists, ergonomists, designers, human-computer interaction researchers, and policy makers. Upon acceptance of the invitation, experts received the Brightr app. To ensure a psychologically safe atmosphere, in which participants felt no barriers to speak freely, developers of the Brightr app (eg, researcher JJ) were excluded from the expert focus group.

Analysis

Qualitative data analysis was aimed to assess and compare issues addressed by end users in interviews and focus groups and by experts in a focus group. Data were collected from March 2015 to July 2015.

A codebook was constructed to analyze all transcripts. The codebook uses constructs from user satisfaction and technology acceptance models to understand and evaluate factors explaining users' perception about information systems to assess actual usage of these systems. Definitions used in the codebook of this study are adapted from the framework of Wixom and Todd [48], Bailey and Pearson [56], and Vosbergen et al [46] and specified further to the mHealth app that was used in this study. The final codebook can be found in Multimedia Appendix 1.

Data were categorized according to the following scheme: domain from the codebook, topic from the codebook, and whether the quote was positive, negative, neutral, or a recommendation, comparable to the analysis performed by Vosbergen et al [46]. In case a quote addressed multiple topics, it was categorized multiple times using different codes.

Two researchers (EK and NW) independently coded transcripts. After each transcript, they resolved discrepancies in discussion meetings up to the point they reached 80% matching codes, which was at the sixth transcript. The remaining transcripts were then evenly divided between researchers. Coded transcripts were included in Excel (Microsoft). Descriptive statistics were used to assess whether the three different qualitative analyses yielded the same issues evaluating Brightr and to gain insight in experiences and opinions that were obtained in general on drivers and barriers using Brightr in the working context.

Results

Nonparticipants

In the recruitment phase, 79 employees who declined to use Brightr filled in the two questions in Survalyzer on reasons for not using Brightr and conditions under which they would consider using an app such as Brightr. This group consisted of employees who never started using Brightr and employees who stopped using Brightr after a short period of time. How many employees never started to use Brightr is not known, nor is it known how long employees used Brightr before they stopped using it. This may have varied between just having a look at the app to using it for about 3 weeks. Figure 2 shows the main reasons of employees for not using Brightr. The most important reasons for not starting or quitting with Brightr were the large battery consumption of the app, not having a mobile phone, and the app had no relevance for the person. A total of 51 employees indicated that they would consider using Brightr under certain conditions. Most important conditions to consider using Brightr were improvements in battery use, clearer relevance for the user, and when the app would function on their mobile phone. A total of 28 employees would not consider using Brightr at all.

Participants

Reminders to participate in the study were sent twice via a pop-up message in the Brightr app to all users. After recruitment, 59 employees agreed to participate in the study. They received an invitation to plan an appointment for an interview or focus group. With 41 employees, an interview or focus group was planned. With 18 employees, it was not possible to plan an appointment because they did not respond to email messages or were absent from work because of sickness or vacation. Due to difficulties to recruit employees for the study, it was not possible to create homogeneous groups for interviews and focus groups.

With 22 employees, interviews were planned. The three focus groups with employees consisted of 4, 5, and 6 participants, respectively. Six more people were planned to participate in a focus group but declined, and 2 of them participated in an interview later on. Employee characteristics are shown in Table 1. Six experts (1 male, 5 female) participated in the focus group for experts. All participants obtained a university MSc and/or PhD in artificial intelligence, computer science, public administration, social sciences, or human movement sciences. They had expertise in the areas of behavior change, machine learning, big data and sensor data analysis, work-related stress, shiftwork, sustainable employability, electronic health or mHealth, mental resilience, PA, and intervention methods. All of the experts used Brightr for 3 weeks.

Issues Yielded With Three Qualitative Methods

Interviewing employees yielded 785 quotes, focus groups with employees yielded 266 quotes, and the focus group with experts yielded 132 quotes (Table 2).

Overview of Similarities and Differences per Domain

Table 3 gives an overview of issues (neutral, positive, or negative) per domain. Interviews with employees yielded the highest percentage of issues within the domain of usefulness (25.5%, 200/785), followed by information quality (23.3%, 183/785). Focus groups with employees yielded also the most issues in the usefulness domain (27.4%, 73/266), which was followed by system quality (21.1%, 56/266). The focus group with experts yielded most issues in the system quality domain (23.5%, 31/132), followed by usefulness (22.7%, 30/132). In general, least issues were yielded on service quality.

Figure 2. Main reasons (number of times mentioned) of 79 employees on why they declined to use Brightr and therefore, did not participate in the study.

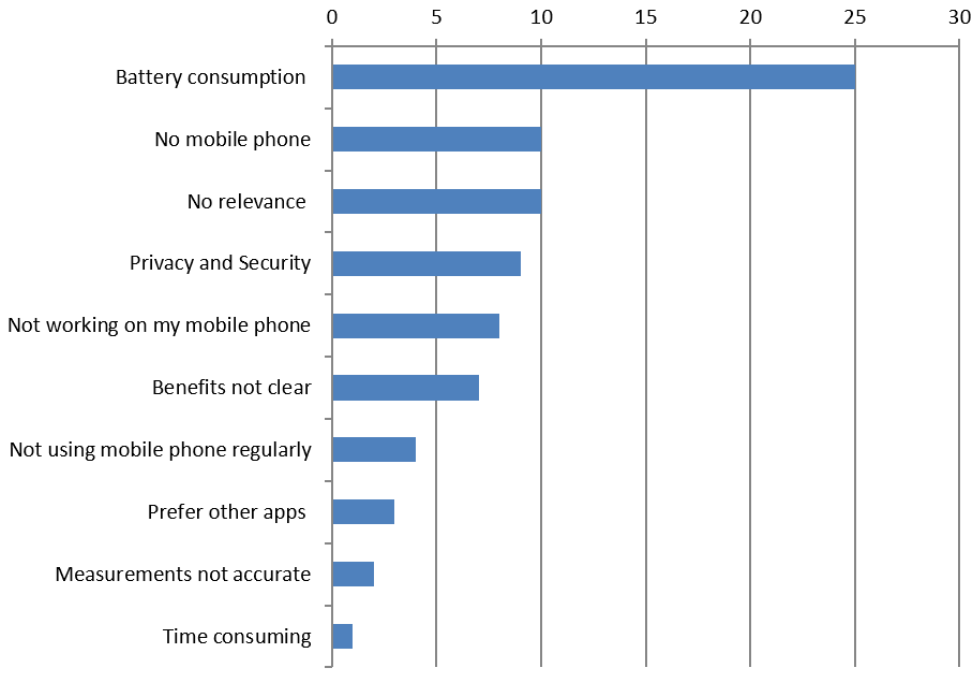


Table 1. Employee characteristics.

Characteristics	Interviews	Focus groups
Number of employees, n	22	15
Years working at company, mean (SD)	6.6 (5.6)	10.4 (6.6)
Age (years), mean (SD)	39.0 (8.7)	45.2 (11.1)
Gender, n		
Male	17	13
Female	5	2
Function, n		
Operations and order fulfillment	7	5
Sales and customer support	1	1
Development and engineering	9	5
Support function	5	4
Working hours, n		
Flexible or 0 hours	0	0
24 hours or less	1	0
24-32 hours	2	3
More than 32 hours	19	12

Table 2. Number of participants in interviews and focus groups and number of quotes that were yielded with three different qualitative methods.

Qualitative method characteristics	Interviews employees, n	Focus groups employees, n	Focus group experts, n
Number of participants	22	15	6
Number of quotes	785	266	132

Table 3. Overview of issues per domain (number and percentage).

Domain	Issues, n (%)		
	Interviews employees	Focus groups employees	Focus group experts
System quality	98 (12.5)	56 (21.1)	31 (23.5)
Information quality	183 (23.3)	47 (17.7)	19 (14.4)
Service quality	8 (1.0)	3 (1.1)	0 (0.0)
Usefulness	200 (25.5)	73 (27.4)	30 (22.7)
Ease of use	48 (6.1)	8 (3.0)	11 (8.3)
Outcome expectations	126 (16.1)	39 (14.7)	17 (12.9)
Organizational factors	121 (15.4)	40 (15.0)	24 (18.2)

Overview of the Value of Issues per Domain

Table 4 shows the number and percentage of positive, negative, or neutral issues and recommendations per domain.

Interviews yielded mostly recommendations within the domain of information quality and organizational factors. This method generated mainly negative issues in the domains of system quality, usefulness, ease of use, and outcome expectations. In contrast to both other methods, employee focus groups yielded mostly neutral issues within two domains: service quality and organizational factors. This method also generated mainly positive issues in the usefulness domain. Employee focus groups only yielded mostly recommendations in the domain of outcome expectations. This method generated mostly negative issues in the domains of system quality, information quality, and ease of use.

Experts gave mostly recommendations within the domains of system quality, outcome expectations, and organizational factors. No issues were yielded within the domain of service quality. In all other domains, experts mainly generated negative issues.

Similarities and Differences per Topic

In Table 5 for each domain the underlying topics that were yielded by the employees (interviews and focus groups) and experts (focus group) are shown. An overview of illustrative examples of quotes is shown in Multimedia Appendix 2.

System Quality

Within the domain of system quality, issues of experts mostly focused on the topic "tailoring" (42%, 13/31), about 3 to 4 times as many as addressed by employees in respective interviews and focus groups (Table 5.). Experts especially stress the importance to tailor the app to the goals of the user and to personalize behavior change techniques, preferably using learning algorithms. Employees typically recommend tailoring the app to age, condition, and functioning type (ie, heavy work or desk work).

Employees mostly focused on the topic "performance of the system" (55/98, 56% and 21/56, 38% of the quotes in interviews and focus groups, respectively), whereas only 7% (2/7) of the quotes of experts were about this topic. Employees' quotes mainly focused on the high battery use; this was often a reason for quitting the use of Brightr. None of the experts made a quote on batteries. The system not working properly was another important issue on system performance for employees; it was either working too slow or having bugs.

In addition, in both focus groups, "time lines" was the second most addressed topic, 21% (12/98) and 23% (7/31) for employees and experts, respectively, almost twice as many as in the interviews (10%, 10/98). Issues on time lines mainly addressed the moments people use the app. An employee from the focus group stated:

> *When I receive a message, I take a look at the app. However, I take a look less often now, mostly in the evening or when I am at the toilet.* [Neutral quote]

Information Quality

For the information quality domain, about one-third of the issues were yielded on the topic "content" of the app; this was similar for all types of methods. Employees mainly addressed the topics they would like to see in the app, for instance, food, sports, or work-rest schedules. An interviewed employee gave the following recommendation (see Multimedia Appendix 2):

> *I would like more information about food, what you should eat. Shift workers have to eat very fast at times (and therefore, the choices are not always healthy). I would like tips about food that is healthy and that you can eat fast.* [Recommendation]

Experts were mainly positive about the different aspects that were addressed by the app and gave recommendations on the content of the feedback:

> *I think of an app that shows the effects of your behavior, for example to show visually "what you have done now leads to this effect."* [Recommendation]

Next to the topic "content," interviews with employees yielded much issues on "format" (45/183, 24.6%; most employees liked the look and feel of the app). For both focus groups, "accuracy" of the app was an important topic (16/47, 34% with employees and 5/19, 26% with experts). Often, people doubted accuracy of the sleep measurements.

Table 4. Number and percentage of positive (+), negative (−), and neutral (0) issues or recommendations (R) within each domain.

Domain and value	Issues within domain, n (%)		
	Interviews employees	Focus groups employees	Focus group experts
System quality			
+[a]	11 (11)	2 (4)	0 (0)
_[b]	51 (52)	31 (55)	5 (16)
0[c]	11 (11)	9 (16)	8 (26)
R[d]	25 (26)	14 (25)	18 (58)
Information quality			
+	43 (23.5)	6 (13)	6 (32)
−	59 (32.2)	24 (51)	10 (53)
0	10 (5.5)	1 (2)	0 (0)
R	71 (38.8)	16 (34)	3 (16)
Service quality			
+	3 (38)	1 (33)	0 (0)
−	2 (25)	0 (0)	0 (0)
0	0 (0)	2 (67)	0 (0)
R	3 (38)	0 (0)	0 (0)
Usefulness			
+	53 (26.5)	29 (40)	6 (20)
−	70 (35.0)	16 (22)	14 (47)
0	39 (19.5)	7 (10)	7 (23)
R	38 (19.0)	21 (29)	3 (10)
Ease of use			
+	20 (42)	0 (0)	0 (0)
−	21 (44)	6 (75)	7 (64)
0	0 (0)	2 (25)	2 (18)
R	7 (15)	0 (0)	2 (18)
Outcome expectations			
+	32 (25.4)	8 (21)	1 (6)
−	55 (43.7)	11 (28)	3 (18)
0	12 (9.5)	6 (15)	5 (29)
R	27 (21.4)	14 (36)	8 (47)
Organizational factors			
+	13 (10.7)	4 (10)	0 (0)
−	27 (22.3)	8 (20)	2 (8)
0	37 (30.6)	15 (38)	3 (13)
R	44 (36.4)	13 (33)	19 (79)

[a]+ symbol signifies positive.

[b]− symbol signifies negative.

[c]0 signifies neutral.

[d]R signifies recommendations.

Table 5. Topics of issues (number and percentage within domain).

Domain and Topic	Issues within domain, n (%)		
	Interviews employees	Focus groups employees	Focus group experts
System quality			
Accessibility	0 (0)	0 (0)	0 (0)
Time lines (responsiveness)	10 (10)	12 (21)	7 (23)
Flexibility	10 (10)	5 (9)	5 (16)
Integration	5 (5)	8 (14)	2 (7)
Efficiency	5 (5)	1 (2)	0 (0)
Tailoring	13 (13)	6 (11)	13 (42)
Language	0 (0)	1 (2)	1 (3)
Errors or error prevention	0 (0)	2 (4)	1 (3)
Performance	55 (56)	21 (38)	2 (7)
Information quality			
Accuracy	34 (18.6)	16 (34)	5 (26)
Precision	5 (2.7)	0 (0)	0 (0)
Reliability	1 (0.5)	4 (9)	1 (5)
Currency	5 (2.7)	2 (4)	0 (0)
Completeness	15 (8.2)	4 (9)	2 (11)
Format	45 (24.6)	4 (9)	3 (16)
Volume	9 (4.9)	1 (2)	2 (11)
Content	69 (37.7)	16 (34)	6 (32)
Visibility of system status	0 (0.0)	0 (0)	0 (0)
Service quality			
Relationship with app provider	2 (25)	0 (0)	0 (0)
Communication with app provider	2 (25)	2 (67)	0 (0)
Technical competence of app provider	1 (13)	0 (0)	0 (0)
Attitude of app provider	0 (0)	0 (0)	0 (0)
Schedule of products or services	2 (25)	0 (0)	0 (0)
Processing of change requests	0 (0)	0 (0)	0 (0)
Response time	0 (0)	0 (0)	0 (0)
Means of input with app provider	1 (13)	1 (33)	0 (0)
Usefulness			
Usefulness	14 (7.0)	18 (25)	4 (13)
Relevancy	110 (55.0)	42 (58)	13 (43)
Adherence	76 (38.0)	13 (18)	13 (43)
Ease of use			
User-friendly	21 (44)	3 (38)	1 (9)
Easy to use	8 (17)	0 (0)	0 (0)
Learnability	18 (38)	5 (63)	10 (91)
Memorability	1 (2)	0 (0)	0 (0)
Outcome expectations			
Expectations	30 (23.8)	5 (13)	0 (0)
Understanding of system	4 (3.2)	0 (0)	0 (0)

Domain and Topic	Issues within domain, n (%)		
	Interviews employees	Focus groups employees	Focus group experts
Confidence in the system	14 (11.1)	5 (13)	1 (6)
Feelings of participation	2 (1.6)	5 (13)	2 (12)
Feelings of control	23 (18.3)	11 (28)	6 (35)
Degree of training	0 (0.0)	0 (0)	1 (6)
Accuracy	12 (9.5)	4 (10)	0 (0)
Health and performance effects	41 (32.5)	9 (23)	7 (41)
Organizational factors			
Management involvement	6 (5.0)	4 (10)	5 (21)
Organizational competition	5 (4.1)	3 (8)	6 (25)
Security of data	39 (32.2)	15 (38)	7 (29)
Documentation	0 (0.0)	4 (10)	3 (13)
Timing	22 (18.2)	6 (15)	0 (0)
Communication	49 (40.5)	8 (20)	3 (13)

Service Quality

Service quality was the least mentioned domain. Experts did not mention this domain and its topics at all. Interviews, as well as focus groups with employees, yielded the topics ‘communication with the app provider and “means of input with app provider.” In addition, in interviews, extra topics were addressed compared with the focus groups with employees: relationship with app provider, technical competence of app provider, and schedule of products and services.

Usefulness

Within the domain of usefulness, “relevancy” was the most addressed topic for each of the evaluation methods: 55.0% (110/200) of the quotes in employee interviews, 58% (42/73) in employee focus groups, and 43% (13/30) in expert focus groups.

All groups mainly focused on the extent to which the app or different aspects of the app helped to solve their problems (eg, sleep, stress, and healthy eating) or whether it addressed interests (eg, sports and food). An illustrative quote from an employee interview is as follows:

> *The best part, for me, is the shiftwork part (I work morning, evening, night shift). Since I try to follow the advices about maintaining a healthy lifestyle and working with shift hours. It helped me to keep down the stress in my body. I felt that I could focus better on the task during the daily (nightly) work.* [Positive quote]

An employee in a focus group stated:

> *The mental resilience part is doing absolutely nothing for me. I often think: for what reason am I doing this? If you are doing well, it has no added value.* [Negative quote]

An example of an expert quote is as follows:

> *Mental resilience also triggered...well, it yielded only frustration, I did not receive any tips.* [Negative quote]

For employees in the focus groups, “usefulness” was the second most addressed topic (25%, 18/73). One of the employees expressed:

> *It triggers to do things better in your behavior. The fact that I saw that I pretty quickly reached my physical activity goals was good, to see that it was not a problem for me.* [Positive quote]

For the other two groups, this was “adherence” (76/200, 38.0% for interviewed employees, 13/30, 43% for experts). Results showed that employees quit using the app mainly because of system failures, extensive battery use, or absence of relevancy, while push messages stimulate the use. Overall, many employees mentioned a decrease in use over time. Experts also mentioned system failures as a reason for attrition and stressed the importance of addressing user motivation.

Ease of Use

Within the domain “ease of use,” employees as well as experts experienced problems with discovering certain content and features of the app. One expert stated:

> *I found out only after a week that there was more than just physical activity. I swiped once accidentally and there they were: all sorts of modules!* [Neutral quote]

Interviewed employees focused mainly on the topic “user friendliness” (21/48, 44% of the issues, concerning positive as well as negative user experiences), followed by “learnability” (38%, 18/48). Results were opposite for both focus groups: the topic “learnability” was most important for employees and experts in focus groups (5/8, 63% and 10/11, 91%, respectively). In contrast with interviews, within both focus groups, the topics “ease of use” and “memorability” were not mentioned at all.

Outcome Expectations

The topic "health and performance effects" was mentioned most often within the domain of outcome expectations; for interviewed employees and experts, it was the number one most addressed topic (41/126, 32.5% and 7/17, 41%, respectively), and for employees in focus groups, it was the second most addressed topic (23%, 9/39). The opinions on health and performance effects of interviewed employees were mixed: some declared that the app actually helped them to behave healthier, some think that an app such as Brightr is able to raise at least awareness, and others have doubts about the ability to change behavior or affect health. One of the interviewed employees stated:

> *There are many different kinds of workers in our company, some need physical activity advice (eg, they lift weights a lot at work), others have to exercise more (eg, sitting at desk to much). An app can help them to become aware. Goal of such an app is to try to get people think whether they are in balance. Do they have sufficient activity? I think it is possible that an app could help to reach goals. Reaching some goals must be possible.* [Positive quote]

Employees in focus groups showed similar opinions. Experts also showed mixed opinions about health and performance effects, but they focused more on different types of intervention functions apps might have, such as raise awareness, provide insight, give instruction, or change behavior and whether Brightr was able to do that (some agreed, some disagreed). For both focus groups, feelings of control appeared to be the second most important topic. Experts mainly stressed the importance of giving control to app users, for instance to set personal goals. They also discussed whether a user is able to decide for himself what he needs from a health perspective. Although employees also mentioned the significance of user autonomy, they were more focused on the possibilities to adjust missing data (eg, when they did not carry their mobile phone with them) or incorrect data (eg, app measuring walking instead of cycling).

Organizational Factors

"Organizational factors" is an important domain to assess issues that influence uptake and implementation of mHealth apps in the working context. For the interviewed employees, "communication" was the most addressed topic within the domain of organizational factors (49/121, 40.5% of issues). It mainly addressed the way the app was implemented within their organization and how this was influenced by the relationship between employer and employee. Often they focused on whether management should play a role in implementation (management setting an example) or not (an organization should keep a certain distance when it comes to such personal data). For focus groups, security of data was most important; it was the second most addressed topic for the interviewed employees. Employees in interviews as well as in focus groups showed mixed opinions on data privacy and security. For some it is an important issue, for others it is not. Some employees mentioned that giving feedback to managers on an aggregated level might provide useful information for management. Experts mostly stressed the importance of being very concise and transparent on what happens to the data. "Management involvement" and "organizational competition" (congruence between assessment and feedback provided by the system and an external health professional or system [eg, coach, other app, and other system]) were least addressed by employees in interviews and focus groups, but gained much more attention by the experts. Experts mainly recommended organizations to embed an app such as Brightr in a bigger health or vitality program:

> *App should be a part of a bigger program, in terms of intervention. It is supportive within an intervention.* [Recommendation]

Discussion

Drivers and Barriers Using Mobile Health in the Working Context

The findings in this study suggest a number of valued characteristics, as well as challenges that organizations might consider for mHealth app and implementation and developers might use for design to enhance user satisfaction and technology acceptance. Overall, participants muted enthusiasm about the app. This is in line with the research of Dennison et al [20] who found similar results in their qualitative study on mobile phone apps supporting health behavior change among young adults. However, Dennison et al [20] found context sensing and social interaction features to be unnecessary and off-putting. This is in contrast with our study in which participants recommended to develop these features in future versions of the app, for example, the interest to compare personal data with organizational means or tailoring the personal advice to the shift work schedules. Apparently, to take context into account is very important for the application of mHealth in the working context but might be less important for other contexts of use. Combining results from the three evaluation methods that we used in our study, results show the following recommendations when designing mHealth apps for health and well-being at work.

Technology

System failures or poor performance (eg, high battery use) does influence adoption and adherence to mHealth apps negatively. Accuracy of measurements largely influences the confidence of users in the app and thereby influences its use. Accuracy (actual as well as perceived) but also the quality of the advice largely influences the possibility to reach behavior change and in line with that health and performance effects. It should therefore be based on solid evidence.

User Characteristics

Relevancy and benefits of the app should be made clear to the (potential) user, within the app itself, as well as in communication guiding the implementation of the app. Furthermore, the app has to address users' characteristics (age, condition, health, function, and [work] activities), motivation, and needs (eg, health [risks] and well-being). A next step in developing apps should aim at using machine learning and learning algorithms to tailor the app to user characteristics automatically. A point of attention is giving users much autonomy, for instance, in ways to use the app, setting and adjusting goals, and when and how to receive feedback. Giving

users autonomy in what they should need from a health point of view should be considered carefully, as users might not be aware of their health behaviors.

Context

It is very important to take into account the work context in which the app is being used. For instance, sometimes it is not possible to use a mobile phone in specific work contexts (eg, clean rooms), which affects the accuracy of the measurements. A suggestion might be to combine mobile phone apps with a wearable sensor that is possible to wear continuously in all (work) contexts. This suggestion is in line with Coursaris and Kim [57] who suggest to design interfaces and apps that fit particular contextual settings, while being flexible to accommodate others: "focus beyond the interface when designing applications" [57]. Furthermore, implementation plays a large role in the adoption and use of an app; this should thus be planned carefully, of which considering how and to what extent the management should be involved is an important factor. Experts suggest to embed such apps within a larger intervention to improve opportunities for success.

Privacy and Autonomy

Results showed that for different end users privacy was either not an issue or an important issue. Van Lieshout et al [58] give some implications for dealing with apps that are offered by employers to their employees: an app offered by the employer always has to be used on a voluntary basis. Employees always should be alerted to their right to privacy and before apps are offered, and employees must be properly informed. In addition, within an organization, it should be very clear what happens to the data. Moreover, users should be given autonomy in deciding what happens to the data; various tools offer guidelines, for instance, Privacy by Design or Privacy Impact assessment [58,59].

Applying Qualitative Methods Within a Working Context

Although studies have used qualitative evaluation methods in testing mobile apps [47,51,60-62] or compared qualitative evaluation methods in other apps, such as testing websites (eg, [46,63-67]), to our knowledge, this study was the first to assess whether different qualitative methods yield the same or different issues when testing an mHealth app for health and well-being at work.

The results of this study showed that issues revealed by experts only slightly overlapped with those expressed by employees. In addition, it was seen that interviews yielded different results compared with those from focus groups. These results are in line with conclusions from other studies comparing different qualitative evaluation methods: different methods identify unique issues, often more than common issues (eg, [47,51,63]).

Our study showed that the *type of evaluators* influences the kinds of issues an evaluation yields. The differences were seen in the attention that was given to the higher level of domains, as well as on the underlying topics that were addressed. For instance, the usefulness domain was given most attention by employees, whereas experts gave most attention to system quality. Moreover, differences were found in the values of remarks: positive, negative, neutral, or a recommendation. Although it was expected that experts would give many recommendations for improvement, they also yielded many negative remarks. Finally, analyzing the remarks itself, it was seen that even similar coded remarks were different in nature.

Employees gave insight into immediate practical experiences. The degree to which the app meets the needs of the employees and addressed their problems or interests is important for starting or continuing the use of the app. Furthermore, they described what motivated them to use the app, what prevented them from using it (such as system failures), and whether privacy of data played a role in using the app. This is in line with the findings of Vosbergen et al [46], but less in line with Lathan et al [67], who examined a Web-based system and found that users were mainly interested in efficient and effective use of the system. Results of this study are also in line with the work of Nielsen and Randall [68] on evaluating organizational-level interventions, who argue that insight into employee experiences is important to match an intervention to identified problems and to match it with the specific individual working context.

In this study, experts were more focused on higher level issues, building on their knowledge of theories and models, and using approaches derived from scientific knowledge and expertise. This is in line with Vosbergen et al [46] and Jaspers [41]. The experts in this study emphasized quality and evidence base of the information and ways to enhance adoption and continuous use by employees: accuracy of measurements, tailoring the app to user needs and providing users with autonomy (within certain boundaries), addressing user motivation, implementation of the app within the organization, and embedding in larger health or vitality programs. When implementing an app such as Brightr, they stressed that the intervention function of an app should be clear: raising awareness, providing insights, giving instructions, or changing behavior, as this influences the design of the app. Finally, they stressed the importance of transparency of data. According to Nielsen and Randall [68], who developed a model for evaluating organizational-level interventions, expert opinions are important as they are focused on the broader context of interventions and the use of theories. They understand the links between work and health and the underlying mechanisms, which is necessary to develop and implement effective interventions such as mHealth apps.

Tan et al [63] conclude that methods using experts or using end users complement each other and that neither method could be replaced by the other. They suggest using experts especially in the early design stages of development as they address user issues on a higher level, whereas user testing should be conducted in later stages as it needs a well-developed test bed. Vosbergen et al [46] concluded that an evaluation cannot be performed without end users, and the results of our study subscribe these conclusions. Vermeeren et al [51] and Adams and Cox [69] describe the importance of recruiting experts with required expertise, preferably with the right domain expertise.

Our study also revealed that the *type of evaluation* influences the kinds of issues an evaluation yields: issues addressed by employees in interviews differed from the issues addressed by

employees in focus groups. This was seen in the attention that was given to certain domains, the values of the remarks within the domains, as well as the topics within each domain. Zapata et al [47] found four different evaluation methods in their systematic review that were used in mHealth evaluations: questionnaires, interviews, logs, and "think out loud" method. Questionnaires were the most applied method, followed by interviews. They did not find studies that used focus groups as an evaluation method for mHealth apps. This study shows that conducting focus groups for evaluating mHealth apps in the working context provides valuable information.

Often, a method is chosen on the basis of practicability [51,69]. Focus groups seem efficient because it gives a quick overview of opinions of multiple users at the same time [54]. Conducting interviews is a time-consuming process but offers the possibility of obtaining detailed and thorough information compared with, for instance, a questionnaire [69]. Some issues are for ethical and privacy reasons better dealt with in interviews, whereas a focus group will allow for easier reflection on common experiences [69]. This study did not confirm the idea that interviews lead to deeper insights or more detailed information as Van Boeijen et al [54] state; in this study, differences were found in the domains and underlying topics that were addressed, and results seemed of similar level of detail. Nor did this study confirm that ethical and privacy issues were better dealt with in interviews compared with focus groups [69]. In both settings, interviews and focus groups, employees in this study felt free to speak. From a practical point of view, our study showed that conducting focus groups is a more efficient qualitative method to evaluate an mHealth app than conducting interviews. Although both evaluation methods address overlapping issues, a focus group might offer more information on common or different experiences, for example, on factors such as (middle) management support, employee support, participation, information, and communication. In interviews, detailed individual experiences might have a more prominent role, such as the individual working conditions and individual factors such as readiness for change, perceptions, and appraisals.

Limitations

Several limitations of our study have to be discussed. Due to difficulties to recruit employees for the study, it was not possible to create homogeneous groups for interviews and focus groups. Results on the analysis of the questionnaire data of nonparticipants showed that our final group of employees probably has been biased. Within our sample of employees, individuals who were more motivated to respond (for instance, because they have strong opinions on the mHealth app) might have been overrepresented, as we used a self-selection protocol during recruitment.

Furthermore, although the total number of participants is larger than in most studies on user experiences, all three evaluator groups differed in size: 22 employees were interviewed, 15 employees participated in three focus groups, and 6 experts participated in one focus group. As a consequence, large differences between the number of remarks yielded by each method were found. To compare between methods, we therefore used percentages.

In addition, the three methods differed in the evaluation technique and the instructions that were given. These variations influenced results and made it difficult to examine the causes of the differences that were found between the three evaluation methods. However, the goal was to compare three different methods in the way they are commonly used in practice, not to compare them in an experimental setting with controlled variations. For this purpose, three methods were compared using one case study with the Brightr app to make a systematic comparison of methods; the study would have to be repeated in more settings.

Moreover, an early version of the Brightr app was used while conducting the study. On one hand, this might have skewed the responses to focus more on system quality and accuracy as compared with an app that has been developed further. On the other hand, this might have provided extra points of feedback that might otherwise not have been compared between qualitative methods.

Finally, a limitation of our study lies within the rating process. For time efficiency reasons, 2 raters independently coded remarks and resolved discrepancies in discussion meetings up to the point they reached 80% matching codes, at the sixth transcript. The remaining transcripts were then evenly divided between researchers. Although this procedure has been followed to reach a certain degree of reliability, no interrater reliability tests have been performed, and raters might have used different interpretations in rating the remaining transcripts.

Conclusions

Findings in this study provide the following recommendations for organizations planning to provide mHealth apps to their workers, as well as for developers of mHealth apps: (1) system performance influences adoption and adherence, (2) relevancy and benefits of the mHealth app should be clear to the user and should address users' characteristics, (3) app should take into account the work context, and (4) employees should be alerted to their right to privacy and use of personal data.

When considering which qualitative method to apply in a work setting, findings in this study showed that the type of evaluators as well as type of evaluation method influences which kinds of issues will be generated. The results revealed that different evaluation methods are complementary and therefore, evaluation processes might advantage from combining more than one method, which is also concluded by others [47,51,62-64]. Factors to consider when selecting methods for a qualitative evaluation of mHealth apps in the occupational setting are as follows: required information on the design and implementation of the mHealth app, the working contexts in which it is being used and participants' mental models on the mHealth app and context; the development stage of the app; practicability; resources; and skills required of experts and/ or users.

However, more scientific insight on these issues is still necessary. Furthermore, which methods work best in what situation and which methods work well together are still questions under research.

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Conflicts of Interest

JJ was working at Sense Health at the time of the study where he worked on the development of the Brightr app. He was responsible for implementing the Brightr app at the high-tech company and providing the app to the experts. Though he helped with the practical setup of the study and writing the manuscript, he did not take part in any focus groups or interviews, nor did he take part in analyzing the data. Brightr product development has been able to benefit from this research by using the feedback to further develop Brightr. Currently, Brightr version 3.6 is being deployed at several organizations.

Multimedia Appendix 1

Codebook.

[PDF File (Adobe PDF File), 472KB - mhealth_v6i3e72_app1.pdf]

Multimedia Appendix 2

Illustrative quotes.

[PDF File (Adobe PDF File), 502KB - mhealth_v6i3e72_app2.pdf]

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Abbreviations

mHealth: mobile health
PA: physical activity

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Original Paper

Crush the Crave: Development and Formative Evaluation of a Smartphone App for Smoking Cessation

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Abstract

Background: Emerging evidence supports the use of smartphone apps for smoking cessation, especially in young adults given their high smoking rates and high smartphone ownership rates. Although evaluative evidence is encouraging for supporting smoking cessation, there remains a paucity of research describing the design and development processes of mobile health (mHealth) interventions.

Objective: The aim of this paper was to describe the process of developing Crush the Crave (CTC), an evidence-informed app to support smoking cessation in young adults, and the results of a formative evaluation of app usage behavior, as part of a broader program of research that seeks to establish the effectiveness of the CTC app.

Methods: The Spiral Technology Action Research (STAR) 5-cycle model (listen, plan, do, act, and study) was employed to guide the development, implementation, and dissemination of CTC. The approach to development and formative evaluation included focus groups with young adult smokers (n=78) across 2 phases, analysis of the content of existing apps, 2 sessions with content experts, and Google Analytics to assess user behavior during a 12-month pilot.

Results: LISTEN—focus groups revealed young adult smoker preferences of (1) positive reinforcement, (2) personalization, (3) social support, (4) quit support, (5) tracking the behavior, and (6) tracking quit benefits. PLAN—informed by evidence for smoking cessation, young adult preferences and an assessment of popular cessation apps, content experts produced a mind map and a storyboard describing app content and structure. DO—focus groups with young adult smokers provided feedback on the first version of the app with opinions on content and suggestions for improvement such as providing alerts and distractions from craving. ACT—refinements were made, and app content was organized using the 4 key design components informed by principles of persuasive technology for behavior change: credibility, task support, dialogue support, and social support. CTC was launched in April 2013 and piloted from the period July 2013 to June 2014 where 1987 Android users had 18,567 sessions, resulting in 59,384 page views and 89.58% (1780/1987) of users returning within the same day to use CTC. STUDY—a pragmatic randomized controlled trial of CTC was launched in August 2014 to demonstrate that including mHealth technology as a population-based intervention can help young adult smokers to quit. The results of this phase will be presented in a subsequent publication.

Conclusions: CTC is one of the first smoking cessation apps designed to meet the needs of young adult smokers. The development was informed by the inclusion of young adults in the design and the systematic application of multiple stakeholder input, scientific evidence, and theory. The STAR model approach was followed from the beginning of intervention development, which should facilitate optimization of mHealth interventions in the future.

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

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KEYWORDS

mobile app; smoking cessation; young adult; software design; formative feedback

Introduction

There is a need to develop innovative smoking cessation interventions directed toward young adults aged 18 to 34 years because this age demographic maintains higher smoking prevalence rates compared with their older adult counterparts [1,2], and few smoking cessation interventions are tailored to this population [3]. One promising direction is the use of smartphone technology for enhancing smoking cessation interventions directed toward this population [4]. Smartphone ownership among both US and Canadian young adults aged 18 to 34 years is nearly ubiquitous at 92% and 94%, respectively [5].

Background

The use of smartphone apps has become particularly popular among young adults, with evidence indicating that they are the most likely age demographic to download apps and are the most intense users of apps [6]. Smartphone apps are available at any point in time and can host complex functions, including audio and video, bidirectional communication, as well as the retrieval of additional content when there is Internet connection [6]. The features enabled by smartphones are a clear advancement over websites and SMS text messaging (short message service, SMS) cessation programs because of their high potential to boost user engagement [7], which has been consistently documented as a strong predictor of smoking cessation [8-11]. Recently, researchers have also found that young adults prefer more intense smoking cessation programming than what is currently offered via SMS text messaging-based smoking cessation interventions [12,13].

While there are dozens of smoking cessation smartphone apps, only a small minority of apps for smoking cessation adhere to the US Clinical Practice Guidelines (USCPG), which serves as the current standard in smoking cessation interventions [14,15]. Even when apps do follow the USCPG, it has been suggested that this is likely not enough to promote cessation. Several meta-analyses of websites and SMS text messaging interventions that follow the USCPG reported that their average intent-to-treat, 30-day point prevalence quit rates at 12 months post randomization were remarkably similar, ranging from 7% to 10% [11,16-18]. It has been suggested, therefore, that apps that go beyond the USCPG and incorporate behavior change theories into their content hold even greater promise to produce higher quit rates [7,19].

Literature Review

A recent systematic review assessed which smoking cessation apps available in the app stores are informed by evidence in their design [20]. The authors found that, of the 6 evidence-informed apps identified, only 3 were still running, and only 2 were ranked among the top 50 popular apps for smoking cessation [20]. Not only is there a lack of evidence-informed apps available, there is a lack of apps that specifically target young adults. Therefore, to capitalize on the potential of smartphone technology for young adult smoking cessation, as well as to help close the gap between existing smartphone apps and what works to help young adults quit smoking, we developed and piloted Crush the Crave (CTC).

CTC is a quit smoking app that specifically targets young adults, made available for Android and iOS devices in both English and French. The features and functions incorporated into the app were informed by principles of persuasive technology for behavior change [21], as well as evidence on what works to help individuals quit smoking according to the USCPG [22]. The model of principles of persuasive technology for behavior change contains 28 persuasive system design techniques that fall under 4 categories: task support, dialogue support, social support, and credibility support [23]. Task support aims to persuade the user to complete a task by supporting their efforts, such as offering craving distractions. Dialogue support provides feedback to encourage the user toward the intended behavior, such as providing rewards. Social support aims to strengthen the persuasiveness of a software system by leveraging human interactions, such as connecting with others about the desired behavior change. Finally, credibility support includes principles on designing a system that is more credible, and therefore, more persuasive.

Informed by this model, CTC offers features that include a customized quit plan, the tracking of cravings and smoking habits, notifications of money saved and health improvements achieved, direct dial-up to telephone-based support, virtual awards that credit performance toward reaching milestones, evidence-informed credible information (eg, nicotine replacement therapy), and the ability to connect with a community of people for social support via social media (eg, Facebook). Recently, Ubhi and colleagues [24] conducted a review of 137 smoking cessation apps for the presence or absence of evidence-informed behavior change techniques, and CTC addressed 4 out of 5 behavior change strategies as compared with an average of only 1 across the 137 apps reviewed. They also assessed CTC as having an ease of use score of 95%, which was the same as the average of all apps reviewed, and 82% for user engagement compared with only 45% overall.

Objective

Emerging evidence supports the use of smartphone apps for smoking cessation [7,25-27]. However, there remains a paucity of research describing the design and development processes of mobile health (mHealth) interventions, leaving unanswered questions about how to productively leverage apps for quitting smoking [28]. To address this gap, this paper describes the process of developing the CTC app for smoking cessation and the results of a formative evaluation of app usage behavior, as part of a broader program of research that seeks to establish the effectiveness of the CTC app.

Methods

Overview

CTC was developed in 2012, to which the Spiral Technology Action Research (STAR) model [29] was employed to guide development, implementation, and dissemination. The STAR model includes the following 5 iterative cycles: listen (engage with end users to identify their needs and preferences), plan (develop a plan to address needs of end users), do (implement prototype and review with end users), act (launch intervention), and study (conduct ongoing evaluation) [29]. The STAR model provides a comprehensive yet practical guide for the development and evaluation of eHealth health promotion interventions.

Phase I: Listen

To develop the content of CTC, we engaged with young adult smokers using a focus group methodology [30] to listen and collect information on end-user needs and preferences. Four focus groups were conducted in Waterloo, Ontario, and the sessions were guided by an interview schedule. Twenty-one participants were recruited by telephone via a panel of young adult smokers and were given an information letter and provided informed consent. Participants comprised 12 males and 9 females, and 9 with high school education or less, 9 with college diplomas, and 3 with university degrees. The age range was from 19 to 29 years. Fourteen participants smoked 10 or more cigarettes per day, 6 smoked less than 10 cigarettes per day, and the last one did not report the number of daily cigarettes smoked. Focus groups were split by gender. The focus group discussion began with questions around previous quit attempts and what helped them to make a quit attempt. Questions on usage of smartphone apps for quitting smoking and preferred features in an app were asked. Finally, participants were asked to describe their thoughts and feelings concerning a smartphone app concept that was displayed to them on a screen. Questions included what was liked and disliked about the app, followed by a question on whether participants thought that a smartphone app for quitting smoking would work. Focus groups lasted 1 hour, and 2 researchers participated in each group. One researcher facilitated the session, and the other assisted and took notes. The focus groups were audio-recorded and transcribed verbatim. Two independent researchers (LS and DD) analyzed the transcripts using an inductive framework approach to thematic analysis [31]. Codes were attached to text segments that appeared to indicate important material in relation to app content, and analysis progressed in an iterative fashion between the researchers to develop a set of themes that captured the essence of the focus group discussions. To validate coding, the second (LS) and third author (DD) independently coded the first focus group responses and then compared for consistency. Any discrepancies in coding were discussed and resolved with the first author (NB). In this way, each author could critically challenge one another on differing perspectives and any potential biases.

A thematic framework was developed by generating major themes and subthemes in relation to the focus group questions and categorizing the associated responses iteratively. To maintain the context of focus group participant responses, they were listed under the questions from which they were derived and then categorized separately as a type of response. Throughout the coding process, regular meetings were held between the 3 authors to discuss and refine the thematic framework. Indexing was accomplished by coding each response in NVivo version 10 qualitative software (QSR International Pty Ltd, Burlington, MA, USA) with reliability checked by the second and third author through review of the NVivo file. Codes were considered saturated if more than 6 individuals supported the code, which is an appropriate number in qualitative data analysis [32]. At the final stage, the original responses were grouped according to the finalized themes and subthemes. Representative quotes were selected from the focus group responses to illustrate key themes and subthemes.

Phase II: Plan

To address the needs identified in phase I, a plan was developed for the creation of the mobile phone app. First, a review of the most popular smoking cessation apps available on Google Play and the Apple Store was undertaken. Apps were assessed by their overall user ranking and number of downloads. The most popular and frequently downloaded cessation apps were then coded (Y or N) for feature content such as calculating days smoke-free, money saved, social support, health information tips and facts, quit planning, tracking performance and success, rewards, connection to quitline, and cost to purchase. Second, 2 sessions with experts were undertaken.

The first session was a mental mind mapping exercise that brought together a 5-person team of smoking cessation, behavior change, social media, and app development experts to design the content and the functions of CTC. This session lasted for 3 hours and was led by the team lead (NB). The session involved brainstorming with the objective of forming a shared understanding of the major facets that will be included in the app content to meet the needs of end users [33,34]. Experts were provided with the results of the review of mobile phone cessation apps by Abroms and colleagues [15], the findings from the assessment of the most popular and frequently downloaded cessation apps, and the summarized results of the focus groups with young adult smokers from phase I before engaging in the mind mapping exercise. The mind mapping exercise continued to evolve during the session until participants no longer had ideas to contribute and consensus was reached on the proposed content.

With the initial shared understanding of app content completed, the second session involved the design of the specific content and functionality of the app, which included 3 smoking cessation experts and 2 programmers. This session was facilitated by the team lead (NB) and employed a storyboarding design technique to carefully diagram the app content, user interface, and needed functionality [35].

Phase III: Do

CTC was developed as a mobile hybrid and native app for the Android platform using the Web Informatics Development Environment technologies and toolkit [36]. Development of the app was done iteratively with the programming and research

team and took 5 months. To seek feedback on the proposed features in the app from end users, 8 focus groups were conducted in Ottawa, Ontario, in a similar manner to phase I. Four focus groups were conducted in English and 4 in French. All focus groups included a mix of male and female participants. Fifty-seven participants were recruited by telephone via a panel of young adult smokers and were given an information letter and provided informed consent. Participants comprised 31 males and 26 females, and 20 with high school education or less, 16 with college diplomas or trade certificates, and 21 with university degrees. The age range was from 19 to 29 years. Thirty-one participants smoked 10 or more cigarettes per day and the remaining 25 smoked less than 10 per day, and one participant did not respond.

The sessions were guided by an interview schedule and focused on pilot testing of CTC. Each participant was given an Android smartphone with the app to try. Questions included asking what was liked and disliked about the app features and functionality, followed by questions on whether participants thought there was anything missing from the app. Focus groups lasted for 1 to 2 hours, and 2 researchers participated in each group. One researcher facilitated the session, and the other assisted and took notes. The thematic analysis of the focus group transcripts was conducted in the same manner as phase I.

Phase IV: Act

This phase marked the launch of the CTC intervention, which was made available on Google Play Store and Apple iOS as of April 2013. The app's final content and functions were modified according to the analysis of the feedback from focus groups in phase III. Phase IV provided the opportunity to track user behavior as a formative evaluation method over 1 year from July 2013 to June 2014. To assess app usage behavior, Google Analytics was implemented for Android users during the development of CTC. Usage statistics including number of users, age and gender of users, sessions, page views, average session duration, returning visitors, bounce rate (number of users who have left the app after only viewing the home page), and entrances and exits were monitored. For example, sessions refer to periods of time when users are actively engaged with the app, page views refer to the number of app pages that users look at, entrances are the number of times a user entered the app through a specific page, and bounce rate refers to the percentage of single-page visits. The data were quantitatively summarized to describe overall app usage. The usage data answered 2 key questions in terms of the formative evaluation: (1) how do users behave and interact with CTC? and (2) what content are users exposed to?

Phase V: Study

This phase represents the outcome evaluation of an intervention. A rigorous evaluation of CTC was undertaken with the primary aim of determining its effectiveness for smoking cessation [23] (ClinicalTrials.gov NCT01983150). A parallel randomized controlled trial (RCT) with 2 arms was conducted in Canada with participants randomized to receive the CTC app (treatment) or an evidence-informed, self-help guide known as *On the Road to Quitting* (control) for a period of 6 months. The results of this phase will be presented in a subsequent publication.

Results

Phase I: Listen

Through the display of one of the most popular smoking cessation apps at the time (LiveStrong) and asking questions about cessation apps in general, young adults' preferences regarding the content and features that they would like to see included in a smartphone app for smoking cessation were elicited. The focus group data resulted in 6 key themes: (1) positive reinforcement, (2) personalization, (3) social support, (4) quit support, (5) tracking the behavior, and (6) tracking quit benefits. Table 1 presents the major themes and associated subthemes, with representative quotes.

Phase II: Plan

The 25 most popular rated (ranked 4.0 and higher out of 5) and downloaded apps (5000+ downloads) from Google Play and the Apple App Store as of January 2012 were assessed in terms of features. Fourteen of the apps included a calculation of days smoke-free, 13 provided money saved, 8 included social support or networking capability, 13 included health information tips and facts, 10 included a quit planning feature, 12 provided the ability to track performance and success, only 3 featured rewards for accomplishing goals, only 1 included the option to connect to a quitline, and 14 were free and of no cost to the user. Interestingly, 5 of the most popular apps promoted hypnosis as an approach to quitting smoking, an approach to quitting that is not empirically supported. Informed by the results of phase I and the cessation app feature assessment, mind mapping and storyboarding sessions were held with experts in smoking cessation and app programming. First, a mind map was generated that represented the ideas of experts for an evidence-informed cessation app. Second, the ideas were translated into app components and functionality using storyboards. Figure 1 is an example of a story board for CTC.

Phase III: Do

Using a storyboarding technique with a group of experts and input from phase I focus groups, a prototype was developed on a whiteboard. Following this exercise, a digital prototype was developed and tested using smartphones with young adult smokers. Feedback was solicited from young adults regarding content and features, functionality, and whether anything was missing in the app that they would like to see. This stage also focused on usability of the app and user experience with the components to determine whether the app was perceived as helpful, motivating, and visually appealing. Findings from these focus groups were organized according to the app features and subfeatures, and then categorized as 2 types of user feedback: (1) user opinion and (2) suggested improvements. Table 2 presents representative quotes highlighting the major feedback from young adult app users.

Table 1. Phase I: Listen—User preferences for features and content in a smoking cessation smartphone app.

Theme and subtheme	Representative quote
Encouragement	
Supportive messaging	"So have positive feedback and stuff like that. Just positive feedback, not negative."
Receiving awards	"...if you're like a week without smoking or something, it comes up and tells you [that] you've done a week without smoking, good job..."
Personalization	
Comprehensive profile setup	"Yes, I like that it has all the questions...It knows how old you are, it know how much you smoke, it knows what you want to keep track of, what you don't, it knows how much money you're spending on cigarettes on a daily basis. I like that."
Adding a personal touch	"Like [upload] a photo of your kid if you're trying to quit for your kid."
Social support	
Social networking	"I like that idea...I'm not one to have everything on Facebook, but if it was something that I was proud of myself for, which would be quitting smoking, yeah, I'd like everyone to...acknowledge that."
Networking with other app users	"...maybe within the app have a network of everyone who is using the app and then that way anyone that you're reaching out to is going to know exactly what you're going through..."
Quit buddy	"I think that's good to have someone there that knows what's going on."
Quit support	
Craving distractions	"I'd say, let's say you get a craving right? You go into your phone and you whip out the app and you push a button and it gives you like a quick tip...like have a mint, have a sip of water something like that."
Immediate, live support	"I think that quick support thing is a good idea because if you're talking with someone about your craving you're probably not going to be having a cigarette while doing it."
Flexible quit approach	"The more options you can give the person who's trying to quit, the better, whether they want to quit by themselves or quit today or quit 2 weeks from now or even a year from now. They should have that choice."
Tracking the behavior	
Identifying triggers	"I would use it to track...my cigarettes when I'm wanting to quit. Because I was looking for an efficient way to do that and I was actually carrying around a little pocket book for a while just so I could see. Because that's where you have to start. That's where I had to start anyway. So I definitely would use it in the planning stages to say like okay, I'm smoking now with who, what time and why."
Smoking frequency	"I don't keep track of how many I smoke. I just assume, so if I was to keep track I'd probably be shocked. Yeah, this would be really helpful."
Tracking quit benefits	
Money saved	"Just because [money is] the most pressing on a day-to-day [basis]...You can see [money] coming out of your bank account on a daily basis...so it's very easy to keep track of how much you would be saving...it's an immediate thing."
Health benefit	"Yeah, the whole after 10 minutes of not smoking, you're back to whatever [health], after 10 days of not smoking, back to this. Have a little timeline of what you're doing so you can actually see the benefits of not smoking."

Figure 1. Phase II—example of storyboarding session results.

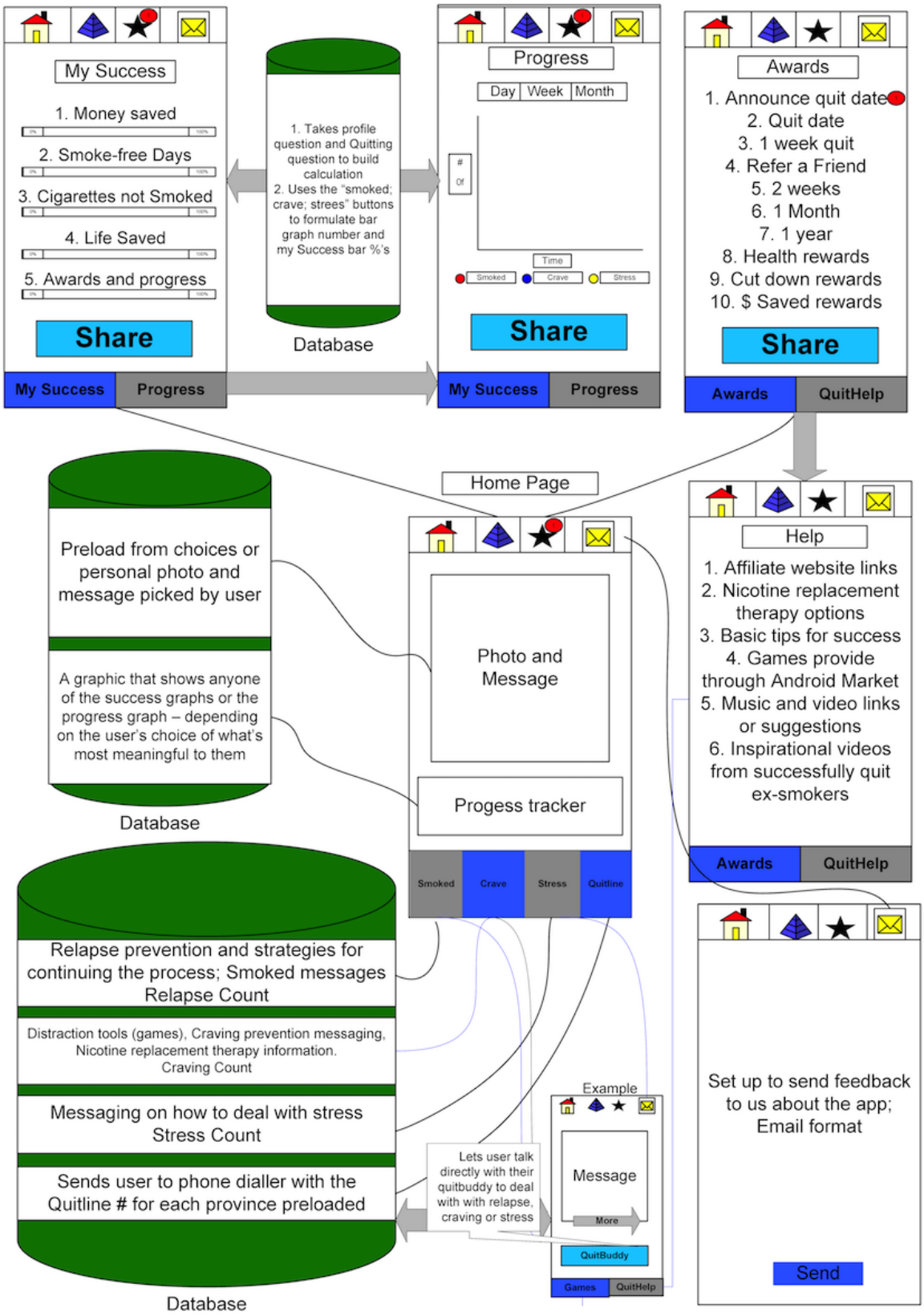
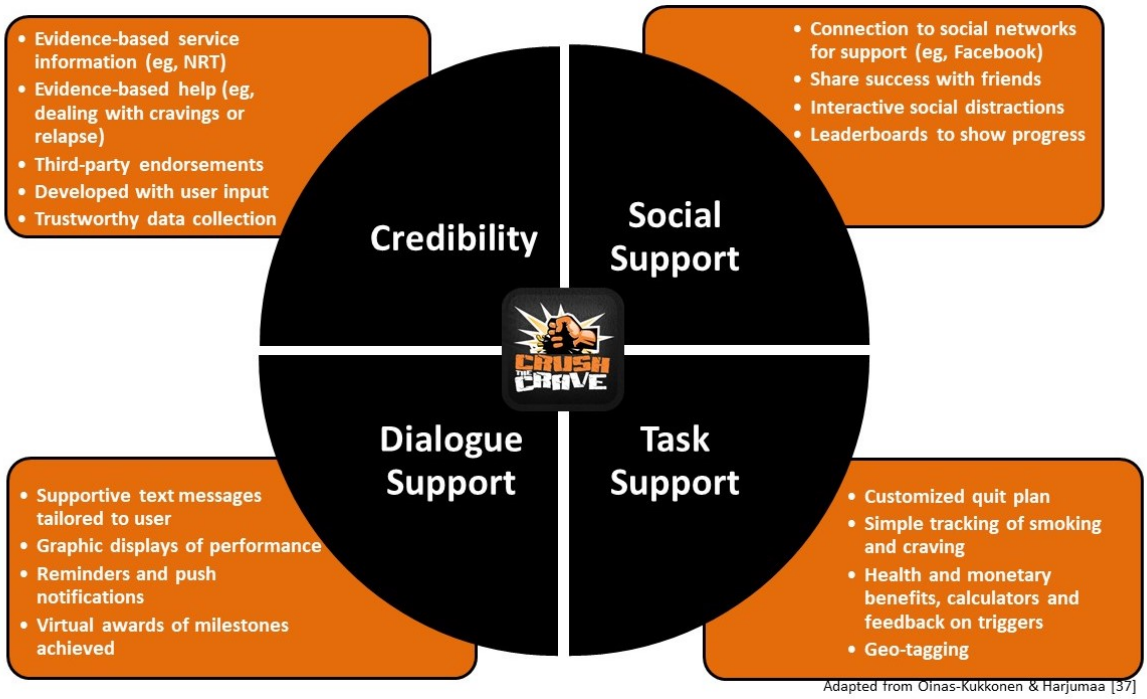


Table 2. Phase III: Do—Thoughts and opinions from Crush the Crave (CTC) pilot test focus groups.

Feature and feedback type	Representative quote
Awards	
User opinion	"[It's] fun and interactive. It's almost like an old-school video game where it's like, 'You've unlocked this!'"
	"I find it's good because after so many days it takes time and it shows you. You see the savings of $1,000...and you see how much value there is and how much money you've saved."
Suggested improvements	"Money is nice, and then you also show material things based on personal likes. You could have bought PlayStation 3. You saved enough to buy a PlayStation 3. If you didn't smoke all these days, you could have bought that. Show them a picture of it, too. Again, people are visual. If you allow them to see, good."
	"So for people that are quitting for financial reasons it might be nice to be able to set up an alert at the end of the day saying "Way to go. You just saved ten bucks" so that I don't have to maybe look at it. That little extra high five."
Social supports through Facebook	
User opinion	"I know a lot of people who have quit and they always post on Facebook about it, and then they get their friends to support them. They're like, oh me too, and they have conversations about it and talk over."
	"Facebook...It's like, 'Oh, first day of quitting. This sucks.' And people are just like, 'Oh, you'll get through it, man.' Just having your friends to support you while you're doing that I think is helpful if you want that kind of connection."
Suggested improvements	"If it's more of an anonymous forum where you can just kind of say, 'I'm really stressed out and smoking,' as opposed to calling somebody up and talking to them, I might be inclined to use a forum...whereas Facebook, the quitter's line or the call buddy, realistically, I'm never going to use that, so this would be an outlet perhaps that I might."
Progress page to track smoking behavior and quit benefits	
User opinion	"It gives you a better idea of when you're smoking most often and then you can figure out if you're in those places hopefully not to smoke."
	"I find it's good. A lot of people don't understand why they smoke and in what situations and in the other screen it tells you, how do you feel and perhaps you don't need to hang out with friends."
	"It gives a reminder, always in your face, so it really makes you realize, especially the saving money part. You could go out and buy a pack of smokes and then think nothing of it, but if it's counting up how much money you're spending, it's like really eye opening."
Suggested improvements	"...so now that I know my triggers are...and then what? If it continues to happen, what do I do? Just looking at it a couple of times a day is the same thing. A line graph would be a lot easier to read when you're seeing your spikes. A bar graph...just shows volume...it's like well, when during the day did you have 10 smokes? Did you have 10 smokes in 15 minutes, did you have 10 smokes in 15 hours?"
Quit help	
User opinion	"It goes directly to the games, I like that on my telephone. I can go on Facebook or Twitter [directly]. When I'm on Facebook or Twitter you think about something else. I think it's a super good idea."
	"I also really liked how much information there was. The fact that it was in point form, it's easy to read. It wasn't long paragraphs, it was just the key points, and then if you wanted to learn more, you could go out on your own and look it up. I thought that was a good idea, because I wouldn't read it if I saw a huge paragraph."
Suggested improvements	"[Suggest] distractions in my area kind of thing, stuff to do, whether it be like go to the mall or the nature museum...Something other than I'm going to sit here with my phone and bugger around with my phone all day. Go get added distraction[s] from outside and stuff."
	"To have almost like a glossary page with all the different information and everything right there at my fingertips I think I'd be more likely to use that. Just in regards to the app itself it's kind of the 1 page that is really jammed with stuff. Every other page is really, really simple."
	"It's not that it was too much; it was that it was, like it comes at you like a jumble. You can organize or index it somehow."

Figure 2. Evidence-informed design components of Crush the Crave (CTC).



Phase IV: Act

Building on the findings from phase III, refinements were made to CTC. For example, the quit help information was beneficial but the organization was confusing. This was modified, and the information was rearranged in the future iteration of the app. Refinements also included the addition of a line graph to track progress rather than a bar graph. Furthermore, customization throughout the app was requested as a valuable and personal touch to CTC. For instance, enhancing personalization beyond a photo with the option to input affirmations or personal reasons for quitting and having user-specific smoking trigger situations in a database was indicated as helpful. Figure 2 details the ways in which the app content was organized using the persuasive technology framework by Oinas-Kukkonen and Harjumaa [37], which includes 4 key design components: credibility, task support, dialogue support, and social support. Figure 3 provides example screenshots of CTC. The app was launched on Google Play and iTunes on April 10, 2013.

In the 12 months from July 2013 to June 2014, there were 1987 Android users of CTC and 18,567 sessions, resulting in 59,384 page views or 3.2 pages per session. Users (n=1987) were 45.99% (914/1987) female and 60.99% (1212/1987) were between 18 and 34 years, 28.98% (576/1987) were 35 to 54 years, and 9.96% (198/1987) were older than 55 years. For sessions, 89.58% (1780/1987) were returning users, and 10.42% (207/1987) were new users (someone who had not previously registered with CTC). Overall session duration was 2:22 min on average. New users visited 6.4 pages per session with an average total visiting time of 4:23 min, whereas returning users visited 2.8 pages per session with an average total visiting time of 2:07 min per session.

User Behavior

The overall bounce rate was 58.6% (see Table 3) and ranged from 8.9% to 66.7% depending on the topic. For example, the bounce rate for the CTC home page indicates that 55.02% of users exited CTC from that page. In terms of user engagement, 59.39% (1180/1987) had between 9 and 200+ sessions with CTC. In addition, user engagement was strong with 89.58% (1780/1987) of users returning within the same day to use CTC. However, the majority, 70.99%, of these sessions had a duration or time on page of less than 10 seconds and 58.99% of these sessions involved only 1 page view, indicating opportunities for gaining additional insights into user behavior and improvements to CTC.

Content Exposure

Table 3 shows the pages viewed by users, with an overall average time per page of 1:04 min. The most viewed pages were the home page and quit help pages, followed by charting of progress toward reaching smoke-free goals and the message page associated with smoking. Entrances provide insight into the pages that serve as an entrance into using CTC, with the home page and progress pages serving that purpose more than others. Further, exits represent the last viewed page by users, and while this could indicate that users became frustrated or discouraged, it may indicate that users found what they are looking for. The craving distraction page and the helpful messages on encouraging users to quit smoking had the highest rates of exit (see Table 3).

Figure 3. Sample screenshots of Crush the Crave (CTC).

Phase V: Study

The results of phase V will be presented in an upcoming publication. The rigorous study of CTC using an RCT will add to the growing body of the evidence on the effectiveness of smartphone apps for smoking cessation. This evidence is necessary to move forward on decision making regarding the inclusion of technology-based mobile phone interventions as part of existing smoking cessation efforts made by policy makers and health care providers. Evidence from the trial will also inform the development of future apps, provide a deeper understanding of the factors that drive change in smoking behavior using an app, and improve the design of smoking cessation apps. The CTC trial is among the first to assess the effect of a comprehensive and evidence-informed mHealth smoking cessation app on a large sample of young adult smokers. Strengths of the trial include the high-quality research design and in-depth assessment of implementation. If effective, the trial has the potential to demonstrate that including mHealth technology as a population-based intervention strategy can cost-effectively reach a greater proportion of the population and help young adult smokers to quit.

Table 3. User behavior associated with Crush the Crave (CTC) app pages—July 2013 to June 2014.

Page	Topic	Page views	Unique Page views	Average time on page (min)	Entrances	Bounce rate (%)	Exits (%)
All pages	OVERALL	59,384	40,087	1:04	18,567	58.63	32.27
/homepage	Home page	13,165	8193	1:16	3,977	55.02	32.51
/quitHelppage	Quit help pages	5232	1219	0:31	383	8.88	10.07
/progressPage	Charting Progress	4770	3341	1:00	1176	53.23	26.21
/smoked	Smoke messaging	4153	2847	4:17	591	55.16	41.70
/morePage	More features	3971	2422	1:15	1114	62.48	32.21
/awardsPage	Awards received	3260	2328	0:49	919	66.70	32.09
/craved	Crave messaging	1927	1520	1:19	153	28.10	19.72
/locationPage	Location of smoking	1647	1154	0:04	124	—[a]	1.88
/triggersPage	Smoking triggers	1096	819	1:50	14	—	21.35
/distractMePage	Craving distractions	778	677	3:06	2	—	46.27
/quitlne	Quitline number page	131	118	1:26	1	—	14.5
/shareaward	Share an award on Facebook	32	19	0:13	3	—	28.12

[a]Data is not applicable.

Discussion

Principal Findings

In this paper, a step-by-step example of how evidence, theory, and user-driven feedback were incorporated into a smoking cessation app for young adults, CTC, is described. Development of this app was inspired by evidence that young adults should be a priority population for smoking cessation efforts [1,2], that young adults have saturated the mobile phone market [5], and that most available smoking cessation apps have been developed in isolation of theory and evidence [14,15,19,24]. The iterative process behind the development of CTC to address these gaps was made transparent through this paper. In doing this, leveraging smartphone technology for engaging young adult smokers may be enhanced [28,38,39].

To meet the needs of young adult smokers with a smartphone app, the design of the CTC was informed by multiple stakeholders at several points in time, including young adult smokers, tobacco control experts, social media experts, and researchers. This stakeholder input was combined with the USCPG [22] and principles of persuasive technology, which includes a systematic approach to behavior change using technology [21], to result in an evidence-informed app to help young adults quit smoking. In this regard, CTC included 4 key design components to meet young adults' needs using persuasive technology: (1) credibility—ensuring that CTC was developed and backed by credible sources; (2) social support—providing opportunities to harness social support; (3) task support—providing young adults with practical support to help them with the task of quitting smoking; and (4) dialogue support—ensuring that young adults receive encouragement [37]. Findings from this formative evaluation demonstrate that CTC is a feasible and appealing option for helping young adults quit smoking, providing support for the development approach entailed. CTC is being used as intended with a high level of return visits and interaction with many of the key components of the app. It is noteworthy that the return visit rate was 89.58% (1780/1987) , which indicates that users were motivated to use CTC after downloading it.

A comprehensive look at how users respond to different aspects of the app was enabled through the use of both Google Analytics data and qualitative data via focus groups. Statistics on the uptake and use of the various app features and functions were provided through the analytics data, whereas user perceptions, usage, and contextual factors that might influence adoption and use were revealed through the qualitative data. This triangulation of data sources during formative evaluation of an mHealth intervention served an important role in shedding light on common themes and patterns of use that align with these common themes, as well as deviations. For example, whereas findings from focus groups were positive about the various aspects of the app, analytics data indicated low utilization of some features and functions, namely sharing awards via Facebook, using the quitline, tracking smoking location, documenting triggers, and using the craving distractions. Given that mHealth interventions operate in a real-world setting, it is of utmost importance to gather both types of data to cue attention to areas of strength, which may be enhanced, and areas of potential weakness, which may be further investigated and addressed [40]. Given the relative novelty of mobile platforms for health behavior interventions, efforts to understand user engagement via various measures is critical to the design of effective mHealth interventions [41].

In keeping with the STAR model approach [29], CTC is currently being evaluated in an RCT [23]. Young adult smokers were randomly allocated to CTC or the control group. Findings from this study will be used to inform intervention optimization by identifying aspects of the app that have the most potential to positively influence behavior change. Depending on the findings, CTC will be revised and subsequently tested.

Limitations

There are several limitations of this study. First, the perceptions shared by phase I focus group participants were discussions of a hypothetical app. User perceptions reflected in the focus groups may change when an actual app is tested and used by the target population. Also, the perceptions shared by phase III focus group participants were discussions of an existing app, potentially constraining feedback to the existing functionality of the app. In addition, there may be differential preferences according to subgroups of young adults, particularly gender, and this should be an area for future research. Furthermore, group bias during focus groups may have kept alternative opinions from being voiced. In addition, although Apple iOS users likely reflected the same usage trends as Androids users, Apple iOS usage was not represented in the Google Analytics results and was limited in terms of descriptive statistics. Another limitation is the speed of technological changes and changing sophistication of users, which may limit the applicability of these findings for future app development. Furthermore, this rapidly changing context inherently requires constant refinement of the app. Finally, it must be noted that some segments of the young adult population may not own a smartphone and cannot be reached via smartphone interventions. However, this is changing, with smartphone ownership on the rise, and this might be a great way of closing a gap.

Future Work

Although the results of this formative evaluation indicate that young adults have positively received CTC, engagement with the app and its related features and functions are critical to success [8-11]. Therefore, there is a need for more in-depth research on user engagement with the different components of the app and behavior change outcomes, and the results of the upcoming RCT will address this gap. In addition to this formal testing of the app, there is a need for additional qualitative research to shed light on some of the questions that remain about why certain features were more popular than others and what contextual factors influenced these trends. Given that mHealth interventions are situated in the contextually laden lives of end users, the value of qualitative research in mHealth is apparent.

The CTC app targets young adults. Given the existing knowledge gap in relation to mHealth intervention development for this population, efforts to standardize developmental practices are needed. Researchers are therefore encouraged to apply this development methodology to other app development projects to help refine and expand the development process of cessation apps.

Conclusions

CTC is one of the first smoking cessation apps designed to meet the needs of young adult smokers. The development was informed by the inclusion of young adults in the design and the systematic application of multiple stakeholder input, scientific evidence, and theory. The STAR model approach proved to be a practical and comprehensive guide for development and evaluation, and it should facilitate optimization of mHealth interventions in the future.

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Authors' Contributions

NBB led the conceptualization and design of the study, and LLS and DD contributed to the design of the study. LLS, NBB, and DD conducted the analysis and drafted the manuscript. NBB, LLS, and DD critically revised the manuscript for important intellectual content. NBB is the principal investigator on the research funding application. NBB supervised the study. NBB is the guarantor.

Conflicts of Interest

None declared.

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Abbreviations

CTC: Crush the Crave
mHealth: mobile health
RCT: randomized controlled trial
SMS: short message service
STAR: Spiral Technology Action Research
USCPG: US Clinical Practice Guidelines

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Original Paper

More Stamina, a Gamified mHealth Solution for Persons with Multiple Sclerosis: Research Through Design

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Abstract

Background: Multiple sclerosis (MS) is one of the world's most common neurologic disorders. Fatigue is one of most common symptoms that persons with MS experience, having significant impact on their quality of life and limiting their activity levels. Self-management strategies are used to support them in the care of their health. Mobile health (mHealth) solutions are a way to offer persons with chronic conditions tools to successfully manage their symptoms and problems. Gamification is a current trend among mHealth apps used to create engaging user experiences and is suggested to be effective for behavioral change. To be effective, mHealth solutions need to be designed to specifically meet the intended audience needs. User-centered design (UCD) is a design philosophy that proposes placing end users' needs and characteristics in the center of design and development, involving users early in the different phases of the software life cycle. There is a current gap in mHealth apps for persons with MS, which presents an interesting area to explore.

Objective: The purpose of this study was to describe the design and evaluation process of a gamified mHealth solution for behavioral change in persons with MS using UCD.

Methods: Building on previous work of our team where we identified needs, barriers, and facilitators for mHealth apps for persons with MS, we followed UCD to design and evaluate a mobile app prototype aimed to help persons with MS self-manage their fatigue. Design decisions were evidence-driven and guided by behavioral change models (BCM). Usability was assessed through inspection methods using Nielsen's heuristic evaluation.

Results: The mHealth solution *More Stamina* was designed. It is a task organization tool designed to help persons with MS manage their energy to minimize the impact of fatigue in their day-to-day life. The tool acts as a to-do list where users can input tasks in a simple manner and assign *Stamina Credits*, a representation of perceived effort, to the task to help energy management and energy profiling. The app also features personalization and positive feedback. The design process gave way to relevant lessons to the design of a gamified behavioral change mHealth app such as the importance of metaphors in concept design, negotiate requirements with the BCM constructs, and tailoring of gamified experiences among others. Several usability problems were discovered during heuristic evaluation and guided the iterative design of our solution.

Conclusions: In this paper, we designed an app targeted for helping persons with MS in their fatigue management needs. We illustrate how UCD can help in designing mHealth apps and the benefits and challenges that designers might face when using this approach. This paper provides insight into the design process of gamified behavioral change mHealth apps and the negotiation process implied in it.

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KEYWORDS

multiple sclerosis; telemedicine; fatigue; mobile applications; video games; qualitative research; exercise; chronic disease; user-computer interface; software design

Introduction

Background

Multiple sclerosis (MS) is one of the world's most common neurologic disorders, accounting for more than 2.3 million people, with higher incidence in Northern European descent and in temperate climates [1]. Twice as many women are affected as men, and the condition typically presents in young adults 20 to 45 years of age [2]. MS symptoms range from fatigue to visual disturbances, altered sensation, cognitive problems, and difficulties with mobility [2]. Some types of MS have stretches of periods in which symptoms worsen and these are called attacks or "relapses" [1,2]. Persons with MS are typically less active [3] and have reduced their levels of physical activity (PA) for many reasons such as the fear of relapse, less physical resistance, and fatigue [4-6]. Fatigue is a sense of physical tiredness and lack of energy, distinct from sadness or weakness [7]. Different scores and scales exist to assess persons with MS such as the Expanded Disability Status Scale (EDSS) [8] and the Fatigue Severity Scale (FSS) [9] or Chalder Fatigue Scale (CFS) to explore fatigue [10]. Living with MS often requires individuals to be more engaged with their health as their quality of life is affected in many ways [11], leading to self-management needs [2]. Current research shows that to successfully manage chronic conditions, patients require support to both learn about and manage their symptoms and problems [12-14]. Adopting health behavior changes is difficult because the majority of self-management in chronic diseases takes place away from health care settings [15], and patients also have the additional challenge of maintaining this new approach over time.

Mobile health (mHealth) is the delivery of health care or health care–related services through the use of portable devices [16]. The use of mHealth software apps has grown in recent years to the point where commercial app stores hold thousands of health care–related apps [17]. Commercially available mHealth apps mostly focus on wellness and well-being [17], neglecting condition-specific solutions. In medicine, every treatment needs to be administered considering the patient's needs and prescribed with an understanding of its benefits and risks; this should also be true in mHealth. In a preliminary review, we found that only a handful of mHealth solutions for persons with MS are currently available [18]; this presents an interesting area to explore as these tools could help them be more active in their own health management and health decision-making process. Studies show that tailored interventions are more likely to be seen as engaging and relevant by the intended population [19]. Current trends of health information technology (IT) interventions point out that solutions should be designed to be not only effective, acceptable, and nonharmful but also pleasant and engaging [14,20]. However, scientific literature tends to focus on the clinical evaluation of health IT solutions with little discussion on the design process and its importance to the success of an IT solution [21,22].

It is important to extract target users' requirements about functionality and usability so that one can identify what creates meaningful user experiences [14]. Failure to meet end users' needs results in misused or underutilized solutions, which will ultimately defeat their intended objectives [21,23,24]. Addressing these factors seems particularly relevant for mHealth, considering that over one-fifth of mobile apps are abandoned by the user after only a single use [25,26]. The use of game elements in nongame contexts, commonly called gamification [27], has also been gaining traction in health apps and is now a popular strategy in both commercial and academic fields to drive behaviors [28,29].

User-Centered Design

User-centered design (UCD) is a design philosophy that proposes placing the needs and characteristics of end users in the center of software design and development, involving users early in the different phases of the software life cycle [22,30,31]. The goal of UCD is attempting to create solutions specific to the characteristics and tasks of the intended users [22,31]. Following UCD principles generates systems that are easy to learn and have higher user acceptance and satisfaction and lower user errors [22,31,32]. In addition, the incorporation of good design principles early on not only saves time and money [33] but also decreases design changes late in the development process [32,34]. The overall process of UCD comprises the following: specification of the context of use (understand users, their characteristics, and environment), specification of the requirements (identify the granular requirements and needs), production of solutions (start an iterative process of design and development), and evaluation (testing to find critical feedback on the product) [30,35].

Commonly used methods in UCD consist of iterative involvement of the end user in the design process, idea generation techniques such as brainstorming [36], early and rapid prototyping, and usability testing of the system. Following UCD ensures that mHealth solutions are more likely to meet end users' needs and expectations [21,37].

Prototyping

Prototypes are one of the means by which designers organically and evolutionarily learn, discover, generate, and refine designs. Prototypes stimulate reflections, and designers use them to frame, refine, and discover possibilities in a design space [38]. The goal of prototyping is framing and exploring the design space in its simplest form to filter the qualities in which designers are interested, without distorting the understanding of the whole [39]. Low-fidelity prototyping techniques such as paper prototyping are low cost and are often used to visualize possible tool interfaces and support discussions with participants about more concrete ideas and requirements [14,40].

Usability Evaluation

The evaluation of usability in human-computer interactions (HCI) entails a wide array of methodologies that vary in terms

of research design, complexity, cost, and duration [41]. Different methods can be used to evaluate a first system design on its usability; expert-based inspections and user-based testing methods exist to facilitate this process [42]. Involving end users implies a recruitment process, scheduling, and technical resources that require time and money. Inspection methods are widely used when it is difficult to involve end users or when costs have to be reduced. Inspection methods are based on reviews of a system guided by usability heuristics such as Nielsen's [43] or user tasks, among others [41,44].

Gamification and Game Elements

Gamification [27] is generally understood as the integration of specific features into the greater context of mobile apps for purposes of bolstering usability and compelling continued use [45,46]. The following are game elements established in both literature and practice for impacting health behavior [47-51]:

- Badges, achievements, and trophies are used to reward individuals on the accomplishment of specific tasks.
- Leaderboards dynamically rank individual users' progress and achievements as compared with their peers.
- Points and leveling systems are implemented to inform the user of his or her level of familiarity and reward continued expertise and knowledge using the system.
- Challenges and quests are used to provide objectives and narrative, indicating that the user is, indeed, using and progressing through the system as it was meant to be used.
- Social features are added to support and reinforce interaction between users.

Behavioral Change

The core principle of implementing healthy behavior change is making the healthy choice the easy choice. Several behavioral change models (BCM) and theories are used in health behavior science such as the health belief model (HBM) [52], the theory of planned behavior (TPB) [53], the goal-setting theory (GST) [54], and the self-determination theory (SDT) [55], among others.

According to HBM, individuals will take a recommended health-related action only if they feel that it will help them avoid a negative health condition. TPB states that the intention of performing an action is a cognitive representation of a person's readiness to perform a given behavior, and it is considered to be the immediate antecedent of behavior. This intention is determined by 3 things: their attitude toward the specific behavior; their beliefs about how people they care about will view the behavior in question, called subjective norms; and their perceived control over their behavior. GST proposes that having goals provides individuals a measure for "excellent" performance against which to judge their own performance. GST identifies 5 principles that were important in setting goals that will motivate others. These principles are as follows: clarity, challenge, commitment, feedback, and task complexity. In traditional goal setting, a single specific goal (or group of goals) is set by a third party to achieve. Goal setting is generally more effective for simple tasks, with well-defined parameters, in part, because it is easier for a person to see the connection between effort and goal achievement [56]. Finally, SDT establishes 3 psychological needs that motivate the self to initiate behavior, which include the need for feelings of efficiency and success (competence), of a sense of volition (autonomy), and of social interaction (relatedness).

Health messages can be framed in terms of their benefits (gain-framed messages) or their detrimental consequences (loss-framed messages). Using a gain frame is recommended as it is usually more easily processed and readily accepted [57].

The Study

In previous studies, we completed the first two phases of the UCD process. We studied the state of the practice of mHealth solutions for MS through a systematic app review [18]; we explored the needs, barriers, and facilitators to mHealth apps in persons with MS and the corresponding health care team using focus groups and interviews [58]; and we created MS "personas" to aid in the design process [58]. The understanding gained from previous phases guides the design of our mHealth solution.

The work presented here describes the design process, prototyping, and usability testing of a gamified mHealth solution for behavioral change in persons with MS following UCD principles.

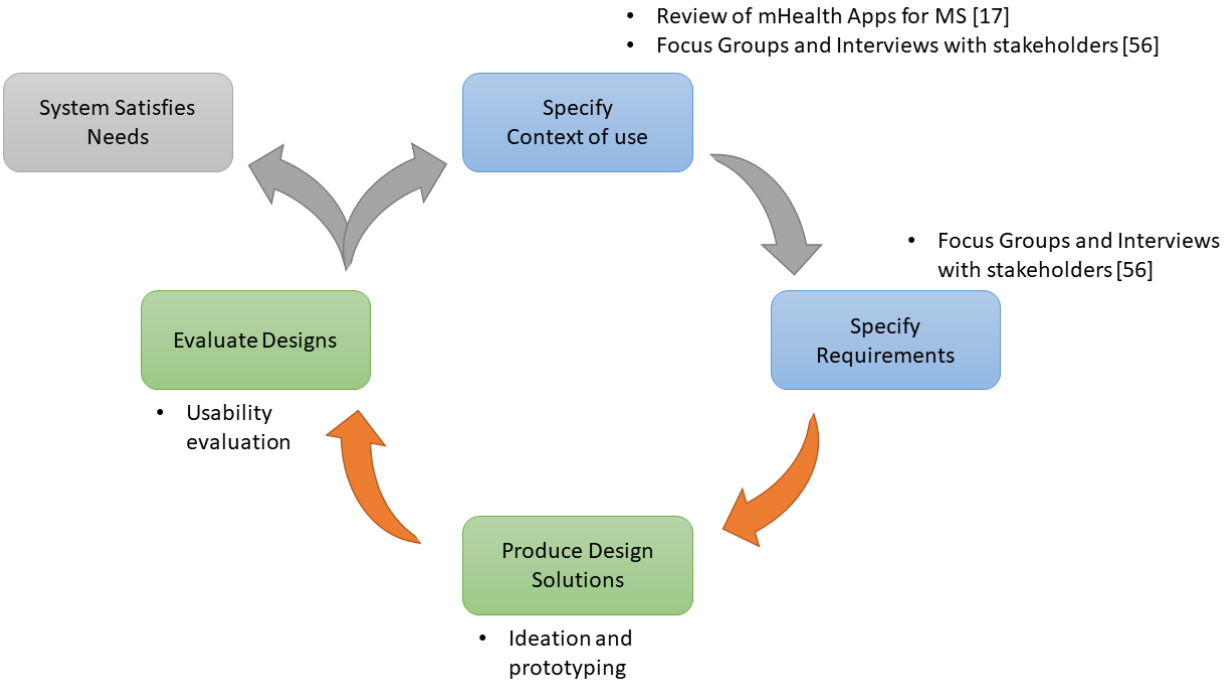
Methods

In this section, we provide the context for the work, report the design goals that were trying to be achieved, and explain the methods used to evaluate the usability of the solution. UCD principles were followed to iteratively design a gamified mHealth behavioral change solution for persons with MS. See Figure 1 for the scope of this study.

Study Design

This work follows a design through research process where user requirements were obtained in a previous study [58], which considered the views and needs from persons with MS and health care providers and the available scientific literature.

Figure 1. Phases of user-centered design. Green represents the areas covered in this study. Detailed results of our mobile health (mHealth) app review for multiple sclerosis and focus groups and interviews with stakeholders can be found in their respective studies.



Setting

This study is part of a collaborative project between researchers and collaborators of different institutions. The work took place in different stages and countries across Europe:

Salumedia Tecnologias, Spain (Salumedia), is a digital health company, spin-off out of the University of Seville, Spain (USE), that provides technological solutions in the health domain. The company is specialized in the application of social media, games, and mobile technologies for health with a long list of experience working on digital health research projects.

The University of Oulu, Finland, is an international science university that creates knowledge through multidisciplinary research and education. The INTERACT research unit at the University of Oulu focuses on understanding and supporting participatory design, UCD, value cocreation, user-driven innovation, and human interaction in information technologies.

Kliniken Valens is a rehabilitation center located in Valens, Switzerland, specialized in neurological, musculoskeletal, and geriatric rehabilitation. The clinic employs a multidisciplinary staff of neurologists, rheumatologists, geriatricians, nurses, social workers, and therapists (physio-, occupational, speech-, and sports).

The USE is the main house of learning in the Andalusian province of Spain that provides superior education by means of studies, teaching, and research, as well as the generation, development, and diffusion of knowledge to serve citizens and society. The USE has a present student body of over 65,000 and is one of the top-ranked universities in the country.

Salumedia and the University of Oulu are part of the Connected Health Early-Stage Researcher Support System Initial Training Network (CHESS ITN). CHESS ITN is a European Union Horizon 2020 Program under the Marie Skłodowska-Curie grant agreement No. 676201 with the goal of fostering connected health professionals who can communicate in an interdisciplinary world and who can operate across the education, industry, health, and policy sectors.

Work Group

Guido Giunti is a physician specialized in eHealth who works as a researcher and medical advisor at Salumedia. He is a PhD candidate at the University of Oulu on the use of persuasive technologies and gamification in patients with chronic conditions. His work is part of the CHESS ITN program.

Vasiliki Mylonopoulou has a bachelor's degree in computer engineering and a master's degree in human-computer Interaction. She currently works in the INTERACT research unit at the University of Oulu as part of the CHESS ITN program.

Octavio Rivera-Romero is assistant professor and postdoctoral researcher at the USE, with a focus on human-computer interaction in the health domain.

Jan Kool is a physiotherapist specialized in physical rehabilitation of neurological conditions and the head of research and development at Kliniken Valens.

Joaquin Chacon-Galvez is an ICT engineer and has a master's degree in computers and network engineering from the USE with experience in mobile apps development in the health care environment for both iOS and Android. Joaquin was the lead programmer at Salumedia during this project.

Enrique Dorronzoro-Zubiete is a postdoctoral researcher at the USE and scientific advisor at Salumedia.

Textbox 1. Desired features and characteristics for mobile health (mHealth) solutions for persons with multiple sclerosis (MS).

Customizable goal setting

- Challenges need to be tailored to the specific person with multiple sclerosis (MS) characteristics

Energy profiles and fatigue management

- Information and tools that help users in managing their day-to-day activities

Patient education

- Offer verified information that is helpful and reliable

Data visualization

- Information must be presented in a way that is meaningful to persons with MS

Positive feedback system

- Rewards and incentives for completing tasks and objectives

Activity tracking

- Register metrics such as steps, calorie consumption, heartbeat, and quality of sleep among others

Exercise library

- An array of different activities specific to MS such as fitness or relaxation techniques that can be selected

Game-like attitude

- Engaging in a playful mindset in a way that is highly pleasurable and motivating

Stron evidence base

- Features and information offered should have a solid scientific foundation

Remote monitoring

- Health care providers can follow the progress of persons with MS and give feedback

Optional sociability

- Ability to opt out of social media features such as messaging, feeds, or other kinds of social comparisons

Reminders system

- Notifications that reminds persons with MS to engage in activities

Personal data management

- Access to personal information and data defined by the user case by case

Target Population

The mHealth solution's intended audience are young adults who have been diagnosed with MS, have none to moderate physical disability (EDSS<4.5); and are mobile phone users.

Technological Specifications

This study focuses on the design process of a gamified mHealth behavioral change solutions for persons with MS; therefore technical aspects of the software development will be kept to a minimum as they will be featured in a future work regarding the evaluation of the intervention.

Design Goals

In our previous study that explored the needs of persons with MS through qualitative research, a series of features and characteristics for mHealth solutions emerged. An overview of such features is shown in Textbox 1 in order of importance, and more information can be found in the full study [58]. Persons with MS stated the need for something that would allow them to manage their fatigue and help them visualize their energy in a more concrete way; they also reported that they wanted encouragement and positive feedback to reach their objectives. More importantly, they wanted mHealth solutions to be specific to them. Health care professionals shared these views and emphasized the need for strong evidence and theory base.

Textbox 2. Nielsen's usability heuristics summary.

Visibility of system status

- The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.

Match between system and the real world

- The system should speak the user's language, with words, phrases, and concepts familiar to the user, rather than system-oriented terms.

User control and freedom

- Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state.

Consistency and standards

- Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.

Error prevention

- Even better than good error messages is a careful design that prevents a problem from occurring in the first place.

Recognition rather than recall

- Minimize the user's memory load by making objects, actions, and options visible whenever appropriate.

Flexibility and efficiency of use

- Accelerators—unseen by the novice user—may often speed up the interaction for the expert user. Allow users to tailor frequent actions.

Aesthetic and minimalist design

- Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.

Help users recognize, diagnose, and recover from errors

- Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.

Help and documentation

- Any such information should be easy to search, focused on the user's task, and list concrete steps to be carried out, and should not be too large.

In our studies, persons with MS patients expressed specific needs that could not be addressed together at the same time, so we prioritized those that they deemed more important in the literature and in our previous study [58]. Our goal was to design a behavioral change mHealth solution that (1) allowed persons with MS to manage their fatigue and energy, (2) provided positive feedback, (3) had customizable goals, (4) presented data in a meaningful way, (5) allowed for playful attitudes, and (6) was strongly based on behavioral change evidence.

Usability Evaluation

Nielsen's heuristics [43] are presented in Textbox 2; these were used as design guidelines, and one additional external HCI researcher used them to evaluate the usability of the resulting prototype. The evaluator team (2 designers and 1 HCI researcher) independently examined each heuristic for all prototype screens. Notes were taken on major and minor issues discovered, to be later contrasted among them. Major usability problems are those that have serious potential for confusing users or causing them to use the system erroneously while minor problems may slow down the interaction or inconvenience users unnecessarily. After each heuristic evaluation, the prototype was modified and assessed again. This process was iterated until all usability issues were addressed.

Results

During brainstorming sessions, we kept the observed needs of users and stakeholders in mind and attempted to find a design concept that would support them. An mHealth solution was designed to help persons with MS manage their energy with game elements following a combination gain-framed messages and behavior change models such as HBM, TPB, GST, and SDT. We called this solution *More Stamina*.

Prototyping efforts are presented next, followed by a feature description of *More Stamina*, design decisions and considerations, design implications, and, finally, the results of usability evaluation.

Prototyping

A series of sketches were drawn isolating design aspects to center on task management and energy as resource concepts. Initial sketches dealt with building a visual vocabulary and consecuently refining user flow and navigation. Reducing clutter and improving ease of use were the main concerns (see Figure 2 for examples of main screen). The paper prototypes were developed low in visuals and content to focus on the main features of the app and navigation experience; main attributes

were captured but do not represent the look of a live system. The final paper prototype designs can be seen in Figure 3.

Figure 2. Successive iterations on main screen design.

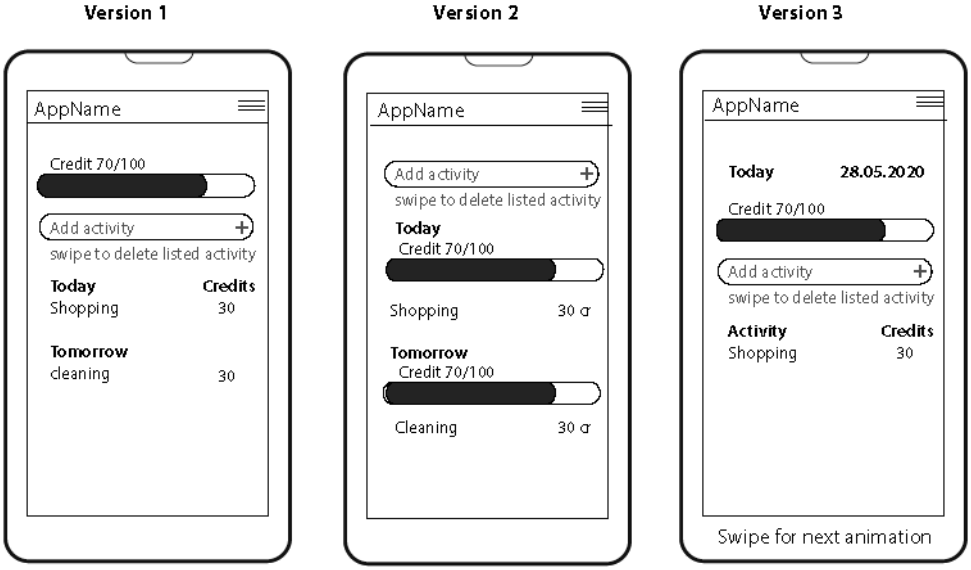


Figure 3. Final paper prototype design: (a) initial main screen; (b) new task input; (c) Stamina Credits assignment; (d) main screen with tasks; (e) edition and completion of tasks; (f) effort estimation; (g) effort recommendation; and (h) user profile.

More Stamina

More Stamina is a task organization tool designed to help persons with MS manage their energy and to minimize the impact of fatigue in their day-to-day life. The tool acts as a to-do list where users can input the tasks they want to accomplish that day in a simple manner, but *More Stamina* proposes extra features to help manage fatigue.

A person's overall energy is represented through a visual metaphor: a progress bar composed of *Stamina Credits*, a unit we devised to quantify the estimated effort an activity might take. Users start their day with 100 points or *Stamina Credits* and assign a certain amount of them to activities for that day (see a in Figure 3). Each day starts with a clean list so that the persons with MS can be more intentional about the things they want to accomplish. Users can enter all kinds of tasks in *More Stamina* as input is, from the user's perspective, free text (see b in Figure 3). All activity names or labels are stored so that the next time the user is typing to add a task, previously used activities will be prompted to them. Users can create daily life activities in broad strokes such as going to work, running, or shopping; or they can be more specific in their tracking and assessments such as walking in the park, meeting with Andrew, or doing the dishes. The amount of *Stamina Credits* users can assign to activities will differ; for example, "doing the dishes" may be worth 15 credits whereas "running" may take 30 or 40 credits to represent the difference in efforts (see c in Figure 3).

As persons with MS "spend" their *Stamina Credits*, they will get a more tangible notion of how much energy they will have left, thus bridging the gap between the abstract concept of "energy" to a representation of the actual experience at the end of the day. As determining the amount of *Stamina Credits* for each activity quantifies the estimated effort for that task and that is entirely subjective to the person, users can set the number as they see fit. Reminders can also be set for each task.

Adding tasks to the to-do list is only half of the equation; as users complete activities, they will mark them as done in the tool (see e in Figure 3). At this point, they will be prompted to assess whether their effort was under-, over-, or properly estimated for that activity (see f in Figure 3). *More Stamina* will keep track of these answers as data points and start analyzing and creating a trend for each activity, for example, "shopping." Repeated use of *More Stamina* allows it to learn about the user's habits; once sufficient information is gathered on "shopping," the next time the user is entering it, he or she will be reminded of his or her tendency and offered to modify his or her assessment (see g in Figure 3). Usage statistics are gathered locally for each added activity to keep track and collect assessments; the user can choose to share these statistics to a secure server for analysis.

More Stamina also has a user profile feature that collects and aggregates information about the user's condition (see h in Figure 3). Surveys, questionnaires, and other assessment tools such as the FSS and CFS are optionally available for completion. Users will have full control as to which information to disclose and with whom, whether it is personal, clinical, or treatment-related. Additionally, they can opt in to send deidentified information for research purposes.

As persons with MS use the tool, a track record will be shown in the user profile, awarding medals for completing certain objectives to congratulate them for staying on course. "Medals" will be given for completing fixed objectives such as completing all daily tasks 3 days in a row, always responding effort assessments, or continuously assessing correctly one task, among other specific objectives or "challenges." These will provide clear and unambiguous feedback to the users that they are progressing and encourage them to keep heading in the "right" direction. The users can connect their social media accounts to the app to share specific achievements with their social circle.

Design Decisions

As we worked on the design of this project, we came to understand a series of lessons that are relevant to the design of gamified behavioral change mHealth solutions. A summary of design takeaway points can be found in Textbox 3.

Our vision for *More Stamina* was a solution for persons with MS that made organizing daily efforts a conscious action. The attempt was to make energy expenditure management into something tangible, as easily understood as moving "bricks" of time and effort or using up a gasoline. The need for presenting information in a meaningful way was a priority. Assessing the potential users' views and those of other relevant stakeholders such as members of the health care professional team helped recognize and prioritize needs that had to be met.

During the brainstorming sessions in our team, discussions turned around the possible ways in which this could be conceptualized. We centered our ideas on our MS personas as user representations and analyzed how these would affect them in concrete ways. As we wanted to increase the chances of adoption, we discarded those solutions that required the purchase of additional and expensive wearable devices and focused on smartphone's inherent capabilities. People with MS can also experience blurry vision as a symptom, so we had to consider this a design challenge: too many fine details presented on a small screen would be an issue for them. Additionally, because this is a behavioral change intervention, we also kept in mind BCM theories in our design discussions.

BCM were key players during requirement negotiations. Each design concept was deconstructed to find matches with current models. When a specific part of a BCM was not addressed by a design concept, the concept was explored further until integration with the BCM felt natural or the concept was discarded. To facilitate this process, we created an ad hoc diagram representing the GST, SDT, TPB, and HBM constructs and arranged them based on their similarities. This allowed us to generate guiding questions for our design decisions. In Figure 4, we present an example of this diagram with guiding questions and the different behavioral change constructs.

Textbox 3. Design takeaway points.

Use positive message and presentations

- The way information is presented to users influences the emotional response. Consider the implications of your design choice:
  - Watering plants as metaphor creates an association with death. Plants die if you do not water them.
  - Users manage their energy instead of their fatigue.

Meaningful and clear representations

- Concepts should be easy to understand and relate to things users are familiar with. It is important to keep in mind to do the following:
  - Build on concepts that users know such as currency systems, visual metaphors, or stories.
  - Provide elements that allow the user to enter a different mindset; present an invitation to play.

Understand the condition-specific issues

- Chronic conditions carry an array of design challenges that should be kept in mind when creating mobile health (mHealth) solutions. In the case of multiple sclerosis (MS), some clearly influence the design:
  - Blurry vision is common in MS, which mHealth apps need to consider for increased usability.
  - MS varies greatly between patients, so customization and personalization needs are high.

Negotiate requirements with existing behavioral change models

- Behavioral change interventions with a strong theory-based approach have greater impact than those that do not, so it is important to acknowledge the current models in the design process.
  - Incorporate behavioral change knowledge into the idea-generation process.
  - Contrast designs with your selected behavioral change model to see how they fit within its constructs.

Contextualize socialization

- Family and social support are very important parts of life, but not all individuals may wish to share details of their condition with others.
  - An mHealth solution must take into account that health information is sensitive; sharing and disclosing should be optional.
  - Allow family, friends, and informal caregivers a role in your solution.

Tailor gamification features

- Designers should define how deep of a game experience will mHealth solution provide based on the intended audience's needs and expectations.
  - Game elements must be integrated to your design and not just a hastily added afterthought.
  - The overall experience is more important than individual features or the amount of elements.

As we settled on the concept of activities draining energy, we started to question how best to translate the experience. As MS is more common in women than men, we explored metaphors that were in line with traditional themes. The metaphor of watering a plant and using water as a substitute for "energy" was discussed, but the association of a dying plant was deemed as an image too negative to use. Thinking of energy as a form of virtual currency or points was chosen as people are used to handling financial day-to-day matters, and it worked as a familiar shortcut. The unit "credits" was chosen versus "coins" or "points" because points are usually considered as something you gain, whereas a credit is a form of deferred payment, which was more in line with the overarching metaphor. As performing an activity consumes *Stamina Credits*, we explored how users would regain energy. Sleeping is an activity that would allow users to recuperate energy, and there are activities that require short-term efforts but produce long-term benefits such as PA. The conversations turned around whether it should be the system that gives back these "deposits" or whether the users should decide the estimated "return of investment" for their sleep or PA routine. However, incorporating the concept of "depositing" *Stamina Credits* was postponed as this quantification seemed too complex for individuals, and standardized quantification was difficult to implement. Another aspect of *Stamina Credits* is that the use of credits would allow users to engage in playful attitudes; as they start managing them and finding ways to optimize their actions, using the mHealth solution would become an experience similar to when playing strategy games. Once we consolidated the idea of a progress bar and *Stamina Credits* to represent energy expenditure, we moved on to task organization.

Task input, grouping, and scheduling were features that required several iterations to polish. The main challenge here was making the experience flow and keeping visual and cognitive load to a

minimum. Voice command was one of the solutions we considered because typing could be too cumbersome for people with MS in the more advanced stages. Technical complications were assessed, and in the end, we decided to follow a more frugal engineering approach.

Persons with MS who are suffering an MS relapse have their physical abilities affected and may feel tasks are even more difficult than usual, so the need of having some way of informing the system that a relapse is happening was discussed during our sessions. As designers, we considered the idea of reducing the amount of total *Stamina Credits* (eg, from 100 to 80) to reflect this new scenario but decided against it. *Stamina Credits* act as a percentage of total available energy to "spend," and thus the percentage would always represent the total. When users flag that a relapse is happening, *More Stamina* uses that as a sign to increase encouraging feedback and also to modulate the statistical calculations for each activity.

Family and social support are very important to persons with MS, which is why we included the option of sharing achievements through social media. Further social involvement was discussed such as including messaging features or remote tracking of progress, but these were considered pertinent to address in later versions of the app.

Usability Evaluation

Several usability problems were discovered during heuristic evaluation. Among the major usability problems were establishing the proper way of presenting the metaphor between *Stamina Credits* and physical energy (match between the system and the real world), ensuring that users will not create duplicate entries for the tasks (error prevention), and adequately documenting and informing the user (help and documentation). Some minor problems included lack of means of canceling an action or escaping some screens (user control and freedom), dialogue messages using different icons and symbols (consistency and standards), and the inclusion of some shortcuts for more advanced users (flexibility and efficiency of use). In Figure 5, examples of usability issues can be found. Usability issues were addressed and the latest iteration of the app presented no additional usability issues.

Figure 4. Guiding design questions. GST: goal-setting theory; SDT: self-determination theory; TPB: theory of planned behavior; HBM: health belief model.

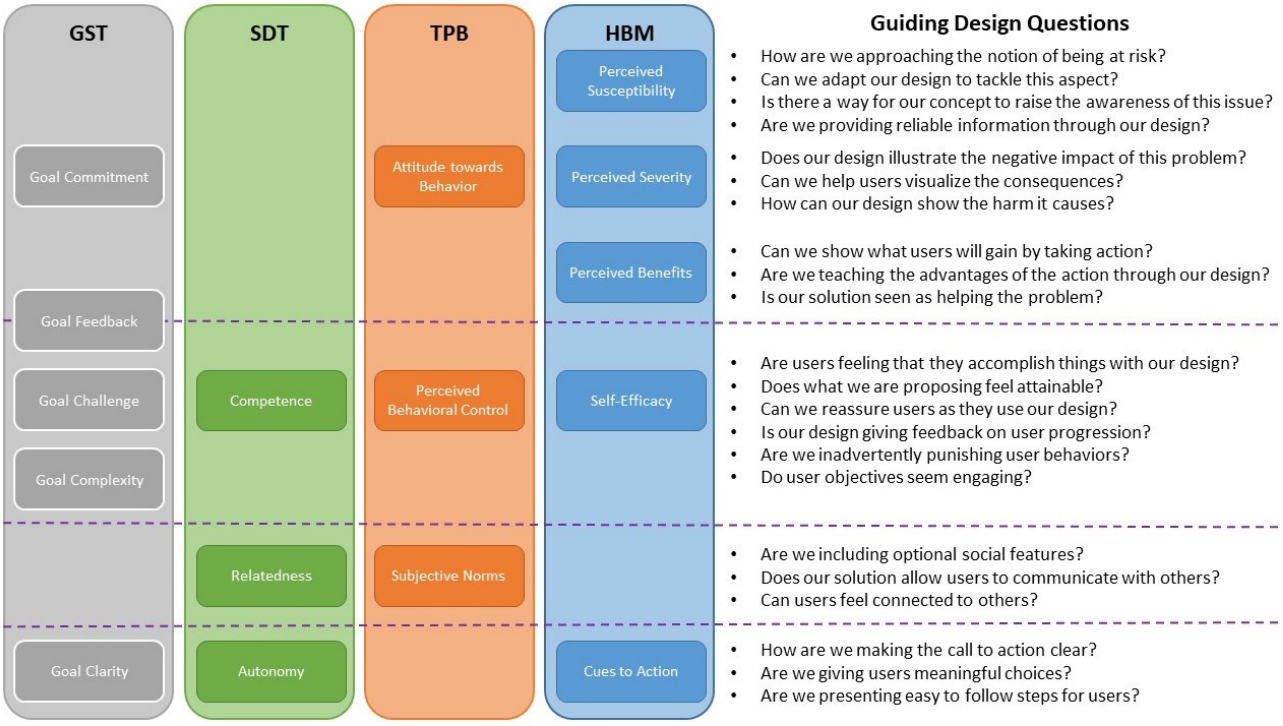
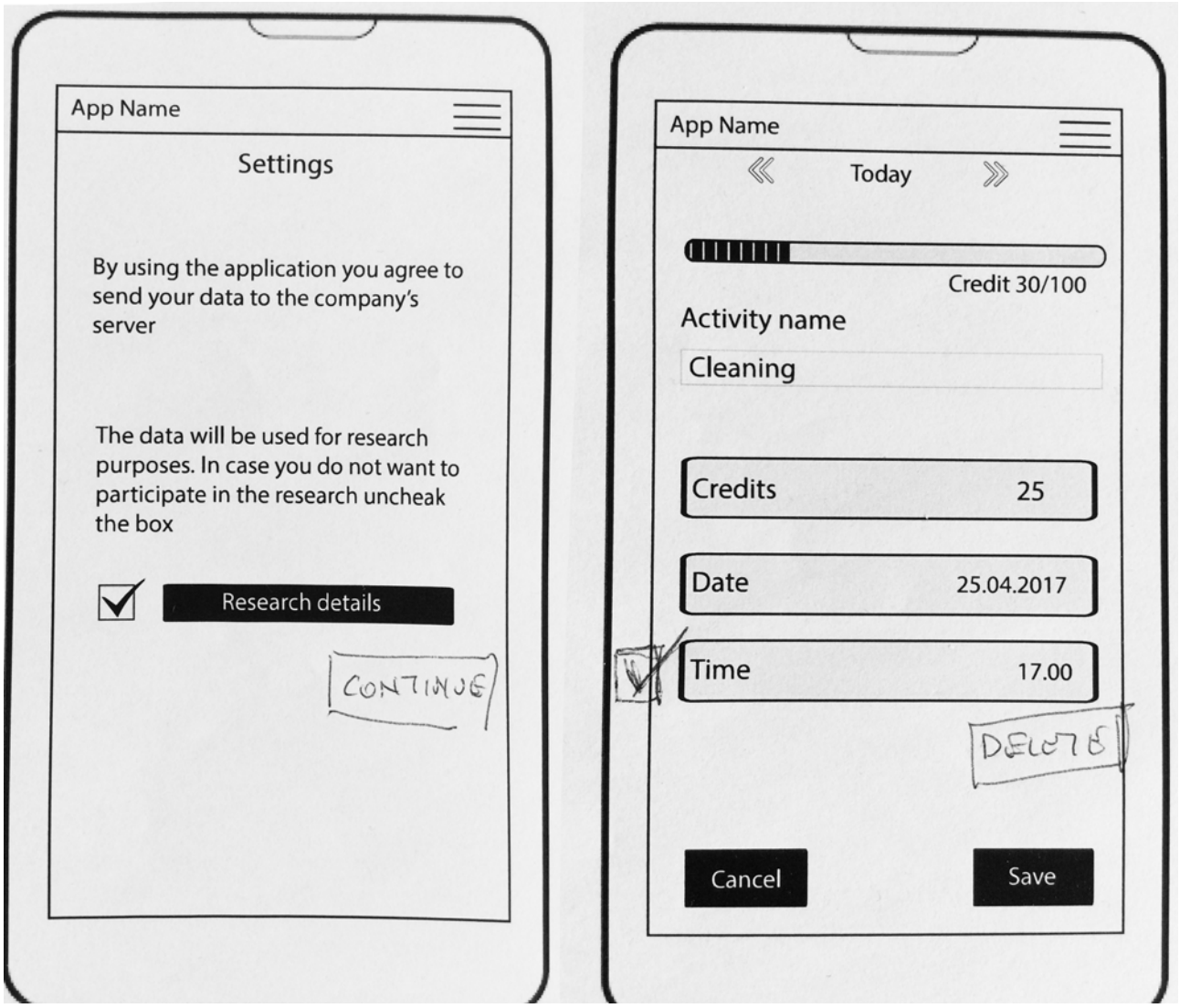


Figure 5. Usability errors and fixes. User control and freedom (left) and error prevention (right).



Discussion

Principal Findings

The work presented here describes the design process, prototyping, and usability testing of a gamified mHealth solution for behavioral change in persons with MS following UCD principles. It provides insights into design decisions and considerations relevant to the design of a health IT behavioral change intervention, the use of gamification in health apps, and the evaluation of usability problems found during this process.

Comparison With Prior Work

The rapid proliferation of mHealth apps makes it increasingly difficult for the different stakeholders (patients, health professionals, and researchers) to identify and assess useful or even harmful health apps. A concern that keeps being raised is the absence of involvement of health care professionals in the development of mHealth solutions [18,59-63]. Simultaneously, persons with MS hold in high regard the input from health care professionals [64,65], acknowledging their perspectives in the design process would be considered beneficial. By centering the design of our mHealth solution around an identified patient need, we have increased the chances of it being perceived as useful [24]. The need for solutions that are robust, usable, and effectively support healthful behaviors in consumers' daily lives is often highlighted [21,24].

Goal setting within rehabilitation is a common practice and has been explored in many different conditions [66,67]. Goal-setting activities should be patient-centered as patients are often more motivated to engage if they see the value of their efforts [68-71]. Few mHealth apps exist that allow users the type of goal-setting activities that are important for patients.

Energy conservation education programs and fatigue management are common approaches in MS [72,73]. The goal is to help the patient save energy through the implementation of different strategies such as work simplification or the use of task prioritization. One of the main problems fatigue management has is that there are activities that persons with MS cannot avoid (eg, work). The goal of our solution is to provide the means for more strategic planning and prioritize the activities that persons with MS need to get done.

Fatigue is a nonspecific symptom that can be caused by many conditions and syndromes such as the chronic fatigue syndrome, anemia, hypothyroidism, or sleep apnea [74]. It is possible that our *More Stamina* solution could be of use in other conditions

that require fatigue management, but this would need to be explored separately.

App quality and safety do not necessarily align with functionality and must be considered separately. Ethics in the area of IT in general is lacking, and in the development of mHealth services it is close to nonexistent [75]. Designers of health and well-being apps need to consider the consequences of errors in the development. Ensuring that mHealth technologies are appropriately designed and targeted to the end users' needs is essential before using them as health interventions, or there is a risk that they will be misused or underutilized and fail to meet their original objectives [23]. Understanding and addressing design deficiencies are critical, which is why the use of UCD has been proposed as a possible solution. The creation of our mHealth solution followed UCD principles and techniques in an attempt to design a health app that is easy to use and provides value to persons with MS . Using low visuals and contents when prototyping improves willingness to criticize or make suggestions about a design [40], which was true in our case for this process.

Gamification and Game Elements

Studies discuss gamification as a single unified concept, whereas in practice, the specific designs and considerations of gamification can be quite diverse. The use of game design elements can take many forms and combinations, which is why the impact of the different elements should be considered within a given context. Reviews on gamification in mHealth report low use of theoretical models, both for game elements and for the use of health behavior theory constructs [28].

Usually, gamification has been commonly associated with points, levels, and leaderboards [27,49]. These elements are considered different types of goal metrics that represent and sometimes even define player success [45]. They function as positive, informational performance granular feedback and afford opportunities for players to satisfy their need for competence [55]. Virtual currencies are a form of "points," which in our solution take the form of *Stamina Credits*. Representing the total amount of energy as a progress bar provides visual and sustained feedback on performance [76]. The use of specific objectives external to the user such as the "challenges" and associating medals to a series of player actions become "achievements" or "badges" that provide cumulative feedback [76]. In our previous study [58], persons with MS had indicated that they preferred more collaborative activities rather than competing with others; this led us to exclude the use of competitive leaderboards [47-51] as a feature.

Behavioral Change

No single theory can explain the complexity of human behavior and this has been discussed in health intervention design literature [77-79]. Recommendations exist of using multitheory approaches for improved results [80], hence our combination of models.

Following TPB, persons with MS who would download a tool such as *More Stamina* would already have the intention to change. Their attitude toward fatigue, the way people they care about view managing their energy, and their perceived control about this behavior are clear. According to HBM, persons with MS will follow fatigue management techniques if they feel that it will help them avoid feeling fatigue. The use of checklists has been shown to produce improved outcomes in a number of health care–related and other disciplines [67,81]. Task management is in accordance to GST and is generally more effective for simple tasks with well-defined parameters, in part, because it is easier for a person to see the connection between effort and goal achievement [56]. By allowing persons with MS to set their own tasks, we give them a sense of volition (autonomy); completing their goals and receiving positive feedback increase their feelings of efficiency and success (competence), and sharing these achievements through social media allows for positive social interactions (relatedness). This is in line with SDT.

Usability Evaluation

A commonly cited cause for failures in health interventions is poor design [21,23,24]; usability factors are a major obstacle to their adoption. Effective usability evaluation improves predictability of products and saves development time and costs [43]. In our study, we assessed the usability of our design through heuristic evaluation involving 3 HCI researchers and addressed all resulting issues. Recommendations on heuristic evaluation state that 2 to 3 experienced evaluators or 3 to 5 less experienced evaluators are sufficient to find most usability problems [82,83].

Limitations

The findings of this study should be interpreted in the context of its limitations. The nature of design is a creative expression and thus it is an inherently subjective endeavor [84]. There are many ways in which design challenges can be addressed and design decisions may differ.

Goal setting and positive feedback are widely employed motivational methods. However, without a meaningful context, they may seem trivial and not effectively engage users. Also, although gamification is proposed as a method to compel continued use [45,46], there are studies that challenge that notion [85-88]. It is important to evaluate behavioral change interventions outcome to understand whether they are effective or not. This study is not focused on the evaluation of the behavioral change intervention, therefore, this is not addressed here but will be in future studies.

Some of the usability principles assessed are subjective by nature (eg, aesthetic and minimalist design), which may cause discrepancies in criteria. Although the number of evaluators used here is within conventions, involving a greater number or more experienced evaluators could have resulted in a different heuristic evaluation outcome. Usability research shows that heuristic evaluation is effective when evaluators are usability experts [82,89]. Further usability assessments with intended users would have provided valuable information.

Conclusions

In this paper, we illustrate how UCD thinking can help in designing mHealth solutions and the benefits and challenges that designers might face when using this approach. We

followed a design through research process where user requirements were obtained considering stakeholders' perspectives and the available scientific literature; design decisions were driven by evidence and BCM, resulting in an mHealth solution targeted for helping persons with MS in their fatigue management needs.

Future Research

The next step in our research is to develop an interactive version of the prototype and continue to explore its usability and validate its value proposition through user testing. We will conduct think-aloud protocols with groups of persons with MS to ensure no usability issues are present and conduct interviews to assess *More Stamina* 's value proposition. A pilot study of the mHealth solution effectiveness will shortly follow.

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Authors' Contributions

GG conceived, designed, and led the overall study conduct; led design efforts; carried out analysis and interpretation of the data; and drafted the manuscript. VM led prototyping and usability testing efforts and participated in overall study conduct, collection, analysis, and interpretation of study data. OR contributed to the analysis and interpretation of study data and usability testing, and reviewed and worked on the manuscript draft. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BCM: behavioral change models
CFS: Chalder Fatigue Scale

CHESS ITN: Connected Health Early-Stage Researcher Support System Initial Training Network
EDSS: Expanded Disability Status Scale
FSS: Fatigue Severity Scale
GST: goal-setting theory
HBM: health belief model
HCI: human-computer interactions
IT: information technology
mHealth: mobile health
MS: multiple sclerosis
PA: physical activity
Salumedia: Salumedia Tecnologias
SDT: self-determination theory
TPB: theory of planned behavior
UCD: user-centered design
USE: University of Seville, Spain

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Review

Quality of Publicly Available Physical Activity Apps: Review and Content Analysis

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Abstract

Background: Within the new digital health landscape, the rise of health apps creates novel prospects for health promotion. The market is saturated with apps that aim to increase physical activity (PA). Despite the wide distribution and popularity of PA apps, there are limited data on their effectiveness, user experience, and safety of personal data.

Objective: The purpose of this review and content analysis was to evaluate the quality of the most popular PA apps on the market using health care quality indicators.

Methods: The top-ranked 400 free and paid apps from iTunes and Google Play stores were screened. Apps were included if the primary behavior targeted was PA, targeted users were adults, and the apps had stand-alone functionality. The apps were downloaded on mobile phones and assessed by 2 reviewers against the following quality assessment criteria: (1) users' data privacy and security, (2) presence of behavior change techniques (BCTs) and quality of the development and evaluation processes, and (3) user ratings and usability.

Results: Out of 400 apps, 156 met the inclusion criteria, of which 65 apps were randomly selected to be downloaded and assessed. Almost 30% apps (19/65) did not have privacy policy. Every app contained at least one BCT, with an average number of 7 and a maximum of 13 BCTs. All but one app had commercial affiliation, 12 consulted an expert, and none reported involving users in the app development. Only 12 of 65 apps had a peer-reviewed study connected to the app. User ratings were high, with only a quarter of the ratings falling below 4 stars. The median usability score was excellent—86.3 out of 100.

Conclusions: Despite the popularity of PA apps available on the commercial market, there were substantial shortcomings in the areas of data safety and likelihood of effectiveness of the apps assessed. The limited quality of the apps may represent a missed opportunity for PA promotion.

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KEYWORDS

exercise; health behavior; mobile applications; health promotion; mHealth; eHealth review

Introduction

Background

Physical inactivity is an established independent risk factor for a range of serious health conditions including cardiovascular disease, diabetes mellitus, and cancer [1-3]. Physical activity (PA) is also associated with improved mental health [4,5]. The World Health Organization recommends 150 min of moderate or 75 min of vigorous intensity PA per week, yet 31.1% of adults globally fail to achieve this [6]. Behavior change interventions aiming to increase PA tend to have small to moderate effects, with sustainability of intervention effects not well established [7].

Within the new digital health care landscape, the rise of apps creates novel prospects for prevention opportunities and disease management [8]. Mobile health (mHealth) apps, as opposed to traditional face-to-face interventions, are more accessible [9] and provide a range of technology-enhanced features such as accelerometers, visualizations, tailored feedback, and reminders. In addition, recent data show that mobile phone access is now as high among ethnic minority groups in higher income countries as in the rest of the population [10], and the use of mobile phones is increasing steadily in older populations [11], thereby decreasing concerns about the effect of the digital divide on health inequalities. Hence, behavior change interventions delivered using mHealth apps could have the potential to reach a large proportion of the population, thus increasing the public health impact of their small effects [12].

The mHealth app industry has doubled in the last 2 years, with around 165,000 health apps available in the major app stores in 2016 [13]; many of them aiming to increase PA levels. Despite the wide distribution and popularity of health apps, many of them have been rapidly developed [14], and there is lack of evidence of their efficacy. For example, a meta-analysis published by Direito et al [15] found only 7 randomized controlled trials (RCTs) evaluating app intervention for PA and sedentary behavior. It is clearly not feasible for all PA apps to be evaluated by rigorous RCTs, and therefore, alternative methods of evaluating apps are needed. One way of assessing the likely effectiveness of apps is to assess the degree to which they use behavior change theory and adhere to PA guidelines. This research suggests that most PA apps only include a limited number of behavior change techniques (BCTs) [16-18], and they often fail to adhere to PA guidelines [19].

However, quality is about more than effectiveness, although there has been considerable debate about how exactly *app quality* should be defined, with a variety of frameworks available. Recent reviews by BinDhim et al [14] and Bardus et al [20] categorized and evaluated the methods used for quality assessment of apps. Both studies found a considerable variability in methods and measures used to review the quality of health apps. The approaches used to conceptualize and measure quality varied substantially, and the studies tended to focus on either the design quality or on the presence of evidence-based content but not both [20]. The authors called for more research to assess the quality of both design and content of health apps.

Health apps have the potential to be an important health care tool [21]; hence, health care quality indicators were considered appropriate to apply when assessing the quality of the apps. The concept of quality in health care is complex and multifaceted [22]. Maxwell [23] proposed six dimension of health care quality: accessibility (ease of access to all patient groups), relevance to the need of the community, effectiveness, equity (fairness in the distribution), acceptability, efficiency, and economy (desired health outcomes at the lowest cost). On the other hand, Donabedian [24] proposed a different categorization and argued for three crucial elements that pertain to the quality of health care: structure (facilities and health care professionals available), process (actions by which health care is provided), and outcomes (the results of the actions).

The dimensions of quality proposed by Maxwell and Donabedian were developed before the existence of mobile phones and apps and are perhaps more applicable to health care services provided at the point of need, that is, face-to-face. Potential new health care tools apps need a more concise approach, one that *High quality care for all*: *NHS Next Stage Review Final Report* [25] appears to provide. This report outlined the 10-year vision for the National Health Service (NHS) with strategies to improve the quality of care. In this report, high-quality health care was defined as being (1) safe, (2) effective, and (3) providing the most positive experience possible. These quality indicators are simple yet comprehensive and sufficiently flexible to apply to potential new health care tools such as PA apps.

Objective

In this study, we focused on the most popular apps, which we defined as being in the top rankings of the two major app stores. What constitutes the algorithm that determines the app ranking is unknown. However, variables that indicate popularity such as user ratings, volume of ratings and reviews, download and install counts, usage, and uninstalls are likely to contribute to the ranking in the app stores [26]. In addition, potential users are more likely to focus on the top results and rarely examine the search results thoroughly [27]. This method of defining popularity has been used in other studies assessing apps [28-30], and it was selected to gain a representative sample of apps that are most likely to be used and to simulate the user experience of browsing the store to select a health app.

The aim of this study was to assess the quality of publicly available PA apps. Specific objectives were to assess the safety, effectiveness, and provision of the most positive experience in the most popular PA apps.

Methods

Study Design

This study is a review and a content analysis of the most popular, publicly available PA apps on the market. *Quality and Risk of Bias Checklist for Studies That Review Smartphone Applications* was used to ensure that methods for apps' review are adequately described [14].

Textbox 1. Inclusion criteria.

Apps were included if

- Their main goal was to increase physical activity
- They were targeted at healthy adults
- They had stand-alone functionality

Textbox 2. Exclusion criteria.

Apps were excluded if

- The app focused on multiple behaviors, as it would have been difficult to isolate the content pertaining to physical activity
- The target population was patients with a specific health condition, as these users were likely to have different needs to healthy adults
- They were sold as part of a pack ("bundle"), as it would not have been possible to assess the popularity of the individual apps in this bundle

Sample Identification

A sample of top-ranked 400 PA apps was obtained from the UK's versions of the iTunes and Google Play stores on October 17, 2016. As previous research indicated an association between price and inclusion of BCTs [18,31,32], both free and paid apps were included in the study. Apps' titles and descriptions from the "Health and Fitness" category in both stores (100 iTunes free + 100 iTunes paid + 100 Google Play free + 100 Google Play paid) were screened against the inclusion and exclusion criteria. (Textboxes 1 and 2)

Sample Assessment

From the apps identified, 65 were randomly selected for the assessment using the random number generator function in Excel (Microsoft). As the largest subset of health apps on the market (30%) [13] target PA, it was expected that a high number of apps would fulfil the inclusion criteria. We were undertaking a parallel study to assess the association between quality indicators and user rating, and the choice of n=65 was based on the power calculation for that parallel study.

The apps were downloaded onto an iPhone SE and 6 (running iPhone operating system [iOS, Apple Inc] 10.2.1 and 9.3.4 software, respectively) and Android Samsung Galaxy S6 and J5 (running 6.0.1 or 5.1.1 software, respectively) and assessed using a pro forma evaluation. Each app was left running in the background for 2 days for the assessors to explore any reminders or notifications. If two apps were identified as duplicates and there appeared to be consistency of design and content between both operating systems, the apps were assessed on an iPhone only. The sample identification and assessment was conducted independently by two reviewers (PB and GA), and any discrepancies were resolved through discussion.

Data Extraction

Descriptive Data

We extracted the following descriptive data from both app stores: app's name, brief description, type of PA targeted (eg, running, walking, and whole body workout), platform on which the app was available, developer's name, rank, number of ratings, cost, size, last update, and version.

Application of Health Care Quality Indicators to Physical Activity Apps

The methods of operationalizing the three quality indicators of safety, effectiveness, and provision of the most positive experience possible for the selected apps is described below.

Safety of Physical Activity Apps

For the safety indicator of health apps, privacy and security of users' data were considered. The privacy and security assessment was based on the recommendations of the Information Commissioners Office [33] and Online Trust Alliance [34]. It comprises of 8 questions evaluating the availability, accessibility of privacy policy, data gathering and sharing practices, and data security as is discussed in the privacy statement (see Multimedia Appendix 1 for data privacy and security assessment).

Likelihood of Effectiveness of Physical Activity Apps

As research on PA app efficacy is lacking, the likelihood of effectiveness was assessed by quantifying the presence of BCTs. Furthermore, many quality assessment procedures include an evaluation of the intervention development processes [35,36]. For example, involving key stakeholders in the development process is important to produce an intervention that meets user needs and increases the likelihood of intervention implementation [37]. Hence, data on the organizational affiliation of the developer, as well as expert and user involvement in the development process was collected. In addition, any evidence of scientific evaluation was also extracted.

Behavior Change Techniques

The BCT taxonomy v1 [38] was used to assess the number of BCTs in each app and the frequency of each BCT in the app sample overall. The coding manual provides guidelines to investigate the presence of 93 BCTs in behavior change interventions and has been used in previous studies that aimed to characterize BCTs in health apps [16,28,39-41]. In line with the instructions, we coded each BCT as Absent, Present + (BCT present in all probability but evidence unclear), and Present ++ (BCT present beyond all reasonably doubt).

Table 1. The application of the health care quality indicators to physical activity apps.

Quality indicator of health care	Applying the indicator to health apps
Safety	Privacy and security of data
Effectiveness	Behavior change techniques (Michie et al [38])
	Development and evaluation process: Organizational affiliation; Expert involvement; User involvement; and Evidence of scientific evaluation
Positive experience	User ratings
	Usability

Quality of Development Process and Evidence for Evaluation

The evaluation of the quality of development process was based on the information provided in the app stores, the app website (if existent), and within the app itself. The following characteristics of the app content development were extracted: organizational affiliation (university, medical, government, or other nonprofit institutions); expert involvement (eg, fitness expert, behavior change specialist, and medical professional); and evidence for user involvement in the development of an app. The evidence for app evaluation was assessed by searching the name of the app in the following scientific databases: PubMed, ACM Digital Library, IEEE Xplore, and Google Scholar.

Provision of the Most Positive Experience in Physical Activity Apps

The provision of the most positive experience was operationalized using (1) the user ratings in app stores and (2) through formal usability assessment conducted by the two reviewers using the System Usability Scale (SUS) [42]. The average star rating (range: 1-5 stars) was calculated by summing the number of stars and dividing them by the number of users who submitted ratings. SUS is a valid and reliable measure of overall usability (from 0-100) and consists of 10 items that are ranked on a 5-point Likert scale, from *strongly disagree* to *strongly agree*. The wording of the 8th statement was changed from *cumbersome* to *awkward* as recommended [43-45]. Second, the word *system* was replaced by *app* to make the scale applicable to the sample in this study. The interpretation of the SUS score used the thresholds proposed and validated by Bangor et al [43].

Summary of Application of Quality Indicators

The application of health care quality indicators to apps is summarized in Table 1.

Interrater Reliability

Interrater reliability for the presence or absence of the BCTs was ascertained by calculating Cohen kappa statistic [46] for each item. In addition, prevalence-adjusted bias-adjusted kappa (PABAK) [47] was assessed for the presence or absence of BCTs. The occurrence of high prevalence of negative agreement (when both rates agree that the BCT is absent) is very likely in the context of inclusion of BCTs in an app. When high prevalence of the identical response is seen, the kappa value results in low proportion of agreement, although the observed agreement is high [48]. The a priori strategy for assessing the sample was to complete the extraction of data for 10 apps to resolve any discrepancies in understanding of the measures before extracting the rest of data. Hence, the interrater reliability was assessed on 55 apps.

Statistical Analysis

The number of BCTs in the apps was summarized using the mean, standard deviation, median, 25th and 75th percentiles, and the maximum and minimum. Similar statistics were used to summarize user ratings, cost, size, and SUS score. Proportions were used to summarize the variables: data privacy and security, organization affiliation, expert and user involvement, and the evidence of evaluation in peer-reviewed journals.

The summary descriptive tables were presented for each store for free and paid apps separately and in total as app stores have separate rankings based on the cost. To assess if there was a difference in store characteristics between free and paid apps, *t* tests were used to compare the average user ratings, size, and the number of BCTs; Wilcoxon test was used to compare the number of ratings; and Fisher exact was used for last update (<3 months, 3-6 months, and >6 months), organizational affiliation, expert and user involvement, and presence of any peer-reviewed studies.

Results

Sample Identification

Out of 400 apps, 244 apps were excluded (209 apps did not target PA, 22 apps needed a peripheral device or paid membership to use the app, and 13 apps focused on multiple health behaviors), and 156 met the inclusion criteria (see Figure 1). A total of 31 duplicates were found. Subsequently, a sample of 125 unique apps was identified. A total of 65 apps, 32 free and 33 paid, were assessed.

Sample Characteristics

Descriptive data for the app sample are presented in Tables 2 and 3, whereas the data for each app separately is presented in Multimedia Appendix 2. There were no statistically significant differences in the number of ratings, cost, size, and last update between the free and paid apps in either iTunes or Google Play store.

Figure 1. Flowchart of the apps included in the analysis. PA: physical activity.

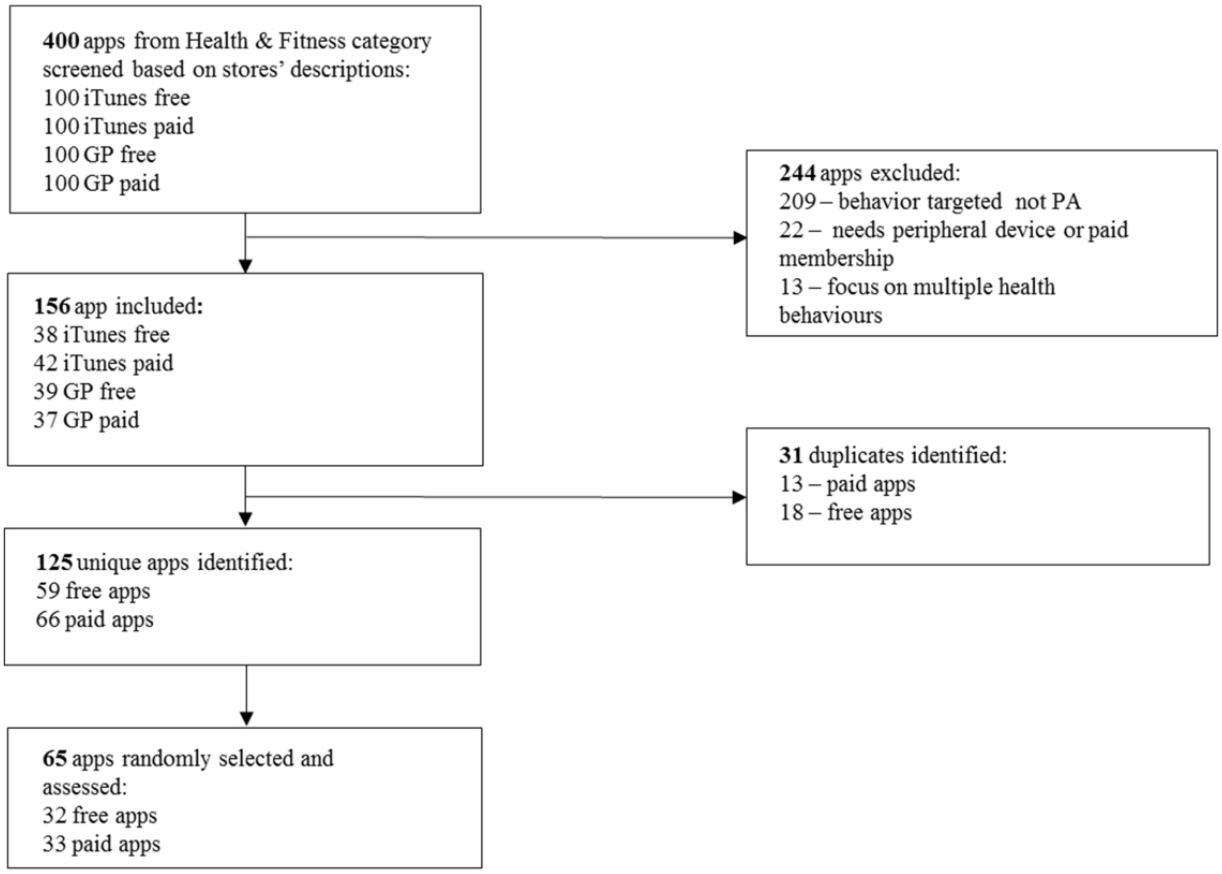

Table 2. Descriptive data for iTunes store.

Descriptive data for iTunes	Free—iTunes (N=21)	Paid—iTunes (N=24)	Total—iTunes (N=45)	*P* value
Number of ratings				
Mean (SD)	3408.4 (5848.4)	773.7 (1187.0)	2031.2 (4289.7)	.49
Median	758	127	550	
25-75 percentile	438.0-3698.0	47.0-1247.0	85.5-1719.0	
Min-max	14-24530	11-3845	11-24530	
Cost—iTunes (GBP[a])				
Mean (SD)	N/A[b]	2.5 (1.5)	N/A	
Median	N/A	2.3	N/A	
25-75 percentile	N/A	1.5-3.0	N/A	
Min-max	N/A	1-8	N/A	
Size of app (megabyte)				
Mean (SD)	88.4 (49.8)	94.9 (75.4)	91.8 (64.1)	.74
Median	74.3	83.3	82.2	
25-75 percentile	52.0-131.0	61.7-102.0	58.1-104.0	
Min-max	11-164	9-376	9-376	
Last update				
<3 months, n (%)	13 (61.9)	7 (29.2)	20 (44.4)	.09
3-6 months, n (%)	3 (14.3)	7 (29.2)	10 (22.2)	

[a]GBP: British pound.

[b]N/A: not applicable.

Table 3. Descriptive data for Google Play store.

Descriptive data for Google Play	Free—Google Play (N=21)	Paid—Google Play (N=16)	Total—Google Play (N=37)	*P* value
Number of ratings				
Mean (SD)	119000.7 (165085.0)	14457.9 (43700.8)	73793.0 (136723.2)	>.99
Median	44923	1720.5	5856	
25-75 percentile	5827.0-199596.0	384.5-6452.0	1475.0-78204.0	
Min-max	206-625077	7-177277	7-625077	
Cost—Google Play (GBP[a])				
Mean (SD)	N/A[b]	3.6 (2.3)	N/A	
Median	N/A	2.7	N/A	
25-75 percentile	N/A	2.3-5.0	N/A	
Min-max	N/A	1-9	N/A	
Size of app (megabyte)				
Mean (SD)	28.4 (21.2)	43.4 (34.2)	34.9 (28.2)	.11
Median	26.8	31.5	29.6	
25-75 percentile	12.2-38.5	27.7-54.0	15.4-43.9	
Min-max	2-73	1-145	1-145	
Last update				
<3 months, n (%)	16 (76)	7 (44)	23 (62)	.12
3-6 months, n (%)	1 (5)	3 (19)	4 (11)	
>6 months, n (%)	4 (19)	6 (38)	10 (27)	

[a]GBP: British pound.

[b]N/A: not applicable.

The apps were categorized into five groups according to their primary focus. These were as follows: workout apps that demonstrate various exercises (31/65, 47%), tracking of movement apps that provide mapping of the running or walking or cycling routes (13/65, 20%), running programs that have prespecified goals reached by incremental increase in run-to-walk ratio (12/65, 18%), pedometers-based apps that count steps (6/65, 9%), and interval timers that enable the user to time their work or rest period (3/65, 4%).

Data Privacy and Security

Availability and Accessibility of Privacy Policy

The privacy policy was available for 46 (70%, 46/65) apps overall. In one case, the link to the privacy policy was provided but did not work, and the app was indicated as not having a privacy policy. Of those that had privacy policy, only 4 (8%, 4/46) apps had a short form privacy and security notice that highlighted key data practices that were disclosed in detail in the full privacy policy (see Table 4). There were nine instances where the short form notice was not applicable because of the policy already being concise. Multilingual policies were rare, with only 5 apps having a policy in another language. Apps that were developed outside the United Kingdom were more likely to provide multilingual policies.

Data Gathering and Sharing

Most of the apps (80%) reported collecting personally identifiable information. In one instance, the developer did not discuss the data gathering practices. In 34 instances (80%, 34/46), the developers stated that they share the data they gather with 3rd parties. There were two instances where the developer did not discuss data sharing practices. In many cases, the policies stated that “data shall not be shared, except for” followed by a list of exceptions that were vague and general. In these instances, the reviewers considered that the data were shared by the 3rd party.

Data Security

Only 41% (19/46) of the apps described how the users’ data were protected. The privacy policies stated that data safety is important to their practices but did not provide information on how data security was ensured.

The Presence of Behavior Change Techniques

There was “almost perfect” agreement between the reviewers for the coding of BCT presence or absence: PABAK=0.94, 95% CI 0.93-0.95, kappa=.78 (“substantial”), 95% CI 0.75-0.81.

Table 4. Data gathering, sharing and security as described in the privacy policy (within those that had the policy, N=46). Note: 29% (19/65) did not have a privacy policy available.

Data gathering, sharing, and security as described in the privacy policy	Free (N=24), n (%)	Paid (N=22), n (%)	Total (N=46), n (%)
Is the privacy policy available without the need to download the app?			
Yes	24 (100)	22 (100)	46 (100)
Is the privacy policy available within the app?			
No	13 (44)	16 (55)	29 (63)
Yes	11 (64)	6 (35)	17 (36)
Is there a short form notice (in plain English) highlighting key data practices?			
No	17 (70)	16 (72)	33 (71)
Yes	4 (16)	0 (0)	4 (8)
Not applicable	3 (12)	6 (27)	9 (19)
Is the privacy policy available in any other languages?			
No	20 (83)	21 (95)	41 (89)
Yes	4 (16)	1 (4)	5 (10)
Does the app collect personally identifiable information?			
No	2 (8)	6 (27)	8 (17)
Yes	21 (87)	16 (72)	37 (80)
Not specified	1 (4)	0 (0)	1 (2)
Does the app share users' data with a 3rd party?			
No	2 (8)	8 (36)	10 (22)
Yes	21 (87)	13 (59)	34 (74)
Not specified	1 (4)	1 (4)	2 (4)
Does the app say how the users' data security is ensured? For example, encryption, authentication, and firewall			
No	13 (54)	14 (63)	27 (58)
Yes	11 (45)	8 (36)	19 (41)

Table 5. Descriptive statistics for the inclusion of the behavior change techniques (BCTs).

Inclusion of the BCTs	Free (N=32)	Paid (N=33)	Total (N=65)	*P* value
Total BCTs				
Mean (SD)	6.6 (3.0)	7.5 (2.9)	7.0 (2.9)	.21
Median	7	8	8	
25-75 percentile	5.0-8.0	6.0-10.0	5.0-9.0	
Min-max	1-12	1-13	1-13	

The total number of BCTs for free and paid apps sample was similar (see Table 5). Every app contained at least one BCT, and the maximum number of BCTs was 12 for free and 13 for paid apps. The median number of BCTs was 7 for free and 8 for paid apps (see Multimedia Appendix 3 for the graph of the distribution of the BCTs in apps).

Figure 2 shows the frequency of the common BCT groups. The "Feedback and monitoring" group was the most common, with 92.3% of apps containing at least one BCT of this group, most commonly "Feedback on behavior" and "Feedback on outcome(s) of behavior" BTCs. "Goals and planning" ("Goal setting" and "Action planning" BCTs) were also well represented at 84.6%. More than half of the apps included BCTs from the "Comparison of behavior" group (66.2%), which most likely was "Demonstration on the behavior" (see Figure 3 for the examples of the app features that included BCTs from the most common BCT groups). "Social support" (64.6%), "Shaping knowledge" groups (60%), and "Associations" (46.2%) were common, but only one BCT from each of these groups were present. "Reward and threat" group (53.8%) was common with two BCTs only ("Social reward" and "Nonspecific incentive"). Other BCT groups were rare: less than 15% of apps contained

BCTs from the "Comparison of outcomes" group; "Natural consequences" and "Antecedents" represented 10.8% and 6.2% of the total BCTs, respectively. The remaining BCT groups were nonexistent in the PA apps. Multimedia Appendix 4 presents the frequency of individual BCTs within the groups' BCTs (BCTs that occurred in at least five apps are shown).

Quality of App Development and Evaluation Process

Only 1 app had a noncommercial affiliation, *One You Couch to 5K*, which was developed by Public Health England (see Table 6). None of the apps reported user involvement during development. Twelve out of 65 apps (4 free and 8 paid) consulted with experts to design the content of the app. Nine out of 23 free apps (28.1%) had a study associated with the apps published in a peer-reviewed journal. In comparison, for only 3 paid apps (9.1%), there was a peer-reviewed study found.

Positive Experience

User Ratings

The median user rating in iTunes was 4.4 and 4.5 in Google Play and did not differ between free and paid apps in either stores (see Table 7).

In both stores, the 25th percentile was around 4 stars (4.0 in iTunes and 4.4 in Google Play), suggesting that the user ratings tended to be high, and only 25% of ratings were below 4 stars. The histograms of star ratings in both stores (Figure 4) showed the skewness of the star average distribution.

Usability

The average SUS score for the apps was similar for both free and paid apps, with median of 86.3 (see Table 8). Using the descriptors suggested by Bangor et al [43], the score can be described as "excellent." Fifty percent of the total average SUS score fell between 75.0 and 92.5, and 25% had a score higher than 92.5, suggesting that more than 75% of the app sample assessed could be described as having "good" to "excellent" usability. See Multimedia Appendix 5 for the graph of the distribution of the SUS score averaged between the two reviewers.

Figure 2. Frequency of behavior change techniques (BCTs) incorporated by physical activity (PA) apps, presented by BCT groups.

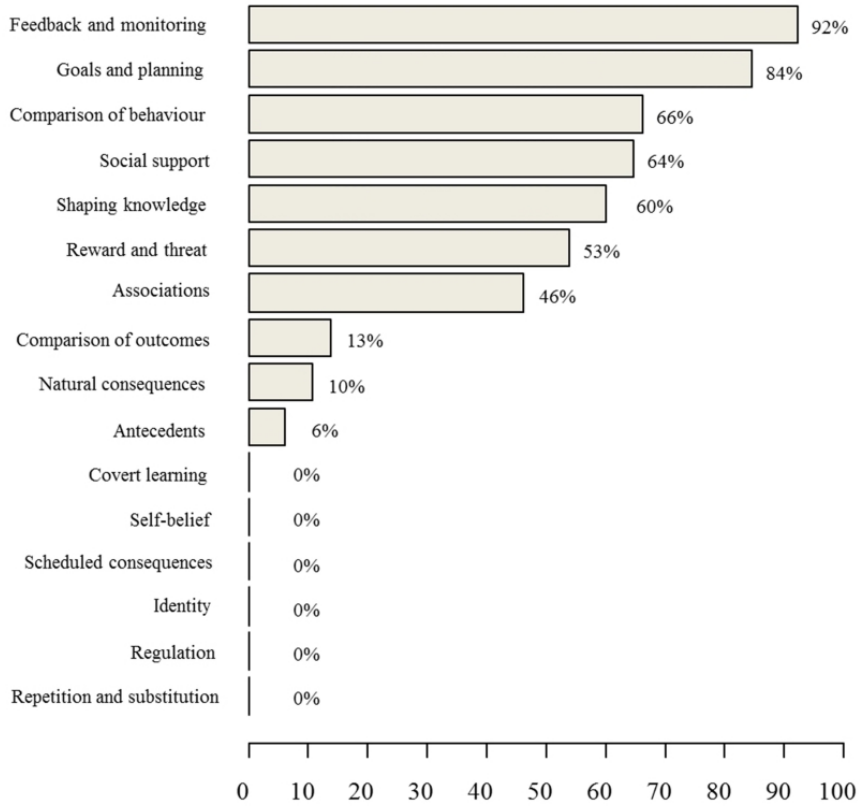

Figure 3. Examples of the most common behavior change techniques (BCTs) from the most frequent BCT groups: (1) goals and planning: 1.1 Goal setting (behavior), (2) feedback and monitoring: 2.2 Feedback on behavior, and (3) comparison of behavior: 6.1 Demonstration of the behavior.

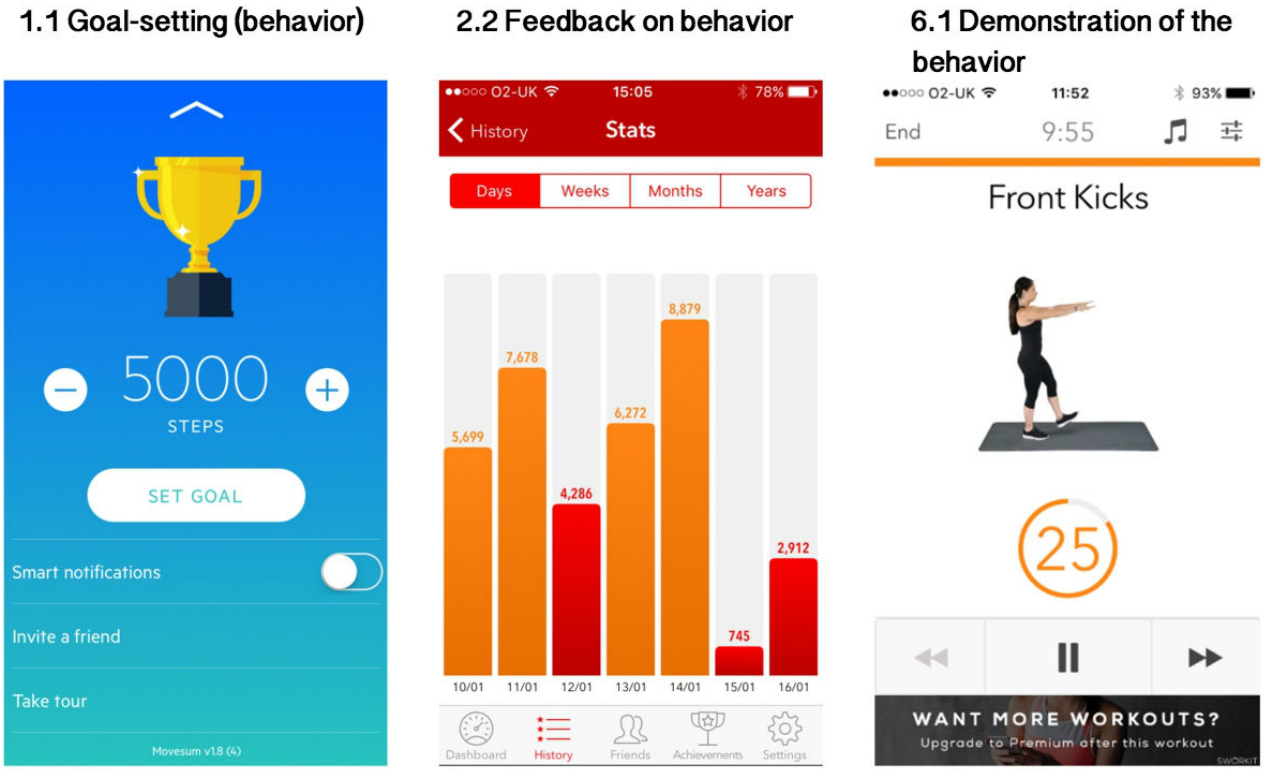

Table 6. Descriptive data for the quality of app development and evaluation process: organizational affiliation, expert and user involvement, and evidence of evaluation in peer-reviewed journals.

The quality of app development and evaluation process	Free (N=32), n (%)	Paid (N=33), n (%)	Total (N=65), n (%)	*P* value
Any affiliation				
Commercial	31 (96)	33 (100)	64 (98)	.49
Government institution	1 (3)	0 (0)	1 (1)	
Any expert				
No	28 (87)	25 (75)	53 (81)	.34
Yes	4 (12)	8 (24)	12 (18)	
Any user involvement				
No	32 (100)	33 (100)	65 (100)	
Any peer journal				
No	23 (71)	30 (90)	53 (81)	.06
Yes	9 (28)	3 (9)	12 (18)	

Table 7. Descriptive statistics for user ratings (1-5 stars) in iTunes and Google Play.

User ratings	Free	Paid	Total	*P* value
iTunes	(N=21)	(N=24)	(N=45)	
Mean (SD)	4.1 (0.8)	4.3 (0.6)	4.2 (0.7)	.22
Median	4.4	4.6	4.4	
25-75 percentile	4.0-4.6	4.0-4.8	4.0-4.6	
Min-max	2-5	3-5	2-5	
Google Play	(N=21)	(N=16)	(N=37)	
Mean (SD)	4.4 (0.5)	4.4 (0.3)	4.4 (0.4)	.90
Median	4.5	4.5	4.5	
25-75 percentile	4.4-4.6	4.4-4.6	4.4-4.6	
Min-max	2-5	4-5	2-5	

Figure 4. Distribution of user ratings in iTunes and Google Play.

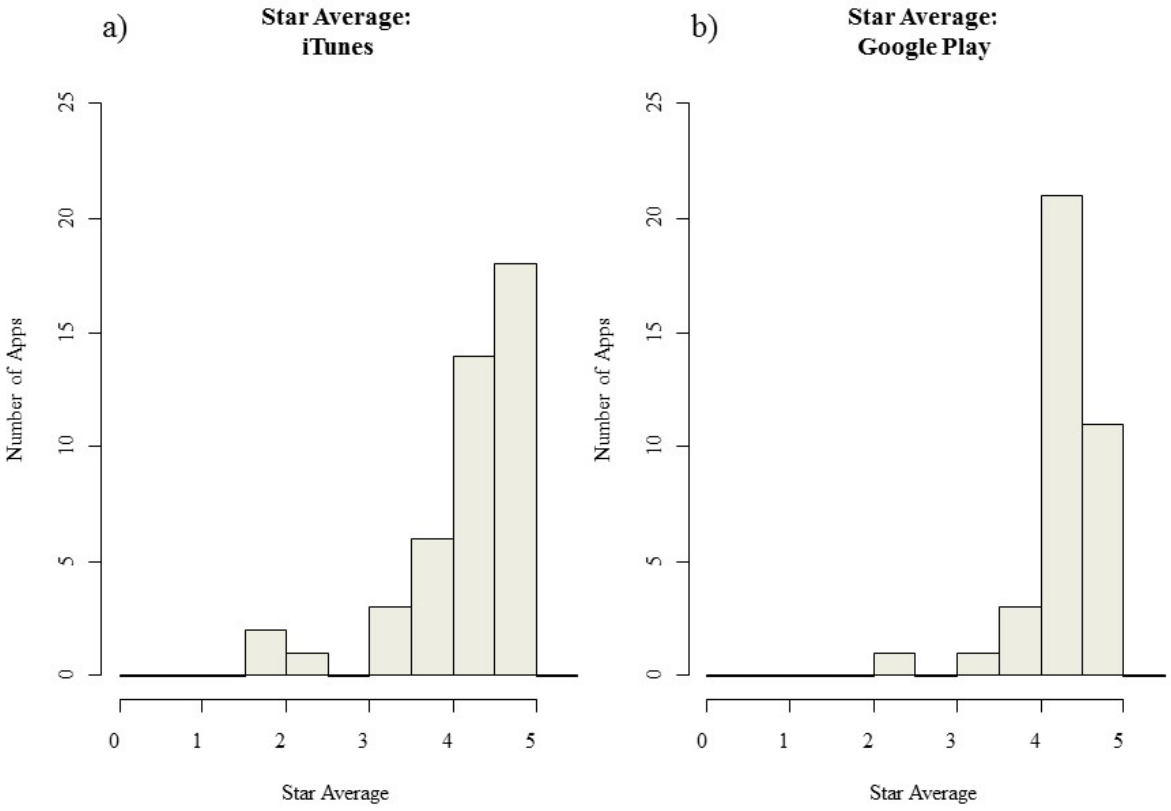

Table 8. Descriptive data for the System Usability Scale (SUS) assessment.

Usability assessment	Free (N=32)	Paid (N=33)	Total (N=65)	*P* value
SUS score				.17
Mean (SD)	81.3 (12.6)	85.5 (11.9)	83.4 (12.4)	
Median	85	87.5	86.3	
25-75 percentile	71.9-91.3	80.0-93.8	75.0-92.5	
Min-max	53-100	58-100	53-100	

Discussion

Principal Findings

This study described the most popular PA apps on the market, focusing on the quality determinants of safety (data privacy and security), effectiveness (BCTs and development and evaluation quality), and provision of the most positive experience possible (user ratings and usability). Overall, our findings suggest that most of the apps in this sample were of reasonable quality in terms of the user experience, but there were substantial shortcomings in the areas of safety and effectiveness. The assessment of data privacy and security showed that the privacy policy was not available for 29.2% of the apps. Most apps collected personally identifiable information, shared users' data with a third party, and more than half of the apps did not specify how they ensure data security. Every app contained at least one BCT, with an average of 7. The maximum number of BCTs was 13, and the most common BCTs related to provision of feedback on behavior. All but one app had commercial affiliation, 12 consulted an expert, and none reported involving users in the app development. Only 12 of 65 apps had a peer-reviewed study connected to the app but only one app was assessed for efficacy in a trial [49]. User ratings were high, with only a quarter of the ratings falling below 4 stars. Similarly, the usability scores were "good" to "excellent." There was no statistically significant difference between free and paid apps on the characteristics or quality indicators.

Safety of Apps

The assessment of privacy policy showed that privacy and security of users' data could be substantially improved. Our results are consistent with previous studies assessing data safety. Huckvale et al [8], who assessed the apps from the NHS Apps Library, found that 20% of apps did not have privacy policy, and most of the apps breached users' data privacy and security. Collecting and analyzing consumer data by app developers can have advantages for the users, such as personalization and improvement of the products [35]. However, the information about these practices ought to be transparent and understandable [36] to enable the potential user to make an informed decision to download the app. Regulatory oversight concerning data protection is challenging because of the large scale of the app market. In consequence, ensuring the privacy and security of data is left in the hands of app developers [50].

Likelihood of Effectiveness

The apps in the review contained, on average, 7 BCTs. The results of this study are similar to those found in previous reviews of PA apps: Middelweerd et al [17] found that, on average, 5 BCTs were used in each app; Conroy et al [16] reported between 1 and 13 BCTs with a mean of 4.2; and a study using the same BCT taxonomy as the one in this study found, on average, 6.6 BCTs [18].

The most common BCTs were feedback and monitoring, goal setting, and action planning. These self-regulation strategies have been shown to be effective in increasing PA behavior [51,52]. However, the BCTs from 9 out of 16 BCT groups were rare or nonexistent in the apps assessed, and the BCTs that were present constituted 14% of the current BCT taxonomy.

The effect of the number of BCTs on efficacy of the interventions remains inconclusive. Although there is some evidence that higher number of BCTs produces larger effect sizes in Web-based interventions [53], others show no effect [51]. The evidence of what BCTs are most likely to increase the likelihood of behavior change is unknown. It is possible that certain BCTs are more efficacious when present together producing a synergistic effect [54]. The use of variety of BCTs groups, as well as the techniques within the BCT group, would theoretically increase effectiveness by addressing various barriers to PA. For example, within the "Goals and planning" BCT group, only 3 out of 9 BCTs were utilized. Implementing features that utilize other BCTs that enable goal setting and planning (eg, problem-solving technique, asking the user to commit to their goal, and providing an opportunity for the user to review their goal) might increase the likelihood of effectiveness of the app.

The use of evidence and theoretical frameworks is vital in developing behavior change interventions [55]. The COM-B (capability, opportunity, motivation, and *behavior*) model of behavior change [56] enables developers to systematically identify the barriers and facilitators of the behavior targeted and to select intervention components that will address these barriers to increase the likelihood of behavior change.

The results suggest that the quality of the app development and evaluation process could be improved. We did not find any evidence of user involvement, and most apps were commercially developed with the rare involvement of experts. Similar results were found in previous reviews [28,57], and there is evidence to suggest that expert involvement predict the number of app download [58]. Indeed, the user-centered design framework stresses the importance of understanding the contextual experiences of potential users, as well as inclusion of multidisciplinary skills and perspectives when developing products and services. Our results also support previous research showing the lack of evidence for scientific evaluation of the apps on the market [59,60]. We found only 12 studies in peer-reviewed journals that were associated with the apps. However, only one app was used in a pragmatic RCT [49], and the study was not conducted by the app developer.

Positive Experience

The usability of the apps reviewed was high. Likewise, user ratings of the PA apps were high, with only a quarter of the ratings receiving less than 4 stars. Similarly, Mendiola et al [61] found that usability was related to user ratings in a general sample of health apps. The competition for customer in the app stores is high, with 90% of apps in the app stores not attracting enough attention to feature in the ranking of the app stores and consequently not visible for the user, called "App Zombies" [62]. High-quality graphic design, visual appeal, and ease of use are more likely to attract potential customers to download and engage with the app. However, it is unknown whether these variables relate to effectiveness of the apps. There is evidence to suggest that Web-based interventions with higher usability tend to be more effective [54]. However, continued engagement

with an app may suggest engagement with the intervention or unhealthy dependence [63].

Strengths

The strengths of this study include a systematic approach to sample identification and assessment. First, the sample of apps was identified by screening 400 apps in two major app distribution platforms, including both free and paid apps. Second, the sample was identified and assessed by 2 independent reviewers. Third, the assessment tools covered various aspects of quality, both inclusion of theory as well as user experience using subjective (user ratings) and objective (usability) measures.

Limitations

First, it is unknown what variables are included in the ranking algorithm of the top apps from which the sample was selected. It is likely that usage data and user ratings comprise the ranking [26], but other unknown variables may also be included. Second, the possibility that user ratings were influenced by fake reviews cannot be excluded. [64,65]. However, there is a reliance on genuine users of the app to mark it down if the app does not live to their expectations, and this review included popular apps with high number of ratings (2.8 million). Third, data privacy and security assessment was limited to the analysis of the policy. There is evidence of inconsistency between the policy statement and the actual practices of app developers [8]. Fourth, the quality of app development process was based on the information provided in the app stores, the app website, and within the app itself; hence, it is possible that some data were missed if they were not available on the Web. Finally, the evidence for app evaluation was assessed by searching the name of the app in the popular scientific databases. If the name of the app was absent in the title or abstract, then the relevant paper would not have been found.

Implications

More studies are needed to assess what predicts higher user rating. It is unknown what features or characteristics of apps users like and perceive to be effective in increasing their PA. It is possible that there is a discrepancy between what is liked and what is more likely to be effective. Second, research is needed to understand the use of PA apps to design effective digital tools. There is little knowledge concerning how users adopt these apps into their routines and what are the facilitators and barriers to increasing PA using apps. Third, the optimal number of BCTs in PA app remains unknown. It is likely that different BCTs may be more suitable for different modes of delivery (face-to-face, Web-based, and app), For example, social support might produce better results when delivered face-to-face rather than via an app. Alternatively, automatic monitoring and feedback on PA in apps can facilitate self-regulation and may be considered as a more efficient method than self-monitoring using diaries.

Although popularity of the apps is high, health care professionals and potential users need to be aware of the limitation in the safety of personal data, as well as the limitation in the quality of the apps to change behavior. Currently, it is not possible to recommend apps that are most effective, but attempts to create a database of high-quality apps are in progress. For example, the National Information Board is developing an app accreditation model that consists of a 4-stage assessment framework that aims to establish a database of high-quality health apps [66].

Conclusions

This study examined the quality of the most popular PA apps currently available on the market. Although usability and user ratings of app were high, there was a concerning lack of safety controls for users' personal data for the majority of the apps, the apps included limited number of BCTs that mostly related to feedback on behavior, and the quality of the content and development processes were suboptimal. The technological development and the potential for profit far outpaced the research on the ability of these apps to support PA behavior change. With 165,000 apps on the market, this represents a loss of opportunity for health promotion on a large scale.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Data privacy and security assessment based in the content of privacy policy.

[PDF File (Adobe PDF File), 99KB - mhealth_v6i3e53_app1.pdf]

Multimedia Appendix 2

Individual-level data for the sample of apps assessed.

[PDF File (Adobe PDF File), 649KB - mhealth_v6i3e53_app2.pdf]

Multimedia Appendix 3

Graph of the distribution of the BCTs in PA apps.

[JPG File, 52KB - mhealth_v6i3e53_app3.jpg]

Multimedia Appendix 4

Frequency of individual BCTs within the groups BCTs (BCTs that occurred in at least five apps are shown).

[JPG File, 217KB - mhealth_v6i3e53_app4.jpg]

Multimedia Appendix 5

Graph of the distribution of the SUS score averaged between the two reviewers.

[PDF File (Adobe PDF File), 101KB - mhealth_v6i3e53_app5.pdf]

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Abbreviations

BCT: behavior change technique
mHealth: mobile health
NHS: National Health Service
PA: physical activity
PABAK: prevalence-adjusted bias-adjusted kappa
RCT: randomized controlled trial
SUS: System Usability Scale

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Review

Consumer Mobile Apps for Potential Drug-Drug Interaction Check: Systematic Review and Content Analysis Using the Mobile App Rating Scale (MARS)

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Abstract

Background: General consumers can now easily access drug information and quickly check for potential drug-drug interactions (PDDIs) through mobile health (mHealth) apps. With aging population in Canada, more people have chronic diseases and comorbidities leading to increasing numbers of medications. The use of mHealth apps for checking PDDIs can be helpful in ensuring patient safety and empowerment.

Objective: The aim of this study was to review the characteristics and quality of publicly available mHealth apps that check for PDDIs.

Methods: Apple App Store and Google Play were searched to identify apps with PDDI functionality. The apps' general and feature characteristics were extracted. The Mobile App Rating Scale (MARS) was used to assess the quality.

Results: A total of 23 apps were included for the review—12 from Apple App Store and 11 from Google Play. Only 5 of these were paid apps, with an average price of $7.19 CAD. The mean MARS score was 3.23 out of 5 (interquartile range 1.34). The mean MARS scores for the apps from Google Play and Apple App Store were not statistically different (P=.84). The information dimension was associated with the highest score (3.63), whereas the engagement dimension resulted in the lowest score (2.75). The total number of features per app, average rating, and price were significantly associated with the total MARS score.

Conclusions: Some apps provided accurate and comprehensive information about potential adverse drug effects from PDDIs. Given the potentially severe consequences of incorrect drug information, there is a need for oversight to eliminate low quality and potentially harmful apps. Because managing PDDIs is complex in the absence of complete information, secondary features such as medication reminder, refill reminder, medication history tracking, and pill identification could help enhance the effectiveness of PDDI apps.

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KEYWORDS

drug interactions; telemedicine; mobile applications; smartphone; consumer health informatics; consumer health information

Introduction

Potential drug-drug interactions (PDDI) have been a prevalent source of preventable problems that can occur in any age group and increase costs to the health care systems [1]. A PDDI occurs when an individual is prescribed two drugs that are known to interact. An occurrence of drug-drug interaction (DDI) is defined as a clinical alteration of the exposure or response to a drug as a result of coadministration. DDIs can be clinically relevant when the result of the interaction warrants the attention of health

care professionals (HCPs). When the outcome of the DDI is harmful, it is referred to as an adverse drug reaction (ADR) [2]. DDIs have a profound impact on the safety of patients, and it has been found to be involved in 26% of all ADR-related hospital admissions [3]. Furthermore, in the United States, emergency visits because of ADR cost in average US $3704 per patient [4,5], demonstrating a huge economical impact.

Most PDDIs are preventable, but it remains a significant problem to patients and the health care system [3,6]. It has been observed that physicians are not always aware of clinically significant drug interactions [7,8] and may underestimate the effects of PDDIs [9]. Other factors such as high workload in pharmacy could also lead to higher risk of PDDIs for patients [10,11]. DDIs have also been identified as a significant portion of the overall ADRs resulting in hospitalization among older adults [12].

One possible solution that has been proposed is to use a decision support system to detect and avoid PDDIs [7,9]. With the rise of smartphones and mobile apps, decision support systems for PDDIs are now within the reach of consumers and patients and no longer exclusive to HCPs. This is an opportunity that can engage and empower patients by providing necessary tools to detect, avoid, and report ADR events stemming from DDIs [13-17]. The potential benefit for older adults with polypharmacy—the use of multiple medications—is deemed greater because of multiple prescribing providers involved in the care, which is a substantial risk factor for medication errors and ADR events [18].

Mobile health (mHealth) apps with PDDI decision support are not subject to the Food and Drug Administration regulation [19], and this may pose a substantial threat to the safety of consumers and patients. To our knowledge, the quantity, features, characteristics, or efficacy of the available PDDI mHealth apps on the market have never been systematically assessed. Therefore, understanding the characteristics of these mHealth apps is important in planning future interventions or policies aiming at patient-centered care and patient safety. This study systematically reviewed and assessed PDDI decision support mHealth apps available in Canada through the Google Play Store (Google Inc, Canada) and Apple's App Store (Apple Inc, Canada) using the Mobile App Rating Scale (MARS) [20].

Methods

Systematic Review Design

This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses systematic review protocol [21] as closely as possible, but it deviated in few instances because of the characteristics of mHealth app databases, which differ from scholarly reference databases for published articles. To ensure the review process is transparent and replicable, the detailed descriptions of each step are provided below.

App Search Strategy

Our review aimed to search apps that were publicly available to Canadians in English. Two most popular mobile app databases, Apple's App Store and the Google Play Store, which account for over 80.0% of mobile apps market in 2016 [22], were searched in this study.

This study developed a keyword search procedure to identify potentially eligible apps (Textbox 1). First, the searcher was instructed to log out from the Google account on a browser to prevent any personalized search results. Apple's App Store and the Google Play Store were searched with the search terms related to drug interactions. The search terms were specifically developed to be in all lower case letters and in quotations for consistent and comprehensive search results. As operating systems and apps are updated routinely, searches on both stores were conducted on the same day in December 2016. Additionally, the searches were performed on a designated set of devices and the same network to obtain consistent search results and avoid deviations by personalized search results [23]. Search results were extracted and saved in a spreadsheet for the next stage of app selection.

App Selection

Following the search of the two databases, for each search term, all the identified apps were screened in two stages. First, the reviewers verified the eligibility of the apps against the inclusion criteria by reading the apps' descriptions available in the app stores. This study included apps that claim to check for PDDIs in their description, published in English, and last updated in 2016 or later. Apps were excluded if they targeted nongeneral consumers, passively informed users of PDDIs (does not allow pair-wise or combinational interaction check), checked for drug interactions for pets and animals, and specific to a particular disease or drug class. After screening the results for each search term, the selected app names were aggregated. If an app was listed in both stores, this study considered them separately and examined both versions to capture potentially varying features and user reviews. Second, the authors downloaded and installed the remaining apps from the first step to verify their eligibility one more time. Apps that failed to launch after three attempts on the test devices were excluded. All Apple test devices ran iPhone operating system (iOS, Apple Inc) 10, and all Android test devices ran Android 6.0.

Data Collection Process

A set of general information about the apps were extracted following previous app review studies [24,25]. General app information provides contextual information such as availability, affordability, and user satisfaction level. A set of secondary features that can further empower end users beyond the PDDI check feature was identified from literature review [24,26-28].

Textbox 1. Search strategy with an example for Google Play Store.

Preparing your device for the search:

- Connected to the University of Waterloo network
- Log out from Google in your browser

Search procedure:

- Search the following terms in the respective store
- Search terms must be in quotation (eg, “drug interaction”)
- All search terms should be entered in lower case letters

Search terms (number of hits)

1. drug interaction (66)
2. drugs interaction (8)
3. drug interactions (193)
4. drugs interactions (16)
5. drug-interaction (66)
6. pill interaction (3)
7. pills interaction (0)
8. pill interactions (3)
9. pills interactions (0)
10. pill-interaction (3)
11. medication interaction (10)
12. medications interaction (0)
13. medication interactions (192)
14. medications interactions (0)
15. medication-interaction (10)

In summary, the two extracted sets of information were as follows: (1) general information about the apps: last updated date, price, and user rating and (2) other relevant secondary features that the apps offered:

- Medication management related features: reminder to take medication, reminder to refill medication, medication history tracking, pill identification, searching medication using generic or brand names, and access to medication database
- Security and privacy related features: password protection for user data and multiple user support
- Data sharing and social media: sharing user data with a third party
- Clinician and technical support: customer support

Multimedia Appendix 1 presents the secondary features extracted and examined for each app.

Critical Appraisal of the Apps (Quality Assessment)

The MARS, a 23-item, expert-based rating scale with a purpose of assessing the quality of mHealth apps, was used to critically and systematically evaluate the quality of the mHealth apps [20] (See Multimedia Appendix 2 for a detailed MARS score for all included apps). Each question from MARS used a 5-point scale (1=inadequate, 2=poor, 3=acceptable, 4=good, and 5=excellent). This expert scale consists of multiple dimensions that assess different quality aspects of apps, including end-user engagement, features, aesthetics, content quality, and subjective quality [20]. This expert rating scale has been increasingly adopted in recent years for evaluating mHealth apps such as mindfulness [29], weight loss [25,30], smoking cessation [30], self-care [31], online well-being [32], and medication adherence [24]. A previous study has shown high internal consistencies in the total score and subscales, as well as strong interrater reliability (IRR) [20]. Moreover, use of a standardized assessment scale such as MARS for evaluating mHealth apps has been recommended by various researchers [33-35]. The popularity of MARS led to the further development of an Italian version [36] and an end-user version for nonresearchers [37].

The last dimension of MARS is app subjective quality, which takes the subjective opinions of the reviewers. To ensure the quality assessment process is as consistent and objective as possible, the subjective quality dimension was omitted from this review. A previous study that employed MARS as an objective method to assess quality also excluded the subjective quality dimension [25]. Instead, relevant information was captured from the app databases, including the price and app ratings.

Before rating the apps, each rater read and familiarized themselves with the MARS protocol. A group discussion was followed to achieve a consensus on the rating criteria, and the first app was rated as a group. The need for an objective example of PDDIs arose for the MARS questions (#15 and #16) that assess comprehensiveness and accuracy of the content and information. On the basis of a careful review of the literature [38,39], we developed a list of PDDIs with 20 true positive and six false positive examples (Multimedia Appendix 3). The percentage of correctly identified and described PDDIs was scaled to a range from 1 to 5 for questions #15 and #16. No previous studies have reported on the details of how the accuracy and comprehensiveness of app content were assessed.

Two raters assessed each app individually. Weighted kappa, Krippendorff alpha, and intraclass correlation (ICC) were used to estimate IRR for MARS tool. The kappa value was assessed by putting quadratic weights for differing values. The ICC coefficient was calculated with a two-way random model and for agreement level. The weighted kappa, Krippendorff alpha, and ICC were calculated per dimension and for all apps.

Statistical Analyses

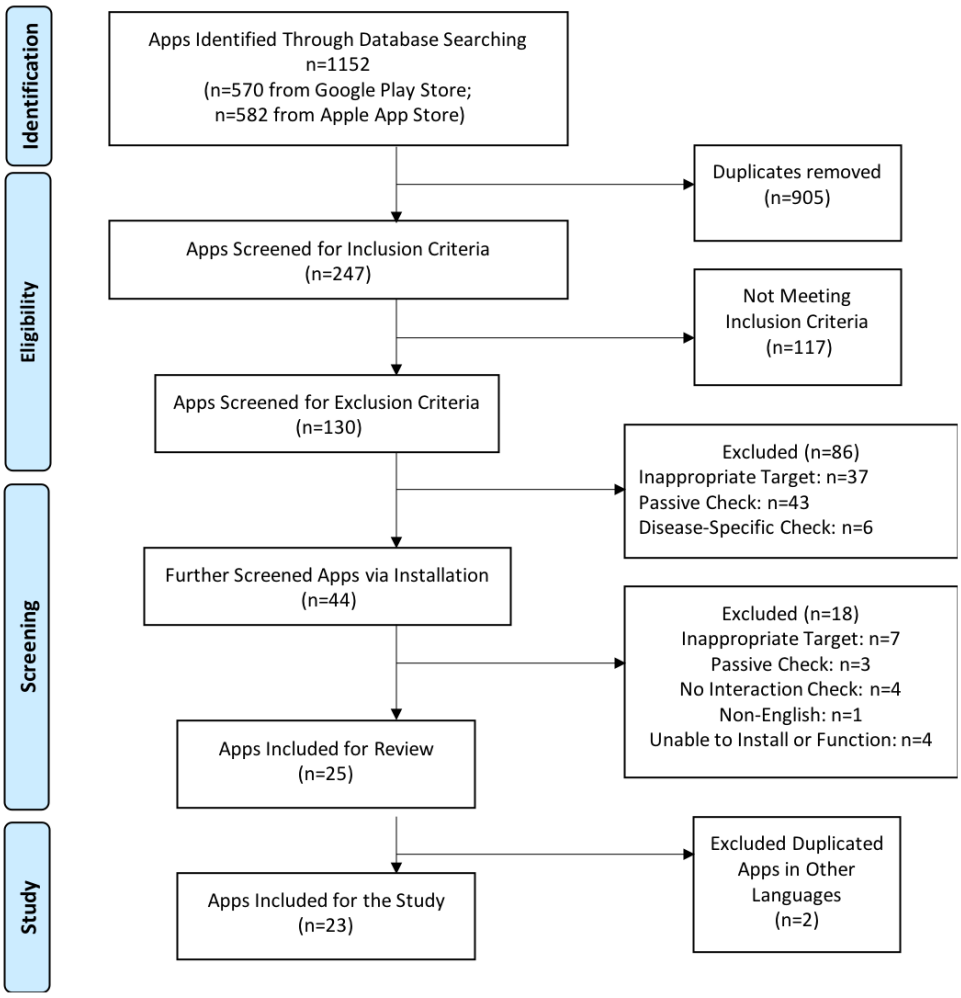
Each dimension in MARS was analyzed using the mean value as recommended by the developers [20]. The difference in app quality between the two app stores was analyzed by *t* tests. The relationships among four dimensions of the MARS score—MARS total score, price, average rating, and number of features—were examined by the Spearman correlation. A significance level of .05 was used in this study. All analyses were performed in R version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Systematic Search Results

The app store search was conducted in December 2016. This study identified 570 apps from Google Play and 582 apps from Apple App Store (Figure 1). After removing duplicates in each database, the authors reviewed the descriptions of 247 apps against the inclusion and exclusion criteria (Figure 1). Apps found to be eligible based on their descriptions (n=44) were installed for another round of review against the criteria (Figure 1). Review was initiated for 25 apps, but the authors excluded two additional apps identified as duplicates in multi-language versions, leaving a total of 23 apps for this study (Figure 1).

Figure 1. App selection process.



General Information

Twenty-three apps—12 from Apple App Store and 11 from Google Play—were developed by 15 developers. Seven apps were listed in both stores. Table 1 summarizes the general information of the reviewed apps and the mean MARS scores.

There were five paid apps, three from Apple App Store and two from Google Play, with an average price of $7.19 CAD. The average prices of paid apps were $7.32 CAD and $6.99 CAD for Apple's App Store and the Google Play Store, respectively. Four apps, two apps from each store, "Drug Interactions" and "Prescription Checker" by the same developer, were functionally identical but listed at two different prices: $10.99 CAD and $6.99 CAD in Apple's App Store and $9.33 CAD and $4.65 CAD in the Google Play Store, respectively.

The last updated dates for the Android apps were from April 2016 to December 2016, whereas the iOS apps ranged from July to December 2016.

The average rating for the apps from the Google Play Store was 3.82, with a minimum of 2.1 and a maximum of 4.8 (interquartile range, IQR 0.85). On the other hand, the apps from Apple's App Store averaged 4.5 based on the two apps with valid user ratings.

App Features

Secondary features, features other than PDDI check, were extracted and examined for each app. On average, they had 3.67 features with a minimum of zero for "DrugChecker—Interactions (Lite)" and a maximum of eight for GenieMD in both stores (IQR 3). The overall number of apps per secondary feature is shown in Figure 2. Medication refill reminder was among the least incorporated features (2/23). The option to search medications with their generic and brand name (20/23), multiple user support (17/23), access to the app's medication database (16/23), password protection (14/23), and customer support (14/23) were the most common features.

Table 1. General information about the eligible apps, developer, tested version, cost, average rating, and mean Mobile App Rating Scale (MARS) score. iOS: iPhone operating system. NA: not available.

App number and name		Platform	Developer	Tested app version	Cost ($ CAD)	Average rating (out of 5)	Mean MARS score (out of 5)
1	Drug center—pediatric oncall	iOS	Pediatric Oncall	3	Free	NA	3.15
2	Drug interactions	iOS	Pierre Chaillet	1.5.3	10.99	NA	2.29
3	DrugChecker—Interactions (Lite)	iOS	SYSTEM YOSHII	1.2.1	Free	NA	2.00
4	Drugs.com Medication Guide	iOS	Drugsite Trust	2.7.24	Free	4	4.06
5	GenieMD	iOS	GenieMD	7.4	Free	5	3.92
6	MyRxProfile	iOS	MyRxProfile	1.0.2	Free	NA	3.02
7	PharmaGuide	iOS	Asif Baig	1.0.5	Free	NA	1.94
8	Pharmazam	iOS	Pharmazam	2	Free	NA	2.94
9	Pharmacist Pro—Drug Interactions Checker	iOS	Yury Dubovoy	2	3.99	NA	3.60
10	PillSync Drug Facts Identifier	iOS	ScanIDme	1.2	Free	NA	3.23
11	Prescription Checker	iOS	Pierre Chaillet	1.1	6.99	NA	2.29
12	ZibdyHealth	iOS	Zibdy	1.5	Free	NA	2.29
13	Assist IE—Drug Interactions	Android	Infomed Mobile	1.0.41	Free	3.9	3.60
14	Assist UK—Drug Interactions	Android	Infomed Mobile	1.0.41	Free	4.0	3.60
15	CVS Caremark	Android	CVS Caremark	4.15	Free	3.5	4.10
16	Drug Center—Pediatric Oncall	Android	Pediatric Oncall	3.2	Free	4.4	3.33
17	Drug Interactions	Android	Pierre Chaillet	1.5.4	$9.33	2.7	2.29
18	Drugs.com Medication Guide	Android	Drugs.com	2.0.7.28	Free	4.3	4.06
19	Epocrates Plus	Android	Epocrates	17.1	Free	4.3	4.25
20	GenieMD	Android	GenieMD	5.9.9.54	Free	4.8	3.75
21	PillSync Drug Facts Identifier	Android	ScanIDme	4.3.0	Free	2.1	2.29
22	Prescription Checker	Android	Pierre Chaillet	1.5.4	$4.65	3.5	2.29
23	ZibdyHealth	Android	Zibdy	2.0	Free	4.5	3.60

Figure 2. The number of apps that contain the secondary features listed on the x-axis.

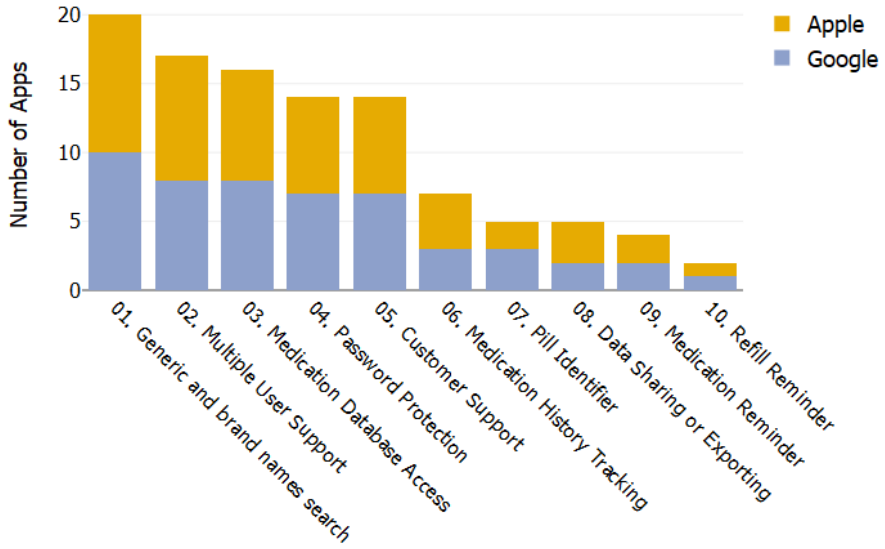
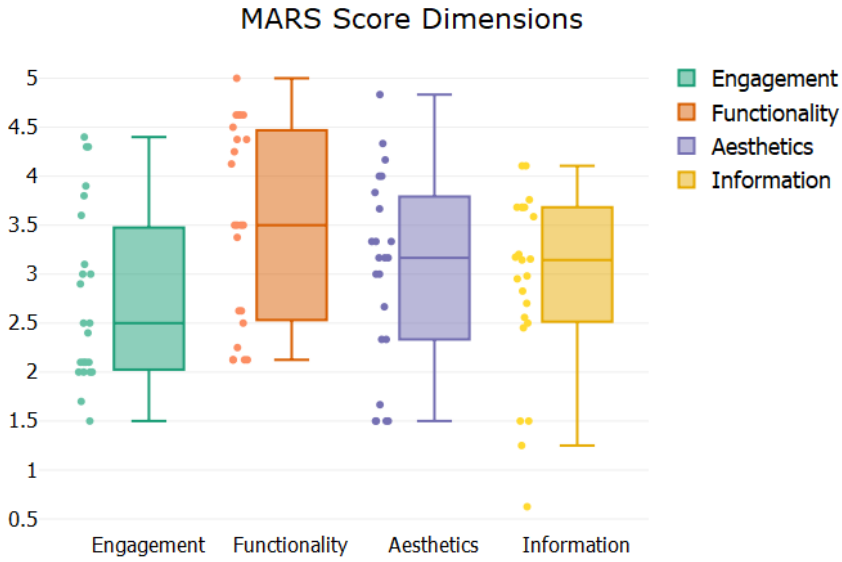


Figure 3. Mobile App Rating Scale (MARS) dimension scores. Each point represents the score for an individual app. The box plot shows the median, first, and third quartiles and minimum and maximum scores.



Critical Appraisal of App Quality

Overall App Quality

The mean MARS score of the 23 apps was 3.05 (IQR 1.55), with a maximum of 4.40 for “Epocrates Plus” and a minimum of 1.87 for “PharmaGuide” (Table 1). The mean MARS score for the apps from Google Play and App Store were comparable at 3.25 and 2.86, respectively, with no statistical difference (*P*=.96). The IRR between two raters as assessed by the weighted kappa was .63 (95% CI 0.58-0.68), the ICC was .64 (95% CI 0.59-0.68), and the Krippendorff alpha was .63 (95% CI 0.58-0.66). Detailed IRR results are presented in Multimedia Appendix 4.

The mean scores of the four dimensions of MARS were examined to investigate the magnitude of the differences in quality in each dimension. Functionality dimension resulted in the highest mean score (3.52), whereas engagement dimension showed the lowest average score (2.75). The functionality dimension had the most variability (Figure 3).

Relationships Between App Characteristics and Quality

General and functional characteristics of the 23 apps were examined for a correlation with the MARS score (Table 2). The general and functional characteristics, including average user rating and total number of features, were statistically significantly associated with the total MARS score (Table 2). Statistically significant associations were observed between the general and functional characteristics, including the total number of features and the price and average user rating (Table 2). Within the MARS dimensions, all were statistically significantly correlated with each other except for information dimension (Table 2).

Table 2. Correlations among total Mobile App Rating Scale (MARS) score, four MARS dimension scores, price, rating, and number of features.

Characteristics	MARS					Price	Average rating	Number of features
	Total	Engagement	Feature	Aesthetics	Information			
MARS								
Total	1.00							
Engagement	.87[a]	1.00						
Feature	.72[a]	.49[b]	1.00					
Aesthetics	.88[a]	.91[a]	.64[a]	1.00				
Information	.43[b]	.30	−.08	.12	1.00			
Price	−.37	−.49[b]	−.47[b]	−.55[a]	.35	1.00		
Rating	.61[a]	.49[b]	.39	.41[b]	.43[b]	−.26	1.00	
Number of features	.47[b]	.70[a]	.06	.56[a]	.16	−.43[b]	.42[b]	1.00

[a]$P<.01$.

[b]$P<.05$.

Discussion

Principal Findings

In this app review study, a systematic search strategy was used to find PDDI apps. To our knowledge, this is the first systematic review on apps that offers decision support for PDDI checking. The 23 included apps were analyzed to extract general characteristics and functional characteristics, and their quality was assessed using MARS. Only five of the 23 apps (22%) were paid apps. This proportion of paid apps is consistent with other studies that systematically reviewed the Google Play Store and Apple's App Store [24,25]. App price had statistically significant negative correlations with three of four MARS dimensions and number of features. This demonstrates that app quality is not always represented by the selling price. A plausible explanation for this counterintuitive and inverse relationship is that free apps may have been developed by companies and organizations with sufficient resources; hence, apps were developed to expand consumer reach, whereas individual developers who may have limited resources may rely on generating revenue from app sales, while the quality of app may not be as high as the apps developed by companies and organizations that can afford to hire a group of expert developers. Further research should investigate the relationship between the price of consumer mHealth apps and its quality, as well as its impact on consumer perception.

The primary features of the examined mHealth apps were providing drug information to users and checking for PDDIs. Despite this aim of these apps, a low average score in the information dimension was found based on MARS. This indicates that the PDDI check feature is of low quality, delivering inaccurate and potentially unsafe information about PDDIs. In particular, MARS questions #15 and #16, which assessed the accuracy and comprehensiveness, scored on average 2.9 and 2.4, respectively. This is alarming as only slightly more than half of 26 investigated PDDIs (58%, 3/5) have been identified by the apps. To worsen the problem, less than half of the correctly identified PDDIs (2.4 out of 5) have correctly described the interactions. Inability to detect PDDIs and providing incomplete and incorrect information is a significant threat to patient safety. It also diminishes mHealth app's value as an avenue for patient empowerment. It must be noted that there was a large variability in the accuracy of PDDIs among the tested apps, where 48% (11/23) apps scored 4 or higher out of 5 for question #15, whereas 30% (7 / 23) apps scored less than 1 out of 5. This polarized quality of information found in mHealth apps further raises the question about the tools available for consumers to evaluate and select high quality apps. The average user rating was significantly correlated with the information dimension, and it indicates that the average user rating can potentially be an important tool for selecting mHealth apps. There are other resources available such as app clearinghouses that make recommendations for mHealth apps to consumers based on the results from systematically evaluating the usability, quality, accuracy, or evidence of the app and its content [40]. Examples of app clearinghouses include National Health Service Health App Library and iMedicalApps [40]. These app clearinghouses hold promise to enhance consumer safety of mHealth apps, but they have not been investigated against MARS or other validated tools that assess the quality of mHealth apps.

The low average MARS score for the engagement dimension can be partially explained by the primary purpose of the included apps. The investigated apps work as a reference to check for PDDIs, and these apps do not rely on user engagement to elicit behaviour change. On the other hand, other mHealth apps that focus on behaviour change tend to score higher in the engagement dimension, as the success of behaviour change may heavily depend on how successfully they engage the user [24].

Most MARS dimensions were correlated with each other except information. This is consistent with the findings from Bardus and colleagues who assessed weight management mHealth apps [25], where all dimensions but the information and engagement dimensions were significantly associated. A very strong

correlation between the aesthetics and engagement dimensions can be explained by many user interface design, and usability studies that found attractive and appealing aesthetics lead to greater user engagement and perceived usability [41-43]. Interpreting the correlation between the total MARS score and each dimension's score should take caution as the total MARS score is derived from the scores from all dimension of MARS. The number of features was strongly correlated with the engagement dimension but not with the features dimension that measures functionality, performance, and ease of use [20]. This result may represent the trade-off between ease of use and the complexity of an app that attempts to provide more features at the cost of performance. A similar relationship has been found in a previous website design and usability study [44].

Secondary Features Offered to Consumers

Besides the PDDI check feature, maintaining medication adherence is a challenging problem in individuals taking medication, particularly for older adults [45,46] and those with chronic diseases [47]. Improving medication adherence can ensure the effectiveness of a treatment, thereby impacting maintaining health and managing chronic diseases [48]. There are many barriers for medication adherence, but forgetfulness has been reported as the most common cause, and much research has focused on overcoming this barrier [49,50]. A well-researched solution to overcoming forgetfulness is medication reminders and refill reminders [47,51]. Such reminders have increased patient medication adherence by encouraging timely refill and further demonstrated feasibility in cognitively impaired populations [47,51]. Therefore, these features can also be useful to individuals using PDDI apps. The usefulness of refill reminders has been acknowledged by the US government and made the refill reminder an exception to the Health Insurance Portability and Accountability Act [52]. Despite sufficient ground for implementing these features, only two apps featured a refill reminder (GenieMD in both stores), whereas five had a medication reminder.

Patients with comorbidities are usually cared for by a general physician and several specialists, which tends to lead to a heterogeneous list of medications [53,54]. The PDDI check feature can inspect for possible adverse effects, but this would be accurate only when the medication list is complete. Unfortunately, only 30% (7/23) of the reviewed apps had a feature to track medication history (Multimedia Appendix 1). Medication history tracking is also important in understanding PDDIs for drugs with long half-lives or over-the-counter drugs [55]. Therefore, mHealth apps that can track the history of medication can further prevent other drug complications. Such a feature can empower patients by enabling them to take charge of their medication list and minimizing PDDIs stemming from many HCPs with multiple prescriptions.

Every over-the-counter and prescription medication must have a unique appearance and imprint code for identification by the Food and Drug Administration [56]. Code imprint, size, color, and shape of the medication together permit identification of the product and manufacturer. However, using this identification system can be difficult for end users, and only 22% (5/23) of the apps had a feature to automatically identify pills from its physical attributes (Multimedia Appendix 1). Identification by drug name can also be difficult because of the discrepancies between generic and brand names. This review found that 87% (20/23) of the apps allow searching by both generic and brand names, and 70% (16/23) provide further drug information by allowing users to access a drug database. These features can help older adults who have developed polypharmacy to identify and distinguish drugs from one another, as a large number of medications and confusing names are often causes for medication error, even among trained clinicians [57].

Another issue that PDDI app users may be concerned about is data security as privacy is a major concern for collecting personal health information [58]. Overall, 61% (14/23) of the PDDI apps had password protection, and 74% (17/23) had support for multiple users on the same device (Figure 2). Given that smartphones and tablets can be protected with a password, an additional app-level password protection provides another level of security. Information and Privacy Commissioner of Ontario [59] and the Health Insurance Portability and Accountability Act state that password protection is required, but this may not be secure enough. Data encryption is recommended for added security. This is an area that can be greatly improved with a more stringent guideline and oversight by regulators and governments. Moreover, future research should investigate the level of data encryption presented in mHealth apps and its implication for consumers.

Our review also investigated availability of other features related to medication management in the apps. For instance, one study [60] has described data sharing via social networking sites as a potential communication platform to pharmaceutical companies to give feedback. Furthermore, social media can facilitate the interactions among patients, clinicians, researchers, and vendors [60]. The capabilities of data exporting, synthesized reporting for clinicians, and sharing on social media were found only in 22% (5/23) of the apps. In the context of mHealth apps that check for PDDIs, social media can provide a medium for consumers to interact with other drug users to share side effects and other relevant information. As Steele described [60], it may also help pharmaceutical companies interact with the users and gain insights into rare side effects, PDDIs, or high-risk subpopulations such as older adults.

Finally, in the event that information provided by the apps is not satisfactory, users should be able to get additional help. Of all, 61% of the apps (14/23) provided some level of customer support. Given the seriousness of potential ADRs that can be caused from the exposure to the PDDIs, an option to contact a clinician, preferably a pharmacist, would be ideal. It is worthwhile to note that no apps have provided contact information for reporting ADRs to local regulatory bodies. Providing a formal way to report potential ADRs to regulatory bodies can enhance public health programs for monitor PDDIs and ADRs.

Limitations

This review is not without limitations. We limited our focus on English apps available in Canada, but other researchers may benefit from extending this review to other regions and languages. Moreover, mHealth apps are frequently updated,

and new apps are published daily. Fast evolving app market can limit the generalizability of the results. Another limitation of reviewing app stores is the app databases' nontransparent search algorithms. Although we reported our search strategy as transparent as possible, the underlying search algorithm can change without the public's knowledge. This can undermine the reproducibility of our study. Finally, our review unveiled the quality of existing PDDI mHealth apps on the market, but this does not necessarily translate to how consumers use these apps in the real world. This knowledge gap should be further investigated in future research.

Conclusions

Checking for PDDIs has been a task reserved for clinicians and pharmacists. With the increased popularity of smartphones and other information technologies, they promise more features and functionalities to enhance our lives and well-being. In this study, we searched the most popular mobile app databases and found 23 apps that can check for PDDIs. Some of these apps provided high quality, accurate, and comprehensive information about PDDIs. However, not all apps conformed to high standards, and given the high stake of incorrect drug information, the need for oversight was clear to ensure end-user safety. We also identified secondary features that future apps should incorporate to further benefit the end users. These features can support medication management, improve data security and privacy, and facilitate communications.

Acknowledgments

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Authors' Contributions

The idea for the study was conceived, and the review design was established by AS and BK in 2016. The search and screening phases were performed by AS, BK, EW, and NT. AS, BK, and NT extracted data from included apps and performed the analysis. AS, BK, and NT contributed to preparing and developing the manuscript. EW generated the flowchart and organized references. JL reviewed and refined the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Extracted secondary features and their presence among included apps.

[PDF File (Adobe PDF File), 357KB - mhealth_v6i3e74_app1.pdf]

Multimedia Appendix 2

A detailed MARS score for all included apps.

[PDF File (Adobe PDF File), 382KB - mhealth_v6i3e74_app2.pdf]

Multimedia Appendix 3

List of drug-drug interactions tested for the MARS #15 and #16.

[PDF File (Adobe PDF File), 313KB - mhealth_v6i3e74_app3.pdf]

Multimedia Appendix 4

Detailed inter-rater reliability as analyzed by the weighted kappa, intraclass correlation, and Krippendorff alpha for each MARS dimension.

[PDF File (Adobe PDF File), 188KB - mhealth_v6i3e74_app4.pdf]

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Abbreviations

ADR: adverse drug reaction
DDI: drug-drug interaction
HCP: health care professional
ICC: intraclass correlation
iOS: iPhone operating system
IQR: interquartile range
IRR: interrater reliability
MARS: Mobile App Rating Scale
mHealth: mobile health
PDDI: potential drug-drug interactions

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Viewpoint

Patient Involvement With Home-Based Exercise Programs: Can Connected Health Interventions Influence Adherence?

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Abstract

Adherence to home exercise in rehabilitation is a significant problem, with estimates of nonadherence as high as 50%, potentially having a detrimental effect on clinical outcomes. In this viewpoint, we discuss the many reasons why patients may not adhere to a prescribed exercise program and explore how connected health technologies have the ability to offer numerous interventions to enhance adherence; however, it is hard to judge the efficacy of these interventions without a robust measurement tool. We highlight how well-designed connected health technologies, such as the use of mobile devices, including mobile phones and tablets, as well as inertial measurement units, provide us with the opportunity to better support the patient and clinician, with a data-driven approach that incorporates features designed to increase adherence to exercise such as coaching, self-monitoring and education, as well as remotely monitor adherence rates more objectively.

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KEYWORDS

patient compliance; rehabilitation; exercise therapy; biomedical technology; review

Introduction

The success of certain medical interventions depends largely on patient adherence to advice and prescribed rehabilitation regimes. After injury or surgery, many patients are given specific exercises to do unsupervised at home to aid their recovery, for example after knee replacement. These exercises are specifically targeted at certain muscle groups or joints, rather than global physical activity, for example a straight leg raise for quadriceps strength or a heel slide for knee range of movement. Evidence suggests that noncompliance to these home exercises in musculoskeletal cohorts can be between 30% and 50%, making it a significant issue that places additional burden on patients and health care providers, and may be partially to blame for poor clinical outcomes [1,2]. Clinicians who fail to consider patient adherence in rehabilitation programs may unnecessarily alter their treatment approach, face persistent patient complaints; or refer patients for alternative opinion, thereby contributing to possible unnecessary surgical intervention and additional health care costs [1]. Adherence is currently defined by the World Health Organization (WHO) as “the extent to which a person’s behaviour…corresponds with agreed recommendations from a health care provider” [3]. The majority of research into adherence relates to medication, and this definition has been developed to encompass a multitude of health-related behaviors [3], however, it does not yet include exercise prescription. In this viewpoint, we aim to comment on the current evidence in patient adherence to prescribed home exercise programs, the factors affecting these adherence rates, and then discuss design opportunities that connected health interventions provide to improve adherence rates.

The term *connected health* describes the use of a variety of technologies to inform and aid health care delivery in a data-driven manner with the individual at the center. It covers a broad domain, including digital, mobile health and telehealth and ensures all stakeholders are connected with data that is

accurate and timely [4]. Mobile technology, including smartphones and tablets can support connected health solutions by providing access to a number of features within the device, including inertial measurement units (IMUs), cloud computing, and back-end development including machine-learning classification [5]. Equally, various methods such as telerehabilitation using videoconferencing [6], or motion capture using camera systems [7] have been employed with the aim to better support patients in their rehabilitation and improve their adherence. But what are the design features that can be harnessed in new connected health solutions that will impact adherence to exercise?

Adherence to Exercise Programs

An Operational Definition of Adherence in Exercise Science

Although medical adherence has been defined by the WHO, it is arguable that there is more than one factor to consider when specifically defining exercise adherence. To form a definition, the authors of this paper have considered on a macro level, the requirements needed to demonstrate strong adherence. Clinicians first need to know whether the patient is exercising, then whether they are exercising to the required amount of repetitions and sets, and finally whether they are performing the correct technique with relation to load, velocity, and alignment. The following operational definition has been built specifically relating to exercise, adapted from the WHO definition, and defines exercise adherence as "the extent to which an individual corresponds with the quantity and quality of exercise, as prescribed by their healthcare professional." Those who perform their exercises to the required repetitions may not be deemed adherent should their technique be erroneous or incorrect, as these individuals will not be gaining maximum benefit from their exercise program.

The Effect of Adherence on Outcome

Patient adherence is important in all aspects of medical care. Adherence is reported to have clear links to the impact on clinical outcome in medication research, as well as placing significant additional economic burdens on health care providers [8]. Poor medication adherence has been shown to increase the occurrence of hospitalizations and complications in a number of chronic metabolic conditions [9] and an increase in the number of adverse events and annual medical costs in cardiac patients [10].

In an exercise rehabilitation context among the musculoskeletal population, strong adherence enhances the effectiveness of the intervention and is suggested to reduce persistent, disabling complaints [11]. Patients who fail to adhere to the prescribed exercise program may extend the duration of their treatment, negatively impact on the therapeutic relationship, and make treatment less effective [12]. It can also impact health care providers with increased waiting times and poor efficiency [11], while poor adherence rates may also potentially have a role to play in nonsignificant outcomes of research papers [13]. A number of studies have also linked strong exercise adherence to improved treatment outcome in patients experiencing neck and back pain and osteoarthritis symptoms [14-16].

Rates of Adherence

In an exercise context, it was reported that only 35.0% (42/120) of patients were highly adherent with home exercises in a short-term study of patients with nonspecific low back pain [17]. This study went on to state that 50.8% (61/120) of those who received an individualized exercise program demonstrated non/low adherence across the entire rehabilitation regime based on patient self-report. Yet the literature demonstrates some inconsistency in the use of the term non/low adherence, and there is no clearly documented category to which adherence can be defined as poor [18]. A more recent systematic review of interventions designed to improve adherence in a variety of musculoskeletal and medical populations found an average rate of 67% (12 studies) adherence to prescribed home exercise programs [19]. A regularly cited study by Sluijs et al [2] concluded that patients' compliance to physiotherapy is unsatisfactory, but was unwilling to draw a sound conclusion on the degree of nonadherence due to the lack of valid and reliable measures available. From these findings, it is clear that adherence rates to home exercise plans are an issue, but it is not possible to accurately say to what extent, and how much this might impact the clinical outcome, as a consistently valid and reliable method of measurement has not yet been designed.

Measuring Adherence

It is important to consider that studies assessing adherence are limited in their quality and conclusions because of the lack of objective and reliable outcome measures used in clinical practice. It is widely accepted that at present, there is no gold standard for the measurement of adherence to unsupervised home-based exercise, as the significant proportion of outcome measures used in the literature rely on patient self-report and are therefore susceptible to bias [19,20]. In a systematic review of 61 different self-reported outcome measures for adherence to home-based rehabilitation, only two measures scored positively for a single psychometric property of validation [20]. Furthermore, the outcome of any research studies using paper diaries or retrospective recall has been called into question as it is highly prone to recall and self-serving bias [21]. Equally, these measures make no allowance for the quality of performance, as highlighted in the abovementioned definition.

Sensing platforms such as the use of IMUs or motion capture camera are rapidly advancing and could be an opportunity to make a more objective assessment of adherence, continuously tracking motion data obtained from an individual [22,23]. However, the use of these devices to measure adherence is questionable as they arguably influence/enhance adherence itself by means of the user knowing that they are being recorded. In this way the end point is influenced greatly by the measurement strategy, leading to questionable results as the patient no longer has the choice on whether to adhere [20]. Regardless of the challenges with accurately measuring adherence, it is clear that there are problems with adherence to prescribed exercise in the home setting. Investigations of whether technology can play a role in this are still in their infancy, therefore, understanding what factors affect adherence

can highlight design considerations a connected health solution can employ to improve adherence and aid self-management.

Factors Affecting Adherence

Overview

The factors that may affect adherence to home exercise rehabilitation in musculoskeletal populations have been discussed in numerous papers, and a number of characteristics have been highlighted as potential reasons that may affect or predict adherence rates [24] such as perceived barriers, the patient's own beliefs, or their self-efficacy with the exercise task. Good adherence requires the individual to change, alter, or even maintain a behavior, hence it is relevant to consider the psychological factors associated with theories of behavior change, as guidelines suggest these should all have a theoretical underpinning [25]. While there are numerous theories of behavior change [26], very few physiotherapy studies (12%, 3/25) discuss these theories [27]. While behavior change is inherently included within the factors affecting adherence, and indeed within the design solutions offered, given the expansive nature of behavior change, the broad factors and barriers to adherence will be addressed in this paper.

Self-Efficacy

Self-efficacy has been strongly linked as a psychological factor affecting treatment adherence. It is a term used to describe an individual's belief in their own capability to achieve a task that will produce a targeted result. It is situation-specific and depends on the activity, but it is considered that a person has a general level of self-efficacy across tasks [28]. Four strands of efficacy information are proposed within the concept; mastery experiences based on past and current successful performance, social observation learning from those around the individual, persuasive information particularly from influential people in the individual's life, and emotional states considering the mood the individual is in [29]. Self-efficacy has been closely linked with a positive association of adherence in orthopedic and musculoskeletal cohorts [24,30,31]. It is worth noting however, that one study found that self-efficacy did not predict adherence in the home or clinic setting, although this was assessed in a sports rehabilitation context, and therefore may not be generalized to other cohorts [32]. When designing connected health solutions, there is an opportunity to use interventions to improve self-efficacy within the technology design. Methods such as machine learning with biofeedback, interactive education using videos and weblinks, and self-monitoring similar to that used in commercially available fitness trackers, have the potential to improve the self-efficacy and ultimately the adherence of users.

Threat and Beliefs

The beliefs a patient holds regarding their condition are also said to be a direct factor affecting adherence, and the decisions made by patients are based on their own beliefs, personal experiences, and the information they receive [33]. This study noted that those who did not perceive their injury to be serious demonstrated lower levels of adherence, and in fact, the authors suggested that enhancing participants' level of threat to further injury or disability would improve adherence, although this is a questionable technique in the wider context of patient management. Indeed, others have stated that providing too much information to patients and overloading them will also negatively affect adherence, as patients can become confused [2]. Enhanced threat can also have other negative implications, such as hemophiliac patients who may have had a threat of increased bleeding and arthropathy with physical activity [34], and therefore treatment should be about correcting falsely construed beliefs and tailoring individual care, rather than solely modifying the threat appraisal for all patients. This individualized care is an important consideration in the design of connected health solutions, as the end user needs to be considered and technology should be used to augment the clinician's management, rather than to replace in a *one size fits all* approach that may incorrectly adjust a user's beliefs. Symptoms also need to be perceived to have a sufficient effect on quality of life to encourage adherence [35], with another viewpoint that the beliefs a patient holds places them in a similar category as consumers, who want to take their own decisions when confronted with a particular condition [8].

Locus of Control

A recent systematic review into factors affecting adherence in low back pain suggested that a higher health locus of control had moderate evidence to be a factor affecting adherence [36]. Locus of control can be biased toward either the internal (person is responsible for their own outcomes), to chance, or to powerful others (individuals of higher authority are responsible for outcome) [37]. It is suggested that patients with an external locus of control demonstrate a lesser degree of adherence with medical intervention [2]. Hence, as a clinician it is imperative that both the patient's beliefs and understanding of their locus of control are addressed at an early stage when considering a connected health solution to ensure the patient understands the condition and that possible misinformed beliefs can be corrected.

Pain

Pain levels during exercise in musculoskeletal patients presented strong evidence as a barrier to adherence in a systematic review, but there was conflicting evidence that higher pain levels at baseline had an effect on adherence [24]. The authors suggested that those who experienced pain during their exercises were less likely to adhere to their program. Contradictory to this is the large study from the Netherlands that found there was no significant difference in reported pain from exercise between those with high and low adherence [2]. Brewer et al on the other hand, make links between pessimism and pain, with patients low in pessimism completing the exercises irrelevant of pain, while highly pessimistic individuals demonstrated a reduction in adherence when their pain levels were higher following cruciate ligament reconstruction [38]. Mobile technology has the ability to capture pain scores with a method requiring little interference in the user's life, and when combined with the ability to objectively monitor adherence, may provide greater levels of understanding on the relationship between pain and adherence in future research. Connected health solutions may also be used to change the way care is provided, with the user completing regular Web-based outcome scores, and an increase

in pain flagged to the clinician remotely, giving the health care professional an opportunity to make an informed decision on that patient's care to ensure they maintain strong adherence.

Physical Activity

The level of physical activity of individuals at their baseline has also been discussed as a potential barrier to adherence. Studies suggest that those who are physically active at baseline demonstrate significantly better adherence to home exercise programs [16,24]. Physical activity is also said to be a source of self-identity, and that individuals who have lower athletic identity would have a lower rate of adherence [38]. Connected health solutions have the opportunity to encourage physical activity through self-monitoring and gamification which could then, in-turn, contribute to the behavior change required for stronger adherence in rehabilitation. However, given that baseline physical activity cannot be altered by commencing use of a connected health solution, the design of the intervention needs to be future present and independent of the user's baseline physical activity.

Psychological Symptoms

Depression as a barrier to adherence has strong supporting evidence [24], with the literature also discussing other traits including anxiety and neuroticism. These symptoms have been suggested to negatively impact adherence in general musculoskeletal and fibromyalgia populations [38-40]. More recently, a study of cruciate ligament reconstruction participants found no link between anxiety at baseline and adherence [38], although interestingly it went on to suggest that day-to-day variance in stress may contribute to adherence to home exercises. If connected health technology can be used to either counteract these symptoms through recognized support methods or be able to flag to the clinician that adherence has dropped; this can lead to a more proactive method of health care to identify the reasons for this reduction.

Social Support

The social support network of the patient has also been suggested as a possible factor in adherence [2,41]. This network can be friends and family members, as well as support from the therapist. In the sporting population, significant findings were made that both social support as task appreciation, and emotional support from friends and family predict adherence in both the clinic and home setting [32]. Further exploratory work in the sporting population made suggestions that those who made use of social support displayed greater adherence and recommended that in this setting, the coach and wider support network are involved in the rehabilitation pathway to offer support and motivation [42]. Connected health solutions have the potential to offer social support through online forums or networks where users are able to interact with others in a similar situation, wherever they may be. It is not impossible to foresee a social network built into many mobile health technologies to enhance patient experience and improve adherence. A recently published systematic review found relatively strong evidence that social support can predict adherence, but as discussed earlier, highlighted the challenge of measurement of adherence as a significant limitation across the field [18].

Perceived Barriers

Patients' perceived barriers is one of the most widely documented barriers to adherence, with examples such as forgetting to exercise, not having the time, or not fitting into the daily routine all being cited as reasons for nonadherence [2,42-44]. Another study also found perceived barriers included time, work schedules, and transportation and recommended that these issues should be taken into consideration by health care providers [17]. By using a selection of the design considerations discussed below, connected health solutions have the potential to positively influence some of these perceived barriers.

Design Considerations for Connected Health Solutions

Overview

When designing future connected health solutions, it is important to have an understanding of the range of possible cognitive, behavioral, and practical barriers that can have an effect on a patient's willingness to adhere to their program [45]. The use of mobile devices connected with a form of sensing platform (camera or IMU) in home-based exercise rehabilitation have the potential to provide the clinician with a greater amount of actionable data, which will assist in the management of each case and shift to a more proactive approach to health care. By understanding the factors discussed previously, it is possible to build features and interventions in to new solutions with the aim of enhancing patient adherence and ultimately, clinical outcome.

Coaching

By incorporating regularly combined strategies of supervision, feedback, and reinforcement as a design consideration, it is possible to offer the greater coaching input that a patient receives in clinic with their health care professional but in the convenience of their home environment. When physiotherapists provide positive feedback, and monitor both performance of exercises and the progression of symptoms, adherence rates have been found to be higher [2]. The design of connected health interventions can then offer supervision in the form of remote monitoring via online cloud-based portals. This coaching system can be augmented with remote communication using platforms such as videocalling, instant messaging, or email to offer further coaching components. Telerehabilitation has been extensively researched by a Canadian group who in one study of postoperative knee replacement patients found telerehabilitation in the form of videoconferencing to be as effective as usual care and had the potential to increase access to services [6].

Incorporating real-time exercise coaching into a connected health technology is a challenge, but research is ongoing to establish the feasibility of this process using an IMU to measure and classify commonly prescribed home-based exercises [5]. Bassett discussed how feedback from exercise testing can increase adherence in home-based exercises, as patients who know they are performing the task correctly are more likely to adhere, and results of the testing will increase self-efficacy [46]. One study of athletes after sports injury found that patients reported regular coaching was useful to aid adherence for two

reasons: improving on exercise technique and also to act as a reinforcement to complete the exercises [42]. Technology can potentially offer this coaching in more visually stimulating ways than previously imagined, with audio reinforcement during use and 3D modeling using an avatar with input from devices including cameras or sensors. For example, the VERA system by Reflexion Health utilizes the Microsoft Kinect Camera to feed in to an avatar on the laptop or television screen which mirrors the user's movements and guides them through an exercise program [7].

Task appreciation, when patients are complimented for their achievements, particularly for adherence [47], is particularly applicable in the gamification of health interventions to further compliment a user's achievements. Whether this is via rankings, rewards, in-exercise games, or simply augmenting the experience with an avatar type feedback, the user can enjoy a more immersive experience within a connected health technology, potentially impacting on their adherence.

Goal Setting

Goal-setting is regularly used to motivate and encourage adherence in physiotherapy, yet the literature seems to offer conflicting evidence on its effectiveness. Bassett and Petrie found no significant difference in adherence when comparing the use of goal setting [48]. This paper concluded that goal setting may not be a suitable motivational tool in patients with lower limb injury, although it did note that collaboratively set goals appear to have a higher level of adherence than those dictated from the therapist, although the issues with measuring this using diaries has been discussed earlier. A more recent study supported goals in clinic-based rehabilitation alongside other adherence improving interventions [32], and goals that were set with the support of a psychologist found significant differences in adherence in a moderate quality study of a younger athletic population [49]. A systematic review recently performed, concluded that while goal setting may be effective, there was insufficient data to make an endorsement, and more specialized skills may be required for goals and goal setting to be effective [19]. Arguably by making a prescription of exercise, a physiotherapist is already setting a goal for their patient, and therefore measuring the effect of formal goals is more difficult.

Self-Monitoring

A number of studies use self-monitoring as a form of measurement, yet this in itself could be considered an adherence facilitator [21]. Activity monitors have been used to provide visual feedback to patients on their physical activity and exercise frequency. This intervention was found to have a positive association to adherence, when compared with a control group with the same monitor but without feedback. However, this was not in the musculoskeletal population and was targeted at general physical activity rather than targeted home exercises [34]. Talbot et al [50] also undertook a randomized trial using an accelerometer to allow for self-monitoring as part of an arthritis self-management program and found a notable increase in general physical activity. Self-monitoring with the use of IMUs therefore provides a method of reliable, objective self-monitoring, taking the concepts from the extremely successful fitness sector and applying them to health care in connected health applications.

Education

Education is also an intervention to improve adherence; it is multifactorial and can affect perceived barriers and the patients' beliefs/perceived threats that are discussed above. Studies using solely education are few and far between, but in a systematic review, no statistically significant findings were made on 2 fair quality studies, but the provision of written information in supplement to verbal instruction did improve adherence compared with verbal instruction alone [19]. A recent symposium piece also concluded that patients rarely need just more education, they need assistance with behavior change in an integrated program [51], perhaps suggesting that clinicians should be more aware of the psychological theories discussed previously. Whether Web-, tablet-, or mobile phone-based, connected health solutions can easily offer educational material in a variety of formats, including more interactive methods such as videos that would not have been available in the past to patients.

The majority of these interventions have been combined to form a self-management plan, and this is widely done in clinical practice. Evidence would support the use of varying strategies, targeting patient education and behavior modification and would be suggested as the most effective method of improving adherence provided it is tailored to each individual's needs [52]. Although specific to the arthritis population, a systematic review concluded that at the time that there was limited evidence for adherence interventions for exercise, though adherence was not the primary outcome for some studies included [53]. Furthermore, although insufficient evidence was noted, Peek et al [19] concluded that pending further research, written information should be integrated into routine practice to enhance adherence, and this is easily provided in both written and video format in connected health solutions. Supporting the potential connected health opportunities, they suggested again with support of future research that activity monitors in the form of IMUs could be effective and simple to use to promote and monitor adherence. They also noted that this type of strategy would be increasingly acceptable as the population becomes more skilled with technology.

Other simple features that can be incorporated into the design for future solutions include automatic reminders with consideration for the patient's daily routine [42], regular patient reported outcome measures specific to the target population to provide more meaningful data back to the clinician, and social forums that allow the user to interact with peers and share experiences, offering the social support discussed earlier. A number of these features were discussed by patients when interviewed regarding their expectations of new technologies in this area, with feedback to improve performance and encouraging a feeling of being more supported being recurring themes [54]. A recent parallel-group trial suggested that app-based exercise programs with remote support can improve adherence in exercise rehabilitation based on self-report, compared with paper handouts [55], but arguably, there is more that technology can offer to further improve and measure this

facet of rehabilitation. Bassett sums up the objective well, when stating that prevention of nonadherence is the ideal way of maximizing adherence [1], and using connected health to move toward a more proactive model of care achieves this.

Conclusions

Adherence to home exercises in rehabilitation is a significant problem, and the reasons for this are multifactorial, covering both psychological and situational factors that vary between each individual, and that need to be considered by clinicians in the design of personalized exercise programs. Techniques discussed in this paper can be built into connected health solutions with the aim to improve self-efficacy and ensure the patient feels better supported in their rehabilitation; this may have an effect on adherence rates and will provide clinicians with more meaningful data to base their clinical decision on. Furthermore, published research needs to investigate the impact of these solutions on adherence rates, as this is sparse at present, yet this is understandable given the difficulties in measuring adherence discussed within the paper.

Connected health technology has the potential to make an impact in the way we manage health and can provide a platform for a far more proactive method of management utilizing numerous interventions to further improve adherence, and ultimately rehabilitation outcomes for patients. There is an emerging market in the use of sensing systems to support patients in their rehabilitation, particularly around adherence to home exercise, although the published research is still in its infancy. These systems have the ability to include many of the design features discussed in this viewpoint within the developed system and have the ability to utilize ubiquitous and cost-effective hardware in the form of mobile phones and tablets. It may then also be possible for these systems to provide a more objective method of measuring adherence across clinical populations.

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Conflicts of Interest

None declared.

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Abbreviations

IMU: inertial measurement unit
WHO: World Health Organization

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Review

Medication Adherence Apps: Review and Content Analysis

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Abstract

Background: Medication adherence is an expensive and damaging problem for patients and health care providers. Patients adhere to only 50% of drugs prescribed for chronic diseases in developed nations. Digital health has paved the way for innovative smartphone solutions to tackle this challenge. However, despite numerous apps available claiming to improve adherence, a thorough review of adherence apps has not been carried out to date.

Objective: The aims of this study were to (1) review medication adherence apps available in app repositories in terms of their evidence base, medical professional involvement in development, and strategies used to facilitate behavior change and improve adherence and (2) provide a system of classification for these apps.

Methods: In April 2015, relevant medication adherence apps were identified by searching the Apple App Store and the Google Play Store using a combination of relevant search terms. Data extracted included app store source, app price, documentation of health care professional (HCP) involvement during app development, and evidence base for each respective app. Free apps were downloaded to explore the strategies used to promote medication adherence. Testing involved a standardized medication regimen of three reminders over a 4-hour period. Nonadherence features designed to enhance user experience were also documented.

Results: The app repository search identified a total of 5881 apps. Of these, 805 fulfilled the inclusion criteria initially and were tested. Furthermore, 681 apps were further analyzed for data extraction. Of these, 420 apps were free for testing, 58 were inaccessible and 203 required payment. Of the 420 free apps, 57 apps were developed with HCP involvement and an evidence base was identified in only 4 apps. Of the paid apps, 9 apps had HCP involvement, 1 app had a documented evidence base, and 1 app had both. In addition, 18 inaccessible apps were produced with HCP involvement, whereas 2 apps had a documented evidence base. The 420 free apps were further analyzed to identify strategies used to improve medication adherence. This identified three broad categories of adherence strategies, *reminder*, *behavioral*, and *educational*. A total of 250 apps utilized a single method, 149 apps used two methods, and only 22 apps utilized all three methods.

Conclusions: To our knowledge, this is the first study to systematically review all available medication adherence apps on the two largest app repositories. The results demonstrate a concerning lack of HCP involvement in app development and evidence base of effectiveness. More collaboration is required between relevant stakeholders to ensure development of high quality and relevant adherence apps with well-powered and robust clinical trials investigating the effectiveness of these interventions. A sound evidence base will encourage the adoption of effective adherence apps, and thus improve patient welfare in the process.

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KEYWORDS

medication adherence; patient compliance; mobile apps; telemedicine; smartphone; reminder systems; treatment outcome

Introduction

Adherence Problems and Opportunities

In the age of advanced medical treatments, a significant obstacle to improve outcomes is the failure of patients to adhere to medication prescribed by their physicians. Medication adherence and compliance can be defined as the "act of (the patient) conforming to the recommendations made by the provider with respect to timing, dosage, and frequency of medication taking" [1].

A World Health Organization report on adherence to long-term therapies suggests that patients adhere to only 50% of drugs prescribed for chronic diseases in developed nations, a figure that is even lower in developing countries. The same report also highlights two major consequences of nonadherence: (1) suboptimal health outcomes for patients and (2) rising health care costs [2].

The rapid growth of mobile technologies and their uptake by consumers worldwide presents opportunities and solutions that attempt to address the problems within health care systems. This use of portable technology in health care is called mobile health (mHealth) [3]. With an estimated 2 billion smartphone users worldwide [4] and apps becoming a ubiquitous part of people's lives, it is no surprise that there are over 97,000 mHealth apps available on various app repositories, and the mHealth app market is projected to reach a revenue of US $26 billion by 2017 [5]. The fifth biggest category of mHealth apps relate to medical condition management [5]. This category contains apps, which help users adhere to medication and monitor intake [5].

Previous studies on adherence apps have focused on the prevalence of behavior change techniques, ideal features, health literacy, content, and usability [6-9]. A literature review found only 14 papers and 4 app-related reports in which the "majority of reviewed studies showed a positive impact on the use of existing mobile apps for medication adherence" [10]. A review of diabetic self-management apps showed that there is a gulf between diabetes self-management guidelines and the features available on apps to meet these guidelines [11]. However, no thorough review has been conducted to evaluate all adherence apps with respect to their degree of evidence base, or medical professional involvement in their development.

The Objective

The aim of this study was to review the currently available medication adherence apps in the two largest app repositories, the Apple App Store and the Google Play Store, in terms of their evidence base, medical professional involvement in development, and strategies used to facilitate behavior change and improve adherence.

Methods

Initial Search

Relevant medication adherence apps were identified by interrogating the Apple App Store and Google Play Store using the primary search terms, which are "medication," "medicine," "pill," "drug," and "tablet," combined with secondary search terms, which are "reminder," "alarm," "manager," "tracker," "list," "organizer," "helper," "compliance," "adherence," and "accordance." The search and review took place in April 2015.

Any identified app designed to facilitate patient adherence to medications was included. The term *medication* in this study was defined as physical pharmacological treatment only . Apps designed primarily for nonpatient groups, for example, health care professionals (HCPs), and those providing no adherence support were excluded. Apps that provided lists of medicines or conditions such as encyclopedias were excluded. Apps that were available as a larger bundle (groups of up to 10 apps sold together at a reduced price) were also excluded. These apps were all tested individually, hence not requiring download of the bundle. Apps in languages other than English were excluded.

Data were extracted for each app from the app repository overview and the developer's website. Not all apps provided a website address; therefore, for a number of apps, information was gleaned from testing alone. Relevant data items included (1) documentation during the development of the app, and (2) availability of evidence base pertaining to the app (either relating to its design and development, or its efficacy). Other datasets were collected but found irrelevant to analysis; these are stated in Multimedia Appendix 1.

HCP involvement was defined as any individual working within the health care industry who was directly involved with the distribution or prescription of medication to patients. Hence, this included physicians, pharmacists, and nurses.

Evidence base was defined as an app providing data on trials or studies that are carried out utilizing the app to indicate effectiveness. This was only accepted once a report, study, or trial was seen by testers to validate the claim.

Testing Phase

Free apps were downloaded for further testing to explore the specific adherence strategies utilized by apps to promote medication adherence (eg, alarms and push notification reminders). Any additional feature not contributing specifically to adherence but designed to enhance user experience was also documented (eg, pharmacy locator function and refill reminder). In the case of inaccessible and paid apps, the identification of features was based on the app description and publisher website. Inaccesible apps were those that could only be accessed with authorization provided by a specific health care organization, pharmacy or health care provider.

Four researchers performed the data extraction. They identified the adherence methods used by apps and within those features, which subsets were utilized. Once a feature was identified, it was placed within an Excel spreadsheet alongside the app's name, which all reviewers had access to.

To provide reliability throughout testing, definitions for each adherence feature were established and agreed upon by all 4 reviewers.

A devised medication regime was input into all identified apps, and this was used by all 4 reviewers to test the apps in terms of adherence mechanisms utilized. If there was any uncertainty or doubt about an app's adherence mechanisms, it was resolved by consensus among the 4 reviewers.

All 4 reviewers tested the first 10 apps identified within the Apple App Store and the Google Play Store independently. Results of individual reviewers were then compared, and the interrater reliability was determined using the Fleiss Kappa coefficient.

The remaining apps were then equally allocated among reviewers. Data were extracted and placed into a spreadsheet for analysis.

During testing, any app that did not function was excluded, and details were kept in a separate spreadsheet, including the reasons for nonfunctioning. Only apps that functioned and fulfilled an adherence function were included for testing.

Results

Interrater Reliability

Interrater reliability between the 4 testers was calculated using the Fleiss Kappa coefficient (reproducibility between more than 2 testers). A sample of 20 apps (10 from each respective app store) was used, which resulted in a coefficient of .61 (SE 0.078; 95% CI 0.46-0.76). This suggests good reproducibility between the reviewers according to the Landis and Koch rules for interpreting Fleiss Kappa coefficient values [12].

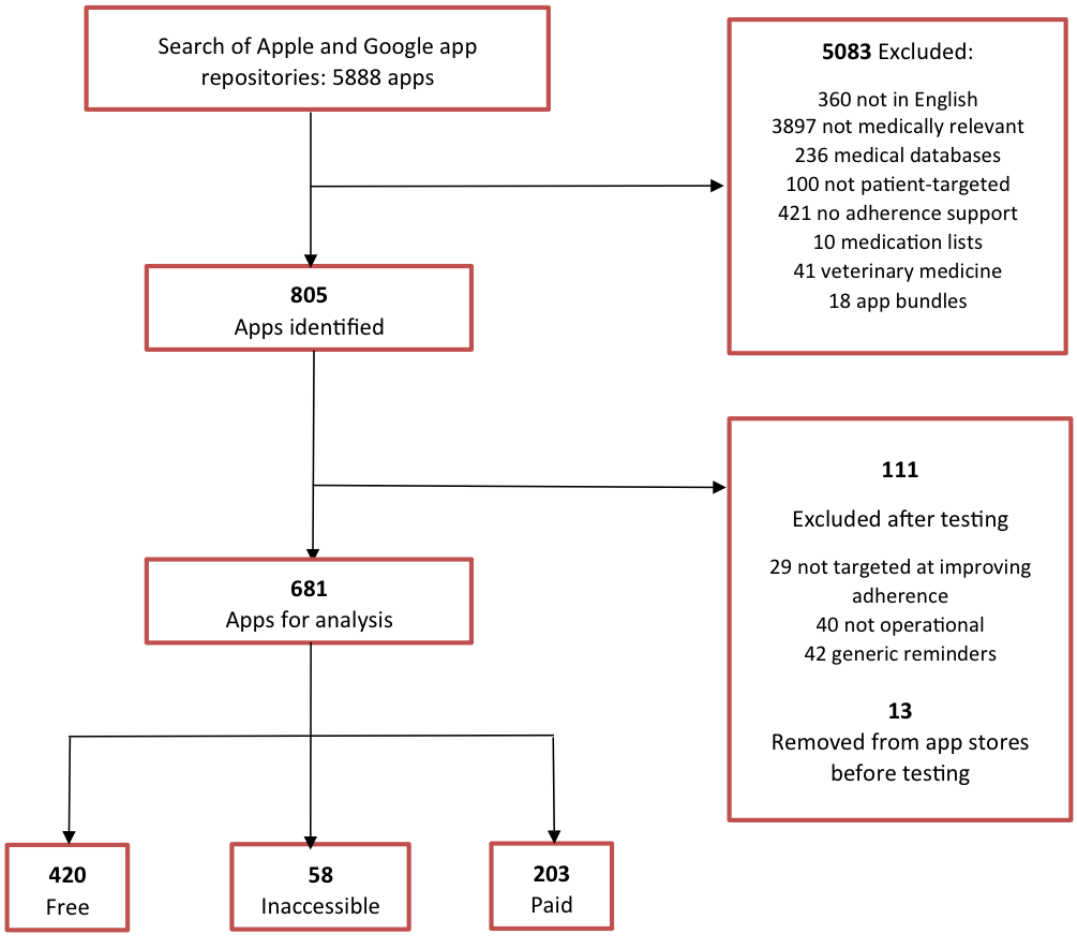
App Identification

The app repository search identified 5888 apps, of which 5207 apps were excluded, leaving 681 apps for analysis (see Figure 1).

The majority of those excluded were medically not relevant; these included various apps, for example, video games, magazine apps, to-do list, and wall paper apps.

Where possible data were extracted through app testing and from developer websites, where apps had a linked website. Of the free apps, 260 apps provided a website, with 160 apps providing no website.

Figure 1. Flowchart of identification of applications.



Moreover, 186 apps were solely found in the Google Play Store, 136 apps originated from the Apple App Store, and 98 apps were found in both repositories.

Download Stats were only available for Google Play Store apps. Of the 284 apps available for analysis, 168 (59.2%) had fewer than 10,000 downloads (<10,000), 63 (22.2%) apps had over 10,000 downloads (>10,000), and 53 (18.7%) apps had no available Download Stat.

Health Care Professional Involvement in App Development and Evidence Base

Of the 420 free apps, 13.6% (57/420) of the apps were developed with involvement from HCPs in the medical or pharmaceutical industry.

Meanwhile, mention of an evidence base (either in relation to the development process or of app effectiveness) was identified in only 1.0% (4/420) of apps. One app referenced trialing and testing by a patient panel from myhealthapps.net (network). Another app described following evidence-based patient safety practices recommended by the Minnesota Alliance for Patient Safety. The final 2 of the 4 apps specifically highlighted patient pilots and clinical trials in which their apps were used and have published the data.

Of the paid apps, 4.4% (9/203) of apps had HCP involvement in development, 0.5% (1/203) of apps had a documented evidence base, and 0.5% (1/203) of apps had both. The single evidence-based app was subjected to a randomized controlled trial and proved to be beneficial with 95% of participants adhering to medication. There was also one app, which was supported by the National Health Service Health Apps Library.

In addition, 31% (18/58) of inaccessible apps were produced with HCP involvement, whereas 3% (2/58) of apps had a documented evidence base. One of the 2 apps had produced a case study based on their app; however, this was not available for access. The other had developed a case study with a partnered company using their work, detailing the benefits of the companies offering. There were no clinical trials.

Download and Testing Phase

A total of 420 free apps were downloaded and further analyzed to identify strategies used to improve medication adherence. This led to the identification of three broad categories of adherence strategies: *reminder*, *educational*, and *behavioral*. The reminder category was defined as any strategy that acted to inform the user that it was time to take medication. The educational category was defined as any strategy that better informs patients regarding the importance of medication adherence. The behavioral category was defined as behavior change strategies used by apps to encourage adherence. A total of 59.5% (250/420) of apps utilized a single method, 35.5% (149/420) of apps used two methods, and only 5.2% (22/420) of apps utilized all three methods to improve adherence. The breakdown of apps according to the methods used is shown in Table 1.

It was apparent following the download and testing of apps that the behavioral and reminder categories could be further subdivided in line with the various identified techniques used by apps. This allowed the development of a taxonomy of adherence strategies utilized by apps (Figure 2).

The reminder classification was subdivided into three subcategories: (1) *Alarm*, which referred to the mobile device providing an audio alert at a preset time , (2) *Push Notification*, which was an internal message appearing on the mobile device at a set time indicating need to take medication, and (3) *Short Messaging Service (SMS)*, which delivered a text message indicating a reminder for taking medication at a set time.

The subcategories for the behavioral classification were (1) *External Monitoring*, (2) *Personal Tracking*, *and* (3) *Gamification.* External monitoring was a strategy that enabled users to send adherence-related data to third parties (such as family, friends, or HCP). Personal tracking referred to any capacity of the app to allow users to track their medication taking and create a record of it. Gamification was defined as any method to provide video game-like elements to the medication-taking process to encourage good medication adherence. An example applied to medication adherence would include in app rewards for high levels of adherence, such as badges or providing a level scheme.

Reminder

Almost all apps utilized a reminder function of some sort to facilitate adherence to medications; the number totaled 387 apps, amounting to 92.1% (387/420) of all apps tested. The largest subcategory was *Push Notifications*; 80.2% (337/420) of apps utilized this method. *Alarms* were ranked second with 134 apps, and finally very few, 1.4%, (6/420) of apps incorporated *SMS Reminders*. A breakdown of the app numbers utilizing various reminder subcategories are provided in Table 2.

Reviewing the reminder function according to the number of downloads revealed in the <10,000 downloads group that 88.1% (148/168) of apps utilized a reminder function. In the over >10,000 downloads group, 90% (57/63) of apps possessed a reminder function, and in the group where download data were unavailable, 100% (53/53) of apps utilized a reminder function (Figure 3). These results relate only to apps within the Google Play Store.

Comparison of apps according to app repository revealed that 170 (91.4%) apps of 186 Google Play Store only apps, 129 (94.9%) apps of 136 Apple App Store only apps, and 88 (89.8%) apps of 98 apps in both store utilized a reminder function (Figure 4).

Table 1. Numbers of apps adopting the various adherence strategies.

Strategy	Number of apps
Reminder	220
Behavioral	28
Education	1
Reminder, behavioral	133
Reminder, education	12
Behavioral, education	4
Reminder, behavioral, education	22
Total	420

Figure 2. Taxonomy of identified adherence strategies.

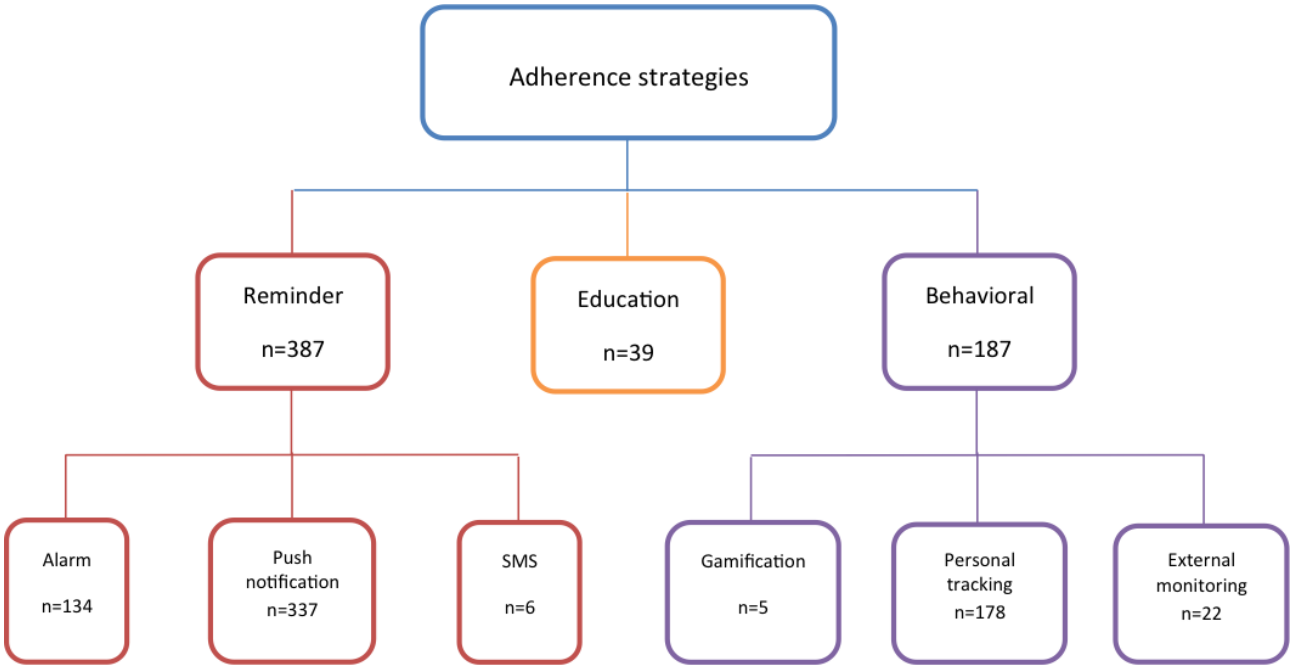


Table 2. Number of apps adopting reminder strategies.

Strategy	Number of apps
Alarm	48
Push notifcation	248
Short messaging service	2
Alarm, push notification	85
Alarm, short messaging service	0
Short messaging service, push notification	3
Alarm, short messaging service, push notification	1
Total	387

Figure 3. Chart comparing reminder function percentage according to downloads.

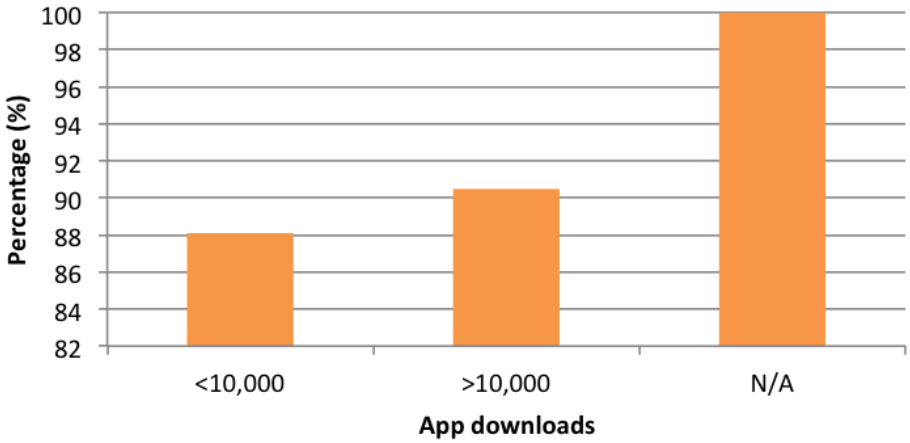
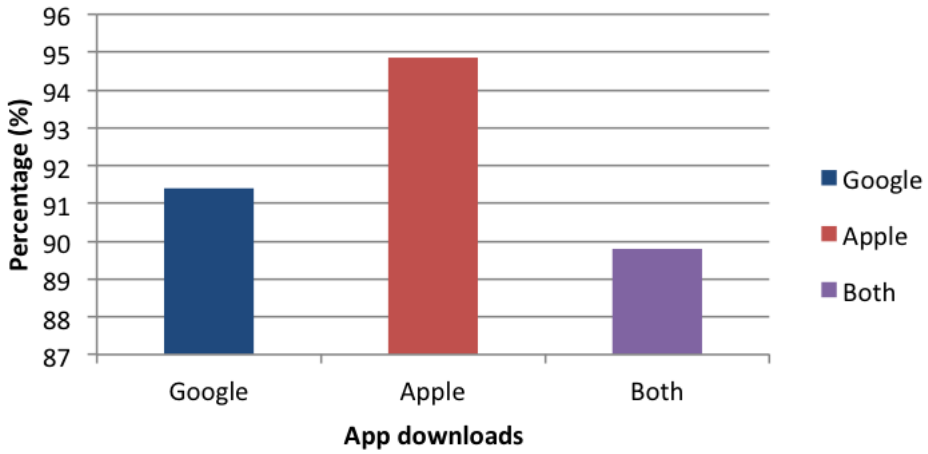


Figure 4. Chart comparing reminder function percentage among apps in different app stores.



Behavioral

This category was the second largest, with 44.5% of apps (187/420) utilizing one or more of the three behavioral technique subcategories. A total of 42.4% of apps (178/420) used the *Personal Tracking* feature. In addition, 95.1% (174/178) of apps using a behavioral strategy incorporated personal tracking.

Comparatively, 22 apps (5.2%) used a form of *External Monitoring*. Last were apps using *Gamification.* Analysis showed that 5 apps (1.2%) utilized this strategy. A breakdown of the app numbers utilizing various behavioral subcategories is provided in Table 3.

Comparing by number of downloads (Google Play Store available apps): in the <10,000 group, 45.2% (76/168) of apps; in >10,000 group, 49% of apps (31/63); and in apps where download data were not available, 37% of apps (20/52) utilized a behavioral function (Figure 5).

Comparison of apps according to app store revealed that 46.2% (86/186) of Google Play Store only apps, 43.4% (59/136) of Apple only apps, and 43% (42/98) of apps in both stores utilized a behavioral function (Figure 6).

Education

A total of 39 apps used education as a method. Comparing by number of downloads (Google Play Store available apps): in the <10,000 group, 7.7% of apps (13/168); in >10,000 group, 3% of apps (2/63), and in apps where download data were not available, 8% of apps (4/53) utilized education as a method (Figure 7).

Comparison of apps according to app repository revealed that 2.7% of (5/186) Google Play Store only apps, 14.7% (20/136) of 136 Apple only apps, and 14% (14/98) of apps in both stores utilized education as a method (Figure 8).

User Features

Through testing, various additional user features were identified; these are listed in Table 4.

Figure 9 provides a breakdown of the offerings of these additional user features according to whether apps were free, inaccessible, or paid. A large number (224/681) of apps did not offer any user features: 38.3% (161/420) of the free apps, 27.6% (56/203) of the paid apps, and 12% (7/58) of the inaccessible apps.

Table 3. Number of apps adopting behavioral strategies.

Strategy	Number of apps
Gamification	1
Personal tracking	161
External tracking	8
Gamification, personal tracking	3
Gamification, external tracking	0
Personal tracking, external tracking	13
Gamification, personal tracking, external tracking	1
Total	187

Figure 5. Chart comparing behavioral function percentage according to downloads.

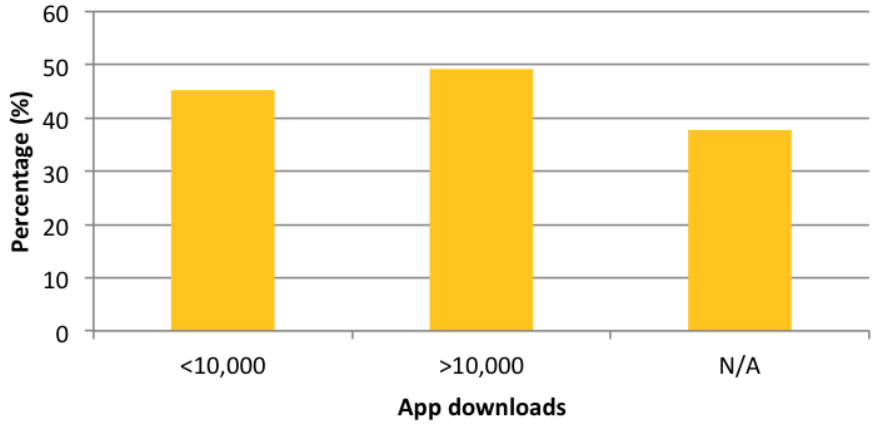


Figure 6. Chart comparing behavioral method percentage among apps in different app stores.

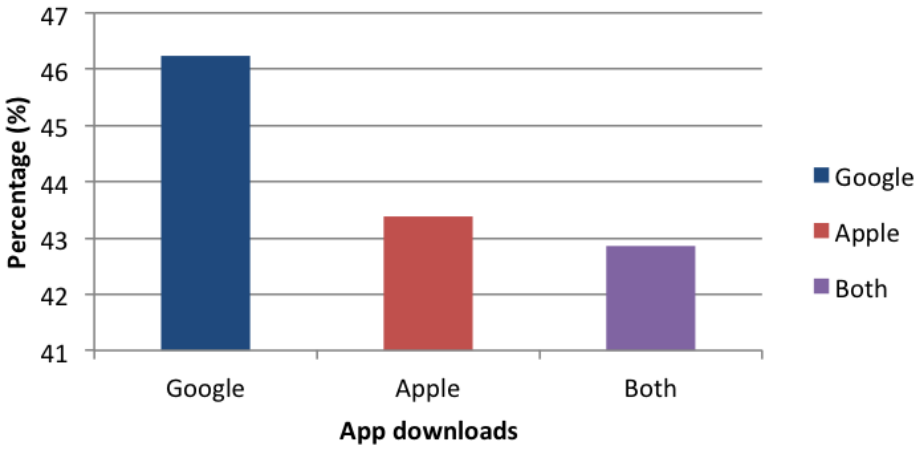


Figure 7. Chart comparing education method percentage according to downloads.

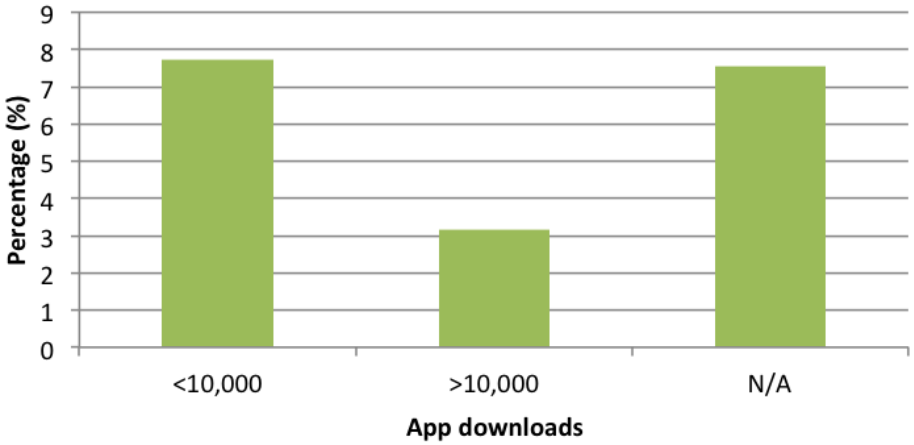


Figure 8. Chart comparing educational method percentage among apps in different app stores.

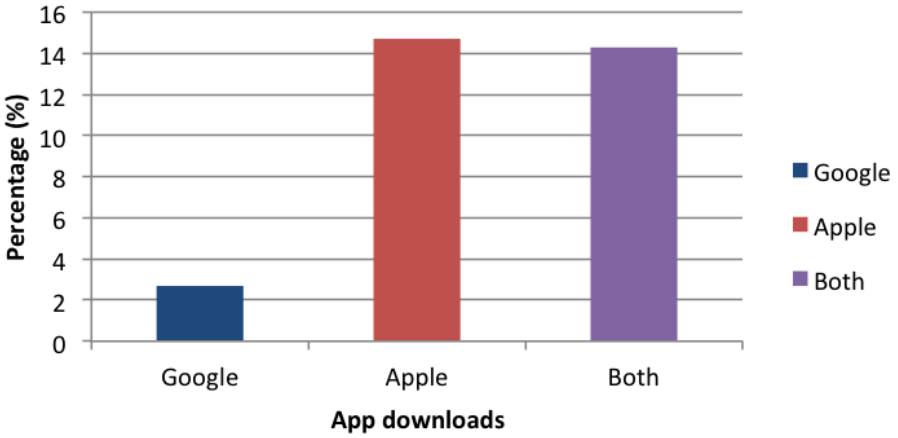
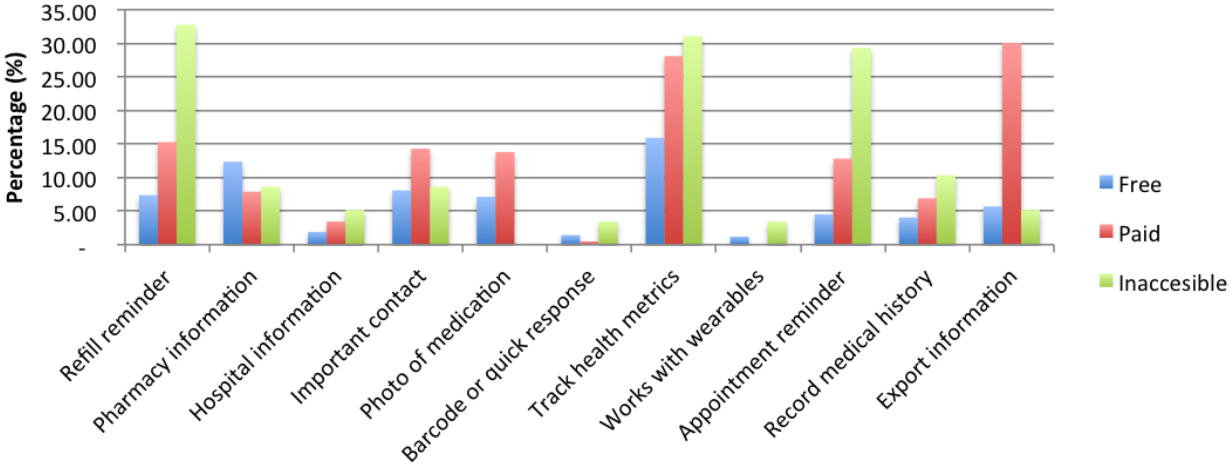


Table 4. User features offered by apps.

User feature	Description of feature	Number of free apps with user feature
Track other health metrics	Such as blood pressure	67
Pharmacy information	Information relating to nearby pharmacies, such as contact information or location	52
Important contacts	Can input information relating to pharmacist, doctor, or emergency contact in the app	34
Refill reminder	An alarm or reminder relating to when the user requires refilling of their medication	31
Photo of medication	Add a picture of the medication or select image from existing gallery to place next to medication on app	30
Export information from app	Can email or send information on medication or adherence record to another person, such as a health care provider	24
Appointment reminder	Reminds you of medical appointments	19
Record medical history	Can act as an electronic medical record by inputting medical history	17
Hospital information	Information relating to nearest hospital, contact information, and location	8
Barcode scanner	Scans barcode and automatically inputs medication according to the barcode	6
Work with wearables	Compatibility with wearable technology	5

Figure 9. Chart comparing user features across payment modalities.



Discussion

Principal Findings

To our knowledge, this is the first study to systematically and exhaustively review all currently available medication adherence apps on the two largest app repositories. Dayer et al [13] is the only comparable study of this nature to look at a wide number of medication adherence apps and explore desirable features. However, only 10 of the highest rated apps were downloaded and user tested compared with 420 apps in this review. This possibly reflects the rapid expansion in mHealth app release year on year [5].

One of the most important findings of this study is the concerning lack of HCP involvement in app development (84/681, 12.3%) and the limited evidence base related to the development and use of such apps (8/681, 1.2%). App reviews focusing on other medical fields have reported similar findings such as colorectal conditions [14], vascular conditions [15], urology [16], orthopedic sports medicine [17], hernias [18], obesity [19], ophthalmology [20], and pain management [21]. Although the involvement of HCPs in app development does not necessarily guarantee app efficacy, it is likely to provide greater insight into patient needs and is suggestive of more reliable content and higher quality.

Of the 8 identified evidence-based apps, only 3 apps related specifically to clinical trials investigating app efficacy (in terms of an improvement in medication adherence rates). In the current era of evidence-based practice, robust evidence supporting the use of app-based interventions is necessary if there is to be widespread HCP buy-in to apps or if apps are to be prescribed and reimbursed by health care systems in the future, in much the same way as drugs currently are. The limited prevalence of evidence-based apps may, in part, be explained by the inherent tension that exists between the slow-paced and arduous nature of gold-standard health care intervention evaluation methodologies (such as the randomized controlled trial) and the fast-paced and evolving nature of app technologies [22,23]. Newer, faster evaluation methodologies may be required to address such challenges going forward.

The testing of adherence apps undertaken in this study has enabled us to create a taxonomy of strategies that have been utilized by such apps to promote behavior change and adherence. The wider adherence literature describes two broad types of nonadherence among patients [24]: (1) unintentional—where patients intend to take their prescribed medicines but ultimately do not (eg, due to forgetfulness) and (2) intentional—where patients make an active decision not to take their medicines. The results of this study indicate that the majority of currently available adherence apps utilize strategies targeting unintentional nonadherence, such as reminders. Push notifications in particular were the predominant technique utilized. Interestingly, only 1.4% (6/420) of apps reviewed in this study used SMS as a means of sending reminders, despite existent evidence demonstrating the effectiveness of SMS reminders in improving adherence [25]. One review concluded that as reminder apps serve a very similar function to but have a broader range of functionality than SMS messaging; the potential for such apps to improve medication adherence will be at least equal to, if not greater than, SMS reminders [13]. This provides a potential explanation for the demonstrated lack of SMS utilization compared with other reminder methods.

Educational strategies, which may be of potential benefit in both unintentional and intentional nonadherers, were also underutilized, despite evidence demonstrating that increasing patient knowledge regarding medicines and the importance of taking prescribed medicines improves adherence [26].

External monitoring was another poorly utilized adherence strategy. This strategy allows third parties to receive adherence information of the patient, giving them greater opportunity to become more actively involved and integrated with patient care. This may be of particular benefit in those with chronic conditions. Although the overall utilization of external monitoring was low, prevalence in the inaccessible groups of apps was much higher (28% [16/58] vs 5.2% [22/420]), highlighting how certain clinics and pharmacies are taking on the responsibility of monitoring and promoting adherence of their patient populations through the use of apps.

Gamification was the least commonly utilized adherence strategy, with just 1.2% (5/420) of apps utilizing this technique. It is an umbrella term used to describe “the use of video game elements in nongaming systems to improve user experience and user engagement” [27]. The evidence base in support of

gamification as a method of promoting behavior change is growing. One systematic review demonstrated that 69% of psychological therapy outcomes and 59% of physical therapy outcomes were improved by video games; results did not differ across age groups [28]. The target markets for the gamification apps identified in this study were not age specific; tailoring apps to an age demographic may allow for the more effective use of gamification. *Pain Squad* is an example of an effective gamification app targeted at a younger audience; it is used to document pain levels in children with cancer and had high compliance and satisfaction ratings [29]. The positive uptake among children and adolescents may be replicable for medication adherence.

Aside from the various adherence strategies provided by apps, a large proportion also offered a host of additional user features and functionality, falling into one of 11 categories. The most common features were health metric tracking, medication refill reminders, pharmacy information, and directories of health care service contacts. The least prevalent features were barcode scanning, connecting with wearable technologies, and hospital information provision. In general, user features were found to be more prevalent among paid apps, offering a more comprehensive service for the individual downloading the app and justifying the cost price.

Although few identified apps provided barcode scanning (using digital quick response code technology to capture the relevant identifier on a drug packet), such technology has been demonstrated to reduce medical error rates, thereby promoting patient safety [30]. Consequently, the provision of barcode scanning within adherence apps should be encouraged.

Finally, the literature highlights that nonadherence is particularly common among the elderly, who are often on multiple, life-long medicines [31,32] and may suffer with memory impairment [32,33]. It stands to reason, therefore, that this demographic potentially stands to gain the most from app-based adherence interventions. Unfortunately, however, this same demographic is less familiar and interested in such technologies and also more likely to suffer from physical ailments such as limited dexterity [34,35]. However, more recent evidence suggests that this trend is changing as interest increases in mHealth [36]. Consequently, it is imperative that developers offer enhanced accessibility features to increase the reach of apps into the older age groups. In this regard, a number of reviewed apps offered the ability to increase the displayed font size and text fields and provided a larger keypad for data entry.

Limitations

Several limitations were identified in this study. First, although we were able to download and test free apps to identify the adherence strategies that they utilized, we were unable to download and test paid apps because of lack of funding. From app repository descriptions, it appears that paid apps offered additional features and functionality and the ability to download such apps may have yielded further useful insights around the strategies used by apps to promote adherence. Similarly, we were also unable to download and test inaccessible apps, which required log-in credentials from an affiliated health care organization or clinic.

As a consequence of the dynamic nature of the mHealth apps market and the rapid turnover of apps, several apps initially identified for inclusion in this review were subsequently withdrawn from app repositories rendering potentially influential data gleaned from such apps redundant.

Finally, because of the rapid production and release of new apps, we acknowledge that as this review was performed, new adherence apps will have been released that have not been included in this study.

Future Research

We have highlighted two main potential areas for future research. First, although we have used HCP involvement as a surrogate market for app quality, other markets are also likely to be important such as patient involvement in the creation of apps. Further research involving focus groups and qualitative assessment of apps with patients will help in addressing this issue.

Second, we have focused on all medication adherence apps irrespective of disease condition to get a broad overview of the market. Future research may therefore focus on apps designed for adherence in specific disease contexts.

Conclusions

This app repository review demonstrates a concerning lack of HCP involvement in app development. Greater collaboration is required among app developers, HCPs, academics, behavioral scientists, and end users to ensure the development of high-quality, relevant adherence apps.

The results have also identified that the vast majority of current adherence app offerings on repositories lack any evidence base of effectiveness. In this regard, well-powered and robust clinical trials investigating the effectiveness of these interventions are needed going forward. Such evidence will enable HCPs to prescribe an adherence app whenever they are prescribing a medicine, thereby resulting in widespread adoption among patients.

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We would like to thank Imperial College Business School for introducing us to our wonderful supervisors and supporting us throughout our intercalated BSc, which resulted in the production of this project.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplementary table.

[PDF File (Adobe PDF File), 15KB - mhealth_v6i3e62_app1.pdf]

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Abbreviations

HCP: health care professional
mHealth: mobile health
SMS: short messaging service

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Original Paper

Reliability of Self-Reported Mobile Phone Ownership in Rural North-Central Nigeria: Cross-Sectional Study

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Abstract

Background: mHealth practitioners seek to leverage the ubiquity of the mobile phone to increase the impact and robustness of their interventions, particularly in resource-limited settings. However, data on the reliability of self-reported mobile phone access is minimal.

Objective: We sought to ascertain the reliability of self-reported ownership of and access to mobile phones among a population of rural dwellers in north-central Nigeria.

Methods: We contacted participants in a community-based HIV testing program by phone to determine actual as opposed to self-reported mobile phone access. A phone script was designed to conduct these calls and descriptive analyses conducted on the findings.

Results: We dialed 349 numbers: 110 (31.5%) were answered by participants who self-reported ownership of the mobile phone; 123 (35.2%) of the phone numbers did not ring at all; 28 (8.0%) rang but were not answered; and 88 (25.2%) were answered by someone other than the participant. We reached a higher proportion of male participants (68/133, 51.1%) than female participants (42/216, 19.4%; $P<.001$).

Conclusions: Self-reported access to mobile phones in rural and low-income areas in north-central Nigeria is higher than actual access. This has implications for mHealth programming, particularly for women's health. mHealth program implementers and researchers need to be cognizant of the low reliability of self-reported mobile phone access. These observations should therefore affect sample-size calculations and, where possible, alternative means of reaching research participants and program beneficiaries should be established.

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KEYWORDS

reliability; phone ownership; resource-limited setting; cell phone use; rural population; developing countries; self report; Nigeria; telemedicine

Introduction

More than 443 million of the 6 billion mobile phone subscribers worldwide are in Africa [1]. Additionally, sub–Saharan Africa has experienced the highest rate of growth in mobile subscriptions globally within the last decade [2]. The penetration level of the subscriber identity module, which in 2010 was just approaching 50%, is now forecasted to be close to 100% [2], with expectation of full coverage by 2021. This burgeoning growth is even more visible in West Africa, which as of 2015 had about 40% of all mobile subscriptions in sub–Saharan Africa [3]. Nigeria has the largest mobile phone market in West Africa and, with over 150 million subscribers [4], is seventh highest in the world for the number of mobile subscriptions [3,5].

The mobile phone has shown remarkable promise in different areas of human endeavor, including health care, commerce, aviation, and entertainment [6]. The potential of mobile telephony to enhance health care and improve health research has been recognized by health care practitioners and researchers worldwide [7-10]. Numerous mHealth interventions have been implemented all over the world with varying degrees of success [11-14]. Furthermore, the use of the mobile phone to enhance the conduct of health research in different settings has been explored widely, with mobile phone–based apps being developed for surveys and follow-up of study participants, among others [15,16]. In many of these interventions, the success of mHealth interventions has been generally limited. Reasons for this have included weak surveillance, drug and logistic stockouts, and a lack of skilled human resources [17,18].

The widespread ownership and use of the mobile phone has been touted as one of the strengths of implementing mobile phone–based health interventions [9]. To benefit maximally from this technology, stakeholders have recommended several strategies to entrench mHealth into national health systems—for example, forging strategic partnerships [19], securing an appropriate policy environment [1,20], and stimulating national political commitment and ownership [19].

Nigeria, recognizing the immense potential of information and communication technology in health care, has developed a policy framework to enhance information and communication technology infrastructure to support efforts toward universal health coverage [21]. Among other things, this policy seeks to provide standards for eHealth and mHealth implementation within a proper governance structure. In the light of this work, the mobile phone, which is ubiquitous, will play a key role in furthering these objectives [21].

There is, however, limited evidence of the reliability of self-reported mobile phone ownership and access, which may be affected by various social and infrastructural factors. This limited reliability of self-reported phone ownership may also affect the effectiveness of mobile phone–based interventions in the event that reliability is less than anticipated.

In this study, we sought to ascertain the reliability of self-reported mobile phone ownership and access, in 7 local government areas in Benue State, north-central Nigeria. This information will inform planning and implementation of future mHealth interventions to maximize their impact and reach.

Preliminary Study: The Healthy Beginning initiative

The Healthy Beginning Initiative (HBI) was a US National Institutes of Health–funded, cluster randomized trial designed to evaluate the comparative effectiveness of church-based, free, confidential, and integrated laboratory testing provided on-site during baby showers for pregnant women and their male partners on HIV testing and linkage to health facilities. This intervention was associated with a higher HIV testing rate (control group: 740/1355, 54.6% vs intervention group: 1514/1647, 91.9%; adjusted odds ratio 11.2, 95% CI 8.77-14.25; $P \leq .001$) [22,23]. HBI used a network of church-based health advisors and clinic-based teams trained in motivational interviewing and quality improvement skills to engage and support HIV-infected women. This program was adopted and scaled up by the US President's Emergency Plan For AIDS Relief via support to Caritas Nigeria in Benue State to achieve community testing targets.

We drew participants for our study from a database of pregnant women and their male partners who participated in the HBI scale-up effort in Benue State, Nigeria between September 1 and December 31, 2016.

Aims of the Study

The overarching objective of this study was to determine the reliability of self-reported mobile phone ownership and use as a means of delivering health care interventions. The aims of the study were to determine the proportion of self-reported mobile phone numbers that (1) ring when called, (2) are answered when called, and (3) are answered by the intended participant when called.

Methods

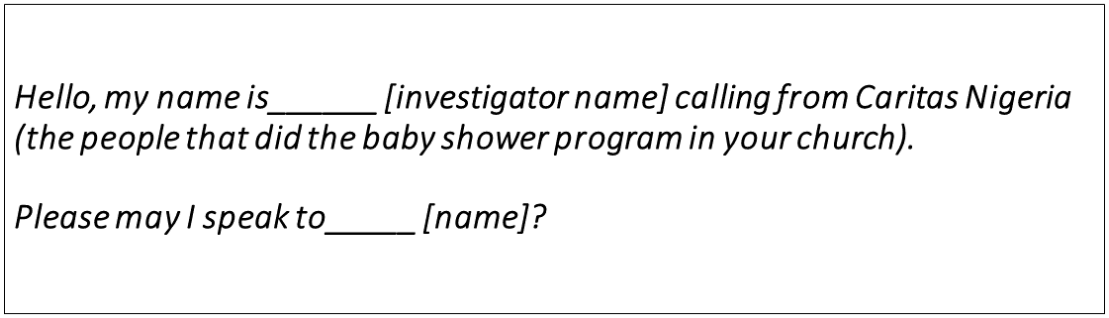
Participant Selection and Sample Size Determination

We used a stratified random sampling procedure. We first stratified data by the participants' sex. Participants were drawn from the HBI program. We selected men and women proportionate to the ratio of female to male participants in the program database (62:38). Sample size for the study was determined by assuming a nominal response rate of 50%, which maximizes the sample-size calculation and a precision of 5%. A total of 2215 participants of known sex in the HBI database had provided telephone numbers. This resulted in a sample size of 328 participants needed for this study. For ease of design and to provide additional participants for robustness, we rounded this number up to 350 participants. Sample-size calculations were performed using the SampSize calculator [24].

Inclusion and Exclusion Criteria

We included male and female participants more than 18 years of age who participated in HBI in Benue State between September 1 and December 31, 2016, and who reported at least one primary mobile phone number on their biodata collection form. We excluded participants who did not provide a mobile phone number from the dataset before sampling.

Figure 1. Script used when respondents were called.



Study Procedures

We developed a script for the phone call to be made to participants. Investigators dialed the participant's phone number and, if the call was answered, read the script (Figure 1).

If the call was answered by another party, the research assistant asked an additional question to ascertain the relationship between the respondent and the intended participant. If the phone rang, but was not answered, an attempt was made for a follow-up call on the next scheduled day, for up to 3 attempts within a 1-week period. Results of each call were documented on a data collection log. This was entered into a Microsoft Excel 2010 spreadsheet (Microsoft Corporation), and the entries were double-checked by research coordinators to ensure completeness and appropriateness. These data were then deidentified and exported to Stata 13 (StataCorp LLC), which we then used to conduct quantitative analysis.

Statistical Analyses

We calculated descriptive statistics for selected clinical characteristics. We used the chi-square test to compute the difference in proportion between the different possible outcomes following the call: did not ring; rang but no answer; answered by another party; and answered by the participant. Among the associations we studied were the participant's sex and marital status. In cases where the calls were answered by individuals other than the intended participants, we drew associations between the participant's sex and their relationship with the eventual respondent. We analyzed differences in respective proportions using the chi-square test.

Results

There were a total of 349 participants in this study. Their ages ranged from 18 to 75 years, with a mean age of 27 years. Most respondents were aged between 21 and 30 years (Table 1). There were 216 women and 133 men, in accordance with the ratio of 62:38 (Table 1).

Of the 349 numbers we attempted to call, 123 were not reachable, and 28 rang but there was no answer. For 88 of them, a party other than the participant answered the call. We reached 110 of the participants (31.2%) on the phone (Table 2).

There were significant differences when we stratified by sex the best outcome of the calls made. Among men, we reached 51.1% (68/133) of the participants, compared with 19.4% (42/216) of women (P<.001) (Table 3). Among women, 34.3% (n=74) of the calls were answered by another party, while among men, the proportion was 10.5% (n=14). Among women whom we did not reach on the numbers they provided, 54.4% (37/68) of the calls were answered by their husbands and 16.2% (11/68) were marked as wrong numbers. Among men, only 13 of the numbers called were answered by parties other than the intended participants, with only 3 (23.08%) being their spouses (Table 4).

Table 1. Participants' characteristics.

Characteristic	Total (N=349), n (%)
Age range (years)	
≤20	67 (19.2)
21-30	201 (57.6)
31-40	68 (19.5)
41-50	9 (2.6)
≥51	4 (1.2)
Sex	
Male	133 (38.1)
Female	216 (61.9)

Table 2. Best outcome after a maximum of 3 call attempts.

Best outcome	Total (N=349), n (%)
Did not ring	123 (35.2)
Rang, no answer	28 (8.0)
Rang, answered by another party	88 (25.2)
Rang, answered by participant	110 (31.5)

Table 3. Outcome stratified by sex.

Best outcome	Sex, n (%)		Total (N=349), n (%)
	Male (n=133)	Female (n=216)	
Did not ring	44 (33.1)	79 (36.6)	123 (35.2)
Rang, no answer	7 (5.3)	21 (9.7)	28 (8.0)
Rang, answered by another party	14 (10.5)	74 (34.3)	88 (25.2)
Rang, answered by participant[a]	68 (51.1)	42 (19.4)	110 (31.5)

[a]$P<.001$.

Table 4. Relationship to participant when the participant's phone rang but was answered by another party[a].

Relationship to participant	Sex of study participant, n (%)		Total (N=81), n (%)
	Male (n=13)	Female (n=68)	
Brother	2 (15)	2 (3)	4 (5)
Brother-in-law	0 (0)	6 (9)	6 (7)
Father	2 (15)	0 (0)	2 (2)
Friend	1 (8)	1 (2)	2 (2)
Spouse	37 (54)	3 (23)	40 (49)
Mother	0 (0)	2 (3)	2 (2)
Neighbor	1 (8)	5 (7)	6 (7)
Sister	1 (8)	2 (3)	3 (4)
Sister-in-law	0 (0)	1 (2)	1 (1)
Son	0 (0)	1 (2)	1 (1)
Wrong number	3 (23)	11 (16)	14 (17)

[a]The relationship to the participant was not specified in a few cases.

Discussion

Principal Findings

Our study examined the reliability of self-reported mobile phone ownership and access in a predominantly rural area in north-central Nigeria. Our findings show that, in spite of high reported mobile phone ownership among participants, only one-third of these numbers were answered by those who reported ownership of those phones when called.

An unusually high proportion (35.2%) of calls we made did not connect. This may be explained by participants giving incorrect numbers. Incorrect numbers being called may have been a result of the generally low level of education among respondents or data entry errors. Other plausible reasons for calls not successfully connecting are the erratic power supply and poor network connectivity in some areas, which have long been recurring problems in Nigeria [25]. This reduces the reliability of household items, such as the mobile phone, that rely primarily on electricity to function. This may partly account for the unusually high proportion of calls that did not ring. Some of the phones that did not ring may have had dead batteries as a result of prolonged periods of power outage.

Of the calls that were answered by parties other than the intended respondents, 82.7% (67/81) were people who knew the participants, revealing the extent to which mobile phones are shared in households. These findings are consistent with those from a survey conducted in a similar setting in Ghana, which found that the practice of phone sharing was common, especially in rural areas [26].

We also observed that only a small proportion of the calls actually connected but were not answered (8.02%). This may be explained by the fact that participants were informed at

enrollment that they would be contacted on their phones and so may have expected our calls, and there is no cost associated with answering phone calls. The population we surveyed was also rural, and most participants were known to not use texts or social media because of low literacy. It is, however, noteworthy that a small proportion of this group may not have answered the calls because they did not recognize the number we used to contact them.

In addition, there were significant differences in control and accessibility of the phones between men and women. This was demonstrated by the huge disparity in the percentage of wives and husbands who answered calls meant for their partners. These findings may be explained by the different gender roles common in many low- and middle-income countries, where men are more economically empowered and women play a subservient role [27]. These traditional gender roles may also explain the difference in outcomes between men and women, where less than half of women were actually reached after 3 attempts.

The results of this study can be more generally applied to other areas within and outside of Nigeria with a similar demographic and socioeconomic structure. A potential limitation of our study may be the nongeneralizability of our findings to more urban populations with higher levels of education and less adherence to traditional gender roles, such as higher-income countries or places within low- and middle-income countries where people do not adhere to traditional gender roles and have higher levels of education.

In light of these findings, certain considerations should be taken into account when designing studies or interventions that depend on participants' self-reported ownership of or access to mobile phones, especially in rural areas. The less-than-optimal and gendered pattern of actual phone access should inform methodology for research and programs, particularly in low- and middle-income areas. These studies should target larger sample sizes or use alternative means of contacting participants due to the possibility of high nonresponse rates.

Conclusion

This study demonstrated that reported mobile phone ownership and access, especially in rural and low-income settings, is higher than what exists in reality. In addition, the high proportion of calls that were answered by husbands of participants is noteworthy. This has implications for mHealth programs, for the purposes of either data gathering or the implementation of health interventions, particularly those that target female participants and their health. mHealth practitioners in these areas therefore need to be cognizant of this and adjust appropriately when planning their programs. This lower-than-expected actual access may also explain the mixed results produced by mHealth interventions, particularly those that depend on phones owned by the intended beneficiaries of these programs.

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Conflicts of Interest

None declared.

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Abbreviations

HBI: Healthy Beginning initiative

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Original Paper

Exploring Digital Health Use and Opinions of University Students: Field Survey Study

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Abstract

Background: During university, students face some potentially serious health risks, and their lifestyle can have a direct effect on health and health behaviors later in life. Concurrently, university students are digital natives having easy access to the internet and new technologies. Digital health interventions offer promising new opportunities for health promotion, disease prevention, and care in this specific population. The description of the current use of and opinions on digital health among university students can inform future digital health strategies and interventions within university settings.

Objective: The aim of this exploratory study was to report on university students' use and opinions regarding information and communication technologies for health and well-being, taking into account sociodemographic and self-rated general and mental health correlates.

Methods: This field survey was conducted from March to April 2017. An informed consent form and a paper questionnaire were given to students aged 18 to 24 years in 4 university campuses in Bordeaux, France. The survey was formulated in 3 sections: (1) sociodemographic characteristics and self-rated general and mental health, (2) information about the use of digital health, and (3) opinions about digital health. Data were analyzed using descriptive statistics and tests of independence.

Results: A total of 59.8% (303/507 females) students completed the questionnaire. Concerning digital health use, 34.9% (174/498) had at least 1 health app mostly for physical activity (49.4%, 86/174) and general health monitoring (41.4%, 72/174,), but only 3.9% (20/507) of students had a wearable device. Almost all (94.8%, 450/476) had searched for Web-based health-related information at least once in the last 12 months. The most sought health-related topics were nutrition (68.1%, 324/476); pain and illnesses (64.5%, 307/476); and stress, anxiety, or depression (51.1%, 243/476). Although Wikipedia (79.7%, 357/448) and general health websites (349/448, 77.9%) were the most consulted sources, students considered institutional or official websites as the most credible sources (309/335, 92.2%). There were significant differences in digital health use by gender, field, and year of study. No statistically significant association was found between digital health use and self-rated general and mental health status. Concerning opinions on digital health, although 94.1% (475/505) of students estimated that today's digital health cannot replace traditional health services and medical consultations, 44.6% (207/464) of students declared that this could be possible in the future, provided that digital health interventions are promoted by institutional or official entities.

Conclusions: University students are largely using the internet for health information seeking, but using less mobile health apps and very few wearable devices. Our data suggest that digital health has the potential for improving health and well-being at the university, especially if digital health interventions take into account students' profiles, interests, and needs.

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KEYWORDS

eHealth; mHealth; students; mobile application; surveys; Internet

Introduction

Background

University students represent almost two-thirds of all young adults in Organisation for Economic Co-operation and Development (OECD) countries [1]. As potential future leaders, politicians, and managers, their health and well-being is a world-wide public health priority [2]. Although they can be viewed as a privileged healthy population, university students often report poor health conditions. They have relatively high rates of sexually transmitted and inflammatory diseases due to risky sexual practices [3]; they are at risk of chronic diseases due to sedentary behavior [4], problematic alcohol consumption [5], and drug use [6]; and frequently report mental health problems such as stress, anxiety, or depression, which are often due to academic load and homesickness [7].

This important segment of the population has necessarily wide access to modern information devices (eg, mobile phones, computers, and tablets). Known as digital natives or net generation [8], university students are among the highest users of the internet and new technologies not only for educational purposes but also for communication, recreation, and learning in general, including searching for Web-based information [9].

In view of this, university students represent an important target for digital health interventions. Digital health is defined as the general use of information and communication technologies for health [10], where health encompasses any state of complete physical, mental, and social well-being. Digital health is inclusive of both internet- and mobile-based tools (ranging from websites to mobile phone apps) aimed to prevent and treat diseases, as well as to promote health and well-being. The important role of digital health for university students has been largely recognized, and today, universities are increasingly recurring to digital solutions to improve their students' health. In the past two decades, several digital health interventions have been tested and diffused in different campuses worldwide. These include, for instance, Web-based programs to promote healthy eating and physical activity [11,12], mobile-based tools to reduce tobacco and drug use [13], apps to decrease sexual risk behaviors [14], and both internet- and mobile-based tools to improve university students' mental health [15,16]. Most studies have been carried out in experimental settings (eg, randomized controlled trials) and Anglo-Saxon university campuses (eg, the United States, Australia).

In parallel, the number of Web pages providing health information is constantly increasing, and the open digital market is becoming overwhelmed with mobile phone apps and wearable devices for health [17]. Although numerous surveys have been conducted to investigate university students' Web-based health information seeking behavior [18,19], few survey-research studies [20] have assessed and cataloged current use of digital health in university students in a natural noncontrolled setting, not limited to health information seeking, but including also the download and use of mobile apps as well as smart watch ownership, for instance. Furthermore, little research [21] has been conducted to describe in the student population the association of digital health use with gender and self-rated health and specific characteristics such as field and year of study. Understanding how these individual factors influence digital health use could inform the development of acceptable and successful internet- and mobile-based health interventions in the university setting.

In most of the OECD countries, universities and attached students' health services are asked to propose health strategies and policies to prevent diseases and promote health within their campuses [22]. Investments in digital health are globally on the rise, but public universities are often constrained by human and economic resources. It is then important to understand which digital health interventions should be implemented as a priority, on which topics and by which means (eg, internet- and mobile-based tools).

Aim of This Study

To help design and implement future digital health strategies and interventions in university campuses, this exploratory study aimed to provide a general overview on patterns of digital health use among university students in France, extending existing research with updated data on Web-based health-related information seeking and related trustworthiness, and on the use of mobile phone apps and wearable devices for health and well-being. The correlation of digital health use with sociodemographic characteristics and self-rated health was also examined.

Methods

Study Population and Recruitment

This study was conducted within the framework of the larger ongoing i-Share cohort study (Internet-Based Students Health Research Enterprise), a French nationwide Web-based survey on the health and well-being of university students, whose principal investigators and operational staff are based at the University of Bordeaux. Drawing on some findings of the i-Share survey [23], we were inspired to look further in the issue of digital health use among university students. This specific cross-sectional questionnaire study was then conducted from March to April 2017 as an exploratory study in a new sample of students at the University of Bordeaux.

A paper questionnaire was administered face-to-face by 9 undergraduate trainees (interviewers) who approached their peers in the halls, canteens, courtyards, and study rooms of 4 campuses, each corresponding to a specific field of study (Literature and Social Sciences, Life and Health Sciences, Science and Technology, and Law and Economy). The quota sampling method was used to recruit students according to their gender and field of study : the interviewers had to approach a predefined number of female and male students in each campus to obtain a representative sample of students according to the student registration database of the University of Bordeaux

2016/2017 (see Multimedia Appendix 1). If students consented to participate in the study, the questioning proceeded after the signature of a written informed consent form. If eligible students declined to participate, interviewers asked them why and documented the reasons for refusal. The inclusion criteria were currently studying in 1 of the 4 university campuses in Bordeaux, France; being French-speaking; and being aged 18-24 years. We excluded those aged 25 years and older because, according to the Bologna process ensuring comparability in the standards and quality of higher education qualifications in Europe, the average age of entrants to the university is 18.5 years [24], and the median age students first graduate from university is under 25 years [25].

Survey Instrument and Ethics

The questionnaire was co-designed by a team of 4 researchers in epidemiology, health communication, health sociology, and mental health, plus 2 public health undergraduate students, following a 5-step collaborative process. According to this methodology [26], the team identified topics of interest (step 1), reviewed relevant existing survey items (step 2) [18,19,27,28], drafted new survey items and adapted existing ones (step 3), tested a first draft version of the questionnaire (step 4), and refined the draft questionnaire providing a final version (step 5).

During steps 1-3, the team checked for the feasibility of the survey, deciding not to include long scales and limiting the length of the entire questionnaire to less than 20 items because it had to demand reasonable time for completion in particular conditions (eg, while attending courses or revising for examinations). The co-design strategy also allowed determining the final 16 health topics of interest for university students. During step 4, a preliminary test phase with 30 students was carried out to verify the coherence of the questions and the easiness to answer. Collected data were not inserted in the final analyses. These 30 students were approached in the different campuses of the University of Bordeaux and asked to sign a consent form stating that their data would not have been included in the final analyses of the project, and that they were contributing to a test phase. At the end of each test questionnaire, interviewers asked students to comment on the length and interest of the questionnaire. When possible, interviewers asked students to comment on each item in detail. This was done by one-fourth (n=5) of the students participating in the test phase. These inputs, in the form of short transcriptions and notes recorded in a separate report, were taken into account when constructing the final version of the questionnaire (step 5).

The final questionnaire was divided into 3 sections:

- Sociodemographic characteristics: gender, month and year of birth, field of study (4 items: Science and Technology, Literature and Social Sciences, Law and Economy, and Life and Health Sciences), year of study (4 items: 1st year, 2nd year, 3rd year, and >3rd year), as well as self-rated general and mental health on a Likert scale (5 items each: very good, good, average, bad, and very bad).
- Questions about use of digital health: participants were asked whether they had a mobile phone (2 items: yes, no), a wearable device (2 items: yes, no), a mobile health app (2 items: yes, no), and, only for those reporting having a mobile health app, its frequency of use (3 items: often, occasionally, never) and name or topic (open-ended item). On the basis of a list, participants were asked about health topics they had searched for on the internet in the last 12 months (15 items: sleep, physical activity, nutrition, sexuality, contraception, pregnancy and maternity, alcohol risks, risks concerning tobacco and e-cigarette, cannabis and other synthetic drugs, stress, anxiety or depression, skin problems, vaccinations, environment and health risks, pain, and illnesses), why they had looked for Web-based health-related information per health topic (3 items: for yourself concerning a specific disease or medical problem which might affect you, out of curiosity, for your studies), and their main source of health information (7 items: forums, general health websites, YouTube, social networks such as Facebook and Twitter, institutional or official websites, blogs, and Wikipedia). They were also asked to rate the trustworthiness of each of these sources (3 items: credible, neither credible nor noncredible, and noncredible), and whether, from the beginning of their university studies, they had already looked online for a health professional or service (2 items: yes, no).
- Questions about opinions on digital health: participants were asked whether obtaining Web-based health information had resulted in a consultation with a health professional or service (2 items: yes, no), their reasons for consulting (3 items: information was insufficient, information was alarming, and information confirmed a real health problem) or not consulting (2 items: information was sufficient and information was not sufficient), and whether Web-based information and advice can be a complementary solution to real-life consultations (2 items: yes, no). Those answering positively to this question were further asked to report when searching for Web-based information could be most useful (3 items: before a consultation to get prepared, after a consultation to better understand the health professional's instructions, and before and after a consultation). Those answering negatively were further asked to state whether Web-based information and advice could be an alternative to real-life consultations now or in the future (4 items: strongly agree, agree, disagree, and strongly disagree).

The English version of the questionnaire is available in Multimedia Appendix 2. The time of administration and completion of the questionnaire was about 10 min.

Ethical Considerations

Ethics approval was obtained through the submission of a declaration detailing the survey implementation and questionnaire items to the attention of the French data protection authority, *Commission Nationale de l'Informatiqueet des Libertés* (National Commission of Informatics and Liberties). The written informed consent dated and signed by participants before answering the questionnaire reassured students of the anonymous format of the survey and use of collected data for research purposes only. For students who refused to participate in the study, we could collect paradata, that is, data documenting the process of data collection, such as reasons for refusal and

information on campus. As a rule, paradata for each sampled person are completely anonymous and can be used for scientific purposes such as preventing or reducing high refusal rates without prior ethics approval [29].

Statistical Analysis

Statistical analysis was performed using SAS (V.9.4; SAS Institute Inc, Cary, NC, USA). Descriptive statistics (eg, means and SDs) were used in the initial data analysis. Chi-square and Fisher exact tests were used to identify associations between sociodemographic characteristics, self-rated general and mental health, and digital health use of the study participants. For the tests of independence, digital health use was summarized in the following 5 components: (1) possessing a mobile health app, (2) possessing a health-related wearable device, (3) searched Web-based health-related information and support topics (for all reasons), (4) consulted Web-based sources for health-related information and support (for all degrees of credibility), and (5) searching online for a health professional or service. The level of statistical significance was set at P value <.05.

Results

Participants

A total of 777 students were approached to answer the survey: 591 of them participated in the study with a response rate of 76.0%. Students who refused to participate in the study were more frequently studying in Life and Health Sciences (71/186, 38.2%) and Law and Economy campuses (59/186, 31.7%). The majority of nonrespondents (99/186, 53.3%) declared they had no time or did not feel like answering a questionnaire. Reasons for refusal for remaining students (87/186, 46.7%) were that they had to attend a class, study at the campus library, or pass their examinations.

A total of 18 students were excluded because their date of birth was missing, 6 because they were younger than 18 years, and 59 because they were older than 24 years (according to the inclusion criteria). A student from a private higher education institute in Bordeaux was excluded as well. The final study sample included 507 students. Missing values were less than 12% and concerned mainly the following items: sources of Web-based health information (59/507, 11.6%), health-related information and support topics (31/507, 6.1%), and consulting or not a health professional or service after having obtained Web-based health information (15/274, 5.5%). We observed that missing values were more numerous for conditional questions and questions presented in a table format. The design of some items of our questionnaire may then explain nonresponse in our study. Missing values were excluded from both the descriptive analyses and the tests of independence.

The sociodemographic and health-related characteristics of study participants are summarized in Table 1.

The mean age of the whole sample was 20.5 years, 59.8% (303/507) of the participants were females, and 43.3% (220/507) were attending the first year of study, as shown in Table 1. As planned by design, the distribution of our sample did not differ from the distribution of the entire University of Bordeaux in 2016/2017 (data available in Multimedia Appendix 1) with regard to gender and field of study (P=.72). More than half of the participants rated both their general and mental health as good, 61.9% (314/507) and 57.6% (292/507), respectively. There were no missing values for data on sociodemographic characteristics and self-rated general and mental health.

Questions About the Use of Digital Health

Concerning mobile-based digital health, almost all students (98.2%, 498/507) declared possessing a mobile phone, and among them, 34.9% (174/498) had at least 1 mobile health app, 62.6% (109/174) were using it occasionally, 27.6% (48/174) often, and 9.8% (17/174) never. Most mobile phone apps were about physical activity, for example, running, fitness (49.4%, 86/174), and general health monitoring (41.4%, 72/174). Other mobile health apps were about sleep (16.7%, 29/174), nutrition (8.0%, 14/74), wellness, for example, yoga (5.7%, 10/174), and gynecology (4.0%, 7/174, and, specifically among female students, 5.5%, 7/127). Moreover, 2 students reported having downloaded a mobile phone app for addictions, whereas 1 student for allergies. Some students (34.5%, 60/174) reported that they had not downloaded such apps, but that they were directly installed on their mobile phones, such as the Health iPhone app. Only 3.9% (20/507) of participants declared having a health-related wearable device.

Concerning internet-based digital health, 94.5% (450/476, with 31 missing values) of students had searched for Web-based information and support on at least 1 health-related topic in the last 12 months. The mean number of health-related topics students had searched for was 5.3 (SD 3.4). For each topic, students were asked to select one or more reasons for Web-based information and support seeking: 78.8% (375/476) mostly searched for themselves concerning a specific disease or medical problem which might affect them, whereas 61.6% (293/476) out of curiosity, and 39.9% (190/476) for their studies. Whatever the reason, the most searched topics were nutrition (68.1%, 324/476); pain and illnesses (64.5%, 307/476); and stress, anxiety, or depression (51.1%, 243/476). All results are shown in Figure 1.

Concerning Web-based sources of health-related information and advice, 99.1% (444/448, with 59 missing values) of students had consulted at least one of the proposed sources. The mean number of consulted Web-based sources was 4.5 (SD 1.9). While consulting several Web-based sources, students rated their credibility differently, as shown in Figure 2.

Although Wikipedia and general health websites were the most consulted sources (357/448, 79.7%, and 349/448 77.9%, respectively), students considered institutional or official websites as the most credible source (309/335, 92.2%,). Social networks and blogs were the least consulted sources (286/448, 63.8% and 175/448, 39.1%, respectively), and students rated them as the most noncredible sources of all (129/286, 45.1% and 56/175, 32.0%, respectively). Finally, 68.2% (344/504, with 3 missing values) of students had already looked online for a health professional or service from the beginning of their university studies.

Table 1. Sociodemographic and health-related characteristics of study participants (N=507).

Sociodemographic characteristics	n (%)
Gender	
Female	303 (59.8)
Male	204 (40.2)
Field of study	
Literature and Social Sciences	91 (17.9)
Life and Health Sciences	181 (35.7)
Science and Technology	89 (17.6)
Law and Economy	146 (28.8)
Year of study	
1st year	220 (43.3)
2nd year	112 (22.1)
3rd year	91 (17.9)
>3rd year	84 (16.7)
Self-rated general health	
Very good	65 (12.8)
Good	314 (61.9)
Average	112 (22.1)
Bad	15 (3.0)
Very bad	1 (0.2)
Self-rated mental health	
Very good	94 (18.5)
Good	292 (57.6)
Average	100 (19.7)
Bad	17 (3.4)
Very bad	4 (0.8)

Sociodemographic and Self-Rated General and Mental Health Correlates of Digital Health Use

We examined the correlation of digital health use, defined by 5 components, with sociodemographic characteristics and self-rated general and mental health. Table 2 reports the detailed results. Gender was significantly associated with all components of digital health use. More precisely, female students were almost twice as likely to use a mobile health app compared with male students (P<.001). Inversely, male students were more than twice as likely to have a health-related wearable device compared with female students (P=.04). However, when interpreting this result, it is important to consider the small number of subjects possessing a health-related wearable device (n=17). Female students used the internet for health information and support seeking as well for searching a health professional or service significantly more than male students (P<.001 and P=.002, respectively). The field of study was significantly associated with possessing a health-related mobile phone app (P=.03), searching the internet for health-related information and support topics (P=.001), and looking online for a health professional or service (P<.001). For these 3 components of digital health use, the highest proportions of students were found in Literature and Social Sciences, as well as in Life and Health Sciences. The year of study was significantly associated with searching online for a health professional or service (P<.001). No statistically significant association was found between all components of digital health use and both self-rated general and mental health status. However, as for health-related wearable devices, the number of students rating both their general and mental health as bad or very bad was small, and results should be interpreted with caution.

Figure 1. Health-related topics sought on the Internet and reasons.

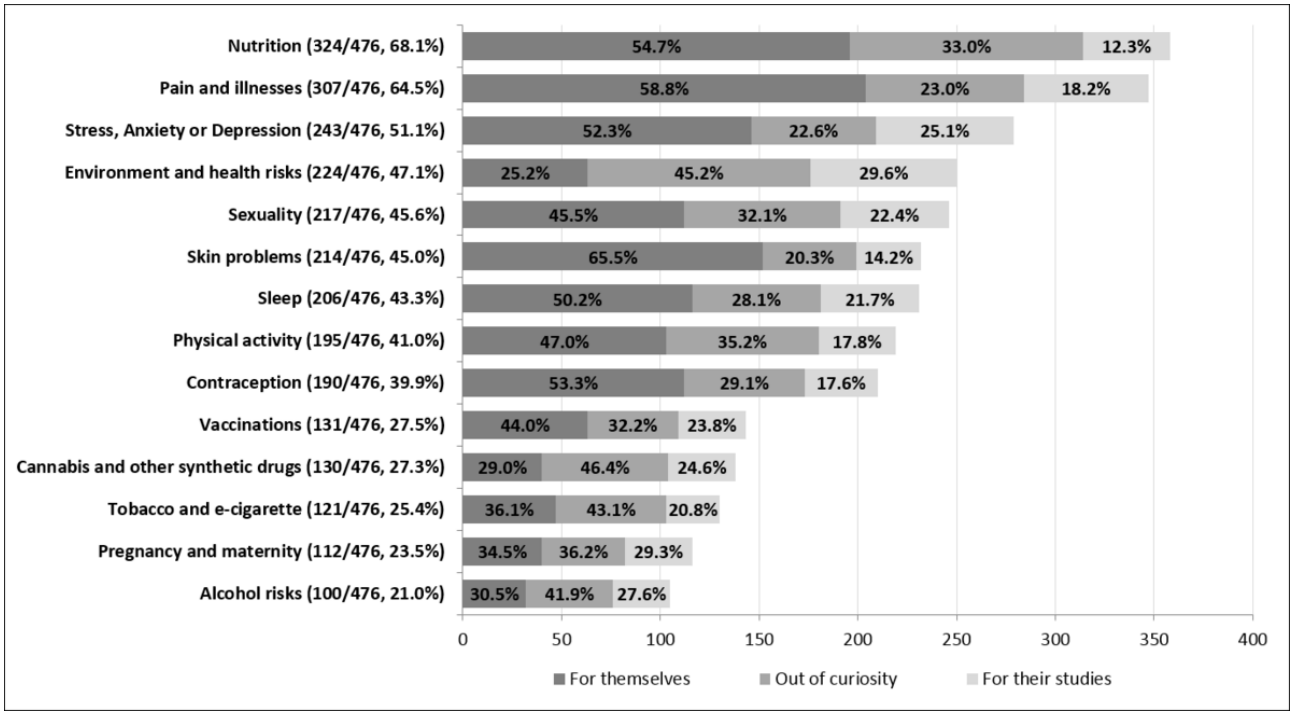

Figure 2. Web-based sources of health information and advice and their credibility.

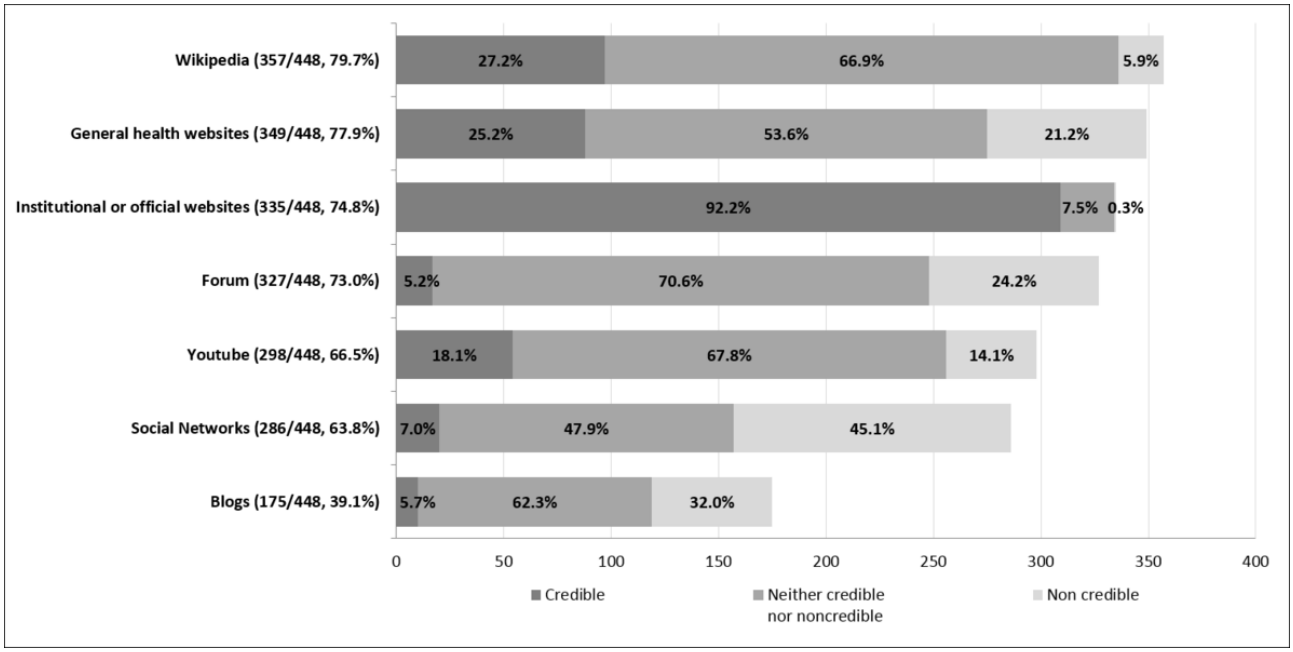

Table 2. Sociodemographic and self-rated health correlates of digital health use. All values are given excluding missing values for each separate component.

Variable	Mobile health app (N=498), n (%)	Health-related wearable device (N=504), n (%)	Health-related information and support topics (N=476)		Consulted online sources (N=448)		Searching health professional or service online (N=504), n (%)
			n	Mean (SD)	n	Mean (SD)	
Overall	174 (34.9)	17 (3.4)	476	5.3 (3.4)	448	4.5 (1.9)	344 (68.3)
Gender	*P*<.001	*P*=.04	*P*<.001		*P*=.049		*P*=.002
Female	127 (42.8)	6 (2.0)	283	5.8 (3.3)	278	4.3 (1.8)	222 (73.5)
Male	47 (23.4)	11 (5.4)	193	4.7 (3.4)	170	4.7 (1.9)	122 (60.4)
Field of study	*P*=.03	*P*=.07	*P*=.001		*P*=.52		*P*<.001
Literature and Social Sciences	35 (39.8)	1 (1.1)	86	6.4 (3.3)	85	4.2 (2.0)	68 (75.6)
Life and Health Sciences	71 (40.1)	11 (6.1)	174	5.6 (3.8)	155	4.6 (1.7)	138 (76.2)
Science and Technology	20 (22.7)	3 (3.4)	84	4.4 (2.9)	77	4.4 (1.8)	49 (55.7)
Law and Economy	48 (33.1)	2 (1.4)	132	4.9 (2.9)	131	4.5 (1.9)	89 (61.4)
Year of study	*P*=.89	*P*=.80	*P*=.86		*P*=.94		*P*<.001
1st year	79 (36.2)	7 (3.2)	206	5.3 (3.4)	186	4.5 (1.8)	128 (58.4)
2nd year	37 (34.9)	4 (3.7)	103	5.1 (3.2)	94	4.4 (1.8)	67 (63.2)
3rd year	32 (35.2)	2 (2.2)	87	5.4 (3.2)	91	4.5 (1.9)	73 (78.5)
>3rd year	26 (31.3)	4 (4.7)	80	5.7 (3.8)	77	4.4 (1.9)	76 (88.4)
Self-rated general health	*P*=.31	*P*=.11	*P*=.39		*P*=.21		*P*=.42
Very good	16 (25.4)	3 (4.6)	62	4.8 (3.7)	55	4.0 (1.7)	38 (58.5)
Good	118 (37.9)	14 (4.5)	293	5.5 (3.4)	278	4.5 (1.9)	218 (69.9)
Average	36 (33.0)	0 (0.0)	107	5.3 (3.1)	99	4.5 (1.8)	77 (69.4)
Bad	4 (28.6)	0 (0.0)	13	4.8 (3.1)	15	4.2 (1.6)	10 (66.7)
Very bad	0 (0.0)	0 (0.0)	1	2.0 (N/A[a])	1	5.0 (1.6)	1 (100.0)
Self-rated mental health	*P*=.95	*P*=.08	*P*=.30		*P*=.66		*P*=.49
Very good	34 (36.6)	6 (6.5)	91	5.1 (3.6)	81	4.6 (1.7)	62 (66.7)
Good	102 (35.7)	7 (2.4)	271	5.2 (3.4)	261	4.4 (1.9)	199 (68.6)
Average	31 (31.6)	2 (2.0)	96	5.8 (3.1)	89	4.5 (1.8)	65 (65.0)
Bad	6 (35.3)	2 (11.8)	14	5.7 (3.6)	13	3.8 (2.1)	14 (82.4)
Very bad	1 (25.0)	0 (0.0)	4	4.8 (2.6)	4	5.0 (1.6)	4 (100.0)

[a]N/A: not applicable.

With regard to the second component of digital health use, we further distinguished the reasons for searching health-related information and support topics online and found that self-rated mental health was significantly associated with a higher mean number of health-related topics searched for themselves, concerning a specific disease or medical problem which might affect the respondents (*P*<.001). We observed a mean of 2.4 (SD 2.5) topics for students reporting very good mental health and a mean of 3.8 (SD 2.6) topics for students rating their mental health as bad. Concerning the field of study, the association with the online search for health-related topics remained significant for the specific reasons, for themselves, and for their studies (*P*<.001 both). However, for each separate reason, the mean number of searched topics was different across the fields of study. On the one hand, the mean number of searched health-related topics “for themselves” was higher in Literature and Social Sciences (4.0, SD 2.9) than in the other fields of study (the lowest mean number being 2.1, SD 1.8, in Law and Economy). On the other hand, the mean number of searched health-related topics for their studies was largely higher in Life and Health Sciences (2.5, SD 3.1) than in the other fields of study (the lowest mean number being 0.3, SD 0.6, in Law and Economy).

Questions About Opinions on Digital Health

Students who reported having searched for at least 1 health-related topic online (N=450) were asked whether information found online had induced them (or not) to consult a health professional or service, as well as related reasons. A total of 38.8% (174/448, with 2 missing values) declared that

information found online had induced them to access care. Reasons were that online information had confirmed a real health problem (50.6%, 88/174), online information was insufficient (37.9%, 66/174), and online information was alarming (30.5%, 53/174). On the contrary, 61.2% (274/448) of students declared that information found online had not induced them to access care. Reasons were that online information was sufficient (78.4%, 203/259, with 15 missing) and online information was reassuring (31.7%, 82/259).

A total of 49.7% of students (251/505, with 2 missing values) declared that online information and advice can be a complementary solution to real-life consultations, before a consultation to get prepared (50.4%, 126/250, with 1 missing), before and after a consultation (32.4%, 91/250), and after a consultation to better understand the health professional's instructions (17.2%, 43/250).

Finally, majority of the students reported that they "strongly disagreed" or "disagreed" that today's digital health can replace real-life consultations, 55.5% (280/505, with 2 missing values) and 38.6% (195/505), respectively. However, among them (n=464, with 11 missing values), 44.6% (207/464) reported that, in the near future, digital health would replace real-life consultations but only if promoted by institutional or official entities, for example, the national ministry of health and the university.

Discussion

Digital Health Use and Correlates

We described digital health use among university students as a multidimensional concept given by 5 components. Regarding the first component (possessing a mobile health app), our results confirmed the large penetration of mobile phone ownership among young people, with almost all participants (498/507, 98.2%) possessing a mobile phone, in line with national statistics (89% of students had a mobile phone in France in 2015) [30] and international ones (more than 80% of people aged 18-34 years had a mobile phone in OECD countries in 2015) [31]. However, in our sample, the use of mobile health apps was less spread: only one-third of students had a mobile health app and used it mostly occasionally. We can hypothesize that university students do not use largely mobile health apps because of the demanding nature of data entry [32], as well as limited storage memory and battery life of their mobile phone [33]. Survey metrics about the use of mobile health apps in the student population worldwide are scarcely documented. A few studies have been conducted in US college students, focusing on fitness and wellness apps [34,35], whereas some qualitative studies have explored the views and experiences of European students on mobile phone apps related to health behavior change [36,37]. Results from our survey and previous studies confirm that students' most-used mobile health apps concern physical activity (eg, running, fitness) and general health monitoring, such as the Health iPhone app. These findings can be interpreted in 2 opposite ways. First, they might suggest that future effective and successful digital health interventions should be based on mobile phone apps for physical activity and general health monitoring because it is well assessed that students appreciate and use them. Second, the opposite interpretation suggests that, because such apps already exist, future digital health interventions should be based on mobile phone apps concerning different health topics, to help students take care of other aspects of their health and well-being. Some mobile phone apps on addictions, sexual risks, and mental health have been developed, tested, and validated among students [13-16] and could be largely disseminated to the general student population. Future research should monitor the diffusion, use, and acceptability of such apps, investigating reasons for (non)adoption and (non)continuance of use.

Concerning the second component (possessing a health-related wearable device), only 1 student out of 25 owned a wearable device for health purposes. However, recent surveys on the general population showed that young people aged between 18 and 35 years represent the highest consumers of wearable devices, ranging from 36% to 49% of the overall interviewed populations [38,39]. Furthermore, a study carried out in the Cardiff Metropolitan University [40] reported that 35% (18/51) of interviewed students aged 18-30 years owned a wearable device. For the remaining 65% (33/51) of students, the main reasons for not owning such a device were concerns about electromagnetic waves emitted by wearable devices, security risks concerning collected data, reluctance to wear the device continuously, and costs which are not always affordable. Our low percentage of students owning a wearable device might be because of one or more of these reasons.

With regard to the third component (searching for health-related information and support online), the level of use of the internet for health-related information seeking for personal reasons reported in our sample (375/476, 78.8%) was slightly higher than prevalence estimates (ranging from 66.1% to 67.7%) found in other university-based surveys worldwide [18,19,27]. We also looked at other reasons for health-related information and support seeking among university students, including for curiosity and for one's studies. All reasons considered, the level of use of the internet for health-related information seeking found in our sample was very high (94.8%, 450/476). These high percentages suggest that the internet represents a very attractive platform to deliver a digital health intervention targeting students. Given the lower use of mobile phone apps compared with the high use of the internet for health purposes, our results suggest that future digital health interventions should be based on mobile-responsive design websites rather than on mobile apps. Web apps could be the most cost- and time-efficient delivery solution for this specific target group. We also observed that the most searched topics in our sample were the same as those reported in previous studies [18,19,27], with pain, illnesses, and nutrition being the most popular health-related topics among surveyed students. On the basis of these findings, future digital health interventions could address these topics to meet students' interests and needs.

As for the fourth component (consulted online sources), almost all students (444/448, 99.1%) had consulted 1 or more online sources to get health-related information and support. Even if Wikipedia and general health websites were the most consulted sources, university students rated institutional or official websites as the most credible source. This suggests that

university students show discerning judgment and pay attention to the trust and credibility of the websites and platforms they consult [41]. Our findings are in line with previous research, reporting that authority of the sources and disclosure of the authors are among the main criteria students use for assessing the accuracy of the information found online [19]. Digital health interventions proposed within the university setting by recognized authorities (eg, health professionals, and faculty) have huge potential in this specific population.

Finally, with regard to the fifth component (searching online for a health professional or service), we observed that one-third of students had already used the internet to search and contact a health professional and service. This might be explained by the fact that students often live far from their family and hometown and recur to the internet to find a health professional or service near their new accommodation. Digital health interventions displaying the closest, safest, and most appropriate health services could meet the needs of a good portion of university students [23].

Effective engagement in a digital health intervention requires careful consideration of current digital health use, but also of personal factors such as sociodemographic characteristics and health status. For this reason, we investigated correlates of digital health use in our sample. Gender was significantly associated with all components of digital health use. Female students were more likely to use mobile health apps and to use the internet for health information and support as well as for searching a health service or professional. Male students, instead, consulted more online sources and possessed more wearable devices compared with female students. These findings are in line with research reporting that women are more engaged in using the internet for health-related information searching because of their higher health awareness and personal disposition of being well-informed as potential patients [42,43]. On the other hand, the higher number of consulted online sources and wearable devices among male students could be because of the fact that men ascribe themselves higher perceived digital and technological competencies [42].

As for the year of study, we were interested in exploring whether freshmen were using digital health differently from other students. The freshmen year of university is a critical period where many social and environmental factors act on students influencing their well-being and putting their health at risk [44]. We did not find any strong association between the year of study and digital health use, but future research should focus on first-year students who usually struggle to cope with their transition to university.

We also expected that university students' digital health use would differ across fields of study, and that, more precisely, students in Life and Health Sciences would use digital health more than their colleagues from other disciplines, given their personal and study interests. Our hypothesis was confirmed because students in Life and Health Sciences were the highest digital health users in our sample. However, students in Literature and Social Sciences, as well as in Law and Economy, were also largely using digital health, especially for personal reasons. Digital health use in Life and Health Sciences can be easily justified by the fact that medical and health students need to be knowledgeable about online health information resources and to stay up-to-date with digital health tools for their studies as well as for their future career as health professionals. Besides, in France, some university curricula are highly demanding and stressful, such as Medicine and Law. Digital health interventions carried out in the university setting should take into account differences across fields of study, targeting students who might be at higher risk of mental health distress, for instance.

Among all personal factors, health is a very important part of the field of consumer health [45]. In our study, neither self-rated general nor mental health was correlated with any component of digital health use. Even if these results must be interpreted with caution because the number of subjects rating their health as bad or very bad was small, thus limiting the strength of our analysis, it is interesting to observe that students were active digital health users independently from their self-rated health status. Practically, this implies that digital health interventions should not be limited exclusively to treatment and care, but could be very useful for preventing diseases and promoting health. University students are generally in good health, as confirmed by our findings, but digital health can help improve and maintain health consciousness in this population [46].

Opinions on Digital Health

We also explored whether seeking Web-based health information influenced students' consultations with health professionals. We found that more than half of the students did not consult any health professional after obtaining Web-based health information, mostly because the information was sufficient. On the contrary, for students having consulted a health professional after obtaining Web-based health information, the main reason was that the obtained information had confirmed they had a real health problem to treat. These findings could suggest that health information obtained on the internet can motivate young people to have a consultation with a health professional, but only if they think they have a real or rather serious problem to take care of. In this transitional phase where students are moving toward attaining autonomy and assuming responsibility for their health care [47], Web-based health-related information can represent support. However, future qualitative studies are warranted to better explore how digital health influences the health-seeking behavior of students.

A prevailing view among participants of our study was that digital health should be an adjunct rather than a replacement to real-life consultations. Digital health was considered most impactful as a mean of enhancing health care services, before or after consultations. Importantly, when asked about the future of digital health, the subset of students who disagreed with the statement regarding Web-based information or advice being an alternative to real-life consultations was positive that internet- and mobile-based health tools could have the potential to replace real-life consultations, provided that such tools are promoted by institutional or official entities, for example, the national ministry of health. Institutions continue to play a central role in most students' lives, especially when it comes to obtaining health information, being treated, and maintaining good health [48]. Therefore, promoting digital health interventions in a

university setting seems to be a promising approach because health and academic authorities are considered as a trustful source of health-related messages and advice.

Limitations

Our study relied on data by a middle-size sample of students, resulting into a small number of units of analysis in some variable categories (eg, self-rated general and mental health). This might have reduced the power of our study and increased margin of error concerning the estimated associations. The field survey methodology may represent a further limitation: questionnaires were administered on campuses during courses and examinations. Interviewers may have been biased in who they decided to approach based on walking speed, what students looked like, or whether they were waiting before a class, for instance. Furthermore, participants might have been not completely at ease when answering the questionnaire because of their timetable, stress for examinations, academic workload, and so on. The face-to-face administration of the questionnaire may represent another bias. Participants might have not felt free to disclose to their peer interviewers that they were concerned by some health problems or that they were interested in specific sensitive health topics such as depression, sexuality, or addictions. Although this bias must be carefully taken into account, it is also noteworthy that, after questionnaire completion, some participants reported to their peer interviewers that they were content with the fact that university researchers were investigating about their health and well-being. The peer-to-peer approach was chosen to maximize the comfort of participants. Students were reassured by their peer interviewers on the possibility to interrupt the survey if they considered it too intrusive and on the fact that university researchers conducting the analyses would not be able to recognize any participant. Finally, our questionnaire did not use validated measures or scales but was constructed by combining items from previous surveys in university students with new ad hoc questions covering our topics of interest. However, both the test phase and the following survey implementation proved that the questionnaire was easy to administer and participants answered readily. Further research, both qualitative and quantitative in nature, including a larger and more representative sample, would improve the findings by describing university students' reasons to use digital health, their behavioral goals, and intention to continuously use digital health. The definition of digital health use could also be enlarged in future studies by exploring more deeply social media use, for instance, as well as other components of the use of both internet- and mobile-based tools for health, such as telehealth technologies and electronic health records [49].

Implications

Although the generalizability of our findings is limited by being based on a sample of university students from one country, our study can provide the wider international community with useful information on how to plan and implement future digital health interventions in the university setting. First, we cataloged the health topics of interest for university students, suggesting some contents for new digital health interventions. Second, we confirmed that university students demand for high-quality health-related information and support, especially in the digital environment. Third, our findings suggested that university students are mostly using the Web (internet and social media), rather than mobile phone apps and wearable devices: at present, bracelets or smartwatches are not the first options for implementing a digital health intervention addressing university students.

Finally, the questionnaire we proposed could be improved and applied in other universities before the conception, development, and diffusion of digital health interventions. Conducting a survey to collect baseline data on university students' needs and opinions with regards to digital health can provide an initial macro-level evidence base that can be used to guide the university's digital health strategy. Similar survey studies, also combined with in-depth qualitative studies, would allow university staff (eg, faculty and health professionals in student health centers) to get more insights on how to design effective digital health interventions (eg, choice of the most appropriate e-tool, topics of interest) and how to diffuse them according to different students' profiles.

Conclusions

In an exploratory approach, we provided a picture of current use and opinions about digital health among university students in France to shed some light on the conception, development, and diffusion of future digital health interventions addressed to this specific public. With the internet still outpacing mobile health apps and wearable devices as sources of health information and support among university students, this population is confident that digital health interventions will replace real-life consultations in the future, provided that they are promoted by official institutions such as the university or the national ministry of health.

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Authors' Contributions

IM, EL, and CT designed the study and questionnaire. TC and TF analyzed the data and synthesized results. IM drafted the manuscript and supervised the data analysis. EL and CT contributed to the final writing of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Table reporting the distribution of students at the University of Bordeaux and in our study according to gender and field of study.

[PDF File (Adobe PDF File), 16KB - mhealth_v6i3e65_app1.pdf]

Multimedia Appendix 2

English version of the questionnaire.

[PDF File (Adobe PDF File), 58KB - mhealth_v6i3e65_app2.pdf]

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Abbreviations

OECD: Organisation for Economic Co-operation and Development

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Original Paper

Evaluation of a Mobile Phone–Based Intervention to Increase Parents' Knowledge About the Measles-Mumps-Rubella Vaccination and Their Psychological Empowerment: Mixed-Method Approach

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Abstract

Background: There is mixed evidence on the effectiveness of vaccination-related interventions. A major limitation of most intervention studies is that they do not apply randomized controlled trials (RCTs), the method that, over the last 2 decades, has increasingly been considered as the only method to provide proof of the effectiveness of an intervention and, consequently, as the most important instrument in deciding whether to adopt an intervention or not. This study, however, holds that methods other than RCTs also can produce meaningful results.

Objective: The aim of this study was to evaluate 2 mobile phone–based interventions aimed at increasing parents' knowledge of the measles-mumps-rubella (MMR) vaccination (through elements of gamification) and their psychological empowerment (through the use of narratives), respectively. The 2 interventions were part of an RCT.

Methods: We conducted 2 studies with the RCT participants: a Web-based survey aimed at assessing their rating of the tool regarding a number of qualities such as usability and usefulness (N=140), and qualitative telephonic interviews to explore participants' experiences with the app (N=60).

Results: The results of the survey showed that participants receiving the knowledge intervention (alone or together with the empowerment intervention) liked the app significantly better compared with the group that only received the empowerment intervention ($F_{2,137}$=15.335; P<.001). Parents who were exposed to the empowerment intervention complained that they did not receive useful information but were only invited to make an informed, autonomous MMR vaccination decision.

Conclusions: The results suggest that efforts to empower patients should always be accompanied by the provision of factual information. Using a narrative format that promotes parents' identification can be an appropriate strategy, but it should be employed together with the presentation of more points of views and notions regarding, for instance, the risks and benefits of the vaccination at the same time.

Trial Registration: International Standard Randomized Controlled Trial Number 30768813; http://www.isrctn.com/ISRCTN30768813 (Archived by WebCite at http://www.webcitation.org/6xOQSJ3w8)

(JMIR Mhealth Uhealth 2018;6(3):e59) doi:10.2196/mhealth.8263

KEYWORDS

qualitative research; measles-mumps-rubella vaccine; surveys and questionnaires; mobile applications; knowledge; patient participation

Introduction

Background

Childhood vaccination coverage is generally high in most developed countries, but clusters of individuals who remain unvaccinated (eg, because they share inaccurate beliefs about one or more immunizations) indicate that the phenomenon of vaccine hesitancy remains a significant problem [1]. It includes not only refusing some or all recommended vaccinations but also accepting them despite doubt and uncertainty. To decrease vaccine hesitancy, a number of interventions employing different designs and based on various frameworks have been proposed [2-8]. Sadaf and colleagues summarized such interventions into 3 groups: (1) passage of state laws (such as school immunization requirements), (2) state- and school-level implementation of laws (procedural complexities of obtaining nonmedical exemptions and school policies for immunization requirements), and (3) parent-centered immunization interventions, generally with information or education purposes [8]. Williams divided the latter type of interventions into different strategies to improve (1) parental attitudes about childhood vaccines, (2) vaccination intent, or (3) vaccination uptake among vaccine-hesitant parents [9]. More recently, Willis and colleagues have proposed a classification that includes 7 main categories that can be used in communication interventions targeting parents or soon-to-be-parents, community members, and health care providers: inform or educate, remind or recall, teach skills, provide support, facilitate decision making, enable communication, and enhance community ownership [10].

A recent review concluded that there is mixed evidence on the effectiveness of vaccination-related interventions involving face-to-face communication interventions, health care provider training, community-based actions, or communication using mass media [2]. A major limitation of most interventions is that they lack a rigorous evaluative assessment [2]. In fact, over the last 2 decades, randomized controlled trials (RCTs) have been increasingly considered as the gold standards in evidence-based practice, the only way to prove the effectiveness of an intervention and, consequently, as the most important instrument in deciding whether to adopt an intervention or not [11]. According to their supporters, RCTs have great ability "to minimize selection and information bias, control confounding, and for ruling out chance" [11]. At the same time, however, RCTs might not be enough to achieve results that are useful in practice [11]. In particular, many of the most important issues faced by RCT participants—their feelings, hopes, and beliefs, for example—cannot be meaningfully reduced to numbers or adequately understood without reference to the immediate context in which they live [12]. Consequently, RCTs are called for that are supplemented by research components that are either qualitative or the combination of qualitative and quantitative methods [11]. This strategy can provide evidence about how the intervention works (or why it did not), for whom, and under what circumstances [12].

Between December 1, 2016 and 10, 2016 our research team delivered 2 immunization interventions through a mobile phone app as an RCT [13]. The app, called MorbiQuiz, is in Italian language and can be downloaded free of charge in the Italian and Swiss Google Play and App Store. In the first intervention, aimed at increasing participants' knowledge about the measles-mumps-rubella (MMR) vaccination using gamification, participants received 35 questions distributed on a time span of 10 days (3-4 questions per day). Once answered, each question unblocked an explanation of the answer through textual content. Each correct answer would earn participants a number of points (stars) according to the weight of each question, whereas no points were given for wrong answers or if no answer was given by midnight of the day. To provide a gamified experience, participants could see their score and compare it with that of the other participants through a leaderboard. Furthermore, participants were awarded a shopping voucher, which increased their performance in the quiz. The design of the app is extensively described in the paper reporting the results of the RCT [13].

In the second intervention, aimed at enhancing psychological empowerment (defined as a set of 4 subdimensions: self-determination, self-efficacy, impact, and meaningfulness), users received 2 videos and 8 messages. In the 2 videos, an actress acting as a mother reports that she was able to make an empowered decision about the MMR vaccination by collecting reliable information from multiple sources, and by thinking about the importance and the impact of the decision. In the end, she addresses her audience, encouraging them to make an informed, empowered decision. The viewer was addressed in the second person to increase participant involvement. The messages were designed to reinforce the messages delivered in the video. Participants received either the first, the second, or both interventions. A control group did not receive any intervention.

The effect of the 2 interventions (combined and alone) was tested on a number of outcomes such as vaccination knowledge, psychological empowerment, intention to vaccinate, confidence in the vaccination decision, vaccination opinion, intention to recommend the vaccination, and control preference in the vaccination decision making. All experimental groups reported a significant increase in their vaccination knowledge compared with the control ($F_{3,179}$=48.58, P<.001), whereas only those participants who received both interventions reported a significant increase in their psychological empowerment (t_{179}=-2.79, P=.006). Only those participants receiving the knowledge intervention had a significantly higher intention to vaccinate (t_{179}=2.111; P=.03) and more confidence in the decision (t_{179}=2.76; P=.006) compared with the control group.

As the experiment was only partially successful, we decided to assess the perceptions of the participants on a number of characteristics of the app and explore their experience with this tool. The effectiveness of the majority of vaccination interventions using new media, such as immunization apps, is simply evaluated looking at statistics regarding their download and usage [14-16]. These evaluative methods, however, provide no insights into participants' perceptions regarding, for instance, the usability of the target tool. Furthermore, evaluations might be useful not only to collect participants' perceptions but also to assess quantitative findings related to the intervention efficacy

or explain why certain features did not have a significant effect on a given outcome.

Objectives

The broader scope of this study is to evaluate 2 interventions administered through a mobile phone app [13]. The 2 interventions aimed at increasing parents' knowledge of the MMR vaccination and their psychological empowerment, respectively, and were part of an RCT conducted in December 2016. Our 2 main research questions are as follows:

1. How did participants perceive the app's usability and usefulness?
2. What was their experience with the tool and its functionalities?

To answer these questions, we conducted 2 studies with the RCT participants and employed a mixed-method approach. study 1 describes a Web-based survey aimed at quantifying participants' rating of the tool regarding different qualities, including usability and usefulness, whereas study 2 takes the shape of a qualitative exploration of participants' experiences with the app and of their feelings related to its use. The results of these studies will be interpreted in light of the quantitative results of the RCT, and practical implications for the design of future mobile phone–based immunization interventions will be discussed.

Methods

Study 1

Study 1 takes the shape of a Web-based survey that was included within the posttest questionnaire we sent via email or WhatsApp to the participants immediately after the end of the experiment. To be included in study 1, participants had to have at least 1 child younger than 15 months, to be a resident in the Lombardy region of Italy, and to own a mobile phone with Internet connection. We added following 2 exclusion criteria: being in the control group (participants who did not receive the app) and not having logged in on the app during the experiment. Recruitment of the participants for the experiment was conducted through registered pediatricians and a marketing agency between April and November 2016. Data were collected between December 11, 2016 and January 15, 2017. Informed consent was obtained before filling out the Web-based questionnaire, where a short paragraph informed participants about the length of time of the survey, which data would be stored, where and for how long, who the investigators were, the general purpose of the study, and that all answers would be analyzed to respect participants' privacy and confidentiality. Participants' could not change the answers provided.

Measures

Mobile App Rating Scale

The Mobile App Rating Scale (MARS) is a 23-item scale developed to assess the quality of mobile health apps [17]. In previous studies, the scale showed high reliability [17,18]. The MARS is composed of 2 subscales, one assessing 4 objective qualities (engagement, functionality, aesthetics, and information quality) and the other assessing subjective qualities [17]. In addition, it provides 6 app-specific items measuring perceived outcomes to be adjusted to each health context [17]. The original scale was adapted to the context of our mobile phone app and included 8 items assessing all aforementioned 4 objective qualities and 2 items assessing subjective qualities. The objective qualities included entertainment, interest, interactivity, ease of use, visual appeal, goals, quality of information, and credibility. They were all measured with 1 item each, and response was recorded on a 5-point Likert scale measuring agreement and anchoring at "Absolutely agree" and "Absolutely disagree." To measure the app's subjective qualities we included a star-rating question (with the possible scores ranging from 1 to 5 stars) and one question asking how likely the participant would recommend the app in the future (with answers ranging from "Very unlikely" to "Very likely" on a 5-point scale).

In addition, we included 3 items assessing participants' perceived impact of the app on their knowledge (MorbiQuiz has helped me deepen my knowledge of vaccination), on their help seeking (MorbiQuiz has increased my desire to collect information about vaccination), and the perceived likelihood of an actual change in the target health behavior (After using MorbiQuiz, do you think that this app could change parents' vaccination decision?). Responses were recorded on a 5-point scale measuring agreement and anchoring at "Absolutely agree" and "Absolutely disagree" for the first 2 items, whereas they were measured on a 7-point scale ranging from "Yes, discouraging vaccination" to "Yes, favoring vaccination" for the third item. A midway option "I don't think it can make a difference" was also provided.

The posttest questionnaire also assessed the experiment's primary and secondary variables measured in the baseline survey (intention to vaccinate, confidence in the decision, etc), participants' social norms regarding the MMR vaccination decision, any problems that prevented a regular access to the app during the experiment, and participants' Web-based information-seeking behaviors. A pretest took place before sending the questionnaire to the participants to ensure content validity.

Sociodemographic Information

We assessed a number of sociodemographic characteristics, including gender, age, education, nationality, number of children, and ZIP code.

Analyses

Participants' responses were captured automatically, and data analysis was performed using the Statistical Package for Social Science (IBM Corp, version 21.0). Analysis of variances (ANOVAs) were performed for each variable to determine whether there were differences among the experimental conditions. Where appropriate, planned contrasts were conducted to analyze significant differences across the experimental conditions.

Study 2

Study 2 is a qualitative study conducted with a subsample of the participants who took part in study 1. Participants were recruited through the posttest questionnaire that followed the

assessment of the experiment. To recruit participants, a final question was added to the questionnaire, asking whether we could contact the participant for a short telephonic interview to share the experience with the app. A lottery was employed as an incentive to participation, with one shopping voucher worth 200 euros to be drawn. If participants accepted to be contacted, they were asked to provide a telephone number. We sent a message to all telephone numbers provided, asking to suggest a suitable date and time when to conduct the interview. We developed a list of semistructured interview questions aimed at exploring the perceptions and experiences of parents with regard to their use of the app (see Multimedia Appendix 1). All questions were open-ended to facilitate our understanding of parents' experiences and feelings, as well as their suggestions and remarks. The interview grid was flexible in the sense that the question order could be changed according to the flow of the conversation. Consent to participate and to have the interview recorded was obtained before starting the interview. We recorded all interviews using a call recorder app and transcribed them verbatim.

Inductive thematic analysis of the transcripts was conducted independently by 2 coders [19]. Initially, the transcripts were read several times and openly coded manually, underlying meaningful parts. At a later stage, all codes were grouped under labels and organized hierarchically using a tree diagram. All labels were finally grouped under broader themes. During the whole process, telephonic and face-to-face meetings between the 2 coders were regularly conducted to compare, discuss, and refine the codes, labels, preliminary themes, and relative quotations. We conducted the interviews between December 19, 2016 and January 13, 2017. Both the transcription and the analysis of the interviews were conducted in the original language (Italian).

Results

Study 1

Participants' Characteristics

In total, 140 participants of the RCT answered questions related to the app's qualities, representing all the participants in the 3 experimental groups of the RCT [13]. The majority of the participants had only 1 child (n=110), were mothers (n=138), and Italian nationals (n=136). Participants' mean age was 33.96 (standard deviation [SD]=5.52, range=21-47). About one-third had completed secondary school (n=43), whereas most had a university degree (n=84). See Table 1 for participants' characteristics and Table 2 for their scores related to the app's qualities.

Table 1. Participants' characteristics (study 1, N=140).

Characteristic	Experimental group		
	1: Quiz only (n=48)	2: Videos and messages only (n=45)	3 Quiz + Videos and messages (n=47)
Gender, n (%)			
Women	43 (90)	43 (96)	46 (98)
Men	5 (10)	2 (4)	1 (2)
Age, mean (SD)	33.44 (4.27)	34.49 (4.46)	33.98 (4.86)
Nationality, n (%)			
Italian	45 (94)	45 (100)	46 (98)
Brazilian	N/A[a]	N/A	1 (2)
Mexican	1 (2)	N/A	N/A
Moroccan	1 (2)	N/A	N/A
Education, n (%)			
Middle School	3 (6)	N/A	1 (2)
University	23 (48)	30 (67)	31 (66)
Secondary School	17 (35)	13 (29)	13 (28)
Apprentice	4 (8)	2 (4)	2 (4)
No. of children, n (%)			
1	40 (84)	35 (78)	35 (74)
2 or more	8 (16)	10 (22)	12 (26)

[a]N/A: Not applicable.

Table 2. Survey results per experimental group.

Quality	Survey item	Experimental group			*F* (degrees of freedom); *P* value	Posthoc test[a]
		1: Quiz only (n=48), mean (SD)	2: Videos and messages only (n=45), mean (SD)	3: Quiz + Videos and messages (n=47), mean (SD)		
Engagement						
Entertainment	Using MorbiQuiz was fun	4.63 (0.57)	3.87(0.94)	4.62 (0.79)	14.248 (2,137); *P*<.001	13 2
Interest	The contents of MorbiQuiz are presented in an interesting way	4.54 (0.74)	3.78 (1.02)	4.45 (0.90)	9.97 (2,137); *P*<.001	13 2
Interactivity	I felt as Sofia was talking to me	N/A[b]	3.80 (1.25)	3.72 (1.19)	0.09 (1,90); *P*=.76	N/A
Functionality						
Ease of use	MorbiQuiz is easy to use	4.81 (0.44)	4.20 (1.01)	4.70 (0.75)	8.35 (2,137); *P*<.001	13 2
Aesthetics						
Visual appeal	I like the graphics of MorbiQuiz	4.65 (1.635)	4.07 (1.03)	4.55 (0.829)	6.252 (2,137); *P*=.003	13 2
Information						
Goals	It is easy to understand what MorbiQuiz is for	4.63 (0.61)	4.20 (0.84)	4.70 (0.55)	7.36 (2,137); *P*=.001	31 2
Quality of information	MorbiQuiz's contents are easy to understand	4.56 (0.58)	4.40 (0.86)	4.36 (0.89)	0.86 (2,137); *P*=.42	N/A
Credibility	The contents of the quiz are reliable	4.5 (0.62)	N/A	4.49 (0.8)	0.005 (1,90); *P*=.94	N/A
	The contents of the videos are reliable	N/A	4.11 (0.86)	4.23 (0.96)	0.42 (1,90); *P*=.52	N/A
Subjective						
Star rating	How would you rate MorbiQuiz?	4.5 (0.55)	3.76 (0.74)	4.23 (0.67)	15.335 (2,137); *P*<.001	13 2
Future recommendation	How likely are you to recommend MorbiQuiz to other parents?	4.27 (0.87)	3.91 (0.7)	4.38 (0.79)	4.419 (2,137); *P*=.01	3 2
App specific						
Awareness/knowledge	MorbiQuiz has helped me deepen my knowledge of vaccination	4.58 (0.58)	3.89 (0.88)	4.70 (0.72)	16.36 (2,137); *P*<.001	31 2
Help seeking	MorbiQuiz has increased my desire to collect information about vaccination	4.42 (0.68)	4.09 (0.90)	4.34 (0.91)	1.93 (2,137); *P*=.15	N/A
Behavior change	After using MorbiQuiz, do you think that this app could change parents' vaccination decision?	—	—	—	—	—

[a]Close groups significantly differ from other.

[b]N/A: Not applicable.

Objective Qualities

Participants' scores related to the app's objective qualities were, overall, high. We found, however, significant differences among the 3 experimental groups for a number of qualities assessed.

Engagement

We found significant differences among the 3 groups regarding entertainment ($F_{2,137}$=14.248; P<.001) and interest ($F_{2,137}$=9.97; P<.001). In particular, participants who received the knowledge intervention, were more likely to report that using MorbiQuiz

was fun (mean 4.63 [SD 0 .57]) and that the contents of MorbiQuiz were presented in an interesting way (mean 4.53 [SD 0 .74]) than respondents who had received the empowerment intervention (mean 3.87 [SD 0.94] and mean 3.78 [SD 1.02]). To understand what gamification adds to the perception of the intervention employing the videos, we also compared the groups receiving the empowerment intervention only with those receiving the combined version. Those in the combined intervention group also scored significantly more on entertainment (mean 4.62 [SD 0.79]) and interest (mean 4.45 [SD 0.90]). Concerning interactivity, which indicates the perception that Sofia (the mother acting in the 2 videos) was directly addressing the participant, we found no statistical difference between the empowerment intervention only and the combined interventions groups ($F_{1,90}$=0.09; P=.76).

Functionality

The 3 experimental groups also significantly differed in their opinion on the extent to which MorbiQuiz is easy to use ($F_{2,137}$=8.35; P<.001). Participants in the group receiving the knowledge intervention reported significantly higher ease of use of the app (mean 4.81 [SD 0.44]) compared with those who received the empowerment intervention (mean 4.20 [SD 1.01]). When we compared the groups receiving the empowerment intervention only with those who received both intervention, we found that the former reported significantly higher ease of use of the app compared with the latter (mean 4.70 [SD 0.75]).

Aesthetics

The 3 groups also showed significant differences in their perceived visual appeal of MorbiQuiz ($F_{2,137}$=6.252; P=.003). Participants in the group receiving the knowledge intervention only reported significantly higher appreciation of the graphics of MorbiQuiz (mean 4.65 [SD 1.635]) compared with those who received the empowerment intervention (mean 4.07 [SD 1.03]). Participants in the group receiving the knowledge and empowerment interventions combined also reported significantly higher appreciation of the graphics of MorbiQuiz compared with those who received the empowerment intervention only (mean 4.55 [SD 0.829]).

Information

Regarding information, we found a statistical difference among experimental groups for goals ($F_{2,137}$=7.36; P=.001) but not for the perceived quality ($F_{2,137}$=0.86; P=.42) and credibility of the information (contents of the quiz: $F_{1,90}$=0.005; P=.94; contents of the videos and messages: $F_{1,90}$=.42; P=.52). In particular, participants in the groups receiving the knowledge intervention reported significantly higher ease in understanding the scope of MorbiQuiz (mean 4.63 [SD 0.61]) compared with those who received the empowerment intervention only (mean 4.20 [SD 0.84]). Those in the knowledge and empowerment interventions combined also reported significantly higher ease in understanding the scope of MorbiQuiz (mean 4.70 [SD 0 .55]) compared with those who received the empowerment intervention only.

Subjective Qualities

Similar to the objective qualities, the app received high scores for the subjective qualities, with significant differences between experimental groups. In terms of rating ($F_{2,137}$=15.335; P<.001), the groups receiving the knowledge intervention only gave MorbiQuiz a significant higher number of stars (mean 4.5 [SD 0.55]) compared with those who received the empowerment intervention only (mean 3.76 [SD 0.74]). Likewise, those in the knowledge and empowerment interventions combined gave MorbiQuiz a significant higher number of stars (mean 4.23 [SD 0.67]) compared with those who received the empowerment intervention only.

In general, disregarding the experimental group, parents would recommend the app (mean 4.19 [SD 0.813]). There are, however, statistically significant differences according to the experimental group ($F_{2,137}$=4.419; P=.01). Those in the combined version group reported the highest score (mean 4.38 [SD 0.79]), which is significantly higher than the group receiving the empowerment intervention only (mean 3.91 [SD 0.7]). The second highest recommendation score is reported by those in the knowledge intervention only group (mean 4.27 [SD 0.87]).

Perceived Impact of the App

Regarding participants' perceived impact of the app on their knowledge, we found statistical differences among groups ($F_{2,137}$=16.36; P<.001), with the combined interventions group reporting the highest impact (mean 4.70 [SD 0.72]), followed by the knowledge intervention group (mean 4.58 [SD 0.58]) and, finally, the empowerment intervention group (mean 3.89 [SD 0.88]). Regarding participants' perceived impact of the app on their information-seeking behavior, the group receiving the knowledge and empowerment interventions combined reported the highest score (mean 4.34 [SD 0.91]), but we did not find any statistical differences between groups ($F_{2,137}$=1.93; P=.15).

Regarding the participants' perceived likelihood of an actual change in the vaccination behavior, only 1.4% of the participants reported that MorbiQuiz discourages vaccination, whereas 12.1% affirmed that it cannot make a difference (6 participants from the knowledge intervention group, 9 from the empowerment intervention group, and 2 from the combined interventions group). The large majority (86.5%) reported that the app could make parents opt for vaccination (41 from the knowledge intervention group, 35 from the empowerment intervention group, and 45 from the combined interventions group).

Study 2

Participants' Characteristics

In total, 115 respondents accepted to participate in the telephonic interview. Of these, one did not provide a telephone number. Of the 114 telephone numbers received, 39 participants did not suggest a date and time to be called. We called 75 participants, of which 15 never answered the call. The final sample (N=60) included 21 participants from the knowledge intervention group, 15 participants from the empowerment intervention group, and

24 participants from the combined knowledge and empowerment interventions group.

Table 3. Participants' characteristics (study 2, N=60).

Characteristic	Experimental group		
	1: Quiz only (n=21)	2: Videos and messages only (n=15)	3 Quiz + Videos and messages (n=24)
Gender, n (%)			
Women	19 (90)	14 (93,5)	23 (96)
Men	2 (10)	1 (6,5)	1 (4)
Age, mean (SD)	33.61 (3.99)	34.4 (5.22)	33.34 (5.61)
Nationality, n (%)			
Italian	21 (100)	15 (100)	23 (96)
Brazilian	N/A[a]	N/A	1 (4)
Education, n (%)			
University	14 (67)	8 (53)	18 (75)
Secondary School	6 (28)	7 (46)	5 (21)
Apprentice	1 (5)	N/A	1 (4)
No. of children, n (%)			
1	18 (85)	12 (80)	17 (66)
2 or more	3 (15)	3 (20)	7 (34)

[a]N/A: not available.

Most participants were women (56/60, 93%), in their early 30s (mean age 33.78 years), Italian nationals (59/60, 99%), and with 1 child (47/60, 78%). See Table 3 for participants' characteristics. The themes extracted were grouped around those related to participants' experience with the quiz and those related to participants' experience with the videos and messages.

General Feedback

When asked about their general opinion of the app, participants spontaneously attributed a number of qualities to MorbiQuiz that covered a range of aspects, from its look to its contents. In general, participants defined the app as useful, innovative, and engaging and described their experience as fun and pleasant. Most participants reported that MorbiQuiz was highly convenient, meaning that it is handy, quick, nondemanding, noninvasive, easily accessible, and functional. They found the duration of the quiz a perfect match between a regular and gradual activity. Other remarks concerned its contents, defined as neutral/unbiased, complete, trustworthy, and rich. They also found the app simple, intuitive, clear, well structured, and captivating. Finally, participants described MorbiQuiz as highly educational and a useful tool that can help parents or soon-to-be parents to make a vaccination decision and stimulate one's information seeking. Participants' experiences with the app were grouped around 4 main themes, 2 related to the knowledge intervention and 2 related to the empowerment themes.

Experiences With the Quiz

When asked how the app helped them make a vaccination decision, participants in the intervention targeting knowledge and that targeting knowledge and empowerment felt that, after using MorbiQuiz, their decision was reinforced, they were more confident, more knowledgeable on the vaccination, and had less fear of the side effects. The majority also complained that the app did not provide links to external resources after each quiz, which could have helped them enrich their knowledge further. To ensure that the app could be useful beyond the 10 days of quiz, about a quarter of the participants suggested to create a database containing all information provided by the quiz that is accessible and constantly updated with news. About half of the participants suggested creating a similar app to inform parents about other vaccinations such as meningococcal vaccination.

Learning From Failure

The large majority of the participants who received the knowledge intervention reported that a major quality of MorbiQuiz is that it offers a novel way of learning about vaccination compared with the most traditional educational tools. Participants described their learning process through the app as an active one, whose main steps comprised receiving a question, seeking adequate information to answer appropriately, providing an answer and learning from the textual outcome of each answer. One participant stated:

> *I would receive a question and, often convinced of my answer which eventually would turn to be wrong, I would go and seek information on why I got it wrong. And thus...In that sense, in my opinion, it helps increasing one's knowledge.* [11053, knowledge intervention]

Most participants also stressed that MorbiQuiz invites to seek information actively and that it does so in a gamified way. They reported that this mechanism makes sure that either in case of a correct or a wrong answer, the participant has a chance to learn. In the first case, he or she will learn from the source

consulted and from the textual content, whereas in the second case, he or she will learn to question the information sources consulted and judge their credibility next time, learning from the textual content:

> *It's a call to play, it's a call to act. It's so interesting to me, when you open the first question, I mean, we have so many tools now to navigate online and find the right answer, don't we? Indeed, it invites you...To understand, read, analyze, right? Then you give your answer. If it's right, fine. You are happy that what you had seen was correct, and you deepen your knowledge with the answer that you receive. If it's wrong, then you start questioning the source that you had looked up, don't you? This challenge needs to be stressed. This means putting yourself on the line, going to seek information, and finally getting active yourself.* [11051, both interventions]

Through the mechanism that provided a textual explanation after any right or wrong answers, most participants found that MorbiQuiz was effective in eliminating their doubts on the vaccination and in providing novel information, as illustrated in the quotes below:

> *[I was] not knowledgeable on the topic, I didn't know...and answering, at the end of each answer it would say if the answer was correct or wrong, and it would provide an explanation to the question and those were really very...very useful, because I had certain doubts and those have...they all have been practically removed.* [11097, knowledge intervention]

> *The modality with the quiz followed by the explanation is undoubtedly very useful, because either in case of correct answer or wrong answer it offers anyway extra information compared to what you already know.* [11194, both interventions]

Around half of the participants reported that the quiz also helped them improve their information-seeking skills:

> *The quiz really enlightened me on aspects that...that I did not know, therefore some questions that I got wrong, it has really put me in the condition to better inform myself on those things that I really did not know...In this sense it has made me more informed.* [11076, knowledge intervention]

Participants appreciated the timeliness of the feedback they received from the quiz, indicating that, when they provided the answer, assessing their answer was quick and straightforward:

> *I have learnt many things, and this is the most important thing because even by making a mistake, there were anyway very clear explanations which gave you points of view...things that I absolutely didn't know. Then it was very immediate as a thing...I mean rather simple the flow from questions to answers.* [11056, both interventions]

A Challenge Against Oneself

When asked how they perceived the app's leaderboard, the majority of the participants reported to have looked at it regularly during the quiz session. However, what emerges from participants' reports is that the presence of the leaderboard does not correspond to a feeling of racing with others but rather competing with oneself, as illustrated in the quotes below:

> *I simply played a game and, in this game, I collected information by receiving answers...Personally, I also like to race as a person, to confront myself...and...I mean, it was not a game against others. It was a game against myself.* [11231, knowledge intervention]

> *It has motivated me, I mean I asked myself...Am I the only one who gets them wrong? [laughs] I was interested in looking at it in the end because I made mistakes and then I would go and look for information on that.* [11053, knowledge intervention]

The majority of the participants found that the leaderboard added fun to the experience of collecting information and pushed to search more information to answer the next questions in a better way:

> *I was a bit broken when I saw I was behind in the rank because I could not answer the questions...but it was fun, and the idea of the leaderboard was very stimulating.* [11042, both interventions]

> *It was fun because you would try to do your best possible. The leaderboard definitely acts as a...push. In a playful way, obviously.* [11113, both interventions]

Few participants reported to feel a sense of social support through the leaderboard, reporting a feeling of not being alone:

> *I think [the leaderboard] was...it was important that other parents have participated and have done the quiz...I felt...How to say...Not alone, that's it.* [11197, knowledge intervention]

Experience With the Video/Messages

When asked how the app helped them make a vaccination decision, participants in the empowerment intervention(s) reported different general feedback. In particular, those exposed to both the quiz and the videos/messages felt that, after using MorbiQuiz, they had more confidence in their decision and knew more on the vaccination. Those participants in the empowerment intervention, on the contrary, were less convinced that the app had made an impact on their decision. In a similar fashion, when we elicited their feedback on the usefulness of the videos and messages, participants reported opposite views.

A Mother Like Me

Participants who received the videos and messages mainly reported comments on the videos, in particular the first one (the main and longest one). Around half of them found the video to be very close to their experience and pushing them to look for more information:

> *I found the video very clear, very close to me. The fact that the protagonist is a mother makes it even closer to the everyday life of us, mothers, rather than a more informative video, how to say, that would be colder, more detached.* [11194, both interventions]

Participants found a similarity between the actress' experience and their struggle to make a sound MMR vaccination decision for their children, reporting that the video appeared to be authentic and trustworthy:

> *I felt it was really made by a...by a regular mother, not by someone...how to say...I mean by a mother like me! So I have to say, it was really nice...She would talk about the same problems that all mothers and fathers have when they have to choose.* [11036, empowerment intervention]

Few participants reported that they found a similarity between the decisional process described in the video and their decision-making process.

> *It felt like being...When I made the decision...like in this case, I mean I saw myself in this mother who gather information on the decision to vaccinate her child or not. I really liked that it was a real mother who talked. The character is trustworthy, it's real, and authentic.* [11051, both interventions]

Some participants felt the video contained a direct message from a mother to another mother, whereas others felt like following the character's story:

> *I interpreted it as a thought from a mother to a mother. I mean, a mother who tells you what she wanted to do with her child, and gives her advice as a mother to another mother.* [11066, both interventions]

> *It felt like following the story of this mother. It felt a bit like knowing her, like you were personally following her […].* [11109, both interventions]

Need for Direction

Around half of the participants declared that they found the video not useful, in the sense that it did not add anything to their knowledge nor stated the direction of the main character's decision. As an alternative, they reported a preference for a video that would rather present information on the vaccination, possible side effects, and main benefits, as echoed by the quotes below:

> *The video does not provide information about the vaccination, it only tells about her that...It does not provide information per se, I did not find it particularly useful. I don't know why, I would have preferred a video with information, and then you use that information to answer the questions of the quiz.* [11238, both interventions]

> *Maybe I was expecting that the mother would say in the end "this is what I chose," maybe I was expecting this...I don't know, it could be that we are used to see in the movies...to see a finale, but this mother was rather...rather cautious, she would say "I collected information before deciding."* [11003, both interventions]

Some parents suggested maintaining the narrative format but replacing the mother with experts or different parents with contrasting opinions. In this sense, some clearly stated that they would not use a tool that is only made to invite them to seek information.

> *If the videos were present or not that would not have made any difference. Cause you could see this mother talking, telling her experience, but...But I think if there were more videos with, say, different opinions, from different mother, that would have maybe been more...more instructive, more of a general picture...* [11225, both interventions]

> *I think it necessarily has to give some kind of information, beyond suggesting parents to seek information, I mean I cannot imagine an app that I simply access to hear "seek information, you have to look for information, yes, go and do it".* [11027, empowerment intervention]

A small number of participants stressed the passive component of the videos, compared with the active characterization of the quiz:

> *Honestly, I was not enthusiastic about the videos. They were kind of redundant. I found more answers and more stimuli in the quiz, maybe because when we are asked a question, it is up to us to answer and it sticks to our head for a longer time, as we think about it to find the correct answer...we think about it longer. But the videos, being a passive thing, did not make me enthusiastic.* [11042, both interventions]

Discussion

Principal Findings

The scope of this mixed-method study was to evaluate 2 interventions delivered through a mobile phone app aimed at increasing parents' knowledge about the MMR vaccination and their empowerment in the MMR vaccination decision. Both interventions were previously tested in an RCT. In particular, we were interested in capturing participants' opinion regarding a number of qualities of the app, such as usability and usefulness, and in acquiring information on their broader experience with the tool. A quantitative and qualitative study was conducted to reach these goals.

A first main finding springing from both studies is that overall participants perceived the app as highly usable and useful to make a vaccination decision. However, the results of the survey showed that the 2 groups receiving the quiz (alone or together with the videos/messages) liked the app significantly better compared with the group that only received the empowerment intervention through videos/messages. Furthermore, participants receiving only the quiz reported higher scores for most app's qualities compared with those receiving the videos/messages in addition to the quiz. Educational interventions are the most commonly cited interventions in the literature [8], which might signal that they are also the most common interventions parents are exposed to and which they are acquainted with. This might explain why the educational version of the app received higher ratings. This is also the first immunization app in the Italian language with educational purposes and the first attempt to empower parents about their vaccination decision through a

mobile device [20-23]. Participants might not be familiar with empowering interventions delivered through a video format and administered through a mobile phone app.

The results of the interviews also shed more light on between-group differences detected for the app's qualities, highlighting different experiences in relation to the type of intervention participants were exposed to. Parents' qualitative reports indicate that the knowledge intervention (employing the quiz and using elements of gamification) was perceived as an active learning experience, compared with the videos, which in turn were perceived as the passive exposure to a story. Furthermore, those in the knowledge group highlighted a number of positive aspects relative to learning, praising the gamified way by which they could not only acquire new information and question their previous knowledge but also improve their information seeking skills.

Parents receiving the empowerment intervention, on the other hand, lamented the lack of factual information that they would expect from a video, highlighting the emotional burden such a call for a self-determined decision might entail. The interview results also showed that mothers liked to identify themselves with the main character of the videos, as they share similar experiences and difficulties. However, beyond recognizing similarities with the protagonist, identification did not seem to be associated by parents with important aspects related to their decision making regarding their child's MMR vaccination.

These results are in line with previous findings that interventions using gamification have the potential to increase engagement and intrinsic motivation [24-26]. In particular, our study confirms previous findings that participation in gamified interventions was associated with users' engagement [27-30], enjoyment of activities [31-33], increased task performance [33-35], higher empowerment [27], learning [36-42], and more positive attitude [28,36,43]. Our participants' reports that they felt more convinced of their vaccination decision after participating in the quiz are also corroborated by a previous study that found gamification to be effective in reinforcing a behavior [42].

The findings of our evaluation study provide more explanation to the results of the previous RCT [13], which found that only the group receiving the knowledge intervention significantly increased their intention to vaccinate against MMR and their confidence in making a vaccination decision. The results of the qualitative study can contribute to explain why we did not find a significant effect of the empowerment intervention on parents' vaccination intention and confidence. Parents need a clear direction or, at least, a comparison between different points of views on vaccinations. Excessively pressuring them to find vaccination-related information and to talk to different people—without providing factual information at the same time—might generate frustration and emotional distress. Indeed, different reviews of the evidence on the effectiveness of interventions aimed at increasing vaccination coverage point out that multicomponent interventions that have educational purposes should consider that the educational component alone might not determine large increase in vaccination acceptance but could smooth the progress of implementation of other components [2,8,44].

Finally, parents indicated to be aware of the impact the app can have on their decision making, with the large majority reporting it could potentially lead parents to opt for the vaccination. Users' awareness of the goal and the high potential of an app are crucial for making an app trustworthy and worth downloading or being recommended [45,46].

Limitations

Although the studies showed to be successful in providing new insights into parents' perceptions of a novel immunization app, a number of limitations should be noted. A first limitation is that both studies' samples were mainly composed of provaccination or unsure parents. Acquiring the report of more vaccination-skeptical parents might have led to different results. A second limitation has to do with the incentives we offered to parents once the survey was completed. This might have played a role when parents reported their rating of the app, as they might have given higher scores to obtain the incentives we promised. Finally, social desirability biases may have occurred during the telephonic interviews. As the interviews were conducted by the team that developed the app, parents might have been led to report a positive experience to please the researchers.

Conclusions

This evaluation study showed to be useful not only to assess the 2 interventions beyond the results of the previous RCT where they were tested but also to understand participants' experience with the tool and contents they were exposed to and collect self-reported data on their perceived usability and usefulness of this instrument. The results can inform the design of future, similar interventions with educational or empowering purposes, suggesting that empowering efforts be always accompanied by the provision of factual information. Using a narrative format that allows identification can be appropriate, as it was reported to be associated with a feeling of social support that is called for by a recent taxonomy of communication interventions to improve routine childhood vaccination [10]. This, however, should not be employed alone but rather together with the presentation of more points of views and notions regarding, for instance, the risks and benefits of the vaccination.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview grid.

[PDF File (Adobe PDF File), 15KB - mhealth_v6i3e59_app1.pdf]

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Abbreviations

MARS: Mobile App Rating Scale
MMR: measles-mumps-rubella
RCTs: randomized controlled trials

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Review

Evaluating the Impact of Physical Activity Apps and Wearables: Interdisciplinary Review

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Abstract

Background: Although many smartphone apps and wearables have been designed to improve physical activity, their rapidly evolving nature and complexity present challenges for evaluating their impact. Traditional methodologies, such as randomized controlled trials (RCTs), can be slow. To keep pace with rapid technological development, evaluations of mobile health technologies must be efficient. Rapid alternative research designs have been proposed, and efficient in-app data collection methods, including in-device sensors and device-generated logs, are available. Along with effectiveness, it is important to measure engagement (ie, users' interaction and usage behavior) and acceptability (ie, users' subjective perceptions and experiences) to help explain how and why apps and wearables work.

Objectives: This study aimed to (1) explore the extent to which evaluations of physical activity apps and wearables: employ rapid research designs; assess engagement, acceptability, as well as effectiveness; use efficient data collection methods; and (2) describe which dimensions of engagement and acceptability are assessed.

Method: An interdisciplinary scoping review using 8 databases from health and computing sciences. Included studies measured physical activity, and evaluated physical activity apps or wearables that provided sensor-based feedback. Results were analyzed using descriptive numerical summaries, chi-square testing, and qualitative thematic analysis.

Results: A total of 1829 abstracts were screened, and 858 articles read in full. Of 111 included studies, 61 (55.0%) were published between 2015 and 2017. Most (55.0%, 61/111) were RCTs, and only 2 studies (1.8%) used rapid research designs: 1 single-case design and 1 multiphase optimization strategy. Other research designs included 23 (22.5%) repeated measures designs, 11 (9.9%) nonrandomized group designs, 10 (9.0%) case studies, and 4 (3.6%) observational studies. Less than one-third of the studies (32.0%, 35/111) investigated effectiveness, engagement, and acceptability together. To measure physical activity, most studies (90.1%, 101/111) employed sensors (either in-device [67.6%, 75/111] or external [23.4%, 26/111]). RCTs were more likely to employ external sensors (accelerometers: P=.005). Studies that assessed engagement (52.3%, 58/111) mostly used device-generated logs (91%, 53/58) to measure the frequency, depth, and length of engagement. Studies that assessed acceptability (57.7%, 64/111) most often used questionnaires (64%, 42/64) and/or qualitative methods (53%, 34/64) to explore appreciation, perceived effectiveness and usefulness, satisfaction, intention to continue use, and social acceptability. Some studies (14.4%, 16/111) assessed dimensions more closely related to usability (ie, burden of sensor wear and use, interface complexity, and perceived technical performance).

Conclusions: The rapid increase of research into the impact of physical activity apps and wearables means that evaluation guidelines are urgently needed to promote efficiency through the use of rapid research designs, in-device sensors and user-logs to assess effectiveness, engagement, and acceptability. Screening articles was time-consuming because reporting across health and computing sciences lacked standardization. Reporting guidelines are therefore needed to facilitate the synthesis of evidence across disciplines.

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KEYWORDS

mobile health; physical activity; smartphone; fitness trackers; wearable electronic devices; research design; evaluation studies as topic; efficiency

Introduction

Physical inactivity is a major public health problem [1], with 23% of adults worldwide not meeting recommended levels of physical activity (only 35% and 40% in the United States and the United Kingdom, respectively [2]). Many smartphone apps and wearables designed to improve physical activity are available. They often use data from in-device sensors to provide self-monitoring and feedback [3]. The potential of apps and wearables to increase physical activity and ultimately improve health outcomes, such as management of cardiovascular disease, obesity, and type 2 diabetes, has been widely recognized [4-9]. However, evaluating the impact of physical activity technologies can be challenging, because of the rapid rate at which they evolve [10-12]. Randomized controlled trials (RCTs), the "gold standard" of effectiveness evaluations, can take several years to conduct [11] and require interventions to be stable and unchanged throughout this period [12]. Consequently, researchers have emphasized the need for greater "efficiency" (ie, rapid, responsive, and relevant [11], or agile [13] research) when evaluating mobile health (mHealth) technologies.

Evaluating the effectiveness of mHealth technologies can be particularly challenging because of their "complexity" [14]. Physical activity apps and wearables often contain multiple components, which can interact with context and produce different outcomes for different people in different settings [15,16]. To understand overall effectiveness, studies should evaluate real-world engagement with, and response to, an intervention [17]. Measuring these factors alongside effectiveness can help interpret and explain variation in effectiveness outcomes, (ie, *why* the intervention worked or did not work [16-19]). Accordingly, mHealth researchers have been encouraged to assess "engagement" and "acceptability" [14,20]. However, how to define and distinguish these constructs is still a subject of debate; for example, some digital health researchers have conceptualized engagement as a behavioral construct [21,22], whereas others propose that it is composed of both behavioral and subjective components [20,23]. The latter view produces overlaps between engagement and acceptability, and therefore for clarity during this review, we define "engagement" as users' interaction and usage behavior (ie, a purely behavioral construct), and "acceptability" as users' subjective perceptions and experiences.

To increase the efficiency of mHealth evaluations, particular research designs and data collection methods have been recommended [11,14,24,25]. Single-case designs or "n-of-1" studies, in which participants serve as their own control, may be conducted relatively quickly and easily using mHealth technology [13,26]. To evaluate overall effectiveness, the Continuous Evaluation of Evolving Behavioral Intervention Technologies was developed to test multiple versions of an app simultaneously [27]. To test the impact of individual components, quick factorial approaches have been developed, including the multiphase optimization strategy (MOST), which rapidly tests many experimental conditions [28,29], and Sequential Multiple Assignment Randomized Trials [30] and micro-randomized trials [31], which both evaluate components that adapt across time.

To improve the efficiency of data collection, researchers can capitalize on the technological capabilities of consumer devices. In-device sensors (ie, accelerometers, gyroscopes, and other sensors embedded in smartphones and wearables) can be used to measure outcomes objectively [24,26]. Their internet connectivity and ability to collect continuous, high-density data remotely can improve efficiency over other "intermittent and limited" methods [24], such as questionnaires and traditional pedometers. Smartphones and wearables can also automatically record user interactions and app use [20]. Human computer interaction (HCI) researchers have used such device-generated logs to measure engagement objectively and remotely [32,33]. Log data has also been used for exploring acceptability, when used alongside qualitative methods [33].

Recommended evaluation designs and methods, as well as multidisciplinary approaches, may advance mHealth research [10,25]. Yet, a recent review of registered clinical trials found that evaluations of mHealth apps targeting a range of clinical conditions did not use either rapid research designs or innovative data collection methods [34]. The authors recommended that future reviews should incorporate a broader set of studies beyond those on ClinicalTrials.gov to identify rapid research designs.

The study team aimed to investigate, across health and HCI disciplines, the extent to which evaluations of physical activity apps and wearables (1) use recommended rapid research designs; (2) assess engagement and acceptability as well as effectiveness; and (3) employ efficient data collection methods (ie, in-device sensors and device-generated logs). The team also aimed to explore those dimensions of engagement and acceptability that are assessed.

Methods

Study Design

The study team conducted an interdisciplinary scoping review of the research designs, objectives, and data collection methods used in evaluations of physical activity apps and wearables. Scoping reviews are used to rigorously and comprehensively map the range of research activities undertaken in an emerging field [35]. In accordance with scoping review methodology [36], the team did not assess quality or reject studies on the basis of research design, as this would have excluded many HCI studies. The team adapted the framework suggested by Arksey & O'Malley [35] and Levac et al [37], to include 4 steps (1) identification of relevant articles; (2) study selection; (3)

charting and extraction of the data; and (4) collation, summarization, and reporting of results.

Identification of Relevant Articles

An initial literature search of 8 databases was conducted between August to September 2015 and updated in March 2017. These included 3 health and clinical databases (PubMed, PsycINFO, and Web of Science), 4 computing science databases (Association for Computing Machinery Digital Library (ACM), Institute of Electrical and Electronics Engineers (IEEE), Springer and Science Direct) and 1 interdisciplinary database (mHealth Evidence). The search terms used for different database are presented in Textbox 1. Articles were restricted to English language. No time limit was specified. Protocols, conference proceedings, and extended abstracts were all eligible. The reference lists of systematic reviews were hand-searched for further relevant articles.

Study Selection

Studies were included if they evaluated mobile technologies that provided sensor-based feedback on physical activity. To describe the full range of data collection methods used to measure physical activity, studies using objective and self-report measures were both included. Exclusion criteria were (1) no empirical data was collected (ie, systematic or methodological reviews, position papers and articles that only described technologies); (2) physical activity was not measured (ie, studies measured only sedentary time, activity skills, and gait); (3) the study only evaluated sensor or algorithmic performance (ie, accuracy in recognizing or classifying physical activity); (4) the sensor was not mobile; (5) the only mobile technology used was a pedometer without the capacity to connect to another device or the internet (this exclusion criterion was included to focus the review on wearable devices with more advanced feedback capabilities than standard pedometers).

All abstracts and full-text articles were reviewed by CM, and 5% of abstracts were independently reviewed by CG or JR. Discrepancies were discussed by the 3 authors, and all were resolved. Any articles representing the same study were merged.

Data Extraction

A data extraction form was developed to include (1) study characteristics (ie, publication year, country of study, number of participants, age of participants, study duration, whether a protocol or full trial); (2) research design details (ie, experimental or nonexperimental design, number of groups, experimental or control group details, randomization), and intervention characteristics (ie, technologies or devices used to deliver intervention, key intervention features); (3) research objectives and outcomes measured; (4) analyses undertaken (descriptive, inferential, thematic); and (5) data collection methods used (eg, in-device or external sensors, user-logs, questionnaires, interviews, focus groups). All reviewers independently extracted 5 papers (5%) to ensure consistency and reliability of data extraction.

Collation, Summarization, and Reporting of Results

The study team adopted a mixed-methods descriptive approach to analyze the extracted data [35]. The team first calculated frequencies in relation to study characteristics and each research design identified and mapped intervention characteristics (ie, the components or app features that studies evaluated). Next, the research objectives and outcomes that studies measured, as reported by authors, were used to categorize studies according to whether they investigated effectiveness (ie, changes in physical activity). Categorizing studies according to whether they investigated engagement and acceptability required a more iterative approach, as definitions of these constructs are less widely agreed. Working definitions of engagement (ie, user interaction with the device or usage behavior) and acceptability (ie, users' subjective perceptions and experiences) were applied to extracted research objectives, outcome measures, and data collection methods to develop a series of broad codes in relation to engagement (ie, engagement, usage, use, adherence, compliance) and acceptability (ie, acceptability, satisfaction, user experience, usability). These codes were applied to all studies to allow them to be categorized according to whether they investigated engagement and/or acceptability. Frequencies are reported for the number of studies in each category.

Textbox 1. Search terms used in the scoping review.

Health and Clinical Databases: PubMed, Web of Science, PsycINFO

Exercise/physical activity/physical activities

AND mobile/mobile phone/smartphone/sensor/smart watch/ wearable/wearable device

AND intervention/program/app/application

AND evaluate/evaluation/ assessment/measure/trial/test MeSH terms (PubMed only): "motor activity", "exercise", "cellular phones" and "studies with evaluation as topic"

Computing Science Databases: ACM, IEEE, Springer, Science Direct

Physical exercise/physical activity/physical activities

AND mobile/"mobile phone"/smartphone/sensor/smartwatch/wearable/wearable device/ubiquitous computing

AND intervention/program/app/application/activity tracking/personal informatics

AND evaluate/evaluation/assessment/measure/trial/test

Interdisciplinary Database: mHealth Evidence

Physical activity/physical exercise

In relation to effectiveness, the team calculated the proportion of studies that used only descriptive statistics (as opposed to inferential statistical analysis) and grouped studies that used sensors to collect physical activity data according to whether they used in-device sensors or external sensors (ie, additional, validated devices). The team then calculated frequencies for the data collection methods used in each group, and a chi-square test of independence was conducted to examine whether the type of sensor used was related to the type of research design using R statistical software (RStudio, version 1.0.136).

In relation to engagement and acceptability, the data collection methods extracts were first used to calculate frequencies in relation to the data collection methods studies employed (eg, user-logs, questionnaires, focus groups, interviews). Each extract was then read carefully to identify detailed subcodes that described the different elements assessed for each construct (ie, any specific behaviors logged, questionnaire items used, or interview or focus group topics described), and the One Sheet of Paper method [38] was used to generate broad dimensions of engagement and acceptability by grouping these subcodes according to their similarity.

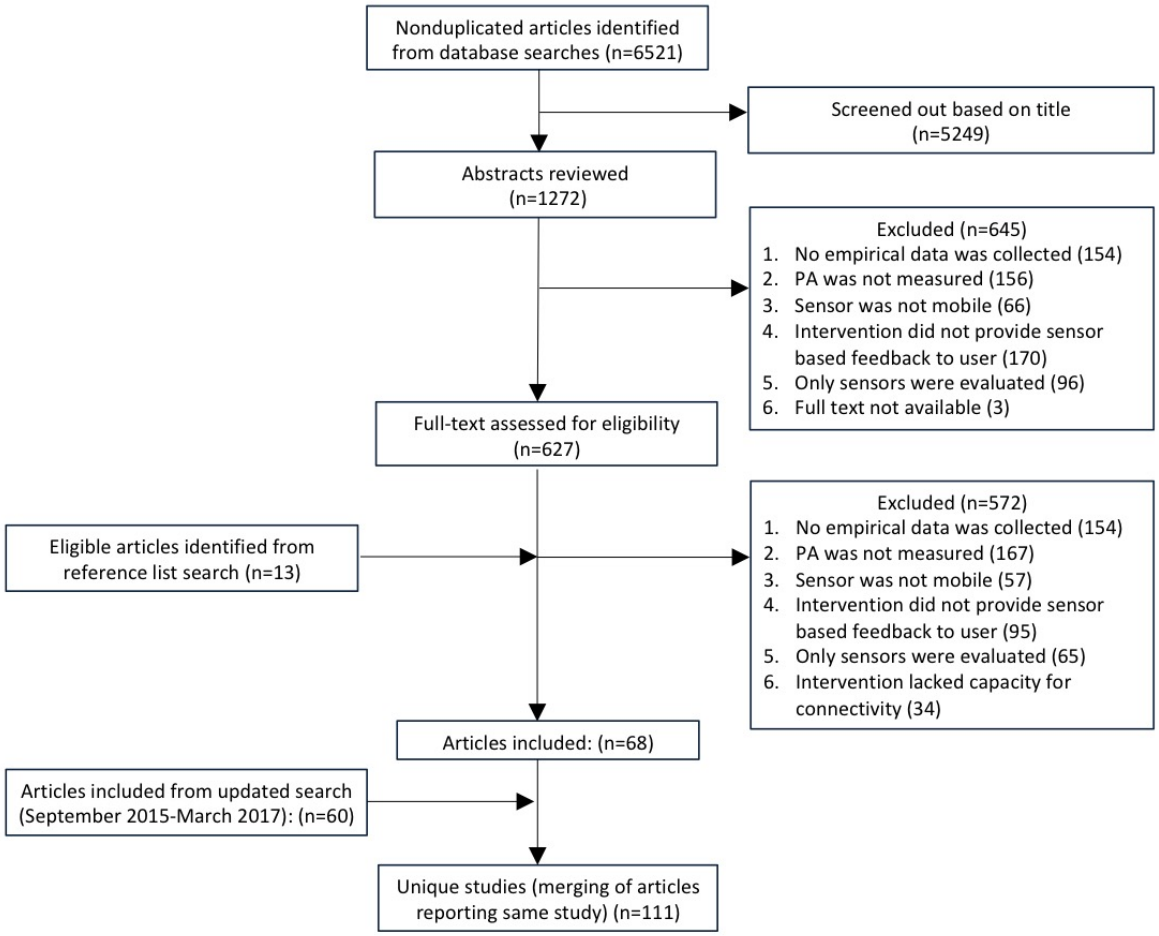
A random sample of all studies (20.7%, 23/111) was independently coded (by CG) to improve rigor in categorizing studies and generating the dimensions in relation to engagement and acceptability; discrepancies were discussed and consensus was reached on the final dimensions. Discussions suggested that some of the dimensions initially associated with acceptability were specifically related to the properties of the app or device and therefore did not relate to acceptability per se. These dimensions were retained and categorized as "usability."

Results

Summary of Search Results

A total of 6521 articles were retrieved during the initial database search (see Figure 1). After title screening, we reviewed 1272 abstracts and excluded 645 articles that did not meet the inclusion criteria. The full texts of the remaining 627 articles, and an additional 13 articles identified from reference lists searches, were read. Furthermore, 572 studies were excluded, leaving 68 articles. An additional 60 articles were included from the updated search in March 2017 (where we reviewed 557 abstracts and excluded 338 articles that did not meet criteria; then 219 full texts and excluded 159 articles that did not meet criteria). Overall, from the 1829 abstracts and 858 full texts read, a total of 128 articles were included in the review [39-166], representing 111 unique studies.

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



Study Characteristics

The study characteristics are presented in Multimedia Appendix 1. Of the included studies, 22/111 (19.8%,) were protocols. Over half (55.0%, 61/111) were published in 2015 or later. Many (42.3%, 47/111) were conducted in the United States. The majority of studies (93.0%, 103/111) involved adult participants; 8/111 studies (7.0%) involved children and adolescents. Participant numbers ranged from 2 [39] to 2980 [40]: 18.9% (21/111) of studies contained fewer than 13 participants. Study duration ranged from less than a day to 52 weeks. Intervention characteristics are included in Multimedia Appendix 2.

Research Designs

Of the included studies (see Multimedia Appendix 3), 61/111 (55.0%) used an RCT design. Most of these (66%, 40/61) were 2-group RCTs; 12 (23%, 12/61) were 3-group RCTs and 9 (15%, 9/61) were 4-group RCTs. Control group participants within RCTs received (1) standard care or minimal contact or print materials (39%, 24/61); (2) active comparison treatments (26%, 16/61); (3) noninteractive devices that did not display feedback (18%, 11/61); or (4) waitlist or no intervention (16%, 10/61). The remaining studies included 23/111 (22.5%) repeated measures designs; 11/111 (9.9%) nonrandomized group designs; 10/111 (9.0%) case studies (6/10 [60%] of which included an experimental baseline phase) and 4/111 (3.6%) observational studies. Only 2/111 studies (1.8%) used rapid research designs: one single-case design and one MOST.

As shown in Textbox 2, studies investigated a variety of intervention components, including the addition of apps or wearables to non-technology based interventions delivered by health care professionals, and a range of in-app components, such as automated adaptive goal-setting versus static or manual input of goals, and different social components.

Objectives and Data Collection Methods

Multimedia Appendix 3 shows the objectives that each study investigated effectiveness, engagement, acceptability and/or usability. Almost all studies (96.4%, 107/111) investigated effectiveness, including 14/111 (12.6%) that explored preliminary impact using only descriptive statistics or visual analysis. Only 35/111 studies (31.5%) investigated effectiveness, engagement and acceptability together, and 14 of these (40%, 14/35), did not use inferential statistics analysis to assess effectiveness. Usability was assessed in 16/111 studies (14.4%).

Effectiveness

The majority of studies (90.9%, 101/111) used sensors to measure physical activity. These were most often the in-device sensors used to deliver feedback on physical activity (67.6%, 75/111) (eg, Fitbit [105,162]). Some studies used external sensors (eg, Acti-Graph GT3X [ActiGraph, Shalimar, FL, USA], Sensewear Armband [BodyMedia, Inc., Pittsburgh, PA], Omron pedometer [Omron Healthcare, Inc., Bannockburn, I]), instead of, or in triangulation with, in-device sensors (23.4%, 26/111). Physical activity data collected via in-device and external sensors included step counts (eg,[159]) and time spent being active (eg, [84,151]). An external device was significantly more likely to be used in RCTs than in other research designs (χ^2_1=7.8, P=.005).

Of the included studies, 10/111 (9.0%) used a questionnaire alone to measure self-reported physical activity, and 17/111 (15.0%) used a questionnaire to triangulate with sensor data. Questionnaires included the International Physical Activity Questionnaire [167], the Community Health Activities Model Program for Seniors [168], the Recent Physical Activity Questionnaire [169], the Godin Leisure-Time Exercise Questionnaire [170], the Active Australia survey [171], the 7-day Sedentary and Light Intensity Physical Activity Log (7-day SLIPA Log [172], the Yale Physical Activity Scale [173], and the WHO Global Physical Activity Questionnaire [174].

Engagement

Engagement (ie, users' interaction with the device and usage behavior) was measured by 58/111 studies (52.3%) (Multimedia Appendix 3), with most (91%, 53/58) using device-generated logs to do so. Seven (12%, 7/58) used both logs and self-report questionnaires as a form of triangulation, and 5/58 (8%) used self-report questionnaires alone. Three dimensions of engagement were identified (1) frequency or amount of use; (2) depth of engagement (ie, active vs passive); and (3) length of use. These are described in Textbox 3.

Textbox 2. Intervention components and features investigated for impact on physical activity in included studies.

- Addition of apps and wearables to nontechnology based interventions with health care professionals [122,133,137].
- Addition of gamification features [115,118,123,148], financial incentives [57,119,144,152,154] and notifications or short messaging service (SMS) texts [102] to self-monitoring interventions.
- Automation of self-monitoring and goal-setting, including automated activity recognition versus manual input by the user [54,73] and automated adaptive goal-setting versus standard static or manual input of goals [50,124,127,150].
- Different social app features that support cooperation or competition [164] or accountability [161], social gaming and interaction [114], and personal versus group-based feedback [92,153]
- Different types of feedback messages, including positive or negative [99] and novel versus familiar [124].
- Different prompt frequencies [104].

Textbox 3. Dimensions of engagement assessed by included studies.

Frequency or amount of use

- Number of log-ins [83,137], number of times app opened [92,103], number of days device worn [139,165,166], self-reported frequency of viewing activity trackers [136]
- Use of social features, including self-reported frequency of viewing social media messages [139], number of social media messages sent [50,106,130,140], number of times leader board page accessed [139], number of likes or posts on Facebook [61], number of YouTube video views [160]
- Frequency of use by health care professional [52]
- Number of physical activity uploads [137]
- Amount of present or missing sensor data [156]

Depth of engagement (ie, active vs passive)

- Whether or not the user manually adjusted preset goals [116,124,150] or the physical activity levels that were inferred by the device [54]
- Number of missions or challenges completed [61]
- Logs indicate glancing (5-second intervals with no looking back at step history), review (use or interaction of up to 60 seconds, scrolling through step history), and engagement (use or interaction over 60 seconds, scrolling through step history), and also time between periods of engagement [124]

Length of use

- Number of times app opened across weeks [92], number of users continuing to post to community board [139], and number of days app used post study [97]

Acceptability

Of the studies included, 64/111 (57.5%) investigated acceptability (ie, users' subjective perceptions and experiences; see Multimedia Appendix 3). Most used questionnaires (64%, 41/64), and just over half (53%, 34/64) used qualitative interviews or focus groups, either alone or in addition to questionnaires. Questionnaires included a range of standardized questionnaires (eg, the IBM Computer Usability Satisfaction Questionnaire [175], the Persuasive Technology Acceptance Model Questionnaire [176], the Intrinsic Motivation Inventory [177], the Fun Toolkit [178] and the Working Alliance Inventory [179]), or questionnaires developed especially for the study (eg, [73,88]). A few studies employed user logs (11%, 7/64), of which, 3 used device-generated usage logs as a "proxy" of users' interest [135] or preferences [143,150]; 4 used user-entered text (eg, the content of social media messages to understand the types of social support that users experienced [86,106,130], and digital diary entries to understand experiences of using the device [106,127]). Studies that used text-based logs also employed face-to-face qualitative methods (ie, interviews, focus groups) or questionnaires, in addition to collecting log data. Five dimensions were identified in relation to measuring acceptability (1) appreciation; (2) perceived effectiveness and usefulness; (3) user satisfaction; (4) users' intention to continue use of the app or device, and (5) social acceptability. These are described in Textbox 4.

Usability

Usability was investigated by 16 studies (14.4%, 16/111), out of which, 9 (56%, 9/16) used questionnaires (eg, the System Usability Scale [180]); 4 (25%, 4/16) used interviews; 2 (13%, 2/16) used focus groups; and 1 (6%, 1/16) [70] used observation of participants' completing timed tasks. Three dimensions were identified in relation to assessing usability (1) burden of device wear and use, (2) interface complexity, and (3) perceived technical performance. These are described in Textbox 5.

Textbox 4. Dimensions of acceptability assessed by included studies.

Appreciation

- Appreciation or liking of the app [39,126,141]
- Whether the app or wearable was perceived as enjoyable, fun, entertaining [61,74,123,127]
- Whether the app or wearable was perceived as pleasant [103], attractive or visually appealing [160]
- What was "missed" about a feature once withdrawn [128]
- How the user "felt" about the app or wearable and its components [39,68,79,99]
- Users' interest and preferences [135,143]
- Teachers' perceptions of whether the app or wearable appealed to students [61]
- Self-reported motivation to pay attention [127]
- Trustworthiness of the app or wearable [39,73]
- Perceived advantages and disadvantages of using the app or wearable [53,115]

Perceived effectiveness and usefulness

- Users' views on whether the app or wearable increased, or will continue to increase and promote, physical activity [39,52,70,75,79,94,103,113,122,123,126,143,145]
- Practice nurses' perceptions of effectiveness for patients [132]
- Users' perceived usefulness or helpfulness of the app or wearable [39,74,103,116] and its components [52,59,136,165,166] in self-monitoring [54], supporting fitness and physical activity [118,136], and supporting them to stay motivated [163]
- Users' perceived persuasiveness or helpfulness of the app or wearable in achieving goals [160]
- Ability of the app or wearable to provide answers to health-related questions [160] and insight into physical activity or health conditions [52]
- Health care professionals' perceptions of the usefulness of information about patients' physical activity or health condition and whether it supported engagement with patients' home care [52]

Satisfaction

- General user satisfaction [41,75]
- User satisfaction with number of reminder short messaging service or calls received [136]
- User satisfaction with length of intervention [61,160]
- User satisfaction with level of personalization [127] and feedback provided by the app or wearable [54]
- Likelihood of users recommending the app or wearable to a friend or other people [116,139,162,165,166]
- Satisfaction with different components or features [116,122,129,145,163,165,166]
- Likelihood of physicians recommending the app or wearable to patients [55]

Users' intention to continue use of the app or wearable

- Intention or willingness to use after the study [39,92,97,103]
- Intention to continue if user had to pay for the app or wearable [156], or intention to purchase the app or wearable after the study [139,160]
- How regularly the user intended to use the app or wearable after the study [54,55]

Social acceptability

- Whether the app or wearable was noticed and remarked upon by others [79,128] or prompted discussion with others [52].
- Whether the app or wearable was used by important others [39].
- Users' attitudes towards sharing data with other people [130].
- Social encouragement [123] and social support received when using (including via) the app or wearable [85,86,110]
- Level of social bonding between the user and virtual coach [73]
- Users' preferences in using individual versus social features [161]
- Whether notifications were received at a socially acceptable time and place [147] or interfered with users' daily activities [122]

Textbox 5. Dimensions of usability assessed by included studies.

Burden of wear and use

- Ease of wear [145], burden or restriction in wearing the device, physical discomfort [142,159], usability regarding the device size [81], suggestions for alternative wear locations [116]
- Ease of use [39,49,143] when syncing to Web-based databases [142,159] and when charging the device [81]
- Whether device interfered with daily activities [122]

Interface complexity

- Complexity and intuitiveness [65], accessibility [159], and comprehension of physical activity feedback [160]
- Ease of reading information [122]
- Difficulties using the interactive interface, users' speed when completing in-app tasks [70]

Perceived technical performance

- Users' perceptions of the accuracy of the app or wearable in recognizing or inferring their physical activity [54,65,142]
- Technical difficulties or barriers encountered by users [113,116]

Discussion

Principal Findings

Of the 111 studies included, around half were published between 2015 and 2017, 55.0% were RCTs, and only 2 studies used rapid designs. Almost all studies measured physical activity objectively using sensors (either in-device or external), with RCTs more likely to employ external sensors (accelerometers). Less than one-third of the studies investigated effectiveness, engagement, and acceptability together. According to our working definitions, studies that measured engagement mostly used device-generated logs to assess the frequency, depth, and length of engagement. Studies exploring acceptability most often used questionnaires and/or qualitative methods to assess appreciation, perceived effectiveness and usefulness, satisfaction, users' intention to continue use of the app or device, and social acceptability. A small number of studies explored usability of the device (including burden of sensor wear and use, interface complexity, perceived technical performance) using questionnaires, qualitative methods, or participant observation.

The fact that more than half of the included studies were published between 2015 and 2017 demonstrates that research into the impact of physical activity apps and wearables is a growing area of interest, underscoring the timeliness of this review. Despite this, we found that only 2 studies used the rapid research designs that have been recommended for evaluating mHealth technologies (single-case design [131] and the MOST approach [164]). A low uptake of rapid research designs was similarly reported in a recent review of clinical mHealth app evaluations [34]; however, while the vast majority of evaluations of clinical apps were RCTs, our findings show that evaluations of physical activity apps and wearables use alternative research designs (including repeated measures designs, nonrandomized group designs, case studies and observational studies) more often. This may reflect the interdisciplinary nature of our review, and the view held by some HCI researchers that RCTs, as well as being impractical and resource intensive, are of limited usefulness [181]. It is nevertheless surprising that few studies used single-case designs and new factorial approaches, as it has been suggested that mHealth technologies can support the data collection procedures and experimental setup these research designs require (ie, frequent measurement and several experimental conditions) [25,26,182].

Further research is needed to explore the reasons that rapid research designs are not being used. It could be that the requirements for these designs are not feasible for some research projects. MOST, for example, requires several decisions to be made in advance of conducting the trial (eg, deciding which specific theory-based components of the intervention should be tested, and assessing the feasibility of carrying out a research design that can often require large sample sizes [29]). These requirements can themselves be time and resource intensive [183]. Barriers to using rapid research designs may also be conceptual: preliminary evidence suggests that the value of, and requirements for, single-case designs were not fully understood by clinical health practitioners [184], which may also apply to mHealth researchers.

In addition to effectiveness, assessing user engagement and acceptability are important to (1) generate a better understanding of the overall impact; (2) explain variation in the outcomes; and (3) reveal (potentially interactive) influences on effectiveness [16,19]. Despite this, only around one-third of the studies (32.0%) investigated all 3 objectives together. Furthermore, 40.0% of these did not use inferential statistics to assess effectiveness (instead using descriptive statistics and visual analysis), and almost one-fifth of all studies (18.9%) contained fewer than 13 participants. These preliminary, small-N studies are typical of iterative HCI research focused on developing novel technologies [185], and are unlikely to be sufficiently powered to test important hypotheses on mediators of effectiveness [17,186]. Although this study did not explore the specific statistical analyses undertaken, Bayesian methods are considered a promising approach for mHealth evaluations [13,25,187] and can be used to investigate mediating variables in small-N studies [188]. As such, Bayesian methods could be key when exploring results from early developmental

evaluations to reveal potential relationships between mHealth engagement, acceptability, and effectiveness.

Many evaluations of physical activity apps and wearables appear to be taking advantage of efficient data collection methods: two-thirds of studies employed in-device sensors in smartphones and wearables to measure physical activity. The fact that RCTs used external, validated sensors more often than other study designs exacerbates their inefficiency (eg, through adding extra resource costs [189]). Furthermore, using external sensors often involves measurement procedures that may reduce the generalizability of findings to real-world contexts (eg, requiring participants to wear additional devices and visit the lab). The coupling of gold standard RCTs and sensors with established validity indicates a well-grounded concern for methodological rigor. Yet, balancing this need for rigor with the need for efficiency requires further investigation. Addressing any "trade-offs" between efficiency and rigor when evaluating physical activity apps and wearables (and mHealth technologies more generally [11]) will require, at the very least, understanding the validity and reliability of internal sensors. Evidence could be quickly accumulated using industry-based "research libraries," such as Fitabase [190], and then used to inform decision making when designing a pragmatic evaluation. Relatedly, empirical evidence is needed to support recently proposed digital health evaluation models that outline all phases of the research process [191,192]: these frameworks combine HCI and implementation science methods to ensure evaluations are both rigorous and sustainable in real-world settings.

Most studies that measured engagement, used device-generated logs: these can be more efficient than qualitative self-report methods, which can be time-consuming and burdensome [20]. In contrast, acceptability was generally assessed via questionnaires and/or qualitative face-to-face methods. HCI researchers have emphasized the need to collect subjective qualitative data alongside device-generated logs to fully understand not only "what" people are doing but "why" [32,33]. We found a handful of studies (11%) used log data (eg, device-generated usage logs or user-entered text logs) to assess some dimensions of acceptability. The validity of this approach (ie, whether either form of log data can sufficiently capture the rich contextual details typically afforded by traditional qualitative methods) should be explored. For example, device-generated logs showing continued engagement with the app could imply user "satisfaction," "appreciation," and "perceived effectiveness or usefulness of the app," whereas investigating "social acceptability" (eg, user attitudes toward publicly sharing data) may require user-entered text logs (eg, from digital diaries, Web-based questionnaires, and social media posts), or even face-to-face methods.

In this review, we defined engagement as users' interaction and usage behavior [21,22] and acceptability as users' subjective perceptions and experiences. The dimensions of engagement and acceptability that we identified rested upon these working definitions. There is still no consensus in mHealth and related fields on what constitutes engagement and acceptability, and how each should be measured. One recent review [23] proposed that engagement is a multidimensional construct that includes not only dimensions related to "usage" (ie, amount, frequency, depth, and duration of engagement) but also subjective experiences of engagement (eg, affect, attention, and interest). Another review conceptualized engagement as "any process by which patients and the public became aware of or understood a digital health intervention" [193]. In response to varying definitions of engagement, researchers have undertaken valuable consensus-building exercises (and have emphasized the need to focus on "effective engagement" that accounts for engagement with behavior change) [20]. Clarification and consensus will advance our understanding of how engagement and acceptability may individually, or interactively, influence effectiveness.

A few studies assessed *usability*. In line with other conceptualizations of usability (ie, whether the device or app is easily used to achieve specified goals successfully and quickly [194,195]), we distinguished usability from acceptability by considering it to be a characteristic of the device. Understanding the degree to which usability varies across users and interacts with context to ultimately influence effectiveness (as opposed to being a stable device characteristic) will determine whether it should be assessed during within effectiveness evaluations (or instead optimized beforehand).

The screening process in this interdisciplinary review involved a very high number of abstracts and full papers being read to identify the final studies for inclusion. Many of the articles retrieved from the database searches had ambiguous titles; and many authors omitted key study details from their abstracts. Furthermore, data extraction from the full-text articles involved negotiating different publication formats across disciplines. These challenges meant the review process was far more time-consuming than originally envisaged. Currently, HCI studies are not required to follow heath science reporting guidelines that promote the inclusion of specific study details in titles and abstracts [196]. Standardized reporting drawing on existing guidelines (eg, CONSORT-EHEALTH [197]) would allow different disciplines to more easily synthesize the large amount of research that is being conducted in this area and would also aid current efforts to develop automated processes to increase the accessibility of evidence from digital health publications [198].

Limitations

The review was conducted systematically and comprehensively across health, clinical, and computing science databases. However, the scoping methodology followed did not include any assessment of the methodological quality of studies [37]. The focus on physical activity, engagement, and acceptability (and usability) meant that other important aspects of evaluation, such as reach and uptake, secondary clinical and psychological outcomes, cost-effectiveness, and the statistical analysis methods that studies used, were not reported. Furthermore, without established definitions of engagement and acceptability, the dimensions identified in this review are necessarily provisional.

The review did not examine the context in which apps and wearables were developed and evaluated, such as within academia versus industry. The development context may influence the assessment and reporting of engagement, acceptability, usability, and effectiveness of the apps and

wearables. Commercially-developed apps, for example, often do not incorporate behavior change techniques that improve effectiveness [199-202] and may focus more on enhancing user experience: therefore, industry professionals may be more likely to assess engagement, acceptability, and usability rather than effectiveness. Finally, to understand whether studies employed in-device sensors to measure physical activity, studies were included only if they evaluated apps and wearables that provide sensor-based feedback on physical activity. Therefore, the findings of the review cannot be generalized to other technologies or health behaviors.

Future Research

Future research should investigate why recommended rapid research designs are not yet widely adopted. For example, qualitative explorations of researchers' and industry professionals' perceptions and daily research practices and experiences would allow an understanding of the practical challenges in using rapid designs in academia and industry; and feasibility studies should explore the extent to which rapid designs can be supported and automated by mHealth technologies [11]. Consensus is needed on how to define and distinguish engagement and acceptability, and on the specific dimensions of these constructs, which could then be tested as potential mediators and moderators of effectiveness. Finally, the validity and usefulness of logging methods for assessing acceptability should be explored.

Conclusions

Despite the rapid increase of evaluations of the impact of physical activity apps and wearables, few are optimized in relation to efficiency and assessment of the key constructs of effectiveness, engagement, and acceptability. The findings of this review will inform future guidance to support health and HCI researchers in making greater use of rapid research designs (eg, single-case designs), in-device sensors, and user-logs to collect effectiveness, engagement, and acceptability data. The difficulties encountered in conducting this interdisciplinary review also highlight the need for standardized reporting guidelines. These would facilitate the synthesis of evidence across health and HCI disciplines, and thus support rapid advancement in understandings of the extent to which apps and wearables can support users to become more physically active.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Study characteristics.

[PDF File (Adobe PDF File), 179KB - mhealth_v6i3e58_app1.pdf]

Multimedia Appendix 2

Intervention characteristics.

[PDF File (Adobe PDF File), 161KB - mhealth_v6i3e58_app2.pdf]

Multimedia Appendix 3

Research designs used in included studies and objectives investigated.

[PDF File (Adobe PDF File), 192KB - mhealth_v6i3e58_app3.pdf]

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Abbreviations

ACM: Association for Computing Machinery Digital Library
HCI: human computer interaction
IEEE: Institute of Electrical and Electronics Engineers
mHealth: mobile health
MOST: multiphase optimisation strategy
RCTs: randomized controlled trials

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Original Paper

Participants' Perceptions on the Use of Wearable Devices to Reduce Sitting Time: Qualitative Analysis

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Abstract

Background: Recent epidemiological evidence indicates that, on average, people are sedentary for approximately 7.7 hours per day. There are deleterious effects of prolonged sedentary behavior that are separate from participation in physical activity and include increased risk of weight gain, cancer, metabolic syndrome, diabetes, and heart disease. Previous trials have used wearable devices to increase physical activity in studies; however, additional research is needed to fully understand how this technology can be used to reduce sitting time.

Objective: The purpose of this study was to explore the potential of wearable devices as an intervention tool in a larger sedentary behavior study through a general inductive and deductive analysis of focus group discussions.

Methods: We conducted four focus groups with 15 participants to discuss 7 different wearable devices with sedentary behavior capabilities. Participants recruited for the focus groups had previously participated in a pilot intervention targeting sedentary behavior over a 3-week period and were knowledgeable about the challenges of reducing sitting time. During the focus groups, participants commented on the wearability, functionality, and feedback mechanism of each device and then identified their two favorite and two least favorite devices. Finally, participants designed and described their ideal or dream wearable device. Two researchers, who have expertise analyzing qualitative data, coded and analyzed the data from the focus groups. A thematic analysis approach using Dedoose software (SocioCultural Research Consultants, LLC version 7.5.9) guided the organization of themes that reflected participants' perspectives.

Results: Analysis resulted in 14 codes that we grouped into themes. Three themes emerged from our data: (1) features of the device, (2) data the device collected, and (3) how data are displayed.

Conclusions: Current wearable devices for increasing physical activity are insufficient to intervene on sitting time. This was especially evident when participants voted, as several participants reported using a "process of elimination" as opposed to choosing favorites because none of the devices were ideal for reducing sitting time. To overcome the limitations in current devices, future wearable devices designed to reduce sitting time should include the following features: waterproof, long battery life, accuracy in measuring sitting time, real time feedback on progress toward sitting reduction goals, and flexible options for prompts to take breaks from sitting.

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KEYWORDS

wearable devices; qualitative research; focus groups; technology

Introduction

Sedentary behavior (SB) is defined as a range of human behaviors that result in an energy expenditure of no more than 1.5 times resting energy expenditure and are typically associated with time spent sitting, reclining, or lying down during waking hours [1-3]. Recent epidemiological evidence indicates that, on average, adults spend approximately 6 hours per day sedentary [4], and older adults are sedentary for approximately 9 hours per day [5]. The fact that individuals are sitting more is problematic because epidemiological studies have found deleterious effects of prolonged SB, including increased risk of cancer, metabolic syndrome, heart disease, and mortality [3,6-9]. Importantly, the negative health outcomes from increased SB are separate from participation in physical activity (PA) [6,7,9].

On the basis of the clear positive benefits associated with increased PA [10], decades of previous research have identified goal setting and self-monitoring as successful intervention strategies to increase PA [10]. Technology as an intervention tool has been used effectively in PA research [11-14]. Pedometers are a powerful change tool that can motivate individuals to increase PA [15-17]. Pedometers are helpful tools in that they allow participants to self-monitor behavior by tracking the number of steps taken throughout the course of the day [15,18]. Additionally, new wearable devices such as Fitbits are based on the same principles as pedometers and combine self-monitoring with individual feedback on progress toward goals [14]. Therefore, wearable devices provide an effective strategy for increasing PA by allowing for tailored goal setting and serving as reinforcement to work toward a specific goal [15].

Although wearable devices have been shown to be effective strategies for increasing PA [14,15], it is unclear how this technology might be applied to SB. One of the many challenges associated with changing SB is the sheer volume of sitting time individuals accumulate throughout the day [2,19]. On the basis of the continuous exposure to the behavior, trying to measure how much time individuals spend sitting can be extremely challenging [20]. Therefore, regular monitoring via technology to reduce participant burden may be an especially valuable intervention tool.

Given the recent surge in epidemiological and laboratory studies highlighting the association between excessive SB and poor health outcomes [6,7,21-24], new interventions to reduce sitting time are necessary. Recent research has explored different methods to interrupt sitting through increased prolonged standing or adding additional sit-to-stand transitions, which are brief postural changes from a seated position into a standing position and back to a seated position. These transitions break up long bouts of sitting and continually interrupt sitting time throughout the course of the day. One potential strategy to interrupt sitting by providing prompts to stand or add transitions is through smartphone apps. Several studies have capitalized on the surge in smartphone apps focusing on health-related outcomes, including PA and SB [25-27].

Just-in-time intervention strategies provide participants with real time feedback regarding their activity; however, a limitation of smartphone apps ability to change sitting time is the likelihood of misclassifying standing as inactivity based on a phone's location. If a participant puts the phone on a desk while he or she takes a standing break, the accelerometer in the phone would fail to capture this behavior as standing and would instead classify it as inactivity. For a participant working toward a goal to reduce sitting through increased standing, this misclassification can be frustrating and may demoralize his or her motivation to work toward accomplishing the goal. Current wearable devices that focus on prompting participants to move more are not designed to reduce sitting time [28]; however, these devices could be repurposed to target sitting reduction. For future devices, it would be especially valuable if developers could overcome these measurement limitations given the difficulty for individuals to monitor sitting time and the ubiquitous nature of the behavior.

Therefore, a wearable device that tracks accumulated sitting time and prompts behavior change throughout the course of the day (eg, vibration and alarms) could be an especially effective intervention tool [15,17,18]; however, more information on participants' perspectives toward these devices is needed. To gather end-user feedback on specific products, marketing and advertising companies use focus groups. The benefit of focus groups over one-on-one interviews is that the group setting promotes spontaneous discussion between participants that is not possible in an individual interview [29,30]. Given the rapid innovations in wearable technology combined with the negative health outcomes associated with prolonged sitting, this study used a focus group methodology to explore the perceived usability and acceptability of current wearable devices for SB. The purpose was to better understand if it would be feasible and appropriate to incorporate wearable devices in a 6-month SB study as an intervention tool.

Methods

Overview

The research was guided by a combination of inductive and deductive methods in that data collected were used to describe results related to wearable devices and SB.

Participants

We recruited participants from a previous SB intervention to participate in the focus groups. The Take a Stand study was a two-arm, randomized, pilot trial funded by the Department of Family Medicine and Public Health at the University of California, San Diego (UCSD). The study tested the feasibility and acceptability of a short-term SB intervention. A full description of the study and the findings have been reported previously [31]. Briefly, 30 participants in the age range of 50 to 70 years, with an equal number of workers and nonworkers, were followed for 21 days while the intervention was delivered. The eligibility criteria for participants are shown in Textbox 1.

Textbox 1. Eligibility criteria for participants in the original Take a Stand pilot intervention.

- Aged 50 to 70 years
- Spent at least an average of 8 hours per day sitting over 5 days
- Able to attend four measurement visits at the University of California, San Diego campus over 4 consecutive weeks
- Willing to wear a thigh-mounted inclinometer 24 hours per day for the entire 21 day study duration
- Able to read and write in English
- Able to provide written informed consent
- Without a serious health condition that would limit their ability to stand

Upon enrollment, participants were randomized to either a decrease sitting or an increase sit-to-stand transition condition. Participants were asked to work on either SB goal over the course of 2 weeks while wearing a thigh-mounted inclinometer called the ActivPAL that objectively measured SB. The device did not provide real time feedback on the behavior, but participants retrospectively viewed the past week's progress during weekly intervention visits.

Qualitative research focuses on participants who are likely to provide rich information about the specific research questions [32]. Therefore, we used a purposive sampling technique [33] to enroll participants from the Take a Stand study because these individuals had previous experience attempting to change their SB and interacting with the ActivPAL, which is considered a wearable SB device. Therefore, these participants provided feedback that is more informed based on their prior exposure to both SB interventions and devices designed to record activity.

We conducted a total of 4 focus groups in September 2014, and each lasted for 2 hours. The groups were stratified by work status (ie, worker or nonworker) and intervention condition (ie, sit less or increase sit-to-stand transitions). We chose to stratify to elucidate information about how wearable devices might work best depending on the participant's work status and intervention goal. Previous SB interventions have focused primarily on worksites, and we wanted to explore how participants might favor wearable devices differently depending on work status [34-38]. Additionally, given the novelty of the sit-to-stand transition behavior, we wanted to understand how current wearable devices could be used for this type of behavior. Therefore, we chose to have separate focus groups to reflect the differences we anticipated. There were between 2 and 5 participants per group, depending on participant availability. All participants signed written informed consent and approval was granted by the Human Research Protections Program of the UCSD (Protocol #130817).

Focus Group Overview

The research team began by identifying wearable devices to include as examples in the focus groups. Current wearable devices focus primarily on PA (ie, steps), but some devices also collect data on SB (ie, inactivity and sitting). We also wanted to include devices that had different wear locations (eg, wrist, back, and thigh) to enhance variability. Participants explored a total of 7 devices with varying features, but all with data on sitting, inactivity, or cues to take breaks from sitting. We defined features as the specific attributes or characteristics of the device (ie, battery life, wear location, and aesthetics). These devices included the ActivPAL, SitFIT, Lumoback, Smart Move shoe insert, Sensoria Sock, Garmin Vivofit, and Jawbone UP (see Table 1).

Given previous research using wearable devices to change PA, we hypothesized that similar devices could be especially effective tools to help reduce sitting time, and we wanted more information from participants regarding the perceived acceptability of current devices on the market. The focus group moderators (JK and KC) have experience with SB research and were involved in the Take a Stand pilot; JK was the principal investigator, and KC was the project manager. However, neither JK nor KC had prior participant interaction during the intervention study, therefore they were able to serve as moderators who were unfamiliar to the participants to allow participants to be as open as possible.

Before beginning the focus groups, participants provided written informed consent, and the moderators stressed the confidential nature of the discussions. Participants were informed that the discussion would be transcribed in real time via a transcriptionist, used for research purposes only, and would not be accessible to anyone outside the research team. To ensure confidentiality, participants did not use their full names. To encourage open communication of thoughts and ideas, the moderator stressed that the opinions of each participant were important, and there were no right or wrong answers. Upon completion of the focus groups, we thanked participants and provided each individual with US $20 as compensation for their participation.

The purpose of the focus groups was to provide insight on wearable devices for SB to inform a larger SB intervention. The overall focus group framework had the following format for each session: (1) a review of the device's functionality, (2) question and answer for each specific device, (3) voting on devices, (4) review of interfaces, (5) voting on interfaces, and (6) design the magic device via paper prototyping.

Table 1. Description of the seven wearable devices reviewed during the focus groups. We organized the devices based on wear location.

Feature of the device	ActivPAL	SitFIT	LUMOback	Vivofit and Jawbone UP	Sensoria Sock and SmartMove
Wear location	Thigh	Pocket	Lower back	Wrist	Foot and ankle
Feedback display	Paper graphs	Device, smartphone, Web	Smartphone	Smartphone, Web Sync with plug	Smartphone, Web
Frequency of feedback	Delayed until visit with study staff	Real time	Real time	Real time	Real time
Prompt type	Vibration	Vibration	Vibration	Red bar[a]; Vibration[b]	Unknown
Prompt adjustable	✓	✓	✓	✓	Unknown
Tracks sitting	✓	✓	✓	Inactivity	Potentially
Tracks sit to stand	✓	✓	✓		Potentially
Tracks steps	✓	✓	✓	✓	✓
Tracks sleep		✓	✓	✓	
Tracks other	None	None	Posture	Calories, distance	Speed, calories, distance, cadence
Waterproof	With tape and supplies			✓	Washable
Battery life	12 days[b]	Unknown	Up to 7 days	1 year[a]; 7 days[b]	Unknown

[a]Feature of the Garmin Vivofit.

[b]Feature of the Jawbone UP.

The first part of the focus groups focused on perceived wearability and functionality of each device. Each participant received a packet with information about each device. The packet included pictures and descriptions of each specific device. To get started, the moderators introduced each device to the participants, including a brief description (see Table 1), and then gave each participant the opportunity to hold the device and see it up close. The moderators then asked participants to describe any benefits or barriers to using the device for an extended period (ie, 6 months).

The first device discussed was the ActivPAL device, which participants wore for 3 weeks during the previous pilot intervention and had experience using. We then moved on to the remaining 6 devices. Participants were probed with questions to determine which device they thought would be the most likely to help them change SB during the course of a 6-month intervention. Questions included “what do you foresee as the biggest challenge to wearing this device for a long-term intervention?” or “what do you think will be make this device helpful?”

The next section of the focus group focused on the interfaces (ie, the medium used to display data to users) for the current devices. The moderators provided a brief overview about interfaces and how they provide feedback about one’s behavior. Some of these interfaces displayed feedback via a smartphone or computer, and others displayed feedback directly on the device itself. The next section focused on discussing the current interfaces available and identifying the benefits and barriers to each. Sample questions included “which do you like the most and why?” and “what do you like least about this interface?” After discussing each interface, participants rated their most and least favorite interfaces.

After having the opportunity to discuss each device, participants had the opportunity to vote on the devices. Specifically, when voting, participants identified their two favorite and two least favorite devices based on their individual preferences. During the final part of the focus group, participants designed their ideal device. This ideal device incorporated the best and worst parts of each of the previously described devices and interfaces, but it could also include elements that do not exist in these devices that would be essential to help individuals reduce their sitting time or increase sit-to-stand transitions. Participants used their creativity to sketch a prototype of the device and describe how it would work. When designing the focus group protocol, we consulted with a colleague who specializes in human computer interaction research, which is the study of how people interact with computers and other technology [39]. The voting and device design sections of the focus group were based on previous work with user experience design, which emphasizes involving the end-users in the initial design process to ensure products are developed that fit user needs [39]. Additionally, we purposely maintained a small number of participants per focus group to ensure that participants had many opportunities to interact with each of the seven devices and participate fully in the voting and design portions. Similar to product testing with consumer companies, we recruited a smaller number of informed participants per group to collect detailed information about the perceived usability and acceptability of the devices.

Data Analyses

A transcriptionist who was present during the entirety of each session transcribed the focus groups in real time. This methodology is especially effective for focus groups in which participants are encouraged to discuss an experience or process and provide feedback on concrete elements such as aesthetics

or ease of use [30]. To facilitate transcription, participants sat behind numbered placards, allowing the transcriptionist to note who was speaking. Two researchers (MT and BL), who have experience coding qualitative data and had worked on the Take a Stand study, analyzed the transcripts. MT completed her doctoral degree at UCSD and has formal training in qualitative and mixed-methods research. BL earned a Master's degree in Public Health and has experience with qualitative research methods. MT developed the focus group guide, and BL served as a device expert during 2 of the focus groups. Neither MT nor BL were involved in the moderation of the focus groups.

A thematic approach guided data analysis and data were organized into themes that reflected participants' perspectives. All analyses were done using Dedoose software. First, each coder read the transcripts independently to familiarize themselves with the content. During the second read through, each coder took notes and highlighted significant passages. The first transcript was coded in Dedoose, together by MT and BL, to create an initial codebook. Segments of the content with similar meaning were assigned to the same code. The remaining transcripts were used to refine the concepts of the initial codebook and combine the codes into key themes. When new codes or themes emerged, the codebook was revised, and the previous transcripts were recoded. Because coding occurred in tandem, any discrepancies were resolved in real time and ensured that all transcripts were coded by both researchers. Coding occurred over the course of several months, and saturation was reached when no new codes were generated after a final review of the transcripts. Key quotes were selected that were representative of the main themes.

Results

Participants

A total of 15 people participated across the 4 focus groups, with the two largest groups having 5 participants and the smallest group, consisting of nonworkers from the sit-to-stand transition intervention condition, having 2 participants. The average age was 59 years, and 87% (13/15) were female (see Table 2). The majority (12/15, 80%) were white, non-Hispanic, and there was an almost equal distribution between work status and intervention condition (8/15, 53%). From the 14 codes analyzed, 3 overall themes emerged related to the pros and cons associated with different aspects of the devices: (1) features of the device, (2) data the device collects, and (3) how data are displayed. Please see Multimedia Appendix 1 for a full description of the codes with definitions and seminal quotes.

Features of the Device

Participants reported mixed feelings about the various features of each device. Some participants liked devices that were directly adhered to the body because they were never forced to remember to put on the device; however, other participants commented that they would not wear an adhered device long-term (eg, ActivPAL). Participants were concerned about the pocket-worn SitFit device because, as one participant described, "most of the pants I wear don't have pockets." They would be more likely to use the device if they could attach it to a belt that they could wear with all pants. However, other participants had no concerns with the pocket placement and could easily incorporate it into their daily lives.

Aesthetics of the device were important both for device look (ie, did the device come in different colors [eg, Jawbone and VivoFit]) and for how the device would fit into an everyday routine. For example, participants struggled to understand how they could incorporate the Sensoria sock device or SmartMOVE shoe insole into everyday routines because not all outfits required socks or tennis shoes. One participant wore "sandals all the time," and another participant reported being "barefoot most of the time," which meant the form and location of these devices would make it challenging to wear consistently. Although this was likely a San Diego warm weather bias and might not be an issue in other areas with different climate.

During the dream device design portion, participants ideally wanted a wear location that could be flexible depending on what they needed for specific days. For example, one participant stated:

> *My ideal device would be kind of adjustable, depending on what you're going to wear and maybe on your back one day or your leg...whether that be [adhered with] some kind of adhesive...or a belt so it can be interchangeable.*

Table 2. Descriptive statistics for participants in the focus groups (N=15).

Characteristic	Value
Age (years), mean (SD)	59 (6.21)
Gender, n (%)	
Female	13 (87)
Race, n (%)	
White, non-Hispanic	12 (80)
Condition, n (%)	
Sit less	8 (53)
Work status, n (%)	
Full-time employed	8 (53)

Feedback was important, and participants wanted control over how often they received the feedback. Most participants requested real time feedback (eg, Jawbone UP and SitFit) as a method to actively work toward the goal throughout the course of the day. Prompts were another desired feature, and again, participants wanted control over the type of prompt (ie, vibration [Jawbone] and visual [Vivofit]), and frequency (ie, ability to deactivate prompts during sleep hours or change prompts depending on work schedule). When designing the dream device, participants emphasized the importance of programmability to allow everyone to choose feedback and prompts that were the most relevant and helpful to them as individuals. A participant said, "the frequency of the feedback would be programmable by the individual."

Participants mentioned practical concerns such as battery life and waterproofing. Longer battery life (eg, Vivofit) was a benefit for several participants as it eliminated the need to remember to charge the device frequently. Finally, whether or not a device was waterproof (eg, Vivofit) and could be worn in the shower, thereby not requiring participants to remove the device and subsequently remember to put the device back on (eg, Jawbone, Lumoback, and Sitfit), impacted participants' willingness to use the device long-term. When describing their dream devices, participants highlighted the importance of these practical features of the device when designing a device for long-term use.

Data the Device Collects

Participants were concerned about device accuracy to detect sitting time and preferred devices that provided information on sitting time as opposed to inactivity. As mentioned previously, most current wearable devices focus on inactivity and thereby classify both sitting and standing as inactivity (eg, Jawbone and Vivofit). However, other devices (eg, ActivPAL, SitFit, and Lumoback) are specifically designed to measure sitting and standing as separate, and participants favored devices able to distinguish between these distinct behaviors. Additionally, some participants doubted a device's accuracy based on the device's wear location (eg, pocket where the SitFit was worn or wrist where the Vivofit and Jawbone were worn were seen as less accurate). As one participant described it when designing the dream device:

> *...it has to track sitting. It has to track sitting to standing based on the goal.*

Participants had mixed reactions to the amount of information different devices collected. For example, some people liked the idea of collecting additional information (eg, sleep, posture, and calories), whereas other people were concerned that by collecting more information, there would be more opportunity to question the accuracy of the data collected. One participant stated:

> *There's more to question when you get a lot of data...If it thinks that I'm driving three hours, but I really only drive one hour but I rode my bicycle 2 hours, and it's confusing bicycling with driving, I might say to myself, oh, this isn't accurate...I will lose confidence with the accuracy of the device.*

Devices that were not able to detect sit-to-stand transitions (eg, Jawbone UP and Vivofit) were viewed less favorably by participants from the sit-to-stand transition condition. Control over data, which allowed participants to choose how the data are displayed and who can access the data, was a priority, with one participant stating:

> *I'd rather have control..., even [if the device is] not comfortable, than no control over something like data.*

How Data Are Displayed

Participants had varying opinions on where and how to display the data. Some participants liked data displayed on a smartphone (eg, Jawbone and Lumoback), whereas others were adamantly against it because they did not own a smartphone and had no plans to purchase one anytime soon. One individual talked about the need to "get away from the phone," which was a barrier to any device tied to a smartphone display. Participants also liked the idea of displaying long-term data on a computer to allow them to see "the progression of change over time." Frequency of feedback also varied as some participants wanted to see progress throughout the course of the day, whereas others would only want to see the data every few days or weekly.

Whatever medium was used, participants wanted the data displayed to be specific to SB. Participants viewed the devices that only displayed information related to activity or inactivity less than ideal, given the focus on SB. Participants preferred interfaces with data displayed in a way that was "easy to understand"; provided a quick summary of overall behaviors; used a combination of graphs, charts, and images; and were visually appealing. Additionally, if the interface used colors to represent behaviors, participants commented that the colors should be intuitive. For example, if they were focusing on reducing sitting with standing, time spent sitting should be highlighted in red, and standing should be represented with green. One of the featured interfaces had reversed these colors, and participants felt this was counterintuitive and confusing. As described by one participant, "it's very dumb." On the contrary, interfaces that had a lot of information with small font, a busy display, and required "too much reading" were viewed negatively. Flexibility was highlighted again when participants were designing dream devices, as participants emphasized that "everybody is different," and being able to modify how the data are presented would be a key feature of the ideal wearable device.

Voting

Across the 4 focus groups, the most popular device was tied between the SitFit and the Jawbone UP or Vivofit, with 11 favorite votes for each, and the least popular device was the Sensoria Sock or SmartMove, with 10 least favorite votes, and the Lumoback received 8 least favorite votes. One theme that arose from this portion of the focus group was that participants had a difficult time choosing favorites because none of the devices were perfect. One participant stated, "I was sort of doing a process of elimination more than I was activity voting for the favorites."

However, the votes reflected the themes because the Sitfit and Jawbone UP or Vivofit were specific to detecting sitting time,

did not require charging, and had prompting capabilities. Although the Sensoria Sock or SmartMove and Lumoback were good at detecting sitting versus standing or posture, the wear location was not conducive for long-term use.

Although participants continued to mention accuracy as an important component during the device review section of the focus group, when they were asked to vote on their most and least favorites, the devices that may have been better at detecting sitting versus standing, but had less than optimal wear locations were viewed less favorably. Given these results, participants seemed more willing to trade on accuracy if it meant they could easily incorporate the device into their daily routines. These results emphasize the need to develop wearable devices that are not only able to distinguish between behaviors, but can be easily incorporated into participants' lives to promote long-term use and sustainability.

Discussion

Principal Findings

As the evidence around the negative health effects associated with increased SB continues to emerge, interventions to reduce this behavior are becoming increasingly important. Wearable devices represent a novel method to intervene on sitting time, given their numerous capabilities that aid in behavior change, including real time feedback and prompts to interrupt the behavior. However, there has been limited research highlighting the perceived usability and acceptability of these devices to change SB in interventions. Furthermore, most of the current devices on the market emphasize PA as a primary focus and encourage movement. Therefore, it is unclear how to incorporate these devices into SB research. This study explored the barriers and benefits associated with existing wearable devices to reduce sitting time using feedback directly from participants who have intimate experience trying to change this behavior.

Overall, participants were amenable to using wearable devices to change behavior; however, a major limitation of the current devices available was the focus on movement or inactivity as opposed to sitting or standing [28,40]. Additionally, few devices collected information on sit-to-stand transitions or provided feedback related to this behavior. As one participant described, "...by not focusing on sitting time, the device would fail to get a reduction in sitting time."

Given that participants frequently commented that feedback is a critical component necessary to change behavior, devices that do not provide feedback on the specific behavior, either sitting or sit-to-stand transitions, would not be effective.

Another key finding is that flexibility across all features (eg, wear location, prompting, and feedback) is essential. A common theme across all focus groups was that everybody is different. For example, some participants thought a wrist-worn device would fit perfectly into their daily routine, whereas others would never wear such a device. Some participants only wanted to view data via a mobile phone, whereas other participants would never view data on their phone. Additionally, practical features of devices (eg, waterproof and battery life) were especially important. Therefore, the design of future wearable devices for SB should highlight flexibility and functionality as much as possible to strengthen buy-in from users.

Our study is not without limitations. Specifically, the sample size was small and the majority of participants were female; white, non-Hispanic. Ideally, focus groups should be larger (ie, more than 4 participants per group), and therefore, the group with only 2 participants was especially small given traditional standards. However, their experience from the previous pilot intervention enabled them to have a more informed perspective on the barriers and benefits to using wearable devices to reduce sitting time, which attenuated this limitation. Also given the interactive nature of the focus groups, we purposely chose to limit number of participants to allow for a more thorough exploration into each device.

Another limitation was that participants only had experience using the ActivPAL device for an extended period of time, which does not provide real time feedback and did not have the opportunity to try the other wearable devices. Therefore, participants may have had better perceptions toward the ActivPAL based on simple familiarity with the device and may not have been able to comment fully on the ability for a device to provide real time feedback given their limited experience with this feature. Future research could have participants try each device for an extended period to get more information on how the device may or may not fit into the everyday routine.

Finally, although we stratified by work status and intervention condition, the themes were consistent across focus groups, which could be because of the fact that the two smallest focus groups consisted of participants from the sit-to-stand transition intervention condition. Future studies could expand upon this. The strengths of our study include the use of qualitative methods to gain more insight into the feasibility of using wearable devices to reduce sitting time.

Conclusions

Evidence shows that excessive SB is unhealthy. Wearable devices represent a novel intervention tool for SB that has the potential for large-scale dissemination and impact. Previous research on a variety of health behaviors (eg, PA, diet) has found that self-monitoring is a key construct for behavior change [41,42]. Currently, there is no self-monitoring tool for sitting. Given the ubiquitous nature of the behavior and the fact that society at large is becoming even more sedentary [8,43], new research into effective self-monitoring tools is necessary. Without proper tools to self-monitor behavior, individuals will continue to struggle to self-assess, which could make behavior change even more challenging. Overall, participants viewed wearable devices as usable and acceptable; however, current models on the market lack a specific focus on SB and are thereby inefficient in targeting behavior change. In light of these challenges, new research that specifically addresses SB is needed to push the field forward. Given the high variability in desired features, feedback, and wear location, research involving the end-user in the design is not only recommended, but should be required.

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Authors' Contributions

JK, KC, MT, BL, CN, and DR designed the study. MT, BL, and SH performed qualitative analysis. MT, BL, JK, KC, SH, JN, HM, CN, and DR wrote and edited the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Themes or codes and seminal participant quotes.

[PDF File (Adobe PDF File), 33KB - mhealth_v6i3e73_app1.pdf]

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Abbreviations

PA: physical activity
SB: sedentary behavior
UCSD: University of California, San Diego

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Review

Using Google Glass in Surgical Settings: Systematic Review

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Abstract

Background: In recent years, wearable devices have become increasingly attractive and the health care industry has been especially drawn to Google Glass because of its ability to serve as a head-mounted wearable device. The use of Google Glass in surgical settings is of particular interest due to the hands-free device potential to streamline workflow and maintain sterile conditions in an operating room environment.

Objective: The aim is to conduct a systematic evaluation of the literature on the feasibility and acceptability of using Google Glass in surgical settings and to assess the potential benefits and limitations of its application.

Methods: The literature was searched for articles published between January 2013 and May 2017. The search included the following databases: PubMed MEDLINE, Embase, Cumulative Index to Nursing and Allied Health Literature, PsycINFO (EBSCO), and IEEE Xplore. Two reviewers independently screened titles and abstracts and assessed full-text articles. Original research articles that evaluated the feasibility, usability, or acceptability of using Google Glass in surgical settings were included. This review was completed following the Preferred Reporting Results of Systematic Reviews and Meta-Analyses guidelines.

Results: Of the 520 records obtained, 31 met all predefined criteria and were included in this review. Google Glass was used in various surgical specialties. Most studies were in the United States (23/31, 74%) and all were conducted in hospital settings: 29 in adult hospitals (29/31, 94%) and two in children's hospitals (2/31, 7%). Sample sizes of participants who wore Google Glass ranged from 1 to 40. Of the 31 studies, 25 (81%) were conducted under real-time conditions or actual clinical care settings, whereas the other six (19%) were conducted under simulated environment. Twenty-six studies were pilot or feasibility studies (84%), three were case studies (10%), and two were randomized controlled trials (6%). The majority of studies examined the potential use of Google Glass as an intraoperative intervention (27/31, 87%), whereas others observed its potential use in preoperative (4/31, 13%) and postoperative settings (5/31, 16%). Google Glass was utilized as a videography and photography device (21/31, 68%), a vital sign monitor (6/31, 19%), a surgical navigation display (5/31, 16%), and as a videoconferencing tool to communicate with remote surgeons intraoperatively (5/31, 16%). Most studies reported moderate or high acceptability of using Google Glass in surgical settings. The main reported limitations of using Google Glass utilization were short battery life (8/31, 26%) and difficulty with hands-free features (5/31, 16%).

Conclusions: There are promising feasibility and usability data of using Google Glass in surgical settings with particular benefits for surgical education and training. Despite existing technical limitations, Google Glass was generally well received and several studies in surgical settings acknowledged its potential for training, consultation, patient monitoring, and audiovisual recording.

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KEYWORDS

Google Glass; wearable; wearable device; head-mounted wearable device; surgery; surgical setting; surgical condition

Introduction

Wearable technology is defined as a compact device worn on the body as an implant or accessory that aids an individual's activities without interfering with the user's movements [1]. The goal of these technologies is to promote convenience and productivity by allowing the user to operate the device through voice and motion commands, thus offering more frequent and proficient multitasking opportunities. Many of these devices also possess the ability to connect to the Internet; therefore, they are capable of fulfilling the same functionality as mobile phones or computers [2]. However, wearable devices retain the added benefits of sustained hands-free portability and real-time ubiquitous access to data [3] compared with mobile phones or computers. One of the most well-known wearable devices is Google Glass (Google Inc, Mountain View, CA, USA), commonly referred to as "Glass," which is an optical head-mounted display worn as a pair of spectacles.

First released as the Google Glass Explorer Edition in 2013, Google Glass emerged as a head-mounted device that employs a wireless interface designed to provide its users with a comfortable, multifunctional virtual or augmented reality experience [4]. Drawing from its Android operating system, Google Glass projects information onto a small screen positioned just above and to the right of the user's right eye, creating little obstruction to his or her line of vision [5]. Google Glass offers a gateway for uninterrupted, instant information accessibility. Although the original Explorer Edition was unable to fully meet the needs of the general consumer population, its voice activation and data transmission capabilities, built-in camera, and flexibility of app customization has garnered the interest of commercial industries and professional operations, including health care [6].

In the health care industry, Google Glass has been used in different settings, including surgical and nonsurgical ones. In nonsurgical settings, Google Glass has been used to help clinicians in providing medical care for patients, health monitoring, and treatment plan support. For example, in patient-centered studies, researchers tested the role of Google Glass in helping colorblind patients identify colors and in providing audiovisual feedback to patients with Parkinson disease to modulate gait [7,8]. Further, as a clinician-centered intervention, Google Glass has been harnessed by health care providers to record medical consultations and to allow remote collaboration between physicians [9,10].

Recently, Google Glass's multitasking capabilities and responsiveness to hands-free voice and motion commands have made it particularly attractive to the surgical field. These advantages present surgeons with the opportunity to better streamline workflow in a setting where maintaining sterile conditions in the operating room and continuously monitoring patients during surgery are crucial. Although the multifaceted capabilities of Google Glass offer the potential to greatly impact the surgical field, health care providers remain uncertain about which tasks can benefit most from Google Glass intervention, what limitations are associated with its use, and the extent to which it can be used to support patients, providers, or both. The objective of this review is to conduct a systematic evaluation of the literature for the feasibility and acceptability of using Google Glass in surgical settings and to assess the potential benefits as well as limitations of its application.

Methods

We performed our systematic review and reporting of evidence in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (Multimedia Appendix 1) [11].

Article Retrieval

A librarian collaboratively developed the search strategies with the senior author (SB) and ran searches in the following databases in April 2017: PubMed MEDLINE, Embase, Cochrane Central Register of Controlled Trials on the Wiley platform, Cumulative Index to Nursing and Allied Health Literature, PsycINFO (EBSCO), and IEEE Xplore. Search strategies for all databases were adapted from the PubMed MEDLINE strategy. Searches were conducted in all databases back to 2013, which is the year that Google Glass was first released. No language limits were applied. The search strategy specified keywords related to Google Glass (see Multimedia Appendix 2 for complete search strategies in each database). We also conducted a hand search for additional related articles in the *Journal of Medical Internet Research* and by searching the reference lists of key studies and relevant systematic reviews.

Study Selection

The inclusion criteria required (1) original research articles; (2) studies that were randomized controlled trials, quasi-experimental studies, or pilot/feasibility studies; (3) Google Glass interventions; (4) studies conducted under surgical settings (preoperative, intraoperative, and postoperative); and (5) studies in clinical settings (real time or simulated). We categorized articles based on different stages or settings related to the surgical process, including the time spent preparing for surgery (preoperative setting), time spent during surgery (intraoperative setting), and time spent recovering from surgery (postoperative settings). The exclusion criteria were applied for (1) studies using technology-based interventions other than Google Glass; (2) nonsurgical setting studies; and (3) articles with more technical description of Google Glass but no clinical, usability, feasibility, and/or acceptability outcomes.

Data Extraction and Analysis

We utilized a standardized form for data extraction that included the following items: authors' names, publication year, country in which the study was performed, surgical application of the study, purpose of the study, description of Google Glass as a surgical intervention, participant demographics (age and sex when available), sample size, study design, results, limitations, and other study considerations. Two authors (NW and AM) screened all articles individually. Discrepancies were resolved through discussion with the senior author (SB) whenever necessary. Data were analyzed quantitatively and qualitatively.

Results

Literature Search

A total of 520 citations were retrieved through a literature search in five different databases. After removing duplicates, 380 original articles remained for screening (Figure 1). Two authors (NW and AM) independently screened the article titles and abstracts of 380 records against the inclusion criteria and a total of 78 records met all predefined inclusion criteria. Two authors (NW and AM) then independently reviewed the full text of these articles against the exclusion criteria, and 47 articles were excluded. A total of 31 articles met all predefined criteria to be included in this review. We did not identify any non-English articles that met our predefined criteria. The study flowchart and reasons for exclusion of full-text articles were documented and summarized in an adapted PRISMA study flowchart (Figure 1).

Description of Included Studies

A summary of the 31 included studies and their Google Glass applications can be found in Table 1. Of the 31 studies, 23 (74%) were conducted in the United States [12-34], three in the United Kingdom (10%) [35-37], and one in each of Spain (3%) [38], Canada (3%) [39], Switzerland (3%) [40], China (3%) [41], Australia (3%) [42], Mongolia (3%) [19], and Brazil and Paraguay (3%) [18]. Of note, two studies from developing countries were in collaboration with researchers from the United States [18,19]. All included studies were conducted in hospital settings; 29 (94%) in adult hospitals [12-26,28-41] and two (7%) in children's hospitals [27,42]. Sample sizes of participants who wore Google Glass ranged from N=1 to N=40. In all, 25 of 31 studies (81%) were conducted under real-time conditions or actual clinical care settings [12,14-16,18-20,23-38,40,42], whereas the other six (19%) were conducted under simulated environments [13,17,21,22,39,41]. In addition, 26 studies (84%) were pilot or feasibility studies [12,13,16-21,23,25,26,28-42], three (10%) were case studies [14,15,27], and two (6%) were randomized controlled trials [22,24].

Figure 1. Flow of studies through the review according to PRISMA guidelines.

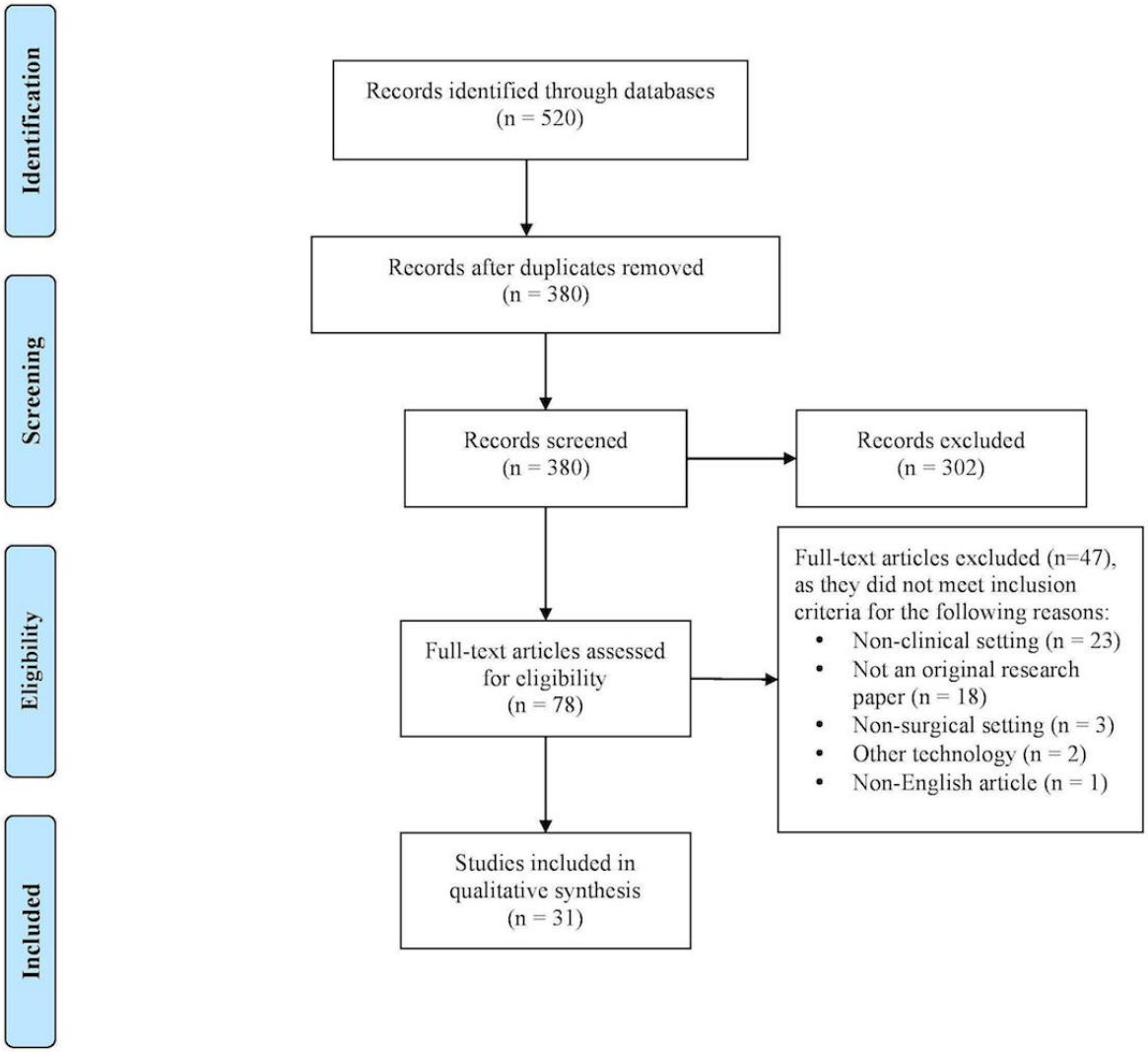

Table 1. Summary of the included studies evaluating the application of Google Glass to surgical medical interventions.

Source (country)	Health condition[a]	Study design	Study setting	Google Glass application[b]
Borgmann et al, 2016 (Spain) [38]	Urology	Pilot/feasibility study	Operative	Used to record first-person point-of-view video and photos and as search engine
Iqbal et al, 2016 (United Kingdom) [35]	Urology	Pilot/feasibility study	Operative	Acted as a heads-up vital sign monitor during surgery to maintain attentiveness to surgical field
Dickey et al, 2016 (United States) [12]	Urology	Pilot/feasibility study	Operative	Served as a surgical training tool in real-time first-person visualization of urologic surgery demonstration
Chimenti & Mitten, 2015 (United States) [13]	Orthopedics	Pilot/feasibility study	Operative (simulated)	Enhanced fluoroscopic visualization of the operative field
Ponce et al, 2014 (United States) [14]	Orthopedics	Case study	Operative	Used in conjunction with the VIPAAR system to livestream video during surgery and facilitate remote telementoring between 2 surgeons, allowing real-time guidance of the operating surgeon
Armstrong et al, 2014 (United States) [15]	Orthopedics	Case study	Operative & postoperative	Facilitated medical documentation and education via video recording
Hashimoto et al, 2016 (United States) [16]	General surgery	Pilot/feasibility study	Operative	Head-mounted display allowed first-person point-of-view video recording in open surgery where placement of external cameras would be otherwise difficult; aided telementoring
Brewer et al, 2016 (United States) [17]	General surgery	Pilot/feasibility study	Operative (simulated)	Livestreamed a surgery between teacher and learner, allowing the teacher to visualize the learner's operative field in real time and provide guidance as needed; facilitated surgical education and telementoring
Stewart & Billinghurst, 2016 (Canada) [39]	General surgery	Pilot/feasibility study	Operative (simulated)	Worn as a surgical navigation tool to help surgeon maintain attentiveness to the operative field
Datta et al, 2015 (Brazil, Paraguay, United States) [18]	General surgery	Pilot/feasibility study	Operative	Used in telementoring and improved access to quality care and education of health care providers in resource-deficient countries
Duong et al, 2015 (United States) [32]	Cardiology	Pilot/feasibility study	Preoperative	Used as a hands-free camera to help increase the accuracy of coronary angiogram interpretation
Schaer et al, 2015 (Switzerland) [40]	Cardiology	Pilot/feasibility study	Operative	Acted as a vital sign monitor; more efficient method of monitoring
Golab et al, 2016 (United Kingdom) [36]	Neurosurgery	Pilot/feasibility study	Operative	Served as an intraoperative monitoring display to decrease need for attention diversion; hands-free capabilities promoted sterility
Nakhla et al, 2017 (United States & Mongolia) [19]	Neurosurgery	Pilot/feasibility study	Preoperative, operative, & postoperative	Livestream abilities allowed students to visualize surgery in real time
Yoon et al, 2016 (United States) [20]	Neurosurgery	Pilot/feasibility study	Operative	Served as a heads-up neuronavigation monitor in pedicle screw placement; also projected video stream from external video-capture device for surgeon to view
Evans et al, 2016 (United States) [21]	Minimally invasive procedure—CVC insertion	Pilot/feasibility study	Operative (simulated)	First-person videography used to capture simulated internal jugular catheter insertions; potential to further medical education
Knight et al, 2015 (United Kingdom) [37]	Minimally invasive procedure—injectable ILR	Pilot/feasibility study	Operative	Live-broadcasted surgeries to trainees to further medical education

Source (country)	Health condition[a]	Study design	Study setting	Google Glass application[b]
Liebert et al, 2016 (United States) [22]	Minimally invasive procedures—bronchoscopy & thoracostomy tube placement	Randomized controlled pilot study	Operative (simulated)	Acted as a continuous vital sign monitor to promote attentiveness and patient safety
Spencer et al, 2014 (United States) [23]	Minimally invasive procedure—tracheal intubation	Pilot/feasibility study	Operative	Helped document airway management procedures using built-in camera
Wu et al, 2014 (United States) [24]	Minimally invasive procedure—ultrasound-guided central line placement	Randomized controlled pilot study	Operative	Served as an ultrasound monitor to decrease surgeon's need to redirect vision between operative field and traditional monitor
Vorraber et al, 2014 (United States) [25]	Minimally invasive procedure—percutaneous transluminal angioplasty	Pilot/feasibility study	Operative	Integrated and projected vital sign data to reduce need for multiple monitors in the operating room; allowed for increased attention to patient
Kantor, 2015 (United States) [26]	Surgical oncology	Pilot/feasibility study	Operative	Recorded photographs of Mohs surgery and gross Mohs sections; aided upload of electronic medical records
Zhang et al, 2016 (China) [41]	Surgical oncology	Pilot/feasibility study	Operative (simulated)	Acted as an ultrasound monitor to offer surgeon real-time feedback about the procedure without need to divert attention from operative field; smaller, more cost-effective alternative to near-infrared fluorescence imaging systems
Muensterer et al, 2014 (United States) [27]	Pediatric surgery	Case study	Preoperative, operative, & postoperative	Established Google+ hangout to permit teleconferencing
Drake-Brockman et al, 2016 (Australia) [42]	Pediatric anesthesiology	Pilot/feasibility study	Operative	Continuously monitored patient's vital signs to decrease need for a separate monitor
Moshtaghi et al, 2015 (United States) [28]	Otolaryngology	Pilot/feasibility study	Operative	Audiovisual capabilities and Internet interface allowed hands-free commands and greater communication
Rahimy & Garg, 2015 (United States) [29]	Ophthalmology	Pilot/feasibility study	Operative	Recorded steps of scleral buckling procedure to be later used for medical education
Sinkin et al, 2016 (United States) [30]	Plastic surgery	Pilot/feasibility study	Operative & postoperative	Promoted sterility in the operating room through hands-free commands and intraoperative photography
Aldaz et al, 2015 (United States) [34]	Chronic wound care	Pilot/feasibility study	Postoperative	Allowed for more hygienic examination and photography of chronic wounds; connected to the Internet to decrease image upload time; reduced administrative errors via hands-free audiovisual recording of note dictation and patient barcodes
Baldwin et al, 2016 (United States) [31]	Organ transplant surgery	Pilot/feasibility study	Operative	Hands-free real-time video allowed quality assurance and collaboration between transplant staff and home surgeons during time-sensitive event
Gupta et al, 2016 (United States) [33]	Emergency medicine surgical consultations	Pilot/feasibility study	Preoperative	Provided near-real-time video used for surgical consultations

[a]CVC: central venous catheter; ILR: implantable loop recorder.

[b]Medical professionals wore Google Glass in all cases. VIPAAR: Virtual Interactive Presence and Augmented Reality.

Table 2. Summary of the study purposes and proposed Google Glass intervention methodology.

Source	Purpose[a]	Intervention[a]
Borgmann et al, 2016 (urology) [38]	To determine the feasibility, safety and usefulness of GG in urological surgery.	Participating surgeons given free rein to use GG's features during surgery, such as taking videos and photographs, reviewing patient EMR and laboratory images, and accessing the Internet; patients were checked for postoperative complications to assess safety of GG use
Iqbal et al, 2016 (urology) [35]	To assess the feasibility of using GG as a vital sign monitor during surgery, specifically prostatectomy	GG has potential to decrease reaction time to abnormal patient vitals during surgery; participants performed a prostatectomy on a GreenLight Simulator using a standard vital signs monitor for 20 min and then using GG for 20 min; effectiveness of GG determined by the time taken to respond to abnormal vital signs, and patient blood loss and injuries
Dickey et al, 2016 (urology) [12]	To determine the feasibility of using GG for open urologic surgery as both a surgical assistant and a surgical training tool during the placement of an IPP	Trainees first shown a directional video on the IPP procedure projected onto the live view of the patient through GG; as trainees performed the IPP procedure, live footage of the OR was streamed to a remote physician through GG's camera feature; the attending physician could provide guidance to the trainee; participants completed postoperative survey on GG
Chimenti & Mitten, 2015 (orthopedics) [13]	To assess the effectiveness of GG as an alternative to standard fluoroscopic techniques in hand surgery	Metacarpal and phalangeal fractures require Kirschner wires to be placed percutaneously with the help of fluoroscopic imaging on an external monitor; GG's heads-up display used to visualize fluoroscopic imaging without diverting attention from the patient's hand
Ponce et al, 2014 (orthopedics) [14]	To test the integration of GG with the VIPAAR system and evaluate the extent to which it affects remote communication and guidance between medical professionals	VIPAAR system was integrated with GG to allow a collaborator to remotely view the surgical field of the operating surgeon and virtually insert his or her hands in the surgical field to offer guidance; 2 orthopedic surgeons wore GG; surgeon A performed the shoulder arthroplasty while streaming live video to surgeon B, who was able to provide remote assistance
Armstrong et al, 2014 (orthopedics) [15]	To assess the use of GG in affecting communication, documentation, and consultation among clinicians during the care of a high-risk extremity	GG facilitated Google Hangout between operating surgeon and fellow colleagues intraoperatively; followed 1 surgeon through an intraoperative case & follow-up clinic with 1 patient; used GG to screen share between senior surgeon and junior resident to assess application to medical education
Hashimoto et al, 2016 (general surgery) [16]	To test the safety of GG use in surgery by analyzing the quality of a telementoring video recording of a Whipple procedure	Surgeons were blinded and shown video of the procedure recorded by GG vs iPhone 5; they were then asked to evaluate the video quality
Brewer et al, 2016 (general surgery) [17]	To study GG's effect on real-time visualization of the trainee's viewpoint by the instructor to enhance surgical education	Measured TTC completion of needle placement when operative field (quadrants) could be visualized by trainer and trainee vs TTC when trainer could no longer see operative field; 5 needles placed per quadrant
Stewart & Billinghurst, 2016 (general surgery) [39]	To determine whether GG can improve attentiveness to the surgical field by directly displaying surgical navigation information.	GG compared to (1) computer monitor and (2) wearable "through-the-lens" display in a simulated surgical task of positioning and orienting a tool on a plastic distal femur; subcondition: test dominant eye vs nondominant eye; to measure attentiveness in either case, response times were measured in response to LED illumination
Datta et al, 2015 (general surgery) [18]	To evaluate the usefulness of GG in surgical telementoring of hernia surgery	HRFU volunteer surgeons from Germany, Brazil, and US first trained 1 local surgeon each in Paraguay and Brazil by demonstrating the Lichtenstein hernioplasty in person; the local surgeons then performed the procedure while wearing GG, allowing the instructors to view a livestream of the surgery and to provide guidance as necessary
Duong et al, 2015 (cardiology) [32]	To assess the accuracy of interpretation of coronary angiograms recorded using GG	GG was used to record 15 coronary angiograms containing 17 critical findings; participants reviewed GG recordings on an iPad and a computer and compared them to the original angiograms on a desktop; participants were given 1 point for each angiogram in which they were able to determine the correct finding (17=max score); a follow-up satisfaction survey was given to evaluate participants' satisfaction with GG image quality and ability to give recommendations based on GG videos

Source	Purpose[a]	Intervention[a]
Schaer et al, 2015 (cardiology) [40]	To determine whether GG could be used as an ECG monitor and decrease the need for surgeons to divert attention from the operative field	Experimenters simulated 210 ECG rhythms that reflected conditions requiring immediate medical attention; participants asked to identify these issues in as little time as possible & received 1 point for a correct answer; experimental condition: ECG rhythms and heart rate displayed on GG; control condition: ECG and heart rate information displayed on a monitor screen
Golab et al, 2016 (neurosurgery) [36]	To enhance the efficiency of spinal surgery, specifically SDR, using GG	SDR procedure: identify and cut the most responsive nerves, determined by using a probe to send a current through them, producing EMG waveform data; during procedure, the neurosurgeon must often obtain a second opinion from a neurophysiologist across the OR to determine which sensory nerves to sever; GG would help maintain sustained concentration by allowing remote communication; SDR also requires reading EMG data, which would be more efficient if the probe could be integrated with GG
Nakhla et al, 2017 (neurosurgery) [19]	To test GG's overall ease of use and effectiveness in hands-free video and photograph capture, consolidating and displaying information, and facilitating communication between medical professionals	(1) Case 1 (preoperative): GG used by attending to show residents how to prepare for a minimally invasive lumbar discectomy; GG allows hands-free commands and ability to save videos for future use; (2) case 2 (intraoperative): GG used by attending as he demonstrates the steps of a craniotomy; (3) case 3 (postoperative): GG used to record patients' postoperative recovery during a surgical mission to Mongolia
Yoon et al, 2016 (neurosurgery) [20]	To assess the safety and feasibility of capturing and streaming neuronavigation images onto GG during spine instrumentation	Video-capture device receives signal from medical imaging device and compresses it to make it compatible with GG; video is streamed on GG screen for the surgeon to watch; measured time it took doctors to place pedicle screws on a spine; control: placed screws using standard image guidance techniques; experimental: placed screws using GG
Evans et al, 2016 (minimally invasive procedures) [21]	To compare first-person video capabilities of GG to traditional third-person techniques	Videos of a simulated CVC internal jugular catheter insertion were taken from first-person perspective using GG and third-person perspective using an observer's head-mounted camera; videos were compared by 3 expert doctors based on 3 methods: 1 checklist and 2 global rating scales (additive and summative)
Knight et al, 2015 (minimally invasive procedures) [37]	To assess GG's ability to stream video to a smartphone and to explore telementoring capabilities	GG was used to broadcast livestream of injectable ILR, LINQ implantation in a 20-year old woman presenting with presyncope-associated palpitations
Liebert et al, 2016 (minimally invasive procedures) [22]	To assess the feasibility of GG for real-time wireless vital sign monitoring during surgery	Control group used a standard bedside digital monitor; experimental group tested GG in combination with a standard vital sign monitor; 2 scenarios: thoracostomy tube placement and bronchoscopy; all subjects from one group switched to the other for the second scenario to test the other technique
Spencer et al, 2014 (minimally invasive procedures) [23]	To explore whether GG could be effective in recording airway management to improve education demonstrations	GG recorded airway assessment and tracheal intubation of a patient with a malocclusion of the mandible; also recorded a direct laryngoscopy of another patient
Wu et al, 2014 (minimally invasive procedures) [24]	To determine whether medical practitioners at various levels of training could use GG to perform an ultrasound-guided procedure	Experimental group: used GG to perform an ultrasound-guided central line; control group: used traditional ultrasound machine during the procedure; video recordings of practitioners' eye and hand movements were analyzed to assess distractibility
Vorraber et al, 2014 (minimally invasive procedures) [25]	To test whether GG can enhance clinical care by providing doctors with vital sign monitoring information continuously and directly within their field of view during various procedures	Physicians used GG as vital sign monitor to perform a percutaneous transluminal angioplasty in 3 patients; participants were interviewed before and after the procedure
Kantor, 2015 (surgical oncology) [26]	To assess the use of GG in Mohs surgery and cutaneous reconstruction	120 Mohs surgery patients were evaluated by physicians wearing GG; patient medical records and history were obtained using GG; calculated rate of patient acceptance of GG

Source	Purpose[a]	Intervention[a]
Zhang et al, 2016 (surgical oncology) [41]	To develop and test a GG system to integrate fluorescence and ultrasound image acquisition to determine sites of near-infrared emitting optical agent uptake	GG used in combination with a camera for fluorescence imaging, 12 LEDs, and an M5 ultrasound probe; phantom was created as a simulation to test feasibility of GG system; GG used to detect fluorescent ICG uptake by lymph nodes; first site where this occurs is the SLN, which normally indicates tumor site; 30 core needle biopsies conducted on the phantom; done to test accuracy of GG's fluorescence/ ultrasound imaging in isolating tumor site under 3 scenarios: (1) GG with dual-mode (fluorescence and ultrasound) imaging, (2) GG with fluorescence imaging alone, and (3) no GG; tested GG's dual-mode fluorescence & ultrasound-guided detection of SLN, core needle biopsy, and SLN excision in an ex vivo breast resection specimen
Muensterer et al, 2014 (pediatric surgery) [27]	To explore potential uses for GG in surgical environments and assess the quality of its functions (eg, Web searches, videoconferencing)	GG worn daily for 4 consecutive weeks by one of research study authors; a diary was kept on all pros, cons, and observations; evaluated the ergonomics, battery life, audiovisual quality, functionality, lag time, connectivity, applications, acceptance, and data privacy issues associated with GG
Drake-Brockman et al, 2016 (pediatric anesthesiology) [42]	To assess the effectiveness of GG as a patient monitoring device in a pediatric anesthetic setting	Developed a program for GG consisting of 3 parts: (1) AnaeVis: runs on GG to display patient vitals, (2) AnaeHQ: runs on laptop to collect information from patient monitoring devices, and (3) AnaeComm: allows integration of computer and GG; anesthesiologist wore GG in the OR and answered follow-up survey
Moshtaghi et al, 2015 (otolaryngology) [28]	To explore the use of GG in otolaryngologic surgery and its role in surgical education and communication	A neurotologist, head and neck surgeon, and a general otolaryngologist used GG in various otolaryngologic procedures; GG also used to communicate to another remote physician for consultation during the surgery; used program, Pristine, in conjunction with GG to stream video of the surgery to a pathologist and aid in a margin analysis
Rahimy & Garg, 2015 (ophthalmology) [29]	To assess the intraoperative use of GG in scleral buckling surgery	GG recorded several steps of scleral buckling surgery
Sinkin et al, 2016 (plastic surgery) [30]	To assess the comfort of GG use during plastic surgery, level of gaze diversion from the operative field, and quality of intraoperative photography	Residents and surgeons used GG over a 7-month period, taking pictures and videos intraoperatively using voice and wink commands; videos and photos were downloaded and reviewed postoperatively; surveys conducted to assess comfort, ease of use, and quality of images
Aldaz et al, 2015 (chronic wound care) [34]	To compare the effectiveness of GG running on the SnapCap app vs iPhone using Epic Haiku in image capture	Part 1a: GG SnapCap vs iPhone-based Epic Haiku apps and took pictures of wound on a mannequin for comparison; Part 1b: follow-up questionnaire on nurse's preferences for (1) current SnapCap system features, (2) app preferences for SnapCap vs Epic Haiku, and (3) for the preference for future SnapCap features; Part 2: examined preference for GG's speech-to-text wound annotation
Baldwin et al, 2016 (organ transplant surgery) [31]	To test GG in a donor organ harvest	Examined GG in live collaboration between an organ retrieval team and home surgeons to assess GG's ability to stream intraoperative video of the organ harvest
Gupta et al, 2016 (emergency department-surgical consultations) [33]	To assess GG's asynchronous, near-real-time recording, uploading, and viewing of visual media capabilities in facilitating remote surgical consults from the emergency department	4 physician assistants assessed patients by photographing significant findings and recording videos and laboratory imaging results using GG; images were then uploaded to a secure server and accessed remotely by a surgeon; surgeon was then able to utilize the data to determine wither changes to the existing clinical management were necessary; changes in surgeon's confidence post GG assessment about the management plan were also evaluated through a questionnaire

[a]CVC: central venous catheter; ECG: electrocardiogram; EMG: electromyography; EMR: electronic medical record; GG: Google Glass; HRFU: Hernia Repair for the Underserved; ICG: indocyanine green; ILR: implantable loop recorder; IPP: inflatable penile prosthesis; OR: operating room; SDR: selective dorsal rhizotomy; SLN=sentinel lymph node; TTC: time-to-task completion; VIPAAR: Virtual Interactive Presence and Augmented Reality.

The vast majority of the studies examined the potential use of Google Glass as an intraoperative intervention (27/31, 87%) [12-31,35-42], whereas others observed its potential use in preoperative (4/31, 13%) [19,27,32,33] and postoperative (5/31, 16%) [15,19,27,30,34] settings. Only a few studies evaluated the use of Google Glass in more than one of these settings (4/31, 13%) [15,19,27,30]. In many cases, multiple functions and applications of Google Glass were tested in a single study. Of the two involving pediatric patients, one study required consent given by the patients' parents or guardians, and all recordings

were shared with them as requested [27]. In the other, Google Glass was not connected to the hospital network or Internet, and no recordings were made [42].

Provider Characteristics of the Included Studies

In all studies, Google Glass was worn exclusively by a medical professional, including nurses, physician assistants, medical school students, medical residents (postgraduate years 1 to 5), attendings, or simulated health care professionals. Reporting of provider demographics varied across all studies. Three studies reported age data of health care professional participants: one reported a range of 27 to 31 years [40], one reported a mean of 29.7 years [22], and one reported a mean age of 28.4 years with a range of 18 to 50 years [39]. Two studies reported health care professional sex information: one study had a participant pool that was 14.3% (1/7) female and 85.7% (6/7) male [40] and the other reported a sample that was 100% (12/12) male [39].

Patient Characteristics of the Included Studies

Reporting of patient demographics was largely limited across all studies. Only two studies provided patient age data: one included a sample of participants with a mean age of 70.6 years [26] and the other was a case report of a patient who was 66 years [14]. Two studies reported patient sex information: one reported a participant sample that was 58% (69/120) male [26] and the other reported one male patient (1/1) [14]. None of the studies reported race or ethnicity information.

Description of Google Glass Use

Table 2 summarizes the goals and intervention details of each study. Six studies utilized Google Glass's heads-up display as a vital sign monitor to facilitate improved patient monitoring and maintain attentiveness to the surgical field (6/31, 19%) [22,25,35,40-42]. Five studies (5/31, 16%) used Google Glass as a surgical navigation display to visualize ultrasound and fluorescence imaging data (3/5, 60%) [13,24,41], to visualize electromyography data (1/5, 20%) [36], and to position placement of tools on the body (1/5, 20%) [39]. Five studies used Google Glass as a videoconferencing tool to communicate with remote surgeons intraoperatively (5/31, 16%) [15,27,28,31,36]. Twenty-one studies (21/31, 68%) used Google Glass as a videography and photography device to document surgeries, laboratory images, or patient electronic medical records (7/21, 33%) [21,26,29,30,32,34,38], to assist in telementoring (4/21, 19%) [14,16-18], to document patient consultations (2/21, 10%) [19,33], to broadcast live streams (2/21, 10%) [31,37], and to enhance surgical education (7/21, 33%) [12,15,17,19-21,23]. One study used Google Glass as a hands-free search engine in the operating room (1/31, 3%) [27].

Google Glass Utilization in Different Surgical Settings

In preoperative settings (4/31, 13%), Google Glass was used in cardiac surgery (1/4, 25%) [32], neurosurgery (1/4, 25%) [19], pediatric surgery (1/4, 25%) [27], and emergency medicine (1/4, 25%) [33]. In these studies, Google Glass was tested primarily for its use in laboratory imaging interpretation and documentation (2/4, 50%) [32,33], surgical consultations (2/4, 50%) [19,33], teleconferencing (1/4, 25%) [27], and surgical education (1/4, 25%) [19].

In operative settings (27/31, 87%), Google Glass was used in various surgical specialties, including urology (3/27, 11%) [12,35,38], orthopedics (3/27, 11%) [13-15], general surgery (4/27, 15%) [16-18,39], cardiac surgery (1/27, 3.7%) [40], neurosurgery (3/27, 11%) [19,20,36], minimally invasive surgical procedures (6/27, 22%) [21-25,37], oncologic surgery (2/27, 7%) [26,41], pediatric surgery (1/27, 4%) [42], pediatric anesthesiology (1/27, 4%) [42], otolaryngology (1/27, 4%) [28], ophthalmology (1/27, 4%) [29], plastic surgery (1/27, 4%) [30], and solid organ transplant surgery (1/27, 4%) [31]. In these studies, Google Glass was utilized as a surgical education instrument (7/27, 26%) [12,15,17,19-21,23], portable surgical imaging display (5/27, 19%) [13,24,36,39,41], live stream transmitter (2/27, 7%) [31,37], vital sign monitor (6/27, 22%) [22,25,35,40-42], communication device (5/27, 19%) [15,27,28,31,36], telementoring tool (4/27, 15%) [14,16-18], audiovisual recording device to document surgeries and patient medical records (5/27, 19%) [21,26,29,30,38], and hands-free search engine (1/27, 4%) [27].

In postoperative settings (5/31, 16%), Google Glass was used in orthopedics (1/5, 20%) [15], neurosurgery (1/5, 20%) [19], pediatric surgery (1/5, 20%) [27], plastic surgery (1/5, 20%) [30], and wound care (1/5, 20%) [34]. These studies examined the utility of using Google Glass in recovery monitoring (2/5, 40%) [15,19], telemonitoring (1/5, 20%) [15], wound management (1/5, 20%) [34], video and photo review (2/5, 40%) [19,30], and administrative billing aid (1/5, 20%) [27].

Feasibility and Acceptability of Google Glass in Surgical Settings

Most studies (20/31, 65%) conducted formal follow-up surveys with study participants to determine the feasibility and usability of Google Glass [12,16-20,22,24-27,30,32,33,35,38-40,42]. Of the 31 studies, 28 (91%) studies assessed feasibility, usability, and/or acceptability by physicians only [12-25,28-32,34-42], two by both physicians and patients (6%) [27,33], and one by patients only (3%) [26]. The two studies (7%) that reported patients' perceptions of using Google Glass cited a generally positive response toward its use [27,33], although one group of patients reported anxiety related to being recorded without their informed consent [27]. Additional user satisfaction, feasibility and technical results can be found in Multimedia Appendix 3.

In 19 of the studies, medical professionals were satisfied with the use of Google Glass (19/31, 61%) [12,14,17,18,20,22-25,27,30,32-38,42]. Five studies did not provide quantitative ratings on Google Glass, but concluded that it was easy to use or used successfully to livestream surgery, record procedures for later use in surgical education, or communicate with colleagues remotely (5/31, 16%) [15,19,28,29,31]. One study found the peripheral display of Google Glass superior to traditional monitors but inferior to another wearable "through-the-lens" display (1/31, 3%) [39]. One study did not find a significant difference in ease of use of reading ECG rhythms on a traditional computer screen versus Google Glass (1/31, 3%) [40]. One study found that 82% of its participants viewed Glass as inferior to traditional methods, such as videography using an Apple iPhone 5 (1/31, 3%) [16]. Three studies did not provide participant-reported ratings on

acceptability (3/31, 10%) [13,21,41]. In the one study evaluating solely patients' acceptability of the device, all patients were receptive to Google Glass (1/31, 3%) [26].

Those who viewed Google Glass favorably cited its usefulness (4/19, 21%) [18,20,22,38], educational helpfulness (4/19, 21%) [12,17,35,38], ease of use (7/19, 37%) [12,14,19,22,27,38,42], comfort (4/19, 21%) [12,24,35,42], low distractibility (4/19, 21%) [17,19,22,42], ability to aid attentiveness (3/19, 16%) [22,25,35], and image quality (1/19, 5%) [27], and acknowledged their consideration for using Google Glass in the future (4/19, 21%) [12,22,35,42]. One study also found that Google Glass allowed for greater situational awareness: during a follow-up interview, one physician remotely observed a vital sign deterioration in a patient that was thought to be stable (1/31, 3%) [25].

Limitations of Google Glass in Surgical Settings

Despite the overall promising data regarding the feasibility and the acceptability of using Google Glass in different surgical settings, several studies (17/31, 55%) have reported a number of possible limitations associated with the use of Google Glass in these settings [13,16,19,20,24,25,27-30,33-35,37,38,40,42]. One study reported that although Google Glass was a beneficial remote communication device, it was unable to capture all relevant anatomy during a certain surgery (1/31, 3%) [28]. Other sources of apprehension arose due to short battery life (8/31, 26%) [13,19,20,25,27,29,35,38]; difficulty in hands-free features, such as the head-tilt zooms and the wink feature (5/31, 16%) [19,27,30,34,42]; data privacy concerns (4/31, 13%) [25,27,33,37]; lighting issues (4/31, 13%) [19,27-29]; Web connectivity issues (2/31, 6%) [19,27]; small screen size (2/31, 6.4%) [20,40]; image quality (1/31, 3%) [16]; distractibility (1/31, 3%) [30]; time lag (2/31, 6%) [19,24]; bulkiness (1/31. 3%) [28]; volume limitations (1/31, 3%) [27]; and overheating (1/31, 3%) [25]. These limitations indicate that further modification of Google Glass Explorer's technical hardware is necessary before the spectacles can be integrated into the surgical field.

Discussion

Principal Findings

As today's technology-centered society continues to place a growing emphasis on multitasking and unfettered access to information, Google Glass and other wearable devices have attracted the attention of consumers and corporations alike. Although Google Glass Explorer Edition failed to cater to the needs of the general public, the promising, multifunctional applications of this hands-free wearable device were appealing to several stakeholders in the health care industry, including surgeons. In this systematic review, we analyzed existing clinical studies on Google Glass to assess the feasibility, acceptability, benefits, and limitations of Google Glass in surgical settings.

Considering both the proposed strengths and limitations of using Google Glass, our review of these studies suggests that Google Glass Explorer could make the greatest potential impact in settings where it has less of an impact on patient safety, such as in aiding the surgical education of medical trainees. In its Explorer form, Google Glass is still restricted by a number of technological limitations, such as inadequate battery life and display overexposure, that might make it a beneficial supplement to traditional patient monitors but less so as an independent external monitor. Similarly, Web connectivity and poor Internet connection in isolated areas of the world still pose issues for Google Glass as a long-distance telementoring tool in situations when real-time surgical decisions are needed. Based on the studies, the environment in which Google Glass seems to provide the greatest benefit at the lowest risk to the patient is surgical education. Short-distance livestreaming of surgeries by physicians to trainees provides a unique first-person vantage point of surgeries, and Google Glass's ability to provide augmented reality guidance in simulated surgeries has the potential to aid medical students in skill acquisition and task comprehension. For example, Evans et al [21] reported a greater checklist score, denoting a higher number of procedural steps visualized by clinicians, when using the first-person perspective Google Glass compared to a third-person external monitor. Brewer et al [17] also found that, when Google Glass was used to visualize a simulated operative field between learner and trainee, the time-to-task completion of a needle placement procedure was significantly lower.

Previous related research assessed the use of both Google Glass and similar heads-up technologies in the contexts of teleconsultation, physical therapy, pain management, telementoring, videography and photography, drug delivery, and image interpretation. However, whereas recent reviews of these studies examined the use of Google Glass in addition to other wearable devices in both general medicine and surgery [43], our systematic review exclusively considers Google Glass in surgical settings alone and draws only from research conducted clinically. Although there has been one systematic review conducted on Google Glass in surgical settings in the past, our review evaluated a greater sample size of studies (N=31) to account for the growing data on the topic; the most recent review on Google Glass in surgery included 17 studies in their analysis and relied on other systematic review articles in addition to original clinical studies in their research [44]. Therefore, our systematic review contributes to the growing evidence for the utilization of Google Glass in surgical settings. Nonetheless, the authors similarly concluded that Google Glass has the potential to positively serve the health care industry, especially in patient care and medical training.

As further research on the use of the original Google Glass in professional settings has arisen, it seems that Google Glass developers have also shifted their focus of Google Glass from the consumer market to industry settings, such as health care. Despite the cessation of Google Glass Explorer Edition production in 2015, Google Glass developer, X, announced in late July of 2017 the arrival of the Google Glass Enterprise Edition [45]. This version, intended to exclusively target businesses and commercial industries, has been quietly undergoing testing with a select group of clients. Of the 33 listed, eight (25%) are health systems (CHI Health, Dignity Health, Christiana Care Health System, Eastern Maine Medical Center, Sutter Health, Trinity Health, TriHealth, Klosterfrau Healthcare Group), and some have already attested to the

benefits of this updated Glass to the medical field [46]. The majority of these corporations have been utilizing Google Glass in streamlining documentation in the consultation room. Using Google Glass as a "remote scribe," doctors at Dignity Health reported a decrease in time spent recording notes from 33% of the day to less than 10%, allowing physicians to double the time they can spend on patient interaction [47].

Although it is uncertain whether the physicians have tested Google Glass Enterprise in a specifically surgical setting, this updated technology has already addressed many of the previously cited limitations and privacy concerns of the previous Glass Explorer. These include an upgrade in camera resolution from 5 megapixels to 8 megapixels, longer battery life, faster processor, a light that signals when video recording is taking place, and faster and more secure wireless connectivity [48]. Based on our review, most of the original research conducted on Glass Explorer that viewed Google Glass as a useful tool, based on promising data, cited these as primary sources of apprehension. Health care providers may be more willing to utilize Google Glass in the workplace if the new edition of Google Glass is able to overcome these known limitations. Thus, further research will determine whether Google Glass Enterprise will be more proficient than its predecessor in surgical settings.

Our findings were also corroborated by a recently published systematic review that assessed the feasibility of Google Glass in nonsurgical settings. In their analysis, Dougherty and Badawy [49] highlighted the responses toward the technical features of Google Glass in studies spanning a broad range of medical specialties as well as patient health concerns, from weight management to developmental disorders. The authors reported that participants, in some studies, were frustrated with Google Glass's inadequate battery life, poor camera quality, hands-free shortcut functions, and potential to infringe on patient privacy. However, although the acceptability of Google Glass was more varied across the studies they included, our review elucidated more globally positive responses to the device in surgical settings. Nonetheless, the authors similarly found that Google Glass was most well received when leveraged as a tool for enhancing medical training. In support of our findings with the value of Google Glass in training and medical education in surgical settings, of the nine studies Dougherty and Badawy reviewed regarding student training, they reported that eight studies recommended the use of Google Glass for training purposes [10,24,42,50-54].

Strengths and Limitations

A number of strengths in our systematic review should be mentioned. First, we completed our review following established guidelines and recommendations for established systematic reviews methodology [55-57]. Second, two authors independently completed all stages of the review process. Finally, our search strategy for different databases was developed in collaboration with a librarian information specialist with more than 10 years of experience in systematic review methodology. In addition, no language restrictions were applied to minimize possible publication bias by including most relevant studies.

Potential methodological limitations in our systematic review should be discussed. First, some studies in our review included a relatively small sample size. Second, our inclusion criteria were limited to original research articles published in peer-reviewed journals, which could have led to a possible publication bias in which only positive study results are being reported and published [58]. Finally, although our literature search of five databases was comprehensive, it is possible that we could have missed a few articles related to our research question, which is also seen in other published systematic reviews [59].

Conclusions

In conclusion, there are promising feasibility and usability data of using Google Glass in surgical settings with particular benefits for surgical education and training. Despite existing technical limitations, Google Glass was generally well received and several studies acknowledged its potential for aiding the surgical field. As Glass Explorer's successor, Glass Enterprise, becomes more integrated in the health care industry, further research will be necessary to evaluate the efficacy of this updated technology in supporting surgeons and their patients, especially with the growing evidence to support the efficacy of technology-based interventions, although cost-effectiveness is worth further study [60-62]. In doing so, clinicians may be able to better understand the environments in which wearable devices, such as Google Glass, can be most successful and how to offer their patients the most advanced comprehensive care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA checklist.

[PDF File (Adobe PDF File), 65KB - mhealth_v6i3e54_app1.pdf]

Multimedia Appendix 2

Search strategies.

[PDF File (Adobe PDF File), 22KB - mhealth_v6i3e54_app2.pdf]

Multimedia Appendix 3

Summary of feasibility and user satisfaction results.

[PDF File (Adobe PDF File), 55KB - mhealth_v6i3e54_app3.pdf]

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Abbreviations

IEEE: Institute of Electrical and Electronics Engineers
MEDLINE: Medical Literature Analysis and Retrieval System Online
PRISMA: Preferred Reporting Results of Systematic Reviews and Meta-Analyses

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Corrigenda and Addenda

Metadata Correction: Clinical Validation of Heart Rate Apps: Mixed-Methods Evaluation Study

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The authors of "Clinical Validation of Heart Rate Apps: Mixed-Methods Evaluation Study" (JMIR Mhealth Uhealth 2017;5(8):e129) overlooked crediting Christophe Mortelmans, Ruth Van Haelst, and Bert Vaes as authors when metadata was entered into the submission system. They are researchers (described in the paper as general practitioners) with the Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium. Their contributions to this paper were significant, and the authors apologize for the omission in the original article.

The corrected article will appear in the online version of the paper on the JMIR website on March 14, 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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Acknowledgement Correction: Face-to-Face Versus Mobile Versus Blended Weight Loss Program: Randomized Clinical Trial

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The authors of "Face-to-Face Versus Mobile Versus Blended Weight Loss Program: Randomized Clinical Trial" (JMIR mHealth uHealth 2018;6(1):e14) would like to change the Acknowledgments section of their paper to the following:

> This project is partially funded and realized in collaboration with imec, Belgium. BrandNewHealth developed the weight loss app.

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